Medicare A Bulletin

A Newsletter for Florida Medicare Part A Providers

In This Issue...

Features

Please share the *Medicare A Bulletin* with appropriate members of your organization.

Routing Suggestions:

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

HCFA Health Care Financing Administration

FIRST COAST SERVICE OPTIONS, INC.
A HCFA Contracted Carrier & Intermediary

Table of Contents

Medicare A Bulletin

Vol. 2, No. 3
June/July
2000

Publications Staff

Millie C. Pérez
Cynthia Moore
Pauline Crutcher
Shari Bailey
Bill Angel

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:

Medicare Part A Publications
P.O. Box 2078
Jacksonville, FL 32231-0048

A Physician's Focus

Improving Claim Payment Error Rate—An Effort by Multiple Stakeholders

The Medicare program pays more than $200 billion to one million health care providers for services provided to 39 million seniors and disabled Americans annually. Promoting the integrity of the Medicare and Medicaid programs is a top priority of the Health Care Financing Administration (HCFA). HCFA states its program integrity goal as being straightforward – "to pay the right amount, to a legitimate provider, for covered, reasonable, and necessary services, provided to an eligible beneficiary." HCFA has set goals for reducing the claim payment error rate.

A claim payment error rate incorporates both over-and underpayment. It is a general measure that reflects aspects of coding, medical necessity, eligibility, benefits, and record keeping. Accurate claim adjudication depends on proper input from multiple stakeholders and proper process, sometimes by multiple stakeholders. This ultimately leads to the outcome of a correct claim payment. Patients, providers, HCFA, and HCFA contractors are the general stakeholders supported by multiple health care professionals.

As a fiscal intermediary (Medicare Part A HCFA contractor), First Coast Service Options, Inc. administers payment of five billion dollars to 1,300 health care providers for services to over two million seniors and disabled Americans in Florida and in other states. Approximately five and a half million claims are processed annually. Intermediaries and other HCFA contractors are implementing programs to improve their claims payment error rates and medical review. These programs supplement the ongoing education programs to help providers document and file claims correctly.

Medicare Peer Review Organizations (PROs), as part of their new scope of work from HCFA, are working with hospitals to analyze, correct, and prevent the billing of inpatient claims that are miscoded, inadequately documented, and unnecessary services. The Florida PRO—Florida Medical Quality Assurance, Inc. (FMQAI)—has expanded its quality improvement activities and initiated this program known as the Payment Error Prevention Program (PEPP). Through PEPP, the FMQAI and all PROs across the nation will focus efforts to ensure that claims for inpatient services are billed and paid correctly. Intermediaries support this program and see opportunities to learn from the providers ways to reduce claim processing errors and the claim payment error rate. The goals are to pay claims right the first time, and to reduce the administrative cost of unnecessary claim resubmission and appeals.

Sincerely,

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

About *The Medicare A Bulletin*

The *Medicare A Bulletin* is a comprehensive, bimonthly magazine for all Florida Part A providers. It is published six times annually (every two months), plus the annual special issue for the HCFA Common Procedure Coding System and Medicare Outpatient Fee Schedule Database Update.

The *Bulletin* is mailed during the first half of the first month of publication (e.g., early August for the August/ September issue).

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 Website 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

Frequency of Billing for Outpatient Services

Florida Medicare is experiencing an increase in providers billing improperly for repetitive Medicare Part B services.

Repetitive Part B services furnished to a single beneficiary must be billed monthly or at the conclusion of treatment. These instructions apply to any facility or entity billing for outpatient services including community mental health centers as well as home health agencies and hospice services billed under Medicare Part A. Example of repetitive Part B services with applicable revenue codes include:

Type of Service	*Revenue Code*
DME Rental	290-299
Therapeutic Radiology	330-339
Therapeutic Nuclear Medicine	342
Respiratory Therapy	410-419
Physical Therapy	420-429
Occupational Therapy	430-439
Speech Pathology	440-449
Home Health Visits	550-599
Kidney Dialysis Treatment	820-859
Cardiac Rehabilitation Services	482, 943
Psychological Services (in a psychiatric facility)	910-919

Billing monthly, or at the conclusion of treatment, avoids Medicare processing costs in holding such bills for monthly review, and reduces bill-processing costs for relatively small claims.

Where there is an inpatient stay or outpatient surgery during a period of repetitive outpatient services, providers may submit one bill for the entire month by using an occurrence span code 74 to encompass the inpatient stay or day of outpatient surgery. This permits providers to submit a single bill for the month and simplifies the fiscal intermediary monthly review of these bills.

Other one time Part B services may be billed at the completion of the services. Bills for outpatient surgery must contain all services provided on the day of the surgery on a single bill (except kidney dialysis services that are billed on a 72(x)-bill type). Outpatient services furnished on a day other than the day of the surgery must not be included on the outpatient surgical bill.

Providers furnishing repetitive services are periodically reviewed for proper billing methods. Billing improperly for these services will result in a return-to-provider action. ❖

New Web Site for Prompt Payment Interest Rate

Medicare contractors are required to pay interest on "clean" claims that are not paid in a timely manner, under section 3902(a) of title 3l, U.S. Code. The Treasury Department determines the interest rate on a 6-month basis, effective every January and July 1st.

Effective January 1, 2000, providers may access the Treasury Department Web page — **www.publicdebt.treas.gov/opd/opdprmt2.htm —** for the new rate.

Interest is paid on clean claims that are not paid by the 30th day after the date of receipt by the contractor. The current rate, from the above Web site, is 6.75 percent. Be sure to access this Web site after July 1, 2000, for the next update to the prompt payment interest rate.

A "clean" claim is defined as a claim that does not require the fiscal intermediary to investigate or develop for additional information external to the Medicare operation on a prepayment basis.

Interest is not paid on:

- Claims requiring external investigation or development by the intermediary (e.g., additional development request)
- Claims on which no payment is due
- Claims denied in full
- Claims not approved for payment by the common working file (CWF) within seven days of the intermediary original claim submission for reasons beyond the intermediary's control
- Claims for which the provider is receiving periodic interim payment (PIP) reimbursement. ❖

***Third party Web sites**. This document contains references to sites operated by third parties. Such references are provided for your convenience only. BCBSF and/or FCSO do not control such sites, and are not responsible for their content. The inclusion of these references within this document does not suggest any endorsement of the material on such sites or any association with their operators.*

Claim Expansion and Line Item Processing Implementation

The claim expansion line item processing (CELIP) project was scheduled for a national implementation on April 1, 2000. The complexity of some of changes to the Fiscal Intermediary Shared System (FISS) required additional time to implement this initiative.

Therefore, the effective date to implement CELIP initiative in preparation for the outpatient prospective payment system (OPPS) is **June 5, 2000**. ❖

Overpayment Interest Rate

Medicare assesses interest on overpaid amounts that are not refunded timely. Interest will be assessed if the overpaid amount is not refunded within 30 days from the date of the overpayment demand letter. The interest rate on overpayments is based on the higher of the private consumer rate (PCR) or the current value of funds (CVF) rate.

Effective May 3, 2000, the interest rate applied to Medicare overpayments is **13.75** percent, based on the new revised PCR rate. The following table lists previous interest rates.

Period	Interest Rate
February 2, 2000 – May 2, 2000	13.50%
October 28, 1999 - February 1, 2000	13.375%
August 4, 1999 - October 27, 1999	13.25%
May 05, 1999 - August 3, 1999	13.375%
February 1, 1999 - May 04, 1999	13.75%
October 23, 1998 - January 31, 1999	13.50%
July 31, 1998 - October 22, 1998	13.75%
May 13, 1998 - July 30, 1998	14.00 %
January 28, 1998 - May 12, 1998	14.50%
October 24, 1997 - January 27, 1998	13.875%
July 25, 1997 - October 23, 1997	13.75%
April 24, 1997 - July 24, 1997	13.50%
January 23, 1997 - April 23, 1997	13.625%
October 24, 1996 - January 22, 1997	13.375% ❖

Reporting of Noncovered Charges and Related Revenue Codes—Change in Implementation Date

In the February/March 2000 *Medicare A Bulletin* page 7, an article was published providing instructions for reporting noncovered charges and related revenue codes. The implementation date for this initiative was published as April 1, 2000.

Since then, the implementation date for reporting outpatient Part B noncovered charges and related revenue codes has been changed to be effective for claims received **on or after October 1, 2000**. ❖

Disclosure of Itemized Statement to an Individual for Items or Services Provided

Section 4311 of the Balanced Budget Act of 1997 requires that if a Medicare beneficiary submits a written request to a health services provider for an itemized statement for any Medicare item or service provided to that beneficiary, the provider must furnish this statement within 30 days of the request. The law also states that a health services provider not furnishing this itemized statement may be subject to a civil monetary penalty of up to $100 for each unfulfilled request. Since most institutional health practices have established an itemized billing system for internal accounting procedures as well as for billing other payers, the furnishing of an itemized statement should not pose any significant additional burden.

Suggested Contents of Itemized Statement

Suggestions for the types of information that might be helpful for a beneficiary to receive on any statement include:

- Beneficiary name
- Date(s) of service
- Description of item or service furnished
- Number of units furnished
- Provider charges
- An internal reference or tracking number

If Medicare has adjudicated the claim, additional information that can be included on the itemized statement may be:

- Amounts paid by Medicare
- Beneficiary responsibility for co-insurance
- Medicare claim number
- Name and telephone number for the beneficiary to call if there are further questions.

The implementation date for this policy is June 1, 2000. ❖

OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

HCFA Announces New Medicare Hospital Outpatient Payment System

The following article is reprinted from a HFCA press release for informational purposes.

The Health Care Financing Administration today [*March 31, 2000*] announced a new Medicare payment system for hospital outpatient services designed to encourage more efficient delivery of care and to ensure more appropriate payment for services by Medicare and its beneficiaries.

Over time, the regulation will save beneficiaries millions of dollars in coinsurance payments for outpatient services. In addition to hospital outpatient services, the new prospective payment system will also apply to partial hospitalization services furnished by community mental health centers.

The final regulation, to be published on April 7 in the *Federal Register*, carries out the payment changes initially proposed by the Clinton Administration, which were enacted in the Balanced Budget Act of 1997 and adjusted in the Balanced Budget Refinement Act of 1999. The proposed regulation was open for comment by individuals and organizations between its publication in September 1998, and July 1999.

HCFA, which oversees the Medicare program, will implement the new payment system expected to go into effect on July 1, 2000. The provisions for provider-based facilities owned by hospitals, including physician office practices, will be effective six months from the publication date.

"This regulation helps Medicare reduce copayments for hospital outpatient services that are being used more frequently by elderly and disabled Americans," said HCFA Administrator Nancy-Ann DeParle. "The new system gives hospitals changed incentives to become more efficient and will result in more consistent payments across hospitals.

"The new prospective payment system increases total payments to hospitals, although individual hospitals may see an increase or a decrease in their payments," DeParle said. "During the transition period, we are protecting hospitals by paying a part of any reduced payments they might incur for outpatient services. For rural hospitals, we will fully cover any payment reductions. And hospitals will receive additional payments for new medical devices and drugs for up to three years."

HCFA will make certain that hospitals and their billing companies have the information and training they need to carry out system changes for the new outpatient prospective payment system. The agency also will monitor the progress of hospitals as they make the necessary changes and will continue to work closely with the hospital associations.

"I am committed to ensuring that the nation's hospitals and other providers are fully educated about this regulation," DeParle said. "We will launch an aggressive and comprehensive campaign to inform people about the rule."

The new payment system is based on groups of services called ambulatory payment classifications (APC), which divides all outpatient services included in the new payment schedule into 451 groups. The services within each group are clinically similar and require comparable resources.

A key provision of the 1997 budget law is a change in beneficiary coinsurance payments. The current coinsurance is based on 20 percent of charges billed by the hospitals and community mental health centers. In fact, for many outpatient services, beneficiaries pay 50 percent or more of the total payment to the hospital for outpatient treatment.

The Clinton Administration has long advocated reducing coinsurance that beneficiaries must pay for hospital outpatient services. In 1997, the administration's budget proposed to reduce coinsurance for beneficiaries to 20 percent of Medicare payment rates by 2007. Congress adopted a variation of the president's proposal in the 1997 budget law.

Coinsurance amounts will be frozen until the coinsurance payment for an APC becomes 20 percent of the total payment. Once coinsurance becomes 20 percent of the total payment, both the Medicare payment and the coinsurance amount will be updated annually so that coinsurance will continue to be 20 percent of the total payment. The actual copayment amounts for an APC will be limited to the Medicare hospital inpatient deductible, which for 2000 is $776. In addition, hospitals have the option of reducing the copayment.

The APC payment rate established for each group applies to all services within the group. Although national payment rates are established for each group, payments will be wage adjusted to reflect geographic differences. Under the final rule, HCFA has developed separate APCs to pay for blood, other blood products and anti-hemophilic factors.

In addition, HCFA modified the proposed regulation to allow a smoother transition to the new fee system for providers. The APC groups were refined based on comments. The changes included paying for corneal tissue, at least temporarily, at its acquisition cost, rather than as part of the payment for overall corneal transplant surgery, and requiring the use of HCPCS codes only for purposes of computing payments for medical visits to clinics and emergency departments.

The regulation excludes ambulance services because a new fee schedule is being developed. Physical, occupational and speech therapies, orthotic and prosthetic devices, durable medical equipment and clinical laboratory services are excluded because they are paid under existing fee schedules.

The final rule incorporates changes in hospital outpatient payments set by the 1999 budget law including:

- Medicare will make additional payments for certain new medical devices and drugs for up to three years.
- During a transition period until 2004, Medicare will pay hospitals a portion of any losses they would otherwise incur resulting from smaller payments than under prior law. For rural hospitals with 100 or fewer beds, these losses will be fully replaced.

HCFA Announces New Medicare Hospital Outpatient Payment System (continued)

- Medicare will make an outlier payment for high-cost cases, with payments projected not to exceed 2.5 percent of total payments to hospital outpatient departments in 2000-2003.
- Certain cancer hospitals will be protected permanently from any reduced Medicare payments.
- Medicare will pay for implanted medical devices under the new payment system, rather than under a medical equipment fee schedule.

HCFA will annually review the APC groups, wages and other adjustments. As part of this review, HCFA will consult with an expert panel composed of provider representatives.

A 60-day comment period in the final regulation applies only to the regulatory changes resulting from the 1999 budget law.

The new regulation also addresses the criteria a facility must meet to be designated "provider-based." In recent years, provider-based facilities have expanded, including an increase in hospitals acquiring physician office practices to use as hospital outpatient departments. The regulation also includes requirements for hospitals to furnish an appropriate level of physician supervision in off-site clinics. ❖

Outpatient Code Editor Modifications for the Outpatient Prospective Payment System

Introduction

The Health Care Financing Administration (HCFA) provides Medicare Part A intermediaries with a software package, named the outpatient code editor (OCE), used for editing and monitoring the accuracy of outpatient claims and billing. This article provides OCE information and specifications that will be used under the OPPS for hospital outpatient departments, community mental health centers (CMHCs), and for limited services provided in a comprehensive outpatient rehabilitation facility (CORF), home health agency (HHA) or to a hospice patient for the treatment of a non-terminal illness. The revised version of the OCE represents a significant change to the software in that it will process claims consisting of multiple dates of service. Effective for claims with dates of service **on or after July 1, 2000,** the intermediary will edit the following bills through the revised OCE:

- All outpatient hospital Part B claims (bill types 12x, 13x, or 14x), with the exception of Indian Health Service and Critical Access Hospital bills
- CMHC bills (bill type 76x)
- CORF bills containing specific CPT/HCPCS codes for r vaccines (bill type 75x)
- HHA and CORF bills containing specific CPT/HCPCS codes for reporting antigens, vaccines, splints and casts (bill type 34x)
- Any bill containing a condition code 07 with certain CPT/HCPCS codes for reporting antigens, vaccines, splints and casts.

Other outpatient bill types with the exception of Indian Health Service hospital bills may pass through the OCE software for purposes of editing diagnosis and line item information to identify coding errors. However, the OCE will not return any payment related information for bill types or conditions other than those listed above, and will only apply partial hospitalization edits for bill type 76x and bills containing condition code 41.

NOTE: For bill type 34x, only vaccines and their administration, splints, casts and antigens will be paid under OPPS. For bill type 75x, only vaccines and their administration are paid under OPPS. For bills containing condition code 07, only splints, casts and antigens will be paid under OPPS.

General Functions of the OCE

The revised OCE will perform two major functions:

- Edit claims data to identify errors and return a series of edit flags; and
- Assign an ambulatory patient classification (APC) number for each service covered under OPPS, and return information to be used as input to the PRICER program.
- To provide these functions, the OCE software will:
- Process claims that span more than one date of service
- Edit claims based on the type of bill and other criteria
- Edit claims using additional parameters
- Identify a disposition based on the OCE edits
- Compute information on OPPS services to be used for payment
- Assign flags to communicate editing, disposition, and payment information

Previous versions of the OCE software focused solely on the presence or absence of specific edits and did not specify the action that should be taken when an edit occurred (e.g., deny claim, suspend claim, etc). Further, the previous OCE versions did not compute any information that would be used for payment purposes. The new OCE version identifies individual errors, indicates actions to be taken, and the reasons why these actions are necessary (e.g., a specific diagnosis that caused the action).

In general, OCE performs all functions that require specific reference to CPT/HCPCS codes, CPT/HCPCS modifiers, and ICD-9-CM diagnosis codes.

Outpatient Code Editor Modifications (continued)

OCE software handles claims spanning more than one date of service by subdividing the claim into separate days for the purpose of determining discounting and multiple visits on the same calendar day. The span of time that a claim represents will be controlled by the *"from and through"* dates on the claim. However, in order to properly apply an ambulatory payment classification (APC), emergency room and observation room services will be reviewed as one date of service even if the service spans more than one day. All applicable services must be on a single claim since APC assignment and some edits are date dependent. For example, a bilateral procedure error will occur if a pair of procedures were billed for the date of service, but not if the dates of service are different.

Information Sent to OCE

The following claim information is sent to the OCE:

- From date
- Through date
- Condition code
- List of ICD-9-CM diagnosis codes
- Age
- Sex
- Type of bill
- Medicare provider number

The *"from* and *through"* dates are used to determine if the claim spans more than one day and therefore represents multiple visits. The condition code (e.g., 41) specifies special claim conditions such as a claim for partial hospitalization that is paid on a per diem basis. The diagnosis codes apply to the entire claim and are not specific to a line item.

The following line information will also be input to the OCE:

- HCPCS code with up to 2 modifiers
- Revenue code
- Service date
- Service units
- Charge

The CPT/HCPCS codes and modifiers are used as the basis of assigning the APCs. Not all line items will contain a HCPCS code. The line item service dates are used to subdivide a claim that spans more than one day into individual visits. The service units indicate the number of times a CPT/HCPCS code was provided (e.g., a lab test with a service unit of two means the lab test was performed twice).

Information Returned from OCE

The occurrence of an edit can result in one of six different dispositions. These dispositions will help to assure that intermediaries in various parts of the country are following similar procedures. The dispositions are:

Claim Rejection

There are one or more edits present the cause the whole claim to be rejected. A claim rejection means that the provider can correct and resubmit the claim but cannot appeal the claim rejection.

Claim Denial

There are one or more edits present that cause the whole claim to be denied. A claim denial means the provider cannot resubmit the claim but can appeal the claim denial.

Claim Return to Provider (RTP)

There are one or more edits present that cause the whole to RTP to the provider. A claim RTP means the provider can resubmit the claim once the problems are corrected.

Claim Suspension

There are one or more edits present that cause the whole claim to be suspended. A claim suspension means that the claim is not RTP, but is not processed for payment until the intermediary makes a determination or obtains further information.

Line Item Rejection

There are one or more edits present that cause one or more individual line items to be rejected. A line item rejection means the claim can be processed for payment with some line items rejected for payment (i.e., the line item can be corrected and resubmitted but cannot be appealed).

Line Item Denials

There are one or more edits present that cause one or more individual line items to be denied. A line item denial means the claim can be processed for payment with some line items denied for payment (i.e., the line item cannot be resubmitted but can be appealed).

In the initial release of the OCE, many of the edits have a disposition of RTP in order to give providers time to adapt to OPPS. In subsequent releases of OCE, the disposition of some edits may change to other more automatic dispositions, such as a line item denial. A single claim can have one or more edits in all six dispositions. ❖

Description of OCE Edits/Claim Reasons

There are currently 42 different OCE edits. Each edit is assigned a number. The provider does not see the OCE edits, but receives a reason/error code related to the OCE edit. For example, if a 75 year-old male had a diagnosis related to pregnancy, it would create a conflict between the diagnosis and age and sex.

Edit	Description	Disposition
1	Invalid diagnosis code	RTP
2	Diagnosis and age conflict	RTP
3	Diagnosis and sex conflict	RTP
4	Medicare secondary payer alert	Suspend
5	E-code as reason for visit	RTP
6	Invalid procedure code	RTP
7	Procedure and age conflict	RTP
8	Procedure and sex conflict	RTP
9	Non-covered service	Line item denial
10	Non-covered service submitted for verification of denial (condition code 21)	Claim denial
11	Non-covered service submitted for review (condition code 20)	Suspend
12	Questionable covered service	Suspend
13	Additional payment for services not provided by Medicare	Line item rejection
14	Code indicates a site of service not included in OPPS	RTP
15	Service unit out of range for procedure	RTP
16	Multiple bilateral procedures without modifier 50 (see Table 7)	RTP
17	Inappropriate specification of bilateral procedure (see Table 7)	Line item rejection
18	Inpatient procedure	Claim denial
19	Mutually exclusive procedure that is not allowed even if appropriate modifier is present	Line item rejection
20	Component of a comprehensive procedure that is not allowed even if appropriate modifier is present	Line item rejection
21	Medical visit on same day as a type “T” or “S” procedure without modifier 25 (see “Multiple Medical and Procedure Visits on the Same Day” below)	Line item rejection
22	Invalid modifier	RTP
23	Invalid date	RTP
24	Date out of OCE range	Suspend
25	Invalid age	RTP
26	Invalid sex	RTP

Edit	Description	Disposition
27	Only incidental services reported	RTP
28	Code not recognized by Medicare; alternate code for same service available	RTP
29	Partial hospitalization service for non-mental health diagnosis	RTP
30	Insufficient services on day of partial hospitalization	Suspend
31	Partial hospitalization on same day as electroconvulsive therapy or type T procedure	Suspend
32	Partial hospitalization claim spans 3 or less days with insufficient services, or electroconvulsive therapy or significant procedure on at least one of the days	Suspend
33	Partial hospitalization claim spans more than 3 days with insufficient number of days having mental health services	Suspend
34	Partial hospitalization claim spans more than 3 days with insufficient number of days meeting partial hospitalization criteria	Suspend
35	Only activity therapy and/or occupational therapy services provided	RTP
36	Extensive mental health services provided on day of electroconvulsive therapy or significant procedure	Suspend
37	Terminated bilateral procedure or terminated procedure with units greater than one	RTP
38	Inconsistency between implanted device and implantation procedure	RTP
39	Mutually exclusive procedure that would be allowed if appropriate modifier were present	Line item rejection
40	Component of a comprehensive procedure that would be allowed if appropriate modifier were present	Line item rejection
41	Invalid revenue code	RTP
42	Multiple medical visits on same day with same revenue code without condition code G0 (See "Rules for Medical and Procedure Visits on Same Day and for Multiple Medical Visits on Same Day")	Line item rejection

NOTE: For edit 15, the OCE edits the claim to identifiy the number of units that are clinically impossible or unreasonable for the service billed. All line atems with the same CPT/HCPCS code on the same date of service will be added together when this edit is applied.

GENERAL COVERAGE

Coverage Revision to Pneumococcal Pneumonia Vaccine

Effective for services furnished **on or after July 1, 2000,** Medicare no longer requires for coverage purposes that the PPV vaccine and its administration be ordered by a doctor of medicine or osteopathy. Therefore, a beneficiary may receive the vaccine upon request without a physician's order, and without physician supervision.

In addition, Medicare is eliminating the need to determine the person's age, health and vaccination status and to provide the person with a record of his or her vaccination. Those administering the vaccine should not require the patient to present an immunization record prior to administering the pneumococcal vaccine, nor should they feel compelled to review the patient's complete medical record if it is not available. Instead, provided that the patient is competent, it is acceptable for them to rely on the patient's verbal history to determine prior vaccination status. If the patient is uncertain about his or her vaccination history in the past five years, the vaccine should be given. However, if the patient is certain he or she was vaccinated in the last five years, the vaccine should not be given. If the patient is certain that the vaccine was given and that more than five years have passed since receipt of the previous dose, revaccination is not appropriate unless the patient is at high risk.

An initial vaccine may be administered only to persons at high risk of pneumococcal disease. Revaccination may be administered only to persons at high risk of serious pneumococcal infection and those likely to have rapid decline in pneumococcal antibody levels, provided that at least five years have passed since receipt of a previous dose of pneumococcal vaccine. ❖

20974: Osteogenic Stimulator for Fracture Healing

Effective for services performed **on or after April 1, 2000,** nonunion of long bone fractures, for both noninvasive and invasive devices, is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of two sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

Prior to **April 1, 2000,** nonunion of long bone fractures was considered to exist only after six or more months had elapsed without healing. ❖

48554: Revision to Pancreas Transplantation Coverage

The Health Care Financing Administration has revised the national coverage for pancreas transplants by correcting the ICD-9-CM code from 52.83 to 52.82. Also, since the Balance Budget Refinement Act of 1999 extended the period of coverage of immunosuppressive therapy following a Medicare covered transplant, the requirement addressing the 36-month period of entitlement has been removed from this policy coverage.

