

Medicare A Bulletin

A Newsletter for Florida Medicare Part A Providers

In This Issue...

Medicare Guidelines on Telehealth Services

Benefit Expansion, Coverage and Conditions for Reimbursement of These Services 5

Medicare eNews Now Available

Join Florida Medicare eNews Mailing List to Receive Important News and Information 9

Expansion of Coverage on Percutaneous Transluminal Angioplasty

Coverage Expansion and Claim Processing Instructions for Hospital Inpatient Services 12

Skilled Nursing Facility Consolidated Billing

Clarification to Health Insurance Prospective Payment System Coding and Billing Guidelines 15

Final Medical Review Policies

10060, 55873, 67221, 71250, 74150, 84155, 85007, 88141, 92225, 93303, A0430, G0030, G0104, G0108, J1561, J1745, J9212, and M0302 22

Outpatient Prospective Payment System

Update and Changes to the Hospital Outpatient Prospective Payment System 87

Reader Survey

Provide your Comments and Feedback on the Medicare Part A Publication and/or our Provider Web Site 103

Features

From the Medical Director	3
Administrative	4
General Information	5
General Coverage	11
End Stage Renal Disease	13
Skilled Nursing Facility Services	14
Comprehensive Outpatient Rehabilitation Facilities	19
Hospital Services	21
Local and Focused Medical Policies	22
Outpatient Prospective Payment Services	87
Fraud and Abuse	92
Provider Audit and Reimbursement	93
Electronic Data Interchange	94

The Medicare A Bulletin should be shared with all health care practitioners and managerial members of the provider/supplier staff.

Publications issued after October 1, 1997, are available at no-cost from our provider Web site at

www.floridamedicare.com.

Routing Suggestions:

- Medicare Manager
- Reimbursement Director
- Chief Financial Officer
- Compliance Officer
- DRG Coordinator
- _____
- _____
- _____



Table of Contents

In This Issue 1

**From the Intermediary Medical Director
A Physician's Focus**

Screening Services vs. Diagnostic Services 3

Administrative

About The Medicare A Bulletin 4

General Information

Expansion of Medicare Reimbursement for
Telehealth Services 5

Services and Items Furnished to Prisoners 7

COB Contractor Fact Sheet for Providers 8

Medical Review of Therapy Services 9

Crossover Updates 9

FCSO Medicare eNews Now Available to
Web site Visitors 9

2001 ICD-9-CM Coding Changes 9

Automated Response Unit for Medicare A
Providers 10

General Coverage

New CLIA Waived Tests 11

Coverage and Billing of Biofeedback Training
for the Treatment of Urinary Incontinence . 12

Expanded Coverage on Percutaneous
Transluminal Angioplasty 12

End of Stage Renal Disease

Intravenous Iron Therapy 13

Skilled Nursing Facility Services

Billing for Audiologic Function Tests for
Beneficiaries that Are Patients if a
Skilled Nursing Facility (SNF) 14

Skilled Nursing Facility Annual Update for
Fiscal Year 2002 14

Clarification to Health Insurance Prospective
Payment System (HIPPS) Coding and
Billing Instructions 15

**Comprehensive Outpatient
Rehabilitation Facility Services**

New Temporary "Q" Codes for Splints and
Cast Used for Reduction of Fractures and
Dislocations 19

Hospital Services

Postacute Care Transfer Policy 21

Independent Laboratory Billing for the TC of
Physician Pathology Services to Hospital
Patients 21

Medical Policies

Medical Policy Table of Contents 22

Use of the American Medical Association's
(AMA's) Current Procedural Terminology
(CPT) Codes on Contractors' Web Sites .. 22

Final Medical Policies

10060: Incision and Drainage of Abscess of
Skin, Subcutaneous and Accessory
Structures 23

55873: Cryosurgical Ablation of the Prostate 25

67221: Ocular Photodynamic Therapy (OPT)
with Verteporfin 27

70450: Computerized Axial Tomography of
the Thorax 29

70450: Computerized Axial Tomography of
the Abdomen 31

84155: Serum Protein 35

85007: Complete Blood Count 38

88141: Pap Smears 42

92225: Ophthalmoscopy 46

93303: Transthoracic and Doppler
Echocardiography and Doppler
Color Flow Velocity Mapping 49

A0430: Air Ambulance Services 54

G0030: Positron Emission Tomography
(PET) Scan 57

G0104: Colorectal Cancer Screening 65

G0108: Diabetes Outpatient Self-
Management Training 68

J1561: Intravenous Immune Globulin 71

J1745: Infliximab (Remicade™) 77

J9212: Interferon 79

M0302: Cardiac Output By Electrical
Bioimpedance 82

**Additions and Revisions to Previously
Published Medical Policy**

70450: Computerized Tomography Scan 86

C1300: Hyperbaric Oxygen Therapy 86

Erythropoietin for Anemia of Chronic
Disease 86

Outpatient Prospective Payment System

Use of Modifier 25 and Modifier 27 in the
Hospital Outpatient Prospective Payment
System 87

Update to the Hospital Outpatient Prospective
Payment System (OPPS) 87

OPPS Pass-Through Devices Categories
Guidelines 91

Fraud and Abuse

Undercover Investigation Reveals Unethical
Tactics 92

Provider Audit and Reimbursement

Audit and Cost Report Settlement Expectations . 29

Electronic Data Interchange

HIPAA-AS Standard-Health Care Claim and
Coordination of Benefits (COB) Transactions . 30

Educational Resources

The Patient Friendly Advisory 95

www.floridamedicare.com—Florida Medicare's
Provider Web Site 96

Medicare Educational Materials Available Now 96

Medicare Educational Material Order Form 97

Medicare Individual Module Order Form 99

Order Form - Part A Materials 101

Reader Survey — Medicare A Bulletin 103

Other Information

Addresses, Medicare Web sites,
and Phone Numbers 111

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The Medicare A Bulletin is published bimonthly by the Medicare Publications Department, to provide timely and useful information to Medicare Part A providers in Florida.

Questions concerning this publication or its contents may be directed in writing to:

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A PHYSICIAN'S FOCUS

Screening Services vs. Diagnostic Services

The July issue of the American Journal of Preventive Medicine featured a study that prioritized 30 preventive services recommended for average risk patients based on the service health benefits and cost effectiveness (*Am J Prev Med* 2001, 21:1:1-9). For example, immunizations for children and anti-smoking counseling for adults ranked highly in medical effectiveness (deaths or injuries avoided in quality-adjusted life years (QALYs) if the preventive service reached the population) and cost effectiveness (net cost of preventive service divided by the QALYs saved). Some screening services ranked highly and others did not.

The Medicare program, modeled after indemnity insurance, initially restricted coverage to services addressing “the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.” Preventive services typically classified as immunizations, chemoprophylaxis, counseling, and screening procedures had limited coverage under the Medicare program until Congress expanded Medicare benefits in recent years for certain preventive services. The covered screening services are added benefits for beneficiaries and should be distinguished from diagnostic services in submitting claims for payment. Examples include breast cancer screening with mammography and colorectal cancer screening with sigmoidoscopy or colonoscopy. Generally, screening services have unique sets of ICD-9 CM diagnosis codes and HCPCS procedure codes distinguishing these services from diagnostic services. Submitting accurate claims not only improves administrative data for health services research but also may directly benefit a Medicare patient since screening services may have lower or no co-payment or deductible. Further information can be obtained at our Web site www.floridamedicare.com.

The U.S. Preventive Services Task Force (USPSTF) was tasked by the U.S. Public Health Service to evaluate clinical research in order to assess the merits of preventive services such as screening. The Task Force’s efforts culminated in the 1989 Guide to Clinical Preventive Services and a second edition of the Guide was published in 1996. Now, the third USPSTF is updating recommendations and addressing new topics. The Agency for Healthcare Research and Quality (AHRQ) currently oversees operation of the USPSTF. Even though Medicare benefits and coverage policies are not always consistent with USPSTF recommendations, the task force recommendations are a good source of information as the Medicare program and its providers look ahead to the growing Medicare population. Providers can review USPSTF recommendations on screening and other preventive services at www.ahrq.gov/clinic/prevenix.htm.



James J. Corcoran, M.D., M.P.H.
Medicare Medical Director

About *The Medicare A Bulletin*

The *Medicare A Bulletin* is a comprehensive magazine for all Florida Part A providers. Beginning in November 2000, the *Medicare A Bulletin* became a quarterly publication. In accordance with the Health Care Financing Administration's 45-day notification parameters, the approximate delivery dates are:

Effective Date of Changes	Publication Date
Changes effective January 1 2001	Mid-November 2000
Changes effective April 2001	Mid-February 2001
Changes effective July 2001	Mid-May 2001
Changes effective October 2001	Mid August, 2001

Important notifications that require communication in between these dates will be published via additional unscheduled special issues and posted to the First Coast Service Option, Inc. (FCSO) website (www.floridamedicare.com). In some cases, notifications posted on the fiscal intermediary website, will also be provided in hard copy format.

Who Receives the *Bulletin*?

If you were previously receiving individually distributed Part A bulletins, you now receive the comprehensive *Medicare A Bulletin*. Please remember that Medicare Part A (First Coast Service Options, Inc.) uses the same mailing address for all correspondence. No issue of the *Bulletin* may be sent to a specific person/department within an office. To ensure continued receipt of all Medicare correspondence, providers must keep their mailing addresses current.

What Is in the *Bulletin*?

The *Bulletin* is divided into several sections addressing general and facility-specific information and coverage guidelines.

The publication always starts with a column by the Intermediary Medical Director. Following an administrative section are usually general information and coverage sections with informational and billing issues, processing guidelines, and medical coverage applicable to all Medicare Part A providers and facilities. Coverage guidelines and billing issues targeting specific facilities or Part A providers are usually included in individual sections named under the applicable facility type. These facility-specific sections are in the *Bulletin* only when an article in that category is published (for example, if no CORF/ORF information is in the issue, that section is omitted.) Also, as needed, the *Bulletin* contains Electronic Data Interchange (EDI) and Fraud and Abuse sections.

The Local Medical Review Policies section contains finalized medical policies and additions, revisions, and corrections to previously published local medical review policies. Whenever possible, the Local Medical Review

Policies section will be placed in the center of the *Bulletin* to allow readers to remove it separately, without disturbing the rest of the magazine.

The Educational Resources section includes educational material, such as Medifest schedules, Medicare Web site information, and reproducible forms. An index and important addresses and phone numbers are on the back.

The Medicare A Bulletin Represents Formal Notice of Coverage Policies

Articles included in each *Medicare A Bulletin* represent formal notice that specific coverage policies have or will take effect on the date given. Providers who receive each issue are expected to read, understand, and abide by the policies outlined in this document to ensure compliance with Medicare coverage and payment guidelines. Medicare Part A (First Coast Service Options, Inc.) maintains the mailing lists for each issue; inclusion on these mailing lists implies that the issue was received by the provider in the event there is a dispute over whether a provider received advance notice regarding coverage of a specific service and the financial liability for it.

Do You Have Comments?

The publications staff welcomes your feedback on the *Bulletin* and appreciates your continued support. Please mail comments to:

Medicare Publications Department
Editor, *Medicare A Bulletin*
P.O. Box 2078
Jacksonville, FL 32231-0048

GENERAL INFORMATION

Expansion of Medicare Reimbursement for Telehealth Services

Section 223 of the Medicare, Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) amended section 1834 of the Social Security Act (the Act) to provide for an expansion of Medicare payment for telehealth services. Section 223 of BIPA limits the existing telehealth provision to services furnished before October 1, 2001, and mandates that the expanded benefit be effective for services furnished on or after October 1, 2001.

Summary of Benefit Expansion

Effective for services furnished on or after October 1, 2001, coverage and payment for Medicare telehealth includes consultation, office visits, individual psychotherapy and pharmacologic management delivered via a telecommunication system. Eligible geographic areas will be expanded beyond rural health professional shortage areas to include counties not in a metropolitan statistical area (MSA). Additionally, federal telemedicine demonstration projects as of December 31, 2000, may serve as the originating site regardless of geographic location. An interactive telecommunication system is required as a condition of payment; however, BIPA does allow the use of asynchronous 'store and forward' technology in delivering these services when the originating site is a federal telemedicine demonstration program in Alaska or Hawaii. BIPA does not require that a practitioner present the patient for interactive telehealth services.

With regard to payment amount, BIPA specifies that payment for the professional service performed by the distant site practitioner (i.e., where the expert physician or practitioner is physically located at time of telemedicine encounter) will be equal to what would have been paid without the use of telemedicine.

Distant site practitioners include only a physician as described in section 1861(r) and a medical practitioner as described in section 1842(b)(18) (C) of the Act. BIPA also expands payment under Medicare to include a \$20 originating site facility fee (location of beneficiary).

Previously, the Balanced Budget Act of 1997 (BBA) limited the scope of Medicare telehealth coverage to consultation services and the implementing regulation prohibited the use of an asynchronous, 'store and forward' telecommunication system. BBA 1997 also required the professional fee to be shared between the referring and consulting practitioners, and prohibited Medicare payment for facility fees and line charges associated with the telemedicine encounter.

BIPA requires that Medicare Part B (Supplementary Medical Insurance) pay for this expansion of telehealth services beginning with services furnished on October 1, 2001.

Time limit for current teleconsultation provision. The current teleconsultation provision as authorized by section 4206 (a) and (b) of the BBA of 1997 and implemented in 42 CFR sections 410.78 and 414.65 applies only to teleconsultations provided on or after January 1, 1999, and before October 1, 2001.

Eligibility Criteria for Telehealth Services

Beneficiaries eligible for telehealth services. Medicare beneficiaries are eligible for telehealth services only if

- they are presented from an originating site located in either a rural health professional shortage area (HPSA) as defined by section 332(a)(1) (A) of the Public Health Services Act, or
- in a county outside of a MSA as defined by section 1886(d)(2)(D) of the Act.

Exception to rural HPSA and non MSA geographic requirements.

Entities participating in a Federal telemedicine demonstration project that were approved by or were receiving funding from the Secretary of Health and Human Services as of December 31, 2000, qualify as originating sites regardless of geographic location. Such entities are not required to be in a rural HPSA or non-MSA.

Originating site defined. An originating site is the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunications system occurs. Originating sites authorized by law are:

- The office of a physician or practitioner
- A hospital
- A critical access hospital
- A rural health clinic
- A federally qualified health center.

Coverage of Telehealth

Scope of coverage. The use of a telecommunication system may substitute for a face-to-face, "hands on" encounter for consultation, office visits, individual psychotherapy and pharmacologic management. These services and corresponding current procedure terminology (CPT) codes are listed below.

- Consultations (CPT codes 99241 - 99275)
- Office or other outpatient visits (CPT codes 99201-99215)
- Individual psychotherapy (CPT codes 90804 - 90809)
- Pharmacologic management (CPT code 90862)

Conditions of Payment

Technology. For Medicare payment to occur, interactive audio and video telecommunications must be used, permitting real-time communication between the distant site physician or practitioner and the Medicare beneficiary. As a condition of payment, the patient must be present and participating in the telehealth visit.

Exception to the interactive telecommunications requirement.

In the case of federal telemedicine demonstration programs conducted in Alaska or Hawaii, Medicare payment is permitted for telemedicine when asynchronous 'store and forward technology', in single or multimedia formats, is used as a substitute for an interactive telecommunication system. The originating site and distant

Expansion of Medicare Reimbursement for Telehealth Services (continued)

site practitioner must be included within the definition of the demonstration program.

Store and forward defined. For purposes of this instruction, store and forward means the asynchronous transmission of medical information to be reviewed at a later time by the physician or practitioner at the distant site. A patient's medical information may include, but not limited to, video clips, still images, X-rays, MRIs, EKGs and EEGs, laboratory results, audio clips, and text. The physician or practitioner at the distant site reviews the case without the patient being present. Store and forward substitutes for an interactive encounter with the patient present; the patient is not present in real-time.

NOTE: Asynchronous telecommunications system in single media format does not include telephone calls, images transmitted via facsimile machines, and text messages without visualization of the patient (electronic mail). Photographs must be specific to the patients' condition and adequate for rendering or confirming a diagnosis and or treatment plan. Dermatological photographs, e.g., a photograph of a skin lesion, may be considered to meet the requirement of a single media format under this instruction.

Telepresenters. A medical professional is not required to present the beneficiary to physician or practitioner at the distant site unless medically necessary. The decision of medical necessity will be made by the physician or practitioner located at the distant site.

Payment Methodology for Physician/Practitioner at the Distant Site

Distant site defined. The term "distant site" means the site where the physician or practitioner, providing the professional service, is located at the time the service is provided via a telecommunication system.

Payment amount (professional fee). The payment amount for the professional service provided via a telecommunication system by the physician or practitioner at the distant site is equal to the current fee schedule amount for the service provided. Payment for an office visit, consultation, individual psychotherapy or pharmacologic management via a telecommunication system should be made at the same amount as when these services are furnished without the use of a telecommunication system. For Medicare payment to occur, the service must be within a practitioner's scope of practice under state law. The beneficiary is responsible for any unmet deductible amount and applicable coinsurance.

Medicare practitioners who may receive payment at the distant site (i.e., at a site other than where the beneficiary is). As a condition of Medicare Part B payment for telehealth services, the physician or practitioner at the distant site must be licensed to provide the service under state law. When the physician or practitioner at the distant site is licensed under state law to provide a covered telehealth service (i.e., professional consultation, office and other outpatient visits, individual psychotherapy, and pharmacologic management) then he or she may bill for and receive payment for this service when delivered via a telecommunication system.

Medicare practitioners who may bill for covered telehealth services are listed below (subject to state law).

- Physician
- Nurse practitioner
- Physician assistant
- Nurse midwife
- Clinical nurse specialist
- Clinical psychologist*
- Clinical social worker*

*Clinical psychologists and clinical social workers cannot bill for psychotherapy services that include medical evaluation and management services under Medicare. These practitioners may not bill or receive payment for the following CPT codes: 90805, 90807, and 90809.

Originating Site Facility Fee Payment Methodology

Originating site defined. The term originating site means the location of an eligible Medicare beneficiary at the time the service being furnished via a telecommunication system occurs. For asynchronous, store and forward telecommunication technologies, an originating site is only a federal telemedicine demonstration program conducted in Alaska or Hawaii.

Facility fee for originating site. For consultation, office or other outpatient visit, psychotherapy and pharmacologic management services delivered via a telecommunication system furnished from October 1, 2001, through December 31, 2002, the originating site fee is the lesser of \$20 or the actual charge. For services furnished on or after January 1 of each subsequent year, the facility fee for the originating site will be updated annually by the Medicare Economic Index (MEI).

Payment amount. For telehealth services furnished from October 1, 2001, through December 31, 2002, the payment amount to the originating site is the lesser of the actual charge or the originating site facility fee of \$20. The beneficiary is responsible for any unmet deductible amount and Medicare coinsurance.

The originating site facility fee payment methodology for each type of facility is clarified below.

Hospital outpatient department. When the originating site is a hospital outpatient department, payment for the originating site facility fee must be made as described above and not under the outpatient prospective payment system. Payment is not based on current fee schedules or other payment methodologies.

Hospital inpatient. When the originating site is for hospital inpatients, payment for the originating site facility fee must be made outside the diagnostic related group (DRG) payment, since this is a Part B benefit, similar to other services paid separately from the DRG payment, (e.g., hemophilia blood clotting factor).

Critical access hospitals. When the originating site is a critical access hospital, payment is made as described above, separately from the cost-based reimbursement methodology.

Expansion of Medicare Reimbursement for Telehealth Services (continued)

Federally qualified health centers (FQHCs) and rural health clinics (RHCs). The originating site facility fee for telehealth services is not an FQHC or RHC service. When an FQHC or RHC serves as the originating site, the originating site facility fee must be paid separately from the center or clinic all-inclusive rate.

Physicians' and practitioners' offices. When the originating site is a physician's or practitioner's office, the payment amount, in accordance with the law, is the lesser of the actual charge or \$20 regardless of geographic location. The geographic practice cost index (GPCI) will not be applied to the originating site facility fee. This fee is statutorily set and is not subject to the geographic payment adjustments authorized under the physician fee schedule.

Instructions for Submission of Telehealth Claims

Telehealth claims for originating site facility must be reported using HCPCS code "Q3014 – telehealth originating site facility fee." By submitting HCPCS code Q3014, the originating site facility authenticates that the facility is located in either a rural HPSA or non-MSA county.

The appropriate bill types for this benefit are: 12x, 13x, 71x, 73x, and 85x.

The originating site facility can be located in a number of revenue centers within a facility, such as an emergency room (450), operating room (360), or clinic (510). Therefore, telehealth claims must be reported under the revenue code where the service was furnished.

The fee for originating site facility telehealth claims will be paid outside of current fee schedules or other payment methodologies (e.g., payment must be made in addition to the DRG, outpatient prospective payment system.) (See "Originating site facility fee payment methodology".)

NOTE: The originating site facility fee is a Part B payment. The fee will be updated yearly based upon the Medicare economic index.

Hospitals and critical access hospitals bill their fiscal intermediary for the originating site facility fee.

Independent and provider-based RHCs and FQHCs bill the appropriate intermediary using the RHC or FQHC bill type and billing number. HCPCS code "Q3104, telehealth originating site facility fee" is the only non-RHC/FQHC service that is billed using the clinic/center bill type and provider number. For all other non-RHC/FQHC services, provider based RHCs and FQHCs must bill using the provider bill type and billing number.

Independent RHCs and FQHCs must bill the carrier for all other non-RHC/FQHC services.

If an RHC/FQHC visit occurs on the same day as a telehealth service, the RHC/FQHC serving as an originating site must bill for HCPCS code "Q3014 telehealth originating site facility fee" on a separate revenue line from the RHC/FQHC visit.

The telehealth professional service payment and originating site facility fee are subject to post payment verification. ❖

Services and Items Furnished to Prisoners

Medicare does not pay for items or services paid directly or indirectly by a federal, state or local governmental entity. Generally, no payment is made for services rendered to prisoners, since the state (or other government component which operates the prison) is responsible for the prisoners' medical care and other needs. Exceptions to this exclusion may be overcome only at the initiative of the state or local governmental entity. When an exception is desired, the state or local governmental entity responsible for the prisoners' medical needs must submit to the Medicare contractor documentation establishing that:

- (a) The state or local law requires that individuals in custody repay the cost of the services.
- (b) The state or local governmental entity enforces the requirement to pay by billing and seeking collection from all individuals in custody with the same legal status (e.g., not guilty by reason of insanity), whether insured or uninsured, and by pursuing collection of the amounts they owe in the same way and with the same vigor that it pursues the collection of other debts. This

includes collection of any Medicare deductible and coinsurance amounts and the cost of items and services not covered by Medicare.

- (c) The state or local entity documents its case with copies of the regulations, manual instructions, directives, etc., spelling out the rules and procedures for billing and collecting amounts paid for prisoners' medical expenses. The state or local governmental entity must produce a representative sample of cases in which prisoners have been billed and payment pursued, randomly selected from both Medicare and non-Medicare eligible. The existence of cases in which the state or local entity did not actually pursue collection, even though there is no indication that the effort would have been unproductive, indicates that the requirement to pay is not enforced.

For the purpose of the Medicare program the term "prisoner" means a person who is in custody of the police, penal authorities, or other agency of a governmental entity. ❖

COB Contractor Fact Sheet for Providers

The following article is being published at the request of the Health Care Financing Administration. This article is a revision to a previous notification published in the December 2000 Medicare A Bulletin Special Issue page 10.

The Health Care Financing Administration (HCFA) has embarked on an important initiative to further expand its campaign against Medicare waste, fraud and abuse under the Medicare Integrity Program. HCFA awarded the Coordination of Benefits (COB) contract to consolidate the activities that support the collection, management, and reporting of other insurance coverage of Medicare beneficiaries.

The awarding of the COB contract provides many benefits for employers, providers, suppliers, third party payers, attorneys, beneficiaries, and federal and state insurance programs. All Medicare secondary payer (MSP) claims investigations are initiated from, and researched at the COB contractor. This is no longer the function of your local Medicare intermediary or carrier. Implementing this single-source development approach will greatly reduce the amount of duplicate MSP investigations. This will also offer a centralized, one-stop customer service approach, for

all MSP-related inquiries, including those seeking general MSP information, but not those related to specific claims or recoveries that serve to protect the Medicare trust funds. The COB contractor provides customer service to all callers from any source, including but not limited to beneficiaries, attorneys/other beneficiary representatives, employers, insurers, providers, and suppliers.

Information Gathering

Medicare generally uses the term Medicare secondary payer or “MSP” when the Medicare program is not responsible for paying a claim first. The COB contractor will use a variety of methods and programs to identify situations in which Medicare beneficiaries have other health insurance that is primary to Medicare. In such situations, the other health plan has the legal obligation to meet the beneficiary’s health care expenses first before Medicare. The table below describes a few of these methods and programs.

<i>Method/Program</i>	<i>Description</i>
Initial Enrollment Questionnaire (IEQ)	Beneficiaries are sent a questionnaire about other insurance coverage approximately three (3) months before they are entitled to Medicare.
IRS/SSA/HCFA Data Match	Under the Omnibus Budget Reconciliation Act of 1989, employers are required to complete a questionnaire that requests Group Health Plan (GHP) information on identified workers who are either entitled to Medicare or married to a Medicare beneficiary.
MSP Claims Investigation	This activity involves the collection of data on other health insurance that may be primary to Medicare based on information submitted on a medical claim or from other sources.
Voluntary MSP Data Match Agreements	Voluntary Agreements allow for the electronic data exchange of GHP eligibility and Medicare information between HCFA and employers or various insurers.

Provider Requests and Questions Regarding Claims Payment

Intermediaries and carriers will continue to process claims submitted for primary or secondary payment. Claims processing will not be a function of the COB contractor. Questions concerning how to bill for payment (e.g., value codes, occurrence codes) should continue to be directed to your local intermediary or carrier. In addition, continue to return inappropriate Medicare payments to the local Medicare contractor. Checks should not be sent to the COB contractor. Questions regarding Medicare claim or service denials and adjustments should continue to be directed to your local intermediary and carrier. If a provider submits a claim on behalf of a beneficiary and there is an indication of MSP, but not sufficient information to disprove the existence of MSP, the claim will be investigated by the COB contractor. This investigation will be performed with the provider or supplier that submitted the claim. MSP investigations will no longer be a function of your local intermediary or carrier. The goal of MSP information gathering and investigation is to identify MSP situations quickly and accurately, thus ensuring correct primary and secondary payments by the responsible party.

Providers, physicians, and other suppliers benefit not only from lower administrative claims costs, but also through enhanced customer service to their Medicare patients.

Medicare Secondary Payer Auxiliary Records in HCFA’s Database

The COB contractor is the sole authority to ensure the accuracy and integrity of the MSP information contained in HCFA’s database (i.e., Common Working File). Information received as a result of MSP gathering and investigation is stored on the CWF in an MSP auxiliary file. The MSP auxiliary file allows for the entry of several auxiliary records, where necessary. MSP data may be updated, as necessary, based on additional information received from external parties (e.g., beneficiaries, providers, attorneys, third party payers). Beneficiary, spouse and/or family member changes in employment, reporting of an accident, illness, or injury, Federal program coverage changes, or any other insurance coverage information should be reported directly to the COB contractor. HCFA also relies on providers and suppliers to ask their Medicare patients about the presence of other primary health care coverage, and to report this information when filing claims with the Medicare program.

*COB Contractor Fact Sheet for Providers (continued)***Termination and Deletion of MSP Auxiliary Records in HCFA's Database**

Intermediaries and carriers will continue to terminate records on the CWF where the provider has received information that MSP no longer applies (e.g. succession of employment, exhaustion of benefits). Termination requests should continue to be directed to your local intermediary or carrier.

MSP records on the CWF that you identify as invalid should be reported to the COB contractor for investigation and deletion.

Contacting the COB Contractor

Effective January 1, 2001, refer all MSP inquiries; including, the reporting of potential MSP situations, invalid MSP auxiliary files, and general MSP questions/concerns to the COB contractor. Continue to call your local intermediary and/or carrier regarding claims-related and recovery questions. The COB Contractor's Customer Call Center toll free number is 1-800-999-1118 or TDD/TYY 1-800-318-8782. Customer service representatives are available to assist you from 8 a.m. to 8 p.m., Monday through Friday, Eastern standard time, except holidays. Clip and post this section in a handy place for access by your office and billing staff. ❖

Medical Review Of Therapy Services

The Centers for Medicare and Medicaid Services (CMS), formerly known as the Health Care Financing Administration (HCFA), has contracted with one of their Program Safeguard Contractors, DynCorp TRP, to perform a number of tasks related to physical therapy, occupational therapy, and speech language pathology services.

Among the tasks is the medical review of therapy services to determine the appropriateness of claim processing results. In order to accomplish this, DynCorp is contacting providers to request medical records associated with the 1998, 1999, and 2000 therapy services. CMS is anticipating that providers comply with the medical records requests and appreciates providers' cooperation.

For more information and education is available by visiting the DynCorp TRP Web site at www.dynpsc.org. ❖

Crossover Updates

The following updates have been added to the Florida Medicare Part A Crossover Insurers list.

Automatic Crossover

- **New Crossover Insurer**

The following private insurers have been added to our list of Automatic Crossover Insurers:

- United American Insurance
- Continental Life Insurance
- Mutual of Omaha ❖

FCSO Medicare eNews Now Available to Web site Visitors

Join our *eNews* mailing list and receive urgent or other critical information issued by your Florida Medicare Carrier and Intermediary, First Coast Service Options, Inc. (FCSO). By signing up, you will receive periodic messages advising you of updates to the provider Web site (www.FloridaMedicare.com) and/or key program alerts, seminar schedules, publications availability, educational tips, critical program changes, etc. To sign up, access the Web site, click on the *eNews* link and select the desired interest group selection. ❖

2002 ICD-9-CM Coding Changes

The 2002 update to the *International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM)* diagnosis coding structure is effective **October 1, 2001**. Providers are required to use the 2002 updated ICD-9-CM coding effective for all hospital discharges and outpatient services occurring **on or after October 1, 2001**. Due to the direct relationship between coding and reimbursement, it is particularly important that providers reimbursed under the prospective payment system (PPS) used the appropriate ICD-9-CM coding. Other providers that code diagnoses and procedures (non-OPPS providers) are also affected. In addition, the new diagnosis coding is used in hospital outpatient billing.

Detailed information regarding the 2002 ICD-9-CM coding update is available on the Florida Medicare Web site – www.floridamedicare.com and on the HCFA Web site – www.hcfa.gov. Changes to local medical review policies affected by the 2002 ICD-9-CM update will be published in future issues of the *Medicare A Bulletin*.

In addition, a new PPS Grouper (version 19.0) will assign diagnosis related groups (DRGs) based on the new codes. The Medicare code editor (MCE version 18.00), and the outpatient code editor (OCE version 2.3) will use the new codes in validating for discharges and outpatient services occurring **on or after October 1, 2000**.

The latest versions of the ICD-9-CM manuals (as well as a variety of other coding materials) may be obtained from:

HealthCare Consultants of America
(800) 253-4945

Medicode Publications
(800) 999-4600

St. Anthony's Publishing
(800) 632-0123

ICD-9-CM and other coding materials may also be obtained from local medical publishing and consulting firms. ❖

Automated Response Unit for Medicare A Providers

To better serve the Medicare Part A provider community, First Coast Service Options, Inc. (FCSO) has implemented the following toll-free telephone number to access the customer services automated response unit (ARU):

1-877-602-8816

The customer services automated response unit (ARU) is available

**Monday-Friday 6:00 a.m. – 6:00 p.m. and
Saturday 9:00 a.m. – 4:25 p.m.**

Please have the Medicare provider number and the beneficiary health insurance claim (HIC) number ready.

All Providers Press 1

For the Top Five Most Commonly Asked Questions, Press 1

For an answer to:

- ☎ Patient's responsibility for non-covered services after signing an advanced beneficiary notice, **Press 1**
- ☎ How to start SNF PPS-perspective payment system billing, **Press 2**
- ☎ New PPS prospective payment system coding for SNF services, **Press 3**
- ☎ Why patients are sometimes informed that their claims are incorrectly billed by billing offices, **Press 4**
- ☎ Why Medicare customers services representatives refer providers to the ARU rather than providing certain information, **Press 5**
- ☎ To repeat the menu, **Press the start (*) key**
- ☎ To return to the main menu, **Press 8**
- ☎ To end this call, **Press 9**

For Claims Currently in the Medicare Part A Systems, Press 2

- ☎ If your telephone keypad *does not display* the letters Q and Z on numbers 7 and 9, **Press 1**
- ☎ If your telephone keypad *does display* the letters Q and Z on numbers 7 and 9, **Press 2**

For Provider Check Information, Press 3

- ☎ To obtain the amount of your last check, **Press 1**
- ☎ To obtain information on an individual check by date, **Press 2**
- ☎ For information on the last 3 checks issues to you, **Press 3**

For Medicare Seminars, HCFA Publications or Medicare Part A Publications, Press 4

- ☎ For information on Medicare Seminars, **Press 1**
- ☎ For information on HCFA publications, **Press 2**
- ☎ For information on Medicare Part A publications, **Press 3**
- ☎ To repeat the menu, **Press the star (*) key**
- ☎ To return to the main menu, **Press 8**
- ☎ To end this call, **Press 9**

For Medicare Patient Eligibility, Press 5

Please be prepared to enter the beneficiary's Medicare number, the first six letters of the beneficiary's last name, the first initial of the beneficiary, the date of birth, and the beneficiary's sex.

- ☎ If your telephone keypad *does not display* the letters Q and Z on numbers 7 and 9, **Press 1**
- ☎ If your telephone keypad *does display* the letters Q and Z on numbers 7 and 9, **Press 2**

For Name, Address and Telephone Number of a Health Care Maintenance Organization, Press 6

This feature provides 30 of the most common referenced HMOs. To get assistance, an HMO number is need. Please enter the four numbers directly following the letter H in the HMO number.

For Description of Commonly Used Reason Codes, Press 7

This feature provides information on the most commonly used reason codes. Please enter the five-digit reason code now.

To Repeat the Menu, Press the Start (*) Key

This feature returns you to the beginning of the menu to make another selection.

To Reach a Customer Service Representative, Press 0

This feature takes you out of the ARU and transfers you to the next available representative.

To End the Call, Press 9

Exits you from the ARU. ❖

GENERAL COVERAGE

New CLIA Waived Tests

Listed below are the latest tests approved by the Center for Disease Control as waived tests under the Clinical Laboratory Improvement Amendments (CLIA). The *Current Procedural Terminology (CPT)* codes for these new tests must have the modifier QW to be recognized as a waived test.

- Worldwide Medical Corporation, First Check® Home Drug Test (THC), **effective June 29, 2000**, CPT code 80101QW
- Worldwide Medical Corporation, First Check® Home Drug Test (THC-COC), **effective June 29, 2000**, CPT code: 80101QW
- Roche Diagnostics Coagu Chek S Systems Test (for prothrombin time), **effective September 6, 2000**, CPT code 85610QW
- Wyntek Signify Mono Test, **effective September 7, 2000**, CPT code 86308QW
- Worldwide Medical Corporation, First Check® Home Drug Test Panel 4 (THC-COC-OPI-MET), **effective December 6, 2000**, CPT code 80101QW
- OraSure Technologies Q.E.D. A-150 Saliva Alcohol Test, **effective December 19, 2000**, CPT code 82055QW
- OraSure Technologies Q.E.D. A-350 Saliva Alcohol Test, **effective December 19, 2000**, CPT code 82055QW
- Genua Menopause Monitor Test, **effective January 12, 2001**, CPT code 83001QW
- Bayer Diagnostics/MICROALBUSTIX™ Reagent Strips, **effective February 16, 2001**, CPT code: 82044QW and 82570QW
- Cholestech LDX® Alanine Aminotransferase (ALT) Test, **effective: April 13, 2001**, CPT code 84460QW.

New waived CPT codes have been assigned for the following tests:

- 83001QW for the Genua Menopause Monitor Test
- 82570QW for creatinine performed by the Bayer Diagnostics/MICROALBUSTIX™ Reagent Strip
- 84460QW for the Cholestech LDX® Alanine Aminotransferase (ALT) Test.

The additional CPT code 82570QW has been added to the Bayer Clinitek 50 Urine Analyzer – for microalbumin and creatinine test.

TEST NAME	MANUFACTURER	CPT CODE	USE
Worldwide Medical Corporation, First Check® Home Drug Test Panel 4 (THC-COC-OPI-MET)	Worldwide Medical Corporation	80101QW	Screening test for the presence/detection of cannabinoids (THC), cocaine metabolites, opiates and methamphetamines in urine
OraSure Technologies Q.E.D. A-150 Saliva Alcohol Test	OraSure Technologies, Inc.	82055QW	Quantitative determination of alcohol (ethanol) in saliva
OraSure Technologies Q.E.D. A-350 Saliva Alcohol Test	OraSure Technologies, Inc.	82055QW	Quantitative determination of alcohol (ethanol) in saliva
Genua Menopause Monitor Test,	Genua 1944 Inc.	83001QW	Detects follicle stimulating hormone in urine
Bayer Diagnostics/MICROALBUSTIX™ Reagent Strip	Bayer Inc.	82044QW 82570QW	Semi-quantitative measurement of microalbumin and creatinine in urine for the detection of patients at risk for developing kidney damage
Cholestech LDX® Alanine Aminotransferase (ALT) Test	CHOLESTECH Corporation	84460QW	Quantitative determination of alanine aminotransferase in whole blood

Coverage and Billing of Biofeedback Training for the Treatment of Urinary Incontinence

Biofeedback for the treatment of urinary incontinence is covered for the treatment of stress and/or urge urinary incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training. A failed trial of PME training is defined as no clinically significant improvement in urinary continence after completing four weeks of an ordered plan of pelvic muscle exercises designed to increase periurethral muscle strength.

Biofeedback for the treatment of urinary incontinence is covered for services provided **on or after July 1, 2001**.

Home use of biofeedback therapy is not covered.

Billing Instructions

The applicable CPT codes to report services for biofeedback for the treatment of urinary incontinence are:

- 90901 *Biofeedback training by any modality; and*
90911 *Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry.*

Payment Requirements

Biofeedback for urinary incontinence is paid as follows when provided in a:

- Hospital outpatient department – payment is under the outpatient prospective payment system (OPPS)
- Skilled nursing facility or comprehensive outpatient rehabilitation facility – payment is under the Medicare physician fee schedule
- A critical access hospital (CAH) – payment is made on a reasonable cost basis

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- Rural health clinics (RHCs)/federally qualified health centers (FQHCs) – payment is made on an all-inclusive rate for the professional component; or based on the provider's payment method for the technical component. (See below for RHC/FQHC instructions.)

Billing Requirements

The applicable bill types for biofeedback for treatment of urinary incontinence are 12x, 13x, 14x, 22x, 23x, 75x and 85x.

The applicable revenue code is 917 (see below for RHCs and FQHCs).

The professional component of a urinary biofeedback service furnished within an RHC/FQHC by a physician or non-physician is considered an RHC/FQHC service. RHCs and FQHCs must bill to their fiscal intermediaries under bill type 71x or 73x for the professional component along with revenue code 52x.

The technical component of a urinary biofeedback service is outside the scope of the RHC/FQHC benefit. If the technical component of this service is furnished within an independent RHC or freestanding FQHC, the provider of that technical service bills the carrier on a HCFA-1500 claim form.

If the technical component of a urinary biofeedback service is furnished within a provider-based RHC/FQHC, the provider of that service bills the fiscal intermediary under bill type 13x, 14x, 22x, 23x, 75x or 85x as appropriate using their outpatient provider number (not the RHC/FQHC provider number since this service is not covered as an RHC/FQHC service). The appropriate revenue code is 917. ❖

Expansion of Coverage on Percutaneous Transluminal Angioplasty

The Health Care Financing Administration (HCFA) has revised section 50-32 of the Coverage Issues Manual (CIM) to reflect that effective for services provided **on or after July 1, 2001**, Medicare will cover percutaneous transluminal angioplasty (PTA) of the carotid artery concurrent with carotid stent placement when furnished in accordance with the Food and Drug Administration (FDA) approved protocols governing Category B Investigational Device Exemption (IDE) clinical trials.

Coverage Expansion

PTA of the carotid artery, when provided **solely** for the purpose of carotid artery dilation concurrent with carotid stent placement, is considered to be a reasonable and necessary service **only** when provided in the context of an FDA approved clinical trial, and therefore is considered a covered service for the purpose of these trials. Consequently, the coverage of this procedure is based on how the service is delivered.

Performance of PTA in the carotid artery when used to treat obstructive lesions outside of approved protocols governing Category B IDE clinical trials remains a noncovered service. PTA of the vertebral and cerebral arteries remains noncovered. The safety and efficacy of these procedures have not been established.

Claim Processing Instructions for Hospital Inpatient Services

To bill for these services, hospital must follow the general bill review instructions in section 3604 of the Medicare Intermediary Manual, Part 3, and the claim processing instructions for Category B IDEs.

Claims for these services are submitted on a UB-92 HCFA-1450 claim form or its electronic equivalent using:

- Type of bill code: 11x
- Principal diagnosis: ICD-9-CM 433.10 or 43.11
- Principal procedures: 39.50 Angioplasty or atherectomy of non-coronary vessel
39.90 Insertion of non-coronary artery stent or stent(s)

PTA of the carotid artery concurrent with carotid stent placement may not be performed in a hospital outpatient setting.

Claims furnished for services for PTA of the carotid artery provided outside of an FDA approved clinical trial will be denied. ❖

ESRD SERVICES

Intravenous Iron Therapy

Iron deficiency is a common condition in end stage renal disease (ESRD) patients undergoing hemodialysis. Iron is a critical structural component of hemoglobin, a key protein found in normal red blood cells (RBCs) which transports oxygen. Without this important building block, anemic patients experience difficulty in restoring adequate, healthy RBCs that improve hematocrit levels.

Clinical management of iron deficiency involves treating patients with iron replacement products while they undergo hemodialysis. Body iron stores can be supplemented with either oral or intravenous (IV) iron products. The available evidence suggests that the mode of intravenous administration is perhaps the most effective treatment for iron deficiency in hemodialysis patients. Unlike oral iron products which must be absorbed through the GI tract, IV iron products are infused directly into the bloodstream in a form that is readily available to the bone marrow for RBC synthesis, resulting in an earlier correction of iron deficiency and anemia.

- A. Effective December 1, 2000, Medicare covers *sodium ferric gluconate complex in sucrose injection* as a first line treatment of iron deficiency anemia when furnished intravenously to patients undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy.
- B. Effective October 1, 2001, Medicare also covers *iron sucrose injection* as a first line treatment of iron deficiency anemia when furnished intravenously to patients undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy.

Coverage for intravenous iron therapy, is revised to add *iron sucrose injection* for first line treatment of iron deficiency anemia in patients undergoing chronic hemodialysis who are receiving supplemental erythropoietin therapy.

Until a more specific HCPCS is assigned, *iron sucrose injection* should be billed using J3490. *Sodium ferric gluconate complex in sucrose injection* should be billed using J2915. ❖

SKILLED NURSING FACILITY SERVICES

Billing for Audiologic Function Tests For Beneficiaries that Are Patients of a Skilled Nursing Facility (SNF)

Some previous Medicare notifications from the Health Care Financing Administration inadvertently included audiologic function testing with speech therapy services which are subject to SNF Part B consolidated billing requirements that must be billed by the SNF when furnished to beneficiaries in Part B SNF stays. However, audiologic function tests furnished to Part B beneficiaries are separately payable under the physician fee schedule.

The provider of service generally bills audiologic function tests to the carrier. For tests that include both a professional component and technical component, the SNF may elect to bill the technical component to the intermediary, but is not required to bill the service. The audiologic function test codes are listed below. All codes listed below have a technical component. Only the two codes identified with an asterisk beside them have a professional component.

Audiologic Function Tests

92552, 92553, 92555, 92556, 92557, 92561, 92562, 92563, 92564, 92565, 92567, 92568, 92569, 92571, 92572, 92573, 92575, 92576, 92577, 92579, 92582, 92583, 92584, 92587*, 92588*, 92589, 92596, and V5299.

Payment to SNFs for audiologic function tests are bundled into the PPS payment amount for beneficiaries in a covered SNF Part A stay, whether provided directly by the SNF or under arrangements by an independent provider based on a contract with the SNF. Independent audiologists may bill the carrier directly for services rendered to beneficiaries not in a SNF Part A covered stay. Payment is made based on the physician fee schedule, whether by the carrier or the intermediary. For beneficiaries not in a covered Part A SNF stay, who are sometimes referred to as beneficiaries in a Part B SNF stay, audiologic function tests are payable under Part B when billed by the SNF as type of bill 22x, or when billed directly to the carrier by the provider of the service.

