Medicare A Bulletin

A Newsletter for Florida Medicare Part A Providers

In This Issue...

Features

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

Publications issued after October 1, 1997, are available at no-cost from our provider Web site at ***www.floridamedicare.com.***

Routing Suggestions:

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

Centers for Medicare & Medicaid Services
(formerly Health Care Financing Adminstration)

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

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

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

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

A PHYSICIAN'S FOCUS

Part A Local Medical Review Policy – Opportunity for Improvement

The Benefits Improvement and Protection Act (BIPA) of 2000 included changes to the Medicare appeals and coverage processes. As the Centers for Medicare & Medicaid Services (CMS) introduces these changes, contractors will adjust their processes and work with providers to improve administration of the Medicare program. Part A local medical review policy (LMRP) development is one area that will be revitalized by process improvements.

Medicare coverage provisions and subsequent policies are based on the authority from the Social Security Act. Medicare contractors make claim decisions using two main types of policies: national coverage decisions and LMRPs. As a traditional Medicare contractor for Florida (Part A fiscal intermediary and Part B carrier), First Coast Service Options, Inc. has responsibility for LMRPs. LMRPs are administrative and educational tools that address coverage and coding requirements of selected services.

The Medicare LMRP development process is prescribed by CMS. Draft LMRPs are researched and developed as an adjunct to new national coverage decisions, clarification of coverage for new technologies, or qualification of unusual utilization of certain services. The draft development includes consideration of the medical literature and solicitation of advice from local medical societies, medical consultants, and providers (physicians, allied professionals, and administrators). There is a formal 45-day draft and comment period when the draft LMRP is posted on the Web site **www.floridamedicare.com.** Hard copies are also mailed to Part A providers (providers that bill the fiscal intermediary). An open public meeting is also scheduled to provide an opportunity for discussion of the draft policy.

For Medicare Part B, the Florida Carrier Advisory Committee (CAC) provides a formal mechanism for Florida physicians to participate in the development of LMRPs in an advisory capacity. The CAC is composed of physicians, beneficiary representatives, and other medical organization representatives such as the Florida Medical Quality Assurance, Inc., and the Florida Hospital Association. On many occasions, Part A LMRPs have corresponding Part B policies since physicians and allied professionals direct many Part A services. The CAC can be a valuable resource to the Part A LMRP development process, but it does not negate the need for Part A organizations (provider and billing staff) to review pertinent draft LMRPs and comment on issues from their perspective. Instructions for mailing written or email comments are included with the draft package and are posted on the Web site **www.floridamedicare.com.**

A Part A organization can help streamline the LMRP process by providing comments when appropriate, placing more emphasis on the coding and coverage requirements. Specific suggestions with supporting documentation are encouraged in addressing a clinical, coding, or billing issue. Please encourage experts in your organizations to participate in the LMRP development process to improve the delivery of care to Medicare beneficiaries.

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

About *The Medicare A Bulletin*

The *Medicare A Bulletin* is a comprehensive magazine published quarterly for Medicare Part A providers in the State of Florida. In accordance with the Centers for Medicare and Medicaid Services notification parameters, the approximate delivery dates are:

Publication Name	Publication Date	Effective Date of Changes
First Quarter 2002	Mid-November 2001	January 1, 2002
Second Quarter 2002	Mid-February 2002	April 1, 2002
Third Quarter 2002	Mid-May 2002	July 1, 2002
Fourth Quarter 2002	Mid August 2002	October 1, 2002

Important notifications that require communication in between these dates will be posted to the First Coast Service Option, Inc. (FCSO) Florida provider Web site **www.floridamedicare.com.** In some cases, additional unscheduled special issues will also be published.

Who Receives the *Bulletin*?

Distribution of the Medicare Part A *Bulletin*, is limited to one copy per medical facility that is actively billing Medicare claims to the fiscal intermediary in the State of Florida. First Coast Service Options, Inc., the Medicare Part a fiscal intermediary, uses the same mailing address for **all** Medicare 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. For additional copies, providers may purchase a separate annual subscription for $75.00. A subscription order form may be found in the Education Resource section in each issue. Issues published since January 1997 may be downloaded from the provider Web site free of charge.

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 policy section contains finalized medical policies and additions, revisions, and corrections to previously published local medical review policies. Whenever possible, the local medical review policy section will be placed in the center of the *Bulletin* to allow readers to remove it separately, without disturbing the rest of the magazine.

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

The Medicare A Bulletin Represents Formal Notice of Coverage Policies

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

Do You Have Comments?

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

Medicare Publications Department
Editor, *Medicare A Bulletin*
P.O. Box 2078 – 18T
Jacksonville, FL 32231-0048

GENERAL INFORMATION

ICD-9-CM Coding for Diagnostic Tests

The following clarifies reporting of the International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) codes for diagnostic tests. As required by the Health Insurance Portability and Accountability Act (HIPAA), the Secretary of Health & Human Services published a rule designating the ICD-9-CM and its *Official ICD-9-CM Guidelines for Coding and Reporting* as one of the approved code sets for use in reporting diagnoses and inpatient procedures. This final rule requires the use of ICD-9-CM and its official coding and reporting guidelines by most health plans (including Medicare) by October 16, 2002.

The *Official ICD-9-CM Guidelines for Coding and Reporting* provides guidance on coding. The ICD-9-CM Coding Guidelines for Outpatient Services, which is part of the *Official ICD-9-CM Guidelines for Coding and Reporting*, provides guidance on diagnoses coding specifically for outpatient facilities and physician offices.

The ICD-9-CM coding guidelines for outpatient services (hospital-based and physician office) have instructed physicians to report diagnoses based on test results. The Coding Clinic for ICD-9-CM confirms this longstanding coding guideline. The Centers for Medicare & Medicaid Services agrees with these coding and reporting guidelines.

The following are instructions for contractors, physicians, hospitals, and other health care providers to use in determining ICD-9-CM codes for coding diagnostic test results. The instructions below provide guidance on the appropriate assignment of ICD-9-CM diagnoses codes to simplify coding for diagnostic tests consistent with the ICD-9-CM guidelines for outpatient services (hospital-based and physician office). Note that physicians are responsible for the accuracy of information submitted on a bill.

Determining the Appropriate Primary ICD-9-CM Diagnosis Code for Diagnostic Tests Ordered Due to Signs and/or Symptoms

If the physician has confirmed a diagnosis based on the results of the diagnostic test, the physician interpreting the test should code that diagnosis. The signs and/or symptoms that prompted ordering the test may be reported as additional diagnoses if they are not fully explained or related to the confirmed diagnosis.

Example 1: A surgical specimen is sent to a pathologist with a diagnosis of "mole". The pathologist personally reviews the slides made from the specimen and makes a diagnosis of "malignant melanoma." The pathologist should report a diagnosis of "malignant melanoma" as the primary diagnosis.

Example 2: A patient is referred to a radiologist for an abdominal CT scan with a diagnosis of abdominal pain. The CT scan reveals the presence of an abscess. The radiologist should report a diagnosis of "intra-abdominal abscess."

Example 3: A patient is referred to a radiologist for a chest X-ray with a diagnosis of "cough." The chest X-ray reveals 3 cm peripheral pulmonary nodule. The radiologist should report a diagnosis of "pulmonary nodule" and may sequence "cough" as an additional diagnosis.

If the diagnostic test did not provide a diagnosis or was normal, the interpreting physician should code the sign(s) or symptom(s) that prompted the treating physician to order the study.

Example 1: A patient is referred to a radiologist for a spine X-ray due to complaints of "back pain." The radiologist performs the X-ray, and the results are normal. The radiologist should report a diagnosis of "back pain" since this was the reason for performing the spine X-ray.

Example 2: A patient is seen in the ER for chest pain. An EKG is normal, and the final diagnosis is chest pain due to suspected gastroesophageal reflux disease (GERD). The patient was told to follow-up with his primary care physician for further evaluation of the suspected GERD. The primary diagnosis code for the EKG should be chest pain. Although the EKG was normal, a definitive cause for the chest pain was not determined.

If the results of the diagnostic test are normal or non-diagnostic, and the referring physician records a diagnosis preceded by words that indicate uncertainty (e.g., probable, suspected, questionable, rule out, or working), then the interpreting physician should not code the referring diagnosis. Rather, the interpreting physician should report the sign(s) or symptom(s) that prompted the study. Diagnoses labeled as uncertain are considered by the ICD-9-CM Coding Guidelines as unconfirmed and should not be reported. This is consistent with the requirement to code the diagnosis to the highest degree of certainty.

Example: A patient is referred to a radiologist for a chest X-ray with a diagnosis of "rule out pneumonia." The radiologist performs a chest X-ray, and the results are normal. The radiologist should report the sign(s) or symptom(s) that prompted the test (e.g., cough).

Instruction to Determine the Reason for the Test

As specified in section 4317(b) of the Balanced Budget Act (BBA), referring physicians are required to provide diagnostic information to the testing entity at the time the test is ordered. As further indicated in 42 CFR 410.32 all diagnostic tests "must be ordered by the physician who is treating the beneficiary." As defined in section 15021 of the Medicare Carrier Manual (MCM), an "order" is a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a

ICD-9-CM Coding for Diagnostic Tests (continued)

beneficiary. An order may include the following forms of communication:

- A written document signed by the treating physician/ practitioner, which is hand-delivered, mailed, or faxed to the testing facility;
- A telephone call by the treating physician/practitioner or his/her office to the testing facility; and
- An electronic mail by the treating physician/practitioner or his/her office to the testing facility.

Note: If the order is communicated via telephone, both the treating physician/practitioner or his/her office and the testing facility must document the telephone call in their respective copies of the beneficiary's medical records.

On the rare occasion when the interpreting physician does not have diagnostic information as to the reason for the test and the referring physician is unavailable to provide such information, it is appropriate to obtain the information directly from the patient or the patient's medical record if it is available. However, an attempt should be made to confirm any information obtained from the patient by contacting the referring physician. Example: A patient is referred to a radiologist for a gastrograffin enema to rule out appendicitis. However, the referring physician does not provide the reason for the referral and is unavailable at the time of the study. The patient is queried and indicates that he/she saw the physician for abdominal pain, and was referred to rule out appendicitis. The radiologist performs the X-ray, and the results are normal. The radiologist should report the abdominal pain as the primary diagnosis.

Incidental Findings

Incidental findings should never be listed as primary diagnoses. If reported, incidental findings may be reported as secondary diagnoses by the physician interpreting the diagnostic test.

Example 1: A patient is referred to a radiologist for an abdominal ultrasound due to jaundice. After review of the ultrasound, the interpreting physician discovers that the patient has an aortic aneurysm. The interpreting physician reports jaundice as the primary diagnosis and may report the aortic aneurysm as a secondary diagnosis because it is an incidental finding.

Example 2: A patient is referred to a radiologist for a chest X-ray because of wheezing. The X- ray is normal except for scoliosis and degenerative joint disease of the thoracic spine. The interpreting physician reports wheezing as the primary diagnosis since it was the reason for the patient's visit, and may report the other findings (scoliosis and degenerative joint disease of the thoracic spine) as additional diagnoses.

Example 3: A patient is referred to a radiologist for a magnetic resonance imaging (MRI) of the lumbar spine with a diagnosis of L-4 radiculopathy. The MRI reveals degenerative joint disease at L1 and L2. The radiologist reports radiculopathy as the primary diagnosis and may report degenerative joint disease of the spine as an additional diagnosis.

Unrelated/Co-Existing Conditions/Diagnoses

The physician interpreting the diagnostic test may report unrelated and co-existing conditions/diagnoses as additional diagnoses.

Example: A patient is referred to a radiologist for a chest X-ray because of a cough. Results of the chest X-ray indicate the patient has pneumonia. During the performance of the diagnostic test, it was determined that the patient has hypertension and diabetes mellitus. The interpreting physician reports a primary diagnosis of pneumonia and may report hypertension and diabetes mellitus as secondary diagnoses.

Diagnostic Tests Ordered in the Absence of Signs and/or Symptoms (e. g., screening tests)

When a diagnostic test is ordered in absence of signs/ symptoms or other evidence of illness or injury, the physician interpreting the diagnostic test should report the reason for the test (e. g., screening) as primary ICD-9-CM diagnosis code. The test results, if reported, may be recorded as additional diagnoses.

Use of ICD-9-CM To The Greatest Degree of Accuracy and Completeness

Note: This section explains certain coding guidelines addressing diagnosis coding. These guidelines are longstanding coding guidelines that have been part of the Official ICD-9-CM Guidelines for Coding and Reporting.

The interpreting physician should code the ICD-9-CM code that provides the highest degree of accuracy and completeness for the diagnosis resulting from test, or for the sign(s)/symptom(s) that prompted ordering the test.

In the past, there has been some confusion about the meaning of "highest degree of specificity," and in "reporting the correct number of digits." In the context of ICD-9-CM coding, the "highest degree of specificity refers to assigning the most precise ICD-9-CM code that most fully explains the narrative description of the symptom or diagnosis.

Example 1: A chest X-ray reveals a primary lung cancer in the left lower lobe. The interpreting physician should report the ICD-9-CM code as 162.5 for malignancy of the left "lower lobe, bronchus or lung," not the code for a malignancy of "other parts of bronchus or lung" (162.8) or the code for "bronchus and lung unspecified" (162.9).

Example 2: If a sputum specimen is sent to a pathologist and the pathologist confirms growth of "streptococcus, type B" which is indicated in the patient's medical record, the pathologist should report a primary diagnosis as 482.32 (Pneumonia due to streptococcus, Group B). However, if the pathologist is unable to specify the organism, then the pathologist

ICD-9-CM Coding for Diagnostic Tests (continued)

should report the primary diagnosis as 486 (Pneumonia, organism unspecified).