The implementation date for the ICD-9-CM revision is scheduled for **October 1, 2000**. ❖

HOSPITAL INFORMATION

Permitting Reclassification of Certain Urban Hospitals as Rural Hospital—Application Procedures

Section 401 of the Balanced Budget Refinement Act (BBRA), enacted on November 29, 1999, amended section 1886(d)(8) of the Social Security Act (the Act) to authorize reclassification of certain urban hospitals as rural if one of the conditions listed below is met. The Health Care Financing Administration (HCFA) regional offices (ROs) will evaluate applications for reclassification. This provision was effective as of January 1, 2000. Additional policy clarification will be published in a forthcoming ***Federal Register.***

Under section 1886(d)(8)(E) of the Act, as added by section 401 of BBRA, the Secretary of Health and Human Services shall treat a hospital as being located in the rural area of the state in which the hospital is located if it is a qualifying hospital. To be a qualifying hospital, the hospital must submit an application to the Secretary and satisfy one of the following criteria:

1. The hospital is located in a rural census tract of a metropolitan statistical area (as determined under the most recent modification of the Goldsmith Modification, originally published in the ***Federal Register*** on February 27, 1992 (57 FR 6725).
2. The hospital is located in an area designated by any law or regulation of such State as a rural area (or is designated by such State as a rural hospital).
3. The hospital would qualify as a rural, regional or national referral center or as a sole community hospital if the hospital is located in a rural area.

The Goldsmith Modification evolved from an outreach grant program sponsored by the Office of Rural Health Policy of the Health Resources and Services Administration in order to establish an operational definition of rural populations lacking easy geographic access to health services. A "Goldsmith area" is a rural census tract located within a large metropolitan county of at least 1,225 square miles so isolated from the metropolitan core by distance or physical features, that it is more rural than urban in character. Hospitals located in counties containing these census tracts that seek redesignation under the Goldsmith Modification may contact their RO for information on determining whether their specific census tract could qualify under this provision.

Section 401 would also enable a hospital that otherwise fulfills regulatory criteria for designation as a critical access hospital (CAH) to be treated as rural and therefore to qualify as a CAH. Similarly, section 401 of BBRA amended section 1833(t) of the Act to provide that, if a hospital is being treated as being located in a rural area under section 1886(d)(8)(E), then the hospital shall be treated as being located in a rural area for purposes of the hospital outpatient prospective payment system.

A hospital seeking redesignation under this section must apply in writing to the RO including documentation of the criteria upon which its request is based. The date of receipt by HCFA is the filing date. Within 5 business days after receiving the hospital application, the RO will send the hospital a letter acknowledging receipt and send a copy of the application to central office. The RO will review the application and forward its approval or disapproval to the hospital within 60 days from this filing date. For fiscal year (FY) 2000, if the hospital is approved for rural redesignation, the hospital will be considered as being located in the rural area of the state in which the hospital is located for all purposes (e.g., standardized rate, wage index, and disproportionate share adjustment under the inpatient prospective payment system) as of the filing date.

Effective Date

For the 60 days following issuance of this notification, a qualifying hospital will be considered to have filed its application on January 1, 2000 and therefore will be considered, as of that date, as being located in the rural area of the state in which it is located for purposes of section 1886(d) of the Act. Following this grace period, a hospital filing date is the date upon which a completed application is received at the HCFA regional office.

Further clarification of the criteria for reclassification will be forthcoming in the ***Federal Register***

This article is being published in order to establish a procedure for processing hospital applications for rural redesignation for FY 2000. The payment impacts of these changes will not be implemented until the October 2000 release of PRICER. Further instructions will be issued regarding adjustment to hospitals for payments affected by discharges that occurred prior to the release of the October 2000 PRICER.

The metro counties (OMB) in the state of Florida with 1,225 square miles or more of area containing one or more Goldsmith areas are:

Collier
Dade
Marion
Osceola
Palm Beach
Polk

Each of these counties contains one or more census tracts that qualify under the system of Rural-Urban Commuting Areas (RUCAs) in the current update of the Goldsmith Modification, as designated by the Federal Office of Rural Health Policy, Health Resources and Services Administration of the United States Department of Health and Human Services.

Permitting Reclassification of Certain Urban Hospitals as Rural Hospital (continued)

To determine whether or not a hospital is located within one of these rural census tracts, the following steps should be taken:

1. The hospital must determine whether it is located within one of the counties listed below.
2. Since only certain census tracts within these named counties qualify as Goldsmith areas, a hospital that finds its county listed must then find the tract number assigned to its specific street location by the U.S. Census Bureau. One way to accomplish this is through an interactive Web site provided by the U.S. Census Bureau: ***<http://tier2.census.gov/ctsl/ctsl.htm>***
3. The hospital should include this 4-digit census tract number in its application to HCFA regional office at:

   Department of Health and Human Services
   Health Care Financing Administration - Region IV
   61 Forsyth Street
   Atlanta, GA 30303

The hospitals below may qualify as "rural" within the Metropolitan Statistical areas (MSAs), under the Goldsmith modifications, if they meet other CAH criteria, including bed size.

Glades General Hospital	Palm Beach
Bartow Memorial Hospital	Polk
Heart Of Florida Hospital.	Polk
Polk General Hospital	Polk
Lake Wales Medical Center	Polk

The RO will utilize census tract data electronically transmitted by HCFA to determine whether the census tract in which the hospital is located is situated in a "Goldsmith area." ❖

Third party Web sites. *This document contains references to sites operated by third parties. Such references are provided for your convenience only. BCBSF and/or FCSO do not control such sites, and are not responsible for their content. The inclusion of these references within this document does not suggest any endorsement of the material on such sites or any association with their operators.*

OUTPATIENT HOSPITAL SERVICES

Hospital Outpatient Radiology Service Fee Schedule

The Radiology Fee Schedule for calendar year (CY) 2000 that provides an annual update of new HCFA Common Procedure Coding System (HCPCS) codes and their corresponding blended payment rates will not be released this year. Based on the planned implementation date of July 1, 2000, for the Outpatient Prospective Payment System (OPPS), payment for radiology services assigned a new CPT/HCPCS code for CY 2000 will be reimbursed on a reasonable cost basis.

Note: Codes 93727 and 93741-44 should be reported under revenue code 921 with the current range of related codes. Those codes currently subject to the blended payment will continue to be paid at the blended payment amount.

All radiology services performed **on or after July 1, 2000,** will be reimbursed based on the appropriate ambulatory payment group (APG) assigned under the OPPS. ❖

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 **July 17, 2000**, and after, unless otherwise noted.

Medical Policy Table of Contents

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 compliyng 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. ❖

*Final LMRPs are available on the Florida Medicare provider World Wide Web (**www.floridamedicare.com**).*

***Third party Web sites**. Some local medical review policies contain references to sites operated by third parties. Such references are provided for your convenience only. BCBSF and/or FCSO do not control such sites, and are not responsible for their content. The inclusion of these references within this document does not suggest any endorsement of the material on such sites or any association with their operators.*

33216: Implantation of Automatic Defibrillators

Revision Overview—Revenue code 360 (General Classification) has been added to the policy.

Policy Number
33216

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Implantation of Automatic Defibrillators

AMA CPT Copyright Statement

HCFA National Coverage Policy
Coverage Issues Manual, section 35-85

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
11/15/99

Revision Effective Date
05/15/2000

Revision Ending Effective Date
05/14/2000

Policy Ending Date
N/A

LMRP Description
The implantable automatic defibrillator is an electronic device designed to detect and treat life threatening tachyarrhythmias. The device consists of a pulse generator and electrodes for sensing and defibrillating.

Indications and Limitations of Coverage and/or Medical Necessity
Effective for services performed on or after January 24, 1986 through July 1, 1991, Medicare considers the implantation of an automatic defibrillator a covered service only when used as a treatment of last resort for patients who have had a documented episode of life threatening ventricular tachyarrhythmia or cardiac arrest not associated with myocardial infarction. Patients must also be found, by electrophysiologic testing, to have an inducible tachyarrhythmia that proves unresponsive to medication or surgical therapy (or be considered unsuitable candidates for surgical therapy). It must be emphasized that unless **all** of the above-described conditions and stipulations are met in a particular case**, including the inducibility of tachyarrhythmia, etc.,** implantation of an automatic defibrillator may not be covered.

Effective for services performed on or after **July 1, 1991,** Medicare considers the implantation of an automatic defibrillator a covered service for patients who have had a documented episode of life-threatening ventricular tachyarrhythmia or cardiac arrest not associated with myocardial infarction.

Effective for services performed on or after **July 1, 1999,** Medicare considers the implantation of an automatic defibrillator a covered service for patients with the following conditions:

1. A documented episode of cardiac arrest due to ventricular fibrillation not due to a transient or reversible cause;
2. Ventricular tachyarrhythmia, either spontaneous or induced, not due to a transient or reversible cause; or,
3. Familial or inherited conditions with a high risk of life-threatening ventricular tachyarrythmias such as long QT syndrome or hypertrophic cardiomyopathy.

HCPCS Section & Benefit Category
Cardiovascular System/Surgery

Type of Bill Code
Hospital -13x
Skilled Nursing Facility - 21x

Revenue Code
360 General Classification
361 Minor Surgery

HCPCS Codes
33216 Insertion or repositioning of a transvenous electrode (15 days or more after initial insertion); single chamber (one electrode) permanent pacemaker or single chamber pacing cardioverter-defibrillator
33217 dual chamber (two electrodes) permanent pacemaker or dual chamber pacing cardioverter-defibrillator
33218 Repair of single transvenous electrode for a single chamber, permanent pacemaker or single chamber pacing cardioverter-defibrillator
33220 Repair of two transvenous electrodes for a dual chamber permanent pacemaker or dual chamber pacing cardioverter-defibrillator
33223 Revision of skin pocket for single or dual chamber pacing cardioverter-defibrillator
33240 Insertion of single or dual chamber pacing cardioverter-defibrillator pulse generator
33241 Subcutaneous removal of single or dual chamber pacing cardioverter-defibrillator pulse generator

33216: Implantation of Automatic Defibrillators (continued)

33243	Removal of single or dual chamber pacing cardioverter-defibrillator electrode(s); by thoracotomy
33244	by transvenous extraction
33245	Insertion of epicardial single or dual chamber pacing cardioverter-defibrillator electrodes by thoracotomy;
33246	with insertion of pulse generator
33249	Insertion or repositioning of electrode lead(s) for single or dual chamber pacing cardioverter-defibrillator and insertion of pulse generator

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

425.1	Hypertrophic obstructive cardiomyopathy
425.4	Other primary cardiomyopathies
427.1	Paroxysmal ventricular tachycardia
427.5	Cardiac arrest
794.31	Abnormal electrocardiogram [ECG][EKG] (long QT syndrome)

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 services 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 operative report.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information

N/A

Advisory Committee Notes

N/A

Start Date of Comment Period

N/A

Start Date of Notice Period

06/01/2000

Revision History

Revision Number:	2
Revised Effective Date:	5/15/2000
Start Date of Comment Period:	N/A
Start Date of Notice Period:	06/01/2000 *June/July 2000 Bulletin*
Explanation of Revision:	The implantation of a defibrillator/pacemaker may be considered a major surgery in certain circumstances and therefore a revenue code revision was necessary.
Start Date of Comment Period:	N/A
Start Date of Notice Period:	12/01/1999 *Dec 1999 Special Issue Bulletin*
Original Effective Date:	11/15/1999
Revision Date/Number:	01/01/2000 (2000 HCPCS)
Start Date of Comment Period:	07/06/1999
Start Date of Notice Period:	10/01/1999 *Oct/Nov 1999 Bulletin*
Original Effective Date:	11/15/1999 ❖

53850: Prostate Treatments

Revision Overview—The " Indications and Limitations of Coverage" section has been revised to remove the post void residual ciriteria for patients undergoing TUMT.

Policy Number
A53850

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Prostate Treatments

AMA CPT Copyright Statement

HCFA National Coverage Policy
N/A

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
01/21/1999

Revision Effective Date
06/01/2000

Revision Ending Effective Date
05/31/2000

Policy Ending Date
N/A

LMRP Description
The prostate gland is located below the internal urethral orifice, behind the symphysis pubis and close to the rectal wall. The gland averages 4 cm in width at its base, 3 cm from top to bottom, 2 cm from front to back, and 20 g in weight.

Clinically, the prostate gland is important because of its affinity for congestive, inflammatory, hyperplastic, and malignant diseases. Since the prostate gland is close to the rectal wall, it is easily palpable by rectal examination, and this makes diagnosis of problems at an early stage possible. Because of the anatomic relationship of the prostate gland to the urethra, most prostatic diseases present as urinary tract symptoms.

Benign prostatic hyperplasia (BPH), the most common benign neoplasm in the aging human male, has a high prevalence that increases progressively with age. The prevalence of histologically identifiable BPH for 60 year old males is greater than 50 percent. By age 85, the prevalence is approximately 90 percent.

BPH is fundamentally a disease that causes morbidity through the urinary symptoms with which it is associated. While a minority of men undergo prostatectomy for absolute indications such as recurrent or refractory urinary retention, urinary tract infections, obstructive uropathy or severe hematuria, the majority of men undergo an operation to relieve bothersome urinary symptoms such as frequency, urgency and sensation of incomplete emptying and to improve their quality of life. For many years prostatectomy, particularly transurethral prostatectomy, has been the standard treatment for symptomatic BPH. More recently, however, a plethora of competing therapies is being used to treat patients with symptomatic BPH. These treatments include transurethral incision for the prostate, laser prostatotomy, balloon dilation, hyperthermia, insertion of prostatic stents, a-adrenergic blocking drugs and hormonal therapy. In addition, a "watchful waiting" approach can be followed.

This policy addresses two treatment options for BPH: Transurethral Microwave Thermotherapy (TUMT), and Transurethral Radiofrequency Thermotherapy.

Indications and Limitations of Coverage and/or Medical Necessity

Transurethral Microwave Thermotherapy (TUMT) [53850]:

TUMT provides simultaneous microwave heating of the prostate with temperatures of 45-55 C and conductive cooling of the urethra. This treatment results in high-power microwave application deep in the lateral lobes, leading to irreversible cell damage of prostatic tissue without damaging the urethra. TUMT effectively maintains temperatures in the urethra sphincter, and rectum at physiologically safe temperatures while targeting heat deep within the prostate transition zone. This is accomplished by combining the use of a water-cooled catheter with microwave radiation to the prostate lobes.

The treatment of symptomatic BPH with microwave thermotherapy is indicated and covered when the treatment is performed using an FDA device approved for this specific indication and the patient meets the following criteria:

- Prostatic lengths between 30-50 mm as determined by ultrasound;
- American Urology Association (AUA) symptom greater than or equal to 9 or Madsen symptom index greater than 8;
- Free peak uroflow rate (PFR) less than 15 cc/sec with a voided volume greater than or equal to 150 cc.

Contraindications

1. Peripheral arterial disease with intermittent claudication or Leriches syndrome (e.g., claudication of the buttocks and perineum).
2. Clinical or histological evidence of prostatic cancer or bladder cancer.
3. Severe urethral stricture preventing catheterization.
4. Presence of an active cardiac pacemaker, an implantable defibrillator, or a metallic implant in the region of the hip or pelvis.

53850: Prostate Treatments (continued)

Note: The use of the device must be prescribed and administered under the direct supervision of a qualified and trained physician, after appropriate urologic evaluation of the patient. The treating physician should be present at all times during the treatment.

Transurethral Radiofrequency Thermotherapy [53852]: Thermotherapy for BPH is based on the principle that heating the adenoma (greater than 45°) causes necrosis of obstructing tissue and leads to relief of prostatic obstruction. Transurethral Radiofrequency Thermotherapy uses radiofrequency (RF) energy (460-490kHz) for prostatic heating. Normally, the RF signal that is generated is carried into the prostate via needles. Thermal energy is generated through inductive heating of water molecules and by friction. The amount of heat energy produced and the subsequent thermal effect are determined by the amount of the tissue contact (length of the needle) and by the wattage energy. These physical properties allow RF energy to achieve: target tissue ablation; precision tissue ablation allowing for the preservation of adjacent tissues and organs; and customized tissue ablation.

The treatment of BPH with radiofrequency thermotherapy is indicated and covered when the treatment is performed using an FDA device approved for this specific indication and the patient meets the following criteria:

- Diagnosis of symptomatic BPH with duration of symptoms greater than 3 months;
- American Urology Association (AUA) symptom score value greater than or equal to 13;
- Peak urine flow rate (Qmax) less than 15cc/sec on a voided volume of greater than 125cc;
- Prostate size greater than 15 grams; and
- Post void residual (PVR) less than 350cc.

Contraindications

1. Active Urinary Tract Infection
2. Prostate or bladder malignancy
3. Prominent median lobe BPH
4. Neurogenic bladder
5. Previous prostate surgery

Note: The use of the device must be prescribed and administered under the direct supervision of a qualified and trained physician, after appropriate urologic evaluation of the patient. The treating physician should be present at all times during the treatment.

HCPCS Section & Benefit Category

Surgery/Urinary System

Type of Bill Code

Hospital - 13x
Skilled Nursing Facility - 21x
Rural Health Clinic - 71x

Revenue Code

361 Minor Surgery

HCPCS Codes

53850 Transurethral destruction of prostate tissue; by microwave thermotherapy
53852 by radiofrequency thermotherapy

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

600 Hyperplasia 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

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 Codes That Support Medical Necessity" section of this policy.

Noncovered Diagnosis

N/A

Coding Guidelines

N/A

Documentation Requirements

Medical records maintained in the patient's file must document the patient's prostatic length and/or size, symptoms, AUA symptoms or Madsen symptom index, and the peak flow rate. For patients undergoing radiofrequency thermotherapy, the patient's post void residual must also be documented. In addition, a description of the thermotherapy procedure must be documented. This information is usually found in the office/progress notes, history and physical, and/or procedure note.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information

Baba, S., Nakamura, K., Tachibana, M., and Murai, M. (1996). Transurethral Microwave Thermotherapy for Management of Benign Prostatic Hyperplasia: Durability of Response. *Urology,* 47(5), 664-671.

Barry, M., Fowler, F., O'Leary M., Bruskewitz, R., Holtsrewe, H., Mebust, W., and Cockett, A. (1992). The American Urological Association Symptom Index for Benign Prostatic Hyperplasia. *The Journal of Urology,* 148, 1549-1557.

BCBSF Technology Assessment: Microwave Thermotherapy and Hyperthermia for Treatment of Benign Prostatic Hypertrophy and Prostatic Carcinoma.

BCA Technology Assessment: Transurethral Microwave Thermotherapy for Benign Prostatic Hyperplasia.

Blute, M. and deWildt, M. (1996). Transurethral Microwave Thermotherapy for BPH. *Contemporary Urology, October 1996,* Vol 8, (10).

53850: Prostate Treatments (continued)

Bruskewitz, R., Issa, M., Roehrborn, C., Naslund, M., Perez-Marrero, R., Shumaker, B., and Oesterling, J. (1998). A prospective, randomized one year clinical trial comparing Transurethral Needle Ablation to Transurethral resection of the prostate for the treatment of symptomatic benign prostatic hyperplasia. *The Journal of Urology,* 159: 1588-1594.

Campo, B., Bergamaschi, F., Corrada, P., and Ordesi, G. (1997). Transurethral Needle Ablation (TUNA™) of the prostate: a clinical and urodynamic evaluation. *Urology,* 49, 847-850.

Department of Heath and Human Services, Center for Devices and Radiological Health of the Food and Drug Administration. Pre-market Approval and Summary of Safety and Effectiveness Data: Prostatron. May 3, 1996.

EDAP Technomed, Inc. (1996). Prostatron, Thermotherapy Compendium, Significant Articles 1991-1995.

EDAP Technomed, Inc. (1996). Transurethral Microwave Thermotherapy, Prostatron. Technology Assessment and Clinical Utility.

Issa, M., Myrick, S., & Symbas, N. (1998). The TUNA Procedure for BPH: Review of the Technology. *Infections in Urology,* July/August, 104-110.

Issa, M., Myrick, S., & Symbas, N. (1998). The TUNA Procedure for BPH: Basic Procedure and Clinical Results. *Infections in Urology*, September/October, 148-154.

Issa, M., and Oesterling, J. (1996). Transurethral needle ablation (TUNA™): an overview of radiofrequency thermal therapy for the treatment of benign prostatic hyperplasia. *Current Opinion in Urology,* 6, 20-27.

Larson, T., Blute, M., Bruskewitz, R., Mayer, R., Ugarte, R., and Utz, W. (1998). A high-efficiency microwave thermoablation system for the treatment of benign prostatic hyperplasia: results of a randomized, sham-controlled, prospective, double-blind, multicenter clinical trial. *Urology,* 51 (5), 731-742.

Millard, R., Harewood, L., and Tamaddon, K. (1996). A study of the efficacy and safety of Transurethral Needle Ablation (TUNA) treatment for benign prostatic hyperplasia. *Neurology and Urodynamics,* 15, 619-629.

Naslund, M. (1997). Transurethral Needle Ablation of the Prostate. *Urology,* 50 (2), 167-172.

Phipps, W., Long, B., and Woods, N. (1983). Medical-Surgical Nursing. St. Louis: The C.V. Mosby Co.

Ramon, J., Lynch, T., Eardley, I., Ekmans, P., Frick, J., Jugwirth, A., Pillai, M., Wiklund, P., Goldwasser, B., and Fitzpatrick, J. (1997). Transurethral needle ablation of the prostate for the treatment of benign prostatic hyperplasia: a collaborative multicentre study. *British Journal of Urology,* 80, 128-135.

Ramsey, E., Miller, P., and Parsons, K. (1998). Transurethral microwave thermotherapy in the treatment of benign prostatic hyperplasia: results obtained with the Urologix T3 device. *World J. Urology*, 16, 96-101.

Rosario, D., Woo, H., Potts, K., Cutinha, P., Hastie, K., and Chapple, C. (1997). Safety and efficacy of transurethral needle ablation of the prostate for symptomatic outlet obstruction. *British Journal of Urology,* 80, 579-586.

Roehrborn, C., Issa, M., Bruskewitz, R., Naslund, M., Oesterling, J., Perez-Marrero, R., Shumaker, B., and Narayan, P. (1998). Transurethral needle ablation for benign prostatic hyperplasia: 12 month results of a prospective, multicenter U.S. study. *Urology*, 51 (3), 415-421.

Rosetti, J., Wildt, M., Alivizatos, G., Froeling, F., and Debruyne, F. (1994). Transurethral Microwave Thermotherapy (TUMT) in benign prostatic hyperplasia: Placebo versus TUMT. *Urology,* 44 (1), 58-62.

Schulman, C., and Zlotta, A. (1997). Transurethral Needle Ablation (TUNA™) of the prostate: Clinical experience with two years follow-up in patients with benign prostatic hyperplasia (BPH). Abstract #380, *Journal of Urology*.

Schulman, C., and Zlotta, A. (1997). Transurethral Needle Ablation (TUNA™) of the prostatic clinical experience with three year follow-up in benign prostatic hyperplasia (BPH). Abstract #785, *SIU Montreal.*

Steele, G., and Sleep, D. (1997). Transurethral Needle Ablation of the prostate: a urodynamic based study with two year follow-up. *The Journal of Urology,* 158, 1834-1838.

U.S. Department of Health and Human Services. (1994). Benign Prostatic Hyperplasia: Diagnosis and Treatment. Clinical Practice Guideline, No. 8, AHCPR Publication No. 94-0582.

Virdi, J., Pandit, A., and Sriram, R. (1997). Transurethral Needle ablation of the prostate: a prospective study with a two year follow-up. Abstract #227, *British Journal of Urology*.

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 the contractor's Advisory Committee, which includes representatives from the Florida Urological Society.

Start Date of Comment Period

N/A

Start Date of Notice Period

06/01/2000

Revision History

Revision Number: 2
Start Date of Comment Period: N/A
Start Date of Notice Period: 06/01/2000
June/July 2000 Bulletin
Revised Effective Date: 06/01/2000
Explanation of Revision: A re-evaluation of the patient coverage criteria for TUMT was performed and resulted in the deletion of the post void residual requirement.

Start Date of Comment Period: N/A
Start Date of Notice Period: 10/01/99 *Oct/Nov 1999 Bulletin*
Original Effective Date: 01/21/99
Revision Date/Number: 11/15/99 1
Revision history: The indications were revised to incorporate information received on another device used for TUMT.

Start Date of Comment Period: 07/17/98
Start Date of Notice Period: 12/07/98
Original Effective Date: 01/21/99 ❖

70541: Magnetic Resonance Angiography (MRA)

Revision Overview—Coverage was expanded for CPT codes 70541 and 73725. Coverage was added for CPT codes 71555 and 74185. ICD-9-CM diagnosis codes 325, 437.4 and 437.6 have been added to the diagnosis list that support medical necessity for CPT code 70541. ICD-9-CM diagnosis lists that support medical necessity have been developed for CPT codes 71555, 73725 and 74185. Revenue codes 615, 616 and 618 have been added to the Revenue Code section of the policy.

Policy Number
70541

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Magnetic Resonance Angiography (MRA)

AMA CPT Copyright Statement

HCFA National Coverage Policy
Coverage Issues Manual 50-14

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
01/21/1999

Revision Effective Date
07/17/2000

Revision Ending Effective Date
07/16/2000

Policy Ending Date
N/A

LMRP Description
Magnetic Resonance Angiography (MRA) is an application of magnetic resonance (MR) imaging that provides visualization of blood flow, as well as images of normal and diseased blood vessels. MRA techniques are typically noninvasive because they do not require the use of contrast media. While contrast media may sometimes be used to enhance the images obtained in MRA, the use of these agents is not necessary. As a result, MRA is an imaging alternative for patients who cannot tolerate contrast media.