Since audiologic function tests are **not** bundled with speech therapy services, payment is made to the provider of service or to the SNF where the services are provided under arrangements with the SNF. This change was effective for services furnished on or after April 1, 2001

Intermediaries will continue using their current payment methodology until July 1, 2001. ❖

Skilled Nursing Facility Annual Update for Fiscal Year 2002

Annual updates to the payment rates for skilled nursing facility (SNF) prospective payment system (PPS) are required by section 1888 (e) of the Social Security Act, as amended by the Medicare, Medicaid and State Child Health Insurance (SCHIP) Program Balanced Budget Refinement Act of 1999, and the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000.

The Centers for Medicare and Medicaid Services (CMS), formerly known as the Health Care Financing Administration (HCFA), will publish the SNF payment rates for fiscal Year (FY) 2002, that is October 1, 2001 through September 30, 2002, before August 1, 2001 in the *Federal Register*.

The methodology used for the update is identical to that used in the previous year. The rates will reflect a number of adjustments required by the statute. These include:

- Update to the federal rates using the latest market basket minus 0.5 percentage point
- Temporary increase in the adjusted federal rates of 20 percent for certain resource utilization groups (RUGs) and 6.7 percent for certain others (as listed in the Notice of Proposed Rule-Making (NPRM) published on May 10, 2001 and also appearing in the publication of the Final Rule)
- An increase of 16.66 in the nursing case-mix component of the rates
- An increase of 4 percent in the adjusted federal rate for FY 2002.

The updated payment rates are effective for SNF services provided on or after October 1, 2001 and ending September 30, 2002. ❖

Clarification to Health Insurance Prospective Payment System (HIPPS) Coding and Billing Instructions

The Health Care Financing Administration (HCFA) has provided further guidance on the use of the new two-digit assessment indicator codes, which are part of the HIPPS rate codes that **were effective with services provided on or after October 1, 2000.**

Health Insurance Prospective Payment System (HIPPS) rate codes are required for billing for Medicare skilled nursing facility (SNF), Part A services, under the SNF PPS. In addition, HCFA has provided clarification of the payment policy with regard to billing based on “off-cycle” minimum data set (MDS) assessments.

There have been no changes in the types of assessments used to bill for Part A services under SNF PPS. There are three types of assessments:

- Medicare required assessments,
- Off-cycle assessments, and
- Significant correction of a prior assessment (SCPA).

The Medicare required assessments are those scheduled for the 5th, 14th, 30th, 60th, and 90th days of the Medicare Part A covered stay. Off-cycle assessments include the Other Medicare Required Assessment (OMRA) and the Significant Change in Status Assessment (SCSA). In addition, the Significant Correction of a Prior Assessment (SCPA) is now designated as an off-cycle assessment and thus, it must be used to “replace” a Medicare required

assessment when the timing and type of assessment being corrected (e.g., comprehensive assessment), warrant the use of this assessment type and the assessment reference date of the SCPA falls at the time that a Medicare required assessment is due to be performed.

SCPAs are only performed to correct major errors in comprehensive assessments, that is, MDS assessments that include care planning and resident assessment protocols. An SCPA may **never** be performed to correct a regularly scheduled Medicare assessment (5-day, 14-day, 30-day, etc.) since none of those are comprehensive MDS assessments.

Example:

A facility realized that the initial admission assessment performed regarding a Medicare beneficiary contained clinical information that was erroneous and did not accurately reflect that beneficiary’s needs or his care plan. The facility realizes that it must do a new assessment, an SCPA, to have an accurate MDS for this beneficiary. The date chosen for the assessment reference date (ARD) for the SCPA was one of the days in the assessment window for the 30-day Medicare assessment. In this situation, the SCPA replaces the 30-day assessment. The rate of payment changes on the ARD of the SCPA.

Table 1 — Medicare Required Assessments and Assessment Windows

Medicare Required Assessment	Assessment Window (includes grace days)	Payment Period
5 – day	Days 1 – 8	Days 1 – 14
14 – day	Days 11 – 19	Days 15 – 30
30 – day	Days 21 – 34	Days 31 – 60
60 – day	Days 51 – 64	Days 61 – 90
90 – day	Days 81 – 94	Days 91 – 100

Use of Assessment Indicators

With the implementation of the two-digit assessment indicators that were effective with services provided on or after October 1, 2000, HCFA added several assessment indicator codes to make it possible for providers to account for, and code, additional combinations of reasons for Medicare required assessments. As a result of the additional codes, the definition for code indicator 38 has changed. To avoid confusion on the part of providers when billing for Part A SNF stays, list below are three sections addressing those assessment indicators for which the definitions have not changed, explain the one that did change, and provide complete definitions for those that have been added.

Assessment Indicators that Have *Not Changed*

- 00 Default Code
- 01 5-day Medicare required assessment/not an initial admission assessment
- 02 30-day Medicare required assessment
- 03 60-day Medicare required assessment
- 04 90-day Medicare required assessment
- 07 14-day Medicare required assessment/not an initial admission assessment
- 08 Other Medicare Required Assessment
- 11 5-day (or readmission/return) Medicare required assessment and initial admission assessment
- 32 SCSA that replaces a Medicare required 30-day assessment
- 33 SCSA that replaces a Medicare required 60-day assessment
- 34 SCSA that replaces a Medicare required 90-day assessment
- 37 SCSA that replaces a Medicare required 14-day assessment
- 41 SCPA that replaces a Medicare required 5-day assessment
- 42 SCPA that replaces a Medicare required 30-day assessment

Clarification to Health Insurance Prospective Payment System (HIPPS) Coding and Billing Instructions (continued)

- 43 SCPA that replaces a Medicare required 60-day assessment
- 44 SCPA that replaces a Medicare required 90-day assessment
- 47 SCPA that replaces a Medicare required 14-day assessment
- 54 A Quarterly assessment that is used as a 90-day Medicare assessment

Assessment indicator codes have been required since the implementation of SNF PPS. The codes are only used for billing Medicare for covered SNF Part A stays. To the extent possible, every combination of reasons for MDS assessment relevant for Medicare payment has been captured by the HIPPS assessment indicator codes. However, to avoid undue complexity and because the information is not relevant for payment, there are some combinations that are not specifically identifiable using the codes. This means that although there are instances in which all of the information contained on the MDS is not captured by the HIPPS assessment indicator code, it is still an accurate code for billing purposes. For example, "08" indicates that the bill is based on an MDS assessment performed to fulfill the Medicare requirement for an OMRA 8 - 10 days after the discontinuation of all rehabilitation therapy. From the standpoint of Medicare payment, it does not matter if the MDS (the required OMRA) was also used to fulfill the clinical requirement for an SCSA or a Quarterly. For this reason, the assessment indicator code "08" is used for billing several different combinations of reasons for assessment, as can be seen in Table 2. The important information for the payer is that the facility performed the required MDS in a timely manner and that the payment rate changes as of the ARD of the assessment. Note that several assessment indicator codes (i.e., "05", "01", "11", and "07"), like "08", are used in multiple situations, but always to convey the most important information from a billing standpoint. (See Tables 2 and 3 for a display of combinations of reasons for assessment and the appropriate assessment indicator code to use for billing.)

Assessment Indicators That Have Changed

- 38 The code now signifies an OMRA that replaces the 60-day Medicare required assessment. Prior to October 1, 2000, "38" signified that the bill was based on either a SCSA only or on a SCSA that was also used to satisfy the requirement for an OMRA.

An SCSA that is performed for a Medicare Part A covered beneficiary (and, as such is to be billed to Medicare) when no Medicare required assessment is due, is now coded as a "30". Indicator code "30" signifies that the only reason for assessment was a SCSA. Similarly, the new HIPPS assessment indicator code for a bill based on an MDS that was performed for the combination of a SCSA and an OMRA, is "08".

Assessment Indicators That Have Been Added

- 5 This code is used to signify that the bill is based on a readmission/return assessment. There may, or may not, be a clinical reason for the assessment.
- 17 This code is used to signify that the bill is based on an MDS that is satisfying two requirements: the clinical requirement for an initial admission assessment and the Medicare payment requirement for a 14-day assessment.
- 18 This code is used to signify that the bill is based on an OMRA that was performed within the window of a Medicare required 5-day assessment and "replaces" the Medicare required 5-day assessment. This combination of assessment types is extremely rare and, accordingly, this code will not likely be used often.
- 28 This code is used to signify that the bill is based on an OMRA that was performed within the window of a Medicare required 30-day assessment and "replaces" the Medicare required 30-day assessment.
- 30 This code is used to signify that the bill is based on a SCSA performed for clinical reasons as required by OBRA 1987. As defined in the *Long Term Care Resident Assessment Instrument User's Manual*, MDS 2.0, a SCSA is appropriate if there is a consistent pattern of change, with either two or more areas of decline or two or more areas of improvement in the beneficiary's clinical status.
- 31 This code is used to signify that the bill is based on a SCSA that was performed for clinical reasons within the window of a Medicare required 5-day assessment and "replaces" the Medicare required 5-day assessment.
- 35 This code is used to signify that the bill is based on a SCSA that was performed within the assessment window for a readmission/return assessment and will "replace" the readmission/return assessment.
- 40 This code is used to signify that the bill is based on a SCPA that was performed for clinical reasons.
- 45 This code is used to signify that the bill is based on a SCPA that was performed within the assessment window of a readmission/return assessment and "replaces" the readmission/return assessment.
- 48 This code is used to signify that the bill is based on an OMRA that was performed within the assessment window of a 90-day Medicare required assessment and "replaces" the Medicare required 90-day assessment.
- 78 This code is used to signify that the bill is based on an OMRA that was performed within the assessment window of a 14-day Medicare required assessment and "replaces" the Medicare required 14-day assessment.

*Clarification to Health Insurance Prospective Payment System (HIPPS) Coding and Billing Instructions (continued)***Billing Based on Off-Cycle MDS Assessments**

If an off-cycle assessment is performed within the assessment window of a Medicare required assessment, it must replace the Medicare required assessment. Payment will change effective with the ARD of the off-cycle assessment that “replaces” the Medicare required assessment and will continue until the next Medicare required assessment or off-cycle assessment, whichever occurs first. This policy is applied when there is a single off-cycle assessment that is performed within the Medicare required assessment window. However, when the ARD of the “replacement” (or off-cycle) assessment is on one of the grace days, the payment rate changes on the day it would have changed based on the regularly schedule assessment.

Example 1: If the ARD of an OMRA is set on day 22 of the Part A covered stay, which is within the assessment window for setting the ARD for the 30-day Medicare required assessment, it must replace the 30 day Medicare required assessment. Payment will change on day 22, the ARD of the OMRA, and will continue until the next Medicare required assessment or off-cycle assessment, whichever occurs first.

Example 2: If the ARD of an OMRA is set for day 32 of the stay and the OMRA is replacing the Medicare 30-day assessment, then the payment will change as of day 31, as if it were a regularly scheduled 30-day assessment. The payment rate changes retrospectively in this case because otherwise, there is no appropriate rate to bill for day 31. Payment based on the 14-day assessment may only go through day 30.

While not a common occurrence, there may be situations in which multiple assessments are performed within one Medicare required assessment window. In these instances, the off-cycle assessment with an ARD closest to, and before, the date on which the Medicare required assessment is due (i.e., day 5, day 14, day 30, day 60 or day 90) is the assessment that must replace the Medicare required assessment. Any other assessment performed in the assessment window must be billed as a stand-alone assessment and cannot replace the Medicare required assessment.

If there is one off-cycle assessment within the assessment window and another off-cycle assessment performed with an ARD on a grace day, the assessment with the grace day ARD must be billed separately as an off-cycle assessment and cannot replace the Medicare required assessment. The assessment with the ARD closest to, and before, the date on which the assessment was due must replace the assessment. In this case, there was an off-cycle assessment with an ARD before the assessment due date, therefore, that assessment is the replacement assessment. The assessment with an ARD in the grace period must be billed separately. There is no longer a Medicare assessment to be replaced. The required Medicare assessment was already replaced by the assessment that was performed within the assessment window and before the due date.

Example 3: A SNF sets the ARD for a SCSA on day 22 of the covered stay. The beneficiary “grouped” into a rehabilitation RUG. Therapy ends on day 24 and the SNF performs an OMRA with an ARD of day 33. The SNF must use the SCSA with the ARD of day 22 of the covered stay to replace the Medicare required assessment. This assessment must be used as the replacement assessment because its ARD is within the assessment window for the Medicare required assessment and is before the date on which the Medicare required assessment is due. The OMRA with an ARD that fell on day 33 of the stay cannot replace the Medicare required assessment since it already has been replaced by the SCSA. Payment to the SNF will change on day 22 (the ARD of the SCSA), since the SCSA must be used to replace the Medicare required assessment, and then again on day 33 of the covered stay, based on the OMRA. The payment associated with the RUG code derived from the OMRA will continue until the next Medicare required assessment or off-cycle assessment, whichever occurs first.

continued on next page

Table 2 — HIPPS Assessment Indicator Codes

Reason for Assessment*	Medicare 5-day			Medicare 30-day			Medicare 60-day			Medicare 90-day			Readmission/Return			Medicare 14-day			Other Medicare Required OMRA				
	A8a	A8b	HIPPS	A8a	A8b	HIPPS	A8a	A8b	HIPPS	A8a	A8b	HIPPS	A8a	A8b	HIPPS	A8a	A8b	HIPPS	A8a	A8b	HIPPS		
Initial Admission	01	1	11	—	—	—	—	—	—	—	—	—	—	—	01	5	11	01	7	17	01	8	08
Annual	02	1	01	02	2	02	02	3	03	02	4	04	02	5	05	02	7	07	02	8	08	08	
Significant Change in Status-SCSA	03	1	31	03	2	32	03	3	33	03	4	34	03	5	35	03	7	37	03	8	08	08	
Significant Correction of Prior Full	04	1	41	04	2	42	04	3	43	04	4	44	04	5	45	04	7	47	04	8	08	08	
Quarterly	05	1	01	05	2	02	05	3	03	05	4	54	05	5	05	05	7	07	05	8	08	08	
Significant Correction of Prior Quarterly	10	1	41	10	2	42	10	3	43	10	4	44	10	5	45	10	7	47	10	8	08	08	
None of the Above	00	1	01	00	2	02	00	3	03	00	4	04	00	5	05	00	7	07	00	8	08	08	

*A8a and A8b are used in the table headings rather than AA8a and AA8b due to space constraints. The two are interchangeable for coding reason for assessment. The values listed for A8a are identical to what will be coded in AA8a, similarly, the values listed for A8b are identical to the coding in AA8b.

Table 3 — HIPPS Assessment Indicator Codes for billing when there are two Medicare reasons for assessment; two codes in MDS item AA8b or no reason for assessment to be coded in AA8b.

Reason for Assessment	Medicare 5-day	Medicare 14-day	Medicare 30-day	Medicare 60-day	Medicare 90-day	Readmission/Return Assessment	SCSA	SCPA
Other State-required assessment*	01	07	02	03	04	05	30	40
OMRA	18	78	28	38	48	18	08	08
No reason for assessment in AA8b	N/A	N/A	N/A	N/A	N/A	N/A	30	40

*This item in Section AA8b of the MDS is not used in every State and has no implications for Medicare billing. It is shown here only in the interest of providing clear and complete information. ❖

COMPREHENSIVE OUTPATIENT REHABILITATION FACILITY SERVICES

New Temporary “Q” Codes for Splints and Casts Used for Reduction of Fractures and Dislocations

In the Medicare physician fee schedule beginning in 2001, the casting supplies were removed from the practice expenses for all HCPCS codes, including the CPT codes for fracture management and for casts and splints. Thus, for settings in which CPT codes are used to pay for services, which include the provision of a cast or splint, new temporary codes are being established to pay physicians and other practitioners for the supplies used in creating casts. The work and practice expenses involved with the creation of the cast or splint should continue to be coded using the appropriate CPT code. The use of the new temporary codes described below will replace less specific coding for the casting and splinting supplies.

Comprehensive outpatient rehabilitation facilities (CORFs) bill type 75x and outpatient therapy facilities (ORFs) bill type 74x are the only facility settings affected by the implementation of new temporary HCPCS “Q” codes for casting and splinting used for reduction of fractures and dislocation.

Therefore, services for casting and splinting supplies provided in a CORF or ORF facility furnished **on or after October 1, 2001**, will be reimbursed under the physician fee schedule established by the Medicare Part B carrier. The HCPCS “Q” codes will be added in the October 1, 2001, version of the Outpatient Code Editor.

The payments for casting and splinting supplies provided in hospital outpatient departments and ambulatory surgical centers are unchanged by this implementation. To the extent these services are provided by home health agencies and to hospice patients for the treatment of a nonterminal illness, the payments for these services are also unchanged. These facilities continue to utilize the appropriate codes in the 29000 through 29750 series of HCPCS Level I codes.

Temporary HCPCS “Q” Codes

The following temporary “Q” codes have been established for the supplies used to create splints and casts used for reduction of fractures and dislocations. The fee amounts established for the remaining of 2001 are also included. Payment for splint and casts furnished on or after October 1, 2001, and before January 1, 2002, will be based on the lower of the actual charge or the fee amount listed below.

HCPCS	Description	Fee Amount
Q4001	Cast supplies, body cast adult, with or without head, plaster	\$34.78
Q4002	Cast supplies, body cast adult, with or without head, fiberglass	\$131.44
Q4003	Cast supplies, application of shoulder cast, adult (11 years +), plaster	\$24.98
Q4004	Cast supplies, application of shoulder cast, adult (11 years +), fiberglass	\$86.48
Q4005	Cast supplies, long arm cast, adult (11 years +), plaster	\$9.21
Q4006	Cast supplies, long arm cast, adult (11 years +), fiberglass	\$20.76
Q4007	Cast supplies, long arm cast, pediatric (0-10 years), plaster	\$4.61
Q4008	Cast supplies, long arm cast, pediatric (0-10 years), fiberglass	\$10.38
Q4009	Cast supplies, short arm cast, adult (11 years +), plaster	\$6.14
Q4010	Cast supplies, short arm cast, adult (11 years +), fiberglass	\$13.84
Q4011	Cast supplies, short arm cast, pediatric (0-10 years), plaster	\$3.07
Q4012	Cast supplies, short arm cast, pediatric (0-10 years), fiberglass	\$6.92
Q4013	Cast supplies, gauntlet cast (includes lower forearm and hand), adult (11 years +), plaster	\$11.18
Q4014	Cast supplies, gauntlet cast (includes lower forearm and hand), adult (11 years +), Fiberglass	\$18.88
Q4015	Cast supplies, gauntlet cast (includes lower forearm and hand, pediatric (0-10 years), Plaster	\$5.59
Q4016	Cast supplies, gauntlet cast (includes lower forearm and hand), pediatric (0-10 years), fiberglass	\$9.44
Q4017	Cast supplies, long arm splint, adult (11 years +), plaster	\$6.47
Q4018	Cast supplies, long arm splint, adult (11 years +), fiberglass	\$10.32
Q4019	Cast supplies, long arm splint, pediatric (0-10 years), plaster	\$3.24
Q4020	Cast supplies, long arm splint, pediatric (0-10 years), fiberglass	\$5.16
Q4021	Cast supplies, short arm splint, adult (11 years +), plaster	\$4.79
Q4022	Cast supplies, short arm splint, adult (11 years +), fiberglass	\$8.64
Q4023	Cast supplies, short arm splint, pediatric (0-10 years), plaster	\$2.40
Q4024	Cast supplies, short arm splint, pediatric (0-10 years), fiberglass	\$4.32
Q4025	Cast supplies, hip spica (one or both legs), adult (11 years +), plaster	\$26.86
Q4026	Cast supplies, hip spica (one or both legs), adult (11 years +), fiberglass	\$83.85
Q4027	Cast supplies, hip spica (one or both legs), pediatric (0-10 years), plaster	\$13.43

HCPCS	Description	Fee Amount
Q4028	Cast supplies, hip spica (one or both legs), pediatric (0-10 years), fiberglass	\$41.93
Q4029	Cast supplies, long leg cast, adult (11 years +), plaster	\$20.53
Q4030	Cast supplies, long leg cast, adult (11 years +), fiberglass	\$54.05
Q4031	Cast supplies, long leg cast, pediatric (0-10 years), plaster	\$10.27
Q4032	Cast supplies, long leg cast, pediatric (0-10 years), fiberglass	\$27.03
Q4033	Cast supplies, long leg cylinder cast, adult (11 years +), plaster	\$19.15
Q4034	Cast supplies, long leg cylinder cast, adult (11 years +), fiberglass	\$47.65
Q4035	Cast supplies, long leg cylinder cast, pediatric (0-10 years), plaster	\$9.58
Q4036	Cast supplies, long leg cylinder cast, pediatric (0-10 years), fiberglass	\$23.83
Q4037	Cast supplies, short leg cast, adult (11 years +), plaster	\$11.69
Q4038	Cast supplies, short leg cast, adult (11 years +), fiberglass	\$29.27
Q4039	Cast supplies, short leg cast, pediatric (0-10 years), plaster	\$5.85
Q4040	Cast supplies, short leg cast, pediatric (0-10 years), fiberglass	\$14.64
Q4041	Cast supplies, long leg splint, adult (11 years +), plaster	\$14.21
Q4042	Cast supplies, long leg splint, adult (11 years +), fiberglass	\$24.25
Q4043	Cast supplies, long leg splint, pediatric (0-10 years), plaster	\$7.10
Q4044	Cast supplies, long leg splint, pediatric (0-10 years), fiberglass	\$12.13
Q4045	Cast supplies, short leg splint, adult (11 years +), plaster	\$8.25
Q4046	Cast supplies, short leg splint, adult (11 years +), fiberglass	\$13.27
Q4047	Cast supplies, short leg splint, pediatric (0-10 years), plaster	\$4.12
Q4048	Cast supplies, short leg splint, pediatric (0-10 years), fiberglass	\$6.64
Q4049	Finger splint, static	\$1.50
Q4050	Cast supplies, for unlisted types and material of casts	IC
Q4051	Splint supplies, miscellaneous (includes thermoplastics, strapping, fasteners, padding and other supplies)	IC

Codes A4570, A4580, A4590, L2102, L2104, L2122, and L2124, which were previously used for billing of splints and casts are invalid for Medicare use effective October 1, 2001.

For claims with dates of service on or after July 1, 2001, jurisdiction for processing claims for splints (previously billed using A4570) were transferred from the durable medical equipment regional carriers (DMERCs) to the local carriers. The local carriers have jurisdiction for processing claims for the new Q codes for splints and casts, which includes codes for splints that may have previously been billed to the DMERCs under code A4570. In addition, for claims with dates of service on or after July 1, 2001, jurisdiction for slings (A4565), will be jointly maintained by the local carriers (for physician claims) and the DMERCs (for supplier claims).

Crosswalk from CPT to HCPCS Codes

To assist providers with the selection of the correct Level II HCPCS code for the cast and splinting supplies, the following crosswalk provides guidance as to which supply codes are applicable for the various types of casts described by Level I or CPT codes.

Level I	Level II	Level I	Level II
29000	Q4001 or Q4002	29126	Q4021 through Q4024
29010	Q4001 or Q4002	29130	Q4049
29015	Q4001 or Q4002	29131	Q4051
29020	Q4001 or Q4002	29305	Q4025 through Q4028
29025	Q4001 or Q4002	29325	Q4025 through Q4028
29035	Q4001 or Q4002	29345	Q4029 through Q4032
29040	Q4001 or Q4002	29355	Q4029 through Q4032
29044	Q4001 or Q4002	29365	Q4033 through Q4036
29046	Q4001 or Q4002	29405	Q4037 through Q4040
29049	Q4050	29425	Q4037 through Q4040
29055	Q4003 or Q4004	29435	Q4037 through Q4040
29058	Q4003	29440	Q4050
29065	Q4005through Q4008	29445	Q4037 through Q4040
29075	Q4009through Q4012	29450	Q4035, Q4036, Q4039, or Q4040
29085	Q4013through Q4016	29505	Q4041 through Q4044
29105	Q4017through Q4020	29515	Q4045 through Q4048
29125	Q4021through Q4024. ❖		

HOSPITAL SERVICES

New Patient Status Codes

The National Uniform Billing Committee (NUBC) has revised form locator 22, patient status, in the UB-92 HCFA-1450 claim form (and equivalent electronic formats), to include two new patient status codes, **effective January 1, 2002**. These new codes are:

- 62** Discharged/transferred to another rehabilitation facility including rehabilitation distinct part units of a hospital.
- 63** Discharged/transferred to a long-term care hospital.

These new codes, previously included as part of patient status code 05, discharged/transferred to another facility, will allow discharge status to be more specifically coded and will be particularly useful in the implementation of Inpatient Rehabilitation Facility Prospective Payment System (IRFPPS). ❖

Hospital Billing for Accommodation Charges

- Q** When billing an inpatient Medicare Part B only claim (type of bill 12x or 22x), should a hospital bill for accommodation charges?
- A** On an ancillary bill (12x and 22x), a provider should not submit accommodation charges. Inpatient ancillary services may be paid under Medicare Part B when the level of care becomes non-covered under Medicare Part A or when the Part A benefits are exhausted. Medicare Part B inpatient ancillary services include radiology, pathology, electrocardiology, electroencephalography, physical therapy, speech pathology, renal dialysis, and medical supplies (prosthetic devices, braces, and splints). ❖

MEDICAL POLICIES

The Health Care Financing Administration (HCFA) instructions regarding development of local medical review policies (LMRPs) are addressed in the Medicare Intermediary Manual (HCFA publication 13-3, section 3911), indicating, "Medical review policy is a composite of statutory provisions, regulations, nationally published Medicare coverage policies, and LMRPs." In the absence of statute, regulations, or national coverage policy, Medicare contractors are instructed to develop LMRPs to describe when and under what circumstances an item or service is covered. LMRPs are also developed to clarify or to provide specific details on national coverage guidelines and are the basis for medical review decisions made by the Medicare contractor's medical review staff.

Medical review initiatives are designed to ensure the appropriateness of medical care and to ensure that medical policies and review guidelines developed are consistent with the accepted standards of medical practice.

LMRP Format

Each LMRP is written in a standard format designed to convey pertinent information about an item or service in an organized and concise manner. The format is divided into distinct sections containing information the provider must know to ensure compliance.

Effective Dates

In accordance with HCFA guidelines, a minimum 30-day advance notice is required when initially implementing a final LMRP. The LMRPs published in this section, are effective approximately 30 days from the date of this publication. Therefore, the policies contained in this section are effective for claims processed **September 21, 2001**, and after, unless otherwise noted.

Medicare Part A Medical Policy Procedures

Medical policies may be applied to Medicare claims on a pre-payment or post-payment basis. Medicare providers are accountable for complying with Medicare coverage/policy information published via national HCFA transmittals, or fiscal intermediary publication of LMRP.

Maintaining Local Medical Review Policies For Reference

Providers are encouraged to maintain all published medical policies on file (e.g., the policies published in this document); perhaps placing them in a manual/binder where they may be accessed/referenced by facility staff. In response to reader comments, the Medical Policy section may be removed separately, without disturbing the rest of the articles in the publication.

Medical Policy Table of Contents

Final Medical Policies

10060: Incision and Drainage of Abscess of Skin, Subcutaneous and Accessory Structures	23
55873: Cryosurgical Ablation of the Prostate	25
67221: Ocular Photodynamic Therapy (OPT) with Verteporfin	27
71250: Computerized Axial Tomography of the Thorax	29
74150: Computerized Axial Tomography of the Abdomen	31
84155: Serum Protein	35
85007: Complete Blood Count	38
88141: Pap Smears	42
92225: Ophthalmoscopy	46
93303: Transthoracic and Doppler Echocardiography and Doppler Color Flow Velocity Mapping	49
A0430: Air Ambulance Services	54
G0030: Positron Emission Tomography (PET) Scan	57
G0104: Colorectal Cancer Screening	65
G0108: Diabetes Outpatient Self-Management Training	68
J1561: Intravenous Immune Globulin	71
J1745: Infliximab (Remicade™)	77
J9212: Interferon	79
M0302: Cardiac Output Electric Bioimpedance	82

Additions and Revisions to Previously Published Medical Policy

70450: Computerized Tomography Scans	86
C1300: Hyperbaric Oxygen Therapy (HBO Therapy)	86
J9293: Mitoxantrone Hydrochloride	86
Erythropoietin for Anemia of Chronic Disease	86

Use of the American Medical Association's (AMA's) Current Procedural Terminology (CPT) Codes on Contractors' Web Sites

The Health Care Financing Administration (HCFA) and the AMA recently signed an amendment to the original 1983 Agreement on HCFA's use of CPT coding. This new amendment covers the use of CPT codes, descriptions, and other materials on contractors' Web sites and in other electronic media. A requirement of the agreement is that contractors must differentiate between CPT and other coding structures, such as HCPCS and ICD-9-CM procedure codes, even though CPT codes are carried on HCPCS.

Florida Medicare provides electronic copies of printed publications (such as the *Medicare A Bulletin*) on our provider Web site exactly as they were produced in hard copy format. This assures that publications downloaded from the Web have the same content as the hard copies that were mailed. In order to maintain this consistency, beginning with this issue, the "HCPCS Codes" section of Florida Medicare's LMRPs will now say "CPT/HCPCS Codes," if there is CPT and non-CPT material, or simply "CPT Codes" if the codes in a policy are exclusively CPT. In the event that a policy contains only HCPCS procedure codes, the section title remains unchanged.

10060: Incision and Drainage of Abscess of Skin, Subcutaneous and Accessory Structures

Policy Number

10060

Contractor Name

First Coast Service Options, Inc.

Contractor Number

090

Contractor Type

Intermediary

LMRP Title

Incision and Drainage of Abscess of Skin, Subcutaneous and Accessory Structures

AMA CPT Copyright Statement

CPT codes, descriptions, and other data only are copyright 2000 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply.

HCFA National Coverage Policy

N/A

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

HCFA Region

Region IV

HCFA Consortium

Southern

Original Policy Effective Date

09/21/2001

Original Policy Ending Date

N/A

Revision Effective Date

N/A

Revision Ending Date

N/A

LMRP Description

An abscess is a cavity containing pus surrounded by inflamed tissue. This cavity is formed as a result of the production and exudation of pus in a localized infection. It is generally associated with pain, swelling and erythema. An abscess often requires incision and drainage to remove the purulent material in order for healing to occur.

Procedure codes 10060 and 10061 represent incision and drainage of an abscess involving the skin, subcutaneous and/or accessory structures. This includes the following types of abscess: furuncle, carbuncle, suppurative hidradenitis, an abscessed cyst, an abscessed paronychia, and/or other abscess involving the cutaneous and/or subcutaneous structures.

Indications and Limitations of Coverage and/or Medical Necessity

Florida Medicare will consider the use of incision and drainage of an abscess of the skin, subcutaneous and/or accessory structures to be medically reasonable and

necessary for the treatment of an actively infected abscess involving these structures. This includes the incision and drainage of the following types of abscess:

- furuncle;
- carbuncle;
- suppurative hidradenitis;
- an abscessed cyst;
- an abscessed paronychia; and/or
- other abscess of cutaneous and/or subcutaneous structures.

It would not generally be expected to see incision and drainage of an abscess of the skin, subcutaneous and/or accessory structures to be repeated frequently and/or multiple times. If frequent repeated incision and drainage is required, the medical record must reflect the reason for persistent/recurrent abscess formation, as well as any measures taken to prevent reoccurrence.

CPT/HCPCS Section & Benefit Category

Integumentary System/Surgery

Type of Bill Code

Hospital – 13x

Skilled Nursing Facility – 21x

Revenue Codes

361 Operating Room Services, Minor Surgery

CPT/HCPCS Codes

- | | |
|-------|----------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 10060 | Incision and drainage of abscess (eg, carbuncle, suppurative hidradenitis, cutaneous or subcutaneous abscess, cyst, furuncle, or paronychia); simple or single |
| 10061 | complicated or multiple |

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

- | | |
|---------------|---------------------------------------------------------------------|
| 528.5 | Diseases of lips (abscess) |
| 607.2 | Other inflammatory disorders of penis (abscess, boil, or carbuncle) |
| 611.0 | Inflammatory disease of breast (abscess) |
| 680.0-680.9 | Carbuncle and furuncle |
| 681.10-681.11 | Cellulitis and abscess of toe |
| 682.0-682.9 | Other cellulitis and abscess |
| 705.83 | Hidradenitis |

Diagnosis that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

Diagnosis that DO NOT Support Medical Necessity

N/A

Reason for Denial

When performed for indications other than those listed in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy.

10060: Incision and Drainage of Abscess of Skin, Subcutaneous and Accessory Structures (continued)

Noncovered ICD-9-CM Code(s)

Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnosis

N/A

Coding Guidelines

Procedure codes 10060 and 10061 represent incision and drainage of an abscess involving the skin, subcutaneous and/or accessory structures. Therefore, the medical necessity diagnosis code must represent an abscess, not the underlying condition causing the abscess. For example, the ICD-9-CM code for sebaceous cyst (706.2) would not meet medical necessity for procedure codes 10060 or 10061. If the patient had an abscess of a sebaceous cyst then it would be appropriate to code the applicable ICD-9-CM code for the abscess (depending upon the anatomical location of the abscess).

Similarly, if billing a covered diagnosis, the medical record must demonstrate that an abscess was present. For example, if billing the diagnosis code for paronychia of the toe (ICD-9-CM code 681.11), the medical record must clearly demonstrate that an abscessed paronychia was present and that incision and drainage of the purulent material occurred, in order to bill procedure code 10060 or 10061. If a nail avulsion occurred and the medical record documentation does not demonstrate that an abscess was present and incision and drainage of purulent material occurred, then the appropriate nail avulsion procedure code (11730 or 11732) should be billed, not procedure codes 10060 or 10061.

Furthermore, there are many other anatomical sites of abscess that are not addressed in this policy. There are numerous incision and drainage procedure codes that are specific to the incisions and drainage of an abscess in various anatomical sites. Therefore, it would be appropriate to bill these more specific incision and drainage codes. For example: an abscess of the eyelid should be billed with procedure code 67700 (Blepharotomy, drainage of abscess, eyelid); a perirectal abscess should be billed with procedure code 46040 (Incision and drainage of ischioanal and/or perirectal abscess); an abscess of the finger should be billed with procedure codes 26010-26011 (Drainage of finger abscess).

Documentation Requirements

Medical record documentation maintained by the performing provider must clearly indicate the medical necessity of the service being billed. As stated in the “Coding Guidelines” section, the medical record must clearly indicate that an abscess was present. This should include the location, size, and appearance of the abscess.

In addition, documentation that the service was performed (incision and drainage of purulent material from an abscess) must be included in the patient’s medical record. This information is normally found in the office/ progress notes, hospital notes, and/or procedure report.

Furthermore, the medical record must clearly document the medical necessity for repeated incision and drainage of an abscess. If frequent incision and drainage is required, the medical record must reflect the reason for persistent/ recurrent abscess formation, as well as any measures taken to prevent reoccurrence. For example, for repeated incision and drainage of an abscessed paronychia, the medical

record should document any additional measures taken to prevent reoccurrence and/or the reason for not performing more definitive treatment (e.g., the patient refuses and/or is not a candidate for permanent, partial or complete nail and nail matrix removal).

Utilization Guidelines

N/A

Other Comments

Terms Defined

Furuncle—a boil that begins as an infected and inflamed gland and/or hair follicle but progresses to form an abscess. Most common sites of occurrence include the back of the neck and the upper back.

Carbuncle—a subcutaneous abscess that contains purulent matter in multiple draining and interconnecting cutaneous sinuses. Purulent drainage eventually discharges to the skin surface through surface openings. Common sites for occurrences include the back of the neck and the buttocks.

Suppurative hidradenitis—an abscess involving a sweat gland most commonly occurring in the axillae, inguinal, and perianal regions.

Cyst—a thin-walled subcutaneous sac containing fluid or semisolid material. Cysts are generally asymptomatic until they rupture. The cyst may then become infected and form an abscess.

Paronychia—an infection of the marginal structures around the nail plate. This infection may result in the collection of purulent material and formation of an abscess.

Cutaneous and/or subcutaneous abscess—any other abscess involving the cutaneous and/or subcutaneous structures.

Sources of Information and Basis for Decision

Anderson, K., Anderson, L., & Glanze, W. (Eds.). (1994). *Mosby’s medical dictionary* (4th ed.). St. Louis: Mosby.
 Coughlin, M., & Mann, R. (eds.). (1999). *Surgery of the foot and ankle* (7th ed.). St. Louis: Mosby.
 Schwarz, S., Shires, G., & Spencer, F. (Eds.). (1994). *Principles of surgery* (6th ed.). New York: McGraw-Hill.

Advisory Committee Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from the Florida Podiatric Medical Association, Florida Society of Dermatology, and the Florida Chapter of American College of Surgeons.

Start Date of Comment Period

02/28/2001

End of Date of Comment Period

04/14/2001

Start Date of Notice Period

08/01/2001

Revision History

Revision Number	Original
Start Date of Comment Period:	02/28/2001
Start Date of Notice Period:	08/01/2001
	4 th Qtr 2001 <i>Bulletin</i>
Original Effective Date	09/21/2001 ❖

55873: Cryosurgical Ablation of the Prostate

Revision Overview: This policy has been revised to incorporate the coverage expansion of cryosurgery of the prostate to include salvage therapy under certain conditions.

Policy Number

55873

Contractor Name

First Coast Service Options, Inc.

Contractor Number

090

Contractor Type

Intermediary

LMRP Title

Cryosurgical Ablation of the Prostate

AMA CPT Copyright Statement

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HCFA National Coverage Policy

Coverage Issues Manual, Section 35-96
Medicare Hospital Manual, Section 425
Medicare Intermediary Manual, Section 3617

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

HCFA Region

Region IV

HCFA Consortium

Southern

Original Policy Effective Date

07/22/1999

Original Policy Ending Date

N/A

Revision Effective Date

07/01/2001

Revision Ending Date

06/30/2001

LMRP Description

Cryosurgery of the prostate gland, also known as cryosurgical ablation of the prostate (CSAP), destroys prostate tissue by applying extremely cold temperatures in order to reduce the size of the prostate gland.

CSAP can be carried out under general or spinal anesthesia and lasts approximately 2-3 hours. Five to six cryoprobe are placed transperineally under transrectal ultrasound (TRUS). Once the probes are in place, freezing is carried out while observing under TRUS the increasing echoes as the block of frozen prostate tissue approaches the rectal mucosa. Such monitoring minimizes the risk of rectal freezing. The possibility of injury to the urethra is decreased by the use of a warming device, which is inserted into the urethra.

Indications and Limitations of Coverage and/or Medical Necessity

Effective for services performed on or after July 1, 1999, Medicare will consider cryosurgery of the prostate medically reasonable and necessary under the following circumstance:

- For primary treatment of patients with clinically localized, stages T1-T3, prostate cancer.

Effective for services performed on or after July 1, 2001, salvage cryosurgery of the prostate for recurrent cancer is medically necessary and appropriate only for those patients with localized disease who:

- Have failed a trial of radiation therapy as their primary treatment; **and**
- Meet one of the following conditions: Stage T2B or below, Gleason score <9, PSA <8ng/mL.

NOTE: Cryosurgery as salvage therapy is not covered under Medicare after failure of other therapies as the primary treatment.

CPT/HCPCS Section & Benefit Category

Male Genital System/Surgery

Type of Bill Code

Hospital – 12x, 13x

Revenue Code

34x Nuclear Medicine

CPT/HCPCS Codes

55873 Cryosurgical ablation of the prostate (includes ultrasonic guidance for interstitial cryosurgical probe placement)

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

185 Malignant neoplasm of prostate

Diagnosis that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

Diagnosis that DO NOT Support Medical Necessity

N/A

Reasons for Denial

When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)

Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

55873: Cryosurgical Ablation of the Prostate (continued)

Noncovered Diagnosis

N/A

Coding Guidelines

N/A

Documentation Requirements

Medical record documentation maintained in the patient's file must demonstrate that the service was performed for the indications identified in this policy. In addition, documentation that the service was performed must be included in the patient's medical record. This information is normally found in the office/progress notes, hospital notes, and/or operative report.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

Bahn, D., Lee, F., Solomon, M., et al. (1995). Prostate cancer: US-guided percutaneous cryoablation. *Radiology*, 194, 551-556.

Benoit, R., Cohen, J., & Miller, R. (1998). Comparison of the hospital costs for radical prostatectomy and cryosurgical ablation of the prostate. *Urology*, 52, 820-824.

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Advisory Committee Notes

N/A

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

08/01/2001

Revision History

Revision Number:	2
Start Date of Comment Period	N/A
Start Date of Notice Period	08/01/2001
	4 th Qtr 2001 <i>Bulletin</i>
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Explanation of Revision:	Change request 1632, dated 6/11/01, expanded coverage to include salvage therapy under certain conditions.
Revision Number:	1
Start Date of Comment Period	N/A
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Explanation of Revision:	Annual 2001 HCPCS Update
Revision Number:	Original
Start Date of Comment Period	N/A
Start Date of Notice Period	06/01//1999
	June/July 1999 <i>Bulletin</i>
Original Effective Date:	07/22/1999 ❖

67221: Ocular Photodynamic Therapy (OPT) with Verteporfin

Revision Overview: "CPT/HCPCS Codes" and "Reason for Denial" sections of this policy have been revised to replace HCPCS code C1203 with temporary HCPCS code Q3013.

Policy Number

67221

Contractor Name

First Coast Service Options, Inc.

Contractor Number

090

Contractor Type

Intermediary

LMRP Title

Ocular Photodynamic Therapy (OPT) with Verteporfin

AMA CPT Copyright Statement

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HCFA National Coverage Policy

Coverage Issues Manual, Sections 35-100 and 45-30
Medicare Hospital Manual, Section 442.7
Medicare Intermediary Manual, Sections 3101.3,
3112.4, 3627.9

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

HCFA Region

Region IV

HCFA Consortium

Southern

Original Policy Effective Date

03/15/2001

Original Policy Ending Date

N/A

Revision Effective Date

07/01/2001

Revision Ending Date

06/30/2001

LMRP Description

Ocular photodynamic therapy (OPT) is a form of treatment for the "wet" or exudative form of age-related macular degeneration. The wet form of macular degeneration involves the growth of abnormal blood vessels called choroidal neovascularization (CNV) beneath the retina resulting in leakage and bleeding. Without treatment, a majority of patients eventually develop scar tissue beneath the macula, which results in loss of central vision. The concept of OPT is to selectively close the abnormal blood vessels, eliminate the bleeding and leakage, and stabilize or improve the vision.

OPT is similar to traditional laser ablation in that abnormal blood vessels are destroyed; however, it is unique in that the low intensity laser activation of the drug verteporfin (VISUDYNE™) preserves the surrounding structures from destruction that is an unfortunate side effect of traditional thermal laser. This feature allows use of this treatment for preservation of vision when the CNV occurs close to the center of the macula.

OPT is a two-step process. In the first step, the patient receives an intravenous injection of verteporfin. The verteporfin circulates through the body and adheres to the walls of the abnormal blood vessels beneath the macula. A laser is then used to shine light into the back of the eye. When this light beam activates the verteporfin, there is closure of the blood vessel. Over time, the body is able to absorb the blood and fluid, which results in stabilization or improvement of visual function.

Over the course of 1-3 months, the blood vessels that have been treated with OPT typically open again and leakage may recur. Treatment is performed at three-month intervals if there is evidence of continued leakage from the blood vessels.

Indications and Limitations of Coverage and/or Medical Necessity

Florida Medicare will consider OPT with verteporfin medically reasonable and necessary when performed for the following indication:

For the treatment of age-related macular degeneration in patients with predominantly classic subfoveal CNV lesions (where the area of classic CNV occupies = 50% of the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram.

Prior to verteporfin OPT retreatment, documentation of the patient's condition must include fluorescein angiographic evidence of current leakage from CNV.

Florida Medicare will not consider the performance of OPT with verteporfin medically reasonable and necessary when any of the following circumstances exist:

- Inability to obtain photographs and an adequate, legible fluorescein angiogram to document CNV (including difficulty with venous access) unless there is a documented history of fluorescein allergy; and
- There is no evidence of CNV leakage (as determined by fluorescein angiography).