In order to report the correct number of digits when using ICD-9-CM, refer to the following instructions:

ICD-9-CM diagnosis codes are composed of codes with three, four, or five digits. Codes with three digits are included in ICD-9-CM as the heading of a category of codes that may be further subdivided by the use of fourth and/or fifth digits to provide greater specificity. Assign three-digit codes only if there are no four-digit codes within that code category. Assign four-digit codes only if there is no fifth-digit subclassification for that category. Assign the fifth-digit subclassification code for those categories where it exists.

Example 3: A patient is referred to a physician with a diagnosis of diabetes mellitus. However, there is no indication that the patient has diabetic complications or that the diabetes is out of control. It would be incorrect to assign code 250 since all codes in this series have five digits. Reporting only three digits of a code that has five digits would be incorrect. One must add two more digits to make it complete. Because the type (adult onset/juvenile) of diabetes is not specified, and there is no indication that the patient has a complication or that the diabetes is out of control, the correct ICD-9-CM code would be 250.00. The fourth and fifth digits of the code would vary depending on the specific condition of the patient.

For the latest ICD-9-CM coding guidelines, please refer to the following Web site: **http://www.cdc.gov/nchs/datawh/ftpserv/ftpicd9/ftpicd9.htm#guide.**

For further guidance on determining the appropriate ICD-9-CM diagnoses codes, refer to the following listing of questions and answers that appeared in the American Hospital Association's Coding Clinic for ICD-9-CM (1st Quarter 2000).

Coding Clinic for ICD-9-CM. Copyright 2000 by the American Hospital Association. All rights reserved. Reprint granted with permission from the American Hospital Association

Question 1: A skin lesion of the cheek is surgically removed and submitted to the pathologist for analysis. The surgeon writes on the pathology order, "skin lesion." The pathology report comes back with the diagnosis of "basal cell carcinoma." A laboratory-billing consultant is recommending that the ordering physician's diagnosis be reported instead of the final diagnosis obtained by the pathologist. Also, an insurance carrier is also suggesting this case be coded to "skin lesion" since the surgeon did not know the nature of the lesion at the time the tissue was sent to pathology. Which code should the pathologist use to report his claim?

Answer 1: The pathologist is a physician and if a diagnosis is made it can be coded. It is appropriate for the pathologist to code what is known at the time of code assignment. For example, if the pathologist has made a diagnosis of basal cell carcinoma, assign code 173.3 – Other malignant neoplasm of skin, skin of other and unspecified parts of face. If the pathologist had not come up with a definitive diagnosis, it would be appropriate to code the reason why the specimen was submitted, in this instance, the skin lesion of the cheek.

Question 2: A patient presents to the hospital for outpatient X-rays with a diagnosis on the physician's orders of questionable stone. The abdominal X-ray diagnosis per the radiologist is "bilateral nephrolithiasis with staghorn calculi." No other documentation is available. Is it correct to code this as 592.0 – Calculus of kidney, based on the radiologist's diagnosis?

Answer 2: The radiologist is a physician and he/she diagnosed the nephrolithiasis. Therefore, it is appropriate to code this case as 592.0 – Calculus of kidney.

Question 3: A patient undergoes outpatient surgery for removal of a breast mass. The pre- and post-operative diagnosis is reported as "breast mass." The pathological diagnosis is fibroadenoma. How should the hospital outpatient coder code this? Previous *Coding Clinic* advice has precluded us from assigning codes on the basis of laboratory findings. Does the same advice apply to pathological reports?

Answer 3: Previously published advice has warned against coding from laboratory results alone, without physician interpretation. However, the pathologist is a physician and the pathology report serves as the pathologist's interpretation and a microscopic confirmatory report regarding the morphology of the tissue excised. Therefore, a pathology report provides greater specificity. Assign code 217 – Benign neoplasm of breast, for the fibroadenoma of the breast. It is appropriate for coders to code based on the physician documentation available at the time of code assignment.

Question 4: A referring physician sent a urine specimen to the cytology lab for analysis with a diagnosis of "hematuria" (code 599.7). However, a cytology report authenticated by the pathologist revealed abnormal cells consistent with transitional cell carcinoma of the bladder. Although the referring physician assigned code 599.7 – Hematuria, the laboratory reported code 188.9 – Malignant neoplasm of bladder, Bladder, part unspecified. For reporting purposes, what would be the appropriate diagnosis code for the laboratory and the referring physician?

ICD-9-CM Coding for Diagnostic Tests (continued)

Answer 4: The laboratory should report code 188.9 – Malignant neoplasm of bladder, Bladder, part unspecified. It is appropriate to code the carcinoma, in this instance, because the cytology report was authenticated by the pathologist and serves as confirmation of the cell type, similar to a pathology report. The referring physician should report code 599.7, Hematuria, if the result of the cytological analysis is not known at the time of code assignment.

Question 5: A patient presents to the physician's office with complaints of urinary frequency and burning. The physician ordered a urinalysis and the findings were positive for bacteria and increased WBCs in the urine.
Based on these findings a urine culture was ordered and was positive for urinary tract infection. Should the lab report the "definitive diagnosis," urinary tract infection, or is it more appropriate for the lab to report the signs and symptoms when submitting the claim?

Answer 5: Since this test does not have physician interpretation, the laboratory (independent or hospital-based) should code the symptoms (i.e., urinary frequency and burning).

Question 6: The physician refers a patient for chest X-ray to outpatient radiology with a diagnosis of weakness and chronic myelogenous leukemia (CML). The radiology report demonstrated no acute disease and moderate hiatal hernia. For reporting purposes, which codes are appropriate for the facility to assign?

Answer 6: Assign code 780.79 – Other malaise and fatigue, and code 205.10 – Myeloid leukemia, without mention of remission, for this encounter. It is not necessary to report code 553.3 – Diaphragmatic hernia, for the hiatal hernia, because it is an incidental finding. [For CMS purposes, the primary diagnosis would be reported as 780.79 – Other malaise and fatigue, and the secondary diagnosis as 205.10 – Myeloid leukemia, without mention of remission, for this encounter.]

Question 7: A patient presents to the doctor's office with a complaint of fatigue. The physician orders a complete blood count (CBC). The CBC reveals a low hemoglobin and hematocrit. Should the lab report the presenting symptom fatigue (code 780.79) or the finding of anemia (code 285.9)?

Answer 7: The laboratory (independent or hospital-based) should code the symptoms, because no physician has interpreted the results. Assign code 780.79 – Other malaise and fatigue, unless the lab calls the physician to confirm the diagnosis of anemia. ❖

Source: CMS Transmittal AB-01-144, CR 1724

Current Status of Coordination of Benefits Contractor Operations

The following article is being published as a request from the Centers for Medicare & Medicaid Services.

Service provided by the Coordination of Benefits (COB) contractor was affected by the World Trade Center disaster. On Monday, September 17, 2001, the COB Contractor began moving its operations to the corporate office of Group Health Incorporated. The COB contractor's call center has since been restored to 80 percent of capacity and, although the call center is not fully staffed, there are no reports of lengthy wait time. The electronic correspondence referral system continues to be up and fully operational.

City officials have inspected the lower Manhattan facility and have found the building to be structurally sound. The air has also been tested and has passed the quality standards. Currently, a skeletal staff made up of the executive and technical support individuals are occupying the building. Full electric power was restored on Tuesday, September 25, 2001. The COB Contractor will relocate staff back to the lower Manhattan facility using a phased-in approach, over a several week period, to guard against the potential for interrupted customer service. In the interim, please continue to notify all callers with COB inquiries of its involvement in the World Trade Center disaster and that telephone service is available Monday through Friday, from 8:00 a.m. to 8:00 p.m., Eastern Time.

Questionnaires and correspondence should continue to be mailed to:

Medicare-COB
Data Match Project
P.O. Box 125
New York, N.Y. 10274-0125

Medicare-COB
MSP Claims Investigation Project
P.O. Box 5041
New York, N.Y. 10274-5041

Medicare-COB
Voluntary Agreement Project
P.O. Box 660
NewYork, N.Y. 10274-0660

Medicare-COB
Initial Enrollment Questionnaire Project
P.O. Box 17521
Baltimore, MD 21203-7521

We appreciate your understanding and cooperation during this difficult time and assure you that we are making every effort to resume full service and minimize your inconvenience. Please continue to visit the COB Web site at **www.hcfa.gov/medicare/cob** so we may keep you abreast of all future developments. ❖

Correction of Payment for Diabetes Outpatient Self-Management Training Services

The Intermediary Manual Part 3, Transmittal 1836, and the Hospital Manual, Transmittal 775, released June 15, 2001, mention two G codes for diabetes education (G0108 and G0109) and the definition change from 60 minutes to 30 minutes. The definition change was made with the January 1, 2001, HCPCS update. However, the payment rate on the Medicare Physician Fee Schedule Date Base (MPFSDB) was not reduced at that time because the final regulation on diabetes education did not become effective until February 27, 2001. The payment rate will be changed in the January 2002 MPFSDB update.

Providers should use the following set of instructions to bill for diabetes outpatient self-management training services provided prior to January 1, 2002 and on or after January 1, 2002.

Billing for Diabetes Training *prior to* January 1, 2002

- Providers reporting one-hour session of diabetes education must report HCPCS code G0108 or G0109 (as appropriate) with a "1" in the form locator 46 (Serv. Units) on claim Form HCFA-1450 (UB-92) or its electronic equivalent. Even though the definition of the codes reads 30 minutes, the rate the provider receives is for 60 minutes.
- Providers reporting a 30-minute service should not bill until the second service of 30-minutes have been completed. In the event that two 30-minutes sessions are provided on different days, the day of the second session should be reported as the date of service.
- Providers reporting a 2-hour session must use a "2" in the units column and not a "4."

Billing for Diabetes Training *on or after* January 1, 2002

- Providers reporting 30-minutes session of diabetes education must report HCPCS code G0108 or G0109 (as appropriate) with a "1" in form locator 46 (Serv. Units) on claim Form HCFA-1450 (UB-92) or its electronic equivalent
- Providers reporting a one-hour session must report a "2" in form locator 46.
- Providers reporting a 2-hour session must report a "4" in form locator 46. ❖

Source: CMS Transmittal AB-01-109; CR 1789

Crossover Updates

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

Automatic Crossover

*New Crossover Insurer

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

- Wisconsin Medicaid
- Tricare, Inc. ❖

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 rate.

Effective August 7, 2001, the interest rate applied to Medicare overpayments is **13.25 percent**, based on the revised PCR. The following table lists previous interest rates.

Period	Interest Rate
April 26, 2001 – August 6, 2001	13.75%
February 7, 2001 – April 25, 2001	14.125%
August 1, 2000 – February 6, 2001	13.875%
May 3, 2000 – July 31, 2000	13.75%
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 5, 1999 – August 3, 1999	13.375%
February 1, 1999 – May 4, 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% ❖

Source: CMS Transmittal AB-01-110; CR 1387

Correction to the Revision of Medicare Reimbursement for Telehealth Services

An article was published in the Fourth Quarter 2001 *Medicare A Bulletin* (pages 5-7) concerning expansion of Medicare reimbursement for telehealth services, effective for services rendered on or after October 1, 2001.

Corrections to that article have since been provided by the Centers for Medicare & Medicaid Services.

Please note the following changes:

- Eliminate intermediary claims processing type of bill (TOB) 12x for telehealth benefits. Site bills originating in inpatient hospitals must be submitted on a TOB 13x (outpatient) using the date of discharge as the line item date of service.
  TOB 12x was incorrectly included on page 5 of Transmittal AB-01-69, Change Request 1650, dated May 1, 2001.
- Q3014 is the correct HCPCS code for telehealth originating site facility fee, not Q3104 as shown one place on the same page. ❖

Source: CMS Transmittal AB-01-120; CR 1827

New Medicare Provider Enrollment Applications

The Centers for Medicare & Medicaid Services (CMS) has revised the Medicare Provider/Supplier Enrollment Application (version 1/98 Form HCFA 855). The revised Medicare Provider/Supplier Enrollment Application (version Form CMS 855) was implemented **on November 1, 2001.**

All 1/98 versions of Form HCFA 855 received through October 31, 2001, will be processed through completion. This includes, but is not limited to, applications that have been returned to the applicant (e.g., application initially received by the contractors or state agency through October 31, 2001 (postmark date), returned to the applicant for any reason, and subsequently resubmitted to the contractor or state agency after October 31, 2001).

Contractors and state agencies will continue to accept and process all 1/98 versions of Form HCFA 855 through December 31, 2001. All 1/98 versions of Form HCFA 855 postmarked and received by the Medicare contractor for the first time after December 31, 2001 will be returned to the applicant. The appropriate November 1, 2001, Form CMS 855 and a written explanation indicating the applicant must complete the new form will be provided.

The appearance of the forms has changed slightly and in addition, all forms will now be printed on white stock with a color coded outside cover as follows:

Form Number	Cover Color	Available from	Completed by
CMS 855A	*Victoria Green*	*Fiscal intermediaries* *CMS regional offices*	*All providers that will bill Medicare intermediaries*
CMS 855B	Light Gray	Carriers CMS regional offices	Suppliers that will bill Medicare carriers
CMS 855I	Venice Blue	Carriers CMS regional offices	Individual health care practitioners
CMS 855R	Sun Orange	Carriers CMS regional offices	Individual health care practitioners to reassign Medicare benefits
CMS 855S	Canary Yellow	National supplier clearinghouses CMS regional offices	Durable medical equipment, prosthetics, orthotics, and supplies suppliers ***only***

With the implementation of the November 1, 2001 versions of Form CMS 855, the **1/98 Form HCFA 855C** (Change of Information Request) will be obsolete. All change requests postmarked **after December 31, 2001,** must be submitted on the appropriate Form CMS 855 with a signed and dated certification statement.