Indications and Limitations of Coverage and/or Medical Necessity
Although MRA appears to be a rapidly developing technology, the clinical safety and effectiveness of this procedure for all anatomical regions has not been proven. As a result Medicare will provide coverage on a limited basis. Below are the indications for which Medicare coverage is allowed for MRA. All other uses of MRA will not be covered.

Head and Neck (for services performed before 7/1/99) (Procedure code 70541)

Medicare will provide coverage for the evaluation of the carotid vessels in the head and neck when all of the following conditions are met:

- For a patient who has a positive ultrasonography; and
- When performed on patients with symptoms associated with carotid stenosis for which surgery may be found to be appropriate based on the results of these tests.

It should be noted that physicians may choose either contrast angiography (CA) or MRA as diagnostic tests **after** a positive ultrasound for their patients. MRA is not performed routinely as an adjunct to CA. CA furnished in addition to MRA might be appropriate **only** when the results from the MRA and the ultrasound are incongruent or inconclusive.

Head and Neck (for services performed on or after 7/1/99) (Procedure code 70541)

Medicare will provide coverage for the evaluation of the vessels in the head and neck when **all** of the following conditions are met:

- To evaluate the carotid arteries, the circle of Willis, the anterior, middle or posterior cerebral arteries, the vertebral or basilar arteries, or the venous sinuses; and
- Be performed on patients with conditions of the head and neck for which surgery is anticipated and may be found to be appropriate based on the MRA. These conditions include, but are not limited to, tumor, aneurysms, vascular malformations, vascular occlusion or thrombosis.

MRA and contrast angiography (CA) are not expected to be performed on the same patient for diagnostic purposes prior to the application of anticipated therapy. Only one of these tests will be covered routinely unless the physician can demonstrate the medical need to perform both tests.

Chest (Procedure code 71555)

Medicare will cover MRA of the chest for the following indications:

For the Diagnosis of Pulmonary Embolism

Medicare will consider MRA of the chest for diagnosing a suspected pulmonary embolism to be a covered service when the following criteria have been met:

70541: Magnetic Resonance Angiography (MRA) (continued)

- A patient is suspected of having a pulmonary embolism and it is contraindicated for the patient to receive intravascular iodinated contrast material.
- A patient is allergic to iodinated contrast material and would face a high risk of developing complications if they undergo pulmonary angiography or computed tomography angiography.

For Pre-operative or Post-operative Evaluation of Thoracic Aortic Dissection and Aneurysm

Medicare will consider MRA of the chest for the evaluation of thoracic aortic dissection and aneurysm to be a covered service when the following criteria are met:

- Depending on the clinical presentation, MRA may be used as an alternative to other non-invasive imaging technologies, such as transesophageal echocardiography and CT.
- Either MRA or CA may be used as a diagnostic test for thoracic aortic dissection and aneurysm, but not both tests on a routine basis.
- If both MRA and CA of the chest are used to diagnose thoracic aortic dissection and aneurysm, the physician must demonstrate the medical need for performing both tests.

Peripheral Arteries of Lower Extremities (Procedure code 73725)

Studies have proven that MRA of peripheral arteries is useful in determining the presence and extent of peripheral vascular disease in lower extremities.

Effective May 1, 1997, Medicare will consider MRA of the arteries of the lower extremities to be a covered service only when the following criteria have been met:

Either MRA or CA can be performed to evaluate peripheral arteries of the lower extremities. However, both MRA and CA may be useful in some cases, such as:

- A patient has had CA and this test was unable to identify a viable run-off for bypass. When exploratory surgery is not believed to be a reasonable medical course of action for this patient, MRA may be performed to identify the viable runoff vessel.
- A patient has had MRA, but the results are inconclusive.

Abdomen (Procedure code 74185)

Studies have proven that MRA is considered a reliable diagnostic tool for the preoperative evaluation of patients who will undergo elective abdominal aortic aneurysm (AAA) repair. In addition, scientific data has revealed that MRA is considered comparable to CA in determining the extent of AAA, as well as evaluation of aortoilliac occlusion disease and renal artery pathology that may be necessary in the surgical planning for AAA repair. These studies also reveal that MRA could provide a net benefit to the patient. If preoperative angiography is not necessary then patients are not exposed to the risks associated with invasive procedures, contrast media, end-organ damage or arterial injury. As with coverage of MRA for other anatomical sites, Medicare will provide coverage for either MRA or CA and not both tests on a routine basis.

The physician may choose between CA or MRA for preoperative imaging, after other tests such as computed tomography (CT) or ultrasound have been used to diagnose AAA and evaluate aneurysm size over time. However, both MRA and CA may be used when the physician can demonstrate the medical need for both tests to be performed, such as when a follow-up CA is necessary to clarify renal artery pathology, which might not be diagnosed definitively by an initial MRA.

HCPCS Section & Benefit Category

Radiology

Type of Bill Code

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

Revenue Code

320 Radiology Diagnostic, General Classification
615 Magnetic Resonance Angiography, Head and Neck
616 Magnetic Resonance Angiography, Lower Extremities
618 Magnetic Resonance Angiography, Other

HCPCS Codes

70541	Magnetic resonance angiography, head and/ or neck, with or without contrast material(s)
71555	Magnetic resonance angiography, chest, (excluding myocardium), with or without contrast material(s)
73725	Magnetic resonance angiography, lower extremity, with or without contrast material(s)
74185	Magnetic resonance angiography, abdomen, with or without contrast material(s)

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

Head and Neck (procedure code 70541)

094.89	Other specified neurosyphilis
191.0-191.9	Malignant neoplasm of brain
192.1	Malignant neoplasm of cerebral meninges
194.5	Malignant neoplasm of carotid body
227.5	Benign neoplasm of carotid body
228.02	Hemangioma, any site, of intracranial structures
239.6	Neoplasms of unspecified nature of brain
325	Phlebitis and thrombophlebitis of intracranial venous sinuses
430	Subarachnoid hemorrhage
431	Intracerebral hemorrhage
432.1	Subdural hemorrhage
432.9	Unspecified intracranial hemorrhage
433.00-433.91	Occlusion and stenosis of precerebral arteries
434.00-434.91	Occlusion of cerebral arteries
435.0-435.9	Transient cerebral ischemia
436	Acute, but ill-defined, cerebrovascular disease
437.3	Cerebral aneurysm, nonruptured
437.4	Cerebral arteritis

70541: Magnetic Resonance Angiography (MRA) (continued)

437.6	Nonpyogenic thrombosis of intracranial venous sinus
442.81	Other aneurysm of artery of neck
446.5	Giant cell arteritis
747.81	Anomalies of cerebrovascular system
900.00-900.9	Injury to blood vessels of head and neck

Chest (procedure code 71555)

415.0	Acute cor pulmonale
415.11-415.19	Pulmonary embolism and infarction
416.0	Primary pulmonary hypertension
416.8	Other chronic pulmonary heart diseases
416.9	Chronic pulmonary heart disease, unspecified
441.01	Thoracic dissection of aorta
441.03	Thoracoabdominal dissection of aorta
441.2	Thoracic aneurysm without mention of rupture
441.7	Thoracoabdominal aneurysm, without mention of rupture
786.00	Respiratory abnormality, unspecified
786.05	Shortness of breath
786.06	Tachypnea
786.3	Hemoptysis

Peripheral Arteries of Lower Extremities (procedure code 73725)

250.70-250.73	Diabetes with peripheral circulatory disorders
440.20-440.29	Atherosclerosis of native arteries of the extremities
440.30-440.32	Atherosclerosis of bypass graft of extremities
442.3	Other aneurysm of artery of lower extremity
443.1	Thromboangiitis obliterans [Buerger's disease]
443.81	Peripheral angiopathy in diseases classified elsewhere
443.89	Other specified peripheral vascular diseases
443.9	Peripheral vascular disease, unspecified
444.22	Arterial embolism and thrombosis of the arteries of the lower extremity

Abdomen (procedure code 74185)

441.02	Abdominal dissection of aorta
441.03	Thorocoabdominal dissection of aorta
441.4	Abdominal aneurysm without mention of rupture
441.7	Thoracoabdominal aneurysm, without mention rupture
441.9	Aortic aneurysm of unspecified site without mention of rupture

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.

HCFA considers the following codes to be noncovered by Medicare:

72159	Magnetic resonance angiography, spinal canal and contents, with or without contrast material(s)
72198	Magnetic resonance angiography, pelvis, with or without contrast material(s)
73225	Magnetic resonance angiography, upper extremity, with or without contrast material(s)

Noncovered ICD-9-CM Code(s)

N/A

Noncovered Diagnosis

N/A

Coding Guidelines

N/A

Documentation Requirements

Documentation maintained in the patient's file must indicate the medical necessity of this procedure. All coverage criteria listed in the "Indications and Limitations of Coverage and/or Medical Necessity" section must be documented in the patient's medical record, as well as a hard copy of the procedure results and made available to Medicare upon request. This information can generally be found in the office/progress notes, history and physical, and/or operative notes.

If the provider of the magnetic resonance angiography study 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. The physician must state the reason for the MRA in his order for the test.

MRA and contrast angiography (CA) are not expected to be performed on the same patient for diagnostic purposes prior to the application of anticipated therapy. Only one of these tests will be covered routinely unless the physician can demonstrate the medical need to perform both tests. The medical record must clearly document the medical necessity of performing both tests.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information

Edelman, R. "MR Angiography: Present and Future", *AJR,* 161:1-11, 1993

Handelsman, H. "Magnetic Resonance Angiography (MRA) for the Determination of Blood Flow and Blood Vessel Morphology."

70541: Magnetic Resonance Angiography (MRA) (continued)

Tierney, L.M., Jr., McPhee, S.J., & Papadakis, M.A. (1998). Current: Medical Diagnosis & Treatment (37th ed.). CT: Appleton & Lange.

Wentz, K. et. al., "Intracranial Vertebrobasilar System: MR Angiography", Radiology, 1 190: 105-110, 1994.

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 the contractor's Advisory Committee, which includes representatives from the Florida Radiological Society, Inc.

Start Date of Comment Period

08/23/99

Start Date of Notice Period

06/01/2000

Revision History

Revision Number: 3
Start Date of Comment Period: 08/23/1999
Start Date of Notice Period: 06/01/2000
June/July 2000 Bulletin
Revised Effective Date: 07/17/2000
Explanation of Revision: Covered ICD-9-CM codes developed for procedure codes 71555, 73725, and 74185

Revision Number: 2
Start Date of Comment Period: N/A
Start Date of Notice Period: 08/01/1999
Aug/Sept 1999 Bulletin
Revised Effective Date: 07/01/1999
Explanation of Revision: ICD-9-CM codes added based on input from CAC member regarding Coverage Issues Manual 50-14

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: 07/01/1999
Explanation of Revision: Original policy struck out. This revision was made due to expanded coverage of national policy as per Coverage Issues Manual 50-14

Revision Number: Original
Start Date of Comment Period: 08/05/1998
Start Date of Notice Period: 12/07/1998
G-354 Bulletin
Original Effective Date: 01/21/1999 ❖

82108: Aluminum

Policy Number
82108

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Aluminum

AMA CPT Copyright Statement

HCFA National Coverage Policy
Coverage Issues Manual 50-17
Intermediary Manual 3167.3
Hospital Manual E204
Renal Dialysis Facility Manual 207

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
07/17/2000

Revision Effective Date
N/A

Revision Ending Effective Date
N/A

Policy Ending Date
N/A

LMRP Description
Aluminum is the third most prevalent element in the earth's crust. The gastrointestinal tract is virtually impervious to aluminum, absorption being around 2 percent. Factors regulating aluminum's crossing of the blood-brain barrier are not well understood. Serum aluminum correlates with encephalopathy. Aluminum toxicity has been recognized in many settings where exposure is heavy or prolonged and/or where renal function is limited.

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will consider serum aluminum testing medically necessary for signs and symptoms of aluminum toxicity associated with:

- Infants on parenteral fluids, particularly parenteral nutrition;
- burn patients through administration of intravenous albumin, particularly with coexisting renal failure;
- adult and pediatric patients with chronic renal failure who accumulate aluminum readily from medications and dialysate;
- adult parenteral nutrition patients**;**
- patients with industrial exposure; and/or
- patients with prolonged exposure to or excessive doses of such medications as antacids, salicylates, antilipemics, antiatherosclerosis medications, and antipruritics, etc.

One or more of the following signs and symptoms of aluminum toxicity must be present for aluminum testing to be considered medically necessary for the above patients:

- encephalopathy (stuttering, gait disturbance, myoclonic jerks, seizures, coma, abnormal EEG)**;**
- osteomalacia or aplastic bone disease (associated with painful spontaneous fractures, tumorous calcinosis);
- proximal myopathy**;**
- increased left ventricular mass and decreased myocardial function; and/or,
- microcytic anemia.

Serum aluminum testing is routinely covered once every three months for hemodialysis, intermittent peritoneal dialysis, continuous cycling peritoneal dialysis, and hemofiltration beneficiaries. Services performed more frequently must meet the medical necessity requirements listed above.

HCPCS Section & Benefit Category
Pathology and Laboratory/Chemistry

Type of Bill Code
Outpatient Hospital: 12x, 13x, 14x
Skilled Nursing Facility - 21x, 22x, 23x
Rural Health Clinic - 71x
End Stage Renal Disease - 72x

Revenue Code
301 Laboratory, Chemistry

HCPCS Codes
82108 Aluminum

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity

268.2	Osteomalacia, unspecified
275.49	Other disorders of calcium metabolism
280.9	Iron deficiency anemia, unspecified [Microcytic (hypochromic) anemia]
284.8	Other specified aplastic anemias [Aplasia, bone marrow (secondary)]
284.9	Aplastic anemia, unspecified [Aplasia, bone marrow (myeloid or idiopathic)]
285.1	Acute posthemorrhagic anemia [Acute microcytic anemia]
294.8	Other specified organic brain syndromes (chronic) [Encephalopathy due to dialysis]
348.3	Encephalopathy, unspecified (acute)
359.4*	Toxic myopathy (due to drugs)
428.1	Left heart failure
429.3	Cardiomegaly
585	Chronic renal failure
733.10-733.19	Pathologic fracture
965.1	Poisoning by salicylates
972.2	Poisoning by antilipemic and antiarteriosclerotic drugs

82108: Aluminum (MRA) (continued)

973.0	Poisoning by antacids and antigastric secretion drugs
976.1	Poisoning by antipruritics
976.2	Poisoning by local astringents and local detergents
976.3	Poisoning by emollients, demulcents, and protectants
985.9	Toxic effect of unspecified metal (industrial exposure)
E858.3	Accidental poisoning by agents primarily affecting cardiovascular system
E858.4	Accidental poisoning by agents primarily affecting gastrointestinal system
E858.7	Accidental poisoning by agents primarily affecting skin and mucous membrane, ophthalmological, otorhinolaryngological, and dental drugs
E935.3	Drugs, medicinal and biological substances causing adverse effects in therapeutic use, salicylates
E942.2	Drugs, medicinal and biological substances causing adverse effects in therapeutic use, antilipemic and antiarteriosclerotic drugs
E943.0	Drugs, medicinal and biological substances causing adverse effects in therapeutic use, antacids and antigastric secretion drugs
E946.2	Drugs, medicinal and biological substances causing adverse effects in therapeutic use, local astringents and local detergents
E946.3	Drugs, medicinal and biological substances causing adverse effects in therapeutic use, emollients, demulcents, and protectants
E950.0	Suicide and self-inflicted poisoning by analgesics, antipyretics, and antirheumatics
E950.4	Suicide and self-inflicted poisoning by other specified drugs and medicinal substances

*This code must be accompanied by the appropriate E diagnosis code to identify the toxic agent

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

When billing for aluminum, use revenue code 301. In addition to the revenue code, the following Types of Bill must bill HCPCS code: Hospital – 12x, 13x, 14x; Skilled Nursing Facility - 23x; Rural Health Clinic - 71x; and End Stage Renal Disease - 72x.

When billing for the indication of toxic myopathy due to drug use, both ICD-9-CM code 359.4 and the appropriate E code identifying the toxic agent must be submitted on the claim form.

Serum aluminum testing is a separately billable ESRD lab service not included in the ESRD composite rate. Serum aluminum tests performed more frequently than once every three months for specified ESRD beneficiaries are only covered if medically justified. A diagnosis of ESRD alone is not sufficient medical evidence for coverage.

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 records.

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

According to Medicare's national coverage policy, serum aluminum testing is routinely covered once every three months for hemodialysis, intermittent peritoneal dialysis, continuous cycling peritoneal dialysis, and hemofiltration beneficiaries.

Other Comments

None

Sources of Information

Jacobs, D., DeMott, W., Finley, P., Horvat, R., Kasten, B., and Tilzer, L. (eds.). *Laboratory Test Handbook* (3rd ed.). 1994. Hudson Cleveland: Lexi-Comp, Inc.

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 the contractor's Advisory Committee, which includes representatives from various specialty societies.

Start Date of Comment Period

05/28/1998

Start Date of Notice Period

06/01/2000

Revision History

Revision Number:	Original
Start Date of Comment Period:	05/28/1998
Start Date of Notice Period:	06/01/2000
	June/July 2000 Bulletin
Original Effective Date:	07/17/2000 ❖

83735: Magnesium

Policy Number
83735

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Magnesium

AMA CPT Copyright Statement

HCFA National Coverage Policy
Medicare Intermediary Manual, Section 3171.2
Renal Dialysis Facility Manual, Sections 240.3

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
07/17/2000

Revision Effective Date
N/A

Revision Ending Effective Date
N/A

Policy Ending Date
N/A

LMRP Description
Magnesium is an important activator ion, participating in the function of many enzymes involved in phosphate transfer reactions. Most of the magnesium found within the body exists intracellularly, and since most of it is bound to adenosine triphosphate, this electrolyte is critical in nearly all metabolic processes and most organ functions. Magnesium exerts physiologic effects on the nervous system resembling those of calcium, acting directly upon the myoneural junction. Furthermore, magnesium acts as a cofactor that modifies the activity of many enzymes. Carbohydrate, protein, and nucleic acid metabolism depend on magnesium. Excretion of magnesium is via the kidney, and altered concentration of magnesium in the plasma usually provokes an associated alteration of calcium and potassium. The normal plasma concentration of magnesium is 1.5-2.5 meq/L, with about one-third bound to protein and two-thirds existing as free cation.

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will consider magnesium testing to be medically necessary under any of the following circumstances:

- In the presence of signs or symptoms of hypomagnesemia, which include weakness, muscle cramping, irritability, tetany, electrocardiographic changes, delirium, anorexia, nausea, and vomiting. Conditions which can produce these signs and symptoms include, but are not limited to the following:
  - -cardiac arrhythmias
  - -malabsorption syndromes
  - -alcoholism
  - -parenteral alimentation with inadequate magnesium content
  - -diarrhea
  - -diabetic ketoacidosis
  - -diuretic therapy
  - -hyperaldosteronism
  - -hypoparathyroidism
  - -hyperthyroidism
  - -chronic renal disease
  - -prolonged I.V. therapy
  - -prolonged nasogastric suction
  - -cis-platinum therapy
  - -aminoglycoside toxicity
  - -amphotericin toxicity
- In the presence of signs or symptoms of hypermagnesemia, including muscle weakness, mental obtundation, and confusion. Weakness and a fall in blood pressure are evident on examination. There may be respiratory muscle paralysis or cardiac arrest. Conditions which can produce these signs and symptoms include, but are not limited to the following:
  - -adrenal insufficiency
  - -renal insufficiency
  - -ingestion of magnesium-containing drugs, such as antacids and laxatives
  - -rhabdomyolysis

HCPCS Section & Benefit Category
Pathology and Laboratory/Chemistry

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

Revenue Code
301 Laboratory, Chemistry

HCPCS Codes
83735 Magnesium

Not Otherwise Classified Codes (NOC)
N/A

83735: Magnesium (continued)

ICD-9-CM Codes that Support Medical Necessity

242.00-242.91	Thyrotoxicosis, with or without goiter
250.10-250.13	Diabetes with ketoacidosis
250.20-250.23	Diabetes with hyperosmolarity
250.30-250.33	Diabetes with other coma
250.40-250.43	Diabetes with renal manifestations
250.50-250.53	Diabetes with ophthalmic manifestations
250.60-250.63	Diabetes with neurological manifestations
250.70-250.73	Diabetes with peripheral circulatory disorders
250.80-250.83	Diabetes with other specified manifestations
252.0	Hyperparathyroidism
252.1	Hypoparathyroidism
252.8	Other specified disorders of parathyroid gland
253.6	Other disorders of neurohypophysis (Syndrome of inappropriate antiduretic hormone, [ADH])
255.1	Hyperaldosteronism
255.4	Corticoadrenal insufficiency
259.3	Ectopic hormone secretion, not elsewhere classified
260	Kwashiorkor
261	Nutritional marasmus
262	Other severe, protein-calorie malnutrition
263.0	Malnutrition of moderate degree
263.8	Other protein-calorie malnutrition
275.2	Disorders of magnesium metabolism
275.40-275.49	Disorders of calcium metabolism
276.2	Acidosis
276.4	Mixed acid-base balance disorder
276.5	Volume depletion
276.7	Hyperpotassemia
276.8	Hypopotassemia
293.0-293.1	Acute and subacute delirium
303.90-303.93	Other and unspecified alcohol dependence
305.00-305.03	Alcohol abuse
307.1	Anorexia nervosa
307.51	Bulimia
307.52	Pica
333.2	Myoclonus
333.3	Tics of organic origin
410.00-410.92	Acute myocardial infarction
424.0	Mitral valve disorders (MVP)
427.0-427.89	Cardiac dysrhythmias
428.0	Congestive heart failure
458.0-458.8	Hypotension
536.2	Persistent vomiting
577.0-577.9	Diseases of pancreas
579.3	Other and unspecified postsurgical malabsorption
579.8	Other specified intestinal malabsorption
584.5-584.9	Acute renal failure
585	Chronic renal failure
588.8	Other specified disorders resulting from impaired renal function
593.81	Vascular disorders of kidney
643.10-643.83	Excessive vomiting in pregnancy
646.80-646.84	Other specified complications of pregnancy
728.89	Other disorders of muscle, ligament, and fascia (rhabdomyolysis)
763.81-763.89	Other specified complications of labor and delivery affecting fetus or newborn
780.01	Coma
780.02	Transient alteration of awareness
780.09	Other alteration of consciousness
780.2	Syncope and collapse
780.31-780.39	Convulsions
781.0	Abnormal involuntary movements
781.7	Tetany
783.0	Anorexia
785.0	Tachycardia, unspecified
785.50-785.59	Shock without mention of trauma
787.01-787.03	Nausea and vomiting
787.91	Diarrhea
790.6	Other abnormal blood chemistry
794.31	Abnormal electrocardiogram [ECG] [EKG]
794.4	Nonspecific abnormal results of function studies, kidney
796.1	Abnormal reflex
799.4	Cachexia
941.00-949.5	Burns
958.4	Traumatic shock
995.2	Unspecified adverse effect of drug, medicinal and biological substance (amphotericin B and digitalis)
997.1	Cardiac complications
998.0	Postoperative shock
V42.0	Organ or tissue replaced by transplant, kidney
V42.7	Organ or tissue replaced by transplant, liver
V56.0	Extracorporeal dialysis
V56.8	Other dialysis
V58.1	Encounter for other and unspecified procedures and aftercare, chemotherapy (Cis-platinum)
V58.69	Long term (current) use of other medications (high risk)

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

Serum Magnesium testing for reasons other than those listed in the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy.

83735: Magnesium (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

Reimbursement for this test is included in the composite rate for End Stage Renal Disease (ESRD) patients.

Documentation Requirements

Medical record documentation (i.e., office notes/ 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 records.

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 study. The physician must state the clinical indication/ medical necessity for the study in the order for the test.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information

Berkow, R., Fletcher, A.J., Bondy, P.K., Dilts, P.V., Jr., Douglas, R.G., Jr., Drossman, D.A. et al (Eds). (1992). *The Merck Manual* (16th ed). Rachway, N.J.: Merck Research Laboratories.

Douban, S., Brodsky, M., Whang, D., Whang, R. (1996). Significance of magnesium in congestive heart failure. *American Heart Journal,* 132, 664-671.

Jacobs, D.S., Demott, W.R., Finley, P.R., et al (Eds). (1994). *Laboratory Test Handbook.* Hudson, Oh.:Lexi-Comp, Inc.

Knochel, J.P. (1998). Disorders of magnesium metabolism. K.J. Isselbacher, E. Braunwald, J. Wilson, J.B. Martin, A.S. Fauci, & D.L. Kasper (Vol. Eds.), *Harrision's Principles of Internal Medicine*: Vol. 1 (14th ed., pp. 2263-2266). New York: McGraw-Hill.

Lichodziejewska, B., Ktos, J., Rezler, J., Grudzka, K., Dluzniewska, M., Budaj, A., Ceremuzynski, L. (1997). Clinical symptoms of mitral valve prolaspe are related to hypomagnesemia and attenuated by magnesium supplementation. *American Journal of Cardiology,* 79, 768-772.

Pagana, K.D. and Pagana, T.J. (1995). *Mosby's Diagnostic and Laboratory Test Reference.* St. Louis: Mosby-Year Book, Inc.

Qureshi, T.I. & Melonakos, T.K. (1996). Acute hypermagnesemia after laxative use. *Annals of Emergency Medicine, 28* (5), 552-555.

Tierney, L.M., Jr., McPhee, S.J., and Papadakis, M.A. (Eds). (1997*). Current Medical Diagnosis and Treatment.* Stamford, CT.: 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 the contractor's Advisory Committee, which includes representatives from numerous societies.