CPT/HCPCS Section & Benefit Category

Surgery/ Eye and Ocular Adnexa

Type of Bill Code

Hospital – 13x

Revenue Code

361 Minor surgery

636 Drugs Requiring Detailed Coding

67221: Ocular Photodynamic Therapy (OPT) with Verteporfin (continued)

CPT/HCPCS Codes

- 67221 Destruction of localized lesion of choroid (eg, choroidal neovascularization); photodynamic therapy (includes intravenous infusion) (Effective 04/01/2001)
- G0184 Destruction of localized lesion of choroid (for example, neovascularization); ocular photodynamic therapy (includes intravenous infusion), other eye
- Q3013 Injection, verteporfin, 15mg

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

- 362.52 Exudative senile macular degeneration

Diagnosis that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

- 362.50 Macular degeneration (senile), unspecified
- 362.51 Nonexudative senile macular degeneration

Diagnosis that DO NOT Support Medical Necessity

N/A

Reasons for Denial

When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

The use of verteporfin with laser activation is the only form of OPT that is FDA-approved. Other drugs for OPT remain experimental, and therefore noncovered by Medicare.

Effective July 1, 2001, Verteporfin (Q3013) that is not used in conjunction with OPT will be denied.

Noncovered ICD-9-CM Code(s)

Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnosis

N/A

Coding Guidelines

CPT code 67221 must be used for claims for photodynamic therapy services performed on or after 04/01/2001.

CPT code G0184 should only be billed when performing OPT on a second eye at the same session as the first eye.

OPT is considered a unilateral service.

Claims submitted for OPT performed on both eyes on the same day will only receive a single reimbursement rate for verteporfin, as a single infusion is adequate for treatment of both eyes.

Revenue code 636 is required for Q3013 (verteporfin) in order to receive a transitional pass-through payment under the outpatient PPS.

Documentation Requirements

Medical record documentation maintained by the performing physician must clearly indicate the medical necessity of the service being billed. In addition, documentation that the service was performed must be included in the patient’s medical record. This information is normally found in the office/progress notes, hospital notes, and/or procedure/operative report.

The documentation maintained by the performing physician should include the following:

- Evaluation and management exam including the name and total calculated drug dose (mg) of the photodynamic therapy drug administered and the patient’s body surface area on which the dose of the drug is based.
- Fluorescein angiography report, which should include the description of the lesion (e.g., predominantly classic, minimally classic, no classic), unless there is a documented history of fluorescein allergy.

Documentation should support the criteria for coverage as set forth in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

Sources of information may be found online under “Medical Policies” in the Part A section on our provider Web site - www.florida.medicare.com.

Advisory Committee Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from the Florida Society of Ophthalmology.

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

08/01/2001

Revision History

- Revision Number: 2
- Start Date of Comment Period: N/A
- Start Date of Notice Period: 08/01/2001
- 4th Qtr 2001 *Bulletin*
- Revised Effective Date: 07/01/2001
- Explanation of Revision: Transmittal A-01-73 indicates the C-code C1203 is replaced by HCPCS code Q3013 effective 07/01/2001. ❖

71250: Computerized Axial Tomography of the Thorax

Policy Number

71250

Contractor Name

First Coast Service Options, Inc.

Contractor Number

090

Contractor Type

Intermediary

LMRP Title

Computerized Axial Tomography of the Thorax

AMA CPT Copyright Statement

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HCFA National Coverage Policy

Coverage Issues Manual, Section 50-12

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

HCFA Region

Region IV

HCFA Consortium

Southern

Original Policy Effective Date

09/21/2001

Original Policy Ending Date

N/A

Revision Effective Date

N/A

Revision Ending Date

N/A

LMRP Description

A computed tomographic (CT) image is a display of the anatomy of a thin slice of the body developed from multiple X-ray absorption measurements made around the body's periphery. Unlike conventional tomography, where the image of a thin section is created by blurring out the information from unwanted regions, the CT image is constructed mathematically using data arising only from the section of interest. Generating such an image is confined to cross sections of the anatomy that are oriented essentially perpendicular to the axial dimensions of the body. Reconstruction of the final image can be accomplished in any plane. The CT of the thorax extends from the lung apices to the posterior costophrenic sulci and may extend inferiorly to image the adrenal glands.

Indications and Limitations of Coverage and/or Medical Necessity

Florida Medicare will consider a CT of the thorax medically reasonable and necessary under the following circumstances:

- Evaluation of abnormalities of the lungs, mediastinum, pleura and chest wall initially found on a standard chest radiograph or barium swallow.
- Evaluation, staging, and follow-up after therapy (e.g., surgery, radiation, and/or chemotherapy) of lung and other primary thoracic malignancies.
- Evaluation of a patient who sustained trauma to the pleura, chest wall, mediastinum, and lung.
- Localization of a thoracic mass prior to biopsy.
- Evaluation of a patient with myasthenia gravis to rule out thymic tumors.
- Performance of CT-guided biopsies and drainage procedures when fluoroscopy is inadequate.
- Evaluation of a patient presenting with signs and/or symptoms suggestive of an aortic dissection. The most common symptom of an aortic dissection (occurring in approximately 90% of the cases) is sudden, excruciating pain most commonly located in the anterior chest. Patients may describe the pain as "cutting," "ripping," or "tearing". A sudden neurologic episode usually accompanies the onset of most instances of "painless" aortic dissection.

NOTE: Posterior and lateral views of the chest represent the basic screening tool in identifying abnormalities involving the thorax. It is expected that the chest X-ray is used to evaluate patients who present with signs and/or symptoms suggestive of chest pathology prior to proceeding to a CT scan.

In addition to the medical necessity requirements, the CT scan must be performed on a model of CT equipment that meets the following criteria:

- The model must be known to the Food and Drug Administration; and
- Must be in the full market release phase of development.

CPT/HCPCS Section & Benefit Category

Radiology/Diagnostic Radiology

Type of Bill Code

Hospital – 12x, 13x, 14x
 Skilled Nursing Facility – 21x, 22x, 23x
 Rural Health Clinic – 71x

Revenue Code

32x Diagnostic Radiology
 350 CT Scan, General Classification

CPT/HCPCS Codes

71250 Computerized axial tomography, thorax; without contrast material
 71260 with contrast material(s)
 71270 without contrast material, followed by contrast material(s) and further sections

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

010.00-010.96 Primary tuberculous infection
 011.00-011.96 Pulmonary tuberculosis

71250: Computerized Axial Tomography of the Thorax (continued)

135	Sarcoidosis
140.0-239.9	Neoplasms
277.00-277.01	Cystic fibrosis
358.0	Myasthenia gravis
415.11	Iatrogenic pulmonary embolism and infarction
417.1	Aneurysm of pulmonary artery
441.00-441.9	Aortic aneurysm and dissection
442.81-442.82, 442.89	Other aneurysm of other specified artery
492.0-492.8	Emphysema
494	Bronchiectasis
500-505	Pneumoconioses and other lung diseases due to external agents
510.0-510.9	Empyema
513.0-513.1	Abscess of lung and mediastinum
515	Postinflammatory pulmonary fibrosis
518.1	Interstitial emphysema
518.2	Compensatory emphysema
710.1	Systemic sclerosis
748.60-748.69	Other anomalies of lung
785.6	Enlargement of lymph nodes
786.00-786.9	Symptoms involving respiratory system and other chest symptoms
793.1	Nonspecific abnormal findings on lung field
793.2	Nonspecific abnormal findings on radiological and other examination of body structure, other intrathoracic organ
793.9	Other nonspecific abnormal findings on radiological and other examination of body structure
809.0-809.1	Ill-defined fractures of bones of trunk
860.0-862.9	Internal injury of thorax
875.0-875.1	Open wound of chest (wall)
908.0	Late effect of internal injury to chest
934.0-934.9	Foreign body in trachea, bronchus, and lung
959.1	Injury, trunk
V10.11-V10.12	Personal history of malignant neoplasm of trachea, bronchus, and lung
V10.20-V10.29	Personal history of malignant neoplasm of other respiratory and intrathoracic organs
V10.3	Personal history of malignant neoplasm of breast
V10.71-V10.79	Personal history of malignant neoplasm of other lymphatic and hematopoietic neoplasms
V10.81	Personal history of malignant neoplasm of bone
V58.0	Encounter for other and unspecified procedures and aftercare, radiotherapy
V58.1	Encounter for other and unspecified procedures and aftercare, chemotherapy
V58.49	Other specified aftercare following surgery
V67.1	Follow-up examination following radiotherapy
V67.2	Follow-up examination following chemotherapy

Diagnosis that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

Diagnosis that DO NOT Support Medical Necessity

N/A

Reasons for Denial

When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)

Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnosis

N/A

Coding Guidelines

N/A

Documentation Requirements

Medical record documentation maintained by the performing physician must clearly indicate the medical necessity of the service being billed. In addition, documentation that the service was performed must be included in the patient’s medical record. This information is normally found in the office/progress notes, hospital notes, and/or procedure report.

Documentation should support the criteria for coverage as set forth in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

Sources of information may be found online under “Medical Policies” in the Part A section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from numerous specialties.

Start Date of Comment Period

06/12/2000

End Date of Comment Period

07/27/2000

Start Date of Notice Period

08/01/2001

Revision History

Revision Number	Original
Start Date of Comment Period:	06/12/2000
Start Date of Notice Period:	08/01/2001
	4 th Qtr 2001 <i>Bulletin</i>
Original Effective Date	09/21/2001 ❖

74150: Computerized Axial Tomography of the Abdomen

Policy Number

74150

Contractor Name

First Coast Service Options, Inc.

Contractor Number

090

Contractor Type

Intermediary

LMRP Title

Computerized Axial Tomography of the Abdomen

AMA CPT Copyright Statement

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HCFA National Coverage Policy

Coverage Issues Manual, Section 50-12
Hospital Manual, Section 443
Intermediary Manual, Section 3604 and 3631
Skilled Nursing Facility Manual, Section Addendum C

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

HCFA Region

Region IV

HCFA Consortium

Southern

Original Policy Effective Date

09/21/2001

Original Policy Ending Date

N/A

Revision Effective Date

N/A

Revision Ending Date

N/A

LMRP Description

A computed tomographic (CT) image is a display of the anatomy of a thin slice of the body developed from multiple X-ray absorption measurements made around the periphery of the body. Unlike conventional tomography, where the image of a thin section is created by blurring out the information from unwanted regions, the CT image is constructed mathematically using data arising only from the section of interest. Generating such an image is confined to cross-sections of the anatomy that are oriented essentially perpendicular to the axial dimensions of the body. Reconstruction of the final image can be accomplished in any plane. The CT of the abdomen extends from the dome of the diaphragm to the pelvic brim or pubis symphysis depending upon whether one groups the pelvis with the abdomen or treats it separately.

Indications and Limitations of Coverage and/or Medical Necessity

Florida Medicare will consider a CT of the abdomen medically reasonable and necessary under the following circumstances:

- Evaluation of abdominal pain.
- Evaluation of known or suspected abdominal masses or fluid collections, primary or metastatic malignancies.
- Evaluation of abdominal inflammatory processes.
- Evaluation of abnormalities of abdominal vascular structures.
- Evaluation of abdominal trauma.
- Clarification of findings from other imaging studies or laboratory abnormalities.
- Guidance for interventional diagnostic or therapeutic procedures within the abdomen.
- Treatment planning for radiation therapy.

In addition to the medical necessity requirements, the CT scan must be performed on a model of CT equipment that meets the following criteria:

- The model must be known to the Food and Drug Administration; and
- Must be in the full market phase of development.

NOTE: Plain and upright or lateral decubitus roentgenograms of the abdomen represent the basic screening tool in identifying abnormalities involving the abdomen. It is expected that the abdominal X-ray is used to evaluate patients who present with signs and symptoms suggestive of abdominal pathology prior to proceeding to a CT scan.

CPT/HCPCS Section & Benefit Category

Radiology/Diagnostic Radiology

Type of Bill Code

Hospital – 12x, 13x, 14x
Skilled Nursing Facility – 21x, 22x, 23x
Rural Health Clinic – 71x

Revenue Code

32X Diagnostic Radiology
350 Computed Tomography Scan, General
Classification

CPT/HCPCS Codes

74150 Computerized axial tomography, abdomen;
without contrast material
74160 with contrast material(s)
74170 without contrast material, followed by
contrast material(s) and further sections

Not Otherwise Classified Codes (NOC)

N/A

74150: Computerized Axial Tomography of the Abdomen (continued)

ICD-9-CM Codes that Support Medical Necessity			
006.0-006.9	Amebiasis	200.23	Burkitt's tumor or lymphoma, intra-abdominal lymph nodes
014.00-014.86	Tuberculosis of intestines, peritoneum, and mesenteric glands	200.26	Burkitt's tumor or lymphoma, intrapelvic lymph nodes
016.00-016.96	Tuberculosis of genitourinary system	200.27	Burkitt's tumor or lymphoma, spleen
017.20-017.26	Tuberculosis of peripheral lymph nodes	200.28	Burkitt's tumor or lymphoma, lymph nodes of multiple sites
017.60-017.66	Tuberculosis of adrenal glands	202.40	Leukemic reticulendotheliosis, unspecified site, extranodal and solid organ sites
017.70-017.76	Tuberculosis of spleen	202.43	Leukemic reticulendotheliosis, intra-abdominal lymph nodes
036.3	Waterhouse-Friderichsen syndrome, meningococcal	202.46	Leukemic reticulendotheliosis, intrapelvic lymph nodes
070.0-070.9	Viral hepatitis	202.47	Leukemic reticulendotheliosis, spleen
120.0-120.9	Schistosomiasis (bilharziasis)	202.88	Other lymphomas of lymph nodes of multiple sites
121.0-121.9	Other trematode infections	211.1	Benign neoplasm of stomach
122.0	Echinococcus granulosus infection of liver	211.2	Benign neoplasm of duodenum, jejunum, and ileum
122.5	Echinococcus multilocularis infection of liver	211.3	Benign neoplasm of colon
122.8	Echinococcus, unspecified, of liver	211.5	Benign neoplasm of liver and biliary passages
150.0-159.9	Malignant neoplasm of digestive organs and peritoneum	211.6	Benign neoplasm of pancreas, except islets of Langerhans
171.5	Malignant neoplasm of connective and other soft tissue, abdomen	211.7	Benign neoplasm of islets of Langerhans
176.3	Kaposi's sarcoma, gastrointestinal sites	211.8	Benign neoplasm of retroperitoneum and peritoneum
179	Malignant neoplasm of uterus, part unspecified	214.3	Lipoma of intra-abdominal organs
180.0-183.9	Malignant neoplasm of cervix uteri, placenta, body of uterus, and ovary and other uterine adnexa (fallopian tubes)	215.5	Other benign neoplasm of abdomen
188.0-188.9	Malignant neoplasm of bladder	218.0-218.9	Uterine leiomyoma
189.0-189.9	Malignant neoplasm of kidney and other and unspecified urinary organs	219.0-219.9	Other benign neoplasm of uterus
194.0	Malignant neoplasm of adrenal gland	220	Benign neoplasm of ovary
195.2	Malignant neoplasm of abdomen	221.0	Benign neoplasm of fallopian tube and uterine ligaments
196.2	Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes	223.0	Benign neoplasm of kidney, except pelvis
197.4-197.8	Secondary malignant neoplasm of digestive system	223.1	Benign neoplasm of renal pelvis
198.0	Secondary malignant neoplasm of kidney	223.2	Benign neoplasm of ureter
198.6	Secondary malignant neoplasm of ovary	223.3	Benign neoplasm of bladder
198.7	Secondary malignant neoplasm of adrenal gland	227.0	Benign neoplasm of adrenal gland
200.00	Reticulosarcoma, unspecified site, extranodal and solid organ sites	228.04	Hemangioma of intra-abdominal structures
200.03	Reticulosarcoma, intra-abdominal lymph nodes	230.2	Carcinoma in situ of stomach
200.06	Reticulosarcoma, intrapelvic lymph nodes	230.3	Carcinoma in situ of colon
200.07	Reticulosarcoma, spleen	230.7	Carcinoma in situ of other and unspecified parts of intestine
200.08	Reticulosarcoma, lymph nodes of multiple sites	230.8	Carcinoma in situ of liver and biliary system
200.10	Lymphosarcoma, unspecified site, extranodal and solid organ sites	230.9	Carcinoma in situ of other and unspecified digestive organs
200.13	Lymphosarcoma, intra-abdominal lymph nodes	233.1	Carcinoma in situ of cervix uteri
200.16	Lymphosarcoma, intrapelvic lymph nodes	233.2	Carcinoma in situ of other and unspecified parts of uterus
200.17	Lymphosarcoma, spleen	235.3	Neoplasm of uncertain behavior of liver and biliary passages
200.18	Lymphosarcoma, lymph nodes of multiple sites	235.4	Neoplasm of uncertain behavior of retroperitoneum and peritoneum
200.20	Burkitt's tumor or lymphoma, unspecified site, extranodal and solid organ sites	236.0	Neoplasm of uncertain behavior of uterus
		236.1	Neoplasm of uncertain behavior of placenta

74150: Computerized Axial Tomography of the Abdomen (continued)

236.2	Neoplasm of uncertain behavior of ovary	569.5	Abscess of intestine
236.7	Neoplasm of uncertain behavior of bladder	569.62	Mechanical complication of colostomy and enterostomy
236.91	Neoplasm of uncertain behavior of kidney and ureter	569.81-569.89	Other specified disorders of intestine
237.2	Neoplasm of uncertain behavior of adrenal gland	570	Acute and subacute necrosis of liver
239.0	Neoplasms of unspecified nature of the digestive system	571.0-571.9	Chronic liver disease and cirrhosis
239.4	Neoplasms of unspecified nature of bladder	572.0-572.8	Liver abscess and sequelae of chronic liver disease
251.4	Abnormality of secretion of glucagon	573.0-573.9	Other disorders of liver
251.5	Abnormality of secretion of gastrin	574.00-574.91	Cholelithiasis
251.8	Other specified disorders of pancreatic internal secretion	575.0-575.9	Other disorders of gallbladder
251.9	Unspecified disorder of pancreatic internal secretion	576.0-576.9	Other disorders of biliary tract
256.2	Postablative ovarian failure	577.0-577.9	Diseases of pancreas
256.3	Other ovarian failure	578.0-578.9	Gastrointestinal hemorrhage
256.4	Polycystic ovaries	590.2	Renal and perinephric abscess
256.9	Unspecified ovarian dysfunction	591	Hydronephrosis
289.4	Hypersplenism	592.0-592.9	Calculus of kidney and ureter
289.50-289.59	Other diseases of spleen	593.0-593.9	Other disorders of kidney and ureter
441.00-441.9	Aortic aneurysm and dissection	599.7	Hematuria
442.1	Other aneurysm of renal artery	750.7	Other specified anomalies of stomach
442.2	Other aneurysm of iliac artery	751.0-751.9	Other congenital anomalies of digestive system
442.83	Other aneurysm of splenic artery	753.0-753.9	Congenital anomalies of the urinary system
442.84	Other aneurysm of other visceral artery	759.0	Anomalies of spleen
444.0	Arterial embolism and thrombosis of abdominal aorta	759.1	Anomalies of adrenal gland
453.3	Other venous embolism and thrombosis of renal vein	785.6	Enlargement of lymph nodes
459.0	Hemorrhage, unspecified	789.00-789.9	Other symptoms involving abdomen and pelvis
531.00-531.91	Gastric ulcer	793.4	Nonspecific abnormal findings on radiological and other examination of gastrointestinal tract
532.00-532.91	Duodenal ulcer	793.5	Nonspecific abnormal findings on radiological and other examination of genitourinary organs
533.00-533.91	Peptic ulcer, site unspecified	793.6	Nonspecific abnormal findings on radiological and other examination of abdominal area, including retroperitoneum
534.00-534.91	Gastrojejunal ulcer	794.4	Nonspecific abnormal results of function studies, kidney
535.00-535.61	Gastritis and duodenitis	794.8	Nonspecific abnormal results of function studies, liver
536.0-536.9	Disorders of function of stomach	794.9	Nonspecific abnormal results of function studies, other
537.0-537.9	Other disorders of stomach and duodenum	863.0-863.99	Injury to gastrointestinal tract
540.0-543.9	Appendicitis	868.00-868.19	Injury to other intra-abdominal organs
550.00-550.93	Inguinal hernia	876.0-876.1	Open wound of back
551.00-551.9	Other hernia of abdominal cavity, with gangrene	879.2	Open wound of abdominal wall, anterior, without mention of complication
552.00-552.9	Other hernia of abdominal cavity, with obstruction, but without mention of gangrene	879.3	Open wound of abdominal wall, anterior, complicated
553.00-553.9	Other hernia of abdominal cavity without mention of obstruction or gangrene	879.4	Open wound of abdominal wall, lateral, without mention of complication
555.0-555.9	Regional enteritis	879.5	Open wound of abdominal wall, lateral, complicated
556.0-556.9	Ulcerative colitis	879.6	Open wound of other and unspecified parts of trunk, without mention of complication
557.0-557.9	Vascular insufficiency of intestine	879.7	Open wound of other and unspecified parts of trunk, complicated
558.1-558.9	Other noninfectious gastroenteritis and colitis		
560.0-560.9	Intestinal obstruction without mention of hernia		
562.00-562.13	Diverticula of intestine		
564.0-564.9	Functional digestive disorders, not elsewhere classified		
567.0-567.9	Peritonitis		
568.0-568.9	Other disorders of peritoneum		

74150: Computerized Axial Tomography of the Abdomen (continued)

- 902.0-902.9 Injury to blood vessels of abdomen and pelvis
- 908.1 Late effect of internal injury to intra-abdominal organs
- 908.4 Late effect of injury to blood vessel of thorax, abdomen, and pelvis
- 935.2 Foreign body in stomach
- 936 Foreign body in intestine and colon
- 938 Foreign body in digestive system, unspecified
- 958.4 Traumatic shock
- 996.30-996.39 Mechanical complication of genitourinary device, implant, and graft
- 996.81 Complications of transplanted organ, kidney
- 996.82 Complications of transplanted organ, liver
- 996.86 Complications of transplanted organ, pancreas
- 996.87 Complications of transplanted organ, intestine
- 996.89 Complications of other specified transplanted organ
- 997.5 Urinary complications
- 998.2 Accidental puncture or laceration during a procedure
- 998.4 Foreign body accidentally left during a procedure
- V42.0 Kidney replaced by transplant
- V42.7 Liver replaced by transplant
- V42.83 Pancreas replaced by transplant
- V42.84 Intestines replaced by transplant
- V44.3 Colostomy status
- V44.50-V44.59 Cystostomy status

Diagnosis that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

Diagnosis that DO NOT Support Medical Necessity

N/A

Reasons for Denial

When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)

Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnosis

N/A

Coding Guidelines

N/A

Documentation Requirements

Medical record documentation maintained by the performing physician must clearly indicate the medical necessity of the service being billed. In addition, documentation that the service was performed must be included in the patient’s medical record. This information is normally found in the office/progress notes, hospital notes, and/or procedure report.

Documentation should support the criteria for coverage as set forth in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

American College of Radiology. (1997). *American College of Radiology Standards*.
 David, A. K., Johnson, T. A. Jr., Phillips, D. M., & Scherger, J. E. (Eds.). (1994). *Family medicine: principles and practice* (4th ed.). New York: Springer-Verlag.
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 Lee, J. K. T., Stanley, R. J., Sagel, S. S., & Keiken, J. P. (Eds.). (1998). *Computed body tomography with MRI correlation* (3rd ed.). Philadelphia: Lippincott-Raven.

Advisory Committee Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from numerous societies.

Start Date of Comment Period

08/15/2000

End Date of Comment Period

09/29/2000

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Revision Number:	Original
Start Date of Comment Period	08/15/2000
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	4 th Qtr 2001 <i>Bulletin</i>
Revised Effective Date:	09/21/2001 ❖

84155: Serum Protein**Policy Number**

84155

Contractor Name

First Coast Service Options, Inc.

Contractor Number

090

Contractor Type

Intermediary

LMRP Title

Serum Protein

AMA CPT Copyright Statement

CPT codes, descriptions, and other data only are copyright 2000 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply.

HCFA National Coverage Policy

Coverage Issues Manual, Section 50-17
Hospital Manual, Sections 238, E204.3, and E211.2
Intermediary Manual, Sections 3167.3 and 3171.2
Renal Dialysis Facility Manual, Sections 207.3 and 240.3D

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

HCFA Region

Region IV

HCFA Consortium

Southern

Original Policy Effective Date

09/21/2001

Original Policy Ending Date

N/A

Revision Effective Date

N/A

Revision Ending Date

N/A

LMRP Description

Proteins are constituents of muscle, enzymes, hormones, transport vehicles, hemoglobin, and several other key functional and structural entities within the body. Proteins are the most significant component contributing to the osmotic pressure within the vascular space. This osmotic pressure keeps fluid within the vascular space, minimizing extravasation of fluid.

Albumin and globulins constitute most of the protein within the body and are measured in the total protein. Serum total protein is defined as the sum of circulating serum proteins. Normal adult total protein is 6.0-8.0 g/dl.

Protein testing aids in the diagnosis of some inflammatory and neoplastic states, nephrotic syndromes, liver diseases, and immune dysfunctions. Protein testing

aids in the evaluation of nutritional states and osmotic pressures in edematous and malnourished patients.

Indications and Limitations of Coverage and/or Medical Necessity

Increased or decreased protein levels cause no symptoms per se. Symptoms may arise, however, from underlying conditions. Therefore, Florida Medicare will consider serum protein testing medically reasonable and necessary under either of the following two conditions:

1. Evaluation of beneficiaries with conditions related to hyperproteinemia:

Hemoconcentration states due to fluid loss (e.g., vomiting, diarrhea, poor kidney function);
Dehydration;
Specific chronic liver disease (e.g., active hepatitis and cirrhosis);
Multiple myeloma and other gammopathies;
Waldenstrom's macroglobulinemia;
Tropical diseases (e.g., kala-azar, leprosy);
Sarcoidosis and other granulomatous diseases;
Collagen disorders (e.g., systemic lupus erythematosus, rheumatoid arthritis);
Chronic inflammatory states; or
Chronic infections.

2. Evaluation of beneficiaries with conditions related to hypoproteinemia:

Insufficient nutritional intake (e.g., starvation, malnutrition, or malabsorption);
Liver disease (e.g., cirrhosis, chronic alcoholism);
Glomerulonephritis;
Nephrotic syndrome;
Crohn's disease and chronic ulcerative colitis;
Severe skin diseases, severe and/or extensive burns;
Severe hemorrhage (when plasma volume is replaced more rapidly than protein);
Heart failure;
Hyperthyroidism/hypothyroidism; or
Prolonged immobilization (e.g., trauma, orthopedic surgery).

Even though a patient has a condition stated above, it is not expected that a serum protein test be performed frequently for stable chronic symptoms that are associated with that disease.

In accordance with national Medicare coverage policy, serum total protein tests (84155 or 84160) are routinely covered at a frequency of once per month for hemodialysis, intermittent peritoneal dialysis, and continuous cycling peritoneal dialysis beneficiaries. Serum total protein tests (84155 or 84160) are also routinely covered at a frequency of once per month if furnished to a continuous ambulatory peritoneal dialysis patient in a certified setting. Services performed at a greater frequency are covered if medically necessary and used in timely medical decision making.

CPT/HCPCS Section & Benefit Category

Pathology and Laboratory/Chemistry

84155: Serum Protein (continued)

Type of Bill Code

- Hospital – 12x, 13x, 14x
- Skilled Nursing Facility – 21x, 22x, 23x
- Rural Health Clinic – 71x
- End Stage Renal Dialysis Facility – 72x

Revenue Code

- 301 Laboratory, Chemistry

CPT/HCPCS Codes

- 84155 Protein; total, except refractometry
- 84160 refractometric

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

- 030.0-030.9 Leprosy
- 085.0 Leishmaniasis, visceral [kala-azar]
- 127.2 Strongyloidiasis
- 135 Sarcoidosis
- 200.00-200.88 Lymphosarcoma and reticulosarcoma
- 202.00-202.98 Other malignant neoplasms of lymphoid and histiocytic tissue
- 203.00-203.01 Multiple myeloma
- 204.00-204.01 Acute lymphoid leukemia
- 204.10-204.11 Chronic lymphoid leukemia
- 205.00-205.91 Myeloid leukemia
- 206.00-206.01 Acute monocytic leukemia
- 242.00-242.91 Thyrotoxicosis with or without goiter
- 244.0-244.9 Acquired hypothyroidism
- 253.6 Other disorders of neurohypophysis
- 260-263.9 Nutritional deficiencies
- 273.0-273.9 Disorders of plasma protein metabolism
- 276.5 Volume depletion
- 284.0 Constitutional aplastic anemia
- 284.8 Other specified aplastic anemias
- 285.8 Other specified anemias
- 285.9 Anemia, unspecified
- 287.3 Primary thrombocytopenia
- 287.4 Secondary thrombocytopenia
- 287.5 Thrombocytopenia, unspecified
- 428.0-428.9 Heart failure
- 555.0-555.9 Regional enteritis [Crohn's disease]
- 556.0-556.3 Ulcerative colitis (chronic)
- 556.5-556.6 Left-sided and universal ulcerative (chronic) colitis
- 570 Acute and subacute necrosis of liver
- 571.0-571.6 Chronic liver disease and cirrhosis
- 572.8 Other sequelae of chronic liver disease
- 573.3 Hepatitis, unspecified
- 573.9 Unspecified disorder of liver
- 577.0 Acute pancreatitis
- 577.1 Chronic pancreatitis
- 579.3 Other and unspecified postsurgical nonabsorption [malnutrition following gastrointestinal surgery]
- 579.8 Other specified intestinal malabsorption [protein-losing enteropathy]
- 580.0-588.9 Nephritis, nephrotic syndrome, and nephrosis

- 694.4 Pemphigus
- 695.89 Other specified erythematous conditions [exfoliative erythroderma]
- 710.0 Systemic lupus erythematosus
- 710.3 Dermatomyositis
- 714.0 Rheumatoid arthritis
- 733.90 Disorder of bone and cartilage, unspecified
- 787.01 Nausea with vomiting
- 787.03 Vomiting alone
- 787.91 Diarrhea
- 788.42 Polyuria
- 791.0 Proteinuria
- 941.30-941.59 Burn of face, head, and neck
- 942.30-942.59 Burn of trunk
- 943.30-943.59 Burn of upper limb, except wrist and hand
- 945.30-945.59 Burn of lower limb(s)
- 946.3-946.5 Burns of multiple specified sites
- 947.0-947.9 Burn of internal organs
- 948.10-948.99 Burns classified according to extent of body surface involved
- 994.2 Effects of hunger [starvation]

Diagnosis that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

Diagnosis that DO NOT Support Medical Necessity

N/A

Reasons for Denial

When performed for indications other than those listed in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy.

Noncovered ICD-9-CM Code(s)

Any diagnosis codes not listed in the "ICD-9-CM Codes That Support Medical Necessity" section of this policy.

Noncovered Diagnosis

N/A

Coding Guidelines

Routine serum total protein laboratory tests (84155 or 84160), those performed at a frequency of one per month for hemodialysis, intermittent peritoneal dialysis, and continuous cycling peritoneal dialysis beneficiaries, are included in the *renal facility's* composite rate and may not be billed separately to the Medicare program. Routine tests performed for continuous ambulatory peritoneal dialysis beneficiaries in a certified setting are also included in the *facility's* composite rate. Services performed at a greater frequency than specified are separately billable if medically necessary. A diagnosis of ESRD (ICD-9-CM code 585) alone is not sufficient medical evidence to warrant coverage of additional tests.

84155: Serum Protein (continued)

Documentation Requirements

Medical record documentation (e.g., office/progress notes) maintained by the ordering/referring physician must indicate the medical necessity for performing the test. Additionally, a copy of the test results should be maintained in the medical record. The medical record documentation must substantiate that these results have been used to determine the beneficiary's course of treatment. The handwritten/typed interpretation for serum protein electrophoresis services may include computer-generated findings. Computer-generated findings however, may not substitute for nor be the only information provided to represent the pathologist's interpretation. A narrative statement from the pathologist is required.

If the provider of service is other than the ordering/referring physician, that provider must maintain hard copy documentation of test results and interpretations, along with copies of the ordering/referring physician's order for the study. The physician must state the clinical indication/medical necessity for the study in his order for the test.

Utilization Guidelines

In accordance with national Medicare coverage policy, serum total protein tests (84155 or 84160) are routinely covered at a frequency of once per month for hemodialysis, intermittent peritoneal dialysis, and continuous cycling peritoneal dialysis beneficiaries. Serum total protein tests (84155 or 84160) are also routinely covered at a frequency of once per month if furnished to a continuous ambulatory peritoneal dialysis patient in a certified setting. Services performed at a greater frequency are covered if medically necessary and used in timely medical decision making.

Other Comments

N/A

Sources of Information and Basis for Decision

Fischbach, F. (2000). *A manual of laboratory and diagnostic tests* (6th ed.). Philadelphia: Lippincott Williams & Wilkins.

Florida Medicare Medical Policy Department. (1998, November). *Clinical pathology consultations and clinical laboratory interpretation services* (80500). Jacksonville, FL: Author.

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Henry, J.B. (1991). *Clinical diagnosis and management by laboratory methods* (18th ed.). Philadelphia: W.B. Saunders Company.

Jacobs, D.S., Demott, W.R., Finley, P.R., Horvat, R.T., Kasten Jr., B.L., & Tilzer, L.L. (1994). *Laboratory test handbook* (3rd ed.). Ohio: Lexi-Comp Inc.

Tierney, L.M., McPhee, S.J., & Papadakis, M.A. (Eds.). (1998). *Current medical diagnosis & treatment* (37th ed.). Stamford: Appleton & Lange.

Advisory Committee Notes

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Start Date of Comment Period

08/15/2000

End Date of Comment Period

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08/01/2001

Revision History

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85007: Complete Blood Count

Revision Overview: This policy has been revised to remove information regarding appropriate diagnosis to submit for certain indications.

Policy Number

85007

Contractor Name

First Coast Service Options, Inc.

Contractor Number

090

Contractor Type

Intermediary

LMRP Title

Complete Blood Count

AMA CPT Copyright Statement

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HCFA National Coverage Policy

Coverage Issues Manual, Section 50-17
Hospital Manual, Sections E204.3 and E211.2A
Intermediary Manual, Section 3167.3
Renal Dialysis Facility Manual, Sections 207.3 and 240.3

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

HCFA Region

Region IV

HCFA Consortium

Southern

Original Policy Effective Date

03/08/1999

Original Policy Ending Date

N/A

Revision Effective Date

07/23/2001

Revision Ending Date

07/22/2001

LMRP Description

The complete blood count (CBC) is a series of tests of the peripheral blood that provides a tremendous amount of information about the hematologic system and many other organ systems, prognosis, response to treatment, and recovery. The CBC consists of the following tests that determine number, variety, percentage, concentrations and quality of blood cells: white blood count (WBC), differential white cell count (Diff), red blood count (RBC), hematocrit (HCT), hemoglobin (HGB), red blood cell indices: mean corpuscular volume (MCV), mean corpuscular hemoglobin (MCH), mean corpuscular hemoglobin concentration (MCHC), blood smear, and platelet count (PLT).

The major function of the *white blood cell* (leukocyte) is to fight infection, react against foreign bodies or tissues, and to produce, or at least transport and distribute antibodies in the immune response. The WBC count has two components. One is a count of the total number of WBCs in 1 mm³ of peripheral venous blood. The other component, the differential count, measures the percentage of each type of leukocyte (i.e., neutrophils, lymphocytes, monocytes, eosinophils and basophils) present in the same specimen. An increased total WBC count (leukocytosis) usually indicates infection, inflammation, tissue necrosis, or leukemic neoplasia. Leukopenia (e.g., a decreased WBC count) occurs in many forms of bone marrow failure (e.g., following antineoplastic chemotherapy or radiation therapy, overwhelming infections and autoimmune diseases).

The *red blood cell count* (erythrocyte) determines the total number of circulating red blood cells in a cubic millimeter of blood. It is an important measurement in the determination of anemia or polycythemia. This test in conjunction with the other red blood cell production tests (HCT and HGB) are closely related. The same underlying conditions will cause an increase/decrease in each of these three tests.

The *hematocrit* is an important measurement in the determination of anemia or polycythemia. The purpose of this test is to determine the red blood cell mass by measuring space occupied by packed red blood cells. The results are expressed as the percentage of red cells in the volume of whole blood. Normal values range from 42%-52% for men and 37%-47% in women.

Hemoglobin, the main component of erythrocytes, serves as the vehicle for the transportation of oxygen and carbon dioxide. It also serves as an important buffer in the extracellular fluid. HGB is important in the evaluation of anemia. Normal values range from 13.5-18 g/dl in men and 12-16 g/dl in women.

The *RBC indices* provide information about the size (MCV and RDW), weight (MCH), and hemoglobin concentration (MCHC) of RBCs. Cell size is indicated by the terms normocytic, microcytic and macrocytic. Hemoglobin content is indicated by the terms normochromic, hypochromic, and hyperchromic. Additional information about the RBC size, shape, color, and intracellular structure can be obtained from the blood smear study. The RBC indices are discussed below:

- 1) Mean corpuscular volume
The MCV is a measure of the average volume or size of a single RBC, and is therefore, used in classifying anemias. MCV is derived by dividing the hematocrit by the total RBC count. Normal values vary according to age and gender. When the MCV value is increased, the RBC is said to be abnormally large, or *macrocytic*. This is most frequently seen in megaloblastic anemias (e.g., vitamin B-12 or folic acid deficiency). When the MCV value is decreased, the RBC is said to be abnormally small, or *microcytic*. This is associated with iron deficiency anemia or thalassemia.

85007: Complete Blood Count (continued)

- 2) Mean corpuscular hemoglobin
The MCH is a measure of the average amount (weight) of hemoglobin within an RBC. MCH is derived by dividing the total hemoglobin concentration by the number of RBCs. Because macrocytic cells generally have more hemoglobin and microcytic cells have less hemoglobin, the causes for these values closely resemble those for the MCV value.
- 3) Mean corpuscular hemoglobin concentration
The MCHC is a measure of the average concentration or percentage of hemoglobin within a single RBC. MCHC is derived by dividing the total hemoglobin concentration by the hematocrit. When values are decreased, the cell has a deficiency of hemoglobin and is said to be *hypochromic* (frequently seen in iron deficiency anemia and thalassemia). When values are normal, the anemia is said to be normocytic (e.g., hemolytic anemia).
- 4) Red blood cell distribution width
The RDW is an indication of the variation in RBC size. It is calculated by a machine using the MCV and RBC values. Variations in the width of the RBCs may be helpful when classifying certain types of anemia. The RDW is essentially an indicator of the degree of anisocytosis, a blood condition characterized by RBCs of variable and abnormal size.

The *blood smear* is the most informative of all hematologic tests. All three hematologic cell lines (RBCs, WBCs, platelets) can be examined. Microscopic examination of the RBCs can reveal variation in RBC size (anisocytosis), shape (poikilocytosis), color, or intracellular content. Classification of RBCs according to these variables is most helpful in identifying the causes of anemia.

The WBCs are examined for total quantity, differential count, and degree of maturity. An increased number of immature WBCs may indicate leukemia. A decreased WBC count indicates failure of marrow to produce WBCs, resulting from drugs, chronic disease, neoplasia, or fibrosis.

The *platelet count* is an actual count of the number of platelets (thrombocytes) per cubic milliliter of blood. Platelet activity is essential to blood clotting. Counts of 150,000 to 400,000/mm³ are considered normal. Counts less than 100,000/mm³ may indicate thrombocytopenia. Causes of thrombocytopenia include:

- Reduced production of platelets (secondary to bone marrow failure or infiltration of fibrosis, tumor, etc.);
- Sequestration of platelets (secondary to hypersplenism);
- Accelerated destruction of platelets (secondary to antibodies, infections, drugs, prosthetic heart valves);

- Consumption of platelets (secondary to disseminated intravascular coagulation); and/or
- Platelet loss from hemorrhage.

Thrombocytosis is said to exist when platelet counts are greater than 400,000/mm³. This may occur as a compensatory response to severe hemorrhage. Other conditions associated with thrombocytosis include polycythemia vera, leukemia, postsplenectomy syndrome and various malignant disorders.

Indications and Limitations of Coverage and/or Medical Necessity

Florida Medicare will consider a complete blood count medically reasonable and necessary for the following conditions:

- Presence of abnormal signs or symptoms such as pallor, weakness, significant tiredness, abnormal bleeding, etc. which may suggest an anemic condition.
- Monitoring of patients with previously diagnosed anemias (e.g., iron deficiency, aplastic, hemolytic).
- Evaluation of patients on medications or treatments that affect blood components (e.g., chemotherapy, radiation therapy, antibiotics, aspirin). Note: there are certain medications especially Gold Salt and penicillamine, used in the rheumatology field that require CBCs every 2-4 weeks during therapy.
- Patients with known acute or chronic diseases (e.g., acute or recurrent peptic disease, renal failure, systemic lupus erythematosus, liver disease, rheumatoid arthritis, eating disorders), injury, leukemia, infections, reaction to inflammation, dehydration if the results can be expected to contribute to the management of the patient.
- Patients with acute or chronic blood loss.
- Patients with splenomegaly (includes post splenectomy).
- Patients undergoing a major surgical procedure (e.g., abdominal, thoracic, carotid, cranial or femoral/popliteal surgery) in which significant blood loss may result.

Platelet counts with a hemogram would be clinically indicated when a condition falls into one of the following categories:

- When signs and symptoms suggest a possible hemorrhagic condition.
- To assess the effects of chemotherapy or radiation therapy on platelet formation.
- To aid in the diagnosis of thrombocytopenia and thrombocytosis.
- To confirm a visual estimate of platelet number and morphology from a previous stained blood film.

A complete blood count can be ordered initially if indications for testing are met. Repeat testing for a CBC or portions thereof will be allowed if it can be expected to

85007: Complete Blood Count (continued)

provide information for further management or to evaluate a response to therapy (e.g., several days after iron therapy for an iron deficiency anemia). Frequent testing is not expected except under unusual circumstances (e.g., acute bleeding).

CPT/HCPCS Section & Benefit Category

Pathology and Laboratory/Hematology and Coagulation

Type of Bill Code

- Hospital – 12x, 13x, 14x
- Skilled Nursing Facility – 21x, 22x, 23x
- Rural Health Clinic – 71x
- End Stage Renal Disease – 72x

Revenue Codes

305 Hematology

CPT/HCPCS Codes

- 85007 Blood count; manual differential WBC count (includes RBC morphology and platelet estimation)
- 85008 manual blood smear examination without differential parameters
- 85009 differential WBC count, buffy coat
- 85013 spun microhematocrit
- 85014 other than spun hematocrit
- 85018 hemoglobin
- 85021 hemogram, automated (RBC, WBC, Hgb, Hct and indices only)
- 85022 hemogram, automated, and manual differential WBC count (CBC)
- 85023 hemogram and platelet count, automated, and manual differential WBC count (CBC)
- 85024 hemogram and platelet count, automated, and automated partial differential WBC count (CBC)
- 85025 hemogram and platelet count, automated, and automated complete differential WBC count (CBC)
- 85027 hemogram and platelet count, automated
- 85031 Blood count; hemogram, manual, complete CBC (RBC, WBC, Hgb, Hct, differential and indices)

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

N/A

Diagnosis that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

Diagnosis that DO NOT Support Medical Necessity

N/A

Reasons for Denial

Complete blood count screening (including routine pre-op) performed on apparent normal and asymptomatic individuals or in the absence of known disease, injury or abnormal signs or symptoms is considered noncovered. Screening CBCs should be billed utilizing diagnosis **V72.6** (Special investigations and exam, laboratory).

When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)

- V01.9 Unspecified communicable disease
- V07.8-V07.9 Other specified or unspecified prophylactic measure
- V40.0-V40.9 Mental and behavioral problems
- V58.9 Unspecified aftercare
- V64.0-V64.4 Persons encountering health services for specific procedures, not carried out
- V67.59 Other follow-up examination s following other treatment
- V67.6 Follow-up examination following combined treatment
- V67.9 Unspecified follow-up examination
- 272.0-272.9 Disorders of lipid metabolism
- 278.00 Obesity, unspecified
- 278.1 Localized adiposity
- 290.0-290.9 Senile and presenile organic psychotic conditions
- 295.00-295.95 Schizophrenic disorders
- 298.0-298.9 Other nonorganic psychoses
- 307.80-307.89 Psychalgia
- 307.9 Other and unspecified special symptoms or syndromes, not elsewhere classified
- 331.0 Alzheimer’s disease
- 331.1 Pick’s disease
- 331.2 Senile degeneration of brain
- 332.0-332.1 Parkinson’s disease
- 366.00-366.9 Cataracts
- 369.00-369.9 Blindness and low vision
- 380.4 Impacted cerumen
- 401.0-401.9 Essential hypertension
- 455.0 Internal hemorrhoids without mention of complication
- 455.3 External hemorrhoids without mention of complication
- 455.6 Unspecified hemorrhoids without mention of complication
- 627.3 Postmenopausal atrophic vaginitis
- 700 Corns and callosities
- 701.0-701.9 Other hypertrophic and atrophic conditions of skin
- 702.0-702.8 Other dermatoses
- 724.00-724.09 Spinal stenosis, other than cervical
- 735.0-735.9 Acquired deformities of toe
- 736.00-736.9 Other acquired deformities of limbs
- 737.0-737.9 Curvature of spine
- 739.0-739.9 Nonallopathic lesions, not elsewhere classified

85007: Complete Blood Count (continued)

743.30-743.39	Congenital cataract and lens anomalies
780.31-780.39	Convulsions
780.50-780.59	Sleep disturbances
780.8	Hyperhidrosis
780.9	Other general symptoms
796.2	Elevated blood pressure without diagnosis of hypertension
799.0-799.9	Other ill-defined and unknown causes of morbidity and mortality
840.0-848.9	Sprains and strains of joints and adjacent muscles

Noncovered Diagnosis

N/A

Coding Guidelines

CPT codes **85023, 85024, 85025, or 85027** should be billed when a complete blood count with platelet is medically indicated. If there are no clear medical indications for the platelet count, the CPT code will be down coded to **85022** and reimbursed accordingly.