The new versions of Form CMS 855 are available for downloading from the Medicare provider Web site, **www.floridamedicare.com.** ❖

Source: CMS Transmittal AB-01-146, CR 1835

Annual Update of Non-routine Medical Supply and Therapy Codes for Home Health Consolidated Billing (CB)

The Centers for Medicare & Medicaid Services provides annual updates to the list of non-routine medical supply and therapy codes included in home health consolidated billing (CB) to reflect the annual Healthcare Common Procedure Coding System code revisions. These codes are bundled into the prospective payment system rate. Therefore, providers and suppliers may not bill for these codes separately while a Medicare beneficiary is in an open home health episode.

The following are the changes to the non-routine medical supply list for dates of service beginning January 1, 2002:

New code subject to CB
A6010: Collagen based wound filler, dry foam

Discontinued code, no longer subject to CB:
A4329: External catheter start set

There are no changes to the list of 69 therapy codes subject to CB. ❖

Source: CMS Transmittal AB-01-128, CR #1854

Revised Diagnosis Coding Requirements for Clinical Trial Routine Care Services

The Centers for Medicare & Medicaid Services has revised the diagnosis coding requirements on claim processing instructions for services provided to Medicare beneficiaries participating in Medicare qualifying clinical trials.

Effective for discharges occurring **on or after January 1, 2002,** routine care for Medicare qualifying clinical trial services must be identified with diagnosis code V70.7 – Examination of participant in clinical trial. ICD-9-CM code V70.7 must be reported as the second or subsequent diagnosis code on the claim Form HCFA-1450 (UB-92) or its electronic claim equivalent.

National coverage guidelines for qualified clinical trial services were published in the October/November 2000 *Medicare A Bulletin* (pages 8-10). ❖

Source: CMS Transmittal AB-01-103, CR 1637

GENERAL COVERAGE

Coverage of Noninvasive Vascular Studies for End Stage Renal Disease (ESRD) Patients

Medicare pays for outpatient maintenance dialysis services furnished by ESRD facilities based on a composite payment rate. This rate is a comprehensive payment and includes all services, equipment, supplies, and certain laboratory tests and drugs that are necessary to furnish a dialysis treatment.

For dialysis to take place, there must be a means of access so that the exchange of waste products may occur. As part of the dialysis treatment, ESRD facilities are responsible for monitoring access, and when occlusions occur, either declot the access or refer the patient for appropriate treatment. Procedures associated with monitoring access involve taking venous pressure, aspirating thrombus, observing elevated recirculation time, reduced urea reduction ratios, or collapsed shunt, etc. All such procedures are covered under the composite rate.

A number of ESRD facilities are monitoring access through noninvasive vascular studies such as duplex and Doppler flow scans and billing separately for these procedures. Noninvasive vascular studies are not covered as a separately billable service if used to monitor a patient's vascular access site. Medicare pays for the technical component of the procedure in the composite payment rate.

An ESRD facility must furnish all necessary services, equipment, and supplies associated with a dialysis treatment, either directly or under arrangements that make the facility financially responsible for the service. If an ESRD facility or a renal physician decides to monitor the patient's access site with a noninvasive vascular study and does not have the equipment to perform the procedure, the facility or physician may arrange for the service to be furnished by another source. The alternative source, such as an independent diagnostic testing facility must look to the ESRD facility for payment. **No separate payment for noninvasive vascular studies for monitoring the access site of an ESRD patient, whether coded as the access site or peripheral site, is permitted to any entity.**

Where there are signs and symptoms of vascular access problems, Doppler flow studies may be used as a means to obtain diagnostic information to permit medical intervention. Doppler flow studies may be considered medically necessary in the presence of signs or symptoms of possible failure of the ESRD patient's vascular access site, and when the results are used in determining a clinical course of treatment for the patient.

The only Current Procedural Terminology (CPT) billing code for noninvasive vascular testing of a hemodialysis access site is 93990. Medicare will deny separate billing of the technical component of this code if it is performed on any patient for whom the ESRD composite rate for dialysis is being paid, unless there is appropriate medical indication of the need for a Doppler flow study.

When a dialysis patient exhibits signs and symptoms of compromise to the vascular access site, Doppler flow studies may provide diagnostic information that will determine the appropriate medical intervention. Medicare considers a Doppler flow study medically necessary when the beneficiary's dialysis access site manifests signs or symptoms associated with vascular compromise, and when the results of this test are necessary to determine the clinical course of treatment.

Examples supporting the medical necessity for Doppler flow studies include:

a. Elevated dynamic venous pressure >200mm HG when measured during dialysis with the blood pump set on a 200cc/min.,
b. Access recirculation of 12 percent or greater,
c. An otherwise unexplained urea reduction ratio <60 percent, and
d. An access with a palpable "water hammer" pulse on examination, (which implies venous outflow obstruction).

Unless documentation is provided supporting the necessity of more than one study, Medicare will limit payment to either a Doppler flow study or an arteriogram (fistulogram, venogram), but not both.

An example of when both studies may be clinically necessary is when a Doppler flow study demonstrates reduced flow (blood flow rate less than 800cc/min or a decreased flow of 25 percent or greater from previous study) and the physician requires an arteriogram to further define the extend of the problem. The patient's medical record(s) must provide documentation supporting the need for more than one imaging study.

This policy is applicable to claims from ESRD facilities and all other sources, such as independent diagnostic testing facilities, and hospital outpatient departments.

The professional component of the procedure is included in the monthly capitation payment (MCP). The professional component will be denied for code 93990 if billed by the MCP physician. Medically necessary services that are included or bundled into the MCP (e.g., test interpretations) are separately payable when furnished by physicians other than the MCP physician.

Billing for monitoring of hemodialysis access using CPT codes for noninvasive vascular studies other than 93990 is considered a misrepresentation of the service actually provided and may be considered for fraud investigation. ❖

Source: CMS Transmittal AB-01-129, CR 1855

Screening Glaucoma Services

The Benefits Improvement and Protection Act of 2000, section 102, provides annual coverage for glaucoma screening for eligible Medicare beneficiaries, i.e., those with diabetes mellitus or a family history of glaucoma, and certain other individuals found to be at high risk for glaucoma as determined by the Centers for Medicare & Medicaid Services.

Medicare will pay for glaucoma screening examinations where they are furnished by or under the direct supervision of an ophthalmologist or optometrist who is legally authorized to perform the services under state law.

Screening for glaucoma is defined to include:

- a dilated eye examination with an intraocular pressure measurement; and
- a direct ophthalmoscopy examination, or a slit-lamp biomicroscopic examination.

Payment may be made for a glaucoma screening examination that is performed on an eligible beneficiary after at least 11 months have passed following the month in which the last covered glaucoma screening examination was performed. Coverage applies to glaucoma screening examination services performed on eligible beneficiaries **on or after January 1, 2002.**

Claim Submission Requirements

Claims for glaucoma screening must be submitted on claim Form HCFA-1450 (UB-92) or its electronic equivalent. Claims must be prepared in accordance with the general bill review instructions in section 3604 of the Medicare Intermediary Manual, Part 3.

Applicable Bill Types

The applicable types of bill for screening glaucoma services are: 13x, 22x, 23x, 71x, 73x, 75x, and 85x.

HCPCS Coding

The following HCPCS codes should be reported when billing for screening glaucoma services:

G0117	Glaucoma screening for high-risk patients furnished by an optometrist or ophthalmologist.
G0118	Glaucoma screening for high-risk patients furnished under the direct supervision of an optometrist or ophthalmologist.

Note: Independent rural health clinics (RHCs) and free standing federally qualified health centers (FQHCs) do not have to report HCPCS.

Revenue Coding

The following revenue codes should be reported when billing for screening glaucoma services:

- Comprehensive outpatient rehabilitation facilities (CORFs), critical access hospitals (CAHs), and skilled nursing facilities (SNFs) bill for this service under revenue code 770.
- Independent and provider-based RHCs and free standing and provider-based FQHCs bill for this service under revenue code 52x.
- Hospital outpatient departments bill for this service under any valid/appropriate revenue code. They are not required to report revenue code 770.

Diagnosis Coding

Providers report glaucoma screening using screening ("V") code V80.1 (special screening for neurological, eye, and ear diseases, glaucoma). Claims submitted without this screening diagnosis code should be returned to the provider as unprocessable.

Payment Methodology

Payment is made for the facility expense as follows:

- Independent and provider-based RHC/free standing and provider-based FQHC – payment is made under the all inclusive rate
- CAH – payment is made on a reasonable cost
- CORF – payment is made under the Medicare physician fee schedule
- Hospital outpatient department – payment is made under outpatient prospective payment system
- Hospital inpatient Part B – payment is made under OPPS
- SNF outpatient – payment is made under the Medicare physician fee schedule
- SNF inpatient Part B – payment is made under MPFS.

Deductible and coinsurance apply.

Determining the 11 Month Period

Once a beneficiary has received a covered glaucoma screening procedure, the beneficiary may receive another procedure after 11 full months have passed. To determine the 11-month period, start the count beginning with the month after the month in which the previous covered screening procedure was performed. ❖

Source: CMS Transmittal A-01-105; CR #1783

Coverage and Billing of Sacral Nerve Stimulation

A sacral nerve stimulator is a pulse generator that transmits electrical impulses to the sacral nerves through an implanted wire. These impulses cause the bladder muscles to contract, which gives the patient ability to void more easily.

Effective January 1, 2002, sacral nerve stimulation is covered for the treatment of urinary urge incontinence, urgency-frequency syndrome and urinary retention. Sacral nerve stimulation involves both a temporary test stimulation to determine if an implantable stimulator would be effective and a permanent implantation in the appropriate candidates. Both the test and permanent implantation are covered.

The following limitations for coverage apply to all indications:

- Patient must be refractory to conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy) and be an appropriate surgical candidate such that implantation with anesthesia can occur.
- Patients with stress incontinence, urinary obstruction, and specific neurologic diseases (e.g., diabetes with peripheral nerve involvement) which are associated with secondary manifestations of the above three indications are excluded.

Coverage and Billing of Sacral Nerve Stimulation (continued)

- Patient must have had a successful test stimulation in order to support subsequent implantation. Before a patient is eligible for permanent implantation, he/she must demonstrate a fifty percent or greater improvement through test stimulation. Improvement is measured through voiding diaries.
- Patient must be able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated.

Applicable CPT and HCPCS Codes

64561	Percutaneous implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)
64581	Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)
64585	Revision or removal of peripheral neurostimulator electrodes
64590	Incision and subcutaneous placement of peripheral neurostimulator pulse generator or receiver, direct or inductive coupling
64595	Revision or removal of peripheral neurostimulator pulse generator or receiver
A4290	Sacral nerve stimulation test lead, each
E0752	Implantable neurostimulator electrodes, each
E0756	Implantable neurostimulator pulse generator
C1767	Generator, neurostimulator (implantable)
C1778	Lead, neurostimulator (implantable)
C1883	Adaptor/extension, pacing lead or neurostimulator lead (implantable)
C1897	Lead, neurostimulator test kit (implantable)

Note: The "C" codes listed above are only applicable when billing under the hospital outpatient prospective payment system.

Applicable Revenue Codes

The applicable revenue code for the test procedures is 920 except for rural health clinics/federally qualified health centers (RHCs/FQHCs) who report these procedures under revenue code 521.

Revenue codes for the implantation can be performed in a number of revenue centers within a hospital such as operating room (360) or clinic (510). Therefore, hospitals must report these implantation services under the revenue center where they are furnished.

Payment Requirements for Test Procedures (CPT codes 64585, 64590, 64595)

Payment is as follows:

- Hospital outpatient departments – Outpatient prospective payment system
- Critical access hospitals – Reasonable cost basis
- Comprehensive outpatient rehabilitation facilities – Medicare physician fee schedules
- Skilled nursing facilities – Medicare physician fee schedules
- Rural health clinics/federally qualified health centers – All inclusive rate, professional component only. The technical component is outside the scope of the RHC/FQHC benefit. Therefore, the provider of that technical service bills the carrier on the claim Form HCFA-1500 or its electronic equivalent and payment is made under the MPFS. For provider-based RHCs/FQHCs payment for the technical component is made as indicated above based on the type of provider the RHC/FQHC is based with.

Deductible and coinsurance apply.

Payment Requirements for Implantation Procedures (CPT codes 64561, 64581)

Payment is as follows:

- Hospital outpatient departments – Outpatient prospective payment system
- Hospital inpatient departments – Hospital prospective payment system
- Critical access hospitals – Reasonable cost basis

Deductible and coinsurance apply.

Payment Requirements for Device Codes, A4290, E0752 and E0756

Payment is made on a reasonable cost basis when these devices are implanted in a CAH. Payment is made under OPPS when these devices are implanted in a hospital outpatient department.

Applicable Bill Types

The applicable bill types for test stimulation procedures are 13x, 14x, 22x, 23x, 71x, 73x, 75x and 85x.

RHCs and FQHCs bill you under bill type 71x and 73x for the professional component. The technical component is outside the scope of the RHC/FQHC benefit. The provider of that technical service bills their carrier on Form HCFA-1500 or electronic equivalent.

The provider typically furnishes the technical component for a provider-based RHC/FQHC. The provider of that service bills the services under bill type 13x, 14x, 22x, 23x or 85x as appropriate using the outpatient provider number (not the RHC/FQHC provider number since these services are not covered as RHC/FQHC services.)