Start Date of Comment Period

07/01/1998

Start Date of Notice Period

06/01/2000

Revision History

Revision Number:	Original
Start Date of Comment Period:	07/01/1998
Start Date of Notice Period:	06/01/2000
	June/July 2000 Bulletin
Original Effective Date:	07/17/2000 ❖

87621: Human Papillomavirus DNA Assay, Amplified Probe Technique

Policy Number
87621

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Human Papillomavirus DNA Assay, Amplified Probe Technique

AMA CPT Copyright Statement

HCFA National Coverage Policy
N/A

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
07/17/2000

Revision Effective Date
N/A

Revision Ending Effective Date
N/A

Policy Ending Date
N/A

LMRP Description
The human papillomavirus (HPV) DNA Assay is a signal amplified solution hybridization antibody capture assay used to qualitatively detect the presence of eighteen HPV types. HPV viruses are classified into low risk types which are principally associated with low grade squamous intraepithelial lesions, (LGSIL) and high risk types which are typically associated with squamous intraepithelial lesions of all grades, especially high grade squamous intraepithelial lesions (HGSIL)and invasive cancer of the cervix.

HPV infection in the female genital tract is recognized by the majority of health care providers as the major risk factor for development of cervical cancer. It is estimated that infection with high risk HPV types is responsible for 95 percent of cases of carcinoma of the cervix. However, the most common abnormal pap test result is one of atypical squamous cells of undetermined significance (ASCUS). The management of these equivocal pap test abnormalities is a complex clinical challenge. Each year an estimated two to three million women in the United States have an equivocal ASCUS Pap result. On follow-up, approximately 10 percent of these women will have pre-cancerous high-grade squamous intraepithelial lesions, with some of those having invasive carcinoma. Immediate referral of all ASCUS cases to colposcopy would provide the highest rate of detection. However, due to the frequency of ASCUS and that approximately 90 percent will turn out to have a benign reactive process, this may not be practical. Current literature supports utilization of the HPV DNA Assay as an additional piece of valuable information to make treatment decisions in patients with abnormal Pap smears (ASCUS or above). For example, patients with an ASCUS Pap result and "HPV negative" (absence of detectable HPV or only low risk HPV detected) could safely be followed up with repeat testing. Those patients with high risk HPV positive test results are expected to give the highest yield of clinically significant cervical lesions on colposcopy.

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will consider the use of HPV DNA Assay testing to be medically reasonable and necessary in the following circumstance:

- To assist in the treatment decision in the patient that has had an abnormal Pap result of ASCUS or above (e.g., AGUS, LGSIL and HGSIL)

HCPCS Section & Benefit Category
Pathology and Laboratory/Microbiology

Type of Bill Code
Hospital - 12x, 13x, 14x
Skilled Nursing Facility - 21x, 22x, 23x
Rural Health Clinic - 71x

Revenue Code
636 Bacteriology and Microbiology

HCPCS Codes
87621 Infectious agent detection by nucleic acid (DNA or RNA); papillomavirus, human, amplified probe technique

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity
795.0 Nonspecific abnormal Papanicolaou smear of cervix

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

87621: Human Papillomavirus DNA Assay, Amplified Probe Technique (continued)

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.

Claims received for HPV DNA testing as a screening test, in the absence of a previous or concurrent abnormal Pap smear of ASCUS or above, 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

N/A

Documentation Requirements

Medical record documentation maintained by the performing physician must clearly indicate the medical necessity of the service being billed. Documentation must include a previous or concurrent abnormal pap result (ASCUS or above). 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.

If the provider of the HPV DNA testing 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 test. The physician must state the reason for the HPV DNA testing in his order for the test.

Utilization Guidelines

N/A

Other Comments

If a liquid based Pap test is utilized, the HPV DNA test can be performed on the original pap specimen up to 21 days after initial collection. This approach would prevent the patient from having to come in for a second visit to obtain the HPV DNA specimen. Thus, this allows for a patient management decision to be made from a single specimen on a single patient visit.

Sources of Information

American Society for Colposcopy and Cervical Pathology. (1996). ASCCP practice guideline: Management guidelines for follow-up of atypical squamous cells of undetermined significance (ASCUS). *The Colposcopist,* Winter, 1-9.

Cox, T. (1999). Evaluating the role of HPV testing for women with equivocal Papanicolaou test findings. *The Journal of the American Medical Association,* 281, 1645-1647.

Cox, T. (1998). HPV testing: Is it useful in triage of minor Pap abnormalities? *The Journal of Family Practice,* 46, 121-123.

Ferris, D., Wright, T., Litaker, M., Richart, R., Lorincz, A., Sun, X., & Woodward, L. (1998). Comparison of two tests for detecting carcinogenic HPV in women with Papanicolaou smear reports of ASCUS and LSIL. *The Journal of Family Practice,* 46 136-141.

Ferris, D., Wright, T., Litaker, M., Richart, R., Lorincz, A., Sun, X., Borgatta, L, Buck, H., Kramer, L., & Rubin, R. (1998). Triage of women with ASCUS and LSIL on Pap smear reports: Management by repeat Pap smear, HPV DNA testing, or colposcopy? *The Journal of Family Practice,* 46, 125-134.

Manos, M., Kinnety, W., Hurley, L., Sherman, M., Shieh-Ngai, J., Kurman, R., Ransley, J., Fetterman, B., Hartinger, J., McIntosh, K., Pawlick, G., & Hiatt, R. (1999). Identifying women with cervical neoplasia: using human papillomavirus DNA testing for equivocal Papanicolaou results. *The Journal of the American Medical Association,* 281, 1605-1610.

Poljak, M., Brencic, A., Seme, K., Vince, A., & Marin, I. (1999). Comparative evaluation of first and second generation Digene hybrid capture assays for detection of human papillomaviruses associated with high or intermediate risk for cervical cancer. *Journal of Clinical Microbiology,* 37, 796-797.

Reid, R., & Lorincz, A. (1996). New generation of human papillomavirus tests. In Rubin, S., and Hoskins, W. (Eds.), *Cervical cancer and preinvasive neoplasia* (pp. 27-47). Philadelphia: Lippincott-Ravin.

Richart, R. (1998). Cervical neoplasia: past, present, and future. *Contemporary OB/GYN,* 117-132.

Wallin, K., Wiklund, F., Angstrom, T., Bergamn, F., Stendahl, U., Wadell, G., Hallmans, G., & Dillner, J. (1999). Type specific persistence of human papillomavirus DNA before the development of invasive cervical cancer. *The New England Journal of Medicine*, 341, 1633-1637.

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 the contractor's Advisory Committee, which includes representatives from the Florida Society of Pathologists and the Florida Obstetrics and Gynecologic Society.

Start Date of Comment Period

02/21/2000

Start Date of Notice Period

06/01/2000

Revision History

Revision Number:	Original
Start Date of Comment Period:	02/21/2000
Start Date of Notice Period:	06/01/2000
	June/July 2000 Bulletin
Original Effective Date:	07/17/2000 ❖

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

Policy Number
93303

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

AMA CPT Copyright Statement

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

Policy Effective Date
07/17/2000

Revision Effective Date
N/A

Revision Ending Effective Date
N/A

Policy Ending Date
N/A

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 that suggest the presence of valvular heart disease (e.g., the patient has a heart murmur that 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 infraction 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.

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 Code

480 Cardiology, General Classification

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

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

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)
402.00-402.01	Malignant hypertensive heart disease
402.10-402.11	Benign hypertensive heart disease
402.90-402.91	Unspecified hypertensive heart disease
403.00-403.91	Hypertensive renal disease
404.00-404.93	Hypertensive heart and renal disease
410.00-410.92	Acute myocardial infarction
411.0	Postmyocardial infarction syndrome
411.1	Intermediate coronary syndrome
411.81	Coronary occlusion without myocardial infarction
411.89	Other acute and subacute forms of ischemic heart disease
412	Old myocardial infarction
413.0-413.9	Angina pectoris
414.00-414.05	Coronary atherosclerosis
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
423.0-423.9	Other diseases of pericardium
424.0-424.3	Other diseases of endocardium
424.90-424.99	Endocarditis, valve unspecified
425.0-425.9	Cardiomyopathy
427.0-427.5	Cardiac dysrhythmias
427.81	Sinoatrial node dysfunction
428.0-428.9	Heart failure
429.3	Cardiomegaly
429.4	Functional disturbances following cardiac surgery
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
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
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
746.2	Ebstein's anomaly
746.3	Congenital stenosis of aortic valve
746.4	Congenital insufficiency of aortic valve
746.5	Congenital mitral stenosis
746.6	Congenital mitral insufficiency
746.7	Hypoplastic left heart syndrome
746.81-746.89	Other specified anomalies of heart
746.9	Unspecified anomaly of heart
747.0	Patent ductus arteriosus
747.10-747.11	Coarctation of aorta
747.3	Anomalies of pulmonary artery
780.2	Syncope and collapse
782.3	Edema
785.2	Undiagnosed cardiac murmurs
785.3	Other abnormal heart sounds
786.02-786.09	Dyspnea and respiratory abnormalities
786.50-786.59	Chest pain
861.00-861.03	Injury to heart, without mention of open wound into thorax
861.10-861.13	Injury to heart, with open wound into thorax
963.1	Poisoning by antineoplastic and immunosuppressive drugs
996.02	Mechanical complication of cardiac device, implant, and graft due to heart valve prosthesis
996.03	Mechanical complication of cardiac device, implant, and graft due to coronary bypass graft
997.1	Cardiac complications
V42.1	Organ or tissue replaced by transplant, heart
V42.2	Organ or tissue replaced by transplant, heart valve
V43.3	Organ or tissue replaced by other means, heart valve
V67.51	Follow-up examination following completed treatment with high-risk medications, not elsewhere classified

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
402.11	Benign hypertensive heart disease with congestive heart failure
402.91	Unspecified hypertensive heart disease with congestive heart failure
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
404.11	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
404.91	Unspecified hypertensive heart and renal disease with congestive heart failure
404.93	Unspecified hypertensive heart and renal disease with congestive heart failure and renal failure
410.00-410.92	Acute myocardial infarction
411.0	Postmyocardial infarction syndrome
411.1	Intermediate coronary syndrome
411.81	Coronary occlusion without myocardial infarction
411.89	Other acute and subacute forms of ischemic heart disease
412	Old myocardial infarction
413.0-413.9	Angina pectoris
414.00	Coronary atherosclerosis of unspecified type of vessel, native or graft
414.01	Coronary atherosclerosis of native coronary artery
414.02	Coronary atherosclerosis of autologous vein bypass graft
414.03	Coronary atherosclerosis of nonautologous biological bypass graft
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
746.2	Ebstein's anomaly
746.3	Congenital stenosis of aortic valve
746.4	Congenital insufficiency of aortic valve
746.5	Congenital mitral stenosis
746.6	Congenital mitral insufficiency
746.7	Hypoplastic left heart syndrome
746.81-746.89	Other specified anomalies of heart
746.9	Unspecified anomaly of heart
747.0	Patent ductus arteriosus
747.10-747.11	Coarctation of aorta
747.3	Anomalies of pulmonary artery
780.2	Syncope and collapse
785.2	Undiagnosed cardiac murmurs
786.50-786.59	Chest pain
996.02	Mechanical complication of cardiac device, implant, and graft due to heart valve prosthesis
996.03	Mechanical complication of cardiac device, implant, and graft due to coronary bypass graft
V42.1	Organ or tissue replaced by transplant, heart
V42.2	Organ or tissue replaced by transplant, heart valve
V43.3	Organ or tissue replaced by other means, heart valve

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 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

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 the contractor's Advisory Committee, which includes representatives from numerous societies.

Start Date of Comment Period

02/21/2000

Start Date of Notice Period

06/01/2000

Revision History

Revision Number:	Original
Start Date of Comment Period:	02/21/2000
Start Date of Notice Period:	06/01/2000
	June/July 2000 Bulletin
Original Effective Date:	07/17/2000 ❖

94010: Spirometry

Revision Overview—A statement was added to the "Coding Guidelines" section of the policy indicating that effective 1/1/1997, procedure code 94150 is non-reportable for Medicare purposes.

Policy Number
94010

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Spirometry

AMA CPT Copyright Statement

HCFA National Coverage Policy
Hospital Manual, section 443

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
01/21/1999

Revision Effective Date
05/11/2000

Revision Ending Effective Date
05/10/2000

Policy Ending Date
N/A

LMRP Description
Spirometry, a component of pulmonary function tests (PFTs) consists of the performance of a set of maneuvers to detect and quantitate disorders of pulmonary ventilation and gas exchange. PFTs are interpreted with respect to predicted values for normal individuals. Predicted values are based on standard linear regression equations that use age, height, and weight in calculating normal values. Typically, a percent of predicted greater than 80 percent considered to be within normal limits. However, a change from a patient's base-line value is more likely to indicate pulmonary injury than is the traditional comparison of values measured in the patient with reference values obtained from population studies.

Spirometry involves the use of an instrument, a spirometer, to measure and record the changes in the gas volume in the lungs with time and thus ventilatory capacity and flow rate. The commonly obtained lung volumes and capacities as seen on a spirogram are: tidal volume, inspiratory reserve volume, expiratory reserve volume, residual volume, inspiratory capacity, and vital capacity.

Indications and Limitations of Coverage and/or Medical Necessity
Pulmonary Function Tests are performed to detect abnormalities in respiratory function and to determine the extent of any pulmonary abnormalities. Florida Medicare will consider PFTs to be medically necessary for the following conditions:

- Preoperative evaluation of the lungs and pulmonary reserve when:
  - thoracic surgery will result in loss of functional pulmonary tissue (i.e., lobectomy); or
  - patients are undergoing major thoracic and/or abdominal surgery and the physician has some reason to believe the patient may have a pre-existing pulmonary limitation (e.g., long history of smoking); or
  - the patient's pulmonary function is already severely compromised by other diseases such as chronic obstructive pulmonary disease (COPD).
- Initial diagnostic workup for the purpose of differentiating between obstructive and restrictive forms of chronic pulmonary disease. Obstructive defects (e.g., emphysema, bronchitis, asthma) occur when ventilation is disturbed by an increase in airway resistance. Expiration is primarily affected. Restrictive defects (e.g., pulmonary fibrosis, tumors, chest wall trauma) occur when ventilation is disturbed by a limitation in chest expansion. Inspiration is primarily affected.
- To assess the indications for and effect of therapy in diseases such as sarcoidosis, diffuse lupus erythematosus, and diffuse interstitial fibrosis syndrome.
- Evaluate patient's response to a newly established bronchodilator anti-inflammatory therapy.
- To monitor the course of asthma and the patient's response to therapy (i.e., especially to confirm home peak expiratory flow measurements).
- Evaluate patients who continue to exhibit increasing shortness of breath (SOB) after initiation of bronchodilator anti-inflammatory therapy.
- Initial evaluation for a patient that presents with new onset (within 1 month) of one or more of the following symptoms: shortness of breath, cough, dyspnea, wheezing, orthopnea, or chest pain.
- Initial diagnostic workup for a patient whose physical exam revealed one of the following: overinflation, expiratory slowing, cyanosis, chest deformity, wheezing, or unexplained crackles.

94010: Spirometry (continued)

- Initial diagnostic workup for a patient with chronic cough. It is not expected that a patient would have a repeat spirometry without new symptomatology.
- Re-evaluation of a patient with or without underlying lung disease who presents with increasing SOB (from previous evaluation) or worsening cough and related qualifying factors such as abnormal breath sounds or decreasing endurance to perform activities of daily living (ADL).
- To establish baseline values for patients being treated with pulmonary toxic regimens (e.g., Amiodarone).
- To monitor patients being treated with pulmonary toxic regimens when any new respiratory symptoms (e.g., exertional dyspnea, nonproductive cough, pleuritic chest pain) may suggest the possibility of pulmonary toxicity.

It is expected that procedure code **94070** will only be performed to make an initial diagnosis of asthma.

Also, it is expected that procedure code 94060 be utilized during the initial diagnostic evaluation of a patient. Once it has been determined that a patient is sensitive to bronchodilators, repeat bronchospasm evaluation is usually not medically necessary, unless one of the following circumstances exist: (1) a patient is exhibiting an acute exacerbation and a bronchospasm evaluation is being performed to determine if the patient will respond to bronchodilators; (2) the initial bronchospasm evaluation was negative for bronchodilator sensivity and the patient presents with new symptoms which suggest the patient has a disease process which may respond to bronchodilators; or (3) the initial bronchospasm evaluation was not diagnostic due to lack of patient effort. Repeat spirometries performed to evaluate patients' response to newly established treatments, monitor the course of asthma/COPD, or evaluate patients continuing with symptomatology after initiation of treatment should be billed with procedure code 94010.

In addition, it is not expected that a pulse oximetry (procedure code 94760 or 94761) for oxygen saturation would routinely be performed with a spirometry. Pulse oximetry is considered medically necessary when the patient has a condition resulting in hypoxemia **and** there is a need to assess the status of a chronic respiratory condition, supplemental oxygen and/or a therapeutic regimen (e.g., acute symptoms).

Usually during an initial evaluation, there is no reason to obtain a spirometry after the administration of bronchodilators in patients who have normal spirometry, normal flow volume loop and normal airway resistance unless there is reason to believe (e.g., symptoms, exam) that a patient has underlying lung disease.

The residual volume (RV) cannot be measured by spirometry because this includes air that cannot be expelled from the lungs, and, therefore is determined by subtracting the expiratory reserve volume (ERV) from the functional residual capacity (FRC). The FRC cannot be measured by simple spirometry either, therefore, procedure code **94240** will be performed when the RV and FRC need to be determined.

The Maximum Voluntary Ventilation (MVV; procedure code **94200**) is a determination of the liters of air that a person can breathe per minute by a maximum voluntary effort. This test measures several physiologic phenomena occurring at the same time. The results and success of this test are effort dependent, therefore routine performance of this test is not recommended, except in cases such as: preoperative evaluation, neuromuscular weakness, upper airway obstruction, or suspicion of Chest Bellows disease.

The Respiratory Flow Volume Loop (procedure code **94375**) is used to evaluate the dynamics of both large and medium size airways. This test is more useful than the conventional spirogram. The procedure is the same for spirometry except for the addition of a maximal forced inspiration at the end of the force expiratory measures.

HCPCS Section & Benefit Category

Medicine/Pulmonary

Type of Bill Code

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

Revenue Code

460 Pulmonary Function, General Classification

HCPCS Codes

94010	Spirometry, including graphic record, total and timed vital capacity, expiratory flow rate measurement(s), with or without maximal voluntary ventilation
94060	Bronchospasm evaluation: spirometry as in 94010, before and after bronchodilator (aerosol or parenteral)
94070	Prolonged postexposure evaluation of bronchospasm with multiple spirometric determinations after antigen, cold air, methacholine or other chemical agent, with subsequent spirometrics
94150	Vital capacity, total (separate procedure)
94200	Maximum breathing capacity, maximal voluntary ventilation
94360	Determination of resistance to airflow, oscillatory or plethysmographic methods
94375	Respiratory flow volume loop

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

135	Sarcoidosis
162.0-162.9	Malignant neoplasm of trachea, bronchus, and lung
197.0	Secondary malignant neoplasm of lung
197.3	Secondary malignant neoplasm of other respiratory organs
212.2	Benign neoplasm of trachea
212.3	Benign neoplasm of bronchus and lung
231.2	Carcinoma in situ of bronchus and lung
415.0	Acute cor pulmonale
415.11-415.19	Pulmonary embolism and infarction

94010: Spirometry (continued)

446.20	Hypersensitivity angiitis, unspecified
466.0-466.19	Acute bronchitis and bronchiolitis
486	Pneumonia, organism unspecified
490	Bronchitis, not specified as acute or chronic
491.0-491.9	Chronic bronchitis
492.0-492.8	Emphysema
493.00-493.91	Asthma
494	Bronchiectasis
495.0-495.9	Extrinsic allergic alveolitis
496	Chronic airway obstruction, not elsewhere classified
508.0-508.9	Respiratory conditions due to other and unspecified external agents
515	Postinflammatory pulmonary fibrosis
517.1-517.8	Lung involvement in conditions classified elsewhere
518.0-518.89	Other diseases of lung
519.1	Other diseases of trachea and bronchus, not elsewhere classified
519.4	Disorders of diaphragm
519.8	Other diseases of respiratory system, not elsewhere classified
780.51	Insomnia with sleep apnea
780.53	Hypersomnia with sleep apnea
780.57	Other and unspecified sleep apnea
786.02-786.09	Dyspnea and respiratory abnormalities
786.2	Cough
786.3	Hemoptysis
793.1	Nonspecific abnormal findings on radiological and other examination of lung field
799.1	Respiratory arrest
E942.9	Other and unspecified agents primarily affecting the cardiovascular system
E945.8	Other and unspecified respiratory drugs primarily acting on the smooth and skeletal muscles and respiratory system
V72.82	Pre-operative respiratory examination

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

Spirometry will not be covered by Florida Medicare if performed on a routine or screening basis in the absence of respiratory disease or abnormal signs or symptoms.

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 multiple spirometric determinations are necessary (e.g., CPT code **94070**) to complete the service described in the CPT code, only one unit of service should be billed.

Effective January 1, 1997, procedure code 94150 is non-reportable for Medicare purposes.

Documentation Requirements

Medical record documentation must indicate the medical necessity for performing the test. In addition, documentation that the service was performed including the results of the Spirometry should be available. This information is normally found in the office notes, progress notes, history and physical, and/or hard copy of the test results.

If the provider of the service 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. The physician must state the clinical indication/medical necessity for the study in his order for the test.

Utilization Guidelines

N/A

Other Comments

Terms Defined:

Tidal Volume (TV or V_T)—volume of air inspired or expired with each normal breath (about 500 ml).

Inspiratory Reserve Volume (IRV)—the maximum volume of air inspired after the end of a normal tidal inspiration (approx 3000 ml).

Expiratory Reserve Volume (ERV)—the largest volume of air that can be exhaled following normal resting inspiration (about 1100 - 1500 ml).

Residual Volume (RV)—the volume of air remaining in the lungs after maximum expiration (approx 1200 - 1500 ml).

Inspiratory Capacity (IC)—the amount of air that can be inspired during a maximal inspiratory effort that starts at the normal resting expiratory level (the sum of IRV and TV; about 2500 - 3600 ml).

Vital Capacity (VC)—the maximum volume of air expired from the maximum inspiratory level (the sum of TV, IRV, and ERV; approx 3000 - 5000 ml).

Total Lung Capacity (TLC)—the volume of air in the lungs after maximum inspiration (the sum of RV + TV + ERV + IRV; about 4000 - 6000 ml).

Forced Vital Capacity (FVC), Forced Expiratory Volume (FEV) and timed volumes (FEV_1, FEV_2, FEV_3) are airway flow rates that provide information about the severity of airway obstruction in terms of air trapping and serve as an index of dynamic function. These flow rates are determined by a spirometer.

94010: Spirometry (continued)

Asthma is a chronic inflammatory disorder of the airways in which many cells play a role, in particular mast cells, eosinophils, and T lymphocytes. In susceptible individuals this inflammation causes recurrent episodes of wheezing, breathlessness, chest tightness, and cough particularly at night and/or in the early morning. These symptoms are usually associated with widespread but variable airflow limitation that is at least partly reversible either spontaneously or with treatment. The inflammation also causes an associated increase in airway responsiveness to a variety of stimuli.

Sources of Information

1998 Physician Desk Reference

Bates, D. (1989). *Respiratory Function in Disease* (3rd ed.). Philadelphia: W.B. Saunders Company.

Baum, G., and Wolinsky, E., (Eds.). (1994). *Textbook of Pulmonary Diseases* (5th ed.). Boston: Little, Brown and Company.

Crapo, R. (1994). Pulmonary-Function Testing, Current Concepts. *The New England Journal of Medicine*. 331(1), 25-30.

Fishman, A., (1988). *Pulmonary Disease and Disorders* (2nd ed.). New York: McGraw-Hill Book Company.

Fischbach, F., (1996). *A Manual of Laboratory and Diagnostic Tests* (5th ed.). Philadelphia: J.B. Lippincott Company.

George, R. Light, R., Matthay, M. and Matthay, R., (Eds.)., (1990). *Chest Medicine: Essentials of Pulmonary and Critical Care Medicine* (2nd ed.) Baltimore: Williams and Wilkins.

Guenter, C., and Welch, M. (Eds.)., (1982). *Pulmonary Medicine* (2nd ed.). Philadelphia: J.B. Lippincott Company.

National Heart, Lung and Blood Institute. (1995). *Global Initiative for Asthma*. Publication No. 95-3659.

Nursing 98 Drug Handbook. (1998). Springhouse: Springhouse Corporation.

Pagana, K., and Pagana, J. (1995)., *Mosby's Diagnostic and Laboratory Test Reference* (2nd ed.). St. Louis: Mosby.

Tilkian, S., Conover, and Tilkian, A., (1987). *Clinical Implications of Laboratory Tests* (4th ed.). St. Louis: C.V. Mosby Company.

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 the contractor's Advisory Committee, which includes representatives from the Pulmonary Society.

Start Date of Comment Period

N/A

Start Date of Notice Period

06/01/2000

Revision History

Revision Number:	2
Revised Effective Date:	05/11/2000
Start Date of Comment Period:	N/A
Start Date of Notice Period:	06/01/2000
	June/July 2000 Bulletin
Explanation of Revision:	Procedure code 94150 is considered a non-reportable code for Medicare purposes, therefore, a statement was added to the Coding Guidelines section of the policy.