CBCs performed for rheumatoid arthritis patients being treated with the following medications should submit the indicated diagnosis on the claim:

- Diagnosis code E933.1 for patients on antineoplastic and immunosuppressive drugs such as Methotrexate and Imuran;
- Diagnosis code E935.6 (Antirheumatics) for patients on Gold Salts; or
- Diagnosis code E933.8 (Other systemic agents not elsewhere classified) for patients on a penicillamine.

Documentation Requirements

Medical record documentation maintained by the ordering/referring physician must indicate the medical necessity for performing the test and the lab results. This information is usually found in the history and physical, office/progress notes, or laboratory report.

If the provider of the service is other than the ordering/referring physician, that provider must maintain hard copy documentation of test results and interpretation, along with copies of the ordering/referring physician's order for the studies. The physician must state the clinical indication/medical necessity for the study in his order for the test.

Utilization Guidelines

Certain laboratory tests are included in the composite rate when performed for End Stage Renal Disease (ESRD) beneficiaries within the frequency identified in the Medicare Intermediary Manual. The following hematology tests are included in the composite rate at the frequency indicated below:

- Hct and Hgb every month for patients undergoing continuous ambulatory peritoneal dialysis (CAPD).
- Hct and Hgb per treatment; CBC every month, for patients undergoing hemodialysis/hemofiltration, peritoneal dialysis and continuous cyclical peritoneal dialysis.

Certain laboratory tests for CAPD patients are billed separately when performed at independent dialysis facilities. The following hematology tests are not included in the composite rate and are separately billable when performed at the frequency identified in the Medicare Intermediary Manual:

- WBC, RBC and platelet count every three months.

Other Comments

Routine testing is not allowed to secure a baseline for minor surgical procedures when performed without associated signs and symptoms or a disease process that demonstrates an anemic condition.

Sources of Information and Basis for Decision

Fischbach, F. (1994). *A manual of laboratory and diagnostic tests*. (4th ed.). Philadelphia: J.B. Lippincott Company.

Pagana, K. (1995). *Mosby's diagnostic and laboratory test reference*. (2nd ed.). St. Louis: Mosby.

Advisory Committee Notes

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Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

08/01/2001

Revision History

Revision Number:	2
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	4 th Qtr 2001 <i>Bulletin</i>
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Explanation of Revision:	Policy revised to delete information regarding appropriate diagnosis to submit for certain indications.

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Explanation of Revision:	HCPCS change occurred prior to implementation

Revision Number:	Original
Start Date of Comment Period	08/05/1998
Start Date of Notice Period	01/21/1999
Original Effective Date:	03/08/1999 ❖

88141: Pap Smears

Revision Overview: This policy has been revised to incorporate the coverage change in the frequency of screening Pap smears for beneficiaries that meet certain criteria.

Policy Number

88141

Contractor Name

First Coast Service Options, Inc.

Contractor Number

090

Contractor Type

Intermediary

LMRP Title

Pap Smears

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HCFA National Coverage Policy

Medicare Coverage Issues Manual, Section 50-20
 Medicare Hospital Manual, Sections 437.1 and 437.2
 Medicare Intermediary Manual, Section 3628.1
 Program Transmittal 1823 (Change Request 1497, dated 02/01/2001)

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

HCFA Region

Region IV

HCFA Consortium

Southern

Original Policy Effective Date

07/22/1999

Original Policy Ending Date

N/A

Revision Effective Date

07/01/2001

Revision Ending Date

06/30/2001

LMRP Description

Pap smear (Papanicolaou smear/test) is a cytologic examination of a vaginal smear for early detection of cancer (especially of the cervix and uterus), employing exfoliated cells and a special staining technique which differentiates diseased tissue.

Indications and Limitations of Coverage and/or Medical Necessity

Diagnostic Pap Smear:

Diagnostic Pap smears and related services are covered under Florida Medicare when ordered by a physician under one of the following conditions:

- Previous cancer of the cervix, uterus or vagina that has been or is presently being treated
- Previous abnormal Pap smear
- Abnormal findings of the vagina, cervix, uterus, ovaries or adnexa
- Significant complaint pertaining to the female reproductive system
- Any signs or symptoms that the physician judges to be reasonably related to a gynecologic disorder. The carrier's medical staff determines whether a previous malignancy at another site is an indication for a diagnostic Pap smear or whether the test must be considered a screening Pap smear.

Screening Pap Smear:

Claims with Dates of Service from January 1, 1998 through June 30, 2001.

Screening Pap smears are covered when ordered and collected by a doctor of medicine or osteopathy, or other authorized practitioners (e.g., a certified nurse midwife, physician assistant, clinical nurse specialist or nurse practitioner) under one of the following conditions:

- No prior test for the preceding 3 years (use ICD-9-CM code V76.2); or
- There is evidence (on the basis of her medical history or other findings) that she is of childbearing age and has had an examination that indicated the presence of cervical or vaginal cancer or other abnormalities during any of the preceding 3 years, **and** at least 11 months have passed following the month that the last covered Pap smear was performed (use ICD-9-CM code V15.89); or
- There is evidence (on the basis of her medical history or other findings) that she is at high risk of developing cervical or vaginal cancer, **and** at least 11 months have passed following the month that the last covered Pap smear was performed (use ICD-9-CM code V15.89).

The high risk factors for cervical cancer include:

- Early onset of sexual activity (under 16 years of age)
- Multiple sexual partners (five or more in a lifetime)
- History of a sexually transmitted disease (including HIV infection)
- Fewer than 3 negative or any Pap smears within the previous 7 years

The high risk factors for vaginal cancer include:

- DES (diethylstilbestrol) - exposed daughters of women who took DES during pregnancy

Claims with Dates Service on or after July 1, 2001.

Screening Pap smears are covered every 2 years instead of 3 years unless the woman does not qualify for a more frequently performed screening Pap smear (i.e., the woman is at high risk or qualifies under the childbearing provision) (See coverage criteria above).

CPT/HCPCS Codes

Diagnostic Pap Smears:

88142 Cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid,

88141: Pap Smears (continued)

88143	automated thin layer preparation; manual screening under physician supervision with manual screening and rescreening under physician supervision		manual screening and computer-assisted rescreening by cytotechnologist under physician supervision
88144	with manual screening and computer-assisted rescreening under physician supervision	G0145	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, with manual screening and computer-assisted rescreening using cell selection and review under physician supervision
88145	with manual screening and computer-assisted rescreening using cell selection and review under physician supervision		
88147	Cytopathology smears, cervical or vaginal; screening by automated system under physician supervision	G0147	Screening cytopathology smears, cervical or vaginal, performed by automated system under physician supervision
88148	Cytopathology smears, cervical or vaginal; screening by automated system with manual rescreening under physician supervision	G0148	Screening cytopathology smears, cervical or vaginal, performed by automated system with manual rescreening
88150	Cytopathology, slides, cervical or vaginal; manual screening under physician supervision	P3000	Screening Papanicolaou smear, cervical or vaginal, up to three smears, by technician under physician supervision
88152	with manual screening and computer-assisted rescreening under physician supervision	P3001	Screening Papanicolaou smear, cervical or vaginal, up to three smears, requiring interpretation by physician
88153	with manual screening and rescreening under physician supervision	Q0091	Screening Papanicolaou smear; obtaining, preparing and conveyance of cervical or vaginal smear to laboratory
88154	with manual screening and computer-assisted rescreening using cell selection and review under physician supervision		
88155	Cytopathology, slides, cervical or vaginal, definitive hormonal evaluation (eg, maturation index, karyopyknotic index, estrogenic index) (List separately in addition to code(s) for other technical and interpretation services)		
88164	Cytopathology, slides, cervical or vaginal (the Bethesda System); manual screening under physician supervision		
88165	with manual screening and rescreening under physician supervision		
88166	with manual screening and computer-assisted rescreening under physician supervision		
88167	with manual screening and computer-assisted rescreening using cell selection and review under physician supervision		
Screening Pap Smears:			
G0123	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, screening by cytotechnologist under physician supervision		
G0124	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservation fluid, automated thin layer preparation, requiring interpretation by physician		
G0141	Screening cytopathology smears, cervical or vaginal, performed by automated system, with manual rescreening, requiring interpretation by physician		
G0143	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, with manual screening and rescreening by cytotechnologist under physician supervision		
G0144	Screening cytopathology, cervical or vaginal (any reporting system), collected in preservative fluid, automated thin layer preparation, with		
			ICD-9-CM Codes that Support Medical Necessity
			For Diagnostic Pap Smears:
		016.70-016.76	Tuberculosis of other female genital organs
		054.10	Genital herpes, unspecified
		054.11	Herpetic vulvovaginitis
		054.12	Herpetic ulceration of vulva
		078.0	Molluscum contagiosum
		078.10-078.19	Viral warts
		090.0-099.9	Syphilis and other venereal diseases
		112.1	Candidiasis of vulva and vagina
		112.2	Candidiasis of other urogenital sites
		131.00-131.9	Trichomoniasis
		170.6	Malignant neoplasm of pelvic bones, sacrum, and coccyx
		171.6	Malignant neoplasm of pelvis
		179	Malignant neoplasm of uterus, part unspecified
		180.0-180.9	Malignant neoplasm of cervix uteri
		181	Malignant neoplasm of placenta
		182.0-182.8	Malignant neoplasm of body of uterus
		183.0-183.8	Malignant neoplasm of ovary and other uterine adnexa
		184.0-184.9	Malignant neoplasm of other and unspecified female genital organs
		198.6	Secondary malignant neoplasm of ovary
		198.82	Secondary malignant neoplasm of genital organs
		218.0-218.9	Uterine leiomyoma
		219.0-219.9	Other benign neoplasm of uterus
		220	Benign neoplasm of ovary
		221.0-221.9	Benign neoplasm of other female genital organs
		233.0-233.3	Carcinoma in situ of breast and genitourinary system, female

88141: Pap Smears (continued)

233.9	Carcinoma in situ of other and unspecified urinary organs
236.0-236.3	Neoplasm of uncertain behavior of genitourinary organs, female
239.5	Neoplasm of unspecified nature of other genitourinary organs
256.0-256.9	Ovarian dysfunction
616.0	Cervicitis and endocervicitis
616.10-616.11	Vaginitis and vulvovaginitis
616.2	Cyst of Bartholin's gland
616.50-616.51	Ulceration of vulva
616.8	Other specified inflammatory diseases of cervix, vagina, and vulva
616.9	Unspecified inflammatory disease of cervix, vagina, and vulva
617.0	Endometriosis of uterus
617.9	Endometriosis, site unspecified
620.0	Follicular cyst of ovary
620.1	Corpus luteum cyst or hematoma
620.2	Other and unspecified ovarian cyst
620.8	Other noninflammatory disorders of ovary, fallopian tube, and broad ligament
621.0	Polyp of corpus uteri
621.1	Chronic subinvolution of uterus
621.2	Hypertrophy of uterus
621.8	Other specified disorders of uterus, not elsewhere classified
622.0	Erosion and ectropion of cervix
622.1	Dysplasia of cervix (uteri)
622.7	Mucous polyp of cervix
622.8	Other specified noninflammatory disorders of cervix
623.0	Dysplasia of vagina
623.5	Leukorrhea, not specified as infective
623.7	Polyp of vagina
623.8	Other specified noninflammatory disorders of vagina
624.6	Polyp of labia and vulva
624.8	Other specified noninflammatory disorders of vulva and perineum
626.2	Excessive or frequent menstruation
626.6	Metrorrhagia
626.7	Postcoital bleeding
626.8	Other disorders of menstruation and other abnormal bleeding from female genital tract
626.9	Unspecified disorders of menstruation and other abnormal bleeding from female genital tract
627.1	Postmenopausal bleeding
627.2	Menopausal or female climacteric states
627.3	Postmenopausal atrophic vaginitis
627.8	Other specified menopausal and postmenopausal disorders
627.9	Unspecified menopausal and postmenopausal disorder
628.0-628.9	Infertility, female
654.10-654.14	Tumors of body of uterus
795.0	Nonspecific abnormal Papanicolaou smear of cervix

For Screening Pap Smears:

V15.89	Other specified personal history presenting hazards to health
V76.2	Special screening for malignant neoplasms, cervix

CPT/HCPCS Section & Benefit Category

Pathology and Laboratory/Cytopathology

Type of Bill

Hospital	– 12x, 13x, 14x
Skilled Nursing Facility	– 21x, 22x, 23x
Rural Health Clinic	– 71x
Comprehensive Outpatient Rehabilitation Facility	– 75x

Revenue Code

311	Cytology
52x	Free-Standing Clinic
923	Other diagnostic services; Pap smear

Not Otherwise Classified Codes (NOC)

N/A

Diagnosis that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

Diagnosis that DO NOT Support Medical Necessity

N/A

Reasons for Denial

Payment will not be allowed for a diagnostic Pap smear (88141-88145; 88147-88148; 88150-88154; 88164-88167) and a screening Pap smear (G0123-G0124; G0141-G0148; P3000-P3001, Q0091) on the same date of service.

Pap smears performed for indications other than those listed in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy.

Noncovered ICD-9-CM Code(s)

Any diagnosis codes not listed in the "ICD-9-CM Codes That Support Medical Necessity" section of this policy.

Noncovered Diagnosis

N/A

Coding Guidelines

Code 88142 is not an add-on code. It is not appropriate to report this code in addition to a code from the 88147-88148, 88150-88154 or 88164-88167 series if the only laboratory procedures performed was a Pap Smear with thin layer preparation.

Code 88155 is listed separately in addition to code(s) for other technical and interpretation services (88142-88145; 88150-88154; 88164-88167).

The applicable bill types for Screening Pap Smears are: 13x, 14x, 22x, 23x and 75x. These services must be billed under Revenue code 311.

The professional component of a screening Pap smear by bill type 71x must be billed under revenue code 52x.

88141: Pap Smears (continued)

The technical component of a screening Pap smear is outside the scope of the RHC/FQHC benefit. If the technical component of this service is furnished within an independent RHC or free-standing FQHC, the provider of that technical service bills the carrier on Form HCFA-1500.

If the technical component of a screening Pap smear is furnished within a provider-based RHC/FQHC, the provider of that service bills under bill type 13x, 14x, 22x, or 23x as appropriate using their outpatient provider number (not the RHC/FQHC provider number since these services are not covered as RHC/FQHC services). The appropriate revenue code is 311.

The following HCPCS codes are physician services and are to be billed to the carrier: 88141, G0124, G0141, P3001, and Q0091.

Providers may choose to bill their Diagnostic Pap Smears with either Revenue code 923 or 311.

Documentation Requirements

Medical record documentation (e.g., history and physical, office/progress notes, and the pathology report) maintained by the ordering/referring physician must indicate the medical necessity for performing the test. This should be maintained in the patient's permanent record, to be made available in the event of a review request.

Utilization Guidelines

N/A

Other Comments

A woman of childbearing age is one who is premenopausal and has been determined by a physician or other qualified practitioner to be of childbearing age, based on her medical history or other findings.

Sources of Information and Basis for Decision

N/A

Advisory Committee Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from numerous societies.

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

08/01/2001

Revision History

Revision Number:	3
Start Date of Comment Period	N/A
Start Date of Notice Period	08/01/2001 4 th Qtr <i>Bulletin</i>
Revised Effective Date:	07/01/2001
Explanation of Revision:	HCFA Transmittal 1823 (Change Request 1497, dated 02/01/2001) revises Screening Pap Smear services by authorizing coverage for screening Pap Smears beginning July 1, 2001, for beneficiaries that meet specific criteria at a frequency of every two years, instead of every three years.

Revision Number:	2
Start Date of Comment Period	N/A
Start Date of Notice Period	12/1999 Dec 1999 <i>Special Issue</i>

Bulletin

Revised Effective Date:	01/01/2000
Explanation of Revision:	2000 HCPCS

Revision Number:	1
Start Date of Comment Period	N/A
Start Date of Notice Period	07/22/1999 Dec/Jan 2000 <i>Bulletin</i>
Revised Effective Date:	12/06/1999

Revision Number:	Original
Start Date of Comment Period	08/05/1998
Start Date of Notice Period	06/07/1999
Original Effective Date:	07/22/1999 ❖

92225: Ophthalmoscopy

Revision Overview: This policy has been revised to add ICD-9-CM code 224.5 as a covered diagnosis for this service.

Policy Number

92225

Contractor Name

First Coast Service Options, Inc.

Contractor Number

090

Contractor Type

Intermediary

LMRP Title

Ophthalmoscopy

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HCFA National Coverage Policy

Medicare Intermediary Manual, Section 3157

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

HCFA Region

Region IV

HCFA Consortium

Southern

Original Policy Effective Date

07/22/1999

Original Policy Ending Date

N/A

Revision Effective Date

07/17/2001

Revision Ending Date

07/16/2001

LMRP Description

Extended ophthalmoscopy is the inspection of the interior of the eye with the pupil dilated. This inspection is fundamental to diagnosis and permits visualization of the optic disk, arteries, veins, retina, choroid, and media and is directed toward the condition of the vessels, the color of the tissue and the character of the optic nerve. The three methods of viewing the ocular fundus include direct ophthalmoscopy, by which a magnification of about 15X is obtained; indirect ophthalmoscopy, by which a larger field is obtained, but with magnification of 2X to 3X; and biomicroscopy combined with a lens to neutralize corneal refracting power.

Indications and Limitations of Coverage and/or Medical Necessity

Florida Medicare will consider ophthalmoscopy (CPT Codes 92225, 92226) to be medically reasonable and necessary if any one of the following circumstances is present:

- The patient has a malignant neoplasm of the retina or choroid. This may appear as a single, round or oval, slightly elevated, gray or nonpigmented lesion.
- The patient has a retained (old) intraocular foreign body, either magnetic or nonmagnetic. Signs and symptoms may include a statement by the patient that something has hit his/her eye (foreign body sensation), normal or blurred vision, pain or no discomfort, and tearing.
- The patient has retinal hemorrhage, edema, ischemia, exudates and deposits, hereditary retinal dystrophies or peripheral retinal degeneration.
- The patient has retinal detachment with or without retinal defect. The patient may complain of light flashes, dark floating specks, and blurred vision that becomes progressively worse. This may be described by the patient as "a curtain came down over my eyes."
- The patient has retinal defects without retinal detachment.
- The patient has diabetic retinopathy (e.g., background retinopathy or proliferative retinopathy), retinal vascular occlusion, or separation of the retinal layers. This may be evidenced by microaneurysms, cotton wool spots, exudates, hemorrhages, or fibrous proliferation.
- The patient has experienced sudden visual loss or transient visual loss. This may be described as trouble seeing or vision going in and out.
- The patient has chorioretinitis, chorioretinal scars or choroidal degeneration, dystrophies, hemorrhage and rupture, or detachment.
- The patient has Vogt-Koyanagi syndrome. This disease is characterized by bilateral uveitis, dysacusia, meningeal irritation, whitening of patches of hair (poliosis), vitiligo, and retinal detachment. The disease can be initiated by a severe headache, deep orbital pain, vertigo, and nausea.
- The patient has sustained a penetrating wound to the orbit resulting in the retention of a foreign body in the eye.
- The patient has disorders of the vitreous body (e.g., vitreous hemorrhage or posterior vitreous detachment). Spots before the eyes (floaters) and flashing lights (photopsia) can be signs/symptoms of these disorders.
- The patient has posterior scleritis. Signs and symptoms may include severe pain and inflammation, proptosis, limited ocular movements, and a loss of a portion of the visual field.
- The patient has degenerative disorders of the globe.
- The patient has retinoschisis and retinal cysts. Patients may complain of light flashes and floaters.
- The patient has signs and symptoms of endophthalmitis which may include severe pain, redness, photophobia, and profound loss of vision.
- The patient has glaucoma or is a glaucoma suspect. This may be evidenced by increased intraocular pressure or progressive cupping of the optic nerve. The patient's medical record must meet the documentation requirements set forth in this policy (see Documentation Requirements).

92225: Ophthalmoscopy (continued)

CPT/HCPCS Section & Benefit Category

Medicine/Ophthalmology

Type of Bill Code

Hospital – 12x, 13x, 14x
 Skilled Nursing Facility – 21x, 22x, 23x
 Rural Health Clinic – 71x

Revenue Codes

920 Other Diagnostic Services: General Classification

CPT/HCPCS Codes

92225 Ophthalmoscopy, extended, with retinal drawing (eg, for retinal detachment, melanoma), with interpretation and report; initial

92226 subsequent

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

115.92 Histoplasmosis, unspecified with retinitis
 130.2 Chorioretinitis due to toxoplasmosis
 190.5 Malignant neoplasm of retina
 190.6 Malignant neoplasm of choroid
 224.5 Benign neoplasm of retina
 224.6 Benign neoplasm of choroid
 225.1 Benign neoplasm of cranial nerves
 360.00-360.04 Purulent endophthalmitis
 360.11 Sympathetic uveitis
 360.12 Panuveitis
 360.13 Parasitic endophthalmitis NOS
 360.19 Other endophthalmitis
 360.21 Progressive high (degenerative) myopia
 360.23 Siderosis
 360.24 Other metallosis
 360.50 Retained (old) foreign body, magnetic, intraocular, unspecified
 360.52 Retained (old) foreign body, magnetic, in iris or ciliary body
 360.54 Retained (old) foreign body, magnetic, in vitreous
 360.60 Retained (old) foreign body, nonmagnetic, intraocular, unspecified
 360.64 Retained (old) foreign body, nonmagnetic, in vitreous
 360.65 Retained (old) foreign body, nonmagnetic, in posterior wall
 361.00-361.07 Retinal detachment with retinal defect
 361.10-361.19 Retinoschisis and retinal cysts
 361.2 Serous retinal detachment
 361.30-361.33 Retinal defects without detachment
 361.81 Traction detachment of retina
 362.01-362.02 Diabetic retinopathy
 362.10-362.18 Other background retinopathy and retinal vascular changes
 362.21-362.29 Other proliferative retinopathy
 362.30-362.37 Retinal vascular occlusion
 362.40-362.43 Separation of retinal layers
 362.50-362.57 Degeneration of macula and posterior pole
 362.60-362.66 Peripheral retinal degenerations

362.70-362.77 Hereditary retinal dystrophies
 362.81 Retinal hemorrhage
 362.82 Retinal exudates and deposits
 362.83 Retinal edema
 362.84 Retinal ischemia
 363.00-363.08 Focal chorioretinitis and focal retinochoroiditis
 363.10-363.15 Disseminated chorioretinitis and disseminated retinochoroiditis
 363.20 Chorioretinitis, unspecified
 363.21 Pars planitis
 363.22 Harada's disease
 363.30-363.35 Chorioretinal scars
 363.40-363.43 Choroidal degenerations
 363.50-363.57 Hereditary choroidal dystrophies
 363.61-363.63 Choroidal hemorrhage and rupture
 363.70-363.72 Choroidal detachment
 364.24 Vogt-Koyanagi syndrome
 365.00-365.04 Borderline glaucoma [glaucoma suspect]
 365.10-365.15 Open-angle glaucoma
 365.20-365.24 Primary angle-closure glaucoma
 365.31-365.32 Corticosteroid-induced glaucoma
 365.41-365.44 Glaucoma associated with congenital anomalies, dystrophies, and systemic syndromes
 365.51-365.59 Glaucoma associated with disorders of the lens
 365.60-365.65 Glaucoma associated with other ocular disorders
 365.81-365.89 Other specified forms of glaucoma
 365.9 Unspecified glaucoma
 368.11 Sudden visual loss
 368.12 Transient visual loss
 368.15 Other visual distortions and entoptic phenomena
 376.6 Retained (old) foreign body following penetrating wound of orbit
 377.00 Papilledema, unspecified
 377.10-377.16 Optic atrophy
 377.21-377.24 Other disorders of optic disc
 377.30 Optic neuritis, unspecified
 377.33 Nutritional optic neuropathy
 377.34 Toxic optic neuropathy
 377.41 Ischemic optic neuropathy
 377.49 Other disorders of optic nerve
 379.07 Posterior scleritis
 379.21-379.29 Disorders of vitreous body
 379.32 Subluxation of lens
 379.34 Posterior dislocation of lens
 743.51-743.59 Congenital anomalies of posterior segment
 759.5 Tuberos scleriosis
 759.6 Other hamartoses, not elsewhere classified
 759.82 Marfan syndrome

Diagnosis that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

92225: Ophthalmoscopy (continued)

Diagnosis that DO NOT Support Medical Necessity

N/A

Reasons for Denial

When performed for indications other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

An eye examination for the purpose of prescribing, fitting or changing eyeglasses is not covered by the Medicare program.

Noncovered ICD-9-CM Code(s)

Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnosis

N/A

Coding Guidelines

Routine ophthalmoscopy is part of an ophthalmologic service and is not reported separately.

Documentation Requirements

Medical record documentation (e.g., office/progress notes) maintained by the ordering/referring physician must indicate the medical necessity of the ophthalmoscopy exam. The records must document the complaint or symptomatology necessitating the ophthalmoscopy exam and must include the examination results/findings.

If the provider of the service is other than the ordering/referring physician, that provider must maintain hard copy documentation of the ophthalmoscopy exam results and interpretation, along with copies of the ordering/referring physician’s order for the ophthalmoscopy. The physician must state the clinical indication/medical necessity for the ophthalmoscopy in the order for the exam.

Documentation in the medical record for a diagnosis of glaucoma (ICD-9-CM Code **365.00-365.9**) must include all of the following:

- a detailed drawing of the optic nerve,
- documentation of cupping, disc rim, pallor, and slope, and
- documentation of any surrounding pathology around the optic nerve.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

Newell, F. (1992). *Ophthalmology-Principles and Concepts*. St. Louis: Mosby.

McPhee, S., Papadakis, M., and Tierney, L., (1996).

Current Medical Diagnosis and Treatment. Stanford: Appleton and Lange.

Advisory Committee Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from the Ophthalmology and Optometrist Societies.

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

08/01/2001

Revision History

Revision Number	2
Start Date of Comment Period	N/A
Start Date of Notice Period	08/01/2001 4 th Qtr 2001 <i>Bulletin</i>
Revised Effective Date:	07/17/20001
Explanation of Revision:	Policy revised to add ICD-9-CM code 224.5
Revision Number:	Original
Start Date of Comment Period	02/08/1999
Start Date of Notice Period	
Original Effective Date:	07/22/1999 ❖

93303: Transthoracic and Doppler Echocardiography and Doppler Color Flow Velocity Mapping

Revision Overview: This policy has been revised to add ICD-9-CM code V58.83 for patients initiating or receiving treatment with a cardiotoxic medication.

Policy Number

A93303

Contractor Name

First Coast Service Options, Inc.

Contractor Number

090

Contractor Type

Intermediary

LMRP Title

Transthoracic and Doppler Echocardiography and Doppler Color Flow Velocity Mapping

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HCFA National Coverage Policy

Coverage Issues Manual, Section 50-7
Hospital Manual, Section 443
Intermediary Manual, Section 3631

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

HCFA Region

Region IV

HCFA Consortium

Southern

Original Policy Effective Date

07/17/2000

Original Policy Ending Date

N/A

Revision Effective Date

07/17/2001

Revision Ending Date

07/16/2001

LMRP Description

Echocardiography is used to image cardiac structures and function and also flow direction and velocities within cardiac chambers and vessels. Usually, these images are obtained from several positions on the chest wall and abdomen using a hand-held transducer. The direction of flow of the red blood cells within the heart is displayed with the use of a doppler transducer. The direction of the flow of the blood is depicted by using color coding of velocity shifts, and the red blood cell velocity is measured through the use of doppler color flow velocity mapping.

Indications and Limitations of Coverage and/or Medical Necessity

Transthoracic Echocardiography for Congenital Cardiac Anomalies:

Florida Medicare will consider transthoracic echocardiography for congenital cardiac anomalies (CPT codes 93303, 93304) medically necessary when they are specifically performed for congenital cardiac anomalies.

Transthoracic Real Time Echocardiography:

Florida Medicare will consider resting real time echocardiography (CPT code 93307, 93308) medically necessary under any one of the following circumstances:

- The patient has a prosthetic heart valve and echocardiography is needed to monitor response to therapy or investigate a change in the patient's clinical condition.
- The patient has clinical findings which suggest the presence of valvular heart disease (e.g., the patient has a heart murmur which is felt to be clinically significant).
- The patient has proven endocarditis or clinical findings suggestive of endocarditis.
- The patient has clinical findings diagnostic of or suggestive of acute myocardial ischemia or infarction, or the patient has complications of acute myocardial infarction such as valvular incompetency, ventricular septal rupture or aneurysm of heart.
- The patient has documented cardiomyopathy, or the patient has clinical findings which suggest possible cardiomyopathy, or the patient has unexplained cardiomegaly.
- The patient has pericardial disease, or the patient has clinical findings suggestive of pericardial disease (e.g., friction rub, pericarditis, pericardial effusion, cardiac tamponade, pericardial tumor or cyst) and echocardiography is necessary for evaluation and/or follow-up.
- The patient has an intracardiac mass (e.g., tumor, thrombus, vegetation). The patient has a thoracic aortic aneurysm or dissection, or the patient has clinical findings suggestive of aortic dissection or aneurysm.
- The patient has confirmed or suspected abnormality of the vena cava or other large intrathoracic venous structure.
- The patient has hypertension along with other clinical evidence of heart disease.
- The patient had dyspnea of suspected cardiac origin based on clinical findings.
- The patient has chest pain with clinical findings which suggest a possible cardiac origin for the pain.

93303: Transthoracic and Doppler Echocardiography and Doppler Color Flow Velocity Mapping (continued)

- The patient exhibits signs or symptoms of cerebral embolism and a cardiac etiology for the embolus is suspected.
- The patient has syncope and a cardiac etiology is suspected based on clinical findings.
- The patient has experienced peripheral embolism and a cardiac origin of embolus is suspected.
- The patient has documented, clinically significant, arrhythmia (e.g., paroxysmal tachycardia, atrial fibrillation or flutter, ventricular fibrillation or flutter, or sinoatrial node dysfunction) and echocardiography is being done to evaluate the patient for associated heart disease.
- The patient has unexplained edema and a cardiac etiology is suspected.
- The patient has sustained chest trauma and cardiac injury is suspected.
- The patient has undergone heart transplantation.
- The patient has cardiac dysfunction, such as post-cardiology syndrome or congestion failure, following surgery or other procedure.
- The patient is under treatment, or being considered for treatment, with a cardiotoxic medication.
- The patient has suspected or confirmed pulmonary hypertension and/or cor pulmonale, and echocardiography is necessary for evaluation and/or follow-up.

Echocardiography would be considered appropriate as part of the initial evaluation of a patient with suspected or confirmed chronic ischemic heart disease.

Doppler Echocardiography and Doppler Color Flow Velocity Mapping:

Florida Medicare will consider doppler echocardiography (CPT code 93320-93321) and doppler color flow velocity mapping (93325) medically necessary under any one of the following circumstances:

- The patient has valvular heart disease or congenital heart disease and echocardiography is needed to define the condition, monitor response to therapy, or to investigate a change in the patient's clinical condition.
- The patient has a prosthetic heart valve and echocardiography is needed to monitor response to therapy or investigate a change in the patient's clinical condition.
- The patient has clinical findings which suggest the presence of valvular heart disease (e.g., the patient has a heart murmur which is felt to be clinically significant).
- The patient has proven endocarditis or clinical findings suggestive of endocarditis.
- The patient has clinical findings diagnostic of or suggestive of acute myocardial ischemia or infarction, or the patient has complications of acute myocardial infarction such as valvular incompetency, ventricular septal rupture or aneurysm of heart.

- The patient has a thoracic aortic aneurysm or dissection, or the patient has clinical findings suggestive of aortic dissection or aneurysm.
- The patient has undergone heart transplantation.
- The patient has suspected or confirmed pulmonary hypertension and/or cor pulmonale, and echocardiography is necessary for evaluation and/or follow-up.

Routine performance of resting echocardiography, doppler echocardiography, or doppler color flow velocity mapping on patients with stable chronic coronary artery disease is not considered medically necessary unless the patient has had a change in clinical status which makes repeat procedures necessary. Also, the performance of procedures on patients with simple hypertension without other evidence of heart disease is considered not medically necessary.

CPT/HCPCS Section & Benefit Category

Medicine/Echocardiography

Type of Bill Code

Hospital – 12x, 13x, 14x
 Skilled Nursing Facility – 21x, 22x, 23x
 Rural Health Clinic – 71x

Revenue Codes

480 Cardiology, General Classification

CPT/HCPCS Codes

- 93303 Transthoracic echocardiography for congenital cardiac anomalies; complete
- 93304 follow-up or limited study
- 93307 Echocardiography, transthoracic, real-time with image documentation (2D) with or without M-mode recording; complete
- 93308 follow-up or limited study
- 93320 Doppler echocardiography, pulsed wave and/or continuous wave with spectral display (List separately in addition to codes for echocardiographic imaging); complete
- 93321 follow-up or limited study (List separately in addition to codes for echocardiographic imaging)
- 93325 Doppler echocardiography color flow velocity mapping (List separately in addition to codes for echocardiography)

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

Transthoracic Real Time Echocardiography (procedure codes 93307 and 93308)

- 164.1 Malignant neoplasm of heart
- 212.7 Benign neoplasm of heart
- 391.0-391.9 Rheumatic fever with heart involvement
- 394.0-394.9 Diseases of mitral valve
- 395.0-395.9 Diseases of aortic valve
- 396.0-396.9 Diseases of mitral and aortic valves
- 397.0-397.9 Diseases of other endocardial structures

93303: Transthoracic and Doppler Echocardiography and Doppler Color Flow Velocity Mapping (continued)

398.91	Rheumatic heart failure (congestive)	746.5	Congenital mitral stenosis
402.00-402.01	Malignant hypertensive heart disease	746.6	Congenital mitral insufficiency
402.10-402.11	Benign hypertensive heart disease	746.7	Hypoplastic left heart syndrome
402.90-402.91	Unspecified hypertensive heart disease	746.81-746.89	Other specified anomalies of heart
403.00-403.91	Hypertensive renal disease	746.9	Unspecified anomaly of heart
404.00-404.93	Hypertensive heart and renal disease	747.0	Patent ductus arteriosus
410.00-410.92	Acute myocardial infarction	747.10-747.11	Coarctation of aorta
411.0	Postmyocardial infarction syndrome	747.3	Anomalies of pulmonary artery
411.1	Intermediate coronary syndrome	780.2	Syncope and collapse
411.81	Coronary occlusion without myocardial infarction	782.3	Edema
		785.2	Undiagnosed cardiac murmurs
411.89	Other acute and subacute forms of ischemic heart disease	785.3	Other abnormal heart sounds
		786.02-786.09	Dyspnea and respiratory abnormalities
412	Old myocardial infarction	786.50-786.59	Chest pain
413.0-413.9	Angina pectoris	861.00-861.03	Injury to heart, without mention of open wound into thorax
414.00-414.05	Coronary atherosclerosis		
414.10-414.19	Aneurysm of heart	861.10-861.13	Injury to heart, with open wound into thorax
416.0	Primary pulmonary hypertension		
416.8	Other chronic pulmonary heart diseases	963.1	Poisoning by antineoplastic and immunosuppressive drugs
416.9	Chronic pulmonary heart disease, unspecified	996.02	Mechanical complication of cardiac device, implant, and graft due to heart valve prosthesis
421.0-421.9	Acute and subacute endocarditis		
423.0-423.9	Other diseases of pericardium		
424.0-424.3	Other diseases of endocardium	996.03	Mechanical complication of cardiac device, implant, and graft due to coronary bypass graft
424.90-424.99	Endocarditis, valve unspecified		
425.0-425.9	Cardiomyopathy		
427.0-427.5	Cardiac dysrhythmias	997.1	Cardiac complications
427.81	Sinoatrial node dysfunction	V42.1	Organ or tissue replaced by transplant, heart
428.0-428.9	Heart failure		
429.3	Cardiomegaly	V42.2	Organ or tissue replaced by transplant, heart valve
429.4	Functional disturbances following cardiac surgery	V43.3	Organ or tissue replaced by other means, heart valve
429.5	Rupture of chordae tendineae		
429.6	Rupture of papillary muscle	V58.83	Encounter for therapeutic drug monitoring
429.71	Acquired cardiac septal defect	V67.51	Follow-up examination following completed treatment with high-risk medications, not elsewhere classified
429.79	Other sequelae of myocardial infarction, not elsewhere classified		
429.81	Other disorders of papillary muscle		
434.10-434.11	Cerebral embolism		
444.21-444.22	Arterial embolism and thrombosis of arteries of the extremities		
444.81-444.89	Arterial embolism and thrombosis of other specified artery		
453.2	Venous embolism and thrombosis of vena cava		
745.0	Common truncus		
745.10-745.19	Transposition of great vessels		
745.2	Tetralogy of Fallot		
745.3	Common ventricle		
745.4	Ventricular septal defect	402.11	Benign hypertensive heart disease with congestive heart failure
745.5	Ostium secundum type atrial septal defect		
745.60-745.69	Endocardial cushion defects	402.91	Unspecified hypertensive heart disease with congestive heart failure
745.7	Cor biloculare		
745.8	Other bulbus cordis anomalies and anomalies of cardiac septal closure	404.01	Malignant hypertensive heart and renal disease with congestive heart failure
		404.03	Malignant hypertensive heart and renal disease with congestive heart failure and renal failure
745.9	Unspecified defect of septal closure		
746.00-746.09	Anomalies of pulmonary valve		
746.1	Tricuspid atresia and stenosis, congenital	404.11	Benign hypertensive heart and renal disease with congestive heart failure
746.2	Ebstein's anomaly		
746.3	Congenital stenosis of aortic valve		
746.4	Congenital insufficiency of aortic valve		

Doppler Echocardiography and Doppler Color Flow Velocity Mapping (procedure codes 93320, 93321, and 93325)

391.0-391.9	Rheumatic fever with heart involvement
394.0-394.9	Diseases of mitral valve
395.0-395.9	Diseases of aortic valve
396.0-396.9	Diseases of mitral and aortic valves
397.0-397.9	Diseases of other endocardial structures
398.91	Rheumatic heart failure (congestive)
402.01	Malignant hypertensive heart disease with congestive heart failure
	Benign hypertensive heart disease with congestive heart failure
	Unspecified hypertensive heart disease with congestive heart failure
	Malignant hypertensive heart and renal disease with congestive heart failure
	Malignant hypertensive heart and renal disease with congestive heart failure and renal failure
	Benign hypertensive heart and renal disease with congestive heart failure

93303: Transthoracic and Doppler Echocardiography and Doppler Color Flow Velocity Mapping (continued)

404.13	Benign hypertensive heart and renal disease with congestive heart failure and renal failure	746.2	Ebstein's anomaly
		746.3	Congenital stenosis of aortic valve
404.91	Unspecified hypertensive heart and renal disease with congestive heart failure	746.4	Congenital insufficiency of aortic valve
		746.5	Congenital mitral stenosis
404.93	Unspecified hypertensive heart and renal disease with congestive heart failure and renal failure	746.6	Congenital mitral insufficiency
		746.7	Hypoplastic left heart syndrome
		746.81-746.89	Other specified anomalies of heart
410.00-410.92	Acute myocardial infarction	746.9	Unspecified anomaly of heart
411.0	Postmyocardial infarction syndrome	747.0	Patent ductus arteriosus
411.1	Intermediate coronary syndrome	747.10-747.11	Coarctation of aorta
411.81	Coronary occlusion without myocardial infarction	747.3	Anomalies of pulmonary artery
		780.2	Syncope and collapse
411.89	Other acute and subacute forms of ischemic heart disease	785.2	Undiagnosed cardiac murmurs
		786.50-786.59	Chest pain
412	Old myocardial infarction	996.02	Mechanical complication of cardiac device, implant, and graft due to heart valve prosthesis
413.0-413.9	Angina pectoris		Mechanical complication of cardiac device, implant, and graft due to coronary bypass graft
414.00	Coronary atherosclerosis of unspecified type of vessel, native or graft	996.03	
414.01	Coronary atherosclerosis of native coronary artery	V42.1	Organ or tissue replaced by transplant, heart
414.02	Coronary atherosclerosis of autologous vein bypass graft	V42.2	Organ or tissue replaced by transplant, heart valve
414.03	Coronary atherosclerosis of nonautologous biological bypass graft	V43.3	Organ or tissue replaced by other means, heart valve
414.04	Coronary atherosclerosis of artery bypass graft		
414.05	Coronary atherosclerosis of unspecified type of bypass graft		
414.10-414.19	Aneurysm of heart		
416.0	Primary pulmonary hypertension		
416.8	Other chronic pulmonary heart diseases		
416.9	Chronic pulmonary heart disease, unspecified		
421.0-421.9	Acute and subacute endocarditis		
424.0-424.3	Other diseases of the endocardium		
424.90	Endocarditis, valve unspecified, unspecified cause		
424.91	Endocarditis in diseases classified elsewhere		
424.99	Other endocarditis, valve unspecified		
428.0-428.9	Heart failure		
429.5	Rupture of chordae tendineae		
429.6	Rupture of papillary muscle		
429.71	Acquired cardiac septal defect		
429.79	Other sequelae of myocardial infarction, not elsewhere classified		
429.81	Other disorders of papillary muscle		
745.0	Common truncus		
745.10-745.19	Transposition of great vessels		
745.2	Tetralogy of Fallot		
745.3	Common ventricle		
745.4	Ventricular septal defect		
745.5	Ostium secundum type atrial septal defect		
745.60-745.69	Endocardial cushion defects		
745.7	Cor biloculare		
745.8	Other bulbus cordis anomalies and anomalies of cardiac septal closure		
745.9	Unspecified defect of septal closure		
746.00-746.09	Anomalies of pulmonary valve		
746.1	Tricuspid atresia and stenosis, congenital		

Diagnosis that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

Diagnosis that DO NOT Support Medical Necessity

N/A

Reasons for Denial

When performed for indications other than those listed in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy.

Noncovered ICD-9-CM Code(s)

Any diagnosis codes not listed in the "ICD-9-CM Codes That Support Medical Necessity" section of this policy.

Noncovered Diagnosis

N/A

Coding Guidelines

Diagnosis code V58.83 should be used when the 2D echocardiogram is being performed for the evaluation and management of a patient under treatment, or being considered for treatment with a cardiotoxic medication.

Documentation Requirements

Medical record documentation must indicate the medical necessity of echocardiographic studies covered by the Medicare program. Also, the results of echocardiographic studies covered by the Medicare program must be included in the patient's medical record. This information is usually found in the office/progress notes, and/or test results.

93303: Transthoracic and Doppler Echocardiography and Doppler Color Flow Velocity Mapping (continued)

If the provider of echocardiographic studies is other than the ordering/referring physician, the provider of the service must maintain hard copy documentation of test results and interpretation, along with copies of the ordering/referring physician's order for the studies. When ordering echocardiographic studies from other providers, the ordering/referring physician must state the reason for the echocardiographic studies in his order for the test(s).

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

Dambro, M. (1997). *Griffith's 5 Minute Clinical Consult*. Baltimore: Williams and Wilkins.
 Fauci, A., Braunwald, E., Isselbacher, K., Wilson, J., Martin, J., Kasper, D., Hauser, S., & Longo, D. (eds.) (1998). *Harrison's Principles of Internal Medicine*. (14th ed.). New York: McGraw-Hill.

Advisory Committee Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from numerous societies.