The applicable bill types for implantation procedures and devices are 11x, 13x, and 85x. ❖

Source: CMS Transmittal AB-01-143; CR 1881

New CLIA Waived Tests

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

- Wyntek OSOM® Ultra Strep A Test, effective July 6, 2000, CPT code: 87880QW
- Beckman Coulter Primary Care Diagnostics ICON FX Strep A Immunochemical Strep A Antigen Test, effective March 16, 2001, *CPT* code: 87880QW
- Phamatech At Home Drug Test (Model 9073T), effective April 24, 2001, *CPT* code: 80101QW
- Beckman Coulter Primary Care Diagnostics Flexsure HP Test for IgG Antibodies to H. Pylori in Whole Blood, effective May 1, 2001, *CPT* code: 86318QW
- Wampole PreVue™ *B. burgdorferi* Antibody Detection Assay, effective June 19, 2001, *CPT* code: 86618QW
- Phamatech At Home Drug Test (Model 9150T), effective July 20, 2001, *CPT* code: 80101QW
- Phamatech At Home Drug Test (Model 9078T), effective July 27, 2001, *CPT* code: 80101QW
- KDK Corporation Lactate Pro System, effective July 27, 2001, *CPT* code: 83605QW
- QuickVue® Dipstick Strep A, effective July 27, 2001, *CPT* code: 87880QW
- Bayer Multisitck Pro 10LS Reagent Strips, effective August 22, 2001, *CPT* codes: 81002 and 82570QW
- Bayer Multisitck Pro 11 Reagent Strips, effective August 22, 2001, *CPT* codes: 81002 and 82570QW
- Bayer Multisitck Pro 7G Reagent Strips, effective August 22, 2001, *CPT* codes: 81002 and 82570QW
- Advantage Diagnostics Advantage Marijuana (THC) and Cocaine Home Drug Test, effective August 22, 2001, *CPT* code: 80101QW
- Beckman Coulter Primary Care Diagnostics Gastrocult®, effective August 30, 2001, *CPT* code: 82273QW
- Medical Instruments Corporation Pronto Dry *H. pylori*, effective August 31, 2001, *CPT* code: 87077QW.

The CPT code has been changed to 86294QW for the Bion Diagnostic Sciences BTA stat test (for home use), effective: September 13, 2001.

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

- 86294QW for the Bion Diagnostic Sciences BTA stat test (for home use)
- 86618QW for the Wampole PreVue™ *B. burgdorferi* Antibody Detection Assay
- 83605QW for the KDK Corporation Lactate Pro System.

Newly Added Tests Granted Waived Status under CLIA

TEST NAME	MANUFACTURER	CPT CODE	USE
Wyntek OSOM® Ultra Strep A	Test Wyntek Diagnositics, Inc.	87880QW	Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever
Beckman Coulter Primary Care Diagnostics ICON FX Strep A Immunochemical Strep A Test	Beckman Coulter	87880QW	Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever
Phamatech At Home Drug Test (Model 9073T)	Phamatech	80101QW	This test may not be covered in all instances. Contact your Medicare carrier for claims instructions) Screening test for the presence/detection of cocaine metabolite in urine
Beckman Coulter Primary Care Diagnostics Flexsure HP Test for IgG Antibodies to H. Pylori in Whole Blood *pylori* in whole blood	Beckman Coulter, Inc.	86318QW	Immunoassay for rapid, qualitative detection of IgG antibodies specific to *Helicobacter*
Wampole PreVue™ *B. burgdorferi* Antibody Detection Assay	Wampole Laboratories	86618QW	Qualitative detection of IgG/IgM antibodies to Borrelia burgdorferi (causative agent of Lyme disease) in whole blood
Phamatech At Home Drug Test (Model 9150T)	Phamatech	80101QW*	Screening test for the presence/detection of amphetamines, cannabinoids (THC), cocaine metabolites, methamphetamines, and opiates in urine

New CLIA Waived Test continued next page

TEST NAME	MANUFACTURER	CPT CODE	USE
Phamatech At Home Drug Test (Model 9078T)	Phamatech	80101QW*	Screening test for the presence/detection of cannabinoids (THC) in urine
KDK Corporation Lactate Pro System	KDK Corporation	83605QW	Quantitative measurement of lactate in whole blood
QuickVue® Dipstick Strep A	Quidel Corporation	87880QW	Rapidly detects GAS antigen from throat swabs and used as an aid in the diagnosis of GAS infection, which typically causes strep throat, tonsillitis, and scarlet fever
Bayer Multisitck Pro 10LS Reagent Strips	Bayer Diagnostics	81002 82570QW	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections and semi-quantitative measurement of creatinine in urine for the detection of patients at risk for developing kidney damage
Bayer Multisitck Pro 11 Reagent Strips	Bayer Diagnostics	81002 82570QW	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections and semi-quantitative measurement of creatinine in urine for the detection of patients at risk for developing kidney damage
Bayer Multisitck Pro 7G Reagent Strips	Bayer Diagnostics	81002 82570QW	Screening of urine to monitor/diagnose various diseases/conditions, such as diabetes, the state of the kidney or urinary tract, and urinary tract infections and semi-quantitative measurement of creatinine in urine for the detection of patients at risk for developing kidney damage
Advantage Diagnostics Advantage Marijuana (THC) and Cocaine Home Drug Test	Advantage Diagnostics Corporation	80101QW*	Screening test for the presence/detection of cannabinoids (THC) and cocaine metabolites in urine
Beckman Coulter Primary Care Diagnostics Gastrocult®	Beckman Coulter, Inc.	82273QW	Rapid screening test to detect the presence of gastric occult blood
Medical Instruments Corporation Pronto Dry *H. pylori*	Medical Instruments Corporation	87077QW	Presumptive identification of *Helicobacter pylori* in gastric biopsy tissue, which has been shown to cause chronic active gastritis (ulcers)

*This test may not be covered in all instances. ❖

Source: Transmittal AB-01-145; CR #1877

Useful Lifetime Expectancy for Breast Prosthesis

Federal regulations at 42 CFR 414.229(g) state that a reasonable useful lifetime of less than five years for prosthetic devices can be established through program instructions. Because of this rule, in the absence of program instructions, durable medical equipment regional carriers (DMERCs) have been allowed to determine the reasonable lifetime of breast prostheses but in no case could it be less than five years.

Revision to the Policy

After review of product information and in consultation with the DMERCs, the Centers for Medicare & Medicaid Services has determined that a period shorter than five years more accurately reflects the useful lifetime expectancy for a breast prosthesis. Based on the most common warranty period provided by manufacturers, this policy revision lowers the useful lifetime expectancy to:

- Two years for silicone breast prostheses
- Six months for fabric, foam, or fiber filled breast prostheses

A breast prosthesis can be replaced at any time if it is lost, irreparably damaged (this does not take in ordinary wear and tear), or if there is a change in the patient's medical condition necessitating a different type of item. If the patient's medical condition changes, the patient's physician must submit a new prescription explaining the need for a different type of breast prosthesis.

Under existing policy the Medicare program will pay for only one breast prosthesis per side.

Medicare does not pay for different types of the same or similar item or for spare or back-up items. However, two prostheses, one per side, are allowed for those persons who have had bilateral mastectomies. Suppliers must use the RT and LT modifiers to delineate the side or sides being billed.

This change is effective for services furnished **on or after April 1, 2002.** ❖

Source: CMS Transmittal AB-01-123, CR 1787

Intestinal Transplants Furnished to Beneficiaries Enrolled in Medicare+Choice (M+C) Plans

Information was published in the Third Quarter 2001 *Medicare A Bulletin* (pages 12-14) concerning a national coverage decision (NCD) for intestinal and multivisceral tranplanation. NCDs are binding on all Medicare carriers, Medicare fiscal intermediaries, peer review organizations, and other contractors. Under 42 CFR 422.256(b), a NCD that expands coverage is also binding on a Medicare+Choice organization.

Medicare regulation 42 CFR 422.109(a) requires that when the Secretary of the Department of Health and Human Services makes a NCD that meets the regulation's test for being a "significant cost," Medicare must pay for the services outside of the payment made to the M+C plan until rates announced in a regular March rate announcement come into effect. The payment for intestinal transplants meets the significant cost test of the NCD; therefore, Medicare must pay for these services outside of the 2001 M+C payment rate.

Thus, **claims with dates of service on or after April 1, 2001, but before January 1, 2002,** for services furnished to a Medicare beneficiary who is enrolled in a Medicare+Choice plan will be processed by the local contractor and not the Medicare+Choice organization. This also includes claims for physician services and immunosuppressive drugs required as a result of the transplant, hospital, and other services related to intestinal transplants meet the Medicare coverage criteria published in the Third Quarter 2001 *Medicare A Bulletin.* Hospital services would be paid based on the applicable diagnosis related group (DRG) as previously published. No payment will be made to the managed care organization unless it is an enrolled provider or supplier. ❖

Source: Transmittal AB-01-115; CR 1760

FRAUD AND ABUSE

Medicare Fraud & Abuse Advisory: No HIPAA Audits

Recently, individuals under the guise of performing Health Insurance Portability and Accountability Act (HIPAA) compliance audits, approached a medical group requesting access to the provider's computers and database. The individuals refused to produce identification or documentation confirming their identity. Access was denied by the provider's billing manager.

The provider's billing manager called the Medicare contractor after becoming suspicious of the two individuals and alerting the police. Both alleged HIPAA auditors refused to produce any identification and/or documentation demonstrating that they were from HIPAA and left the premises.

Health care providers should note that there are currently ***no*** on-site HIPAA audits being conducted. Providers should never allow ANY individuals access to their computers, medical records, billing information, etc., who fail to produce identification and proper documentation from the auditing entity. If providers are approached by individuals who claim to be conducting HIPAA audits, ***DO NOT*** allow them access. In addition, please contact the Medicare contractor and advise them of this activity immediately. Providers may call Florida Medicare toll-free at (877) 602-8816 to report suspected fraud. ❖

HOSPITAL SERVICES

CMS Relaxes Medicare Secondary Payer Instructions for Hospitals

Beneficiary-specific Medicare Secondary Payer (MSP) data is maintained by the Centers for Medicare & Medicaid Services (CMS) for the purpose of ensuring that the Medicare Program pays claims in the correct order of financial liability. The basis for provider collection of this data is found in law and regulations, a synopsis of which is provided below:

MSP Requirements

Based on the law and regulations, providers are required to file claims with Medicare using billing information obtained from the beneficiary to whom the item or service is furnished. Section 1862(b)(6) of the Social Security Act (the Act) (42 USC 1395y(b)(6)) requires all entities seeking payment for any item or service furnished under Part B to complete, on the basis of information obtained from the individual to whom the item or service is furnished, the portion of the claim form relating to the availability of other health insurance. Additionally, 42 CFR 489.20(g) requires that all providers must agree "… to bill other primary payers before billing Medicare..." Thus, any provider that bills Medicare for services rendered to Medicare beneficiaries, including non-patient (e.g., reference lab) services, must determine whether or not Medicare is the primary payer for those services. Questions concerning the beneficiary's MSP status are requested from the Medicare beneficiaries, or their representative. If providers fail to file correct and accurate claims with Medicare, 42 CFR 411.24 permits Medicare to recover its conditional payments from them.

Hospital Manual section 301.2, "Types of Admission Questions to Ask Medicare Beneficiaries," may be used to determine the correct primary payers of claims for all beneficiary services furnished by a hospital.

Note: In order to conform to the law and regulations, the provider should verify MSP information prior to submitting a bill to Medicare. This greatly increases the likelihood the primary payer is billed correctly. Verifying MSP information means confirming the information previously furnished about the presence or absence of another payer that may be primary to Medicare is correct, clear, and complete, and that no changes have occurred.

CMS has recently re-evaluated the paperwork burden associated with hospital collection of certain MSP data and is making changes in operational policy to relax associated data collection requirements, as described below.

Policy for Hospital Reference Labs

Hospitals must collect MSP information from a beneficiary or his/her representative for hospital reference lab services. If the MSP information collected by the hospital, from the beneficiary or his/her representative and used for billing, is no older than sixty calendar days from the date the service was rendered, then that information may be used to bill Medicare for non-patient reference lab services furnished by hospitals. This procedure is available **only** with respect to hospital reference lab services. Hospitals should keep an audit trail to show they collected MSP information from the beneficiary or his/her representative, which is no older than 60 days when submitting bills for their Medicare patients. Acceptable documentation may be the last (dated) update of the MSP information, either electronic or hardcopy. The provider also should document who supplied the MSP information. While a hospital is permitted to bill as described above using information in file from the beneficiary or his/her representative, if the hospital's use of outdated or inaccurate information leads to Medicare making an incorrect primary payment, the hospital will be liable to repay the overpayment. Moreover, the hospital will not be considered to be "without fault" in causing the overpayment under section 1870 of the Act (42 USC 1395gg) because it could have collected, had it chosen to do so, more recent and accurate information from the beneficiary.

Policy for Recurring Outpatient Services

For hospital outpatients receiving recurring services, hospitals must gather or verify beneficiary MSP information. Both the initial collection of MSP information and any subsequent verification of this information must be obtained from the beneficiary or his/her representative. Following the initial collection, the MSP information should be verified once during each subsequent monthly billing cycle during which recurring services are furnished to a Medicare beneficiary. (If a hospital bills on other than a monthly cycle, (e.g., 45 days or 60 days), then it must gather or verify the MSP information within no more than 30 calendar days from the last date the information was gathered or verified).

Note: A Medicare beneficiary is considered to be receiving recurring services if he/she receives identical services and treatments on an outpatient basis more than once within the same monthly billing cycle or, if the billing cycle is longer than monthly, within the same 30-day period.

This procedure is available ONLY with respect to recurring outpatient services. Hospitals should keep an audit trail to show they collected MSP information from the beneficiary or his/her representative, which is no older than 30 days when submitting bills for their Medicare patients.

Acceptable documentation may be the last (dated) update of the MSP information, either electronic or hardcopy. The provider also should document who supplied the MSP information. While a hospital is permitted to bill as described above using information in file from the beneficiary or his/her representative, if the hospital's use of outdated or inaccurate information leads to Medicare making an incorrect primary payment, the hospital will be liable to repay the overpayment.

CMS Relaxes Medicare Secondary Payer Instructions for Hospitals (continued)

Moreover, the hospital will not be considered to be "without fault" in causing the overpayment under section 1870 of the Act (42 USC 1395gg) because it could have collected, had it chosen to do so, more recent and accurate information from the beneficiary.

Policy for Medicare + Choice Organization (M+CO) Members

If the beneficiary is a member of an M+CO, hospitals are not required to ask the MSP questions or to collect, maintain, or report this information.