Start Date of Comment Period:	N/A
Start Date of Notice Period:	01/21/99
Original Effective Date:	01/21/99
Revision Date/Number:	01/01/99 1 (1999 HCPCS)

HCPCS change occurred prior to implementation

Start Date of Comment Period:	07/17/98
Start Date of Notice Period:	12/07/98
Original Effective Date:	01/21/99 G-354 ❖

95004: Allergy Skin Tests

Policy Number
95004

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Allergy Skin Tests

AMA CPT Copyright Statement

HCFA National Coverage Policy
Coverage Issues Manual 50-53
Medicare Hospital Manual, sections 442 and 443

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
07/17/2000

Revision Effective Date
N/A

Revision Ending Effective Date
N/A

Policy Ending Date
N/A

LMRP Description
Allergic or hypersensitivity disorders may be manifested by generalized systemic reactions as well as localized reactions in any part of the body. The reactions may be acute, subacute, or chronic, immediate or delayed, and may be caused by a variety of offending agents; pollen, molds, dust, feathers, fur, venoms, foods, drugs, etc.

Allergy testing is performed to determine a patient's sensitivity to particular allergens and is based on findings during a complete history and physical exam of the patient.

Indications and Limitations of Coverage and/or Medical Necessity

- Florida Medicare will consider allergy testing to be a covered service when medically necessary as evidenced by signs and symptoms or a diagnosis suggestive of allergies such as asthma, allergic rhinitis; or a history of hypersensitivity to animals, hay, pollen, dust, mold, grass, bee/wasp, etc.

The use of sublingual, intracutaneous, and subcutaneous provocative and neutralization testing and neutralization therapy for food allergies are not covered under the Medicare program because available evidence does not show that these tests and therapies are effective.

HCPCS Section & Benefit Category
Medicine/Allergy and Clinical Immunology

Type of Bill Code
Hospital - 13x

Revenue Code
924 Allergy Test

HCPCS Codes

95004	Percutaneous tests (scratch, puncture, prick) with allergenic extracts, immediate type reaction, specify number of tests
95010	Percutaneous tests (scratch, puncture, prick) sequential and incremental, with drugs, biologicals or venoms, immediate type reaction, specify number of tests
95015	Intracutaneous (intradermal) tests, sequential and incremental, with drugs, biologicals, or venoms, intermediate type reaction, specify number of tests
95024	Intracutaneous (intradermal) tests with allergenic extracts, immediate type reaction, specify number of tests
95027	Skin end point titration
95028	Intracutaneous (intradermal) tests with allergenic extracts, delayed type reaction, including reading, specify number of tests
95078	Provocative testing (e.g., Rinkel test)

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.

95004: Allergy Skin Tests (continued)

Noncovered ICD-9-CM Code(s)

The following ICD-9-CM codes are noncovered for procedure codes 95004, 95010, 95015, 95024, 95027, 95028, and 95078:

692.5	Contact dermatitis and other eczema due to food in contact with skin
693.1	Dermatitis due to food
995.60-995.69	Anaphylactic shock due to adverse food reaction

Noncovered Diagnosis

Food allergies are noncovered for procedure codes 95004, 95010, 95015, 95024, 95027, 95028, and 95078.

Coding Guidelines

- When coding for allergy skin tests indicate (1) unit for each test performed. For example, if 18 scratch tests are performed with allergenic extracts, bill procedure code 95004 indicating 18 units.

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 history and physical examination notes, office/progress notes, hospital notes, and/or procedure report.

Utilization Guidelines

N/A

Other Comments

Terms Defined:

Allergen—any substance that causes manifestations of allergy.

Allergy—an acquired, abnormal immune response to a substance (allergen) that does not normally cause a reaction.

Asthma—a disease caused by increased responsiveness of the tracheobronchial tree to various stimuli.

Sources of Information

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 the contractor's Advisory Committee, which includes representatives from numerous societies.

Start Date of Comment Period

02/21/2000

Start Date of Notice Period

06/01/2000

Revision History

Revision Number:	Original
Start Date of Comment Period:	02/21/2000
Start Date of Notice Period:	06/01/2000
	June/July 2000 Bulletin

Original Effective Date: 07/17/2000 ❖

A0320: Ground Ambulance Services

Policy Number
A0320

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Ground Ambulance Services

AMA CPT Copyright Statement

HCFA National Coverage Policy
Medicare Hospital Manual, sections 236, 433
Intermediary Manual, sections 3114, 3660.1
Skilled Nursing Facility Manual, section 539
Program Memorandum B-00-09 (Change request 1065)

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
07/17/2000

Revision Effective Date
N/A

Revision Ending Effective Date
N/A

Policy Ending Date
N/A

LMRP Description
The Medicare program includes an ambulance benefit. Covered services may be provided either by a freestanding ambulance supplier or a participating Part A provider such as a hospital or skilled nursing facility. Three basic requirements must be met for ambulance services to be covered:

The ambulance and crew must meet specific requirements outlined in the Medicare Intermediary Manual.

The transportation must be medically reasonable and necessary as outlined in the Medicare Intermediary Manual. This requires that other means of transportation be medically contraindicated, in other words, that the patient cannot be safely transported by any other means.

The origin and destination requirements outlined in the Medicare Intermediary Manual must be met.

Indications and Limitations of Coverage and/or Medical Necessity
Situations in which a patient is considered to be in a life threatening/acute condition or not able to be safely transported by other than an ambulance cannot be exhaustively defined. Nor can these "conditions" be represented accurately by the current ICD-9-CM diagnosis coding structure. Therefore, the conditions and ICD-9-CM diagnosis codes listed below are used as examples to assume that the patient meets the above coverage requirements during routine claims processing.

The Intermediary reserves the right to validate coverage based on the narrative description of the patient's condition and pertinent physical objective findings of the crew's patient assessment on a pre or post payment basis, whenever it deems necessary, to ensure appropriate payments.

Some of the most common situations which suggest transportation by ambulance would be medically indicated are listed below. Additionally, a listing of ICD-9-CM codes is given upon which the Intermediary will presume medical necessity is met on a **prepayment** basis. In no case will transportation be reimbursed if the patient could have been transported by any other means.

- The patient's condition necessitated emergency care and resulted from an acute injury or illness in which the patient was left in an unstable condition. Examples include a patient that has had a major bone compound fracture where bleeding and signs of shock are present, a patient who has suffered a serious cardiac event where blood pressure and pulse are unstable, and a patient who has suffered multiple trauma, and a spinal cord injury is suspected.
- The patient needed to be restrained to prevent injury to himself or others (e.g., combative, abusive, convulsive).
- The patient was unconscious, unable to respond to stimuli.
- The patient was in shock as evidenced by some of the following signs and symptoms secondary to the patient's condition: blood pressure of less than 90/60, pulse >100 or <45, respirations greater than 24, significant changes in mental status, cold and/or cyanotic skin, excessive perspiration.
- Emergency measures or treatment were required (e.g., administration of emergency drugs, cardiopulmonary resuscitation, continuous cardiac monitoring).
- The patient required IV fluids to maintain adequate blood pressure (e.g., dehydration, bleeding, cardiac arrhythmias, etc.) or an access line was established to administer emergency medication(s).
- The patient's acute condition required oxygen as part of the emergency treatment procedures enroute to destination (this does not include patients who already require oxygen therapy on an ongoing basis to manage an existing condition).

A0320: Ground Ambulance Services (continued)

- The patient required immobilization to prevent further injury of a fracture or possible fracture or was in a condition that movement by any other means of transportation would potentially make the condition worse.
- The patient has sustained an acute stroke or myocardial infarction (this does not include patients who have a history of stroke or myocardial infarction and are able to be transported by other means because no acute medical condition exists).
- The patient was experiencing symptoms indicative of a possible myocardial infarction or stroke.
- The patient has or was experiencing a severe hemorrhage.
- The patient is bed confined (definition of bed confined must be met).

Bed Confined

The patient's condition must be documented to include the reason why the patient was bed confined. Bed confined is defined as unable to get up from bed without assistance, unable to ambulate, and unable to sit in a chair or wheelchair. Bed confined is not synonymous with nonambulatory since the paraplegic or quadriplegic is nonambulatory but spends significant time in a wheelchair. Bed confined is also not equivalent to bedrest, which is a recommended state of affair that does not exclude an occasional ambulation to the commode or chair.

The patient's condition was such that the patient could be moved **only by stretcher** and any other method of transport would result in injury or would be detrimental to the patient's health.

Physician Certification

In addition to the above indications, the final rule as published in the January 25, 1999 *Federal Register* states that ambulance suppliers must obtain a physician's written order certifying the need for scheduled and unscheduled nonemergency ambulance service. In addition to the physician's signature, it is acceptable to obtain signed certification statements when professional services are furnished by physician assistants, nurse practitioners, or clinical nurse specialists (where all applicable State licensure or certification requirements are met).

The physician's certification must be dated no more than 60 days prior to the date that the service is provided. In cases where a beneficiary requires a nonemergency, unscheduled transport, the physician's certification can be obtained 48 hours after the ambulance transportation has been provided. Ambulance suppliers are required to retain the certificate on file and, upon request, present the requested certification. This requirement applies to both repetitive and one-time ambulance transports.

Ambulance suppliers should obtain the signed certification statement prior to the transport. However, there may be instances in which ambulance suppliers have provided transports but are experiencing difficulty in obtaining the required physician certification statement. The guidelines for obtaining the physician certification statement and required steps in obtaining this certification are contained in Program Memorandum B-00-09 (Change request 1065, dated February 2000) with further clarification published in the April/May 2000 Bulletin.

NOTE: A physician's certification is not required for nonemergency, unscheduled transportation of beneficiaries residing at home or in facilities where they are not under the direct care of a physician. These situations should be rare because most transports occur for beneficiaries receiving dialysis or diagnostic tests.

HCPCS Section & Benefit Category

Ambulance

Type of Bill Code

Hospital - 13x
Skilled Nursing Facility - 21x, 22x, 23x

Revenue Code

540 Ambulance, General Classification
542 Ambulance, Medical Transport
543 Ambulance, Heart Mobile
546 Ambulance, Neonatal Ambulance
548 Ambulance, Telephone Transmission EKG

HCPCS Codes

A0320	Ambulance service, BLS, non-emergency transport, supplies included, mileage separately billed
A0322	Ambulance service, BLS, emergency transport, supplies included, mileage separately billed
A0324	Ambulance service, ALS, non-emergency transport, no specialized ALS services rendered, supplies included, mileage separately billed
A0326	Ambulance service, ALS, non-emergency transport, specialized ALS services rendered, supplies included, mileage separately billed
A0328	Ambulance service, ALS, emergency transport, no specialized ALS services rendered, supplies included, mileage separately billed
A0330	Ambulance service, ALS, emergency transport, specialized ALS services rendered, supplies included, mileage separately billed
A0380	BLS mileage (per mile)
A0390	ALS mileage (per mile)

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

250.20-250.23	Diabetes with hyperosmolarity (severe diabetic complication)
250.30-250.33	Diabetes with other coma
251.0	Hypoglycemic coma
255.4	Corticoadrenal insufficiency
293.0	Acute delirium
298.8	Other and unspecified reactive psychosis (psychosis requiring restraints)
345.3	Grand mal status

A0320: Ground Ambulance Services (continued)

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
414.10-414.19	Aneurysm of heart
415.11-415.19	Pulmonary embolism and infarction
426.0-426.9	Conduction disorders
427.0-427.9	Cardiac dysrhythmias
428.0-428.9	Heart failure (severe)
430-434.91, 436	Cerebrovascular disease (severe cerebral vascular problems)
441.00-441.9	Aortic aneurysm and dissection
442.0-442.9	Other aneurysm
493.01, 493.11, 493.21, 493.91	Asthma with status asthmaticus
518.0	Pulmonary collapse
518.4	Acute edema of lung, unspecified
518.5	Pulmonary insufficiency following trauma and surgery
518.81	Acute respiratory failure
518.82	Other pulmonary insufficiency, not elsewhere classified
519.00-519.09	Tracheostomy complications
531.00-531.21, 531.40-531.61, 532.00-532.21, 532.40-532.61, 533.00-533.21, 533.40-533.61, 534.00-534.21, 534.40-534.61, 535.01, 535.11, 535.21, 535.31, 535.41, 535.51, 535.61	Diseases of esophagus, stomach, and duodenum (severe gastrointestinal complication)
578.9	Hemorrhage of gastrointestinal tract, unspecified
669.10-669.14	Shock during or following labor and delivery
669.90-669.94	Unspecified complication of labor and delivery
719.49	Pain in joint, multiple sites (severe joint pain causing immobility)
780.01	Coma
780.2	Syncope and collapse
780.31-780.39	Convulsions
785.50-785.59	Shock without mention of trauma
786.09	Other symptoms involving respiratory system and other chest symptoms (severe respiratory distress)
786.50-786.59	Chest pain
789.00-789.09	Abdominal pain (severe)
799.0	Asphyxia
799.1	Respiratory arrest
800.00-804.99	Fracture of skull
805.00-809.1	Fracture of neck and trunk
820.00-823.92	Fracture of femur, patella, tibia, and fibula
835.00-835.13	Dislocation of hip
850.1-854.19	Intracranial injury, excluding those with skull fracture
860.0-869.1	Internal injury of thorax, abdomen, and pelvis
871.0-871.9	Open wound of eyeball
925.1-929.9	Crushing injury
948.00-948.99	Burns classified according to extent of body surface involved
952.00-952.9	Spinal cord injury without evidence of spinal bone injury
958.4	Traumatic shock
959.01-959.3, 959.6-959.8	Injury, other and unspecified (severe injuries to include those with open fractures, unstable fractures where movement could result in further injury, moderate to heavy bleeding, traumatic amputations, incapacitating pain)
960.0-979.9	Poisoning by drugs, medicinal, and biological substances
980.0-989.9	Toxic effects of substances chiefly nonmedicinal as to source
991.6	Hypothermia (severe with decreased level of consciousness)
993.3	Caisson disease
994.0	Effects of lightening
994.1	Drowning and nonfatal submersion
994.7	Asphyxiation and strangulation
994.8	Electrocution and nonfatal effects of electric current
995.0	Other anaphylactic shock
995.60-995.69	Anaphylactic shock due to adverse food reaction
999.4	Anaphylactic shock due to serum

***Please note that the descriptor listed is the condition that will be presumed to meet medical necessity criteria. It is not always the descriptor as it appears in the ICD-9-CM code book. An example is 789.0, which reads as "abdominal pain" in the book. This code is listed on the previous page with the descriptor of "severe abdominal pain" as only pain of a severe, incapacitating nature would meet the medical necessity criteria.

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

Ambulance services will be denied when the patient's condition does not warrant its use either because the patient could have been safely transported by another means of transportation, independent of whether or not it was available, or if the patient's condition did not require the skills of specially trained staff or equipment due to an acute condition or injury. A denial will also occur if all the requirements identified in the Medicare Intermediary Manual are not met (e.g., ambulance and crew requirements, physician certification, bed confined).

A0320: Ground Ambulance Services (continued)

Noncovered ICD-9-CM Code(s)

N/A

Noncovered Diagnosis

N/A

Coding Guidelines

Origin and destination modifiers are to be used with codes A0320-A0390. 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

The charges for mileage must be coded on a "loaded" basis (e.g., from the pick up of the patient to his/her destination). Separate charges for "unloaded" mileage should not be coded. Charges for unloaded mileage will be denied.

For reporting purposes, line item date of service per revenue code line is required in FL 45 of the claim form. This requires two separate revenue code lines for every ambulance trip (i.e., one for the transportation and one for the mileage). In addition, the reporting of service units is required in FL 46 of the claim form.

Documentation Requirements

Appropriate documentation for review includes a ambulance transport sheet, an itemized breakdown of charges, and a physician certification for nonemergency transports.

If Medicare coverage criteria is not met, a copy of the notice of non-coverage signed and dated by the patient must be available for review. This notice must be given to the patient prior to transport.

If an ICD-9-CM code cannot appropriately be selected which reflects the need for an ambulance transport, the claims should be accompanied by a trip sheet that clearly describes the medical conditions of the patient if submitting a paper claim or a narrative statement via EMC transmission.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information

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 the contractor's Advisory Committee, which includes representatives from numerous societies.

Start Date of Comment Period

02/21/2000

Start Date of Notice Period

06/01/2000

Revision History

Revision Number:	Original
Start Date of Comment Period:	02/21/2000
Start Date of Notice Period:	06/01/2000
	June/July 2000 Bulletin
Original Effective Date:	07/17/2000 ❖

J0207: Amifostine

Policy Number
J0207

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Amifostine

AMA CPT Copyright Statement

HCFA National Coverage Policy
Medicare Hospital Manual, section 442.7
Medicare Intermediary Manual, sections 3101.3, 3112.4, 3133.5, 3627.9, and 3627.10
Rural Health Clinic and Federally Qualified Health Center Manual, section 406.7
Skilled Nursing Facility Manual, section 230.5

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
07/17/2000

Revision Effective Date
N/A

Revision Ending Effective Date
N/A

Policy Ending Date
N/A

LMRP Description
Amifostine (Ethyol®) is categorized as an antineoplastic adjunct and cytoprotective agent.

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will consider Amifostine (Ethyol®) medically reasonable and necessary for any of the following FDA approved indications:

- Nephrotoxicity, Cisplatin-induced (prophylaxis)—to reduce cumulative nephrotoxicity associated with Cisplatin therapy in patients with advanced ovarian carcinoma, non-small cell lung carcinoma (NSCLC), or advanced solid tumors of non-germ cell origin.
- Moderate to severe xerostomia, radiation induced- to reduce the incidence of moderate to severe xerostomia in patients undergoing post operative radiation treatment for head and neck cancers where the radiation port includes a substantial portion of the parotid gland.

Clinical trials have also demonstrated the efficacy of Amifostine in the reduction of additional complications related to antineoplastic administration. Florida Medicare will cover Amifostine for its FDA approved uses as well as for treatment of the following conditions:

- Bone marrow toxicity, antineoplastic agent-induced (prophylaxis)- to reduce acute and cumulative hematologic toxicities associated with a Cisplatin and Cyclophosphamide (CP) regimen in patients with advanced solid tumors of non-germ cell origin. Amifostine is also indicated to decrease bone marrow toxicity during treatment with high dose Cisplatin alone for head and neck carcinoma, Cyclophosphamide alone for malignant lymphoma, Carboplatin for NSCLC, and Carboplatin plus radiation therapy for head and neck carcinoma.
- Neurotoxicity, Cisplatin-induced (prophylaxis)—to decrease the frequency or severity of Cisplatin-induced peripheral neuropathy and ototoxicity.

HCPCS Section & Benefit Category
Drugs and Biologicals

Type of Bill Code
Hospital - 13x
Rural Health Clinic - 71x
Skilled Nursing Facility - 21x, 23x

Revenue Code
636 Drugs Requiring Detailed Coding

HCPCS Codes
J0207 Injection, amifostine, 500 mg

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

J0207: Amifostine (continued)

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)

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

Noncovered Diagnosis

N/A

Coding Guidelines

Infusion Therapy Coding: Use code Q0081 (Infusion therapy, using other than chemotherapeutic drugs, per visit.)

Documentation Requirements

Medical record documentation that is maintained by the ordering/referring physician must substantiate the medical necessity for the use of Amifostine by clearly indicating the condition for which this drug is being used. This documentation is usually found in the history and physical or in the office/progress notes.

If the provider of the service is other than the ordering/referring physician, that provider must maintain copies of the ordering/referring physician's order for the drug. The physician must state the clinical indication/medical need for using this drug in the order.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information

Amifostine package insert, 7/99

United States Pharmacopeia Oncology Drug Information Monograph (June 1998).

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 the contractor's Advisory Committee, which includes representatives from numerous societies.

Start Date of Comment Period

02/21/2000

Start Date of Notice Period

06/01/2000

Revision History

Revision Number:	Original
Start Date of Comment Period:	02/21/2000
Start Date of Notice Period:	06/01/2000
	June/July 2000 Bulletin
Original Effective Date:	07/17/2000 ❖

J2430: Pamidronate (Aredia®, APD)

Policy Number
J2430

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Pamidronate (Aredia®, APD)

AMA CPT Copyright Statement

HCFA National Coverage Policy
Medicare Hospital Manual, section 442.7
Medicare Intermediary Manual, sections 3101.3, 3112.4, 3133.5, 3627.9, and 3627.10
Rural Health Clinic and Federally Qualified Health Center Manual, section 406.7
Skilled Nursing Facility Manual, section 230.5

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
07/17/2000

Revision Effective Date
N/A

Revision Ending Effective Date
N/A

Policy Ending Date
N/A

LMRP Description
Pamidronate, a bisphosphonate which is administered intravenously, is used to inhibit bone resorption and to decrease serum calcium. In Paget's disease (osteitis deformans), Pamidronate reduces the rate of bone turnover by an initial blocking of bone resorption, resulting in a decrease in serum alkaline phosphatase and a decrease in urinary hydroxyproline excretion.

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will consider Pamidronate medically reasonable and necessary for any of the following FDA approved indications:

- Hypercalcemia of malignancy, with or without bone metastases, that is inadequately controlled by hydration alone.
- Symptomatic Paget's disease (osteitis deformans) characterized by abnormal and accelerated bone metabolism in one or more bones. Signs and symptoms may include bone pain, deformity, and/or fractures; neurologic disorders associated with skull lesions and spinal deformities.
- Adjunct treatment of osteolytic lesions of breast cancer or myeloma.

Dosage and Administration

Hypercalcemia—intravenous infusion, 60 mg administered over a period of four to twenty-four hours.

Paget's disease—intravenous infusion, a total of 90 to 180 mg per treatment period.

Breast cancer or Myeloma—intravenous infusion, 90 mg over a period of 2-4 hours once a month.

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 Drug Requiring Detailed Coding

HCPCS Codes
J2430 Injection, pamidronate disodium, per 30 mg

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity

174.0-174.9	Malignant neoplasm of female breast
175.0-175.9	Malignant neoplasm of male breast
203.00-203.01	Multiple myeloma
275.42	Hypercalcemia (associated with malignancy)
731.0	Osteitis deformans without mention of bone tumor (Paget's disease of bone)

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.

J2430: Pamidronate (Aredia®, APD) (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 that are maintained by the ordering/referring physician must substantiate the medical necessity for the use of Pamidronate by clearly indicating the condition for which this drug is being used. This documentation is usually found in the history and physical or in the office/progress notes.

If the provider of the service is other than the ordering/referring physician, that provider must maintain copies of the ordering/referring physician's order for the drug. The physician must state the clinical indication/medical need for using this drug in the order.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information

United States Pharmacopeia Oncology Drug Information Monograph (June 1998).

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 the contractor's Advisory Committee, which includes representatives from numerous societies.

Start Date of Comment Period

02/21/2000

Start Date of Notice Period

06/01/2000

Revision History

Revision Number:	Original
Start Date of Comment Period:	02/21/2000
Start Date of Notice Period:	06/01/2000
	June/July 2000 Bulletin
Original Effective Date:	07/17/2000 ❖

J2792: Rho (D) Immune Globulin Intravenous

Policy Number
J2792

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Rho (D) Immune Globulin Intravenous

AMA CPT Copyright Statement

HCFA National Coverage Policy
N/A

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
07/17/2000

Revision Effective Date
N/A

Revision Ending Effective Date
N/A

Policy Ending Date
N/A

LMRP Description
Rho (D) Immune Globulin Intravenous (Rho [D] IGIV) is a gamma globulin (IgG) which contains antibodies to Rho (D). Rho (D) IGIV currently has two medical applications. The first application is to suppress Rh isoimmunization in nonsensitized Rho (D) antigen-negative individuals following Rho (D) antigen-positive red blood cell or whole blood exposure. Rho (D) antigen-positive red blood cell exposure or whole blood exposure can occur by fetomaternal hemorrhage during delivery of an Rho (D) antigen-positive infant, during an abortion (spontaneous or induced), during amniocentesis, abdominal trauma or during a mismatched transfusion (transfusion accident).

The second application of Rho (D) IGIV is to increase platelets in non-splenectomized, Rho (D) positive children with acute/chronic and adults with chronic immune thrombocytopenic purpura (ITP), or ITP secondary to human immunodeficiency virus (HIV) infection.

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will consider Rho (D) Immune Globulin Intravenous medically necessary for the following Food and Drug Administration (FDA) approved indications:

1.) For the suppression of Rh isoimmunization. These include:

A.) Rho (D) negative female children and adults in their childbearing years upon exposure to incompatible blood transfusions or massive fetal hemorrhage.

B.) Non-sensitized Rho (D) negative women within 72 hours after abortions (spontaneous or induced), amniocentesis, chorionic villus sampling, ruptured tubal pregnancy, abdominal trauma, transplacental hemorrhage, or in the normal course of pregnancy unless the blood type of the fetus or the father is known to be Rho (D) negative. Maternal bleeding due to threatened abortion should be treated by administration of Rho (D) as soon as possible.

C.) Non-sensitized Rho (D) negative women during pregnancy at 28 weeks gestation and within 72 hours following delivery which meet the following criteria:

- The mother must be Rho (D) negative;
- The mother is carrying a child whose father is either Rho (D) positive or Rho (D) unknown;
- The baby is either Rho (D) positive or Rho (D) unknown, and isoimmunized to the Rho (D) factor.

If product recommended dosages are exceeded, the provider must document medical necessity in the record.

2.) For the treatment of immune thrombocytopenic purpura (ITP) for non-splenectomized Rho (D) positive individuals in clinical situations requiring an increase in platelet count to prevent excessive hemorrhage in:

- Children with acute or chronic ITP;
- Adults with chronic ITP;
- Children and adults with ITP secondary to HIV infection.
- For the purpose of this policy, ITP is defined by the following criteria:
- Signs and symptoms of bleeding, a platelet count of less than 30,000/mm3, Rho (D) positive status and nonsplenectomized status;
- Acute ITP: for duration of less than 6 months.
- Chronic ITP: for duration of greater than 6 months.