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

08/01/2001

Revision History

Revision Number	1
Start Date of Comment Period	N/A
Start Date of Notice Period	08/01/2001 4 th Qtr 2001 <i>Bulletin</i>
Revised Effective Date	07/17/2001
Explanation of Revision:	Addition of diagnosis V58.83 for use for patients initiating or receiving treatment with a cardiotoxic medication.
Revision Number	Original
Start Date of Comment Period:	02/21/2000
Start Date of Notice Period:	06/01/2000 June/July 2000 <i>Bulletin</i>
Original Effective Date	07/17/2000

A0430: Air Ambulance Services

Policy Number

A0430

Contractor Name

First Coast Service Options, Inc.

Contractor Number

090

Contractor Type

Intermediary

LMRP Title

Air Ambulance Services

AMA CPT Copyright Statement

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HCFA National Coverage Policy

Medicare Hospital Manual, Sections 236, 279, 433
Intermediary Manual, Sections 3114, 3322, 3660.1
Skilled Nursing Facility Manual, Section 539
Program Memorandum, AB-00-88 (Change Request 1281), dated 09/18/2000
Program Memorandum, AB-00-118 (Change Request 1461), dated 11/30/2000

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

HCFA Region

Region IV

HCFA Consortium

Southern

Original Policy Effective Date

09/21/2001

Original Policy Ending Date

N/A

Revision Effective Date

N/A

Revision Ending Date

N/A

LMRP Description

Air ambulance transportation service, either by means of a helicopter or fixed wing aircraft, is a covered service regardless of the State or region in which it is rendered. However, air ambulance transportation is covered only if the patient's medical condition is such that transportation by either basic or advanced life support land ambulance is not appropriate.

In addition to meeting medical necessity requirements, all other requirements, such as ambulance crew requirements and origin and destination requirements must be met.

Indications and Limitations of Coverage and/or Medical Necessity

Air ambulance transportation services will be considered medically reasonable and necessary when:

1. The patient's medical condition requires immediate and rapid ambulance transportation that could not have been provided by land ambulance; and either
2. The point of pick-up is inaccessible by land vehicle (this condition could be met in Hawaii, Alaska, and in other remote or sparsely populated areas of the continental United States), or
3. Great distances or other obstacles (e.g., heavy traffic) are involved in getting the patient to the nearest hospital with appropriate facilities. The term "appropriate facilities" refers to units or components of a hospital that are capable of providing the required level and type of care for the patient's illness and have available the type of physician or physician specialist needed to treat the patient's condition.

Medical Appropriateness

Medical appropriateness is established when the patient's condition is such that the time needed to transport a patient by land, or the instability of transportation by land, poses a threat to the patient's survival or seriously endangers the patient's health. The following list of conditions are examples of situations which could justify air ambulance transportation. The list is not inclusive of all situations that justify air transportation, nor is it intended to justify air transportation in all locales in the circumstances listed.

- Acute neurological emergencies requiring emergent/time sensitive interventions not available at the sending facility. This includes such conditions as intracerebral hemorrhage, status epilepticus, acute stroke, diffuse cerebral edema, acute hydrocephalus, CNS infection requiring operative intervention, thrombolytics, etc.
- Acute vascular emergencies requiring emergent/time sensitive interventions not available at the sending facility. This includes such conditions as thoracic or abdominal aortic aneurysm with dissection or impending dissection, acute occlusion of major vessels resulting in limb-threatening ischemia, etc.
- Acute surgical emergencies requiring emergent/time sensitive interventions not available at the sending facility.
- Critically ill patients with compromised hemodynamic/respiratory function who require intensive care during transport and whose time of transfer must be minimized during transport.
- Critically ill obstetric patients who require intensive care during transport and whose time of transfer between facilities must be minimized to prevent patient/fetal morbidity. This includes such conditions as a suspected birth weight less than 2000 grams or gestation less than 34 weeks, premature labor with delivery of low birth weight infant, etc.

A0430: Air Ambulance Services (continued)

- Acute cardiac emergencies requiring emergent/time-sensitive intervention not available at the sending facility. This includes such interventions as angioplasty with or without stent placement, cardiac surgery, intra-aortic balloon pump placement, thrombolytics, cardiogenic shock, etc. It is expected that the patients are unstable and the life-saving intervention is needed immediately.
- Critically ill neonatal/pediatric patients with potentially compromised hemodynamic/respiratory function, a metabolic acidosis greater than 2 hours post delivery, sepsis, or meningitis.
- Patients with electrolyte disturbances and toxic exposure requiring immediate life-saving intervention such as hemoperfusion or hemodialysis.
- Transplant patients for which immediate surgical transplantation is needed to enhance successful transplantation of the donor organ(s).
- Patients with life-threatening conditions requiring care in a specialty center. This includes such conditions requiring a hyperbaric oxygen unit, burns requiring treatment in a burn treatment center, potentially life or limb-threatening trauma and/or multiple severe injuries requiring treatment at a trauma center.

Hospital to Hospital Transport

Air ambulance transport is covered for transfer of a patient from one hospital to another if the medical appropriateness requirements are met, that is, transportation by ground ambulance would endanger the patient's health and the transferring hospital does not have adequate facilities to provide the medical services needed by the patient. Examples of such services include burn units, cardiac care units, and trauma units. A patient transported from one hospital to another hospital is covered only if the hospital to which the patient is transferred is the nearest one with appropriate facilities. Coverage is not available for transport from a hospital capable of treating the patient because the patient and/or his or her family prefer a specific hospital or physician.

NOTE: Air ambulance services are not covered for transport to a facility that is not an acute care hospital, such as a nursing facility, physician's office or a patient's home.

CPT/HCPCS Section & Benefit Category

Ambulance

Type of Bill Code

Hospital – 13x
Skilled Nursing Facility – 22x, 23x

Revenue Codes

540 Ambulance, General Classification

CPT/HCPCS Codes

- A0430 Ambulance service, conventional air services, transport, one way (fixed wing)
- A0431 Ambulance service, conventional air services, transport, one way (rotary wing)
- A0435 Fixed wing air mileage, per statute mile

A0436 Rotary wing air mileage, per statute mile

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

N/A

Diagnosis that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

Diagnosis that DO NOT Support Medical Necessity

N/A

Reasons for Denial

When performed for indications other than those listed in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy.

Noncovered ICD-9-CM Code(s)

Any diagnosis codes not listed in the "ICD-9-CM Codes That Support Medical Necessity" section of this policy.

Noncovered Diagnosis

N/A

Coding Guidelines

Origin and destination modifiers are to be used with codes A0430-A0436. The first position alpha code equals origin and the second position alpha code equals destination. The origin and destination codes are:

- D Diagnostic or therapeutic site other than "P" or "H" when these are used as origin codes
- E Residential, domiciliary, custodial facility
- G Hospital-based dialysis facility (hospital or hospital-related)
- H Hospital
- I Site of transfer (e.g., airport or helicopter pad) between modes of ambulance transport
- J Non-hospital based dialysis facility
- N Skilled Nursing Facility (SNF)
- P Physician's office (includes HMO non-hospital facility, clinic, etc.)
- R Residence
- S Scene of accident or acute event
- X* Intermediate stop at physician's office en route to the hospital (includes HMO non-hospital facility, clinic, etc.)

* Destination code only

In addition to the origin and destination codes, one of the following modifiers must be billed with every HCPCS code to describe whether the service was provided under arrangement or directly:

- QM Ambulance service provided under arrangement by a provider of services
- QN Ambulance service furnished directly by a provider of services

A0430: Air Ambulance Services (continued)

Payment for air ambulance mileage services is based on each loaded mile. The loaded miles flown by an air ambulance is expressed in statute miles, not nautical miles.

Documentation Requirements

All services for air ambulance services are reviewed on a prepayment basis. Medical record documentation submitted with the claim must clearly document that the patient's condition requires immediate and rapid ambulance transportation that could not have been provided by land ambulance. This information can be found on the ambulance transport sheet (run sheet), emergency room records, hospital records, and/or progress notes.

For transfers occurring between facilities, it is expected that the person responsible for managing the patient's care indicate in the records the medical condition of the patient and the need for air ambulance transportation in lieu of ground transportation. In addition to the documentation supporting the need for air transportation, when the transferring facility does not have adequate facilities to provide the medical services needed by the patient, the records must support that the time sensitive medical service needed was utilized immediately. For example, it is not expected that air transportation is needed for a stable myocardial infarction patient being transferred for a cardiac catheterization the following day.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

Negotiated Rulemaking Committee. (2000, February).
 Negotiated Rulemaking Committee on Medicare
 Ambulance Fee Schedule: Committee statement.

Advisory Committee Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from numerous societies.

Start Date of Comment Period

02/28/2001

End Date of Comment Period

04/14/2001

Start Date of Notice Period

08/01/2001

Revision History

Revision Number	Original
Start Date of Comment Period:	02/28/2001
Start Date of Notice Period:	08/01/2001
	4 th Qtr 2001 <i>Bulletin</i>
Original Effective Date	09/21/2001 ❖

G0030: Positron Emission Tomography (PET) Scan

Revision Overview: This policy has been revised in its entirety to incorporate the expansion of coverage of PET scans.

Policy Number

AG0030

Contractor Name

First Coast Service Options, Inc.

Contractor Number

090

Contractor Type

Intermediary

LMRP Title

Positron Emission Tomography (PET) Scan

AMA CPT Copyright Statement

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HCFA National Coverage Policy

Coverage Issues Manual, Section 50-36

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

HCFA Region

Region IV

HCFA Consortium

Southern

Original Policy Effective Date

12/03/1998

Original Policy Ending Date

N/A

Revision Effective Date

07/01/2001

Revision Ending Date

06/30/2001

LMRP Description

PET is a noninvasive diagnostic imaging procedure that assesses the level of metabolic activity and perfusion in various organ systems of the human body. A positron camera (tomograph) is used to produce cross-sectional tomographic images, which are obtained from positron emitting radioactive tracer substances (radiopharmaceutical) such as FDG (2-{fluorine-18}-fluoro-2-dexoy-D-glucose) that are usually administered intravenously to the patient. At this time, Medicare only covers FDG PET Scans.

Indications and Limitations of Coverage and/or Medical Necessity

The following indications may be covered for PET under certain circumstances. Details of Medicare PET coverage are discussed later in this policy. Unless otherwise indicated, the clinical conditions below are covered when PET utilizes FDG as the tracer.

NOTE: All other uses of PET scans not listed in this policy are NOT covered.

Clinical Condition	Effective Date	Coverage
Solitary Pulmonary Nodules (SPNs)	January 1, 1998	Characterization
Lung Cancer (Non Small Cell)	January 1, 1998	Initial Staging
Lung Cancer (Non Small Cell)	July 1, 2001	Diagnosis, staging, and restaging
Esophageal Cancer	July 1, 2001	Diagnosis, staging, and restaging
Colorectal Cancer	July 1, 1999	Determining location of tumors if rising CEA level suggests recurrence
Colorectal Cancer	July 1, 2001	Diagnosis, staging, and restaging
Lymphoma	July 1, 1999	Staging and restaging only when used as an alternative to Gallium scan
Lymphoma	July 1, 2001	Diagnosis, staging, and restaging
Melanoma	July 1, 1999	Evaluating recurrence prior to surgery as an alternative to Gallium scan
Melanoma	July 1, 2001	Diagnosis, staging, and restaging; noncovered for evaluating regional nodes
Refractory Seizures	July 1, 2001	Covered for pre-surgical evaluation only
Perfusion of the heart using Rubidium 82* tracer	March 14, 1995	Covered for noninvasive imaging of the perfusion of the heart
Head and Neck Cancer	July 1, 2001	Diagnosis, staging, and restaging: noncovered for CNS and thyroid
Myocardial Viability	July 1, 2001	Covered only following an inconclusive SPECT

*Not FDG PET

G0030: Positron Emission Tomography (PET) Scan (continued)

General Conditions of Coverage

- A. Regardless of any other terms or conditions, all uses of PET scans, in order to be covered by the Medicare program, must meet the following general conditions prior to June 30, 2001:
1. Such scans must be performed using a camera that has either been approved or cleared for marketing by the FDA to image radionuclides in the body.
 2. Submission of claims for payment must include any information Medicare requires to assure that the PET scans performed: (a) were medically necessary; (b) did not unnecessarily duplicate other covered diagnostic tests; and (c) did not involve investigational drugs or procedures using investigational drugs as determined by the FDA.
 3. The PET scan entity submitting claims for payment must keep such patient records as Medicare requires on file for each patient for whom a PET scan claim is made.
- B. Regardless of any other terms or conditions, all uses of PET scans, in order to be covered by the Medicare program, must meet the following general conditions as of July 1, 2001:
- PET scans are covered for those indications otherwise listed in this document. For indications covered beginning July 1, 2001, scans performed with dedicated full-ring scanners will be covered. For those indications covered prior to July 1, 2001, all PET scanners approved or cleared for marketing by the FDA remain covered.
 - The provider should maintain on file the doctor's referral and documentation that the procedure involve only FDA approved drugs and devices, as is normal business practice.
 - The ordering physician is responsible for certifying the medical necessity of the study and that it meets the conditions specified in the instructions. The physician should have documentation in the beneficiary's medical record to support the referral to the PET scan provider.

Covered Indications for PET Scans and Limitations/ Requirements for Usage

For all uses of PET, excluding Rubidium 82 for perfusion of the heart, myocardial viability and refractory seizures the following definitions apply:

Diagnosis – PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal and colorectal cancers, as well as in melanoma, should be rare. PET is not covered for

(testing of patients without specific signs and symptoms (testing of patients without specific signs and symptoms of disease).

Staging and/or Restaging – PET is covered in clinical situations in which (1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or, (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient and, (2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

NOTE: PET is not covered for other diagnostic uses, and is not covered for screening (testing of patients without specific symptoms).

Monitoring – Use of PET to monitor tumor response during the planned course of therapy (i.e. when no change in therapy is being contemplated) is NOT covered. Restaging only occurs after a course of treatment is completed, and this is covered, subject to the conditions above.

Coverage of PET Scans for Noninvasive Imaging of the Perfusion of the Heart

Effective for services performed on or after March 14, 1995, PET scans done at rest or with pharmacological stress used for noninvasive imaging of the perfusion of the heart for the diagnosis and management of patients with known or suspected coronary artery disease using the FDA-approved radiopharmaceutical Rubidium 82 (Rb82) are covered, provided the requirements below are met:

The PET scan, whether rest alone or rest with stress, is used in place of, but not in addition to, a single photon emission computed tomography (SPECT); or

The PET scan, whether rest alone or rest with stress, is used following a SPECT that was found inconclusive. In these cases, the PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the patient. (For purposes of this requirement, an inconclusive test is a test(s) whose results are equivocal, technically uninterpretable, or discordant with a patient's other clinical data and must be documented in the beneficiary's file.)

For any PET scan for which Medicare payment is claimed for dates of service prior to July 1, 2001, the

G0030: Positron Emission Tomography (PET) Scan (continued)

claimant must submit additional specified information on the claim form (including proper codes and/or modifiers), to indicate the results of the PET scan. The claimant must also include information on whether the PET scan was done after an inconclusive noninvasive cardiac test. The information submitted with respect to the previous noninvasive cardiac test must specify the type of test done prior to the PET scan and whether it was inconclusive or unsatisfactory. These codes are in the form of special G codes used for billing PET scans using Rb 82. Beginning July 1, 2001 claims should be submitted with the appropriate codes.

Coverage of FDG PET for Lung Cancer

The coverage for FDG PET for lung cancer, effective January 1, 1998, has been expanded. Beginning July 1, 2001 usage of FDG PET for lung cancer has been expanded to include diagnosis, staging, and restaging of the disease.

- A. Effective for services performed on or after January 1, 1998, Medicare covers regional FDG PET chest scans, on any FDA approved scanner, for the characterization of single pulmonary nodules (SPNs). The primary purpose of such characterization should be to determine the likelihood of malignancy in order to plan future management and treatment for the patient.

Requirements:

There must be evidence of primary tumor. Claims for regional PET chest scans for characterizing SPNs should include evidence of the initial detection of a primary lung tumor, usually by computed tomography (CT). This should include, but is not restricted to, a report on the results of such CT or other detection method, indicating an indeterminate or possible malignant lesion, not exceeding four centimeters (cm) in diameter.

PET scan claims must include the results of concurrent thoracic CT, which is necessary for anatomic information, in order to ensure that the PET scan is properly coordinated with other diagnostic modalities.

In cases of serial evaluation of SPNs using both CT and regional PET chest scanning, such PET scans will not be covered if repeated within 90 days following a negative PET scan.

- Note:** A tissue sampling procedure is not routinely covered in the case of a negative PET scan for characterization of SPNs, since the patient is presumed not to have a malignant lesion, based upon the PET scan results. When there has been a negative PET scan, the provider must submit additional information with the claim to support the necessity of a Tissue Sampling Procedure (TSP), for review by the Medicare contractor.

- B. Effective for services performed from January 1, 1998 through June 30, 2001, Medicare approved coverage of FDG PET for initial staging of non-small-cell lung carcinoma (NSCLC).

Limitations:

This service is covered only when the primary cancerous lung tumor has been pathologically

confirmed; claims for PET must include a statement or other evidence of the detection of such primary lung tumor. The evidence should include, but is not restricted to, a surgical pathology report, which documents the presence of an NSCLC. Whole body PET scan results and results of concurrent computed tomography (CT) and follow-up lymph node biopsy must be properly coordinated with other diagnostic modalities. Claims must include both:

- The results of a concurrent thoracic CT, necessary for anatomic information, and
- The results of any lymph node biopsy performed to finalize whether the patient will be a surgical candidate. The ordering physician is responsible for providing this biopsy result to the PET facility.

NOTE: Where the patient is considered a surgical candidate, (given the presumed absence of metastatic NSCLC unless medical review supports a determination of medical necessity of a biopsy) a lymph node biopsy will not be covered in the case of a negative CT and negative PET. A lymph node biopsy will be covered in all other cases, (i.e., positive CT + positive PET; negative CT + positive PET; positive CT + negative PET).

- C. Beginning July 1, 2001, Medicare covers FDG PET for diagnosis, staging, and restaging of NSCLC. Documentation should be maintained in the beneficiary's medical file to support the medical necessity of the procedure, as is normal business practice.

Requirements: PET is covered in either/or both of the following circumstances:

Diagnosis – PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal and colorectal cancers, as well as in melanoma, should be rare.

Staging and/or Restaging – PET is covered in clinical situations in which (1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or, (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient and, (2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected

G0030: Positron Emission Tomography (PET) Scan (continued)

recurrence, or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

Coverage of FDG PET for Esophageal Cancer

- A. Beginning July 1, 2001, Medicare covers FDG PET for the diagnosis, staging, and restaging of esophageal cancer. Medical evidence is present to support the use of FDG PET in pre-surgical staging of esophageal cancer.

Requirements: PET is covered in either/or both of the following circumstances:

Diagnosis – PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal and colorectal cancers, as well as in melanoma, should be rare.

Staging and/or Restaging – PET is covered in clinical situations in which (1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or, (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient and, (2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

Coverage of FDG PET for Colorectal Cancer

Medicare coverage of FDG PET for colorectal cancer where there is a rising level of carcinoembryonic antigen (CEA) was effective July 1, 1999 through June 30, 2001. Beginning July 1, 2001, usage of FDG PET for colorectal cancer has been expanded to include diagnosis, staging, and restaging of the disease.

- A. Effective July 1, 1999, Medicare covers FDG PET for patients with recurrent colorectal carcinomas, which are suggested by rising levels of the biochemical tumor marker CEA.

Frequency Limitations:

Whole body PET scans for assessment of recurrence of colorectal cancer cannot be ordered more frequently than once every 12 months unless medical necessity documentation supports a separate re-elevation of CEA within this period.

Limitations:

Because this service is covered only in those cases in which there has been a recurrence of colorectal tumor, claims for PET should include a statement or other evidence of previous colorectal tumor, through June 30, 2001.

- B. Beginning July 1, 2001, Medicare coverage has been expanded for colorectal carcinomas for diagnosis, staging, and restaging. New medical evidence supports the use of FDG PET as a useful tool in determining the presence of hepatic/extrahepatic metastases in the primary staging of colorectal carcinoma, prior to selecting a treatment regimen. Use of FDG PET is also supported in evaluating recurrent colorectal cancer beyond the limited presentation of a rising CEA level where the patient presents with clinical signs or symptoms of recurrence.

Requirements: PET is covered in either/or both of the following circumstances:

Diagnosis – PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal and colorectal cancers, as well as in melanoma, should be rare.

Staging and/or Restaging – PET is covered in clinical situations in which (1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or, (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient and, (2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

G0030: Positron Emission Tomography (PET) Scan (continued)**Coverage of FDG PET for Lymphoma**

Medicare coverage of FDG PET to stage and re-stage lymphoma as an alternative to a Gallium scan, was effective July 1, 1999. Beginning July 1, 2001, usage of FDG PET for lymphoma has been expanded to include diagnosis, staging, and restaging of the disease.

- A. Effective July 1, 1999, FDG PET is covered for the staging and restaging of lymphoma.

Requirements:

FDG PET is covered only for staging or follow-up restaging of lymphoma. Claims must include a statement or other evidence of previous diagnosis of lymphoma when used as an alternative to a Gallium scan.

To ensure that the PET scan is properly coordinated with other diagnostic modalities, claims must include results of concurrent computed tomography (CT) and/or other diagnostic modalities when they are necessary for additional anatomic information.

No PET scan may be covered in cases where it is done within 50 days of a Gallium scan done by the same facility where the patient has remained during the 50-day period. Gallium scans done by another facility less than 50 days prior to the PET scan will not be counted against this screen.

Frequency Limitations for Restaging:

PET scans will be allowed for restaging no sooner than 50 days following the last staging PET scan or Gallium scan, unless the medical necessity documentation supports that the restaging at an earlier date is medically necessary.

- B. Effective for services performed on or after July 1, 2001, the Medicare program has broadened coverage of FDG PET for the diagnosis, staging, and restaging of lymphoma.

Requirements:

PET is covered in either/or both of the following circumstances:

Diagnosis – PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal and colorectal cancers, as well as in melanoma, should be rare.

Staging and/or Restaging – PET is covered in clinical situations in which (1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or, (b) the use of PET would also be considered reasonable and necessary if it could

potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient and, (2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

Coverage of FDG PET for Melanoma

Medicare covered the evaluation of recurrent melanoma prior to surgery when used as an alternative to a Gallium scan, effective July 1, 1999. For services performed on or after July 1, 2001, FDG PET is covered for the diagnosis, staging, and restaging of malignant melanoma. FDG PET is not covered for the use of evaluating regional nodes in melanoma patients.

- A. Effective for services furnished July 1, 1999 through June 30, 2001, in the case of patients with recurrent melanoma prior to surgery, FDG PET (when used as an alternative to a Gallium scan) is covered for tumor evaluation.

Frequency Limitations:

Whole body PET scans cannot be ordered more frequently than once every 12 months, unless medical necessity documentation, maintained in the beneficiary's medical record, supports the specific need for anatomic localization of possible recurrent tumor within this period.

Limitations:

The FDG PET is covered only as an alternative to a Gallium scan. No PET scan may be covered in cases where it is done within 50 days of a Gallium scan done by the same facility where the patient has remained during the 50-day period. Gallium scans done by another facility less than 50 days prior to the PET scan will not be counted against this screen.

- B. Effective for services performed on or after July 1, 2001, FDG PET scan coverage for the diagnosis, staging, and restaging of malignant melanoma (not the evaluation of regional nodes) has been broadened.

Limitations:

PET scans are not covered for the evaluation of regional nodes.

Requirements:

PET is covered in either/or both of the following circumstances:

Diagnosis – PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic

G0030: Positron Emission Tomography (PET) Scan (continued)

procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal and colorectal cancers, as well as in melanoma, should be rare.

Staging and/or Restaging – PET is covered in clinical situations in which (1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or, (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient and, (2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

Coverage of FDG PET for Head and Neck Cancers (Cancers of the Central Nervous System [CNS] and thyroid are noncovered)

Effective for services performed on or after July 1, 2001, Medicare will provide coverage for cancer of the head and neck, excluding the central nervous system (CNS) and thyroid.

Limitations:

PET scans for head and neck cancers are not covered for CNS or thyroid cancers.

Requirements:

PET is covered in either/or both of the following circumstances:

Diagnosis – PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal and colorectal cancers, as well as in melanoma, should be rare.

Staging and/or Restaging – PET is covered in clinical situations in which (1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or, (b) the use of PET would also be

considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient and, (2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

Coverage of FDG PET for Myocardial Viability

Beginning July 1, 2001, Medicare covers FDG PET for the determination of myocardial viability, following an inconclusive SPECT.

Limitations:

In the event that a patient has received a single photon computed tomography test (SPECT) with inconclusive results, a PET scan may be covered.

Coverage of FDG PET for Refractory Seizures

Beginning July 1, 2001, Medicare will cover FDG PET for pre-surgical evaluation for the purpose of localization of a focus of refractory seizure activity.

Limitations:

Covered only for pre-surgical evaluation.

CPT/HCPCS Section & Benefit Category

Radiology/Nuclear Medicine

Type of Bill Code

Hospital Outpatient – 13x, 14x

Revenue Codes

404 Positron Emission Tomography (PET)

CPT/HCPCS Codes

- G0030 PET myocardial perfusion imaging, (following previous PET, G0030-G0047); single study, rest or stress (exercise and/or pharmacologic)
- G0031 PET myocardial perfusion imaging, (following previous PET, G0030-G0047); multiple studies, rest or stress (exercise and/or pharmacologic)
- G0032 PET myocardial perfusion imaging, (following rest SPECT, 78464); single study, rest or stress (exercise and/or pharmacologic)
- G0033 PET myocardial perfusion imaging, (following rest SPECT, 78464); multiple studies, rest or stress (exercise and/or pharmacologic)
- G0034 PET myocardial perfusion imaging, (following stress SPECT, 78465); single study, rest or stress (exercise and/or pharmacologic)
- G0035 PET myocardial perfusion imaging, (following stress SPECT, 78465); multiple studies, rest or stress (exercise and/or pharmacologic)
- G0036 PET myocardial perfusion imaging, (following coronary angiography, 93510-93529); single study, rest or stress (exercise and/or pharmacologic)

G0030: Positron Emission Tomography (PET) Scan (continued)

G0037	PET myocardial perfusion imaging, (following coronary angiography, 93510-93529); multiple studies, rest or stress (exercise and/or pharmacologic)	G0220	PET Imaging whole body; diagnosis; lymphoma
G0038	PET myocardial perfusion imaging, (following stress planar myocardial perfusion, 78460; single study, rest or stress (exercise and/or pharmacologic)	G0221	PET Imaging whole body; initial staging; lymphoma (replaces G0164)
G0039	PET myocardial perfusion imaging, (following stress planar myocardial perfusion, 78460; multiple studies, rest or stress (exercise and/or pharmacologic)	G0222	PET Imaging whole body; restaging; lymphoma (replaces G0164)
G0040	PET myocardial perfusion imaging, (following stress echocardiogram, 93350); single study, rest or stress (exercise and/or pharmacologic)	G0223	PET Imaging whole body or regional; diagnosis; head and neck cancer; excluding thyroid and CNS cancers
G0041	PET myocardial perfusion imaging, (following stress echocardiogram, 93350); multiple studies, rest or stress (exercise and/or pharmacologic)	G0224	PET Imaging whole body or regional; initial staging; head and neck cancer; excluding thyroid and CNS cancers
G0042	PET myocardial perfusion imaging, (following stress nuclear ventriculogram, 78481 or 78483); single study, rest or stress (exercise and/or pharmacologic)	G0225	PET Imaging whole body or regional; restaging; head and neck cancer, excluding thyroid and CNS cancers
G0043	PET myocardial perfusion imaging, (following stress nuclear ventriculogram, 78481 or 78483); multiple studies, rest or stress (exercise and/or pharmacologic)	G0226	PET Imaging whole body; diagnosis; esophageal cancer
G0044	PET myocardial perfusion imaging, (following rest ECG, 93000); single study, rest or stress (exercise and/or pharmacologic)	G0227	PET Imaging whole body; initial staging; esophageal cancer
G0045	PET myocardial perfusion imaging, (following rest ECG, 93000); multiple studies, rest or stress (exercise and/or pharmacologic)	G0228	PET Imaging whole body; restaging; esophageal cancer
G0046	PET myocardial perfusion imaging, (following stress ECG, 93015); single study, rest or stress (exercise and/or pharmacologic)	G0229	PET Imaging; Metabolic brain imaging for pre-surgical evaluation of refractory seizures
G0047	PET myocardial perfusion imaging, (following stress ECG, 93015); multiple studies, rest or stress (exercise and/or pharmacologic)	G0230	PET Imaging; Metabolic assessment for myocardial viability following inconclusive SPECT study
G0125	PET lung imaging of solitary pulmonary nodules, using 2-[fluorine-18]-fluoro-2-deoxy-D-glucose (FDG), following CT (71250/71260 or 71270)		
G0210	PET Imaging whole body; diagnosis; lung cancer, non-small cell		
G0211	PET Imaging whole body; initial staging; lung cancer; non-small cell (replaces G0126)		
G0212	PET Imaging whole body; restaging; lung cancer; non-small cell		
G0213	PET Imaging whole body; diagnosis; colorectal cancer		
G0214	PET Imaging whole body; initial staging; colorectal cancer		
G0215	PET Imaging whole body; restaging; colorectal cancer (replaces G0163)		
G0216	PET Imaging whole body; diagnosis; melanoma		
G0217	PET Imaging whole body; initial staging; melanoma		
G0218	PET Imaging whole body; restaging; melanoma (replaces G0165)		
G0219	PET Imaging whole body; melanoma for non-covered indications		

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

The following ICD-9-CM codes are applicable to HCPCS codes G0030-G0047 only:

411.81	Coronary occlusion without myocardial infarction
414.00-414.03	Coronary atherosclerosis
414.11	Aneurysm of coronary vessels
414.8	Other specified forms of chronic ischemic heart disease

Diagnosis that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

Diagnosis that DO NOT Support Medical Necessity

N/A

Reasons for Denial

When performed for indications other than those listed in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy.

Noncovered ICD-9-CM Code(s)

Any diagnosis codes not listed in the "ICD-9-CM Codes That Support Medical Necessity" section of this policy.

Noncovered Diagnosis

N/A

G0030: Positron Emission Tomography (PET) Scan (continued)

Coding Guidelines

N/A

Documentation Requirements

Documentation that the required conditions (as indicated in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy) for each of the FDG PET scans performed has been met must be maintained by the referring physician in the beneficiary’s medical record. PET scan facilities must keep patient record information on file for each Medicare patient for whom such a PET scan claim is made. The medical record must include standard information (e.g., age, sex, and height) along with any annotations regarding body size or type, which indicate a need for a PET scan to determine the patient’s condition.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

N/A

Advisory Committee Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from numerous societies.

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

08/01/2001

Revision History

Revision Number	3
Start Date of Comment Period	N/A
Start Date of Notice Period	08/01/2001
	4 th Qtr 2001 <i>Bulletin</i>
Revised Effective Date	07/01/2001
Explanation of Revision:	Transmittals 136 and AB-01-54 expanded coverage of PET scans effective July 1, 2001.
Revision Number	2
Start Date of Comment Period	N/A
Start Date of Notice Period	06/07/1999
	June/July 1999 <i>Bulletin</i>
Revised Effective Date	07/01/1999
Explanation of Revision:	Changes required due to PROFs 672A and 686A/B
Revision Number	1
Start Date of Comment Period	N/A
Start Date of Notice Period	06/07/1999
Revised Effective Date	06/07/1999
Revision Number	Original
Start Date of Comment Period	05/13/1998
Start Date of Notice Period	09/18/1998
Original Effective Date	12/03/1998 ❖

G0104: Colorectal Cancer Screening

Revision Overview: This policy has been revised to incorporate the expansion of coverage for screening colonoscopies for all individuals, including those not at high risk who had not received a screening colonoscopy within the preceding ten years or a screening flexible sigmoidoscopy within the preceding four years.

Policy Number

G0104

Contractor Name

First Coast Service Options, Inc.

Contractor Number

090

Contractor Type

Intermediary

LMRP Title

Colorectal Cancer Screening

AMA CPT Copyright Statement

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HCFA National Coverage Policy

Medicare Hospital Manual, Section 456
 Medicare Intermediary Manual, Section 3660.17
 Program Transmittal 1824 (Change Request 1552, dated 02/13/2001)

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

HCFA Region

Region IV

HCFA Consortium

Southern

Original Policy Effective Date

07/13/1998

Original Policy Ending Date

N/A

Revision Effective Date

07/01/2001

Revision Ending Date

06/30/2001

LMRP Description

Cancer screening is a means of detecting disease early, in asymptomatic individuals, with the goal of decreasing morbidity and mortality. Generally, screening examinations, tests, or procedures are not diagnostic of cancer but instead indicate that a cancer may be present. The diagnosis is then made following a workup that generally includes a biopsy and pathologic confirmation. Colorectal cancer screening involves the use of fecal occult blood testing, rigid and flexible sigmoidoscopy, radiographic barium contrast studies, and colonoscopy.

Indications and Limitations of Coverage and/or Medical Necessity

Effective for services furnished on or after January 1, 1998, Medicare will cover colorectal cancer screening test/procedures for the early detection of colorectal cancer. The following are the coverage criteria for these new screening services:

- Screening fecal-occult blood tests (code G0107) are covered at a frequency of once every 12 months for beneficiaries who have attained age 50. Screening fecal-occult blood test means a guaiac-based test for peroxidase activity, in which the beneficiary completes it by taking samples from two different sites of three consecutive stools. This screening requires a written order from the beneficiary's attending physician.
- Screening flexible sigmoidoscopies (code G0104) are covered at a frequency of once every 48 months for beneficiaries who have attained age 50. If during the course of a screening flexible sigmoidoscopy a lesion or growth is detected which results in a biopsy or removal of the growth, the appropriate diagnostic procedure classified as a flexible sigmoidoscopy with biopsy or removal (procedure codes 45330-45339) should be billed rather than code G0104.
- Screening colonoscopies (code G0105) are covered at a frequency of once every 24 months for beneficiaries at high risk for colorectal cancer. High risk for colorectal cancer means an individual with one or more of the following:
 - A close relative (sibling, parent, or child) who has had colorectal cancer or an adenomatous polyp;
 - A family history of familial adenomatous polyposis;
 - A family history of hereditary nonpolyposis colorectal cancer;
 - A personal history of adenomatous polyps;
 - A personal history of colorectal cancer; or
 - A personal history of inflammatory bowel disease, including Crohn's Disease, and ulcerative colitis.

If during the course of the screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the growth, the appropriate diagnostic procedure classified as a colonoscopy with biopsy or removal (procedure codes 45378-45385) should be billed rather than code G0105. This screening must be performed by a doctor of medicine or osteopathy.

- Screening barium enema examinations (codes G0106 and G0120) are covered as an alternative to either a screening sigmoidoscopy (code G0104) or a screening colonoscopy (code G0105) examination. The same frequency parameters specified in the law for screening sigmoidoscopy and screening colonoscopy apply.

G0104: Colorectal Cancer Screening (continued)

The screening barium enema must be ordered in writing after a determination that the test is the appropriate screening test. This means that in the case of a particular individual, the attending physician must determine that the estimated screening potential for the barium enema is equal to or greater than the screening potential that has been estimated for a screening flexible sigmoidoscopy, or for a screening colonoscopy, as appropriate, for the same individual. This screening single contrast barium enema also requires a written order from the beneficiary's attending physician in the same manner as described above for the screening double contrast barium enema examination.

It is not expected that these screening services are performed on patients that present with active gastrointestinal symptomatology.

Effective for services furnished on or after July 1, 2001:

- Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk (code G0121) is covered unless he or she has had:
 - A screening colonoscopy (code G0121) within the preceeding ten years; or
 - A screening flexible sigmoidoscopy (code G0104) within the preceeding four years.

If during the course of the screening colonoscopy, a lesion or growth is detected which results in a biopsy or removal of the growth, the appropriate diagnostic procedure classified as a colonoscopy with biopsy or removal (procedure codes 45378-45385) should be billed rather than code G0121. This screening must be performed by a doctor of medicine or osteopathy.

- A screening flexible sigmoidoscopy (code G0104) is allowed once every 48 months unless the beneficiary does not meet the criteria for high risk of developing colorectal cancer **and** he or she has had a screening colonoscopy (code G0121) within the preceeding 10 years.

CPT/HCPCS Section & Benefit Category

Digestive System/Surgery

Type of Bill

Outpatient Hospital – 13x

Revenue Codes

- 30x Laboratory
- 32x Radiology-Diagnostic
- 750 Gastro-intestinal Services; General Classification

CPT/HCPCS Codes

- G0104 Colorectal cancer screening; flexible sigmoidoscopy
- G0105 Colorectal cancer screening; colonoscopy on individual at high risk
- G0106 Colorectal cancer screening; alternative to G0104, screening sigmoidoscopy, barium enema
- G0107 Colorectal cancer screening; fecal-occult blood test, 1-3 simultaneous determinations
- G0120 Colorectal cancer screening; alternative to G0105, screening colonoscopy, barium enema

- G0121 Colorectal cancer screening; colonoscopy on individual not meeting criteria for high risk
- G0122 Colorectal cancer screening; barium enema (non-covered)

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

The following diagnosis list applies only to procedure codes G0105 (Screening colonoscopy) and G0120 (Barium enema):

- 555.0-555.9 Regional enteritis
- 556.0-556.9 Ulcerative colitis
- 558.1-558.9 Other noninfectious gastroenteritis and colitis
- V10.05 Personal history of malignant neoplasm, large intestine
- V10.06 Personal history of malignant neoplasm, rectum, rectosigmoid junction, and anus
- V12.72 Personal history of colonic polyps
- V16.0 Family history of malignant neoplasm, gastrointestinal tract
- V18.5 Family history of certain other specific conditions, digestive disorders

Diagnosis that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

Diagnosis that DO NOT Support Medical Necessity

N/A

Reasons for Denial

Procedure code G0122 should be used when a screening barium enema is performed not as an alternative to either a screening colonoscopy (code G0105) or a screening flexible sigmoidoscopy (code G0104). This service will be denied as non-covered because it fails to meet the requirements of the benefit.

When performed for indications other than those listed in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy.

Noncovered ICD-9-CM Code(s)

Any diagnosis codes not listed in the "ICD-9-CM Codes That Support Medical Necessity" section of this policy.

Noncovered Diagnosis

N/A

Coding Guidelines

When billing for any of the covered services, the following guidelines apply to Type Of Bill 13x:

- Procedure code G0107 must be submitted with revenue code 30x. Payment will be made under the clinical diagnostic laboratory fee schedule.

G0104: Colorectal Cancer Screening (continued)

- Procedure code G0106 and G0120 must be submitted with revenue code 32x. Payment will be made under OPPS for hospital outpatient departments.
- Procedure code G0104 must be submitted with revenue code 750. Payment will be made under OPPS for hospital outpatient departments.
- Procedure code G0105 must be submitted with revenue code 750. Payment will be made under OPPS for hospital outpatient departments.
- Procedure code G0121 must be submitted with revenue code 750.

When these tests/procedures are provided to inpatients of a hospital, they are covered under this benefit. However, the provider must bill under TOB 13x using the discharge date of the hospital stay to avoid editing in the Common Working File (CWF) as a result of the hospital bundling rules.

When billing procedure code G0105 (Screening colonoscopy) or G0120 (Barium enema), submit the applicable ICD-9-CM diagnosis for high risk:

- For patients with a close relative who has had colorectal cancer or a family history of hereditary nonpolyposis colorectal cancer, utilize diagnosis V16.0;
- For patients with a family history of familial adenomatous polyposis, utilize diagnosis V18.5;
- For patients with a personal history of adenomatous polyps, utilize diagnosis V12.72;
- For patients with a personal history of colorectal cancer, utilize diagnosis V10.05 or V10.06;
- For patients with an inflammatory bowel disease utilize diagnosis 555.0-555.9, 556.0-556.9, or 558.1-558.9.

Any time the scheduled colorectal screening service turns into a diagnostic/therapeutic service, the applicable diagnostic/therapeutic procedure code should be billed.

Documentation Requirements

Medical record documentation maintained by the provider must indicate that the service provided was screening in nature. In addition, if procedure code G0105 (Screening colonoscopy) or G0120 (Barium enema) is billed, the documentation should support that the patient is at high risk. This information is usually found in the office/progress notes, history/physical, and/or procedure note.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

Fauci, A., Braunwald, E., Martin, J., Kasper, D., Isselbacher, K., Hauser, S., Wilson, J., & Longo, D. (Eds). (1998). *Harrison's principles of internal medicine* (14th ed.). New York: McGraw-Hill.

Advisory Committee Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from numerous specialties.

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

08/01/2001

Revision History

Revision Number:	2
Start Date of Comment Period	N/A
Start Date of Notice Period	08/01/2001 4 th Qtr Bulletin
Revised Effective Date:	07/01/2001
Explanation of Revision:	HCFA transmittal 1697 (Change Request 1536, dated 02/08/2001) revises Colorectal Cancer Screening by authorizing coverage for screening colonoscopies beginning July 1, 2001, for all individuals, including those not at high risk (code G0121) who had not received a screening colonoscopy (G0121) within the preceding ten years or a screening flexible sigmoidoscopy (G0104) with the preceding four years.

Revision Number:	1
Start Date of Comment Period	N/A
Start Date of Notice Period	08/01/1999 Aug/Sept 1999 Bulletin
Revised Effective Date:	09/23/1999

Revision Number:	Original
Start Date of Comment Period	02/23/1998
Start Date of Notice Period	05/29/1998
Original Effective Date:	07/13/1998 ❖

G0108: Diabetes Outpatient Self-Management Training

Revision Overview: This policy has been revised in its entirety to incorporate the expansion of coverage of diabetes outpatient self-management training based on section 4105 of the Balanced Budget Act of 1997.

Policy Number

G0108

Contractor Name

First Coast Service Options, Inc.

Contractor Number

090

Contractor Type

Intermediary

LMRP Title

Diabetes Outpatient Self-Management Training

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HCFA National Coverage Policy

Medicare Hospital Manual, Section 436
Medicare Intermediary Manual, Section 3619

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

HCFA Region

Region IV

HCFA Consortium

Southern

Original Policy Effective Date

03/15/2000

Original Policy Ending Date

N/A

Revision Effective Date

02/27/2001

Revision Ending Date

02/26/2001

LMRP Description

Diabetes mellitus is a chronic disorder of carbohydrate, fat and protein metabolism, characterized by hyperglycemia and glycosuria from inadequate production or utilization of insulin. The diagnosis of Diabetes mellitus is made based on the test results of a random plasma glucose greater than 200 mg/dl, fasting plasma (8-14 hours) greater than or equal to 126 mg/dl on two occasions, or a two hour plasma glucose greater than 200 mg/dl after a 75 gm glucose challenge.

Diabetes mellitus is classified according to two syndromes: Type 1 diabetes and Type 2 diabetes. Type 1 diabetes is characterized by beta cell destruction, usually leading to absolute insulin deficiency. It has two forms: Immune-Mediated Diabetes Mellitus and Idiopathic Diabetes Mellitus. Type 1 diabetes is usually immune-mediated. Type 2 diabetes is a term for individuals who have insulin resistance and usually have relative (rather than absolute) insulin deficiency.

Since diabetes is a chronic illness, the patient requires continual medical care and education in order to prevent acute complications and reduce the risk of long-term medical problems. A critical element for the successful treatment of all patients with diabetes is participation in a comprehensive self-management care and education program. Ongoing support, maintenance, and modifications in treatment regimes and lifestyle changes all require continued patient and caregiver participation.

A diabetes outpatient self-management training service is a program that educates beneficiaries in the successful self-management of diabetes. An outpatient diabetes self-management and training program includes education about self-monitoring of blood glucose, diet and exercise, an insulin treatment plan developed specifically for the patient who is insulin-dependent, and it motivates patients to use the skills for self-management.

Indications and Limitations of Coverage and/or Medical Necessity

Medicare coverage of diabetes outpatient self-management training was based on Section 80-2 of the Coverage Issues Manual prior to July 1, 1998. Effective for services performed on or after July 1, 1998 until February 26, 2001, coverage of diabetic training was based on the criteria identified in Program Memorandums AB99-46, AB99-30, AB98-36, and AB98-51. Effective for services performed on or after February 27, 2001 expanded coverage of diabetes outpatient self-management training is covered when the following criteria are met.