Policy for Provider Records Retention of MSP Information

42CFR 489.20(f) states the provider agrees to maintain a system that, during the admission process, identifies any primary payers other than Medicare, so that incorrect billing and Medicare overpayments can be prevented. Based on this regulation, hospitals must document and maintain MSP information for Medicare beneficiaries. Without this documentation, the intermediary would have nothing to audit submitted claims against.

Furthermore, since CMS may pursue providers, physicians, and other suppliers under the False Claims Act and the Federal Claims Collection Act for up to ten years after a claim is paid, it would be prudent for hospitals to retain these records for up to ten years. Should a hospital choose not to retain this information for up to ten years, it does so at its own risk.

This policy is effective January 1, 2002. ❖

Source: CMS Transmittal A-01-116; CR 1685

INPATIENT HOSPITAL SERVICES

Implementation of Inpatient Rehabilitation Facility Prospective Payment System (IRF PPS)

Section 4421 of the Balanced Budget Act (BBA) of 1997 (Public Law 105-33), as amended by section 125 of the Balanced Budget Refinement Act of 1999 (Public Law 106-113, Appendix F) and section 305 of the Benefits Improvement and Protection Act of 2000 (BIPA), authorizes the implementation of a per discharge prospective payment system (PPS), through new section 1886(j) of the Social Security Act, for inpatient rehabilitation hospitals and rehabilitation units—referred to as inpatient rehabilitation facilities (IRFs).

The implementation of IRF PPS is effective for cost reporting periods beginning on or after January 1, 2002. These payment rates will cover all costs of furnishing covered IRF services (that is, routine, ancillary, and capital-related costs) other than costs associated with operating approved educational activities as defined in 42 CFR section 413.85 and section 413.86, bad debts, and other costs not covered under the PPS.

Medicare IRF Classification Requirements

In general, the criteria for a facility to be classified as an IRF remains unchanged from the requirements used to classify entities as exempt from the acute care hospital PPS. In order to be paid under the IRF PPS, a facility first must meet the conditions for payment under section 412.604 of the regulations (established in the final rule). In addition, an entity must meet the requirements under section 412.23(b), which in part states that a facility must:

"show that during its most recent 12-month cost reporting period, it served an inpatient population of whom at least 75 percent required intensive rehabilitative services for the treatment of one or more of the following conditions: stroke, spinal cord injury, congenital deformity, amputation, major multiple trauma, fracture of femur (hip fracture), brain injury, polyarthritis (including rheumatoid arthritis), neurological disorders (including multiple sclerosis, motor neuron diseases, polyneuropathy, muscular dystrophy, and Parkinson's disease), and burns."

Hospitals that are not paid under the IRF PPS, but are paid under special payment provisions are:

- Veterans' Administration hospitals
- Hospitals that are reimbursed under state cost control systems approved under 42 CFR Part 403
- Hospitals that are reimbursed in accordance with demonstration projects authorized under section 402(a) of Public Law 90-248 (42 U.S.C. 1395b-1) or section 222(a) of Public Law 92-603 (42 U.S.C. 1395b-1).

Payment to foreign hospitals will be made in accordance with the provisions set forth in section 413.74 of the regulation.

Payment Provisions Under IRF PPS

Section 1886 of the BBA provides the basis for the establishment of the federal payment rates applied under the prospective payment system to IRFs. The PPS will incorporate per discharge federal rates based on average IRF costs in a base year updated for inflation to the first effective period of the system.

Beneficiary liability will operate the same as under the current Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) payment system. Even if Medicare payments are below cost of care for a patient under prospective payment, the patient cannot be billed for the difference in any case.

Payment Adjustment Factors and Rates

The BBA sets forth the methodology for establishing the payment rates as well as the data on which they are based. In addition, this section prescribes adjustments to such rates based on geographic variation and case-mix and other factors the Secretary of Health and Human Services deems necessary to ensure that payment most accurately reflects cost.

Implementation of Inpatient Rehabilitation Facility PPS (continued)

The BBA specifies that payments during fiscal years 2001 and 2002 must be established in a manner that results in the amount of total payments, including any adjustments, being equal to 98 percent of the amount of payments that would have been made during those fiscal years (for operating and capital costs) had the IRF PPS not been enacted. As a result of BIPA, a change has been made to eliminate the payment amount of 98 percent of the FY 2002 expenditures.

Under section 305 of the BIPA 2000, section 1886(j)(3)(b) of the Act is amended to increase the amount of payment to 100 percent of FY 2002 expenditures.

For the initial period of PPS, beginning on or after January 1, 2002, all payment rates and associated rules were published in the **Federal Register** on August 7, 2001. For each succeeding fiscal year, the rates will be published in the **Federal Register** on or before August 1 of the year preceding the affected fiscal year.

Case-Mix Groups

In general, a case will be grouped into a case-mix group (CMG) based on the clinical characteristics of the Medicare beneficiary. We used rehabilitation impairment categories (RICs), functional measurements, age, and comorbidities to develop the CMGs. Specifically, RICs are used to group cases that are similar in clinical characteristics and resource use. The RICs are formed using codes from the International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM). In addition to the RICs, the CMGs are further partitioned using functional measures of motor and cognitive scores. Age also allows us to improve the explanatory power of the CMGs if we split some of the groups based on this variable. Lastly, comorbidites were found to substantially increase the average cost of specific CMGs. The comorbidities are arrayed in three categories (or tiers) based on whether the costs are considered high, medium, or low. If a case has more than one comorbidity, the CMG payment rate will be based on the comorbidity that results in the highest payment.

Case-Level Adjustments

Payment will be based on the CMGs described above, as well as possible adjustments specific to the case and the facility characteristics. Below, we first describe the case-level adjustments of the IRF PPS. More than one case level adjustment may apply to the same case. Thus, for ease of understanding we present the discussion of the case-level adjustments in the same order that will be used to assess whether or not they apply. For instance, a case may be classified as a transfer, but may also receive additional payments because it meets the definition of an outlier case.

Interrupted stays are defined as those cases in which a Medicare beneficiary is discharged from the inpatient rehabilitation facility and returns to the same inpatient rehabilitation facility within three consecutive calendar days. The three consecutive calendar days begin with the day of discharge from the IRF and ends on midnight of the third day. The total length of the IRF stay including the days prior to the interruption and days after the interruption determines the length of stay for these cases.

One CMG payment will be made for interrupted stay cases and the payment will be based on the initial assessment. For example, if a Medicare beneficiary is discharged on February 1, 2001, and is readmitted on February 3, the case would be considered an interrupted stay and only one CMG payment will be made based on the initial assessment. However, if the Medicare beneficiary was readmitted on February 4, then it would not be considered an interrupted stay. A separate diagnosis related group (DRG) payment will not be made to the acute care hospital when the beneficiary is discharged and returns to the same IRF on the same day. However, a DRG payment can be made if the beneficiary does not return to the same IRF on the same day as they were discharged. Other adjustments may apply to this payment amount if a case is determined to be an interrupted stay. For example, the case still may meet the definition of a transfer case described below.

For the IRF PPS, transfer cases are defined as those in which a Medicare beneficiary is transferred to either another rehabilitation facility, a long term care hospital, an inpatient hospital, or a nursing home that accepts payment under either the Medicare program and/or the Medicaid program **and** the length of stay of the case is less than the average length of stay for a given CMG. The transfer policy consists of a per diem payment amount calculated by dividing the per discharge CMG payment rate by the average length of stay for the CMG. Medicare will pay transfer cases a per diem amount and include an additional half-day payment for the first day. Transfer payments will be calculated by first adding the length of stay of the case to 0.5 (to account for the addition of the half day payment for the first day) and then multiplying the result by the CMG per diem amount.

The IRF PPS also includes a payment adjustment for certain cases, such as short-stay cases (for cases that do not meet the definition of a transfer case). A separate CMG payment (5001) will be made for cases with a length of stay of three days or less, without consideration of the clinical characteristics of the patient. Further cases that expire with a length of stay of three days or less will also be classified to CMG 5001.

Separate CMGs will also be made for cases that expire with a length of stay greater than three days. To improve the explanatory power of the groups, Medicare created four additional CMGs to account for cases that expire.

- **CMG 5101** will be used for short-stay, orthopedic, expired cases. This CMG includes those cases that would otherwise be grouped to RICs 07, 08, and 09 and the length of the stay is greater than 3 days, but less than or equal to 13 days.
- **CMG 5102** will be used for orthopedic expired cases where the length of stay is greater than or equal to 14 days.
- **CMG 5103** will be used for short-stay, non-orthopedic, expired cases. This CMG includes those cases that would not be grouped to the orthopedic RICs and the length of the stay is greater than 3 days, but less than or equal to 15 days.

Implementation of Inpatient Rehabilitation Facility PPS (continued)

- **CMG 5104** will be used for non-orthopedic expired cases where the length of stay is greater than or equal to 16 days.

Facility-level Adjustments

Facility-level adjustments apply to all cases and are based on the individual IRF characteristics. The facility-level adjustments include an area wage adjustment, an adjustment for facility's located in rural areas, and an adjustment for treating low-income patients. Outlier payments will also be discussed in this section. Although outlier payments are considered to be a case-level adjustment, a case can only be determined to qualify for these additional payments after all other facility-level adjustments are computed. Thus, for ease of understanding, we present the discussion of these facility-level and outlier adjustments in the same order that will be used to assess their applicability.

To adjust payments for area wage differences, Medicare first identifies the labor-related portion of the prospective payment rates. The labor-related portion is 72.395 percent and the non-labor related portion is 27.605 percent. The labor-related unadjusted federal payment is multiplied by a wage index value to account for area wage differences. Medicare uses the inpatient acute care hospital wage data to compute the wage indices. The wage data excludes the wages for services provided by teaching physicians, interns and residents, and nonphysician anesthetists under Medicare Part B, because these services are not covered under the IRF PPS. The wage index that will apply to the IRF PPS payment rates excludes 100 percent of wages for teaching physicians, residents, and nonphysician anesthetists. IRFs will be divided into labor market areas. As with other CMS payment systems, we define urban areas as a Metropolitan Statistical Area (MSA) or New England County Metropolitan Area, as defined by the Executive Office of Management and Budget. For the purposes of computing the wage index for IRFs, the wage index values for urban and rural areas are determined without regard to geographic reclassification under section 1886(d)(8) or (d)(10) of the Act.

Payments will be adjusted for facilities located in rural areas. Medicare considers a facility to be a rural IRF if they are located in a non-MSA area.

Additional payments will be made for treating low-income patients (LIP). There are two parts in computing this adjustment. The first part is the calculation of the disproportionate share variable (DSH).

This is computed by:

$$\text{DSH} = \frac{\text{SSI Days}}{\text{Total Medicare Days}} + \frac{\text{Medicaid, Non-Medicare Days}}{\text{Total Days}}$$

Once the DSH is calculated, we use this percentage to determine the LIP adjustment as specified in the IRF PPS final rule.

Additional payments will be made for those cases that are high cost outliers. A case will be considered to be an outlier if the estimated cost of the case exceeds an adjusted threshold amount. The estimated cost of the case will be calculated by multiplying the charge by the facility's overall cost-to-charge ratio obtained from the latest settled cost report. If the estimated cost of the case is greater than the sum of the adjusted payment amount and the adjusted threshold amount, then the case is considered an outlier and additional payments will be added to the adjusted payment amount.

The outlier payment will be 80 percent of the difference between the estimated cost of the case and outlier threshold (the sum of the facility-level adjusted CMG payment and the threshold amount multiplied by the facility-level adjustments as described above).

Phase-In Implementation

Under the BBA, the federal fiscal year in which a facility's cost reporting period begins, determines which transition period percentages apply. The first transition period percentages are applicable for cost reporting periods beginning during federal fiscal year 2001. The second transition period percentages are applicable to cost reporting periods beginning during federal fiscal year 2002, that is, periods beginning on or after October 1, 2001 and before October 1, 2002. For cost reporting periods beginning during federal fiscal year 2003 and after, payment is based on 100 percent of the adjusted federal prospective payment.

Since we are implementing the IRF PPS for discharges that occur during the IRF's cost reporting period that begins on or after January 1, 2002, IRFs will be phased directly into the second transition period, where payment will be based on 66$^{2}/_{3}$ percent of the PPS payment and 33$^{1}/_{3}$ percent of the TEFRA payment. A facility will continue to be paid under the TEFRA (reasonable cost-based) system for its **entire** cost reporting period beginning prior to January 1, 2002.

In addition, section 305 of BIPA 2000 states facilities may elect to be paid 100 percent PPS payment, rather than payment based on the transition method. If a facility chooses not to be paid under the transition method, they must notify their intermediary no later than 30 days prior to its first cost-reporting period for which the IRF PPS applies to the facility. The request to make the election must be made in writing to the Medicare fiscal intermediary for the facility. The intermediary must receive the request on or before the 30th day before the applicable cost reporting period begins, regardless of any postmarks or anticipated delivery dates. Requests received, postmarked, or delivered by other means after the 30th day before the cost reporting period begins will not be approved. If the 30th day before the cost reporting period falls on a day the postal service or other delivery sources are not open for business, the facility is responsible for allowing sufficient time for delivery of the request before the deadline. If a facility's request is not received or not approved, payment will be based on the transition method.

Medicare Patient Assessment Instrument

IRF PPS payment is contingent on the requirement that IRFs complete a patient assessment upon admission and discharge for Medicare patients. The final rule contains detailed information regarding the assessment schedule for the patient assessment instrument with respect to transmission requirements, encoding dates, and other pertinent information. Further, an item-by-item guide, which will include detailed instructions regarding the

Implementation of Inpatient Rehabilitation Facility PPS (continued)

manner in which each item on the assessment instrument needs to be completed will be provider later.