All patients should be monitored to determine clinical response by assessing platelet counts, red blood cell counts, hemoglobin (Hgb) and reticulocyte levels.

HCPCS Section & Benefit Category
Drugs and Biologicals

J2792: Rho (D) Immune Globulin Intravenous (continued)

Type of Bill Code
Hospital - 13x
Skilled Nursing Facility - 21x, 23x
Rural Health Clinic - 71x

Revenue Code
636 Drugs Requiring Detailed Coding

HCPCS Codes
J2792 Injection, rho D immune globulin, intravenous, human, solvent detergent, 100 I.U.

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity

287.3	Primary thrombocytopenia
656.10-656.13	Rhesus isoimmunization
773.0	Hemolytic disease due to Rh isoimmunization
999.7	Rh incompatibility reaction

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.

Rho (D) Immune Globulin Intravenous should not be administered as immunoglobulin replacement therapy for immune globulin deficiency syndromes.

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 (e.g. history and physical, office/progress notes) maintained by the performing physician must clearly indicate the medical necessity to initiate Rho (D) Immune Globulin therapy and the continued need thereof. Documentation must clearly indicate relevant signs and symptoms related to the condition for which this therapy is indicated.

Utilization Guidelines
N/A

Other Comments
N/A

Sources of Information

Anemia, Neutropenia and Thrombocytopenia: Pathogenesis and Evolving Treatment Options in HIV-Infected Patients. HIV Clinical Management vol. 10. (1999). Medscape Website. [On-line]. Available: http/:// www.medscape/HIV/ClinicMgmt/CMv10-06.html

Fauci, A., Braunwald, E., Isselbacher, K., Wilson, J., Kasper, D., Hauser, S., & Longo, D. (eds.). (1998). *Harrison's Principles of Internal Medicine*. (14th ed.). New York: McGraw-Hill.

Food and Drug Administration Drug and Device Product Approvals. [On-line.]. Available: http://www.fda.gov/cder/da/ddpa.htm

Jacobs, D., Dermott, W., Grady, H., Horvat, R., Huestis, D., Kasten, B. (1996). *Laboratory Test Handbook* (4th ed.). Ohio: Lexi-Corp.

Physician's Desk Reference Book. (2000). (54th ed.).

Thomas, C.L. (1993). *Taber's Cyclopedic Medical Dictionary* (17th ed.). Philadelphia: F.A. Davis Company.

Tierney, L., McPhee, S., Papadakis, M. (1998). *Current Medical Diagnosis and Treatment* (37th ed.). Stamford: Appleton & Lange.

United States Pharmacopaeia Drug Information (USPDI). 1999.

WinRho SDF™ package insert, 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 the contractor's Advisory Committee, which includes representatives from multiple specialties.

Start Date of Comment Period
02/21/2000

Start Date of Notice Period
06/01/2000

Revision History

Revision Number:	Original
Start Date of Comment Period:	02/21/2000
Start Date of Notice Period:	06/01/2000
	June/July 2000 Bulletin
Original Effective Date:	07/17/2000 ❖

J3240: Thyrotropin Alfa (Thyrogen ®)

Policy Number
J3240

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Thyrotropin Alfa (Thyrogen ®)

AMA CPT Copyright Statement

HCFA National Coverage Policy
N/A

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
07/17/2000

Revision Effective Date
N/A

Revision Ending Effective Date
N/A

Policy Ending Date
N/A

LMRP Description
Thyrotropin Alfa (Thyrogen ®) is a highly purified recombinant form of human thyroid stimulating hormone (TSH). It is used as an adjunctive diagnostic tool for serum thyroglobulin (Tg) testing with or without radioiodine imaging in the follow-up of patients with well-differentiated thyroid cancer.

Patients with thyroid carcinoma generally undergo total or near total thyroidectomy, often followed by radioiodine therapy. After surgery these patients require synthetic thyroid hormone replacement therapy to suppress the secretion of thyrotropin (TSH). This hormone replacement therapy prevents symptoms of hypothyroidism and suppresses serum levels of TSH to avoid TSH-stimulated tumor growth. Although survival rates are good for thyroid carcinoma, these patients require long-term follow-up monitoring for recurrent thyroid carcinoma and/or metastasis, which can occur decades later. This follow-up generally includes periodic serum thyroglobulin (Tg) levels (thyroglobulin levels are used as a tumor marker for thyroid carcinoma) and radioiodine imaging. Serum thyroglobulin testing and radioiodine imaging are the most sensitive for detecting recurrent disease when the serum TSH levels are significantly elevated (ideally between 30-50 microU/ml).

Elevation of TSH can be accomplished by withdrawal of thyroid hormone replacement therapy or administration of recombinant thyroid stimulating hormone (thyrotropin alfa). Withdrawal of thyroid replacement therapy and subsequent high serum levels of TSH result in symptoms of hypothyroidism. These symptoms can include extreme fatigue, depression, weight gain, cold intolerance, muscle weakness and cramps. The severity of these symptoms can be debilitating for some of these patients due to the high TSH levels required to perform these tests.

Thyrotropin alfa provides an alternative to thyroid hormone withdrawal for follow-up thyroid carcinoma testing. However, thyroglobulin testing and radioiodine imaging following administration of thyrotropin alfa have not shown to be as sensitive in detecting metastatic and/or recurrent thyroid carcinoma as testing following hormone withdrawal. This creates a substantial risk of missing recurrent carcinoma or of underestimating the extent of the disease. Therefore, careful consideration should be given when the physician and patient elect to use thyrotropin alfa rather than hormone withdrawal in follow-up testing. The patient should be given adequate education regarding this increased risk before this decision is made.

Indications and Limitations of Coverage and/or Medical Necessity
Thyroid hormone withdrawal thyroglobulin testing with radioiodine imaging remains the standard diagnostic modality to assess the presence, location and extent of thyroid cancer.

Florida Medicare will consider the use of recombinant thyroid stimulating hormone (thyrotropin alfa) to be medically reasonable and necessary for the follow-up monitoring of patients with thyroid carcinoma when the following criteria are met:

- The patient has been diagnosed with well-differentiated thyroid carcinoma and has undergone a total or near total thyroidectomy and follow-up testing is being performed to detect metastatic and/or recurrent thyroid carcinoma; and
- The patient is unable to mount an adequate endogenous TSH response to thyroid hormone withdrawal or hormone withdrawal is medically contraindicated for the patient. This includes, but is not limited to those individuals with a second malignancy, other endocrine diseases, myasthenia gravis, or mental illness (e.g., depression); and/or
- The patient has experienced significant distress during previous thyroid hormone withdrawal, to the extent that the treating physician believes use of a less sensitive test is justified.

J3240: Thyrotropin Alfa (Thyrogen ®) (continued)

The dosage for thyrotropin alfa (Thyrogen®) is 0.9 mg. given intramuscularly every 24 hours for two doses or every 72 hours for three doses. For radioiodine imaging, radioiodine administration should be given 24 hours following the final thyrotropin alfa injection. Scanning should then be performed 48 hours after radioiodine administration. For serum thyroglobulin testing, the serum sample should be obtained 72 hours after the final injection of thyrotropin alfa.

HCPCS Section & Benefit Category
Drugs and Biologicals

Type of Bill Code
Hospital - 13(x)
Skilled Nursing Facility - 21(x)
Rural Health Clinic - 71(x)

Revenue Code
636 Drugs Requiring Detailed Coding

HCPCS Codes
J3240 Injection, thyrotropin alfa, 0.9 mg

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity
193 Malignant neoplasm of thyroid gland
V10.87 Personal history of malignant neoplasm of thyroid

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
For services performed on or after January 1, 2000 use procedure code J3240 (Injection, Thyrotropin Alfa, 0.9 mg.). For services performed before January 1, 2000 use procedure code J3490 (Unclassified drugs).

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
American Association of Clinical Endocrinologists and The American College of Endocrinology. (1996). AACE Clinical Practice Guidelines for the Management of Thyroid Carcinoma. [On-line], Available: http: aace.com/clin/guides/thycancer.html

Braverman, L., & Utiger, R. (Eds.). (1996). *Werner and Ingbar's the Thyroid: A Fundamental and Clinical Text.* Philadelphia: Lippincott-Raven.

Commission on Health Care Policy and Practice Guidelines and Communications Committee. (1997). *Society of Nuclear Medicine Procedure Guidelines Manual 1997* (pp. 23-26).

Ladenson, P., Braverman, L., Mazzaferri, E., Brucker-Davis, F., Cooper, D., Garber, J., Wondisford, F., Davies, T., DeGroot, L., Daniels, G., Ross, D., & Weintraub, B. (1997). Comparison of administration of recombinant human thyrotropin with withdrawal of thyroid hormone for radioactive iodine scanning in patients with thyroid carcinoma. *The New England Journal of Medicine, 337* (13), 888-895.

Ozata, M., Suzuki, S., Miyamoto, T., Tsuan, R., Fierro-Renoy, F., & DeGroot, L. (1994). Serum thyroglobulin in the follow-up of patients with treated differentiated thyroid cancer. *Journal of Clinical Endocrinology and Metabolism,* 79, 98-104.

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 the contractor's Advisory Committee, which includes representatives from numerous societies.

Start Date of Comment Period
02/21/2000

Start Date of Notice Period
06/01/2000

Revision History
Revision Number:	Original
Start Date of Comment Period:	02/21/2000
Start Date of Notice Period:	06/01/2000
	June/July 2000 Bulletin
Original Effective Date:	07/17/2000 ❖

J7190: Hemophilia Clotting Factors

Policy Number
J7190

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Hemophilia Clotting Factors

AMA CPT Copyright Statement

HCFA National Coverage Policy
Coverage Issues Manual, section 45-24
Program Memorandum AB-99-75 (Change request 913)
Hospital Manual, section 230
Intermediary Manual3, sections 3112 and 3610
Skilled Nursing Facility Manual, section 260

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
07/17/2000

Revision Effective Date
N/A

Revision Ending Effective Date
N/A

Policy Ending Date
N/A

LMRP Description
Hemophilia is a hereditary blood disease characterized by greatly prolonged coagulation time. The blood fails to clot and abnormal bleeding occurs. It is a sex-linked hereditary trait transmitted by normal heterozygous females who carry the recessive gene. It occurs almost exclusively in males. For purposes of Medicare coverage, hemophilia encompasses Factor VIII deficiency (classic hemophilia, hemophilia A), Factor IX deficiency (hemophilia B, Christmas disease, plasma thromboplastin component), and von Willebrand's disease. Approximately 80percent of those with hemophilia have type A and both are associated with recurrent, spontaneous, and traumatic hemarthrosis.

The frequency and severity of hemorrhagic events induced by hemophilia are related to the amount of coagulation factor in the blood. Those with mild hemophilia (defined as having from 5percent to 40percent of normal coagulation factor activity) experience complications only afterhaving undergone surgery or experiencing a major physicial trauma. Those with moderate hemophilia (from 1percent to 5percent of coagulation factor activity) experience some spontaneous hemorrhage but normally exhibit bleeding provoked by trauma. Those with wevere hemophilia (less than 1percent of coagulation factor activity) exhibit spontanous hemarthrosis and bleeding. Treatment for these patients is dependent on the severity of the disease and may include the administration of blood clotting factors such as Factor VIII, Factor IX, Factor VIIa and, Anti-inhibitorsto control the bleeding.

Indications and Limitations of Coverage and/or Medical Necessity
Medicare provides coverage of self-administered blood clotting factors for hemophilia patients who are competent to use such factors to control bleeding without medical supervision. Medicare covers blood clotting factors for the following conditions:

- Factor VIII deficiency (classic hemophilia, hemophilia A).
- Factor IX deficiency (hemophilia B, Christmas disease, plasma thromboplastin component).
- von Willebrand's disease.

Anti-inhibitor coagulant complex (AICC) is a drug used to treat hemophilia in patients with factor VIII inhibitor antibodies. AICC has been shown to be safe and effective and is covered by Medicare when furnished to patients with hemophilia A and inhibitor antibodies to factor VIII who have major bleeding episodes and who fail to respond to other less expensive therapies.

HCPCS Section & Benefit Category
Miscellaneous drugs and solutions

Type of Bill Code
Hospital -11x, 13x
Skilled Nursing Facility - 21x, 22x
Rural Health Clinic - 71x

Revenue Code
636 Drugs requiring detailed coding

HCPCS Codes

J7190	Factor VIII (antihemophilic factor, human) per I.U.
J7191	Factor VIII (anti-hemophilic factor [porcine]), per I.U.
J7192	Factor VIII (antihemophilic factor, recombinant) per I.U.
J7194	Factor IX complex, per IU
J7198	Anti-inhibitor, per i.u.
J7199	Hemophilia clotting factor, not otherwise classified
Q0160	Factor IX (antihemophilic factor, purified, non-recombinant) per I.U.
Q0161	Factor IX (antihemophilic factor, recombinant) per I.U.
Q0187	Factor VIIa (coagulation factor, recombinant) per 1.2 mg

J7190: Hemophilia Clotting Factors (continued)

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

286.0	Congenital factor VIII disorder
286.1	Congenital factor IX disorder
286.2	Congenital factor XI deficiency
286.3	Congenital deficiency of other clotting factors
286.4	von Willebrand's 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

Coding Guidelines

Additional payment can be received for the blood clotting factors identified in the Intermediary Manual that is administered to hemophilia inpatients. The add-on payment is calculated based on the pharmaceutical average wholesale price (AWP).

One hundred international units (IUs) of any of the clotting factors equals one unit (excluding code Q0187).

If the number of units is between even hundreds, round to the nearest hundred. Thus, units of 1 to 49 are rounded down to the prior 100 and units of 50 to 99 are rounded up to the next 100 (e.g., 1,249 units are entered on the bill as 12 units; 1,250 units are entered as 13 units).

Reimbursement is based upon the least expensive medically necessary blood clotting factors. The blood clotting factors are available both in a heat treated variety and a non-heat treated variety. The Food and Drug Administration (FDA) has determined that both varieties are safe and effective. Therefore, unless the prescription specifically calls for the heat treated variety (HCPCS code J7190 for factor VIII), reimbursement is based on the less expensive, non-heat treated variety (HCPCS code J7191 for factor VIII).

Documentation Requirements

Medical record documentation maintained in the patient's file must document the condition for which the blood clotting factor is being given. In addition, the name of the factor and the dosage required and/or given must be included in the records. This information is normally found in the office/progress notes, pharmacy forms, hospital records, and/or treatment notes.

Utilization Guidelines

N/A

Other Comments

Terms defined:

Hemophilia A (classic hemophilia, VIII deficiency)—is the most common severe bleeding hereditary disorder and is due to deficiency of the coagulation factor VIII. It is classified as severe if the factor VIII:C levels are less than 1percent, moderate if levels are 1-5percent, and mild if levels are greater than 5percent. Approximately one in 10,000 males are affected. The most common sites of bleeding are into joints (knees, ankles, and elbows), into muscles, and from the gastrointestinal tract.

Hemophilia B (Christmas disease, factor IX hemophilia)—is a hereditary bleeding disorder due to deficiency of coagulation factor IX. Factor IX deficiency is one-seventh as common as factor VIII deficiency but is otherwise clinically and genetically identical. Factor IX deficiency occurs in one in 100,000 male births.

Von Willebrand's disease—is the most common congenital disorder of hemostasis. It is a group of disorders characterized by deficient or defective von Willebrand factor (vWF), a protein that mediates platelet adhesion. The subtypes of von Willebrand's disease are: type I, type IIa, type III, and pseudo-von Willebrand's. This disorder affects both men and women, is usually mild, with most bleeding being mucosal (epistaxis, gingival bleeding, menorrhagia).

Sources of Information

Hemophilia. (1999). [On-line]. Available: http://home.mdconsult.com/das/news/body/ctt.

Tabers Cyclopedic Medical Dictionary (17th ed.). (1993). Philadelphia: F. A. Davis Company.

Tierney, L. M., McPhee, S. J., & Papadakis, M. A. (Eds.). (1998). *Current Medical Diagnosis & Treatment.* (37th ed.). Stamford: Appleton & 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 the contractor's Advisory Committee, which includes representatives from the Florida Chapter of the American Society of Hematology.

Start Date of Comment Period

02/21/2000

Start Date of Notice Period

6/01/2000

Revision History:

Revision Number:	Original
Start Date of Comment Period:	02/21/2000
Start Date of Notice Period:	06/01/2000
	June/July 2000 Bulletin
Original Effective Date:	07/17/2000 ❖

J9999: Antineoplastic Drugs

Revision Overview—The policy have been revised to include eight new drugs. Additional ICD-9-CM diagnosis codes to support the medical necessity have been added to the existing drugs in the policy. Indications and limitations to the existing drugs have been updated, based on new information received from various medical sources.

Policy Number
J9999

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Antineoplastic Drugs

AMA CPT Copyright Statement

HCFA National Coverage Policy
Medicare Hospital Manual, section 442.7
Medicare Intermediary Manual, sections 3101.3, 3112.4, 3627.9, and 3627.10

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

HCFA Region
Region IV

HCFA Consortium
Southern

Policy Effective Date
11/02/1998

Revision Effective Date
07/17/2000

Revision Ending Effective Date
07/16/2000

Policy Ending Date
N/A

LMRP Description
According to Medicare guidelines, certain medical services which are deemed reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member are covered services. FDA approval is often one of the main criteria of Medicare's coverage guidelines for drugs and biologicals. However, in the case of chemotherapeutic agents, FDA approval does not always keep pace with clinically indicated efficacy. Therefore, the need exists to address off-label chemotherapy drug uses which have been validated by clinical trials.

The purpose of this policy is to establish the FDA approved indications of antineoplastic drugs and to indicate the circumstances under which Medicare will consider off-label uses for chemotherapy drugs to be medically reasonable and necessary, and to specify those drugs and their FDA approved and off-label uses as they become available. This policy does not restrict what providers can provide nor what beneficiaries receive. It simply defines what can be covered by Medicare in order to avoid or reduce denials for unapproved treatment.

Indications and Limitations of Coverage and/or Medical Necessity
For off-label use:

Effective January 1, 1994, unlabeled uses of FDA approved drugs and biologicals used singly or in an anti-cancer regimen for a medically accepted indication are evaluated under the conditions described in the following paragraphs. A regimen is a combination of anti-cancer agents which have been clinically recognized for the treatment of a specific type of cancer. An example of a drug regimen is: Cyclophosphamide + Vincristine + Prednisone (CPV) for non-Hodgkin's lymphoma. There may be different regimens or combinations which are used at different phases of the cancer's history (induction, prophylaxis of CNS involvement, post remission, and relapsed or refractory disease). A protocol may specify the combination of drugs, doses, and schedules for administration of the drugs. For purposes of this provision, a cancer treatment regimen includes drugs used to treat toxicities or side effects of the treatment regimen when the drugs are administered incident to a chemotherapy treatment.

To evaluate the off-label uses of chemotherapeutic agents for coverage, the uses must not be listed as "not indicated" by HCFA, the FDA, or the compendia. Justification for approval of off-label uses must be based upon data from clinical trials in which there was a defined combination and dosage schedule, an appropriate study design, an adequate number of trial subjects, and evidence of significant increase in survival rate or life expectancy or an objective and significant decrease in tumor size or reduction in tumor-related symptoms. ***(Stabilization is not considered a response to therapy.)*** The unlabeled uses of a chemotherapy drug must be supported by one of the following:

- The compendia. (If an unlabeled use does not appear in the compendia or is listed there as insufficient data or investigational, the compendia will be contacted to determine whether a report is forthcoming. If a report is forthcoming, the information in that report will be used as a basis for decision making. The compendium process for making decisions regarding unlabeled uses is very thorough and continually updated).
- Phase III clinical trials.

J9999: Antineoplastic Drugs (continued)

- Clinical research that appears in peer reviewed medical literature. This includes scientific, medical, and pharmaceutical publications in which original manuscripts are published, only after having been critically reviewed for scientific accuracy, validity, and reliability by unbiased independent experts. This does not include in-house publications of pharmaceutical manufacturing companies or abstracts (including meeting abstracts).

  Use peer-reviewed medical literature appearing in the following publications:

  - American Journal of Medicine
  - Annals of Internal Medicine
  - The Journal of the American Medical Association
  - Journal of Clinical Oncology
  - Blood
  - Journal of the National Cancer Institute
  - The New England Journal of Medicine
  - British Journal of Cancer
  - British Journal of Hematology
  - British Medical Journal
  - Cancer
  - Drugs
  - European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
  - Lancet
  - Leukemia

The intermediary is not required to maintain copies of these publications. Physicians seeking to establish Medicare coverage for specific off-label uses of chemotherapeutic drugs must submit documentation from any of the above publications supporting the efficacy of each of the off-label uses to the Medicare Medical Policy and Procedures Department.

Following are chemotherapy drugs and their FDA approved and off-label uses for which Florida Medicare considers coverage to be medically reasonable and necessary:

Doxorubicin HCL 10mg (Adriamycin PFS; Adriamycin RDF; Rubex)-J9000

Doxorubicin is an anthracycline glycoside; it is classified as an antibiotic but is not used as an antimicrobial agent. It selectively kills malignant cells and produces tumor regression in a variety of human neoplasms.

Doxorubicin may be administered intravenously, intra-arterially, and as a topical bladder instillation

Doxorubicin is FDA approved for treatment of the following medical conditions:

Acute lymphocytic (lymphoblastic) leukemia, acute nonlymphocytic (myeloblastic) leukemia, bladder carcinoma, breast carcinoma, gastric carcinoma, small cell lung carcinoma, epithelial ovarian carcinoma, thyroid carcinoma, neuroblastoma, Wilm's tumor, Hodgkin's lymphoma, non-Hodgkin's lymphoma, soft tissue sarcoma, and osteosarcoma.

Florida Medicare will cover Doxorubicin for its FDA approved uses, as well as for the treatment of the following off-labeled indications:

- Cervical carcinoma
- Endometrial carcinoma
- Head and neck carcinoma
- Non-small cell lung carcinoma
- Pancreatic carcinoma
- Prostatic carcinoma
- Ovarian germ cell tumors
- Ewing's sarcoma
- Multiple myeloma
- Chronic lymphocytic leukemia
- Primary hepatocelular carcinoma
- Hepatoblastoma
- Thymoma
- Gestational trophoblastic tumors
- AIDS related Kaposi's sarcoma

Doxorubicin, Liposomal (Doxil)-J9001

Doxorubicin is an anthracycline cytotoxic antibiotic. Liposomal Doxorubicin is Doxorubicin excapsulated in long-circulating liposomes. Liposomes are microscopic vesicles composed of a phospholipid bilayer that are capable of encapsulating active drugs. Once within the tumor, the active ingredient Doxorubicin is presumably available to be released locally as the liposomes degrade and become permeable in situ.

Liposomal Doxorubicin is FDA approved for the following medical conditions:

- AIDS-related Kaposi's sarcoma disease that has progressed in spite of prior combination chemotherapy or patients who are intolerant of such therapy.
- Metastatic carcinoma of the ovary that is refractory to treatment.

Aldesleukin (Proleukin®, interleukin-2, recombinant, and rIL-2)-J9015

Aldesleukin is **classified** as a biological response modifier. It increases cellular immunity and inhibits tumor growth. Because of its potential life-threatening toxicities, it is recommended that this medication be given only after careful consideration of the risks and benefits.

Aldesleukin is FDA approved for treatment of renal carcinoma and metastatic melanoma.

Florida Medicare will cover Aldesleukin for its FDA approved uses, as well as for the off-labeled indication, chronic myelogenous leukemia.

Carboplatin (Paraplatin®, Paraplatin-AQ®)-J9045

Carboplatin resembles an alkylating agent. Although the exact mechanism of action is unknown, it is thought to be similar to that of the bifunctional alkylating agents, that is, possible cross-linking and interference with the function of DNA.

Carboplatin is FDA approved for the treatment of ovarian carcinoma, when refractive to standard chemotherapy that did or did not include Cisplatin and for the initial treatment of advanced ovarian carcinoma in combination with other approved chemotherapeutic agents.

Florida Medicare will cover Carboplatin for its FDA approved uses, as well as for the treatment of the following off-labeled indications:

J9999: Antineoplastic Drugs (continued)

- Bladder carcinoma
- Primary brain tumors
- Breast carcinoma
- Endometrial carcinoma
- Head & neck carcinoma
- Small cell and non-small cell lung carcinoma
- Malignant melanoma
- Neuroblastoma
- Retinoblastoma
- Testicular carcinoma
- Wilms' Tumor

Docetaxel (Taxotere®)-J9170

Docetaxel, an antineoplastic agent belonging to the taxoid family, acts by disrupting cell replication. It is a derivative of 10-deacetylbaccatin 111, a compound extracted from the needles of the European yew tree. Docetaxel acts by disrupting the microtubular network in cells, an essential component of vital mitotic and interphase cellular functions.

Taxotere is FDA approved in the treatment of metastatic breast after prior treatment, as a second-line treatment of AIDS-related Kaposi's sarcoma, and for the treatment of cisplatin-resistant, non-small cell lung cancer. Florida Medicare will cover Taxotere for its FDA approved uses, as well as for the treatment of the following off-labeled indications:

- Small cell carcinoma of the lung
- Squamous cell carcinoma of the head and neck
- Ovarian carcinoma
- Gastric carcinoma
- Melanoma
- Prostatic carcinoma

Etoposide (Etopophos®, Toposar®, VePesid®, VP-16)-J9181 & J9182

Etoposide is a podophyllotoxin which inhibits DNA synthesis prior to mitosis by blocking topoisomerase II.

Etoposide is FDA approved for the treatment of testicular carcinoma and small cell lung carcinoma.