General Conditions of Coverage

- The training must be ordered by the physician or qualified nonphysician practitioner treating the beneficiary's diabetes. The order must be part of a comprehensive plan of care established by the physician or qualified nonphysician practitioner and describe the training that the referring physician or qualified non-physician practitioner is ordering and/or any special concerns such as the need for general training, or insulin-dependence.
- The plan of care must be maintained in the medical record of the ordering provider and document the need for training on an individual basis when group is typically covered.
- The order must include a statement signed by the physician that the service is needed.
- The provider of the service must maintain documentation in the file that includes the original order from the physician and any special conditions noted by the physician.
- Any change in the training order must be signed by the physician or qualified nonphysician practitioner treating the beneficiary and maintained in the performing provider's file.
- When a beneficiary has not received initial training meeting the quality standards of this section, they are eligible to receive 10 hours of initial training within a continuous 12-month period. Nine hours of initial training must be provided in a group setting consisting

G0108: Diabetes Outpatient Self-Management Training (continued)

of 2 to 20 individuals unless the ordering physician or nonphysician practitioner certified that a special condition exists that makes it impossible for the beneficiary to attend a group training session. Those conditions include but are not limited to: no group session is available within 2 months of the date the training is ordered; the beneficiary has special needs resulting from problems with hearing, vision, or language limitations or other special conditions identified by the treating physician or nonphysician practitioner; additional insulin instruction is needed.

- The one hour of initial training may be provided on an individual basis for the purpose of conducting an individual assessment and providing specialized training. The 10 hours of initial training may be provided in any combination of half-hour increments within the 12-month period and less than 10 hours of initial training may be used in the 12-month period.
- Two hours of follow-up training is covered each year starting with the calendar year following the year in which the beneficiary completes the initial training. The 2 hours of training may be given in any combination of half-hour increments within each calendar year on either an individual or group basis. The physician or qualified nonphysician practitioner treating the beneficiary must document in the referral for training the specific medical condition that the follow-up training must address.

Medical Eligibility for Coverage

Medicare covers initial training for beneficiaries who have the following medical conditions present prior to the physician's or nonphysician practitioner's order for the training.

- New onset diabetes.
- Inadequate glycemic control as evidenced by a glycosylated hemoglobin (HbA1c) level of 8.5% or more on two consecutive HbA1c determinations 3 or more months apart in the year before the beneficiary begins receiving training.
- A change in treatment regimen from diet control to oral diabetes medication, or from oral diabetes medication to insulin.
- High risk for complications based on inadequate glycemic control (documented acute episodes of severe hypoglycemia or acute severe hyperglycemia occurring in the past year during which the beneficiary needed emergency room visits or hospitalization).
- High risk based on at least one of the following: lack of feeling in the foot or other foot complications such as foot ulcers, deformities, or amputation; pre-proliferative or proliferative retinopathy or prior laser treatment of the eye; kidney complications related to diabetes, when manifested by albuminuria, without other cause, or elevated creatinine.

NOTE: Beneficiaries with diabetes, becoming newly eligible for Medicare, can receive diabetes outpatient self-management training in this program.

Quality Standards

The outpatient diabetes self-management training program must be accredited as meeting approved quality standards, except during the first 18-months after February

27, 2001. HCFA will accept recognition of the American Diabetes Association (ADA) as meeting the National Standards for Diabetes Self-Management Training Programs as published in Diabetes Care, volume 23, number 5. Programs without ADA recognition or accreditation by the HCFA-approved national accreditation organization are not covered after February 27, 2001.

CPT/HCPCS Section & Benefit Category

Medicine

Type of Bill Code

Hospital – 12x, 13x
End Stage Renal Disease – 72x

Revenue Codes

942 Education/Training

CPT/HCPCS Codes

- G0108 Diabetes outpatient self-management training services, individual, per 30 minutes
- G0109 Diabetes outpatient self-management training services, group session (2 or more), per 30 minutes

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

250.00-250.93 Diabetes mellitus

Diagnosis that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

Diagnosis that DO NOT Support Medical Necessity

N/A

Reasons for Denial

When performed for indications other than those listed in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy.

Reimbursement for Diabetic Outpatient Self-Management Training is not separately payable when rendered to a beneficiary in the following type of bills: inpatient in a hospital or skilled nursing facility, hospice care, resident in a nursing home, outpatient in a rural health clinic or federally qualified health center.

The beneficiary has previously received initial training for which Medicare payment was made under this benefit.

Noncovered ICD-9-CM Code(s)

Any diagnosis codes not listed in the "ICD-9-CM Codes That Support Medical Necessity" section of this policy.

Noncovered Diagnosis

N/A

Coding Guidelines

Prior to billing for diabetes outpatient self-management training services, all providers must submit to the Medicare

G0108: Diabetes Outpatient Self-Management Training (continued)

contractor an Education Recognition Program (ERP) certificate from the American Diabetes Association.

Services for diabetes outpatient self-management training must be billed with the appropriate HCPCS code, G0108 or G0109, in 30-minute increments only. The units field on the claim should be adjusted accordingly.

Documentation Requirements

In order for diabetic self-management training sessions to be covered by Medicare, documentation must be available to support that the educational program is certified by the American Diabetes Association as evidenced by the Education Recognition Program (ECP) certificate.

In addition to the above requirement, the following documentation must be maintained in the patient’s medical record:

- The treating physician or qualified nonphysician practitioner must order the diabetic training and describe the training needed for each beneficiary including any special concerns/conditions or rationale for providing individual training versus group training. This order, which includes a statement indicating that the service is needed, must be signed by the ordering or qualified nonphysician practitioner and included as part of a comprehensive plan of care. This plan of care must be maintained in the ordering provider’s medical record.
- The provider of the diabetic training must maintain in the beneficiary’s medical record the original order from the physician/nonphysician practitioner and any special conditions noted by the ordering provider. Any change in the training order must be signed by the physician or qualified nonphysician practitioner treating the beneficiary and maintained in the performing provider’s file.
- An individualized assessment including relevant medical history, cultural influences, health beliefs and attitudes, diabetes knowledge, self-management skills and behaviors, readiness to learn, cognitive ability, physical limitations, family support, and financial status.
- An individualized mutually agreed upon education plan established by the team (patient, physician, and health care team members) based on the individualized assessment, including but not limited to the problems to be addressed, the educational objectives, and educational modality(ies) used to meet the objectives.
- A periodic individualized reassessment between the beneficiary and instructor(s) that indicates the progress toward the goal(s).
- Attendance sheets documenting that the beneficiary was present during each training session must be part of the beneficiary’s file maintained by the provider of the service.
- The referral by the physician or qualified nonphysician practitioner for follow-up training must address the specific medical condition that the training must address. This must be maintained in the performing and ordering provider’s beneficiary medical record.

Utilization Guidelines

Initial training encompasses up to 10 hours of training within a continuous 12-month period. Nine of these hours

must be provided in a group setting unless a special condition exists as identified in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Follow-up training of up to 2 hours training is covered each year starting with the calendar year following the year in which the beneficiary completes the initial training.

Other Comments

Terms defined:

Glycosuria—the presence of glucose in the urine. Traces of sugar, particularly glucose, may occur in normal urine but are not detected by ordinary qualitative methods. In routine urinalyses the presence of a reducing sugar is suspicious of diabetes mellitus.

Hyperglycemia—increase in blood sugar.

Sources of Information and Basis for Decision

Diabetes Medical Practice Guidelines. (1998). *The Journal of the Florida Medical Association*, 85 (2), 39-62.
 National standards for diabetes self-management education. (2000). *Diabetes Care*, 23 (5), 682-689.
 Thomas, C. L. (Ed.). (1993). *Taber’s Cyclopedic Medical Dictionary* (17th ed.). Philadelphia: F. A. Davis.

Advisory Committee Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from numerous societies.

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

08/01/2001

Revision History

Revision Number	2
Start Date of Comment Period	N/A
Start Date of Notice Period	08/01/2001
	4 th Qtr 2001 <i>Bulletin</i>
Revised Effective Date	02/27/2001
Explanation of Revision:	Change request 1455, dated 06/15/2001 expanded coverage of diabetes outpatient self-management trained based on Section 4105 of the Balanced Budget Act of 1997. The effective date was 02/27/2001, however, the change request indicated a 07/17/2001 implementation date.

Revision Number	1
Start Date of Comment Period	N/A
Start Date of Notice Period	02/01/2001
	2 nd Qtr 2001 <i>Bulletin</i>
Revised Effective Date	01/01/2001
Explanation of Revision:	Annual 2001 HCPCS Update

Revision Number	Original
Start Date of Comment Period:	08/99
Start Date of Notice Period:	02/01/2000
	Feb/Mar 2000 <i>Bulletin</i>
Original Effective Date	03/15/2000 ❖

J1561: Intravenous Immune Globulin

Revision Overview: This policy has been revised to provide clarification regarding diagnostic criteria as well as a revised list of approved indications for intravenous immune globulin and a revised list of covered ICD-9-CM diagnosis codes.

Policy Number

AJ1561

Contractor Name

First Coast Service Options, Inc.

Contractor Number

090

Contractor Type

Intermediary

LMRP Title

Intravenous Immune Globulin

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HCFA National Coverage Policy

Medicare Intermediary Manual, Sections 3101.3 and 3112.4

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

HCFA Region

Region IV

HCFA Consortium

Southern

Original Policy Effective Date

01/19/1995

Original Policy Ending Date

N/A

Revision Effective Date

09/21/2001

Revision Ending Date

09/20/2001

LMRP Description

Intravenous Immune Globulin (IVIG) is a solution of human immunoglobulins specifically prepared for intravenous infusion. Immunoglobulin contains a broad range of antibodies that specifically act against bacterial and viral antigens.

Indications and Limitations of Coverage and/or Medical Necessity

The use of intravenous immune globulin should be reserved for patients with serious defects of antibody function. The goal is to provide immunoglobulin G (IgG) antibodies to those who lack them. Florida Medicare will provide coverage for intravenous immune globulin when it is used in treatment of the following conditions:

1. Immunodeficiency Disorders

- a) Primary Humoral Immunodeficiency Syndromes

IVIG is indicated for the treatment of patients with primary immunodeficiency syndromes such as common variable immunodeficiency (CVID), congenital agammaglobulinemia (X-linked agammaglobulinemia), severe combined immunodeficiency (SCID), X-linked immunodeficiency with hyperimmunoglobulin M (IgM), and Wiskott-Aldrich syndrome to replace or boost immunoglobulin G (IgG).

- Common variable immunodeficiency (CVID) (also known as acquired hypogammaglobulinemia, adult-onset hypogammaglobulinemia, and dysgammaglobulinemia) is characterized by reduced serum immunoglobulins, impaired antibody responses, and heterogenous clinical features. It is a rare syndrome, affecting one in 50,000 to one in 200,000 people. In most patients, the onset is in the second or third decade of life. The most common clinical presentation of CVID is an increased susceptibility to infection. Most patients experience severe recurrent and/or chronic sinopulmonary infections such as bronchitis, pneumonia, or bronchiectasis. Patients with CVID can also develop a variety of autoimmune and inflammatory disorders and are also at risk for inflammatory bowel disease.

Once the diagnosis of CVID is suspected based on clinical presentation, laboratory confirmation should be made. A low serum IgG level is the most consistent laboratory abnormality in CVID, with most patients having concurrent deficiencies of IgA and IgM. However, there are rare instances when a patient will have normal IgG levels. Therefore, the serum immunoglobulin measurement alone does not establish a diagnosis of CVID. A definitive diagnosis of CVID is established when a patient does not demonstrate an antibody response to immunization with protein antigens (e.g., tetanus) or carbohydrate antigens (e.g., pneumococcal capsular polysaccharides such as pneumovax).

Therefore, Florida Medicare requires the following diagnostic evidence to support a diagnosis of CVID:

- Laboratory reports demonstrating a normal to low IgG level for the assay utilized;
- Radiological or Computerized Tomography (CT) reports demonstrating severe recurrent and/or chronic sinopulmonary infections such as bronchitis, pneumonia, bronchiectasis or sinusitis; and
- Laboratory reports demonstrating a lack of ability to produce an antibody response to protein or carbohydrate antigens (e.g., tetanus, pneumococcal capsular polysaccharides such as pneumovax).

Florida Medicare will not provide reimbursement for the initiation or continuation of intravenous immune globulin therapy based solely on a low IgG value, or for patients with mild sinopulmonary disease, or for those that do not demonstrate a lack of ability to produce an antibody to protein or carbohydrate antigens. IVIG

J1561: Intravenous Immune Globulin (continued)

therapy for patients with normal humoral immunity but recurrent infections, particularly upper respiratory infections, has no scientific rationale.

The dosing regimen for patients with CVID is not standardized, but is based primarily on the clinical response. Trough levels of IgG and functional antibody levels should also be taken into consideration in the management of the IVIG therapy. A patient will generally receive initial IVIG doses of 200-400 mg/kg/3 to 4 weeks. IVIG replacement in these patients is usually life-long.

- Congenital agammaglobulinemia (X-linked agammaglobulinemia) is an inherited deficiency that appears in the first 3 years of life and occurs in one out of 10,000 people. Quantitative immunoglobulins show marked deficits or absence of all five immunoglobulin classes. Peripheral blood B-lymphocytes are usually absent.
- Severe combined immunodeficiency (SCID) is a rare and fatal inherited syndrome that has an incidence of approximately one in 1,000,000 people. The typical case involves an infant less than one year of age. The lymphocyte counts are significantly below normal, the levels of B- and T-lymphocytes are absent or below normal, the lymphocyte response to mitogen is absent or below normal, and the quantitative measurements of IgG, IgA, and IgM show marked deficits.
- X-linked immunodeficiency with hyperimmunoglobulin M (IgM) is similar to X-linked agammaglobulinemia, however, these patients sometimes have lymphoid hyperplasia. The concentrations of serum IgG, IgA, and IgE are very low, whereas the serum IgM concentration is either normal or, more frequently, greatly elevated and polyclonal.
- Wiskott-Aldrich syndrome is an X-linked recessive syndrome characterized by eczema, thrombocytopenia purpura with normal-appearing megakaryocytes but small defective platelets, and undue susceptibility to infection. Patients usually present during infancy. Survival beyond the teens is rare.

b) Idiopathic Thrombocytopenic Purpura (ITP)

Idiopathic thrombocytopenic purpura (ITP) is a decrease in the circulating number of platelets in absence of toxic exposure or other disease associated with a low platelet count. It occurs as an effect of peripheral platelet destruction. Acute ITP is a disease of childhood, which usually follows an acute infection and has spontaneous resolution within 2 months. Chronic ITP is a disease which persists after 6 months without a specific cause. It is usually seen in adults and persists for months to years.

Patients with platelet counts >50,000 should not be given IVIG. IVIG is also inappropriate for patients with platelet counts >30,000 who are asymptomatic or have only minor purpura.

IVIG is indicated for ITP under the following circumstances:

- When administered preoperatively for patients undergoing elective splenectomy, who have platelet counts <20,000.

- For patients with platelet counts <30,000 who have active bleeding.
- For pregnant women with platelet counts <10,000 in the third trimester.
- For pregnant women with platelet counts 10,000-30,000 who are bleeding.

The duration of treatment is generally a short course of 3 to 5 days.

c) Pediatric Human Immunodeficiency Virus (HIV) Infection

IVIG is indicated for use in HIV-infected children (less than 13 years of age) with a CD-4 lymphocyte count of greater than or equal to 200/mm³ to reduce the risk of serious bacterial infections. Laboratory reports must demonstrate an IgG level that is below the normal age-related ranges for the assay utilized. There must also be evidence of a lack of ability to produce an antibody response to immunization with protein antigens (e.g., tetanus) or carbohydrate antigens (e.g., pneumococcal capsular polysaccharides such as pneumovax). IVIG is *not* indicated for use in adult HIV patients (13 years of age and older).

2. Neurological Disorders

IVIG is indicated for the treatment of patients with neurological disorders such as Guillain-Barre' syndrome, relapsing-remitting multiple sclerosis, chronic inflammatory demyelinating polyneuropathy, myasthenia gravis, refractory polymyositis and refractory dermatomyositis. However, it is noted that not all patients with these diagnoses require treatment with IVIG.

For each of these diseases, the diagnosis of the disorder must be unequivocal. There must be clinical (history, quantitative examination), electrophysiological motor-sensory nerve conductions, electromyography (EMG), cerebrospinal fluid (CSF), and when necessary biopsy (muscle-nerve) data to support the diagnosis.

IVIG therapy will only be considered medically reasonable and necessary for the following neurological diseases when there is evidence of rapid progression of the disease or relapse.

Once treatment is initiated, we expect meticulous documentation of progress. If there is initial improvement, and continued treatment is necessary, then some type of quantitative assessment to monitor the progress is required (e.g., ADL measurements). Changes in these measures must be clearly documented. *Subjective or experiential improvement alone is insufficient to either continue IVIG or to expect coverage.*

There must be an attempt made to wean the dosage when improvement has occurred. There must be an attempt to stop the IVIG infusion if improvement is sustained with dosage reduction. If improvement does not occur with IVIG, then infusion should not continue.

- Guillain-Barre' syndrome is an acute, frequently severe, and fulminant polyneuropathy that occurs at a rate of approximately one case in a million per month. An infection generally precedes the onset of neuropathy by 1 to 3 weeks. A small proportion occurs within 1 to 4 weeks of a surgical procedure. The clinical features

J1561: Intravenous Immune Globulin (continued)

include ascending paralysis, areflexia (absence of reflexes), possibly ascending sensory loss, and high spinal fluid protein levels. Intravenous administration of high-dose immunoglobulin given over 5 days has been proven effective.

- Multiple Sclerosis that is relapsing-remitting is characterized by unpredictable recurrent attacks of neurological dysfunction. Attacks generally evolve over days to weeks and may be followed by complete, partial, or no recovery. Patients with a relapsing-remitting course experience no progression of neurological impairment between attacks. The age of onset is generally between 15 and 60 years.
- Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) includes a group of chronic progressive or relapsing, inflammatory demyelinating peripheral neuropathies that are manifested by physiological abnormalities such as slowed nerve conduction velocities or dispersion of compound muscle action potentials. Clinical features include chronic progressive or relapsing weakness with sensory loss and high spinal fluid protein levels.
- Myasthenia gravis is a disorder of neuromuscular transmission characterized by fluctuating weakness and fatigability. It is attributed to blockage of the acetylcholine receptor at the neuromuscular end-plates by anti-acetylcholine receptor autoantibodies. The diagnosis of myasthenia gravis is confirmed by a positive Tensilon test. Anticholinesterase drugs or thymectomy are generally the first treatments for this condition. IVIG is indicated in those patients with myasthenia gravis who are either **refractory** to corticosteroids over a 6 week period; have been unable to successfully taper corticosteroids below moderately high doses; or develop **severe** side effects due to steroid therapy; **and** have also failed at least one immunosuppressive agent (e.g., azathioprine, Methotrexate, cyclophosphamide, cyclosporine). Length of treatment with IVIG will vary due to the remittent and recurrent nature of this condition.
- Polymyositis and dermatomyositis are conditions in which the skeletal muscle is damaged by a nonsuppurative inflammatory process dominated by lymphocytic infiltration. Polymyositis begins acutely or insidiously with muscle weakness, tenderness, and discomfort. It affects proximal muscles more often than distal muscles. Dermatomyositis involves characteristic skin changes that may precede or follow the muscle syndrome and include a localized or diffuse erythema, maculopapular eruption, scaling eczematoid dermatitis, or rarely, an exfoliative dermatitis. The classic lilac-colored (heliotrope) rash is on the eyelids, bridge of the nose, cheeks (butterfly distribution), forehead, chest, elbows, knees and knuckles, and around the nailbeds. Periorbital edema is frequent. Diagnostic studies to support a diagnosis of polymyositis or dermatomyositis include an elevated creatine phosphokinase (CPK), an abnormal electromyography (EMG), and/or an abnormal muscle biopsy.

IVIG is indicated in those patients with polymyositis or dermatomyositis who are either refractory to corticosteroids over a 6 week period; have been unable to successfully taper corticosteroids below moderately high doses; or develop *severe* side effects due to steroid therapy; and have also failed at least one immunosuppressive agent (e.g., azathioprine, Methotrexate, cyclophosphamide, cyclosporine). Length of treatment with IVIG will vary due to the remittent and recurrent nature of these conditions. The need for continuation of IVIG must be documented and would be demonstrated by continued decreased muscle strength, elevated CPKs, and/or EMG abnormalities.

3. Other Disorders

a) Chronic Lymphocytic Leukemia

Chronic lymphocytic leukemia is a disorder of accumulation of mature-appearing lymphocytes in blood marrow and other organs. The symptoms usually develop gradually and include fatigue, shortness of breath with activity, weight loss, or frequent infections of the skin, lungs, kidneys, or other sites. Recurrent infections are a frequent complication.

IVIG is indicated for the prevention of recurrent bacterial infections in patients with hypogammaglobulinemia associated with B-cell chronic lymphocytic leukemia (CLL) in order to help correct the patient's immunity deficiency.

b) Bone Marrow Transplantation (BMT)

IVIG is indicated to prevent the risk of acute graft-versus-host disease, associated interstitial pneumonia (infectious or idiopathic) and infections (e.g., cytomegalovirus infections [CMV], varicella-zoster virus infection, and recurrent bacterial infection) after BMT in patients 20 years of age or older in the first 100 days after transplantation. It is not indicated in BMT patients younger than 20 years of age, nor is it recommended for autologous transplants.

c) Kawasaki Disease (mucocutaneous Lymph Node Syndrome)

Kawasaki disease is an acute childhood vasculitis, the diagnosis of which is made based on clinical criteria. These criteria include fever of at least 5 days duration and at least 4 of the following: (1) polymorphic exanthem, (2) changes in the oropharynx such as fissured lips and strawberry tongue without discrete lesions, (3) changes in the extremities such as edema of the hands and feet and erythema of the palms and soles, (4) bilateral conjunctival infection without exudate, and (5) cervical lymphadenopathy, often singular and unilateral. IVIG is indicated for the treatment of Kawasaki disease when used in conjunction with aspirin.

d) Autoimmune Hemolytic Anemia

Autoimmune hemolytic anemia is an acquired anemia induced by binding of autoantibodies and/or complement to the red cells. Signs and symptoms may include, but are not limited to, weakness, fatigue, exertional dyspnea, pallor, jaundice, tachycardia, splenomegaly, hepatomegaly, and anemia. In the majority of patients, this disease is controlled by steroid therapy alone, by splenectomy, or by a combination.

J1561: Intravenous Immune Globulin (continued)

Intravenous immune globulin is indicated only for those patients who have failed to respond to other forms of therapy and/or require rapid cessation of hemolysis due to severe or life threatening manifestations of this condition. Duration of treatment is generally a short course of 3-5 weeks.

e) Autoimmune Neutropenia

Autoimmune neutropenia is a hematologic disorder in which there is a decreased number of neutrophilic leukocytes in the blood due to an autoimmune mechanism. The disease is usually benign and self-limiting, and does not require treatment with IVIG. Occasionally, however, it is marked by repeated infection. IVIG may be recommended for the treatment of an absolute neutrophil count less than 800/mm³; with recurrent bacterial infections.

CPT/HCPCS Section & Benefit Category

Drugs and Biologicals

Type of Bill Code

- Hospital – 12x, 13x
- Skilled Nursing Facility – 21x, 22x, 23x
- Rural Health Clinic – 71x
- End Stage Renal Disease – 72x
- Comprehensive Outpatient Rehabilitation Facility – 75x

Revenue Codes

636 Drugs Requiring Detailed Coding

CPT/HCPCS Codes

- J1561 Injection, immune globulin, intravenous, 500 mg
- J1563 Injection, immune globulin, intravenous, 1g

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

- 042 Human immunodeficiency virus (HIV) disease (in children)
- 204.10-204.11 Chronic lymphoid leukemia (with associated hypogammaglobulinemia)
- 279.04 Congenital hypogammaglobulinemia (X-linked agammaglobulinemia)
- 279.05 Immunodeficiency with increased IgM (X-linked with hyper IgM)
- 279.06 Common variable immunodeficiency (CVID)
- 279.12 Wiskott-Aldrich syndrome
- 279.2 Combined immunity deficiency (SCID)
- 283.0 Autoimmune hemolytic anemias
- 287.3 Primary thrombocytopenia (Idiopathic Thrombocytopenic Purpura (ITP))
- 288.0 Agranulocytosis (Autoimmune neutropenia)
- 340 Multiple sclerosis (relapsing-remitting)
- 357.0 Acute infective polyneuritis (Guillain-Barre' syndrome)
- 357.8 Inflammatory and toxic neuropathy, other (Chronic inflammatory demyelinating polyneuritis [CIDP])
- 358.0 Myasthenia gravis
- 446.1 Acute febrile mucocutaneous lymph node syndrome (MCLS, Kawasaki disease)

- 710.3 Dermatomyositis (refractory)
- 710.4 Polymyositis (refractory)
- 996.85 Complications of transplanted organ, bone marrow

Diagnosis that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

Diagnosis that DO NOT Support Medical Necessity

N/A

Reasons for Denial

When performed for indications other than those listed in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy.

Noncovered ICD-9-CM Code(s)

Any diagnosis codes not listed in the "ICD-9-CM Codes That Support Medical Necessity" section of this policy.

Noncovered Diagnosis

N/A

Coding Guidelines

All hospital, skilled nursing facility, rural health clinic and ESRD facility providers of service must bill Intravenous Immune Globulin under Revenue Code 636 - Drugs requiring detailed coding. In addition, HCPC J1561 or J1563 must be included to identify which product was administered. ESRD facility providers must bill procedure code X0051 for gamimune N 5% - 500 mg. Comprehensive outpatient rehabilitation facility (CORF) providers may bill this service if it is directly related to the skilled rehabilitation services required by the beneficiary.

IV immune globulin may be billed by an ESRD facility only if it is actually administered in the facility by the facility staff. Staff time used is covered under the composite rate and may not be billed separately. However, the supplies used to administer this drug may be billed in addition to the composite rate.

Documentation Requirements

Medical record documentation maintained by the treating physician/facility must clearly document the medical necessity to initiate intravenous immune globulin therapy and the continued need thereof. Required documentation of medical necessity should include:

- history and physical;
- office/progress note(s);
- applicable test results with written interpretation;
- an accurate weight in kilograms should be documented prior to the infusion since the dosage is based mg/kg/dosage; and
- prior treatment therapies (where appropriate or referenced by this policy).

In addition, medical record documentation maintained by the treating physician/facility for claims billed with a diagnosis of CVID must include the following: the initial presenting IgG levels, sinus or chest radiological or

J1561: Intravenous Immune Globulin (continued)

computerized tomography reports to support the presence of severe sinus infections, frequent bronchitis, pneumonia, or bronchiectasis, and evidence that the patient has been vaccinated with pneumovax and has had pre-and post-vaccine pneumococcal antibody titers performed to demonstrate the lack of ability to produce an antibody response to protein or carbohydrate antigens.

Documentation should support the criteria for coverage as set forth in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

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J1561: Intravenous Immune Globulin (continued)

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Advisory Committee Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from numerous societies.

Start Date of Comment Period

06/01/2000

End Date of Comment Period

07/16/2000

Start Date of Notice Period

08/01/2001

Revision History

Revision Number	7
Start Date of Comment Period	06/01/2000
Start Date of Notice Period	08/01/2001
Revised Effective Date	4th Qtr 2001 <i>Bulletin</i>
Explanation of Revision:	09/21/2001
	Policy revised to provide clarification regarding diagnostic criteria for conditions, as well as to revise the list of approved indications for IVIG.

Revision Number	6
Start Date of Comment Period	N/A
Start Date of Notice Period	05/01/2001
	3 rd Qtr 2001 <i>Bulletin</i>
Revised Effective Date	02/20/2001
Explanation of Revision:	Explanation of Revision:
	Addition of ICD-9-CM code 340 (Multiple sclerosis) to the policy as a covered indication.
Revision Number	5
Start Date of Comment Period	N/A
Start Date of Notice Period	12/22/2000
	Special 2000 <i>Bulletin</i>
Revised Effective Date	01/01/2001
Explanation of Revision:	Annual 2001 HCPCS Update
Revision Number	4
Start Date of Comment Period	N/A
Start Date of Notice Period	04/2000
	Apr/May 2000 <i>Bulletin</i>
Revised Effective Date	05/2000
Explanation of Revision:	To remove requirement regarding IgG trough levels and revise language in policy to reflect current policy terminology.
Revision Number	3
Start Date of Comment Period	N/A
Start Date of Notice Period	10/01/1999
	Oct/Nov 1999 <i>Bulletin</i>
Revised Effective Date	08/12/1999
Explanation of Revision:	To add a covered ICD-9-CM code for covered indication chronic inflammatory demyelinating polyneuropathy when other therapy has failed or is contraindicated and for a potentially severe or life threatening manifestation.
Revision Number	2a
Start Date of Comment Period	N/A
Start Date of Notice Period	N/A
Explanation of Revision:	(Informational only)
Revision Number	2
Start Date of Comment Period	N/A
Start Date of Notice Period	01/23/1998
Revised Effective Date	01/01/1998
Explanation of Revision:	1998 HCPCS Update
Revision Number	1
Start Date of Comment Period	None needed
Start Date of Notice Period	N/A
Revision Date/Number	07/02/1997
Explanation of Revision:	Original effective date is based on Artificial Intelligence (AI) application implementation date. Revised to ensure ICD-9-CM list consistency between the Carrier and Intermediary.
Original Effective Date	01/19/95 (AI) ❖

J1745: Infliximab (Remicade™)

Revision Overview: “The Indications and Limitations of Coverage” and “Documentation Requirements” sections of this policy were revised to reflect coverage for beneficiaries who are unable to tolerate methotrexate.

Policy Number

J1745

Contractor Name

First Coast Service Options, Inc.

Contractor Number

090

Contractor Type

Intermediary

LMRP Title

Infliximab (Remicade™)

AMA CPT Copyright Statement

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HCFA National Coverage Policy

Medicare Hospital Manual, Section 442.7
Medicare Intermediary Manual, Sections 3112.4 & 3101.3

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

HCFA Region

Region IV

HCFA Consortium

Southern

Original Policy Effective Date

09/15/2000

Original Policy Ending Date

N/A

Revision Effective Date

06/14/2001

Revision Ending Date

06/13/2001

LMRP Description

Infliximab (Remicade™) is a chimeric monoclonal antibody that binds specifically to tumor necrosis factor alpha (TNFα) and blocks its activity. Overproduction of tumor necrosis factor alpha, which is a key inflammatory mediator, leads to inflammation in conditions such as Crohn’s disease, rheumatoid arthritis and other autoimmune diseases.

Indications and Limitations of Coverage and/or Medical Necessity

Florida Medicare will consider the use of Infliximab to be medically reasonable and necessary in the following circumstances:

- To reduce the symptoms of moderately to severely active Crohn’s disease for patients who have had an

inadequate response to conventional therapy (e.g., corticosteroids, aminosaliclates, and immunosuppressive agents). Normally, the patient receives a one-time infusion for this indication with repeat infusions for episodic exacerbations. Subsequent treatments will be covered if the patient responds to the initial treatment as demonstrated by a reduction in signs and symptoms.

- To reduce the number of draining enterocutaneous fistulas for patients with fistulizing Crohn’s disease. Normally, the patient receives an infusion for this indication at weeks 0, 2, & 6. Subsequent treatments will be covered if the patient responds to the initial treatment as demonstrated by a reduction in signs and symptoms.
- When used in combination with methotrexate, to reduce the signs and symptoms and inhibit the progression of structural damage in patients with moderately to severely active rheumatoid arthritis who have had an inadequate response to methotrexate. An adequate trial of methotrexate should last a minimum of three (3) months. Normally, the patient receives an infusion of Infliximab for this indication at weeks 0, 2, & 6 and then approximately every eight (8) weeks.

NOTE: For patients, who are unable to tolerate methotrexate or in the rare instance that methotrexate is contraindicated for a patient, treatment with Infliximab alone will be covered only if documentation is maintained in the patient’s record that clearly indicates the reason that the patient cannot take methotrexate.

CPT/HCPCS Section & Benefit Category

Drugs and Biologicals

Type of Bill Code

Hospital – 13x
Skilled Nursing Facility – 21x, 23x
Rural Health Clinic – 71x

Revenue Code

636 Drugs Requiring Detailed Coding

CPT/HCPCS Codes

J1745 Injection, infliximab, 10mg

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

555.0	Regional enteritis of small intestine
555.1	Regional enteritis of large intestine
555.2	Regional enteritis of small intestine with large intestine
555.9	Regional enteritis of unspecified site
565.1	Anal fistula
569.81	Fistula of intestine, excluding rectum and anus
714.0	Rheumatoid arthritis

J1745: Infliximab (Remicade™) (continued)

Diagnosis that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

Diagnosis that DO NOT Support Medical Necessity

N/A

Reasons for Denial

The use of Infliximab for any clinical indication other than those listed in the “Indications and Limitations of Coverage and/or Medical Necessity” section of this policy.

Noncovered ICD-9-CM Code(s)

Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnosis

N/A

Coding Guidelines

N/A

Documentation Requirements

Medical record documentation that is maintained by the performing physician must substantiate the medical necessity for the use of Infliximab by clearly indicating the relevant clinical signs and symptoms related to the medical condition for which this drug is indicated. The documentation must also include all prior treatment regimes and the patient’s response to that therapy.

For Crohn’s disease, episodic retreatment will be covered if the medical record substantiates that the patient had a reduction in the clinical signs and symptoms of the disease after the initial treatment.

For rheumatoid arthritis, the medical record must clearly indicate:

- the patient is receiving Infliximab in combination with Methotrexate; or
- the patient is intolerant of methotrexate; or
- the patient has a medical condition that contraindicates the use of methotrexate.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

Elliott, M., Maini, R., Feldmann, M., Kalden, J., Antoni, C., Smolen, J., Leeb, B., Breedveld, F., Macfarlane, J., Bijl, H., Woody, J. (1994). Randomized double-blind comparison of chimeric monoclonal antibody to tumour necrosis factor α (cA2) versus placebo in rheumatoid arthritis. *The Lancet*, 344, 1105-1110.

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Remicade™ package insert, 1999 & 2000.

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United States Pharmacopeia Drug Information, Volume 1, Drug Information Monograph 1999.

Advisory Committee Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from numerous societies.

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

08/01/2001

Revision History

Revision Number:	1
Start Date of Comment Period	N/A
Start Date of Notice Period	08/01/2001
	4 th Qtr 2001 <i>Bulletin</i>
Revised Effective Date:	06/14/2001
Explanation of Revision:	Statements regarding Infliximab being allowed as monotherapy were added to the Indications and Limitations and Documentation Requirements Sections of the policy. Statement in the Coding Guidelines section has been removed.

Revision Number:	Original
Start Date of Comment Period	02/21/2000
Start Date of Notice Period	08/01/2000
	Aug/Sept 2000 <i>Bulletin</i>
Original Effective Date:	09/15/2000 ❖

J9212: Interferon

Policy Number

J9212

Contractor Name

First Coast Service Options, Inc.

Contractor Number

090

Contractor Type

Intermediary

LMRP Title

Interferon

AMA CPT Copyright Statement

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HCFA National Coverage Policy

Medicare Intermediary Manual, Sections 3101.3 and 3112.4

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

HCFA Region

Region IV

HCFA Consortium

Southern

Original Policy Effective Date

09/21/2001

Original Policy Ending Date

N/A

Revision Effective Date

N/A

Revision Ending Date

N/A

LMRP Description

Interferons are naturally occurring small proteins with both antiviral and antiproliferative properties. Interferons exert their cellular effects by binding to specific membrane receptors on the cell surface and subsequently initiate a complex sequence of intracellular events.

Interferon alfacon-1 is a recombinant non-naturally occurring type-1 interferon. Interferon alfa-2A and alfa-2B are sterile protein products produced by recombinant DNA techniques. The exact mechanism of action is unknown, but appears to involve direct antiproliferative action against tumor cells or viral cells to inhibit replication, modulation of the host immune response by enhancing the phagocytic activity of macrophages, and augmentation of specific cytotoxicity of lymphocytes for target cells.

Alfa-N3 is a naturally occurring antiviral agent derived from human leukocytes. It attaches to membrane receptors and causes cellular changes, including increased protein synthesis. Gamma-1B, a biological response modifier, is a single-chain polypeptide containing 140 amino acids.

Indications and Limitations of Coverage and/or Medical Necessity

Interferon Alfacon-1 (J9212)

Florida Medicare will consider the administration of **Interferon Alfacon-1** medically reasonable and necessary for the following indications: chronic hepatitis C and hairy cell leukemia.

Interferon alfa-2A (J9213) or Interferon alfa-2B (J9214)

Florida Medicare will consider the administration of **Interferon alfa-2A or Interferon alfa-2B** medically reasonable and necessary for the following indications: acute or chronic hepatitis C, chronic hepatitis B, condylomata acuminata, hairy cell leukemia, malignant melanoma, AIDS-related Kaposi's sarcoma, head and neck cancer, bladder cancer, brain cancer, carcinoid syndrome, chronic lymphocytic leukemia, chronic myelocytic leukemia, cutaneous T-cell lymphoma, esophageal cancer, renal cancer, multiple myeloma, non-Hodgkin's lymphoma, mycosis fungoides, essential thrombocytosis, osteosarcoma, ovarian cancer, pancreatic cancer, skin cancer, colorectal cancer, polycythemia vera, and laryngeal papillomatosis.

Interferon alfa-N3 (J9215)

Florida Medicare will consider the administration of **Interferon alfa-N3** medically reasonable and necessary for the following indications: chronic hepatitis C, condylomata acuminata, hairy cell leukemia, malignant melanoma, AIDS-related Kaposi's sarcoma, bladder cancer, carcinoid syndrome, chronic myelocytic leukemia, renal cancer, multiple myeloma, non-Hodgkin's lymphoma, mycosis fungoides, essential thrombocytosis, ovarian cancer, and laryngeal papillomatosis.

Interferon gamma-1B (J9216)

Florida Medicare will consider the administration of **Interferon gamma-1B** medically reasonable and necessary for the following indication: chronic granulomatous disease.

***Please note the following limitations regarding Interferons:**

The self-administration of Interferons alfacon-1, alfa-2A, alfa-2B, alfa-N3, and gamma-1B are noncovered by Medicare.

The following Interferons are considered self-administered and noncovered by Florida Medicare: J1825 (beta-1a) and J1830 (beta-1b). Please refer to Local Medical Review Policy AJ0001 (Self-Administered Drugs).

The Interferon alfa-2B recombinant and ribavirin combination (Rebetron) is considered noncovered by Florida Medicare and should be billed as a noncovered charge.

CPT/HCPCS Section & Benefit Category

Drugs Administered Other Than Oral Method

Type of Bill Code

- Hospital – 13x
- Skilled Nursing Facility – 21x, 23x
- Rural Health Clinic – 71x
- End Stage Renal Disease – 72x
- Comprehensive Outpatient Rehabilitation Facility – 75x

J9212: Interferon (continued)

Revenue Codes

636 Drugs Requiring Detailed Coding

CPT/HCPCS Codes

- J9212 Injection, interferon Alfacon-1, recombinant, 1 mcg
- J9213 Interferon alfa-2A, recombinant, 3 million units
- J9214 Interferon alfa-2B, recombinant, 1 million units
- J9215 Interferon alfa-N3, (human leukocyte derived), 250,000 IU
- J9216 Interferon gamma-1B, 3 million units

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

For J9212 (Interferon alfacon-1):

- 070.54 Chronic hepatitis C without mention of hepatic coma
- 48.48-48.48 Leukemic reticuloendotheliosis

For J9213 (Interferon alfa-2A) or J9214 (Interferon alfa-2B):

- 070.41 Acute or unspecified hepatitis C with hepatic coma
- 070.44 Chronic hepatitis C with hepatic coma
- 070.51 Acute or unspecified hepatitis C without mention of hepatic coma
- 070.54 Chronic hepatitis C without mention of hepatic coma
- 070.59 Other specified viral hepatitis without mention of hepatic coma
- 078.11 Condyloma acuminatum
- 140.0-149.9 Malignant neoplasm of lip, oral cavity, and pharynx
- 150.0-150.9 Malignant neoplasm of esophagus
- 153.0-153.9 Malignant neoplasm of colon
- 154.0-154.8 Malignant neoplasm of rectum, rectosigmoid junction, and anus
- 157.4 Malignant neoplasm of islets of Langerhans
- 161.0-161.9 Malignant neoplasm of larynx
- 170.0-170.9 Malignant neoplasm of bone and articular cartilage
- 172.0-172.9 Malignant melanoma of skin
- 173.0-173.9 Other malignant neoplasm of skin
- 176.0-176.9 Kaposi's sarcoma
- 183.0-183.9 Malignant neoplasm of ovary and other uterine adnexa
- 188.0-188.9 Malignant neoplasm of bladder
- 189.0 Malignant neoplasm of kidney, except pelvis
- 189.1 Malignant neoplasm of renal pelvis
- 191.0-191.9 Malignant neoplasm of brain
- 200.00-200.88 Lymphosarcoma and reticulosarcoma
- 202.00-202.98 Other malignant neoplasms of lymphoid and histiocytic tissue
- 203.00-203.81 Multiple myeloma and immunoproliferative neoplasms
- 204.10 Chronic lymphoid leukemia without mention of remission

- 205.10 Chronic myeloid leukemia without mention of remission
- 238.4 Neoplasm of uncertain behavior of other and unspecified sites and tissues, polycythemia vera
- 259.2 Carcinoid syndrome
- 9.9 Unspecified diseases of blood and blood-forming organs (essential thrombocytosis)

For J9215 (Interferon alfa-N3):

- 070.54 Chronic hepatitis C without mention of hepatic coma
- 078.11 Condyloma acuminatum
- 161.0-161.9 Malignant neoplasm of larynx
- 172.0-172.9 Malignant melanoma of skin
- 176.0-176.9 Kaposi's sarcoma
- 183.0-183.9 Malignant neoplasm of ovary and other uterine adnexa
- 188.0-188.9 Malignant neoplasm of bladder
- 189.0 Malignant neoplasm of kidney, except pelvis
- 189.1 Malignant neoplasm of renal pelvis
- 200.00-200.88 Lymphosarcoma and reticulosarcoma
- 202.00-202.98 Other malignant neoplasms of lymphoid and histiocytic tissue
- 203.00-203.81 Multiple myeloma and immunoproliferative neoplasms
- 205.10 Chronic myeloid leukemia without mention of remission
- 259.2 Carcinoid syndrome
- 289.9 Unspecified diseases of blood and blood-forming organs (essential thrombocytosis)

For J9216 (Interferon gamma-1B):

- 205.10 Chronic myeloid leukemia without mention of remission

Diagnosis that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

Diagnosis that DO NOT Support Medical Necessity

N/A

Reasons for Denial

When performed for indications other than those listed in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy.

The self-administration of Interferons alfacon-1, alfa-2A, alfa-2B, alfa-N3, and gamma-1B.

The following Interferons are considered self-administered and noncovered by Florida Medicare: J1825 (beta-1a) and J1830 (beta-1b). Please refer to local medical review policy AJ0001 (Self-Administered Drugs).

The Interferon alfa-2B recombinant and ribavirin combination (Rebetron) is considered noncovered by Florida Medicare and should be billed as a noncovered charge.

J9212: Interferon (continued)

Noncovered ICD-9-CM Code(s)

Any diagnosis codes not listed in the “ICD-9-CM Codes That Support Medical Necessity” section of this policy.

Noncovered Diagnosis

N/A

Coding Guidelines

N/A

Documentation Requirements

Medical record documentation maintained by the ordering/referring physician must substantiate the medical necessity for the use of the specific Interferon by indicating the condition for which it is being administered. The drug name, dosage, and route of administration must also be recorded. This information is normally found in the office/progress notes or medication administration record.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

The Association of Community Cancer Centers. (2000). *Compendia-Based Drug Bulletin, Fall Update*. Vol. 9(4). Rockville, MD: The Association of Community Cancer Centers.
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Advisory Committee Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from numerous societies.

Start Date of Comment Period

02/28/2001

End Date of Comment Period

04/14/2001

Start Date of Notice Period

08/01/2001

Revision History

Revision Number	Original
Start Date of Comment Period:	02/28/2001
Start Date of Notice Period:	08/01/2001
	4 th Qtr 2001 <i>Bulletin</i>
Original Effective Date	09/21/2001

M0302: Cardiac Output By Electrical Bioimpedance

Policy Number

M0302

Contractor Name

First Coast Service Options, Inc.

Contractor Number

090

Contractor Type

Intermediary

LMRP Title

Cardiac Output By Electrical Bioimpedance

AMA CPT Copyright Statement

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HCFA National Coverage Policy

Coverage Issues Manual, Section 50-54

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

HCFA Region

Region IV

HCFA Consortium

Southern

Original Policy Effective Date

09/21/2001

Original Policy Ending Date

N/A

Revision Effective Date

N/A

Revision Ending Date

N/A

LMRP Description

Electrical bioimpedance, a form of plethysmography, is a noninvasive method of hemodynamic monitoring that works by applying sensors to the neck and chest to transmit and measure the resistance to a small electrical signal. The changes in resistance are used to measure and calculate hemodynamic parameters.