Claim Processing And Billing Requirements Under IRF PPS

Effective with cost reporting periods beginning on or after January 1, 2002, IRFs are required to report billing data with a new revenue code and a health insurance PPS (HIPPS) rate code on Form HCFA-1450 (UB-92) or its electronic equivalent for all Part A inpatient claims (type of bill 11x) to their intermediaries. The Medicare A 837 Health Care Claim version 3051 implementations 3A.01 and 1A.C1, along with the UB-92 version 6.0 are at **http://www.hcfa.gov/medicare/edi/edi3.htm**. These formats are effective through October 16, 2002. The X12N 837 version 4010 (HIPAA) to UB-92 version 6.0 mapping is at **http://www.hcfa.gov/medicare/edi/hipaadoc.htm.** The 837 version 4010 can be downloaded at **http://www.wpc-edi.com.** The new revenue code, 0024, will be used in conjunction with the HIPPS rate code to identify the CMG group the beneficiary was classified into. In addition to all entries previously required on a UB-92, the following additional instructions must be followed to accurately price and reimburse a claim under PPS. These claims must be submitted on type of bill 11x. The last four digits of the provider number for rehabilitation hospitals is from 3025 to 3099, and for rehabilitation units the third digit will be a T.

- The Revenue Code, Form Locator (FL) 42, (Record Type (RT) 60, field 5), (SV201), must contain revenue code 0024. This code indicates that this claim is being paid under the PPS. This revenue code can only appear on a claim once.
- The following patient status codes are applicable under the transfer policy for IRF PPS: 02, 03, 61, 62, and 63.

Note: IRFs that transfer a beneficiary to a nursing home that accepts payment under Medicare and/or Medicaid should use PS 03, discharged/transferred to a SNF. IRFs that transfer a beneficiary to a nursing facility that does not accept Medicare or Medicaid, should code PS 04, discharged/transferred to an ICF, until such time that a new PS code is established to differentiate between nursing facilities that do not accept Medicare and/or Medicaid and those that do. PS 04 does not constitute a transfer under the IRF PPS policy.

- For typical cases, the HCPCS/Rates, FL44, (RT60, field 6), (SV202-2), must contain a five digit HIPPS Rate/ CMG Code (AXXYY-DXXYY). The first position of the code is an A,B,C, or D. The HIPPS rate code beginning with A in front of the CMG is defined as without comorbidity. The HIPPS rate code containing a B in front of the CMG is defined as with comorbidity for Tier 1. The HIPPS rate code containing a C in front of the CMG is defined as with comorbidity for Tier 2. The HIPPS rate code containing a D in front of the CMG is defined as with comorbidity for Tier 3. The (XX) in the HIPPS rate code is the rehabilitation impairment category (RIC) and the (YY) in the HIPPS rate code is the sequential numbering system within the RIC.

Covered charges, FL47, (RT60, field 10), (SV203), should contain zero covered charges when the revenue code is 0024. For accommodation revenue codes (010x-021x), covered charges must equal the rate times the units. The IRF PRICER will calculate and return the payment amount for the line item with revenue code 0024. Non-outlier payments will not be made based on the total charges shown in revenue code 0001.

- IRF providers will submit one admit thru discharge claim for the stay. Final PPS payment is based upon the discharge bill.
- Should the patient's stay overlap the time in which the PPS applies to the facility, PPS payment will still be based on discharge.
  - If the facility submitted an interim bill, a debit/ credit adjustment must be made prior to PPS payment.
  - If the facility **submits multiple interim bills,** the provider will need to submit cancels, then rebill once the cancels are accepted.
- IRFs can submit adjustment bills (even to correct the CMG), but late charge bills will not be allowed (Type of bill 115).
- If a beneficiary has one day of Medicare coverage during their IRF stay, an entire CMG payment will be made.
- IRFs will be paid under the IRF PPS beginning on the first day of their cost reporting period that begins on or after January 1, 2002.

Billing Ancillary Services under IRF PPS

When coding PPS bills for ancillary services associated with a Part A inpatient stay, the traditional revenue codes will continue to be shown in FL 42, e.g., 0250 - Pharmacy, 042x - Physical Therapy, in conjunction with the appropriate entries in Service Units, FL46 and Total Charges, FL47.

- IRFs are required to report the number of units in FL 46 based on the procedure or service.
- IRFs are required to report the actual charge for each line item, in Total Charges, FL 47.

Benefits Exhausted

If a beneficiary's Part A benefits exhaust during the stay, code an occurrence code A3-C3 (RT 40, field 8-21), 2300 loop HI code BH). If benefits are exhausted prior to the stay, submit a no pay claim, which will be coded by the FI with no pay code B.

Note: For more information on outlier payments when benefits are exhausted, please visit http://www.hcfa.gov/pubforms/transmit/A991760.htm. Although this references an expired instruction specific to inpatient hospital PPS billing, the information presented provides important general information. Should this situation occur in an IRF, IRF providers may apply the same type of logic and an IRF PC Pricer will be made available for assistance. ❖

Source: CMS Transmittal A-01-110, CR: 1851

Payment for Blood Clotting Factor Administered to Hemophilia Inpatients

This article revises the Intermediary Manual section 3610.18, "Payment for Blood Clotting Factor Administered to Hemophilia Inpatients" and the Hospital Manual section 460.1. The list of ICD-9-CM diagnosis codes that must be listed on the bill for payment to be made for the blood clotting factor is being amended to include two ICD-9-CM diagnosis codes: 286.5 – Hemorrhagic disorder due to circulating anticoagulants, and 286.7 – Acquired coagulation factor deficiency. Payment will be made for the blood-clotting factor only if one of the following hemophilia ICD-9-CM diagnosis codes is listed on the bill:

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
286.5 Hemorrhagic disorder due to circulating anticoagulants
286.7 Acquired coagulation factor deficiency.

Note: A revised local medical policy on Hemophilia Clotting Factors – J7190 may be found on pages 68-69 of this issue.

Claim Processing Instructions

Hospitals must follow general bill review instructions in section 3604 of the Intermediary Manual Part 3 on the claim Form HCFA-1450 (UB-92) or its electronic claim equivalent using type of bill 11x. ❖

Source: CMS Transmittal A-01-89, CR: 1695

OUTPATIENT HOSPITAL SERVICES

Instructions for Billing Hospital Outpatient Claims Containing Charges for Epoetin Alfa (EPO)

Hospitals billing for outpatient claims containing charges for epoetin alfa (EPO), (tradenames Epogen and Procrit), for patients with chronic renal failure who are not on a regular course of dialysis, are required to utilize type of bill 13x, and report charges under revenue code 636 with HCPCS code Q0136 and without value codes 48, 49, and 68. Payment will be made under the outpatient prospective payment system (OPPS). This instruction supercedes instructions in section 3644.D.2 of the Medicare Intermediary Manual, Part 3, and section 439.1 of the Medicare Hospital Manual, which states that charges for EPO provided by hospitals are reported under revenue codes 634 or 635 and payment is made on a reasonable cost basis.

With implementation of OPPS, the reasonable cost method of reimbursement was eliminated. The above stated manual sections will be updated at a later date to conform with this notification.

At this point, hospital outpatient claims containing charges for EPO are unable to be processed for payment. The Centers for Medicare & Medicaid Services has provided the fiscal intermediary with special handling instructions to manually release these claims for payment. ❖

Source: CMS Transmittal A-01-106, CR 1839

ESRD SERVICES

End Stage Renal Disease Blood Pricing

The following new End Stage Renal Disease (ESRD) blood pricing, effective for services rendered on and after January 1, 2002, updates the existing *Medicare Part A ESRD Processing Manual*, section 23. Providers may use this pricing update to reconcile Medicare claim payments for applicable services rendered ***on and after January 1, 2002***.

The following procedure codes for blood and blood related services are billable by ESRD providers to Medicare Part A (bill type 72x) using claim Form HCFA-1450 (UB-92) or its electronic equivalent.

Blood and Blood Related Services

Description Name/Description of blood and/or blood related service.

Procedure Code Healthcare Common Procedure Coding System (HCPCS) and/or Current Procedure Terminology (CPT) code reportable on the HCFA 1450 (UB-92) claim form or its electronic equivalent.

Revenue Code Code that identifies a specific accommodation, ancillary service or billing calculation. (Appropriate revenue code must be used with procedure code for reimbursement).

Allowable Price Medicare Part A reimbursement allowance for the blood and/or blood related service.

Note: When a procedure code indicates "diagnosis code required," it should be noted the diagnosis coding requirement is exclusive to diagnosis code 585 (Chronic renal disease).

Description	HCPCS/CPT Code	Revenue Code	Allowable Price
Blood (whole), for transfusion, per unit	P9010	382	$107.48
Cryoprecipitatc (each unit)	P9012	387	$37.81
Leukocyte poor blood (each unit)	P9016	385	$123.79
Plasma, single donor, fresh frozen (each unit)	P9017	383	$56.49
Platelet concentrate (each unit)	P9019	384	$57.11
Red blood cells (each unit)	P9021	38X	$94.48
Washed red blood cells (each unit)	P9022	380	$148.25
Processing packed RBC's	P9030	390	$75.19
Platelets per unit	P9040	390	$362.00
Blood typing; antigen screening for compatible blood unit using reagent serum, per unit screened	X0079	390	$35.21
Blood typing; ABO	X0080	390	$21.00
Blood typing; RBC antigens, other than ABO or Rh(D)each	X0081	390	$37.99
Antibody screen, RBC, each serum technique	X0086	390	$30.48
Antibody identification, RBC antibodies, each panel for each serum technique	X0087	390	$79.49
Compatibility test each unit; immediate spin technique	X0088	390	$64.78
Blood typing; Rh(D)	X0089	390	$23.37
Frozen blood, preparation for freezing, each unit; with freezing & thawing	X0090	390	$187.00
HTLV or HIV antibody, confirmatory test (Western blot)	X0091	390	$100.17
Hepatitis B surface antigen (HBsAg)	X0093	390	$22.72
Hepatitis C antibody	X0094	390	$25.00
Leukocyte transfusion	X0096	390	$612.50
Antibody elution, RBC, each solution	86860	30x/31x	$79.49
Compatibility test each unit; immediate spin tech	86921	30x/31x	$36.55
-incubation tech			
-antiglobulin tech	86922	30x/31x	$41.75
Pooling of palets or other blood products	86965	30x/31x	$169.00

End Stage Renal Disease Blood Pricing (continued)

Listed below is a blood HCPCS crosswalk that lists the current CPT codes for blood processing and the corresponding local X codes required for proper reimbursement.

Current CPT Code	Local "X" Code
86903	X0079
86900	X0080
86905	X0081
86850	X0086
86870	X0087
86920	X0088

Current CPT Code	Local "X" Code
86901	X0089
86932	X0090
86689	X0091
87340	X0093
86803	X0094
86950	X0096

MEDICAL POLICIES

The Centers for Medicare & Medicaid Services (CMS) instructions regarding development of local medical review policies (LMRPs) are addressed in the Medicare Intermediary Manual (CMS 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 CMS 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 **January 1, 2002**, and after, unless otherwise noted.

Medicare Part A Medical Policy Procedures

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

Maintaining Local Medical Review Policies For Reference

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

Medical Policy Table of Contents

Final Medical Policies

Additions and Revisions to Previously Published Medical Policy

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

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

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

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

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

Revision Overview: LMRP Description, Indications and Limitations of Coverage, and Other Comments sections have been revised to ensure that the language in the policy includes coverage of symptomatic abscesses, which are not always infected.

Policy Number
10060

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

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

AMA CPT Copyright Statement

CMS National Coverage Policy
N/A

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

CMS Region
Region IV

CMS Consortium
Southern

Original Policy Effective Date
09/21/2001

Original Policy Ending Date
N/A

Revision Effective Date
10/18/2001

Revision Ending Date
10/17/2001

LMRP Description
An abscess is a cavity containing pus surrounded by inflamed tissue. It is generally associated with pain, swelling and erythema. An abscess often requires incision and drainage to remove the purulent material in order for healing to occur.

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

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will consider the use of incision and drainage of an abscess of the skin, subcutaneous and/or accessory structures to be medically reasonable and necessary for the treatment of a symptomatic abscess (e.g., inflamed, painful, tender) involving these structures. This includes the incision and drainage of the following types of abscess:

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

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

CPT/HCPCS Section & Benefit Category
Integumentary System/Surgery

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

Revenue Codes
361 Operating Room Services, Minor Surgery

CPT/HCPCS Codes

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

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity

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

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

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

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

Noncovered ICD-9-CM Codes

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

Noncovered Diagnosis

N/A

Coding Guidelines

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

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

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

Documentation Requirements

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

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

Furthermore, the medical record must clearly document the medical necessity for repeated incision and drainage of an abscess. If frequent incision and drainage is required, the medical record must reflect the reason for persistent/ recurrent abscess formation, as well as any measures taken to prevent reoccurence. For example, for repeated incision and drainage of an abscessed paronychia, the medical record should document any additional measures taken to prevent reoccurence and/or the reason for not performing more definitive treatment (e.g., the patient refuses and/or is not a candidate for permanent, partial or complete nail and nail matrix removal).

Utilization Guidelines

N/A

Other Comments

Terms Defined

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

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

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

Cyst – a thin-walled subcutaneous sac containing fluid or semisolid material.

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

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

Sources of Information and Basis for Decision

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

Advisory Committee Notes

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

Start Date of Comment Period

N/A

End of Date of Comment Period

N/A

Start Date of Notice Period

11/01/2001

Revision History

Revision Number	1
Start Date of Comment Period	N/A
Start Date of Notice Period	11/01/2001
	1st Qtr 2002 *Bulletin*
Revised Effective Date	10/18/2001

Explanation of Revision: Policy language changed to ensure coverage of symptomatic abscesses, which are not always infected. ❖

11600: Excision of Malignant Skin Lesions

Policy Number
11600

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Excision of Malignant Skin Lesions

AMA CPT Copyright Statement

CMS National Coverage Policy
N/A

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

CMS Region
Region IV

CMS Consortium
Southern

Original Policy Effective Date
01/01/2002

Original Policy Ending Date
N/A

Revision Effective Date
N/A

Revision Ending Date
N/A

LMRP Description
A skin lesion is any alteration in the normal skin architecture. Lesions can be benign, pre-malignant or malignant. The most common malignant lesions are basal cell carcinomas (BCC), squamous cell carcinomas (SCC) and melanomas.