Florida Medicare will cover Etoposide for its FDA approved uses, as well as for the treatment of the following off-labeled indications:

- Gastric carcinoma
- Heptoblastoma
- Neuroblastoma
- Non-small cell lung carcinoma
- Thymoma
- Osteosarcoma
- Ewing's sarcoma
- Soft tissue sarcoma
- Cutaneous T cell lymphomas
- Breast carcinoma
- Kaposi's sarcoma
- Endometrial carcinoma
- Ovarian carcinoma
- Bladder carcinoma
- Wilms' Tumor
- Retinoblastoma

Fludarabine (Fludara®)-J9185

Fludarabine phosphate is a nucleotide analog which is incorporated into DNA and inhibits further DNA synthesis.

Fludarabine is FDA approved for treatment of chronic lymphocytic leukemia.

Florida Medicare will cover Fludarabine for its FDA approved uses, as well as for the treatment of the following off-labeled indications:

- Acute Non-Lymphocytic Leukemia
- Non-Hodgkin's Lymphoma

Gemcitabine (Gemzar®)-J9201

Gemcitabine is a deoxycytidine analogue antimetabolite which is structurally related to cytarabine. In contrast to cytarabine, it has greater membrane permeability and enzyme affinity, as well as prolonged intracellular retention. The compound acts as an inhibitor of DNA synthesis, and its mechanism of action appears to be cell-cycle specific.

Gemzar is FDA approved for treatment of patients with advanced or metastatic adenocarcinoma of the pancreas and non-small cell lung cancer.

Florida Medicare will cover Gemzar for its FDA approved uses, as well as for the treatment of the following off-labeled indications:

- Breast carcinoma
- Ovarian carcinoma
- Bladder carcinoma

Paclitaxel (Taxol®)-J9265

Paclitaxel is an antimicrotubule agent. It interferes with the normal cellular microtubule function that is required for interphase and mitosis.

Paclitaxel is FDA approved for treatment of the following medical conditions:

Breast carcinoma after failure of combination chemotherapy or at relapse within 6 months of adjuvant chemotherapy; advanced carcinoma of ovary; as a second-line treatment for AIDS-associated Kaposi's sarcoma; and non-small cell lung carcinoma in combination with Cisplatin as a first-line treatment for patients who are not candidates for radiation therapy or potentially curative surgery.

Florida Medicare will cover Paclitaxel for its FDA approved uses, as well as for the treatment of the following off-labeled indications:

- Bladder carcinoma
- Cervical carcinoma
- Endometrial carcinoma
- Esophageal carcinoma
- Head & neck carcinoma
- Small cell lung carcinoma
- Prostatic carcinoma
- Gastric carcinoma

Mitomycin (Mutamycin®, mitomycin-C)-J9280, J9290 & J9291

Mitomycin is classified as an antitumor antibiotic. It inhibits DNA synthesis by causing cross-linking. It also inhibits RNA and protein synthesis.

Mitomycin concentrate may be used intravenously or as a topical bladder instillation.

J9999: Antineoplastic Drugs (continued)

Mitomycin is FDA approved for treatment of gastric and pancreatic carcinoma.

Florida Medicare will cover Mitomycin for its FDA approved uses, as well as for the treatment of the following off-labeled indications:

- Bladder carcinoma
- Cervical carcinoma
- Breast carcinoma
- Esophageal carcinoma
- Head & neck carcinoma
- Non-small cell lung carcinoma
- Prostatic carcinoma
- Gallbladder & biliary carcinoma
- Colorectal & anal carcinoma
- Chronic myelocytic & myelomonocytic leukemias

Mitoxantrone Hydrochloride (Novantrone®)-J9293

Mitoxantrone hydrochloride is an anthracenedione which inhibits DNA and RNA synthesis.

Mitoxantrone hydrochloride is FDA approved for treatment of advanced symptomatic prostate carcinoma and acute non-lymphocytic leukemia.

Florida Medicare will cover Mitoxantrone hydrochloride for its FDA approved uses, as well as for the treatment of the following off-labeled indications:

- Breast carcinoma
- Acute lymphocytic Leukemia
- Non-Hodgkin's Lymphoma

Topotecan Hydrochloride (Hycamtin®)-J9350

Topotecan Hydrochloride is a semi-synthetic derivative of camptothecin and is an anti-tumor drug with topoisomerase I-inhibitory activity. The cytotoxicity of topotecan is thought to be due to double strand DNA damage.

Hycamtin is FDA approved for treatment of metastatic carcinoma of the ovary. Florida Medicare will cover Hycamtin for its FDA approved use, as well as for the treatment of the following off-labeled indicatons:

- Non-small cell and small cell carcinoma of the lung
- Myelodysplastic syndrome (MDS)
- Chronic myelomonocytic leukemia (CMML)

Trastuzumab (Herceptin®)-J9355

Trastuzumab is a monoclonal antibody, one of a group of drugs designed to attack specific cancer cells. Transtuzumab's's targets are cancer cells that overexpress an oncogene called HER2 or HER2/neu, which occurs in high numbers in about 25 to 30 percent of breast cancers.

Herceptin is indicated for the treatment of patients with metastatic breast cancer whose tumors overexpress HER2 and who have received one or more chemotherapy regimens for their metastatic disease.

Herceptin, in combination with paclitaxel, is indicated for treatment of patients with metastatic breast cancer whose tumors overexpress HER2 and who have not received chemotherapy for their metastatic disease.

Porfimer (Photofrin®)-J9600

Porfimer is a photosynthesizing agent that in combination with light, can cause cellular damage and tumor death. Tumor selectivity occurs as a result of selective distribution and retention of Porfimer on tumor tissue, and by selective delivery of light. Illumination of target tissue with 630 nanometer wavelength laser light induces a photochemical reaction that activates Porfimer. Porfimer photodynamic therapy causes the release of thromboxane A2, which results in vasoconstriction, activation and aggregation of platelets, and increased clotting. These factors contribute to ischemic necrosis which leads to tissue and tumor death.

Porfimer is for intravenous use. It is supplied as a 75 mg single dose vial. After reconstitution, 2 mg per kg of body weight should be administered slowly over three to five minutes followed by illumination with laser light and debridement of the tumor at appropriate and specific intervals. Photodynamic treatment with Porfimer may be given for a total of three courses of therapy, each separated by at least 30 days.

Porfimer is FDA approved for the palliative treatment of partial or complete obstruction of the esophagus due to esophageal cancer in patients who cannot be satisfactorily treated with Nd:YAG laser therapy alone.

Porfimer is also FDA approved for patients with non-small cell lung cancer (NSCLC) for whom surgery and radiotherapy are not indicated.

Denileukin diftitox (Ontak®)-J9999

Denileukin diftitox is a fusion protein designed to direct the cytocidal action of diphtheria toxin to cells which express the IL-2 receptor.

Ontak is indicated for the treatment of patients with persistent or recurrent cutaneous T-cell lymphoma (CTCL) whose malignant cells express the CD25 component of the IL-2 receptor.

The safety and efficacy of Ontak inpatients with CTCL whose malignant cells do not express the CD25 component of the IL-2 receptor have not been examined.

HCPCS Section & Benefit Category

Chemotherapy Drugs

Type of Bill Code

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

Revenue Code

636 Drugs Requiring Detailed Coding

HCPCS Codes

J9000	Doxorubicin HCl, 10 mg
J9001	Doxorubicin hydrochloride, all lipid formulations, 10 mg
J9015	Aldesleukin, per single use vial
J9045	Carboplatin, 50 mg
J9170	Docetaxel, 20 mg
J9181	Etoposide, 10 mg
J9182	Etoposide, 100 mg
J9185	Fludarabine phosphate, 50 mg
J9201	Gemcitabine HCl, 200 mg
J9265	Paclitaxel, 30 mg
J9280	Mitomycin, 5 mg

J9999: Antineoplastic Drugs (continued)

J9290	Mitomycin, 20 mg
J9291	Mitomycin, 40mg
J9293	Injection, mitoxantrone HCL, per 5 mg
J9350	Topotecan, 4 mg
J9355	Trastuzumab, 10 mg
J9600	Porfimer sodium, 75 mg
J9999	Not otherwise classified, antineoplastic drug

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

J9000-Doxorubicin HCl, 10 mg

150-0-150.9	Malignant neoplasm of esophagus
151.0-151.9	Malignant neoplasm of stomach
155.0	Malignant neoplasm of liver, primary
157.0-157.9	Malignant neoplasm of pancreas
160.0-160.9	Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses
162.2-162.9	Malignant neoplasm of lung (non-small/ small cell lung carcinoma)
164.0	Malignant neoplasm of thymus
170.0-170.9	Malignant neoplasm of bone and articular cartilage
171.0-171.9	Malignant neoplasm of connective and other soft tissue
174.0-174.9	Malignant neoplasm of female breast
175.0-175.9	Malignant neoplasm of male breast
176.0-176.9	Kaposi's sarcoma
180.0-180.9	Malignant neoplasm of cervix uteri
182.0	Malignant neoplasm of corpus uteri, except isthmus
183.0	Malignant neoplasm of ovary
185	Malignant neoplasm of prostate
186.0-186.9	Malignant neoplasm of testis
188.0-188.9	Malignant neoplasm of bladder
189.0	Malignant neoplasm of kidney, except pelvis
193	Malignant neoplasm of thyroid gland
195.0	Malignant neoplasm of head, face, and neck
200.00-200.88	Lymphosarcoma and reticulosarcoma
201.00-201.98	Hodgkin's disease
202.00-202.98	Other malignant neoplasms of lymphoid and histiocytic tissue (non-Hodgkin's lymphoma)
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
236.1	Neoplasm of uncertain behavior of placenta (Gestational trophoblastic tumor)

J9001-Doxorubicin, Liposomal (Doxil)

176.0-176.9	Kaposi's sarcoma
183.0	Malignant neoplasm of ovary

J9015-Aldesleukin (Proleukin®, interleukin-2, recombinant, and rIL-2)

172.0-172.9	Malignant melanoma of skin
189.0	Malignant neoplasm of kidney, except pelvis
189.1	Malignant neoplasm of renal pelvis
205.10-205.11	Chronic myeloid leukemia

J9045-Carboplatin (Paraplatin®, Paraplatin-AQ®)

140.0-149.9	Malignant neoplasm of lip, oral cavity, and pharynx
160.0-160.9	Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses (neuro-blastoma)
161.0-161.9	Malignant neoplasm of larynx
162.2-162.9	Malignant neoplasm of bronchus and lung (small cell & non-small cell)
172.0-172.9	Malignant melanoma of skin
174.0-174.9	Malignant neoplasm of female breast
175.0-175.9	Malignant neoplasm of male breast
182.0	Malignant neoplasm of corpus uteri, except isthmus
183.0	Malignant neoplasm of ovary
186.0-186.9	Malignant neoplasm of testis
188.0-188.9	Malignant neoplasm of bladder
189.0	Malignant neoplasm of kidney, except pelvis (Wilms' Tumor)
190.5	Malignant neoplasm of retina (retinoblastoma)
191.0-191.9	Malignant neoplasm of brain
194.0-194.9	Malignant neoplasm of other endocrine glands and related structures (neuroblastoma)
195.0	Malignant neoplasm of head, face, and neck

J9170-Docetaxel (Taxotere®)

140.0-149.9	Malignant neoplasm of lip, oral cavity, and pharynx
151.0-151.9	Malignant neoplasm of stomach
161.0-161.9	Malignant neoplasm of larynx
162.2-162.9	Malignant neoplasm of lung (non-small/ small cell lung carcinoma)
172.0-172.9	Malignant melanoma of skin
174.0-174.9	Malignant neoplasm of female breast
175.0-175.9	Malignant neoplasm of male breast
176.0-176.9	Kaposi's sarcoma
183.0	Malignant neoplasm of ovary
185	Malignant neoplasm of prostate
195.0	Malignant neoplasm of head and neck

J9181 & J9182-Etoposide (Etopophos®, Toposar®, VePesid®, VP-16)

151.0-151.9	Malignant neoplasm of stomach
155.0	Malignant neoplasm of liver, primary (heptoblastoma)
155.2	Malignant neoplasm of liver, not specified as primary or secondary
160.0-160.9	Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses (neuroblastoma)
162.2-162.9	Malignant neoplasm of bronchus and lung (small cell/non-small cell)
164.0	Malignant neoplasm of thymus
170.0-170.9	Malignant neoplasm of bone and articular cartilage (osteosarcomas and Ewing's sarcoma)

J9999: Antineoplastic Drugs (continued)

171.0-171.9	Malignant neoplasm of connective and other soft tissue
173.0-173.9	Other malignant neoplasm of skin (Cutaneous T-cell lymphoma)
174.0-174.9	Malignant neoplasm of female breast
175.0-175.9	Malignant neoplasm of male breast
176.0-176.9	Kaposi's sarcoma
182.0	Malignant neoplasm of corpus uteri, except isthmus
183.0	Malignant neoplasm of ovary
186.0-186.9	Malignant neoplasm of testis
188.0-188.9	Malignant neoplasm of bladder
189.0	Malignant neoplasm of kidney, except pelvis (Wilms' Tumor)
190.5	Malignant neoplasm of retina (retinoblastoma)
191.0-191.9	Malignant neoplasm of brain
194.0-194.9	Malignant neoplasm of other endocrine glands and related structures (neuroblastoma)
200.00-200.88	Lymphosarcoma and reticulosarcoma
201.00-201.98	Hodgkin's disease
202.00-202.98	Other malignant neoplasma of lymphoid and histiocytic tissue (non-Hodgkin's and cutaneous T-cell lymphoma)
203.00-203.01	Multiple myeloma
204.00-204.01	Acute lymphoid leukemia
205.00-205.01	Acute myeloid leukemia
205.10-205.11	Chronic myeloid leukemia
206.00-206.01	Acute monocytic leukemia
207.00-207.01	Acute erythremia and erythroleukemia
236.1	Neoplasm of uncertain behavior of placenta (Gestational trophoblastic tumor)

J9185-Fludarabine (Fludara®)

200.00-200.88	Lymphosarcoma and reticulosarcoma
202.00-202.98	Other malignant neoplasms of lymphoid and histiocytic tissue (non-Hodgkin's lymphoma)
204.10-204.11	Chronic lymphoid leukemia
205.00-205.01	Acute myeloid leukemia
206.00-206.01	Acute monocytic leukemia
207.00-207.01	Acute erythremia and erythroleukemia

J9201-Gemcitabine (Gemzar®)

157.0-157.9	Malignant neoplasm of pancreas
162.2-162.9	Malignant neoplasm of lung (non-small cell lung carcinoma)
[174.0-174.9	Malignant neoplasm of female breast
175.0-175.9	Malignant neoplasm of male breast
183.0	Malignant neoplasm of ovary
188.0-188.9	Malignant neoplasm of bladder

J9265-Paclitaxel (Taxol®)

140.0-149.9	Malignant neoplasm of lip, oral cavity, and pharynx
150.0-150.9	Malignant neoplasm of esophagus
151.0-151.9	Malignant neoplasm of stomach
161.0-161.9	Malignant neoplasm of larynx
162.2-162.9	Malignant neoplasm of bronchus and lung (small cell/non-small cell)
174.0-174.9	Malignant neoplasm of female breast
175.0-175.9	Malignant neoplasm of male breast
176.0-176.9	Kaposi's sarcoma
180.0-180.9	Malignant neoplasm of cervix uteri
182.0	Malignant neoplasm of corpus uteri, except isthmus
183.0	Malignant neoplasm of ovary
185	Malignant neoplasm of prostate
188.0-188.9	Malignant neoplasm of bladder

J9280, J9290, and J9291-Mitomycin (Mutamycin®, mitomycin-C)

140.0-149.9	Malignant neoplasm of lip, oral cavity, and pharynx
150.0-150.9	Malignant neoplasm of esophagus
151.0-151.9	Malignant neoplasm of stomach
153.0-154.8	Malignant neoplasm of colon, rectum, rectosigmoid juction, and anus
156.0-156.9	Malignant neoplasm of gallbladder and extrahepatic bile ducts
157.0-157.9	Malignant neoplasm of pancreas
161.0-161.9	Malignant neoplasm of larynx
162.2-162.9	Malignant neoplasm of bronchus and lung (non-small cell)
174.0-174.9	Malignant neoplasm of female breast
175.0-175.9	Malignant neoplasm of male breast
180.0-180.9	Malignant neoplasm of cervix uteri
185	Malignant neoplasm of prostate
188.0-188.9	Malignant neoplasm of bladder
195.0	Malignant neoplasm of head, face and neck
205.10-205.11	Chronic myeloid leukemia

J9293-Mitoxantrone Hydrochloride (Novantrone®)

174.0-174.9	Malignant neoplasm of female breast
175.0-175.9	Malignant neoplasm of male breast
185	Malignant neoplasm of prostate
200.00-200.88	Lymphosarcoma and reticulosarcoma
202.00-202.98	Other malignant neoplasms of lymphoid and histiocytic tissue
204.00-204.01	Acute lymphoid leukemia
205.00-205.01	Acute myeloid leukemia
206.00-206.01	Acute monocytic leukemia
207.00-207.01	Acute erythremia and erythroleukemia

J9350-Topotecan Hydrochloride (Hycamtin®)

162.2-162.9	Malignant neoplasm of lung (non-small/ small cell lung carcinoma)
183.0	Malignant neoplasm of ovary
205.10	Chronic myeloid leukemia without mention of remission (CML)
205.11	Chronic myeloid leukemia in remission (CML)
238.7	Neoplasm of uncertain behavior of other lymphatic and hematopoietic tissues (MDS)

J9355-Trastuzumab (Herceptin®)

174.0-174.9	Malignant neoplasm of female breast
175.0-175.9	Malignant neoplasm of male breast
196.0-196.9	Secondary and unspecified malignant neoplasm of lymph nodes
197.0-197.8	Secondary malignant neoplasm of respiratory and digestive systems

J9999: Antineoplastic Drugs (continued)

198.0	Secondary malignant neoplasm of kidney
198.1	Secondary malignant neoplasm of other urinary organs
198.2	Secondary malignant neoplasm of skin
198.4	Secondary malignant neoplasm of other parts of nervous system
198.5	Secondary malignant neoplasm of bone and bone marrow
198.6	Secondary malignant neoplasm of ovary
198.7	Secondary malignant neoplasm of adrenal gland
198.82	Secondary malignant neoplasm of other specified sites, genital organs

Note: **The billing of Herceptin® requires dual diagnoses. To ensure reimbursement for this service, dual diagnoses must be submitted. The primary and secondary site of the malignancy must** *both* **be billed to indicate the breast malignancy is metastatic (e.g., ICD-9-CM code 174.0** *and* **198.5).**

J9600-Porfimer (Photofrin®)

150.0 to 150.9	Malignant neoplasm of esophagus
162.2 to 162.9	Malignant neoplasm of bronchus and lung (non-small cell)

J9999-Denileukin diftitox (Ontak®)

202.10-202.18	Mycosis fungoides
202.20-202.28	Sezary's 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

Coding Guidelines

When billing a chemotherapy drug that has a specific HCPCS code, use the appropriate ICD-9-CM diagnosis code which indicates the medical condition being treated.

When billing for Trastuzumab 10mg, use HCPCS code J9355 and include the name of the drug and the appropriate ICD-9-CM diagnosis code which indicates the medical condition being treated. The primary and secondary site of the malignancy must **both** be billed to indicate the breast malignancy is metastatic (e.g., ICD-9-CM code 174.0 **and** 198.5). Documentation which demonstrates that the patient's tumor overexpresses the HER2 protein or gene must be maintained in the patient's medical record.

When billing for Denileukin diftitox, use HCPCS code J9999 and include the name of the drug and the appropriate ICD-9-CM diagnosis code which indicates the medical condition being treated.
Documentation which demonstrates that the patient's malignant cells express CD25 must be maintained in the patient's medical record.

Hospitals may also use the following alpha-numeric code (in addition to the drug code):

Q0084 - Chemotherapy administration by infusion technique only, per visit. (Revenue code 335-Chemotherapy/IV)

Hospitals should **not** use HCPCS 96400-96540 to report chemotherapy, as these are non-reportable HCPCS codes.

Documentation Requirements

Medical record documentation maintained by the ordering/referring physician must substantiate the medical need for the use of these chemotherapy drugs by clearly indicating the condition for which these drugs are being used. This documentation is usually found in the history and physical or in the office/progress notes.

If the provider of the service is other than the ordering/referring physician, that provider must maintain copies of the ordering/referring physician's order for the chemotherapy drug. The physician must state the clinical indication/medical need for using the chemotherapy drug in the order.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information

Abramowicz, M. (Ed.) (1996). On Drugs and Therapeutics. *The Medical Letter*, 39.
21-24.

Deglin, J.H., Vallerand, A.H. (Eds.) (1995). *Davis' Drug Guide for Nurses* (4th ed.). Philadelphia: F.A. Davis Company.

DeVita, V.T., Hellman, S., Rosenberg, S.A. (Eds.). (1996). *Cancer Principles and Practice of Oncology* (5th ed.). Philadelphia: J.B. Lippincott Company.

United States Pharmacopoeia Drug Information

JOURNAL ARTICLES PERTAINING TO GEMZAR:

Abratt, R.P., Bezwoda, W.R., Goedhals, L. And Hacking, D.J. (1997). Weekly Gemcitabine With Monthly Cisplatin: Effective Chemotherapy for Advanced Non-Small Cell Lung Cancer. *Journal of Clinical Oncology,* 15 (2), 744-749.

Crino, L., Scagliotti, G., Marangola, M., Figola, F., Clerici, M., et al. (1997). Cisplatin-Gemcitabine Combination in Advanced Non-Small Cell Lung Cancer. *Journal of Clinical Oncology*, 15 (1), 297-303.

Kelly, K. (1997). Overview of the Randomized Phase III Trials in Non-Small Cell Lung Cancer in North America. *Seminars in Oncology*, 24 (3), S8.2-S8.5.

J9999: Antineoplastic Drugs (continued)

JOURNAL ARTICLES PERTAINING TO TAXOTERE:

Aamdal, S., Wolff, I., Kaplan, S., et al. (1994). Docetaxel (Taxotere) In Advanced Malignant Melanoma: a Phase II Study of the EORTC Early Clinical Trials Group. *European Journal of Cancer,* 30A, 1061-1064.

Bedikian, A., Weiss, G., Legha, S., et al. (1995). Phase II Trial of Docetaxel in Patients With Advanced Cutaneous Malignant Melanoma Previously Untreated with Chemotherapy. *Journal of Clinical Oncology,* 13, 2895-2899.

Dreyfuss, A., Clark, J., Norris, C., et al. (1996). Docetaxel: An Active Drug Against Squamous Cell Carcinoma of the Head and Neck. *Journal of Clinical Oncology,* 14, 1672-1678.

Fossella, F., Lee, J., Shin, D., et al. (1995). Phase II Study of Docetaxel for Platinum-Refractory Non-Small Cell Lung Cancer. *Journal of Clinical Oncology,* 13, 645-651.

Francis, P., Schneider, J., Hann, L., et al. (1994). Phase II Trial of Docetaxel in Patients With Platinum-Refractory Advanced Ovarian Cancer. *Journal of Clinical Oncology,* 12, 2301-2308.

Miller, V., Rigas, J., Francis, P., et al. (1995). Phase II Trial of a 75-mg/m2 Dose of Docetaxel with Prednisone Premedication For Patients With Advanced Non-Small Cell Lung Cancer. *Cancer,* 75, 968-972.

Piccart, M., Gore, M., Ten Bokkel Huinink, W., et al. (1995). Docetaxel: An Active New Drug For Treatment of Advanced Epithelial Ovarian Cancer. *Journal of the National Cancer Institute*, 87, 676-681.

Smyth, J., Smith, I., Sessa, C., et al. (1994). Activity of Docetaxel in Small Cell Lung Cancer. *European Journal of Cancer*. 30A, 1058-1060.

Sulkes, A., Smyth, J., Sessa, C., et al. (1994). Docetaxel (Taxotere®) in Advanced Gastric Cancer: Results of a Phase II Clinical Trial. *British Journal of Cancer*. 70, 380-383.

JOURNAL ARTICLES PERTAINING TO HYCAMTIN:

Ardizzoni, A., Hansen, H., Dombernowsky, P., et al. (1997). Topotecan, a New Active Drug in the Second-Line Treatment of Small-Cell Lung Cancer: A Phase II Study in Patients With Refractory and Sensitive Disease. *Journal of Clinical Oncology,* 15 (5), 2090-2096.

Masuda, N., Fukuoka, M., Kusunoki, Y., et al. (1992). CPT-II: A New Derivative of Camptothecin for the Treatment of Refractory or Relapsed Small Cell Lung Cancer. *Journal of Clinical Oncology,* 10 (8), 1225-1229.

Perez-Soler, R., Glisson, B.S., Lee, J.S., et al. (1996). Treatment of Patients With Small Cell Lung Cancer Refractory to Etoposide and Cisplatin With the Topoisomerase I Poison Topotecan. *Journal of Clinical Oncology,* 14 (10), 2785-2790.

Schiller, J.H., Kim, K., Hutson, P., et al. (1996). Phase II Study of Topotecan in Patients With Extensive-Stage Small Cell Carcinoma of the Lung: An Eastern Cooperative Oncology Group Trial. *Journal of Clinical Oncology,* 14 (8), 2345-2352.

JOURNAL ARTICLES PERTAINING TO PHOTOFRIN:

Barkin, J.S., O'Phelan, C.A. (Eds.) (1994). *Advanced Therapeutic Endoscopy* (2nd ed.). New York: Raven Press, Ltd.

Heier, S., Rothman, K., et al. (1995). Photodynamic Therapy for Obstructing Esophageal Cancer: Light Dosimetry and Randomized Comparison with Nd:YAG Laser Therapy. *Gastroenterology,* 109, 63-72.