Four dual electrodes are placed on the lateral aspects of the neck and thorax. The inferior neck electrodes are positioned at the base or root of the neck. The superior thoracic electrodes are placed at the mid-axillary line, even with the xyphoid. A low-amplitude, high-frequency electrical signal is emitted from the outer sensors through the thorax.

Because electricity follows the path of least resistance, the electrical signal travels along the most conductive area, the blood-filled aorta. A baseline level of impedance, or resistance to electrical signal, is determined. As the volume and velocity of blood in the aorta change with each

heartbeat, the device measures the changes in impedance to the electrical signal. Monitoring these changes permits continuous determination of stroke volume, indices of contractility such as velocity and acceleration of blood flow, systemic vascular resistance (SVR) and index, cardiac output (CO) and index, and thoracic fluid content.

Thoracic fluid content represents conductivity contributions of three compartments of the thorax, namely intravascular, intraalveolar, and interstitial. An excessive thoracic fluid content indicates an excess in thoracic fluids.

Indications and Limitations of Coverage and/or Medical Necessity

Cardiac output monitoring using electrical bioimpedance, a form of plethysmography, is covered by Medicare effective for services furnished on or after July 1, 1999.

These devices utilize electrical bioimpedance to noninvasively produce hemodynamic measurements of cardiac output, specifically stroke volume, contractility, systemic vascular resistance, and thoracic fluid content. These devices are covered for the following indications:

- Noninvasive diagnosis or monitoring of hemodynamics in patients with suspected or known cardiovascular disease;
- Differentiation of cardiogenic from pulmonary causes of **acute** dyspnea;
- Optimization of atrioventricular interval for a patient with an atrioventricular sequential cardiac pacemaker;
- Patients with need of determination for intravenous inotropic therapy;
- Post heart transplant myocardial biopsy patients; and/or
- Patients with a need for fluid management.

The following are examples of appropriate clinical indications for which Florida Medicare will consider the assessment of cardiac output by electrical bioimpedance medically reasonable and necessary:

- For patients with structural heart disease (with an ejection fraction < 40%) associated with the development of congestive heart failure (e.g., valvular and congenital, post myocardial infarction, rheumatic heart disease);
- For patients with inflammatory heart disease (with an ejection fraction < 40%) associated with the development of congestive heart failure (e.g., myocarditis and cardiomyopathy, pericarditis and constrictive pericardial scarring, rheumatic heart disease);
- For patients with ischemic heart disease (with an ejection fraction < 40%) associated with the development of congestive heart failure (e.g., post myocardial infarction, ischemic cardiomyopathy, ischemic mitral valve or left ventricular dysfunction);
- For patients with cardiac disease resulting in congestive heart failure with normal left ventricular function (e.g., diastolic dysfunction, restrictive cardiomyopathy/ infiltrative such as amyloidosis or cancer of the heart);
- For patients with pulmonary disease associated with congestive heart failure (e.g., cor pulmonale and the need to distinguish between pulmonary and cardiac

M0302: Cardiac Output by Electric Bioimpedance (continued)

- disease as the cause, pulmonary hypertension);
- For acute conditions for which the patient might present to an outpatient setting and in which a decision regarding intervention is necessary (e.g., pericardial effusion with possible tamponade, myocardial infarction, cardiac trauma);
- For patients with recent pacemaker implants who demonstrate clinical manifestations of unexplained fatigue, symptomatic hypotension, or congestive heart failure;
- For the titration of therapeutic agents in the setting of symptomatic congestive heart failure;
- For acute heart rejection during outpatient follow-up of heart transplant patients (as a supplement to invasive endomyocardial biopsy); and/or
- For patients with acute/chronic renal failure or end stage renal disease/dialysis, who demonstrate clinical manifestations of unexplained shortness of breath, unexplained reduced access flow, symptomatic hypotension/hypertension.

The frequency of measurements of cardiac output by electrical bioimpedance which Florida Medicare will consider medically reasonable and necessary will be based on the purpose for which the measurement is obtained. The following are examples of categories of use and the general guidelines regarding measurement frequency:

Diagnostic – Frequency of use for diagnostic purposes will apply to patients in whom congestive heart failure is evident, yet its etiology is unclear. An initial measurement may be sufficient, with infrequent follow-up assessments. Examples include (but are not limited to):

- A patient with respiratory failure and the need to distinguish the presence of a cardiac component of the illness.
- Pericardial effusion of uncertain hemodynamic significance.
- Suspected diastolic dysfunction or the presence of congestive heart failure in the setting of normal left ventricular function.

Titration of Therapeutic Agents – Frequency of use for monitoring therapeutic drug response will require more frequent measurements, and may vary. The frequency at which titration of the therapeutic agents is considered medically reasonable and necessary will be based on whether the drug is approved for use in a regimented fashion. Examples include (but are not limited to):

- Medication adjustments in patients with refractory congestive heart failure due to either systolic or diastolic dysfunction (especially patients with a left ventricular ejection fraction < 40%).
- Medication adjustments for patients receiving a hemodynamically active anti-hypertensive medication for which a regimented or standardized approach exists. Weekly assessments may be considered reasonable in patients undergoing titration of medications for which there is a regimented approach to titration (e.g., carvedilol). Because individual tolerance is quite variable and the side effects make it difficult to ascertain whether the patient is realizing maximal

benefit, knowledge of the cardiac output as an objective measure would assist the practitioner in decisions regarding titration. ACE inhibitors may also fall into this category, yet a maximum of 4 to 6 weekly measurements may be sufficient, with subsequent measurements at 1-3 month intervals.

Monitoring – Frequency of use for monitoring of a patient for a period of clinical assessment should be thought of as a single use. Examples include:

- To determine the effect of changes in pacemaker programming where several adjustments might be made during a single visit to optimize pacemaker function.
- Hemodynamic monitoring during a surgical procedure that takes place in the physician’s office.

NOTE: Measurement of cardiac output by electrical bioimpedance is not considered medically reasonable and necessary upon each visit or for each change in the patient’s medication regimen.

LIMITATIONS OF COVERAGE

Cardiac output by electrical bioimpedance is **not covered** for the following indications:

- Monitoring of patients with proven or suspected disease involving severe regurgitation of the aorta;
- Patients with minute ventilation (MV) sensor function pacemakers (since the device may adversely affect the functioning of that type of pacemaker);
- Cardiac bypass patients while on a cardiopulmonary bypass machine (since the device does not render accurate measurements under this circumstance);
- Routine assessment of cardiac output by electrical bioimpedance in an asymptomatic patient (i.e., a patient that presents with no clinical manifestations of illness or injury); and/or
- The use of electrical bioimpedance for the routine assessment of hypertensive patients (those who have demonstrated a blood pressure reading of systolic > 140 or diastolic > 90 on three separate occasions) who have not undergone a course of combination drug therapy that has failed to control the hypertension.

CPT/HCPCS Section & Benefit Category

Medicine/Cardiovascular

Type of Bill Code

Hospital – 13x, 14x
 Skilled Nursing Facility – 21x
 Rural Health Clinic – 71x
 End Stage Renal Disease – 72x

Revenue Codes

920 Other Diagnostic Services, General Classification
 940 Other Therapeutic Services, General Classification

CPT/HCPCS Codes

M0302 Assessment of cardiac output by electrical bioimpedance

Not Otherwise Classified Codes (NOC)

N/A

M0302: Cardiac Output by Electric Bioimpedance (continued)

ICD-9-CM Codes that Support Medical Necessity

391.0-391.9	Rheumatic fever with heart involvement
394.0-394.9	Diseases of mitral valve
397.0-397.9	Diseases of other endocardial structures
398.90-398.91	Other and unspecified rheumatic heart diseases
401.0	Malignant essential hypertension
401.9	Unspecified essential hypertension
402.00-402.01	Malignant hypertensive heart disease
402.11	Benign hypertensive heart disease with congestive heart failure
402.91	Unspecified hypertensive heart disease with congestive heart failure
403.00-403.01	Malignant hypertensive renal disease
403.11	Benign hypertensive renal disease with renal failure
403.91	Unspecified hypertensive renal disease with renal failure
404.00-404.03	Malignant hypertensive heart and renal disease
404.11	Benign hypertensive heart and renal disease with congestive heart failure
404.12	Benign hypertensive heart and renal disease with renal failure
404.13	Benign hypertensive heart and renal disease with congestive heart failure and renal failure
404.91	Unspecified hypertensive heart and renal disease with congestive heart failure
404.92	Unspecified hypertensive heart and renal disease with renal failure
404.93	Unspecified hypertensive heart and renal disease with congestive heart failure and renal failure
405.01-405.09	Malignant secondary hypertension
405.91-405.99	Unspecified secondary hypertension
410.00-410.92	Acute myocardial infarction
411.0-411.89	Other acute and subacute forms of ischemic heart disease
413.0-413.9	Angina pectoris
414.00-414.8	Other forms of chronic ischemic heart disease
415.0-415.19	Acute pulmonary heart disease
420.0-420.99	Acute pericarditis
421.0-421.9	Acute and subacute endocarditis
422.0-422.99	Acute myocarditis
423.0-423.9	Other diseases of pericardium
424.0	Mitral valve disorders
424.2-424.99	Other diseases of endocardium
425.0-425.8	Cardiomyopathy
428.0-428.9	Heart failure
429.3	Cardiomegaly
429.4	Functional disturbances following cardiac surgery
430	Subarachnoid hemorrhage
518.4	Acute edema of lung, unspecified

Diagnosis that Support Medical Necessity

N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity

N/A

Diagnosis that DO NOT Support Medical Necessity

N/A

Reasons for Denial

The use of electrical bioimpedance for monitoring of patients with proven or suspected disease involving severe regurgitation of the aorta.

The use of electrical bioimpedance for patients with minute ventilation (MV) sensor function pacemakers (since the device may adversely affect the functioning of that type of pacemaker).

The use of electrical bioimpedance for cardiac bypass patients while on a cardiopulmonary bypass machine (since the device does not render accurate measurements under this circumstance).

The use of electrical bioimpedance for routine assessment of cardiac output in an asymptomatic patient (i.e., a patient that presents with no clinical manifestations of illness or injury).

The use of electrical bioimpedance for the routine assessment of hypertensive patients (those who have demonstrated a blood pressure reading of systolic > 140 or diastolic > 90 on three separate occasions) who have not undergone a course of combination drug therapy that has failed to control the hypertension.

When performed for indications other than those listed in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy.

Noncovered ICD-9-CM Code(s)

Any diagnosis codes not listed in the "ICD-9-CM Codes That Support Medical Necessity" section of this policy.

Noncovered Diagnosis

N/A

Coding Guidelines

The only appropriate HCPCS code to use for the assessment of cardiac output by electrical bioimpedance is M0302. HCPCS codes 93720-93722 must not be used to represent this service.

If the service is performed for diagnostic purposes, bill revenue code 920. If the service is performed for therapeutic purposes, bill revenue code 940. However, revenue code 940 is not applicable for type of bill 14x or 72x.

Documentation Requirements

Medical record documentation (e.g., office/progress notes) maintained by the ordering/referring physician must indicate the medical necessity for assessment of cardiac output by electrical bioimpedance.

Additionally, a copy of the measurements acquired through the use of the electrical bioimpedance device, with the physician's signature, must be maintained in the medical record.

M0302: Cardiac Output by Electric Bioimpedance (continued)

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

Asensio, J., Demetriades, D., Berne, T., & Shoemaker, W. (1996). Invasive and noninvasive monitoring for early recognition and treatment of shock in high-risk trauma and surgical patients. *Surgical Clinics of North America*, 76 (4).

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Klocke, R., Mager, G., Kux, A., Sengpiel, C., Osterspey, A., Winter, U., Hopp, H., & Hilger, H. (1990). Noninvasive assessment of hemodynamics in patients with different pacemaker functions using bioimpedance. *Pacemaker Therapy and Electrophysiology*, 1, 18-26.

Lasater, R.N., MSN, CCRN, M. (1998). The view within: The emerging technology of thoracic electrical bioimpedance. *Critical Care Nursing Quarterly*, 21 (3), 97-101.

Marrocco, A., Eskin, B., Nashed, A., et al. (1998). Noninvasive bioimpedance monitoring differentiates cardiogenic from pulmonary causes of acute dyspnea in the emergency department. *SAEM 1998 Annual Meeting Academic Emergency Medicine*, 5 (5), 476-477.

Milzman, D., Hogan, C., Zlindenny, A., et al. (1998). The utility of thoracic impedance to evaluate chest radiograph changes from acute heart failure patients in the emergency department. *Journal of Cardiac Failure*, 4 (3), Supplement 1.

Shoemaker, W., Charles, C., Wo, B., Michael, H., et al. (1996). Noninvasive hemodynamic monitoring of critical care patients in the emergency department. *Academic Emergency Medicine*, 3, 675-681.

Weinhold, M.D., C., Reichenspurner, M.D., PhD, H., Fulle, M.D., P., Nollert, M.D., G., & Reichart, M.D., B. (1993). Registration of thoracic electrical bioimpedance for early diagnosis of rejection after heart transplantation. *The Journal of Heart and Lung Transplantation*, 12, 832-836.

1999 World Health Organization-International Society of Hypertension guidelines for the management of hypertension. Guidelines Subcommittee. *Journal of Hypertension*, 17 (2), 151-183.

Advisory Committee Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which includes representatives from the Florida Chapter, American College of Cardiology.

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

08/01/2001

Revision History

Revision Number	Original
Start Date of Comment Period	08/23/1999
Start Date of Notice Period	08/01/2001
	4 th Qtr 2001 <i>Bulletin</i>
Original Effective Date	09/21/2001 ❖

70450: Computerized Tomography Scans – Revision to Policy

The local medical review policy (LMRP) for Computerized Tomography Scan – 70450 was published in the Third Quarter 2001 *Medicare A Bulletin* on pages 38-41. Since then, separate policies have been developed for Computerized Tomography of the Thorax (CPT codes 71250-71270) and Computerized Tomography of the Abdomen (CPT codes 74150-74170). These policies are published on pages 29 and 31 of this issue. Therefore, all references to procedure codes 71250-71270 and 74150-74170 have been removed from the Computerized Tomography Scan policy. ❖

C1300: Hyperbaric Oxygen Therapy (HBO Therapy)

The local medical review policy (LMRP) for Hyperbaric Oxygen Therapy – C1300 was published in the First Quarter 2001 *Medicare A Bulletin* on page 20. Since then, the national coverage policy for HBO therapy has been revised to indicate that a physician no longer requires to be present during an HBO therapy session. However, Florida Medicare has made a local decision to continue to deny services performed in the absence of a physician (HCPCS code G0167 – Hyperbaric oxygen treatment not requiring physician attendance, per treatment session). ❖

J9293: Mitoxantrone Hydrochloride – Revision to Policy

The local medical review policy (LMRP) for Mitoxantrone Hydrochloride – J9293 was published in the Third Quarter 2001 *Medicare A Bulletin* on pages 64-65. Since then, the “Coding Guidelines” section of the policy has been revised. The information in this section should be replaced with the following statement:

Chemotherapy administration code Q0084 is to be used when Mitoxantrone is being infused for the treatment of a patient with a cancer diagnosis. Infusion code Q0081 should be used when this drug is being given for the treatment of Multiple Sclerosis (ICD-9 code 340). ❖

Erythropoietin for Anemia of Chronic Disease

Anemia of chronic disease (ACD) is a condition that accompanies chronic inflammatory, infectious, or neoplastic disorders. ACD is associated with an underproduction of red cells, a decrease in iron utilization, and failure of the bone marrow to respond to increased erythropoietin (EPO) levels (blunted EPO response). Laboratory values of patients experiencing ACD usually include a low hemoglobin, reticulocyte count, serum iron with normal or increased iron stores (ferritin level).

Florida Medicare has received several articles from the manufacturer, dating back as far as 1990. Many of these articles focused on patients with rheumatoid arthritis, the critically ill, and a few on patients with neoplastic disease. The articles pertaining to the critically ill encompassed a minimal number of patients in the ICU setting in which phlebotomy, inflammation, nutritional deficiencies, and blood loss contribute significantly to the development of anemia. The majority of these patients required immediate correction of anemia via blood transfusions and their anemia are not associated with ACD. Procrit® is not indicated for patients who require immediate correction of anemia. No studies were received regarding the use of Procrit® in infection and other inflammatory diseases with the exception of rheumatoid arthritis. Many additional studies were reviewed and some of them revealed that use of erythropoietin in anemic patients with cancer demonstrated some benefit but recommended further investigation.

Based on review of the medical literature, there currently is not enough peer-reviewed literature to support the use of Procrit® for patients with anemia of chronic disease. The latest recommendation for patients with ACD is to treat the underlying cause. Further studies are needed to support the use of Procrit® in this population. Therefore, based on this review, erythropoietin given for ACD will remain a noncovered indication. ❖

OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

Use of Modifier 25 and Modifier 27 in the Hospital Outpatient Prospective Payment System

The Health Care Financing Administration (HCFA) has provided clarification on reporting modifier 25 and modifier 27 under the hospital outpatient prospective payment system (OPPS).

The *Current Procedural Terminology (CPT-4)* defines **modifier 25** as “significant, separately identifiable evaluation and management service by the same physician on the same day of the procedure or other service.” Modifier 25 was approved for hospital outpatient use effective June 5, 2000.

The CPT defines **modifier 27** as “multiple outpatient hospital evaluation and management encounters on the same date.” HCFA recognizes and accepts the use of modifier 27 on hospital OPPS claims **effective for services on or after October 1, 2001**. Although HCFA will accept modifier 27 for OPPS claims, this modifier will not replace condition code G0. The reporting requirements for condition code G0 have not changed. Providers must continue to report condition code G0 for multiple medical visits that occur on the same day in the same revenue centers.

For further clarification on both modifiers, refer to the *CPT 2001* edition. Below are general guidelines in reporting modifiers 25 and 27 under the hospital OPPS.

General Guidelines for Modifier 25

- A. Modifier 25 must be appended only to evaluation and management (E/M) CPT service codes within the range of 92002-92014, 99201-99499, and with HCPCS codes G0101 and G0175.
- B. To append modifier 25 appropriately to an E/M code, the service provided must meet the definition of “significant, separately identifiable E/M service” as defined by *CPT*.

- C. Although it was previously stated that Medicare requires that modifier 25 “always be appended to the Emergency Department E/M codes when provided . . .” (see August/September 2000 Medicare A Bulletin pages 12-13), the Outpatient Code Editor (OCE) only requires the use of modifier 25 on an E/M code when it is reported with a procedure code that has a status indicator of “S” or “T.” Nevertheless, such an edit does not preclude the reporting of modifier 25 on E/M codes that are reported with procedure codes that are assigned to other than “S” or “T” status indicators, if the procedure meets the definition of “significant, separately identifiable E/M service.”

Note the OCE will continue to process claims for those procedure codes that are assigned to other than “S” or “T” status indicators if it is reported with an E/M code and a modifier 25

General Guidelines for Modifier 27

- A. Modifier 27 must be appended only to E/M service codes within the range of 92002-92014, 99201-99499, and with HCPCS codes G0101 and G0175.
- B. Hospitals may append modifier 27 to the second and subsequent E/M code when more than one E/M service is provided to indicate that the E/M service is “separate and distinct E/M encounter” from the service previously provided that same day in the same or different hospital outpatient setting.
- C. When reporting modifier 27, report with condition code G0 when multiple medical visits occur on the same day in the same revenue centers.

As is true for any modifier, the use of **modifiers 25 and 27** must be substantiated in the patient’s medical record. ❖

Update to the Hospital Outpatient Prospective Payment System (OPPS)

This article addresses the changes implemented with the July 2001 update to the hospital OPPS.

Included in this article are a list of *Current Procedural Terminology (CPT)* codes removed from the “**inpatient only list**” and moved to the OPPS list as reportable procedures, status indicator changes, ambulatory payment classification (APC) changes, short descriptor changes, and an updated list of payment rates for transitional pass-through drugs and biologicals that are reportable under the hospital OPPS. Also included is a list of the new pass-through device category C-codes as well as a listing of new HCFA Common Procedure Coding System (HCPCS) codes reportable under the hospital OPPS. Unless otherwise indicated, the effective date for items listed in this notification is July 1, 2001.

New Technology Procedure/Service

The following is a list of the “new technology procedure/service” reportable under OPPS.

HCPCS	APC	Descriptor Code
C9702*	981	Checkmate Intravascular Brachytherapy System, Novoste Beta-Cath Intravascular Brachytherapy System, Galileo Intravascular Radiotherapy System
C9708	975	Preview Treatment Planning Software

*The descriptor above for C9702 supercedes any previously published long descriptor for this HCPCS code. The Checkmate Intravascular Brachytherapy system was

Update to the Hospital Outpatient Prospective Payment System (continued)

effective January 01, 2001. The Novoste and Galileo Intravascular Brachytherapy systems are effective July 1, 2001.

New Drugs Eligible for Pass-Through Payments

The following is a list of new drugs eligible for transitional pass-through payments.

HCPCS	APC	Descriptor Code
A9700	9016	Supply of injectable contrast material for use in echocardiography, per study
C9018	9018	Botulinum toxin type B, per 100 units
C9019	9019	Caspofungin acetate, 50 mg
C9020	9020	Sirolimus tablet, 1 mg
J7506	7050	Prednisone, oral, per 5 mg
J7517	9015	Mycophenolate mofetil, oral, 250 mg

New Pass-Through Device Category C-Codes and Revision of a Category C-code Descriptor

The following is a list of new pass-through device category C-code reportable under OPSS effective July 1, 2001.

New Pass-Through Device Categories

The following categories were created based on applications received by December 1, 2000, and prior to the implementation of the categories that became effective April 1, 2001. Category C1765 was created as a result of procedures that were moved from the inpatient only list to the OPSS list effective July 1, 2001. Category C1766 was created based on additional information submitted to HCFA, which further clarified the need for this category.

HCPCS	APC	Descriptor
C1765	1765	Adhesion barrier
C1766	1766	Introducer/sheath, guiding, intracardiac electrophysiological, steerable, other than peel-away

Category C1766 was effective April 1, 2001.

Revised Category C-code Descriptors

The descriptor for these category C-codes supercede what was published previously.

HCPCS	APC	Descriptor
C1729	1729	Catheter, drainage (Note: This was previously listed as “Catheter, drainage, biliary”.)
C1733	1733	Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, other than cool-tip (Note: This was previously listed as “Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, other than temperature-controlled”.)
C2630	2630	Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, cool-tip (Note: This was previously listed as “Catheter, electrophysiology, diagnostic/ablation, other than 3D or vector mapping, temperature-controlled”.)

New HCPCS Codes Reportable Under OPSS

The new Positron Emission Tomography (PET) codes, ranging from G0210 to G0230, are reportable under OPSS effective July 1, 2001 and have been assigned APC 981.

C-Codes Replaced With Designated National HCPCS Codes

The national HCPCS codes (referred as replacement HCPCS codes below) should be reported on hospital OPSS claims rather than the temporary C-codes. Since the national HCPCS codes were reportable effective January 1, 2001, the C-codes listed below were retired effective July 1, 2001, and no longer reportable under the hospital OPSS. All the C-codes listed below have been granted their 90-day grace period; therefore, this grace period will not be extended.

The following list of HCPCS C-codes are no longer reportable under the hospital OPSS.

C-Code	APC	Replacement HCPCS Code	APC
C1009	1009	P9044	1009
C1024	1024	J2770	1024
C1059	1059	J7330	1059
C1084	1084	J9160	1084
C1086	1086	J8700	1086
C1203	1203	Q3013	1203
C1205	1205	A9510	1205
C9005	9005	J2993	9005
C9106	9106	J7520	9106
C9500	9500	P9032	9500
C9501	9501	P9034	9501
C9502	9502	P9036	9502
C9504	9504	P9039	9504
C9505	9505	P9038	9505

APC Changes for Imaging Procedures

Section 430 of BIPA required to create additional APCs to distinguish between radiological procedures that are performed with and without contrast media, **effective July 1, 2001**. To implement this provision, three of the APCs to which some of these procedures were assigned have been reconfigured.

The APC titles for APCs 0283 and 0284 have been modified, and reads as follows effective July 1, 2001.

- 0283** Computerized Axial Tomography With Contrast. (Formerly listed as “Level II Computerized Axial Tomography”). The following HCPCS codes requiring the use of contrast media are still assigned to the revised APCs 0283:
70460 70481 70487 70491 71260 72126
72129 72132 72193 73201 73701 4160.
- 0284** Magnetic Resonance Imaging and Angiography with Contrast. (Formerly listed as “Magnetic Resonance Imaging”). The following HCPCS codes requiring the use of contrast media are still assigned to the revised APCs 0284:
70542 70545 70548 70552 71551 72142
72147 72149 72196 73219 73222 73719
73722 744182 75553.

Update to the Hospital Outpatient Prospective Payment System (continued)

Following are the titles for the new **six** APCs:

APC	Title
0332	Computerized Angiography and Computerized Axial Tomography Without Contrast
0333	Computerized Tomography Angiography and Computerized Axial Tomography Without Contrast Followed by With Contrast
0335	Magnetic Resonance Imaging, Other (Non-Contrast)
0336	Magnetic Resonance Angiography and Imaging Without Contrast
0337	Magnetic Resonance Angiography and Imaging Without Contrast Followed by With Contrast
0338	Magnetic Resonance Angiography and Imaging With Contrast

APC Changes Effective July 1, 2001

The HCPCS codes listed in this section have been assigned to the new APCs as designated below beginning with dates of service furnished on or after July 1, 2001.

HCPCS Old Code	Old APC	New APC	HCPCS Old Code	Old APC	New APC
70336	0284	0335	72156	0284	0337
70450	0283	0332	72157	0284	0337
70470	0283	0333	72158	0284	0337
70480	0283	0332	72191	0283	0332
70482	0283	0333	72192	0283	0332
70488	0283	0333	72194	0283	0333
70490	0283	0332	72195	0284	0336
70492	0283	0333	72197	0284	0337
70496	0283	0332	73200	0283	0332
70498	0283	0332	73202	0283	0333
70540	0284	0336	73206	0283	0332
70543	0284	0337	73218	0284	0336
70544	0284	0336	73220	0284	0337
70546	0284	0337	73221	0284	0336
70547	0284	0336	73223	0284	0337
70549	0284	0337	73700	0283	0332
70551	0284	0336	73702	0283	0333
70553	0284	0337	73706	0283	0332
71250	0283	0332	73718	0284	0336
71270	0283	0333	73720	0284	0337
71275	0283	0332	73721	0284	0336
71550	0284	0336	73723	0284	0337
71552	0284	0337	73725*	0284	0338
71555*	0284	0338	74150	0283	0332
72125	0283	0332	74170	0283	0333
72127	283	0333	74175	0283	0332
72128	0283	0332	74181	0284	0336
72130	0283	0333	74183	0284	0337
72131	0283	0332	74185*	0284	0338
72133	0283	0333	75552	0284	0336
72141	0284	0336	76093	0284	0338
72146	0284	0336	76094	0284	0338
72148	0284	0336			

*Refer to guidelines changes for further information on this HCPCS code for dates of service furnished on or after October 1, 2001.

APC Changes Effective October 1, 2001

The HCPCS codes listed in this section have been assigned to the new APCs as designated below beginning with dates of service furnished on or after October 1, 2001.

HCPCS Code	Old APC	New APC
70486	0282	0332
75554	0284	0335
75555	0284	0335
75635	0283	0333
76390	0284	0335
76400	0284	0335

Below is a listing of the newly created C-codes and the CPT codes that they will replace effective for dates of service furnished **on or after October 1, 2001**. These C-codes were established solely for use by hospitals to differentiate OPSS payment for certain magnetic resonance angiography and magnetic resonance imaging procedures performed with, without, or with and without contrast. Physicians will continue to bill the appropriate CPT code for these procedures.

Since these C-codes will not take effect until October 1, 2001, the period from July 1, 2001, through September 30, 2001, constitutes the 90-day grace period normally associated with such code changes. Therefore, effective **October 1, 2001**, the five CPT codes in bolded text below will be considered invalid codes for billing OPSS services.

Effective for dates of service furnished **on or after October 1, 2001**, APC 0338 will be eliminated. Five of the seven HCPCS codes assigned to this APC will also be eliminated and replaced by C-codes, that is, 71555, 73725, 74185, 76093, and 76094. HCPCS codes 75554 and 75555 will be reassigned to APC 0335 **effective October 1, 2001**.

74185 Magnetic resonance angiography, abdomen, with or without contrast

HCPCS	APC	Descriptor
C8900	0284	Magnetic resonance angiography with contrast, abdomen
C8901	0336	Magnetic resonance angiography without contrast, abdomen
C8902	0337	Magnetic resonance angiography without contrast followed by with contrast, abdomen

76093 Magnetic resonance imaging, breast, without and/or with contrast; unilateral

HCPCS	APC	Descriptor
C8903	0284	Magnetic resonance imaging with contrast, breast; unilateral
C8904	0336	Magnetic resonance imaging without contrast, breast; unilateral
C8905	0337	Magnetic resonance imaging without contrast followed by with contrast, breast; unilateral

OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

Update to the Hospital Outpatient Prospective Payment System (continued)

76094 Magnetic resonance imaging, breast, without and/or with contrast; bilateral			HCPCS Codes	APC	HCPCS Codes	APC
HCPCS	APC	Long Descriptor				
C8906	0284	Magnetic resonance imaging with contrast, breast; bilateral	63003	52	87482	349
C8907	0336	Magnetic resonance imaging without contrast, breast; bilateral	63005	52	87487	349
C8908	0337	Magnetic resonance imaging without contrast followed by with contrast, breast; bilateral	63011	52	87492	349
			63012	52	87497	349
			63015	52	87512	349
			63016	52	87517	349
			63017	52	87522	349
			63020	52	87527	349
			63030	52	87530	349
			63035	52	87533	349
			63040	52	87536	349
			63042	52	87539	349
			63045	52	87542	349
			63046	52	87552	349
			63047	52	87557	349
			63055	52	87562	349
			63056	52	87582	349
			63057	52	87592	349
			63064	52	87622	349
			63066	52	87652	349
			80201	349	87799	349
			84512	349	88142	349
			86148	349	G0151*	0
			86361	349	G0152	0
			87472	349	G0153	0
			87477	349	G0154	0
					G0155	0
					G0156	0

The following codes will be moved from APC 0332 to APC 0333 effective for dates of service furnished on or after October 1, 2001: HCPCS Codes **70496, 70498, 71275, 72191, 73206, 73706, 74175**.

HCPCS Codes Removed from the "Inpatient Only" List

Several of the HCPCS codes listed below were previously listed in the "inpatient only" list but are now reportable under the hospital OPPS. These codes in some instances have been assigned to new APCs. Refer below for the latest APC assignment for each specific HCPCS code.

*This HCPCS code may not be paid under OPPS, but may be paid under other Medicare payment systems.

Pass-Through Items No Longer Eligible for Pass-Through Payments

C-Code Descriptor

C9107*	Injection, tinzaparin sodium, per 2ml vial
Q0181**	Unspecified oral dosage form, FDA approved prescription anti-emetic, for use as a complete therapeutic substitute for an IV anti-emetic at the time of chemotherapy treatment, not to exceed a 48 hour dosage regimen

*Drug is a low molecular weight heparin and like other low molecular weight heparin, is not eligible for pass-through status under the hospital OPPS effective July 1, 2001.

**Specific oral anti-emetic drugs are covered under OPPS, therefore, this unspecified oral anti-emetic HCPCS code is no longer reportable under OPPS effective July 1, 2001. ❖

OPPS PASS-THROUGH DEVICES CATEGORY GUIDELINES

Explanations of Terms—Revised

Anchor for opposing bone-to-bone or soft tissue-to-bone – Implantable pins and/or screws that are used to oppose soft tissue-to-bone, tendon-to-bone, or bone-to-bone.

Screws oppose tissues via drilling as follows: soft tissue-to-bone, tendon-to-bone, or bone-to-bone fixation. Pins are inserted or drilled into bone, principally with the intent to facilitate stabilization or oppose bone-to-bone. Anchors do not include screws, **washers**, and **nuts** used for anchoring plates to bone. (**Note:** This definition has been revised to include the terms “washers” and “nuts.” This definition supercedes the definition listed previously.)

Adhesion barrier – A bioresorbable substance placed on and around the neural structures, which inhibits cell migration (fibroblasts) and minimizes scar tissue formation. It is principally used in spine surgeries, such as laminectomies and discectomies.

Drainage catheter – Intended to be used for percutaneous drainage of fluids. (**Note:** This category does NOT include Foley catheters or suprapubic catheters. Refer to category C2627 to report suprapubic catheters.)

Electrophysiology (EP) catheter --Assists in providing anatomic and physiologic information about the cardiac electrical conduction system. Electrophysiology catheters are categorized into two main groups: (1) diagnostic catheters that are used for mapping, pacing, and/or recording only, and (2) ablation (therapeutic) catheters that also have diagnostic capability. The electrophysiology ablation catheters are distinct from non-cardiac ablation catheters.

Electrophysiology catheters designated as “cool-tip” refer to catheters with tips cooled by infused and/or circulating saline. Catheters designated as “other than cool-tip” refer to the termister tip catheter with temperature probe that measures temperature at the tissue catheter interface.

Infusion pump, non-programmable, temporary (implantable) – Short-term pain management system that is a component of a permanent implantable system used for chronic pain management. ❖

FRAUD AND ABUSE

Undercover Investigation Reveals Unethical Tactics

A recent Federal undercover investigation of a national consulting firm revealed that it was giving poor advice to its customers—primarily physicians and their staff concerning the Medicare program. The report of the investigation indicated that the consulting firm hosted and conducted seminars in which they furnished inappropriate advice to physicians in filing claims to the Medicare program. Some of the advice consisted of the following:

- How to maximize reimbursements (e.g., upcoding services or unbundling services),
- Not to refund overpaid funds to Medicare, unless Medicare notifies the physician of the overpayment,
- How to ensure payment by using specific diagnosis codes, etc.

Although the consulting firm does not receive payment from the Medicare program, physicians who unwittingly follow their advice assist in the perpetration of fraud against the Medicare program. Unfortunately, healthcare providers who follow poor advice from a consultant or other source risks the possibility of investigation and subsequent prosecution.

Seeking advice on the Medicare program from private organizations is not illegal. However, healthcare providers who do utilize the services of consultants, billing companies, or other entities with respect to filing claims to the Medicare program must consider the validity of their resources.

It is understood that the majority of consulting firms and billing companies as well (as healthcare providers) are honest and attempt to file claims to the Medicare program correctly. Providers need to be aware of those who are not. ❖

COST REPORTING ISSUES

Audit and Cost Report Settlement Expectations

The following article is being published at the request of the Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA).

This notification clarifies CMS's audit and cost report expectations and highlights the key issues regarding the audit and settlement audit.

Cost Report Submission:

Providers must use the information contained in the provider statistical and reimbursement report (PS&R) to prepare their Medicare cost reports. All providers are required to submit a cost report within five months of the cost reporting fiscal year end (FYE) or 30 days after a PS&R is sent to the provider by the intermediary whichever is later.

Medicare Cost Report Submission Requirements:

From a hospital provider or other providers filing electronic cost reports (ECRs):

1. A diskette of the ECR utilizing a CMS approved vendor with the current specification date submitted.
2. An ECR that passes all level 1 edits.
3. A submitted print image file of the cost report.
4. The certification page (worksheet S) of the ECR file with the actual signature of an officer (administrator or chief financial officer).
5. An exact match of the encryption code, date and time for the ECR displayed on the certification page to that of the ECR file encryption code, date and time.
6. An exact match of the encryption code, date and time for the print image displayed on the certification page to that of the print image file encryption code, date and time.
7. For teaching hospitals, a complete intern and resident information system (IRIS) diskette that will pass all IRIS system edits.
8. Agreement of the settlement summary on the electronic certification page with the settlement summary on the Medicare cost report produced from the electronic file.
9. A complete, signed Form HCFA-339 (must be an original signature).

From all other providers:

1. A completed and legible cost report on the proper forms.
2. A general information and certification page which includes the original signature of an officer (administrator or chief financial officer).
3. A complete, signed Form HCFA-339.

For all providers as appropriate, the submitted cost report package must also include:

1. Correctly updated graduate medical education (GME) per resident amounts.
2. All applicable documentation required per Form HCFA-2552-96.
3. All required documentation per the Form HCFA-339.
4. Documentation supporting exceptions to level 2 ECR and HCRIS edits.
5. A copy of the working trial balance.
6. A copy of the audited financial statements where applicable.
7. Where applicable, the supporting documentation for reclassifications, adjustments, related organizations, contracted therapists, and protested items.

The intermediaries will reject a cost report package that does not contain all items identified above. If the last five items are not received with the cost report an additional 15 days will be given to submit these items.

Home Office Cost Statements

Home office cost statements must be submitted within 150 days of the chain home office's FYE.

Documentation Guidelines

The provider will be notified in the engagement letter of documentation that is required for the review. This documentation should be available on the first day of the audit. All additional documentation requests will be made in writing. At the pre-exit conference the provider will be given a list of any documentation that is still outstanding. They will have four weeks to provide this documentation. If documentation is not received timely all related cost will be disallowed. As a general rule cost reports will not be reopened for documentation that is submitted late. ❖

ELECTRONIC DATA INTERCHANGE

HIPAA-AS Standard-Health Care Claim and Coordination of Benefits (COB) Transactions

The Health Insurance Portability and Accountability Act—Administrative Simplification (HIPAA-AS) provisions direct the Secretary of Health and Human Services to adopt standards for administrative transactions, code sets, and identifiers, as well as standards for protecting the security and privacy of health data. On August 17, 2000, a final rule designating standards for eight administrative transactions and for medical code sets used in these transactions became effective.

The following information is of importance to Medicare providers and third party provider billing agents, provider clearinghouses, and the COB trading partners with whom they interact electronically.

- Medicare will no longer issue non-version 4010 COB transactions nor accept version 4010 837 electronic claims as of October 2002.
- The IG and X12N data dictionary can be downloaded without charge from www.wpc-edi.com/HIPAA.
- Medicare will switch to exclusive use of the outbound COB by October 16, 2002.
- Each provider that has elected to submit claims electronically must submit all of their claims in compliance with 837 version 4010 Implementation Guidelines (IG) requirements. Vendors that submit electronic claims for Medicare providers must also comply with these requirements.
- Each trading partner that has elected to exchange COB electronically must accept the 837 version 4010 Implementation Guide claim format, or contract with a clearinghouse to translate their claim data into the 837 version 4010 format. They must furnish that clearinghouse with all data required by the Implementation Guide.
- A provider, provider agent, trading partner, that elects to use a clearinghouse for translation services is liable for those costs.
- If an EDI submitter is using a vendor, clearinghouse, or billing service to generate a certain transaction and that entity has passed testing requirements for a specific transaction and is using the same program to generate the transaction for all of their clients, then all clients of the vendor/clearinghouse/billing service will not be required to test prior to intermediary acceptance of production data.
- EDI submitters should request a testing appointment as soon as possible to be assured they could complete testing and correct any detected system problems prior to October 2002. There is no Medicare charge for this system testing. Appointment slots will be assigned on a first come basis. This fiscal intermediary will not be able to guarantee testing by the end of September 2002 for any entities that delay scheduling testing until late in the transition period. Specific information regarding testing appointments will be sent directly to our EDI customers.
- COB trading partners must either request system compatibility testing for use of the COB transaction prior to October 2002, or be confident that they have completed system changes as required to accept production COB transactions by October 2002. Any trading partner that prefers to have COB testing conducted prior to transmission of production data must schedule testing with this intermediary as soon as possible to assure testing will be completed before October 2002. Current trading partners will automatically be sent production X12N 837 version 4010 transactions in October 2002 unless a notification is received indicating that they want to terminate their COB agreement.
- As result of the large number of providers, agents, clearinghouses, and trading partners to be tested and the number of HIPAA standard transactions, it will not be feasible to test each entity during the last quarter of the transition process.

Although Medicare will furnish providers with basic information on HIPAA transaction requirements, Medicare will not furnish in-depth training on the use and interpretation of the standard Implementation Guide.

Providers who have questions about their 4010 migration should contact their vendor. ❖

THE PATIENT FRIENDLY ADVISORY

Toll-Free Helpline Available to Assist Patients with Medicare Questions

Elder patients often look to their health care providers for advice and information about Medicare and other health insurance concerns. As a trusted information source, you can assist your elder patients by providing resources that will help answer their questions. First Coast Service Options, Inc. would like to provide your facility with the “Patient Friendly Advisory,” beginning with this issue of the *Medicare A Bulletin*. Our mission with this advisory is to provide the medical staff in your facility with quick access to Medicare information to assist you in answering your patients’ questions in a timely and efficient manner.

One of the first resources to whom you can refer your patients is the toll-free Medicare Helpline at 1-800-MEDICARE (1-800-633-4227). Established in 1999 by the Centers for Medicare and Medicaid Services (CMS) – formerly the Health Care Financing Administration (HCFA), the helpline is available throughout the United States and is the only national toll-free phone line that provides up-to-date information about Medicare. By calling 1-800-MEDICARE (1-800-633-4227), your patients with Medicare can speak with a customer service representative in English or Spanish to get general information about Medicare, as well as answers questions on:

- Medicare health plan options in the community, including original fee-for-service Medicare and, where available, managed care
- Specific quality and satisfaction information about available managed care plans
- General information about Medicare supplemental insurance (Medigap)
- Telephone numbers for help with a variety of related issues, such as billing questions about Medicare claims, or for help with more complex questions about health insurance.

Callers with access to a teletype-writer (TTY) or telecommunications device for the deaf (TDD) can call 1-877-486-2048.

Customer service representatives are currently available between the hours of 8 a.m. and 4:30 p.m., local time Monday through Friday. Starting October 1, 2001, however, customer service representatives at 1-800-MEDICARE (1-800-633-4227) will be available 24 hours a day, 7 days a week, to respond to questions from beneficiaries and their caregivers. Also, effective October 1, 2001, callers will be able to get immediately by phone information about the choices which best meet their needs and will also be offered the option of receiving a copy of the information in the mail for further discussion and review.

***Please continue to look for
“The Patient Friendly Advisory”
in future issues of the Medicare A Bulletin***

EDUCATIONAL RESOURCES

www.floridamedicare.com — Florida Medicare Provider Web site

The following outlines information that is available on the First Coast Service Options, Inc. (FCSO) Florida Medicare provider Web site.

What's New

“*Medicare Hot Topics!*” — Provides a brief introduction to recent additions to specific areas of the site. Also provides items of immediate interest to providers.

Part A

- **PPS** - (Prospective Payment System) Includes Florida Special Issue newsletters and links to helpful information on the HCFA website (www.HCFA.gov) such as satellite broadcasts, hospital outpatient PPS reference guide, home health PPS main web page, and more.
- **Reason Codes** - A listing of codes used by Part A to explain actions taken on line items/claims.
- **Draft and Final LMRPs** - FCSO's final and draft Part A Local and Focused Medical Review Policies (LMRPs/ FMRPs).
- **Fraud & Abuse** - Articles of interest concerning fraud, abuse, and waste in the Medicare program.
- **Publications** - *Medicare A Bulletins* from 1997 through the present.

Part B

- **Draft and Final LMRPs** - FCSO's final and draft Part B Local and Focused Medical Review Policies (LMRPs/ FMRPs).
- **Fraud & Abuse** - Articles of interest concerning fraud, abuse and waste in the Medicare program.
- **MEDIGAP Insurer Listing** - Information about claim crossovers (e.g., list of auto-crossovers, etc.).
- **Publications** - *Medicare B Updates!* from 1997 through the present.

Shared (information shared by Part A and Part B)

- **Education** - Medicare Educational resources and a Calendar of Events.
- **Fee Schedules**
- **UPIN Directory**
- **MEDPARD Directory**
- **Forms** - Various enrollment applications and materials order forms (e.g., HCFA Form 855, claim review request, etc.).

EDI (Electronic Data Interchange)

- **HIPAA** - Information regarding the Health Insurance Portability and Accountability Act
- **Forms** - Various EDI applications' enrollment forms such as EMC, ERN, electronic claims status, etc.
- **Specs** - Florida specific format specification manuals for programmers.
- **HCFA** - Link to HCFA website for ANSI specification manuals
- **Other** - EDI Vendor List and other important news and information.

Extra

- **Site Help**
- **Contact Us** - Important telephone numbers and addresses for Medicare Part A and Part B and website design comment form (to Webmaster).
- **Links** - Helpful links to other websites (e.g., HCFA, Medicare Learning Network, etc.).