Four of the most common methods of treatment of malignant skin lesions are:

- Surgical excision,
- Electrodesccation (tissue destruction by heat),
- Radiation therapy, or
- Cryosurgery (tissue destruction by freezing)

The treatment of choice for malignant skin lesions is complete excision that includes a variable margin of surrounding tissue in order to eradicate microscopic tumor cells, which may have spread beyond the visible borders of the lesion.

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will consider the excision of a malignant skin lesion (procedure codes 11600-11646) medically necessary when a pathology report verifies the existence of a malignancy.

When a lesion is excised that is a neoplasm of uncertain morphology (e.g., melanoma vs. dyplastic nevi), choose the correct CPT code based on the manner in which the lesion is excised rather than the final pathological diagnosis. The CPT code should reflect the knowledge, skill, time and effort that the provider invests in the excision of the lesion. For example, an ambiguous, but low-suspicion lesion might be excised with minimal surrounding, grossly normal skin/soft tissue margins, as for a benign lesion. This would be most appropriately reported using the excision of benign lesion codes 11400-11446. An ambiguous, but moderate to high suspicion lesion would be excised with moderate to wide surrounding grossly normal skin/soft tissue margins, as for a malignant lesion. This type of excision would be most appropriately reported using the excision of malignant lesion codes 11600-11646.

CPT/HCPCS Section & Benefit Category
Surgery/Integumentary System

Type of Bill Code
Hospital – 13x
Rural Health Clinic – 71x

Revenue Codes
360 Operating Room Services, General Classification
361 Minor Surgery

CPT/HCPCS Codes
11600 Excision, malignant lesion, trunk, arms, or legs; lesion diameter 0.5 cm or less
11601 lesion diameter 0.6 to 1.0 cm
11602 lesion diameter 1.1 to 2.0 cm
11603 lesion diameter 2.1 to 3.0 cm
11604 lesion diameter 3.1 to 4.0 cm
11606 lesion diameter over 4.0 cm
11620 Excision, malignant lesion, scalp, neck, hands, feet, genitalia; lesion diameter 0.5 cm or less
11621 lesion diameter 0.6 to 1.0 cm
11622 lesion diameter 1.1 to 2.0 cm
11623 lesion diameter 2.1 to 3.0 cm
11624 lesion diameter 3.1 to 4.0 cm
11626 lesion diameter over 4.0 cm
11640 Excision, malignant lesion, face, ears, eyelids, nose, lips; lesion diameter 0.5 cm or less
11641 lesion diameter 0.6 to 1.0 cm
11642 lesion diameter 1.1 to 2.0 cm
11643 lesion diameter 2.1 to 3.0 cm
11644 lesion diameter 3.1 to 4.0 cm
11646 lesion diameter over 4.0 cm

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity
Procedure Codes 11600-11606
172.5 Malignant melanoma of trunk, except scrotum

11600: Excision of Malignant Skin Lesions (continued)

172.6	Malignant melanoma of upper limb, including shoulder
172.7	Malignant melanoma of lower limb, including hip
173.5	Other malignant neoplasm of skin of trunk, except scrotum
173.6	Other malignant neoplasm of skin of upper limb, including shoulder
173.7	Other malignant neoplasm of skin of lower limb, including hip
195.1-195.8	Malignant neoplasm of other and ill-defined sites, except head, face and neck
232.5	Carcinoma in situ of trunk, except scrotum
232.6	Carcinoma in situ of upper limb, including shoulder
232.7	Carcinoma in situ of lower limb, including hip
232.8	Carcinoma in situ of other specified sites of skin
*238.2	Neoplasm of uncertain behavior of skin (atypical melanocytic lesions)

*Please see the "Other Comments" section of the policy for a list of synonymous terms that might be found in the operative report or medical record to reflect these indications.

Procedure Codes 11620-11626

172.4	Malignant melanoma of scalp and neck
172.6	Malignant melanoma of upper limb, including shoulder
172.7	Malignant melanoma of lower limb, including hip
173.4	Other malignant neoplasm of scalp and skin of neck
173.6	Other malignant neoplasm of skin of upper limb, including shoulder
173.7	Other malignant neoplasm of skin of lower limb, including hip
184.0-184.8	Malignant neoplasm of other and unspecified female genital organs
187.1-187.4	Malignant neoplasm of penis
187.7	Malignant neoplasm of the scrotum
195.0	Malignant neoplasm of head and neck
195.3-195.5	Malignant neoplasm of pelvis, upper limb and lower limb
232.4	Carcinoma in situ of scalp and skin of neck
232.6	Carcinoma in situ of upper limb, including shoulder
232.7	Carcinoma in situ of lower limb, including hip
232.8	Carcinoma in situ of other specified sites of skin
233.3	Carcinoma in situ of other and unspecified female genital organs
233.5-233.6	Carcinoma in situ of penis and other and unspecified male genital organs
*238.2	Neoplasm of uncertain behavior of skin (atypical melanocytic lesions)

*Please see the "Other Comments" section of the policy for a list of synonymous terms that might be found in the operative report or medical record to reflect these indications.

Procedure Codes 11640-11646

140.0-149.9	Malignant neoplasm of lip, oral cavity, and pharynx
172.0-172.3	Malignant melanoma of lip, eyelid, ear and other and unspecified parts of the face
172.8	Malignant melanoma of skin, other specified sites
173.0-173.3	Other malignant neoplasm of lip, eyelid, ear and other and unspecified parts of the face
173.8	Other malignant neoplasm of skin, other specified sites
195.0	Malignant neoplasm of head, face and neck
230.0	Carcinoma in situ of lip
232.0-232.3	Carcinoma in situ of lip, eyelid, ear and other and unspecified parts of the face
232.8	Carcinoma in situ of other specified sites of skin
*238.2	Neoplasm of uncertain behavior of skin (atypical melanocytic lesions)

*Please see the "Other Comments" section of the policy for a list of synonymous terms that might be found in the operative report or medical record to reflect these indications.

Diagnoses that Support Medical Necessity

N/A

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

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Reasons for Denials

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 Codes

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

Noncovered Diagnosis

N/A

Coding Guidelines

Procedure code range 11600-11646, Excision, Malignant Lesions, includes simple (non-layered) closure and local anesthesia.

For excision of malignant lesions requiring more than simple closure (i.e., requiring intermediate or complex closure) report 11600-11646 in addition to the appropriate intermediate (12031-12057) or complex (13100-13153) closure codes.

When coding the removal of a lesion, measure the lesion removed. Do not report the size of the surgical defect created or the affected area when determining the correct procedure code to use.

11600: Excision of Malignant Skin Lesions (continued)

For billing purposes, when determining the correct size of the lesion removed, refer to the operative report not the pathology report.

A biopsy of a basal cell carcinoma (BCC), squamous cell carcinoma (SCC), atypical melanoma or malignant melanoma may require a follow-up excision. The wider excision may or may not show residual malignancy. Re-excisions of a malignant lesion to obtain clear margins should be coded using the 11600-11646 series for the appropriate area. All related pathology reports should be maintained in the clinical record.

Documentation Requirements

The medical record/ progress note should indicate the removal of a malignant or an ambiguous, but moderate to high suspicion lesion with a corresponding pathology report. The size and location of the lesion should be documented in the operative report.

Utilization Guidelines

N/A

Other Comments

The following terms may be found in the in the operative report, pathology report or medical record and may be used to describe neoplasms of uncertain behavior of the skin (238.2). This is not an all-inclusive list:

- Atypical melanocytic lesions
- Atypical melanocytic proliferation
- Clark's nevus
- Dysplastic nevus
- Melanocytic lesion of uncertain malignant potential
- Nevus with atypia or dysplasia
- Spitz' nevus
- Atypical mole

Sources of Information and Basis for Decision

American Medical Association. (1995). Measuring and coding the removal of a lesion. *cpt™Assistant,* 5(3), 3-4.

American Medical Association. (2000). Reviewing of the integumentary excision lesion codes (11400-11646). *cpt™Assistant,* 10(8), 5-7.

Huether, S. E. (1998). Structure, function, and disorders of the integument. In K.L. McCance & S.E. Huether (Eds.), *Pathophysiology: The biologic basis for disease in adults and children* (pp. 1517-1554). New York: Mosby.

Rigel, D.S. & Carucci, J.A. (2000). Malignant melanoma: Prevention, early detection, and treatment in the 21st century. *CA: A Cancer Journal for Clinicians* [On-Line], 50. Available: http://ca-journal.org/articles/50/4/215-236/50_215-236.html

Ross. M. & Balch, C. (1998). Surgical treatment of primary melanoma. In C. M. Balch, A. N. Houghton, A.J. Sober & S. Soong (Eds.), *Cutaneous melanoma* (pp. 141-153). St. Louis, Missouri: Quality Medical Publishing, Inc.

The American Society of Plastic Surgeons (1997) Skin lesions. *Plastic Surgery Information Service* [On-Line]. Available: http://www.plasticsurgery.org/profinfo/pospap/skinles.html

Advisory Committee Notes

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

Start Date of Comment Period

02/28/2001

End Date of Comment Period

04/14/2001

Start Date of Notice Period

11/01/2001

Revision History

Revision Number:	Original
Start Date of Comment Period	02/28/2001
Start Date of Notice Period	11/01/2001
	1st Qtr 2002 *Bulletin*
Original Effective Date:	01/01/2002 ❖

29540: Strapping

Revision Overview: The diagnosis code 736.70 has been added to the "ICD-9-CM Codes that Support Medical Necessity" section for CPT codes 29540 and 29550.

Policy Number
29540

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Strapping

AMA CPT Copyright Statement

CMS National Coverage Policy
N/A

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

CMS Region
Region IV

CMS Consortium
Southern

Original Policy Effective Date
06/22/2001

Original Policy Ending Date
N/A

Revision Effective Date
10/01/2001

Revision Ending Date
09/30/2001

LMRP Description
Strapping of the ankle and/or toe(s) consists of the application of nonmedicated, adhesive gauze dressings, applied by overlapping wraps of gauze to exert pressure and hold a structure in place for the purpose of providing structural support, immobilization or compression for the ankle, foot and/or toe(s).

Unna boot is a paste bandage which consists of gauze that has been impregnated with zinc oxide, gelatin, glycerin, and sometimes calamine. The bandage is applied to the leg from the toe to the knee by overlapping wraps of impregnated gauze. The Unna boot forms a semirigid soft cast which should be left in place for 4 to 7 days.

The Unna boot bandage restricts the volume of the leg, controls edema, and encourages more normal prograde venous blood flow with reduction in the subcutaneous blood pressure. The net effect is improved healing of venous stasis ulcers of the lower extremities.

Indications and Limitations of Coverage and/or Medical Necessity

Strapping (Procedure codes 29540 and 29550)

Florida Medicare will consider Strapping of the ankle and/or toe(s) medically reasonable and necessary for the following symptomatic conditions:

- Strains, sprains, dislocations, tendinitis and certain fractures not accompanied by ulceration. It is not generally expected that strapping of the ankle and/or toe(s) would be done more often than weekly. However, there are circumstances that warrant application of straps several times per week, such as, whirlpool treatments which require removal and reapplication of the straps.

Unna boot (Procedure code 29580)

Florida Medicare will consider the use of the Unna boot bandage medically reasonable and necessary for the following indications:

- To treat venous vascular insufficiency;
- For the treatment of ulcers with and without inflammation of the lower extremities which are caused by increased venous pressure, venous insufficiency or capillary dysfunction; and
- For the management of sprains, strains, dislocations and minor fractures.

It is not expected that Unna boot application would be done more often than once or twice per seven days. Unna boot application is not indicated for use with ulcers resulting from arterial disease or diabetes.