Lightdale, C., Heier, S., et al (1995). Photodynamic Therapy with Porfimer Sodium Versus Thermal Ablation Therapy with Nd:YAG Laser for Palliation of Esophageal Cancer: A Multicenter Randomized Trial. *Gastrointestinal Endoscopy,* 42, 507-512.

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 the contractor's Advisory Committee, which includes representatives from numerous societies.

Start Date of Comment Period

02/21/2000

Start Date of Notice Period

06/01/2000

Revision History

Revision Number: 5
Start Date of Comment Period: 02/21/2000
Start Date of Notice Period: 06/01/2000
June/July 2000 Bulletin
Revised Effective Date: 07/17/2000
Explanation of Revision: Added eight new drugs to policy

Start Date of Comment Period: N/A
Start Date of Notice Period: 12/01/1999
Dec 1999 Special Issue Bulletin
Original Effective Date: 11/02/1998
Revision Date/Number: 01/17/2000 4
(HCPCS 2000)

Start Date of Comment Period: 07/06/1999
Start Date of Notice Period: 12/01/1999
Dec/Jan 1999 Bulletin
Original Effective Date: 11/02/1998
Revision Date/Number: 01/17/2000 3
Explanation of Revision: Additional indication for J9000

Start Date of Comment Period: N/A
Start Date of Notice Period: 08/01/1999
Aug/Sept 1999 Bulletin
Original Effective Date: 11/02/1998
Revision Date/Number: 09/23/1999 2
Explanation of Revision: Additional indication for J9000

Start Date of Comment Period: 02/08/99
Start Date of Notice Period:
Original Effective Date: 11/02/98
Revision Date/Number: 07/22/99 1
Explanation of Revision: Additional off-label indications approved

Start Date of Comment Period: 05/29/98
Start Date of Notice Period: 09/18/98
Original Effective Date: 11/02/98 ❖

Medicare Noncovered Services - Investigational Status

The following medical services are noncovered procedures by Florida Medicare on the basis of being investigational/ experimental.

62263: Percutaneous Lysis of Epidural Adhesions

Percutaneous lysis of epidural adhesions (62263) is commonly referred to as "Percutaneous neurolysis of adhesions" or "Percutaneous epidural neuroplasty." This procedure received its own procedure code (62263) for 2000.

62263 Percutaneous lysis of epidural adhesions using solution injection (eg, hypertonic saline, enzyme) or mechanical means (eg, spring-loaded catheter) including radiologic localization (includes contrast when administered).

Percutaneous epidural neuroplasty is an interventional pain management technique that is used to treat radiculopathy with low back pain. The stated goals for epidural neuroplasty are to break down fibrous adhesions that may prevent free movement of structures in the intervertebral foramen and in the bony vertebral canal, to remove any barriers (scar) that prevent application of medication to structures believed to be the source of pain, and to apply medication to the structures (e.g., anesthetics, corticosteroids). However, there are limited peer reviewed published studies documenting the safety and effectiveness of this procedure. There are also published articles that call into question the improved patient outcomes, the therapeutic mechanism of the procedure, and address the significant adverse effects that can result from this procedure.

Therefore, Florida Medicare considers procedure code 62263 to be investigational, therefore, should be billed as a noncovered service.

Note: **Procedure codes 62281 and/or 62282 must not be billed to represent percutaneous lysis of epidural adhesions (62263).**

Effective Date: 07/17/2000

A9270: Arthroscopic Laser Arthrodesis

Recently, Florida Medicare has been receiving claims for a surgical procedure referred to as an arthroscopic laser arthrodesis/ rhizotomy of the facet joint with cancellous bone allograft and autologous platelet gel patch. Florida Medicare has determined that this procedure is investigational and therefore noncovered by Medicare. This surgical procedure must be billed as a noncovered service.

Effective Date: 07/17/2000.. ❖

SKILLED NURSING FACILITY SERVICES

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

Medicare will cover skilled nursing facility (SNF) care for beneficiaries **involuntarily** disenrolling from M+C plans as a result of a M+C plan termination when the beneficiary does not have a 3-day prospective payment system (PPS) hospital stay before an SNF admission. If Medicare does not cover these claims, beneficiaries will be liable to pay them. Beneficiaries in this situation have not been aware of their potential financial liability for their SNF care. The Health Care Financing Administration is in the process of developing policy documents that will provide specific instructions for future years.

Counting of the 100-days of care will start with the SNF admission date (regardless of whether the beneficiary met the skilled level of care requirements on that date). All other original Medicare rules apply, such as the requirement that beneficiaries meet the skilled level of care requirement (for the period for which the original Medicare fee-for-service program is being billed).

To address this situation for enrollees disenrolling from terminating M+C plans, the 3-day hospitalization met requirement will be deemed. This policy will continue until further instructions are issued by the Health Care Financing Administration.

Reimbursement Conditions

To be reimbursed for these bills:

- Providers must use ***condition code 58*** on the first fee-for-service (also known as "Original Medicare") claim for a beneficiary who was in a terminating M+C plan, and was an inpatient of a SNF at the time of termination.
- The beneficiary must be assigned to a ***resource utilization group (RUG)***. Original Medicare coverage rules regarding the skilled level of care requirements will be applied. Payment will be made only for claims submitted for beneficiaries in certified SNF beds.

Original Medicare fee-for-service rules regarding beneficiary cost sharing apply to these cases. That is, providers may only charge beneficiaries for SNF coinsurance amounts. ❖

ESRD

ESRD Facilities—Billing for Iron Dextran

As a result of the 2000 Health Care Financing Administration Common Procedure Coding System (HCPCS) update, the HCPCS code for reporting iron dextran injection, 2cc, (J1760) was discontinued and may no longer be used.

Therefore, effective **January 1, 2000,** HCPCS code **J1750** must be used to bill for this drug.

J1750 Injection, iron dextran, 50mg

Medicare Allowance $17.91. ❖

FRAUD AND ABUSE

Caveat Emptor - Let the Buyer Beware

The Medicare program is the single largest payer of health care benefits in this country. As such, Medicare is big business and has attracted, as big businesses sometimes do, a few unsavory characters. Although the majority of health care providers (e.g., physicians, hospitals, laboratories, medical equipment suppliers, etc.) and other organizations that may be indirectly involved in the Medicare program (billing agencies, medical management firms, consultants, etc.) are honest, those few who are not cause billions of taxpayer dollars to be inappropriately paid each year. Thus, it is important that health care providers and others understand the risks that may be associated with conducting business within the Medicare program.

In some instances, a scam or fraudulent activity may not result in a direct loss to the Medicare program. However, the scam or activity may mislead a health care provider into making unsound business decisions or, as a result, cause improper payments to be made by the Medicare program. The example of such an activity that follows is based on the use of a private billing company or consulting firm, it is not meant as an indictment of those entities.

An advertisement is sent to health care providers outlining the benefits of hiring a billing company to file their Medicare claims electronically for the provider. This activity in itself is not illegal; Medicare encourages providers to file electronically. However, some advertising may include the following kinds of statements:

> The company indicates it is affiliated with either the Health Care Financing Administration (HCFA) or the Medicare contractor(s). *Neither HCFA nor Medicare contractors have any affiliation with private billing companies, consulting firms, or the like.*
>
> The company misrepresents or exaggerates the time it takes to process claims filed electronically versus those filed on paper. *While it is true that "clean" claims filed electronically are paid sooner than "clean" paper claims, some advertising leads the readers to believe that paper claims are not even looked at or entered into the claim processing system until the 27th day after they are submitted. This statement is not true—to be more accurate, a "clean" electronic claim is paid on the 14th day after it is submitted and a "clean" paper claim is paid on the 27th day after it is submitted.*
>
> The company indicates that electronic claims are paid without question and that paper claims are paid only on a "funds availability" basis. *All covered services reported on a claim (regardless of how it is submitted)* ***must*** *be paid by the Medicare program. There is no "funds availability" policy.*
>
> The company indicates that the provider may be at risk of losing their participation status with the Medicare program if they do not file claims electronically, or the company indicates that there is an additional fee or "penalty" associated with filing paper claims to Medicare. *There is no mandate that requires health care providers to file their claims electronically to Medicare. Health care providers are only required to submit claims for qualified Medicare recipients to whom services and items are furnished. The method of submission is the choice of the provider. Again, however, there are benefits to filing claims electronically.*
>
> Some companies indicate they can assist the provider "maximize" reimbursements from the Medicare program. *Although health care providers should be paid appropriately for the services and items they furnish, they should exercise caution when attempting to "maximize" their payments as this may lead to improper billing, "upcoding" or even misrepresentation of claims or records. If done willfully and knowingly, this type of activity is considered fraud and is punishable by law.*

To ensure that a health care provider or other organization conducts business appropriately in the Medicare program, several safeguard practices should be considered. Regardless of whether a provider contracts with a private billing company or consulting firm or hires its own employees, here are a few suggestions to considered:

- The employees, billing company, or consulting firm should have at least a working knowledge of the Medicare program as it pertains to their particular business. Information regarding the Medicare program, its policies and its guidelines can be obtained from a number of resources such as: seminars or workshops, publications, web sites, health care attorneys, consultants, and, of course, the Medicare contractors.
- The provider or organization may consider implementing a compliance program to ensure that they not only adhere to Medicare regulations, but to ensure that they are engaged in sound, ethical business practices. Note that compliance programs are not required, but have proven to be effective for many health care providers.
- Periodic "self-checks" or audits may be conducted to ensure compliance with regulations and billing guidelines. In addition, the audits may serve as a method for identifying areas for improvement as well as identifying inappropriate practices or payments.
- Ensure that the employees, billing company, or consulting firm maintains the integrity and confidentiality of medical records, patients' health insurance information, and providers' billing numbers.

Billing agencies, medical management firms, and consultants provide services that can be of value to a provider's practice, although these companies do not do anything a provider cannot do for him or herself. Following the guidelines autlined in this article will allow providers to minimize risks while doing business within the Medicare program. ❖

EDUCATIONAL RESOURCES

MEDICARE PROVIDER EDUCATION AND TRAINING EVENTS FOR YEAR 2000

MEDIFEST 2000
The Cutting Edge Training Conference

The Tampa/St. Petersburg (July 11 & 12) and Orlando (August 8 & 9) MEDIFEST events are sold out!!! Check out the remaining events Medicare Education and Outreach will conduct in 2000:

Provider Education and Training (PET) Advisory Council Meetings for Medicare Part A and B Providers
Education – A Team Effort

- Effect change by contributing to the development of user-friendly, high-quality curricula and reference materials
- Partner with Medicare to review and create materials that meet your educational needs
- Network with other providers, members of state medical/hospital associations, and Medicare consultants

Let's Talk With Medicare: Part A Sessions
Providers and Medicare – Working Together to Achieve Results

- Receive information about the latest Medicare regulations – Hot Topics
- Have your questions answered by Medicare experts
- Find out proven ways to resolve Medicare denials
- Meet your Medicare representatives
- Discover new Medicare technologies and different avenues of education
- Make contacts and network with other providers who face some of the same challenges you do
- Obtain tips to avoid claim processing denials and/or RTPs

Let's Talk With Medicare: Part B Sessions
Providers and Medicare – Working Together to Achieve Results

- Receive the latest Medicare News – Hot Topics
- Have your questions answered by Medicare experts
- Find out proven ways to resolve Medicare denials
- Meet your Medicare representatives
- Discover new Medicare technologies and different avenues of education
- Make contacts and network with other providers who face some of the same challenges you do
- Obtain tips to avoid electronic rejects, claim filing denials, and unprocessable claims

Medical Specialty Seminar Schedule

Look! Read!

Have you ever struggled with your work or wasted your time trying to learn by "trial and error?
If you answered "yes" then come to Medicare's Specialty Seminar Classes

- Medicare Training that respects your time and your budget!
- From basics to the tough stuff, learn tips and techniques that multiply your productivity.
- Learn how to file claims quickly, easily, and correctly for your specialty

FREE!!!

Part A & B:

Jacksonville - July 26, 2000
Blue Cross Blue Shield Bldg.
532 Riverside Ave.
(904) 792-8299

8:30 – 11:30 a.m.

❑ Rehabilitative Services

If you have questions for the above seminar please call (904) 791-8299.

Four Easy Steps to Register:

STEP 1: FAX registration form to (904)791-6035

OR

STEP 2: Mail this form to:

Seminar Registration
PO Box 45157
Jacksonville, FL 32231

STEP 3: Directions to the facility and a confirmation number will be faxed within 10 days of receiving your registration. Bring this with you the day of the event. If you do not receive a confirmation number, please call (904) 791-8299

Register TODAY!!
Seating is Limited!

Provider/Company Name: _____

Registrant's Name: _____

Registrant's Title or Position: _____

Medicare Billing Provider/Group Number: _____

Address: _____

City, State, ZIP Code: _____

Phone: ( ) _____ Fax: ( ) _____

"Let's Talk With Medicare" - Part B Session

MEDICARE PART B PROVIDERS

Would You Like to Discuss Billing and/or Program Issues With Your Medicare Part B Representatives?

First Coast Service Options, Inc., is offering you the opportunity to discuss your questions or concerns (face-to-face) with representatives from the many departments within Medicare. Help us help you! We are excited about the opportunity to meet you and address/resolve your inquiries. Register for one of Medicare's "Let's Talk" Sessions.

To help us address your questions and/or concerns, we need them ***ten (10) days prior to the event***. Please complete this survey and fax it to:
Medicare Education and Outreach at (904) 791-6035

Describe specific topics that require further clarification. Include examples and/or any supporting documentation.

Claims Submission *(e.g., claim filing questions, unprocessible claims, denials, etc.)*

_____
_____
_____

Electronic Claims Submission *(e.g., electronic funds transfer, mailbox questions, PC-ACE™, etc.)*

_____
_____
_____

Inquiries, Appeals and Overpayments: *(e.g., questions about reviews, customer service, returning money to Medicare, etc.)*

_____
_____
_____

Medical Policy/Review: *(e.g., medical review process, utilization denials, etc.)*

_____
_____
_____

Questions Concerning Your Specialty *(e.g., chiropractic, radiology, pathology, etc.)*

_____
_____
_____

Other

_____
_____
_____

"Let's Talk With Medicare" - Part B Session

FOUR IMPORTANT STEPS

Four Easy Steps to Register:

STEP 1: FAX registration form to (904)791-6035

STEP 2: Mail this form to:

Seminar Registration
PO Box 45157
Jacksonville, FL 32231

STEP 3: Directions to the facility and a confirmation number will be faxed within 10 days of receiving your registration. Bring this with you the day of the event. If you do not receive a confirmation number, please call (904) 791-8299

Register TODAY!!
Seating is Limited!

MEDICARE PART B PROVIDER - REGISTRATION FORM

Registrant's Name: _____

Registrant's Title/Position _____

Provider's Name: _____

Medicare Billing Provider/Group Number: _____

Address: _____

City, State, ZIP Code: _____

Phone: ( ) _____ Fax: ( ) _____

Time: 1:00 p.m. - 4:30 p.m.

FREE!!!

❑ **July 28, 2000**

Location: FCSO/Blue Cross Blue Shield of FL
532 Riverside Ave.
Jacksonville, FL 32202

"Let's Talk With Medicare" - Part A Session

MEDICARE PART A PROVIDERS

Would You Like to Discuss Billing and/or Program Issues With Your Medicare Part A Representatives?

First Coast Service Options, Inc., is offering you the opportunity to discuss your questions or concerns (face-to-face) with representatives from the many departments within Medicare. Help us help you! We are excited about the opportunity to meet you and address/resolve your inquiries. Register for one of Medicare's "Let's Talk" Sessions.

To help us address your questions and/or concerns, we need them ***ten (10) days prior to the event***. Please complete this survey and fax it to:
Medicare Education and Outreach at (904) 791-6035

Describe specific topics that require further clarification. Include examples and/or any supporting documentation.

Claims Submission *(e.g., claim filing, return to provider reason codes, denial reason codes)*

Direct Data Entry *(e.g., screens, field values, navigation, onilne reports)*

Medicare Part A Reports *(e.g., consolidated provider profile report, 201 report)*

Medical Policy *(e.g., medical review process, additional development correspondence)*

Questions Concerning Your Specialty *(e.g., Skilled Nursing Facility, End Stage Renal Disease, etc.)*

Other

"Let's Talk With Medicare: Part A Session"

FOUR IMPORTANT STEPS

Four Easy Steps to Register:

STEP 1: FAX registration form to (904)791-6035

STEP 2: Mail this form to:

Seminar Registration
PO Box 45157
Jacksonville, FL 32231

STEP 3: Directions to the facility and a confirmation number will be faxed within 10 days of receiving your registration. Bring this with you the day of the event. If you do not receive a confirmation number, please call (904) 791-8299

Register TODAY!!
Seating is Limited!

MEDICARE PART A PROVIDER - REGISTRATION FORM

Registrant's Name: _____

Registrant's Title/Position _____

Provider's Name: _____

Medicare Billing Provider/Group Number: _____

Address: _____

City, State, ZIP Code: _____

Phone: ( ) _____ Fax: ( ) _____

Please select one of the following dates

Time: 8:30 a.m. - 12:00 p.m. **FREE!!!**

❑ **July 28, 2000**

Location: FCSO/Blue Cross Blue Shield of FL
532 Riverside Ave.
Jacksonville, FL 32202

Provider Education and Training Advisory Meeting

Medicare Education and Outreach cordially invites you to attend our quarterly Part A and Part B Provider Education and Training Advisory Meeting on September 27, 2000 in Jacksonville.

First Coast Service Options, Inc. is excited about offering a forum to encourage open dialogue between the Medicare contractor and representatives from state medical societies, specialty associations, provider organizations, practitioners, consultants, billing staffs, and others.

During this session the contractor will share important information about Medicare initiates, trends, aberrancies, other significant issues.

With the help of individuals like you we have proven that partnership works to help us make operational improvements. We are seeking your help to:

- Recommend areas for additional policy clarifications/provider training
- Assist in the improvement of our *Medicare A Bulletin* and *Medicare B Update!*
- Enhance our customer service ARU system
- Recommend topics for special curriculum development
- Evaluate the value and effectiveness of educational sessions attended
- Alert First Coast Service Options to claim processing/system irregularities effecting provider billing

How to prepare for this meeting:

1. Note your recommendations or topics of concern in the space provided below (additional pages are welcome)
2. Fax your registration and comments 10 days prior to the event (September 15, 2000)
3. Be prepared to discuss your ideas in an open and relaxed forum

_____

_____

_____

Please come and spend an exciting and informative half day with us! Your contributions are vital to the success of your carrier/ intermediary. You will not be disappointed.

Register Today! Seating is limited

FOR MORE INFORMATION CALL (904) 791-8299

REGISTRATION FORM

for Quarterly Medicare Part A and Part B
Provider Education and Training Advisory Meeting

Please complete one form per person

Registrant's Name:_____

Registrant's Title/Position:_____

Provider's Name:_____

Specialty Association Name:_____

Medicare Billing Provider Number:_____

Address:_____

City, State, ZIP Code:_____

Phone: ( )_____ Fax: ( )_____

Cost: FREE!!

Please fax your registration form to (904) 791-6035

Location: **First Coast Service Options, Inc.**
532 Riverside Avenue
Jacksonville, FL 32202

Directions to our building will be faxed with your confirmation

Time: **8:30 a.m. - 12:30 a.m.**

❑ **September 27, 2000**

Please RSVP 10 days prior to the event
Mark your calendar!

Two New Computer Based Training Courses Available

In an effort to increase awareness of preventive health services that are covered by Medicare, the Health Care Financing Administration (HCFA) has made available via the Medicare Online Training Website (www.medicaretraining.com), two new *free* computer based training (CBT) courses – *Women's Health* and *Adult Immunizations*.

Every year, pneumonia and flu take the lives of 40,000 to 70,000 Americans. Ninety percent of these deaths are in the Medicare population. The goals of the *Adult Immunizations* course are to help physicians better understand the importance of immunizations, and identify ways to increase immunization rates in the healthcare community. The *Women's Health* course describes Medicare's coverage criteria as they relate to mammograms, pap tests, pelvic exams, and colorectal screenings. The course also identifies how physicians should bill for these services.

In an effort to reach larger audiences with their message in 1999, HCFA provided a series of satellite broadcasts for healthcare professionals throughout the United States. Broadcast attendees were given the opportunity to interact with a panel of medical and healthcare industry experts who discussed important healthcare issues in a national context. Free video tapes of these broadcasts may be ordered for a limited time via the Medicare Online Training Website (***www.medicaretraining.com***).

The CBT courses offer the convenience of learning at one's own pace. In each course, users are given the opportunity to practice what they've learned through quizzes and tests. Users may take as long as they want to complete each course, and may take them as often as they like.

With the addition of *Women's Health* and *Adult Immunizations*, there are now 10 free CBT courses available. They include:

- *World of Medicare* - an introduction to the Medicare program
- *ICD-9-CM Coding* - instructs providers in the proper use of the ICD-9-CM manual for correct diagnosis coding
- *Medicare Fraud & Abuse* - emphasizes the prevention and early detection of fraud and abuse
- *Front Office Management* - provides essential knowledge needed for "checking in" Medicare patients
- *Medicare Secondary Payer (MSP)* - provides basic information about the MSP program
- *HCFA-1500* - provides essential information required to properly complete the HCFA-1500 claim form
- *HCFA-1450 (or UB-92)* - provides essential information required to properly complete the HCFA-1450 claim form.
- *Medicare Home Health Benefit* - emphasizes the guidelines that providers must follow when dealing with Home Health Agencies

Two additional CBT courses on *Medicare Coverage and Payment* and *Medicare Appeals* are scheduled for release later in 2000.

Medicare Provider Website Replaces BBS

A new website for Medicare providers serviced by First Coast Service Options, Inc. (FCSO) is now available at ***www.floridamedicare.com***. Medicare is migrating (gradually moving) *all* information currently on the Medicare Online Bulletin Board System (BBS) to the website. Once the migration is complete, the BBS will be phased out within *three to six months*. Therefore, BBS users may wish to start becoming familiar with the new website.

Information Available on *www.floridamedicare.com*

- Medicare Part A: final and draft LMRPs, reason code list
- Medicare Part B: Medigap list, crossover information, final LMRPs
- Shared information (pertains to Medicare Part A and B): EDI forms and programming specifications, UPIN, HMO, Medpard listings
- And more coming soon!

Features

- Search through documents for specific information
- Download any file to your own computer for future offline access

Most files on the site are in PDF® format

PDF® (Portable Document Format) is an Adobe® Systems, Inc. file format that preserves the look and feel of an original document, complete with fonts, colors, images, and layout. Because PDF® lets a user view and print a document exactly as the author designed it, regardless of the original application, it has become an Internet standard for electronic distribution.

Providers wishing to view files on ***www.floridamedicare.com*** need *Adobe Acrobat Reader®* on their computers. Acrobat Reader® is free (and freely distributable) software that lets users view and print PDF® documents. Most Internet browsers and new computers come with Acrobat Reader®; it can also be downloaded from the Adobe® website at ***www.adobe.com.***

Third party Web sites. *This document contains references to sites operated by third parties. Such references are provided for your convenience only. BCBSF and/or FCSO do not control such sites, and are not responsible for their content. The inclusion of these references within this document does not suggest any endorsement of the material on such sites or any association with their operators.*

ORDER FORM - 2000 PART A MATERIALS

The following materials are available for purchase by Medicare providers. To order these items, please complete and **submit this form along with your check/money order (PAYABLE TO: First Coast Service Options, Inc. account number 756134)**

NUMBER ORDERED	ITEM	ACCOUNT NUMBER	COST PER ITEM
_____	**Additional Medicare Part A Bulletin Subscriptions** - For non-providers (e.g., billing agencies, consultants, software vendors, etc.) or providers who need additional copies at other office locations, an annual subscription is available. This subscription includes all Medicare bulletins published during calendar year 2000. Please check here if this will be a Subscription Renewal [ ] or New Subscription [ ]	756134	$75.00

Subtotal $ _____

Tax **(6.5%)** $ _____

Total $ _____

Mail this form with payment to:

First Coast Service Options, Inc.

Medicare Publications - ROC 6T

P.O. Box 45280

Jacksonville, FL 32232-5280

Facility Name:_____

Mailing Address:_____

City:_____ State:_____ Zip Code:_____

Attention:_____ Area Code/Telephone Number:_____

Procedure Codes

Medicine, 90281-99199

HCPCS Codes

HCPCS Codes (continued)

* Special *Bulletins*

Addresses

CLAIMS STATUS

Coverage Guidelines
Billing Issues Regarding
Outpatient Services, CORF, 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

"Getting Started"
Direct Data Entry (DDE)
P. O. Box 44071
Jacksonville, FL 32231
(904) 791-8131

FRAUD AND ABUSE

Medicare 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

Medicare Websites

PROVIDERS

Florida Medicare Contractor
www.floridamedicare.com
Health Care Financing Administation
www.hcfa.gov

BENEFICIARIES

Florida Medicare Contractor
www.medicarefla.com
Health Care Financing Administation
www.medicare.gov

Phone Numbers

PROVIDERS

Automated Response Unit
904-355-8899

Customer Service Representatives:
904-355-8899

MEDICARE ONLINE BBS

Access
800-838-8859
904-791-6991

Technical Problems
904-791-8384

BENEFICIARY

904-355-8899

ELECTRONIC MEDIA CLAIMS

EMC Start-Up:
904-791-8767

EMC Front-End Edits/Rejects:
904-791-8767

Electronic Remittance Advice
904-791-6895

Electronic Claim Status
904-791-6895

Electronic Eligibility
904-791-6895

PC-ACE Support
904-355-0313

Testing:
904-791-6865

Help Desk (Confirmation/ Transmission)
904-791-9880