Search

Enables visitors to search the entire site or individual areas for specific topics or subjects. ❖

Medicare Educational Materials Available Now

First Coast Service Options, Inc. has developed a series of Medicare educational materials that are available for purchase by Medicare Part A and Part B providers.

Two order forms have been developed to order these educational materials:

- The “Resource Manual Order Form” may be used when ordering the comprehensive *Medicare Part A Resource Manual* and or the *Medicare Part B Resource Manual*. These manuals contain information on coverage guidelines and processing instructions on the most popular Medicare issues and topics (See page 97). These comprehensive and detailed resource manuals are just \$80.00 each.
- Those providers that do not wish to order the complete resource manuals, and are looking only for certain topics or specific specialty information may use the “Individual Module Order Form”. See page 99 for a list of individual topic and specific specialty manuals. These comprehensive and detailed resource manuals are just \$35.00 each.

Both order forms are also available through the Florida Medicare Web site www.FloridaMedicare.com. Order yours today! ❖

INSTRUCTIONS: Complete all portions of this form and follow the payment instructions outlined in #3 below.

NOTE: Do not include your Medicare provider number.

1. TELL US ABOUT YOURSELF. <i>PLEASE PRINT</i>			
Name			
Title/Position			
Company/Organization			
Address			
City, State, Zip Code			
Phone Number	() -	Extension:	
Fax Number	() -		
E-Mail Address			
2. PLEASE INDICATE THE MATERIALS YOU WOULD LIKE TO PURCHASE.			
QUANTITY	TITLE	PRICE (EA.)	TOTAL
	Medicare Part B Resource Manual Includes our most popular subjects: Advanced Beneficiary Notice; ARNP/PA Guidelines; CPT Coding; Electronic Media Claims; Evaluation and Management Documentation and Coding; Focused Medical Review; Fraud and Abuse; Global Surgery; HCFA-1500 Claims Filing; HIPAA-AS; How to Help Patients Understand Medicare; ICD-9-CM Coding; Inquiries, Appeals, and Overpayments; Medical Review; Medicare Part C; Medicare Secondary Payer; PC-ACE™ for HCFA-1500; Primary Care; Provider Enrollment; and Reimbursement Efficiency	\$80.00	\$
	Medicare Part A Resource Manual Includes our most popular subjects: Direct Data Entry (DDE); Fraud and Abuse; HIPAA; How to Help Patients Understand Medicare; Introduction to Cost Report Auditing; Introduction to Cost Reports; Medical Review; Medicare Part C; Medicare Secondary Payer; PC-ACE™ for UB-92; Provider Enrollment; Provider-Based Regulations; Reconsiderations, Reviews, and Inquiries; Reimbursement Efficiency; and UB-92 Claims Filing	\$80.00	\$
		Sub-Total	\$
		Add 7% Tax	\$
		Total	\$
3. PLEASE SUBMIT YOUR PAYMENT			
➡ SEND YOUR PAYMENT	Submit the completed form with your check or money order: <ul style="list-style-type: none"> ▪ <i>Payable to First Coast Service Options, Inc. #756245</i> ▪ <i>Mail to Medicare Education and Training, Resource Material Orders, P.O. Box 45270, Jacksonville, FL 32232</i> Your order will be shipped within four to six weeks.		

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INSTRUCTIONS: Complete all portions of this form and follow the payment instructions outlined in #3 below.

NOTE: Do not include your Medicare provider number.

1. TELL US ABOUT YOURSELF. <i>PLEASE PRINT</i>	
Name	
Title/Position	
Company/Organization	
Address	
City, State, Zip Code	
Phone Number	() - Extension:
Fax Number	() -
E-Mail Address	

2. PLEASE INDICATE WHICH INDIVIDUAL MODULES YOU WANT BY CLEARLY PRINTING THEIR NAMES IN THE LINES PROVIDED BELOW THE LIST. EACH MODULE COSTS \$35.00. (Modules followed by * are included in a resource manual)

Advanced Beneficiary Notice*	HCFA-1500 Claims Filing*	Pathology
Ambulance Regulations	HIPAA-AS*	PC-ACE™ for HCFA-1500*
Anesthesia	How to Help Patients Understand Medicare*	PC-ACE™ for UB-92*
ARNP/PA Guidelines*	ICD-9-CM Coding*	Podiatry
Cardiology	Independent Diagnostic Testing Facilities	Primary Care*
Chiropractic	Inquiries, Appeals, & Overpayments*	Provider Enrollment*
CPT Coding*	Introduction to Cost Report Auditing*	Provider-Based Regulations*
Dermatology	Introduction to Cost Reports*	Radiology
Direct Data Entry (DDE)*	Medical Review*	Reconsiderations, Reviews, & Inquiries*
Electronic Media Claims (EMC)*	Medicare Part C*	Rehabilitation Services
E/M Coding*	Medicare Secondary Payer*	Reimbursement Efficiency: Part A*
E/M Documentation*	Mental Health Services	Reimbursement Efficiency: Part B*
End Stage Renal Disease (ESRD)	Nephrology	SNF/Consolidated Billing
Focused Medical Review*	Oncology	UB-92 Claims Filing*
Fraud and Abuse*	Orthopedics	Vision
Global Surgery*	Partial Hospitalization Program	

QUANTITY	TITLE	PRICE (EA.)	TOTAL
		\$35.00	
		Sub-Total	\$
		Add 7% Tax	
		Total	\$

3. PLEASE SUBMIT YOUR PAYMENT

SEND YOUR PAYMENT	<p>Submit the completed form with your check or money order:</p> <ul style="list-style-type: none"> ▪ Payable to First Coast Service Options, Inc. #756245 ▪ Mail to Medicare Education and Training, Resource Material Orders, P.O. Box 45270, Jacksonville, FL 32232 <p>Your order will be shipped within four to six weeks.</p>
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ORDER FORM - PART A MATERIALS

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A

Abortion Services, Medicare Coverage of Feb/Mar 2000 11
 Advance Beneficiary Notices for Services for
 Which Institutional Part B Claims Are
 Processed by Fiscal Intermediaries Aug/Sep 2000 52
Ambulance Services:
 Clarification of Medicare Policies
 Concerning Ambulance Services Apr/May 2000 6
 Crosswalk to New Codes Dec 2000 9
 Fee Schedule Initiative Dec 2000 3
 Fee Schedule Initiative, Implementation Date ... Dec 2000 3
 Questions & Answers Apr/May 2000 7
 Questions & Answers Dec 1999/Jan 2000 6
Ambulatory Surgical Center (ASC):
 Update of Codes and Payment Group Dec 2000 11
 Update of Rates for Payments Oct/Nov 2000 6
 Apligraf™ (Graftskin) Services, Billing for Feb/Mar 2000 10
 Assisted Suicide Funding Restriction
 Act of 1997 Aug/Sep 1999 5
 Autologous Stem Cell Transportation,
 Additional Coverage for Dec 2000 12

B

Beneficiary Right to Itemized Statement for
 Medicare Items and Services Jun/Jul 1999 8
 Billing Guidelines for Influenza and
 Pneumococcal Pneumonia Vaccines Oct/Nov 1999 6
 Billing for Outpatient Services, Frequency of .. Jun/Jul 2000 5
 BIPA Changes to the 2001 Payment
 Amounts for DMEPOS 3rd Qtr 2001 7
 Blood Clotting Factor Administered to
 Hemophilia Inpatients, Payment for Jun/Jul 1999 113

C

Cervical Cancer Awareness and the Benefit
 of Pap Tests 3rd Qtr 21001 8
 Circulator Boot System Aug/Sep 2000 47
 Claim Expansion and Line Item Processing
 Implementation Jun/Jul 2000 5
 Claim Processing Requirement Modifications .. Oct/Nov 1999 16
 Clarification and HCPCS Coding Update:
 Part B Fee Schedule and Consolidated Billing
 for Skilled Nursing Facility (SNF) Services 3rd Qtr 22
 Clarification of Dialysis Coverage for
 Skilled Nursing Facility Residents Oct/Nov 1999 48
 Clinical Diagnostic Laboratory Organ or
 Disease Panels Feb/Mar 2000 8
 Clinical Diagnostic Laboratory Organ or
 Disease Panels - Revision to Policy Apr/May 2000 17
 Clinical Diagnostic Laboratory Tests Furnish
 by Critical Access Hospitals 3rd Qtr 2001 26
 Disease Panels - Revision to Policy Apr/May 2000 17
 Clinical Trials, Medicare Beneficiaries
 Participating in Medicare Qualifying Oct/Nov 2000 8
 COB Contractor Fact Sheet for Providers Dec 2000 10
 Colorectal Cancer Screening Campaign
 Print Materials 3rd Qtr 2001 10
 Colorectal Cancer!, Some Important Facts
 You Should Know 3rd Qtr 2001 11
 Continuous Subcutaneous Insulin Infusion
 (CSII) Pump Coverage Feb/Mar 2000 8
 Consolidated Billing for Skilled Nursing
 Facilities, Delay in Edit Implementation 3rd Qtr 2001 24
 Consolidated Billing for Skilled Nursing
 Facilities Apr/May 2000 44

C (continued)

Consolidated Billing for Skilled Nursing
 Facility Services, Fee Schedule 2nd Qtr 2001 12
 Coordination of Benefits—Trading Partners 2nd Qtr 2001 6
 Correct Coding Initiative—Two New Versions 1st Qtr 2001 17
 Correct Coding Initiative Apr/May 2000 16
 Cost Report Change, Reopenings for Sole
 Community and Medicare Dependent Hospital
 Open Cost Reports Affected by the Jun/Jul 1999 113
 Cost Reports, More Information About the
 Extension of Due Date for Filing Provider Jun/Jul 1999 9
 Coverage Expansion of Certain Oral
 Anti-Cancer Drugs to Include FDA
 Approved Oral Anti-Cancer Prodrugs Aug/Sep 1999 9

D

Deductible and Coinsurance for Calendar
 Year 2001, Medicare 1st Qtr 2001 6
 Deductible and Coinsurance for Calendar
 Year 2000, Medicare Feb/Mar 2000 5
 Description of OCE Edits/Claim Reasons Jun/Jul 2000 10
 Diagnostic and Screening Mammograms
 Performed with New Technologies,
 Payment Revisions 3rd Qtr 2001 5
 Disclosure of Itemized Statement to an
 Individual for Items or Services Provided Jun/Jul 2000 6
 “Do not Forward” Initiative Dec 2000 11
 Drugs, Biologicals and Supplies in a
 Comprehensive Outpatient Rehabilitation
 Facility, Payment of 2nd Qtr 2001 19

E

Edits Requiring Providers to Submit Home
 Health Claims in Sequence, Removal of Jun/Jul 1999 6
 Electronic Health Care Transaction
 Formats, Adoption of Standard Oct/Nov 1999 46
 Elimination of HCFA Free Billing Software 3rd Qtr 2001 30
 End of Grace Period for 2000 HCPCS Update .. Apr/May 2000 14
End Stage Renal Disease:
 Drug Pricing Update 3rd Qtr 2001 19
 Blood Pricing Update Dec 2000 15
 Blood Pricing Update Feb/Mar 2000 13
 Drug Pricing Update Aug/Sep 2000 60
 Drug Pricing Update Dec 1999/Jan 2000 32
 ESRD Claims Processed under Outpatient
 Prospective Payment System 1st Qtr 2001 12
 ESRD Facilities—Billing for Iron Dextran Jun/Jul 2000 68
 Home Dialysis Method Election and Claim
 Processing, Clarification of Fiscal
 Intermediary and DMERC Responsibilities . 1st Qtr 2001 11
 Enhanced External Counterpulsation (EECP) –
 Revision to Coverage and Billing Guidelines . Aug/Sep 1999 12
 Erythropoietin for Anemia of Chronic Disease 3rd Qtr 2001 66
 Evacuation, Billing for Services During the
 Time of Apr/May 2000 52
 Extracorporeal Immunoabsorption (ECI)
 Using Protein A Columns 1st Qtr 2001 7

F

Factor VIIa (Coagulation Factor, Recombinant),
 Processing Guidelines for Dec 1999/Jan 2000 10
 Financial Limitation for Outpatient
 Rehabilitation Services, Extension of
 Moratorium on the Application of the \$1,500 ... 3rd Qtr 2001 25

F (continued)

Fraud and Abuse:

Caveat Emptor - Let the Buyer Beware	Jun/Jul 2000	69
DHHS Announces Expanded "Senior Patrol" Grants to Help Spot Waste, Fraud, and Abuse in Medicare and Medicaid	Aug/Sep 1999	38
Floridians Can Help Fight Medicare Fraud and Abuse	Oct/Nov 1999	17
Fraud and Abuse in the Medicare Program ..	3rd Qtr 2007	27
Fraud and Abuse in the Medicare Program	Feb/Mar 2000	15
Office of Inspector General - Special Fraud Alert	Apr/May 2000	47
Justice Recovers Record \$1.5 Billion in Fraud Payments	2nd Qtr 2001	20
Wheels of Justice Do Turn, The	Dec 1999/Jan 2000	36
Reassignment of Benefits	Aug/Sep 2000	70

H

HCFA Announces New Medicare Hospital Outpatient Payment System	Jun/Jul 2000	7
HCFA Promotes Eye Exams for People with Diabetes	1st Qtr 2001	8
HCFA Web Site for Beneficiary Outreach Events	Dec 1999/Jan 2000	8
Health Care Related Web Sites	Aug/Sep 1999	6
HCPCS Annual Update, 2001: Additional Changes and Corrections	Dec 2000	11
Grace Period Established for	1st Qtr 2001	32
Local Medical Review Policy Changes	Dec 2000	13
Modifiers/Procedure Codes Discontinued	1st Qtr 2001	38
Modifiers/Procedure Codes Reactivated	1st Qtr 2001	37
Modifiers/Procedure Codes Revised	1st Qtr 2001	33
Health Insurance Portability and Accountability Act (HIPAA), The	1st Qtr 2001	14
Health Insurance Portability and Accountability Act (HIPAA) Web Site—Correction	Dec 1999/Jan 2000	15
Hemodialysis Flow Studies	Aug/Sep 2000	69
Hepatitis C Lookback, Qualified Candidates for ...	Jun/Jul 1999	110
Home Health Agency, Fifteen-Minute Increment Reporting Update	Aug/Sep 1999	39
Hospital Services, Use of Modifiers for Reporting	Dec 1999/Jan 2000	11
Hospital Outpatient Radiology Service Fee Schedule	Jun/Jul 2000	14

I

ICD-9-CM:

Medical Policy Changes related to the 2001 Coding Update	Oct/Nov 2000	53
Coding Changes – Year 2001	Aug/Sep 2000	57
Millennium Edition	Feb/Mar 2000	7
Immunosuppressive Drugs, Elimination of Time Limit on Medicare Benefits	3rd Qtr 2001	6
Immunosuppressive Drugs, Extension of Medicare Benefits for	Feb/Mar 2000	8
Implementation of Outpatient Prospective Payment System – Guidelines Revisions ..	Aug/Sep 2000	5
Implementation Guidelines of Outpatient Prospective Payment System for Multi- Purpose Hospital Outpatient Facilities	Aug/Sep 2000	6
Independent Laboratory Billing for the Technical Component of Physician Pathology Services to Hospital Patient	3rd Qtr 2001	18
Influenza Virus Vaccine Benefit, 1999 Medicare	Oct/Nov 1999	7

I (continued)

Influenza Vaccine Benefit Questions & Answers, 1999 Medicare	Oct/Nov 1999	7
Influenza Vaccine Roster, 1999 Medicare	Oct/Nov 1999	55
Inpatient Hospital Payments and Disproportionate Share Hospital Thresholds and Adjustments, Implementation of Updates to the FY 2001	3rd 2001	29
"Inpatient Only" Code Changes, Interim Process for Certain	Oct/Nov 2000	12
Instructions for Cost Outlier Bills with Benefits Exhausted	Dec 1999/Jan 2000	13
Interest Rate for Overpayments	3rd Qtr 2001	6
Interim Process for Certain	Oct/Nov 2000	12
Intermittent Catheterization, Clarification to Coverage of	Dec 1999/Jan 2000	9
Intestinal and Multi-Visceral Transplantation ...	3rd Qtr 2001	12
Intestinal Transplantation	2nd Qtr 2001	10
Intrathecal Baclofen under the Outpatient Prospective Payment System, Proper Billing of Units for	Oct/Nov 2000	12
Intravenous Iron Therapy	2nd Qtr 2001	7
Iron Dextran, Billing for—ESRD Facilities	Jun/Jul 2000	68
Is Your Office Ready to Process Claims in the Year 2000?	Dec 1999/Jan 2000	15

L

Laboratory Tests and Venipunctures Performed in a RHC	Jun/Jul 1999	114
Line Item Date of Service	Jun/Jul 1999	7
Liver Transplant Centers, Addition to List of Approved	Oct/Nov 1999	16
Liver Transplantation (Adult), Clarification to Policy	Apr/May 2000	19

M

Mandatory Assignment Now Required for Drugs and Biologicals	2nd Qtr 2001	5
Mammography Screening Payment Limit for Calendar Year 2001	1st Qtr 2001	5
Medical Policy Changes Relating to the Outpatient Prospective Payment System ..	Aug/Sep 2000	48
Medical Review Process Revision to Medical Records Requests	2nd Qtr 2001	5
Medicare Appeal Workloads in FY 2001	2nd Qtr 2001	5
Medicare Coverage of Noninvasive Vascular Studies when Used to Monitor the Access Site of End Stage Renal Disease (ESRD) Patients	Aug/Sep 2000	68
Medicare Contractors Applying Deductible, Coinsurance and Payment Updates Beginning January 10, 2000	Feb/Mar 2000	5
Medicare Remarks Codes, Additions and Changes to the	Jun/Jul 1999	9
Method II Home Dialysis Supplies, Payment for	2nd Qtr 2001	9
Millennium Rollover Year-End Claim Processing, Notification of	Dec 1999/Jan 2000	5
Modifiers for Reporting Outpatient Hospital Services, Addition to	Apr/May 2000	41
Modifier 25 in Reporting Hospital Outpatient Services, Further Information on the Use of	Aug/Sep 2000	12

N

Need to Reprocess Inpatient or Hospice Claims
in Sequence When Liability Changes Jun/Jul 1999 7

New Electronic Mailing Listservs for Outpatient
Prospective Payment Initiative Aug/Sep 2000 20

New Form to Report Unsolicited/
Voluntary Refund Checks Aug/Sep 1999 7

New Waived Tests 3rd Qtr 2001 12

New Waived Tests 2nd Qtr 2001 8

New CLIA Waived Test Aug/Sep 2000 58

New Waived Tests Apr/May 2000 17

New Waived Tests Jun/Jul 1999 110

New Waived Tests Aug/Sep 1999 11

Noncovered Charges and Related
Revenue Codes, Reporting of Feb/Mar 2000 7

O

Ocular Photodynamic Therapy (OPT) Oct/Nov 2000 7

Ocular Photodynamic Therapy (OPT) Aug/Sep 2000 57

Off Label Use of Oral Chemotherapy Drugs
Methotrexate and Cyclophosphamide Dec 2000 12

Outpatient Code Editor Modifications for the
Outpatient Prospective Payment System Jun/Jul 2000 8

Outpatient Pathology Services under the
Outpatient Prospective System, Proper
Billing of 1st Qtr 2001 9

Outpatient Prospective Payment System
Initiative Questions and Answers Aug/Sep 2000 13

Outpatient Prospective Payment System
Initiative HCFA Website Aug/Sep 2000 20

Outpatient Services Fee Schedule:

Clinical Laboratory, 2001 Dec 2000 17

Clinical Laboratory, 2001—Additions and
Revisions 2nd Qtr 2001 9

Medicare Services Fee Schedule, 2001 Dec 2000 17

Orthotic/Prosthetic Devices Dec 2000 24

Outpatient Rehabilitation, 2001 Dec 2000 29

Outpatient Rehabilitation, 2000 Feb/Mar 2000 16

Surgical Dressing Items Dec 2000 29

Outpatient Services Fee Schedule,
Correction to 2001 2nd Qtr 2001 9

Overpayment Interest Rate 3rd Qtr 2001 6

Overpayment Refund Form Aug/Sep 1999 8

P

PAINREH: Pain Rehabilitation Oct/Nov 1999 41

PAINREH: Pain Rehabilitation –
Revision to Policy Feb/Mar 2000 20

Payment of Skilled Nursing Facility Claims for
Beneficiaries Disenrolling from Terminating
Medicare+Choice (M+C) Plans Who Have
Not Met the 3-Day Stay Requirement Oct/Nov 2000 14

..... Jun/Jul 2000 67

Implementation Rescinded by HCFA Aug/Sep 2000 51

Percutaneous Transluminal Angioplasty
and Carotid Stents 2nd Qtr 2001 92

Physical Medicine – Clarification on Current
Procedural Terminology (CPT) Coding
Guidelines Apr/May 2000 12

Pneumococcal Pneumonia Vaccine,
Coverage Revision Jun/Jul 2000 12

Pneumococcal Vaccine (PPV) Benefit,
1999 Medicare Oct/Nov 1999 11

Pneumococcal Vaccine (PPV) Benefit
Questions & Answers, 1999 Medicare Oct/Nov 1999 12

P (continued)

Pneumococcal Vaccine Roster,
1999 Medicare Oct/Nov 1999 56

Positron Emission Tomography (PET) Scans
and Related Claims Processing Changes .. 3rd Qtr 2001 14

Postacute Care Transfer Policy 3rd Qtr 2001 17

Pre-Discharged Delivery of Durable Medical
Equipment and Prosthetic and Orthotics
Devices for Fitting and Training Apr/May 2000 42

Promoting Colorectal Cancer Screening 3rd Qtr 2001 9

Promoting Influenza and
Pneumococcal Vaccinations Aug/Sep 1999 7

Prospective Payment System:

Assessment Indicators, Corrections 1st Qtr 2001 13

Background, Outpatient Services Apr/May 2000 39

Categories for Use in Coding Devices Eligible
for Transitional Pass-Through Payments 3rd Qtr 2001 80

Claim Expansion and Line Item
Processing Apr/May 2000 8

C-Codes for Categories Used in Coding
Devices Eligible for Transitional Pass-
Through Payments 3rd Qtr 2001 84

Coding Information for Hospital Outpatient
Services Oct/Nov 2000 56

Coding Information for Hospital Outpatient,
January 2001 Update 2nd Qtr 2001 93

Comprehensive Outpatient Rehabilitation
Facility Services, All Apr/May 2000 46

Cross-Walk to new Categories C-codes
Used in Coding Devices Eligible for Transitional
Pass-Through Payments 3rd Qtr 2001 85

Devices Eligible for Transitional Pass-
Through Payments 3rd Qtr 2001 68

First Update to the Oct/Nov 2000 71

Further Guidance for Billing Under OPPS 3rd Qtr 2001 106

Intrathecal Baclofen, Proper Billing of Units .. Oct/Nov 2000 12

Medical Policy Changes Relating to the
Outpatient PPS Aug/Sep 2000 48

Outpatient Rehabilitation Services and
the Financial Limitation Aug/Sep 2000 7

Outpatient Rehabilitation Services,
Questions and Answers, Regarding Apr/May 2000 8

Procedures Subject to Home Health
Consolidated Billing 3rd Qtr 2001 108

Technical Corrections to Coding Information
for Hospital Outpatient 1st Qtr 2001 15

Technical Corrections to the January 2001
Update Coding Information for Hospital
Outpatient 2nd Qtr 2001 15

Transitional Pass-Through Devices and Durgs,
Additional Information 3rd Qtr 2001 78

Workshops for Home Health Agencies Aug/Sep 2000 21

Pass-Through Payment Corrections for
Two Radiopharmaceuticals 2nd Qtr 2001 103

Prostate Screening Billing Correction .. Dec 1999/Jan 2000 9

Provider Billing Issues - Outpatient
Rehabilitation Services Aug/Sep 2000 56

Provider Y2K Testing—Myth Versus Reality Dec 1999/Jan 2000 16

R

Radiochemicals not Covered Jun/Jul 1999 110

Reason Code, 30715—The Common
(but Avoidable) RTP Feb/Mar 2000 7

Reclassification of Certain Urban Hospitals
as Rural Hospitals—Application Procedures .. Jun/Jul 2000 13

R (continued)

Religious Nonmedical Health Care Institutions (RNHCIs), Services Provided in	Apr/May 2000	15
Remittance Advice Notice, Changes to the ...	Oct/Nov 2000	6
Replacement of Prosthetic Devices and Parts	2nd Qtr 2001	7
Reporting Of Noncovered Charges and Related Revenue Codes	Aug/Sep 2000	51
Requirement to Submit Bills in Sequence for a Continuous Inpatient Stay or Course of Treatment	Jun/Jul 1999	6
Reporting of Noncovered Charges and Related Revenue Codes – Change in Implementation Date	Jun/Jul 2000	6
Revision and Clarification of Final Rule on Ambulance Services	Oct/Nov 1999	44
Revisions to Previously Published Policies: 64573, 72192, 76075, J9000	Aug/Sep 1999	14

S

Salary Equivalence Guidelines Update Factors	3rd Qtr 2001	26
Sanctioned Provider Information Available on the Internet	Aug/Sep 1999	6
.....	Dec 1999/Jan 2000	8
Settlement Agreement – INNAMED	Apr/May 2000	16
Skilled Nursing Facility Adjustment Billing: Adjustments to HIPPS Codes Resulting from MDS Corrections	Oct/Nov 2000	13
SNF Prospective Payment Rates, Special Adjustment for	Feb/Mar 2000	12
Stem Cell Transplantation, Additional Coverage for Autologous	1st Qtr 2001	8
Stem Cell Transplantation, Additional Coverage for Autologous	Oct/Nov 2000	7
Submitting, Processing, and Paying Medicare Claims in the Year 2000	Oct/Nov 1999	5
Swing-Bed Facility Services, Change in Payment	2nd Qtr 2001	11

T

Therapy Students, Questions & Answers Regarding Payment	Third Qtr 2001	6
Timely Filing Guidelines for All Medicare A Providers	1st Qtr 2001	5
Timely Filing Guidelines for All Medicare A Providers	Aug/Sep 2000	49
Tips to Submit Medical Review Documentation After a Utilization Audit	Apr/May 2000	15
Toll-Free Telephone Numbers, New	3rd Qtr 2001	4
Transitional Corridor Payments	Aug/Sep 2000	11
Transmyocardial Revascularization (TMR) for Treatment of Severe Angina	Jun/Jul 1999	109
Two-Year Moratorium on Financial Limitation for Outpatient Rehabilitation Services	Feb/Mar 2000	6

U

Ultrasonic Osteogenic Stimulator	Dec 2000	12
UPIN Directory Available on the Internet	Apr/May 2000	16
Urokinase (Abbokinase®) Shortage	1st Qtr 2001	7

V

Verteporfin	3rd Qtr 2001	16
-------------------	--------------	----

W

Web Site for Prompt Payment Interest Rate, New	Jun/Jul 2000	5
Written Statement of Intent (SOI) to Claim Medicare Benefits	Aug/Sep 2000	49

Y

Y2K Future Date Testing Available	Aug/Sep 1999	5
Y2K Outreach Toll-Free Line Implementation of HCFA	Jun/Jul 1999	6
Y2K Provider Readiness Survey Results Reveal Providers Have Some Work to Do .	Aug/Sep 1999	5
Y2K Readiness for PC-ACE™ Software	Oct/Nov 1999	6
Year 2000, Are You Ready for the	Jun/Jul 1999	5

Procedure Codes

CPT Codes

Anesthesia/Surgery, 00100-69979

20974: Osteogenic Stimulator for Fracture Healing ..	Jun/Jul 2000	12
29540 Strapping	3rd Qtr	32
33216: Implantation of Automatic Defibrillators	Jun/Jul 2000	16
33216: Implantation of Automatic Defibrillators ...	2nd Qtr 2001	22
33223: Implantation of Automatic Defibrillators ..	Oct/Nov 1999	19
33246: Implantation of Automatic Defibrillators	Jun/Jul 1999	107
33282: Insertable :oop Recorder (ILR)	3rd Qtr	34
44388: Colonoscopy	Oct/Nov 2000	18
Addition to Policy	2nd Qtr 2001	91
48554: Pancreas Transplantation	Jun/Jul 1999	108
48554: Revision to Pancreas Transplantation Coverage	Jun/Jul 2000	12
48554: Revision to Pancreas Transplantation Coverage	Oct/Nov 1999	45
53850: Prostate Treatments	Jun/Jul 2000	18
53850: Prostate Treatments	Oct/Nov 1999	20
55873: Crysurgical Ablation of the Prostate ...	2nd Qtr 2001	24
59840, 59841, 59850-59852, 59855-59857, 59866: Elective Abortion	Jun/Jul 1999	31
61885, 64573, 64585, 64590, 64595, 95970, 95971, 95974, 95975: Vagus Nerve Stimulation	Jun/Jul 1999	33
62263: Percutaneous Lysis of Epidural Adhesions	2nd Qtr 2001	26
.....	Jun/Jul 2000	
66821: YAG Laser Capsulotomy	1st Qtr 2001	21
67221: Ocular Photodynamic Therapy (OPT) with Verteporfin	3rd Qtr	36

Diagnostic Tests, 70010-89399

70450: Computerized Tomography Scans	3rd Qtr 2001	38
.....	Aug/Sep 1999	15
70544: Magnetic Resonance Angiography (MRA)	2nd Qtr 2001	28
70541: Magnetic Resonance Angiography (MRA)	Jun/Jul 2000	21
.....	Aug/Sep 1999	18
70551: Magnetic Resonance Imaging of the Brain	2nd Qtr 2001	31
71010: Chest X-ray	Aug/Sep 2000	24
Addition to Policy	1st Qtr 2001	19
72192-72194: Computed Tomography of the Pelvis	2nd Qtr 2001	33
.....	Jun/Jul 1999	37
76090: Diagnostic Mammography	3rd Qtr 2001	42

Diagnostic Tests, 70010-89399 (continued)

76092: Screening Mammograms	3rd Qtr 2001	44
77336: Radiation Physics Consultation	Aug/Sep 2000	32
78472: Cardiac Blood Pool Imaging	Oct/Nov 2000	22
.....	Feb/Mar 2000	21
80100: Qualitative Drug Screen	2nd Qtr 2001	38
.....	Oct/Nov 2000	25
.....	Jun/Jul 1999	44
82105: Tumor Makers	2nd Qtr 2001	40
82108: Aluminum	Jun/Jul 2000	25
Addition to Policy	2nd Qtr 2001	91
82270: Fecal Occult Blood Testing	Jun/Jul 1999	47
82310: Total Calcium	2nd Qtr 2001	43
82378: Carcinoembryonic Antigen (CEA)	1st Qtr 2001	23
82435: Chloride	2nd Qtr 2001	46
82607: Vitamin B-12 (Cyanocobalamin) Assay	Feb/Mar 2000	24
82728: Serum Ferritin	Aug/Sep 2000	34
82947: Blood Glucose Testing	3rd Qtr 2001	46
83540: Iron	Oct/Nov 2000	28
83735: Magnesium	Jun/Jul 2000	27
84100: Serum Phosphorus	1st Qtr 2001	25
84152: Complexed and Free Prostate Specific Antigen	2nd Qtr 2001	48
84153: Prostate Specific Antigen	Dec 1999/Jan 2000	20
84154: Free Prostate Specific Antigen	Jun/Jul 1999	52
84436: Thyroid Function Test	December 1999	29
84436: Thyroid Function Test - Revision to Policy	Feb/Mar 2000	20
84436: Thyroid Function Test - Revision to Policy	Apr/May 2000	21
84484: Troponin	Oct/Nov 2000	30
85044: Reticulocyte Count	Aug/Sep 1999	20
86235: Extractable Nuclear Antigen	Jun/Jul 1999	54
86353: Lymphocyte Transformation	3rd Qtr 2001	49
86706: Hepatitis B Surface Antibody and Surface Antigen	Oct/Nov 1999	23
86781: Fluorescent Treponemal Antibody Absorption (FTA-abs)	Aug/Sep 1999	21
87086: Urine Bacterial Culture	Dec 1999/Jan 2000	22
87621: Human Papillomavirus DNA Assay, Amplified Probe Technique	Jun/Jul 2000	30
Revision to Policy	Aug/Sep 2000	47
88142-88155, 88164-88167, G0123, G0143-G0145, G0147, G0148, P3000: Pap Smears	Jun/Jul 1999	56
88155: Pap Smears—Revision to Policy .	Dec 1999/Jan 2000	18
88230: Cytogenetic Studies	Oct/Nov 1999	27

Medicine, 90281-99199

90846, 90847, 90849: Family Psychotherapy ..	Jun/Jul 1999	61
92081-92083: Visual Field Examination	Jun/Jul 1999	64
92135: Scanning Computerized Ophthalmic Diagnostic Imaging	Aug/Sep 2000	36
92225, 92226: Ophthalmoscopy	Jun/Jul 1999	70
92235: Fluorescein Angiography	Jun/Jul 1999	74
92240: Indocyanine-Green Angiography	Jun/Jul 1999	78
93000: Electrocardiography	2nd Qtr 2001	50
.....	Aug/Sep 1999	22
93000: Electrocardiography - Revision to Policy	Apr/May 2000	21
93012, 93268, 93270, 93271, G0004-G0006, G0015: Patient Demand Single or Multiple Event Recorder	Jun/Jul 1999	84
93224-93227, 93231-93237: Holter Monitoring ...	Jun/Jul 1999	80

Medicine, 90281-99199 (continued)

93268: Patient Demand Single or Multiple Event Recorder - Revision to Policy	Feb/Mar 2000	20
93303: Transthoracic and Doppler Echocardiography and Doppler Color Flow Velocity Mapping	Jun/Jul 2000	32
93312: Transesophageal Echocardiogram ...	2nd Qtr 2001	53
93333: Electrocardiography - Revision to Policy	Feb/Mar 2000	20
93501, 93510, 93511, 93514, 93524, 93527-93529, 93530-93533: Cardiac Catheterization	Jun/Jul 1999	89
93501: Cardiac Catheterization	Feb/Mar 2000	26
93501: Cardiac Catheterization - Revision to Policy	Apr/May 2000	21
93724: Electronic Analysis of Pacemaker System and Pacer Cardioverter-Defibrillator	2nd Qtr 2001	56
93875: Noninvasive Extracranial Arterial Studies	Oct/Nov 2000	33
.....	Oct/Nov 1999	29
93886: Transcranial Doppler Studies ...	Dec 1999/Jan 2000	24
93922: Noninvasive Physiologic Studies of Upper or Lower Extremity Arteries	3rd Qtr 2001	51
.....	Apr/May 2000	22
93925: Duplex Scan of Lower Extremity Arteries	Feb/Mar 2000	30
93930: Duplex Scan of Upper Extremity Arterial By-pass Grafts	Feb/Mar 2000	32
93965: Noninvasive Evaluation of Extremity Veins	Feb/Mar 2000	33
93965: Noninvasive Evaluation of Extremity Veins	Aug/Sep 2000	39
Addition to Policy	2nd Qtr 2001	92
Addition to Policy	Apr/May 2000	21
93975-93979: Duplex Scanning	Jun/Jul 1999	95
93990: Duplex Scan of Hemodialysis Access ...	2nd Qtr 2001	59
94010: Spirometry	Jun/Jul 2000	37
94642: Aerosolized Pentamidine Isethionate	Aug/Sep 2000	41
94664: Diagnostic Aerosol or Vapor Inhalation	Dec 1999/Jan 2000	26
94760: Noninvasive Ear or Pulse Oximetry for Oxygen Saturation	Feb/Mar 2000	35
95004: Allergy Skin Test	Oct/Nov 2000	37
.....	Jun/Jul 2000	41
95115: Allergen Immunotherapy	2nd Qtr 2001	61
.....	Oct/Nov 2000	39
95930: Visual Evoked Potential (VEP) Testing .	Feb/Mar 2000	37
95934: H-Reflex Study	Oct/Nov 2000	41
95900: Nerve Conduction Studies	2nd Quarter 2001	63
95925: Somatosensory Testing	1st Qtr 2001	28
97016: Coverage and Billing Guidelines for Enhanced External Counterpulsation (EECP) ...	Jun/Jul 1999	108
99183: Hyperbaric Oxygen (HBO) Therapy	Jun/Jul 1999	101
Delay in Implementation of	Aug/Sep 1999	14
Delay in Coverage Policy	Apr/May 2000	21
Revision to National Policy	1st Qtr 2001	20

HCPCS Codes

A0426: Ground Ambulance Services	2nd Qtr 2001	22
A0320: Ground Ambulance Services	Jun/Jul 2000	43
A9270: Arthroscopic Laser Arthrodesis	Jun/Jul 2000	65
C1203: Ocular Photodynamic Therapy (OPT) with Vereporfin	2nd Qtr 2001	70
C1300: Hyperbaric Oxygen (HBO) Therapy ...	3rd Qtr 2001	54
C1305: Apligraf® (Graftskin)	3rd Qtr 2001	59
G0030-G0047, G0125, G0126,		

HCPCS Codes (continued)

G0163-G0165: PET Scan	Jun/Jul 1999	13
G0102: Prostate Cancer Screening	Oct/Nov 2000	43
G0102-G0103: Coverage for Prostate Cancer Screening	Oct/Nov 1999	45
G0104: Colorectal Cancer Screening	Aug/Sep 1999	24
G0108: Diabetes Outpatient Self- Management Training	Feb/Mar 2000	39
Addition to Policy	2nd Qtr 2001	92
G0160, G0161: Cryosurgery of Prostate	Jun/Jul 1999	107
G0160, G0161: Cryosurgical Ablation of the Prostate	Jun/Jul 1999	20
G0166: Enhanced External Counterpulsation	Dec 1999/Jan 2000	28
G0166: External Counterpulsation for Severe Angina - Revision to Policy	Apr/May 2000	17
J0001: Self-Administered Drugs	Oct/Nov 2000	45
J0205, J1785: Ceredase/Cerezyme	Jun/Jul 1999	22
J0207: Amifostine (Ethyol®)	3rd Qtr 2001	62
.....	Jun/Jul 2000	47
J0585: Botulinum Toxin Type A (Botox)	Oct/Nov 1999	32
J0850: Cytomegalovirus Immune Globulin (Human), Intravenous (CMV-IGIV)	Aug/Sep 1999	26
J1440: G-CSF (Filgrastim, Neopogen®)	Oct/Nov 2000	47
J1561: Intravenous Immune Globulin	Oct/Nov 1999	35
J1561: Intravenous Immune Globulin	Apr/May 2000	25
J1745: Infliximab (Remicade™)	Aug/Sep 2000	43
J1950: Leuprolide Acetate	Oct/Nov 2000	45
.....	Oct/Nov 1999	39
Addition to Policy	2nd Qtr 2001	92
J2355: Oprelvekin (Neumega®)	Dec 1999/Jan 2000	30
J2430: Pamidronate (Aredia®, APD)	Jun/Jul 2000	49
Addition to Policy	Aug/Sep 2000	47
J2792: Rho (D) Immune Globulin Intravenous	Jun/Jul 2000	51
J3240: Thyroprotin Alfa Thyrogen®)	Jun/Jul 2000	53
J7190: Hemophilia Clotting Factors	Jun/Jul 2000	55
Addition to Policy	2nd Qtr 2001	92
J9000, J9170, J9350, J9999: Antineoplastic Drugs	Jun/Jul 1999	24
J9293: Mitoxantrone Hydrochloride	3rd Qtr 2001	64
J9999: Antineoplastic Drugs	2nd Qtr 2001	73
.....	Jun/Jul 2000	57
J9999: Antineoplastic Drugs—Irinotecan (Camptosar®)— Addition to Policy	Oct/Nov 2000	53
J9999: Antineoplastic Drugs— Addition to Policy	Dec 1999/Jan 2000	19
L8614: Cochlear Device System— Correction to Fee Schedule	Apr/May 2000	16
M0302: Cardiac Output Monitoring by Electrical Bioimpedance	Jun/Jul 1999	107
Q0136: Non-ESRD Epoetin (Procrit®)	Oct/Nov 2000	50
Revision to Policy	1st Qtr 2001	19
Q0163-Q0181: Coverage Modification for Oral Antiemetic Drugs	Aug/Sep 1999	9
Q9920: Chronic Renal Failure Erythropoietin (Epogen)	Aug/Sep 1999	27
DYSPHRT: Dysphagia/Swallowing Diagnosis and Therapy	2nd Qtr 2001	72
PHPPROG: Psychiatric Partial Hospitalization Program	2nd Qtr 2001	83
.....	Apr/May 2000	29

Special Bulletins

<i>Biomedical Equipment Year 2000 (Y2K) Compliance</i>	<i>August 9, 1999</i>
<i>HCFA Requires Mitigation Plans for Immediate PRO Review Requests During Possible Y2K-Induced Telecommunication Disruption</i>	<i>August 16, 1999</i>
<i>2000 HCFA Common Procedure Coding System and Medicare Outpatient Services</i>	<i>December 1999</i>
<i>2000 Outpatient Fee Schedule for Clinical Laboratory Services</i>	<i>February 25, 2000</i>
<i>Implementation of Outpatient Prospective Payment System</i>	<i>May 1, 2000</i>
<i>June 5, 2000 Implementation of Claim Expansion and Line Item Processing Initiative</i>	<i>*June 1, 2000</i>
<i>Implementation Delay Hospital Outpatient Prospective Payment System Initiative Effective August 1, 2000</i>	<i>*June 12, 2000</i>
<i>New Electronic Mailing Listservs for Outpatient Prospective Payment Initiative</i>	<i>*June 28, 2000</i>
<i>2001 ICD-9-CM Coding Update</i>	<i>*August 10, 2000</i>
* This special issue is available only on the website www.floridamedicare.com	

Addresses

CLAIMS STATUS

Coverage Guidelines

Billing Issues Regarding

Outpatient Services, CORE, ORF, PHP

Medicare Part A Customer Service

P. O. Box 2711

Jacksonville, FL 32231

(904) 355-8899

APPEAL RECONSIDERATIONS

Claim Denials (outpatient services only)

Medicare Fair Hearings (Part A)

P. O. Box 45203

Jacksonville, FL

MEDICARE SECONDARY PAYER (MSP)

Information on Hospital Protocols

Admission Questionnaires

Audits

Medicare Secondary Payer

Hospital Review

P. O. Box 45267

Jacksonville, FL 32231

General MSP Information

Completion of UB-92 (MSP Related)

Conditional Payment

Medicare Secondary Payer

P. O. Box 2711

Jacksonville, FL 32231

(904) 355-8899

Automobile Accident Cases

Settlements/Lawsuits

Other Liabilities

Medicare Secondary Payer Subrogation

P. O. Box 44179

Jacksonville, FL 32231

ELECTRONIC CLAIM FILING

“DDE Startup”

Direct Data Entry (DDE)

P. O. Box 44071

Jacksonville, FL 32231

(904) 791-8131

FRAUD AND ABUSE

Medicare Anti-fraud Branch

P. O. Box 45087

Jacksonville, FL 32231

(904) 355-8899

REVIEW REQUEST

Denied claims that may have been payable under the Medicare Part A program

Medicare Part A Reconsiderations

P. O. Box 45053

Jacksonville, FL 32232

OVERPAYMENT COLLECTIONS

Repayment Plans for Part A Participating Providers

Cost Reports (original and amended)

Receipts and Acceptances

Tentative Settlement Determinations

Provider Statistical and Reimbursement (PS&R) Reports

Cost Report Settlement (payments due to provider or Program)

Interim Rate Determinations

TEFRA Target Limit and Skilled Nursing Facility Routine Cost Limit Exceptions

Freedom of Information Act Requests (relative to cost reports and audits)

Provider Audit and Reimbursement

Department (PARD)

P.O. Box 45268

Jacksonville, FL 32232-5268

(904) 791-8430

Phone Numbers

PROVIDERS

Customer Service Representatives:

1-877-602-8816

BENEFICIARY

1-800-333-7586

ELECTRONIC MEDIA CLAIMS

EMC Start-Up:

904-791-8767

Electronic Eligibility

904-791-8131

Electronic Remittance Advice

904-791-6865

Direct Data Entry (DDE) Support:

904-791-8131

PC-ACE Support

904-355-0313

Testing:

904-791-6865

Help Desk (Confirmation/Transmission)

904-905-8880

Medicare Websites

PROVIDERS

Florida Medicare Contractor

www.floridamedicare.com

Health Care Financing Administration

www.hcfa.gov

BENEFICIARIES

Florida Medicare Contractor

www.medicarefla.com

Health Care Financing Administration

www.medicare.gov



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