CPT/HCPCS Section & Benefit Category
Surgery/Musculoskeletal System

Type of Bill Code
Hospital – 13x
Skilled Nursing Facility – 21x, 22x, 23x
Rural Health Clinic – 71x
Outpatient Rehabilitation Facility – 74x
Comprehensive Outpatient Rehabilitation Facility – 75x

Revenue Code
42x Physical Therapy
43x Occupational Therapy
510 Clinic

CPT/HCPCS Codes

29540	Strapping; ankle
29550	Strapping; toes
29580	Strapping; Unna boot

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity

For CPT codes **29540** and **29550**, the following diagnoses are considered medically reasonable and necessary:

718.37	Recurrent dislocation of joint, ankle and foot
718.87	Other joint derangement, not elsewhere classified, ankle and foot

29540: Strapping (continued)

719.27	Villonodular synovitis, ankle and foot
726.70	Enthesopathy of ankle and tarsus, unspecified
726.71	Achilles bursitis or tendinitis
726.72	Tibialis tendinitis
726.73	Calcaneal spur
726.79	Enthesopathy of ankle and tarsus, other
727.06	Tenosynovitis of foot and ankle
735.0	Hallux valgus (acquired)
728.71	Plantar fascial fibromatosis
734	Flat foot
735.1	Hallux varus (acquired)
735.3	Hallux malleus
735.4	Other hammer toe (acquired)
735.5	Claw toe (acquired)
735.8	Other acquired deformities of the toe
736.70	Unspecified deformity of ankle and foot, acquired
736.79	Other acquired deformities of the ankle and foot
824.0	Fracture of medial malleolus, closed
824.2	Fracture of lateral malleolus, closed
825.0	Fracture of calcaneus, closed
825.20-825.29	Fracture of other tarsal and metatalsal bones, closed
826.0	Fracture of one or more phalanges of foot, closed
837.0	Closed dislocation of ankle
838.00-838.09	Closed dislocation of foot
845.00-845.19	Sprains and strains of ankle and foot
924.20-924.21	Contusion of ankle and foot, excluding toe(s)
924.3	Contusion of toe

For CPT code **29580**, the following diagnoses are considered medically reasonable and necessary:

451.0-451.2	Phlebitis and thrombophlebitis of lower extremities
454.0	Varicose veins of lower extremities, with ulcer
454.1	Varicose veins of lower extremities, with inflammation
454.2	Varicose veins of lower extremities, with ulcer and inflammation
824.0-824.9	Fracture of ankle
825.0	Fracture of calcaneus, closed
825.20-825.29	Fracture of other tarsal and metatarsal bones, closed
826.0	Fracture of one or more phalanges of foot, closed
837.0-837.1	Dislocation of ankle
838.00-838.19	Dislocation of foot
845.00-845.19	Sprains and strains of ankle and foot

Diagnosis that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnosis that DO NOT Support Medical Necessity
N/A

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

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

Noncovered Diagnosis
N/A

Coding Guidelines
N/A

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

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

Utilization Guidelines
N/A

Other Comments
N/A

Sources of Information and Basis for Decision
Sources of information may be found online under "Medical Policies" in the Part A section on our provider Web site – **www.floridamedicare.com.**

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

Start Date of Comment Period
N/A

End Date of Comment Period
N/A

Start Date of Notice Period
11/01/2001

Revision History

Revision Number:	1
Start Date of Comment Period	N/A
Start Date of Notice Period	11/01/2001
	1st Qtr 2002 *Bulletin*
Revised Effective Date:	10/01/2001

Explanation of Revision: Added ICD-9-CM code 736.70 to the "ICD-9-CM Codes that Support Medical Necessity" Section of the policy for the strapping procedure codes, 29540 and 29550. ❖

33282: Insertable Loop Recorder (ILR)

Revision Overview: Revenue code 278 has been added and revenue code 636 has been removed from the "Revenue Codes" section. The "Coding Guidelines" section of the policy has been revised to reflect this change.

Policy Number
33282

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Insertable Loop Recorder (ILR)

AMA CPT Copyright Statement

CMS National Coverage Policy
N/A

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

CMS Region
Region IV

CMS Consortium
Southern

Original Policy Effective Date
02/25/2000

Original Policy Ending Date
N/A

Revision Effective Date
01/01/2002

Revision Ending Date
12/31/2001

LMRP Description
A 510 (k) approval (substantially equivalent device) was granted for the Medtronic Reveal® ILR on January 16, 1998, for use as "an implantable patient-activated monitoring system that records subcutaneous electrocardiogram and is indicated for patients who experience transient symptoms that may suggest a cardiac arrhythmia".

The Reveal® ILR device is implanted subcutaneously in a single incision procedure in the left pectoral or mammary location. It measures 61mm x 19mm x 8mm and weighs 17 grams. Its projected longevity is 14 months, due to a low battery condition. The manufacturer recommends that the device be removed when it is no longer clinically necessary or when the battery is depleted.

	SYSTEM
Reveal® ILR	Subcutaneously placed, programmable cardiac event recorder with looping memory
Reveal® Activator	Hand-held, telemetry unit used by the patient to activate ECG storage
9790 Programmer	Used to program Reveal® ILR and retrieve, display, and print stored data

Indications and Limitations of Coverage and/or Medical Necessity
An ILR is indicated in patients with syncope or presyncope who have had recurrent but infrequent syncopal or presyncopal episodes that have defied diagnosis by conventional means. These patients will frequently have a history of injury or even hospitalization directly attributed to prior syncopal or presyncopal events. Syncope, for the purpose of this policy, is defined as a sudden but transient total loss of consciousness with spontaneous resolution.

Florida Medicare will consider an ILR medically reasonable and necessary only if a definitive diagnosis has not been made after ALL of the following conditions have been met:

- Complete history and physical examination;
- An appropriate selective diagnostic work-up;
- Electrocardiogram; and
- A 2 to 4 week period of long-term electrocardiographic monitoring with an external loop recorder that fails to determine whether cardiac arrhythmia is the cause of recurrent syncope or presyncope.

CPT/HCPCS Section & Benefit Category
Cardiovascular System/Surgery/Medicine

Type of Bill Code
Hospital – 13x

Revenue Codes
278 Medical/Surgical Supplies and Devices, Other Implants
361 Minor Surgery
739 Other EKG/ECG

CPT/HCPCS Codes
33282	Implantation of patient-activated cardiac event recorder (Initial implantation includes programming. For subsequent electronic analysis and/or reprogramming, use 93727)
33284	Removal of an implantable, patient-activated cardiac event recorder
93727	Electronic analysis of implantable loop recorder (ILR) system (Includes retrieval of recorded and stored ECG data, physician review and interpretation of retrieved ECG data and reprogramming)
C1764	Event recorder, cardiac (implantable)

Not Otherwise Classified Codes (NOC)
N/A

33282: Insertable Loop Recorder (ILR) (continued)

ICD-9-CM Codes that Support Medical Necessity

780.2 Syncope and collapse

Diagnoses that Support Medical Necessity

N/A

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

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Reasons for Denials

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

The insertion of the ILR device for patients in whom the prerequisite studies have not been completed due to patient noncompliance.

Noncovered ICD-9-CM Codes

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

ILR device implantation should be coded as 33282, with revenue code 361.

IRL device removal should be coded as 33284, with revenue code 361.

ILR interrogation should be coded as 93727, with revenue code 739.

The ILR device itself should be coded as C1764 with revenue code 278.

Electrocardiogram analyses obtained during device insertion for signal quality and amplification purposes are considered part of the implant procedure and should not be separately billed.

Removal of an ILR device on the same day as the insertion of a cardiac pacemaker in any given patient is considered to be part of the pacemaker insertion procedure and will not be reimbursed separately. This limitation applies whether or not the ILR implantation site is used for the pacemaker pocket.

Documentation Requirements

Medical record documentation (e.g., office/progress notes) must be maintained by the ordering/referring physician and must support that all of the conditions for ILR coverage as set forth under the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy have been met (e.g., the prior testing performed and the results, the patient history of the syncopal or presyncopal incident and symptomatology). Additionally, documentation must also support that the service billed was actually performed (e.g., an operative note/report).

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

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

Advisory Committee Notes

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

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

11/01/2001

Revision History

Revision Number	3
Start Date of Comment Period	N/A
Start Date of Notice Period	11/01/2001 1st Qtr 2002 *Bulletin*
Revised Effective Date	01/01/2002

Explanation of Revision: Transmittal A-01-50 dated April 12, 2001 provided appropriate revenue codes to report medical devices that have been granted pass-through status. Therefore, revenue code 636 (Drugs Requiring Detailed Coding) has been replaced with revenue code 278 (Medical/Surgical Supplies and Devices, Other Implants).

Revision Number	2
Start Date of Comment Period	N/A
Start Date of Notice Period	05/01/2001 3rd Qtr 2001 *Bulletin*
Revised Effective Date	06/22/2001

Explanation of Revision: The establishment of categories for use in coding devices eligible for transitional pass-through payments under the hospital OP PPS.

Revision Number	1
Start Date of Comment Period	N/A
Start Date of Notice Period	08/01/2000 Aug/Sept 2000 *Bulletin*
Revised Effective Date	08/01/2000

Explanation of Revision: Outpatient PPS Implementation

Revision Number	Original
Start Date of Comment Period:	08/23/1999
Start Date of Notice Period:	12/1999 Dec 1999 Special Issue Bulletin
Original Effective Date	02/25/2000 ❖

76075: Bone Mineral Density Studies

Revision Overview: Policy has been revised to incorporate the 2002 Annual ICD-9-CM Update.

Policy Number
76075

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Bone Mineral Density Studies

AMA CPT Copyright Statement

CMS National Coverage Policy
Coverage Issues Manual, Section 50-44
42 Code of Federal Regulation, Section 410.32 A(3)

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

CMS Region
Region IV

CMS Consortium
Southern

Original Policy Effective Date
03/04/1999

Original Policy Ending Date
N/A

Revision Effective Date
10/01/2001

Revision Ending Date
09/30/2001

LMRP Description
Osteoporosis has classically been defined as skeletal fragility due to low bone mass, which results in fractures associated with minimal trauma. To quantify this concept, osteoporosis has been defined as bone mass more than 2.5 standard deviations below the mean of young normals. Osteoporosis is a major health problem, and it has been estimated that 70% of fractures in women age 45 and older are the types associated with osteoporosis. Multiple risk factors have been identified that increase the risk for developing osteoporosis (heredity, estrogen deficiency, alcoholism, race and sex being the most prominent).

Bone mineral density studies are performed to establish the diagnosis of osteoporosis and to assess the individual's risk for subsequent fracture. Bone densitometry includes the use of single photon absorptiometry (SPA), single energy X-ray absorptiometry (SEXA), dual photon absorptiometry (DPA), dual energy radiographic absorptiometry (DEXA), quantitative computed tomography (QCT), and bone ultrasound densitometry (BUD). Low radiation dose, availability and ease of use have made DEXA the most widely used technique for measuring bone density in clinical trials and epidemiological studies.

Bone density can be measured at the wrist, spine, hip or calcaneus. The medical literature is divided on the accuracy of predicting osteoporosis of the spine or hip by measuring peripheral sites (wrist, calcaneus). It does appear, however, that measurement of bone density of the bone involved gives a better measurement of osteoporosis than does measurement of another bone not known to be involved.

Precise calibration of the equipment is required for accuracy and to reduce variation of test results and risk of misclassification of the degree of bone density. Lack of standardization in bone mineral measurement remains an issue, and tests are best done on the same suitably precise instrument to insure accuracy. It is important to use results obtained with the same scanner when comparing a patient to a control population, as systematic differences among scanners have been found. To ensure reliability of bone mass measurements, the densitometry technologist must have proper training in performing this procedure. Malpositioning of a patient or analyzing a scan incorrectly can lead to great errors in bone mineral density studies.

A stationary bone densitometer is a device that is permanently located in an office.

A mobile densitometer is one that is transported by vehicle from site to site.

A portable densitometer is one that can be picked up and moved from one site to another.

Indications and Limitations of Coverage and/or Medical Necessity
Medicare considers a bone mineral density study to be medically reasonable and necessary for the following indications: In addition, all coverage criteria listed below must be met.

- A patient with vertebral abnormalities as demonstrated by an X-ray to be indicative of osteoporosis, osteopenia (low bone mass), or vertebral fracture. For this indication use **ICD-9-CM code 733.02** for idiopathic osteoporosis, use **ICD-9-CM Code 733.90** for osteopenia, or use **ICD-9-CM codes 805.00-806.9** for vertebral fractures.
- A patient being monitored to assess the response to or efficacy of an FDA-approved osteoporosis drug therapy. Use **ICD-9-CM code 733.00** for unspecified osteoporosis, **ICD-9-CM code 733.01** for postmenopausal osteoporosis, or **ICD-9-CM code 733.02** for idiopathic osteoporosis.
- A patient with known primary hyperparathyroidism. Use **ICD-9-CM code 252.0** for hyperparathyroidism.
- A patient receiving (or expecting to receive) glucocorticoid (steroid) therapy (greater than 3 months, on the **equivalent dose** of 30 mg cortisone [or 7.5 mg prednisone or greater per day. Use **ICD-9-CM code 733.09** for drug-induced osteoporosis and **E932.0** for adrenal cortical steroids.

76075: Bone Mineral Density Studies (continued)

- A woman who has been determined by the physician or a qualified non physician practitioner treating her to be estrogen-deficient and at clinical risk for osteoporosis, based on her medical history and other findings. For this indication use **ICD-9-CM code 256.2** (postablative ovarian failure), **256.31-256.39** (other ovarian failure) or **627.2** (menopausal states).

Coverage criteria for bone mass measurements are as follows:

- There must be an order by the individual's physician or qualified nonphysician practitioner treating the patient following an evaluation of the need for a measurement, including a determination as to the medically appropriate measurement to be used for the individual. A physician or qualified nonphysician practitioner treating the beneficiary for purposes of this provision is one who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the patient. For the purpose of the bone mass measurement benefit, qualified nonphysician practioners include physician assistants, nurse practioners, clinical nurse specialists and certified nurse midwives.
- This service must be furnished by a qualified supplier or provider of such services under at least the general level of supervision of a physician;
- This service must be reasonable and necessary for diagnosing, treating, or monitoring a qualified individual as defined above; and
- This service must be performed with a bone densitometer or a bone sonometer device approved or cleared for marketing by the Food and Drug Administration for bone mass measurement purposes, with the exception of dual photon absorptiometry devices.
- Is performed at a frequency that conforms to the requirements described below.

Note: Since not every woman who has been prescribed estrogen replacement therapy (ERT) maybe receiving an "adequate" dose of the therapy, the fact that a woman is receiving ERT should not preclude her treating physician or other qualified treating nonphysician practitioner from ordering a bone mass measurement for her. If a bone mass measurement is ordered for a woman following a careful evaluation of her medical need, however, it is expected that the ordering treating physician (or other qualified treating nonphysician practitioner) will document in her medical record why he or she believes that the woman is estrogen-deficient and at clinical risk for osteoporosis.

Medicare may cover a bone mass measurement for a patient once every 2 years. However, if medically necessary, Medicare may cover a bone mass measurement for a patient more frequently than every 2 years. Examples of situations where more frequent bone mass measurements procedures may be medically necessary include, but are not limited to, the following medical circumstances:

- Monitoring patients on long-term glucocorticoid (steroid) therapy of more than 3 months; and
- Allowing for a confirmatory baseline bone mass measurement (either central or peripheral) to permit monitoring of patients in the future if the initial test was performed with a technique that is different from the proposed monitoring method (for example, if the initial test was performed using bone sonometry and monitoring is anticipated using bone densitometry, Medicare will allow coverage of baseline measurement using bone densitometry).

A bone mineral density study code should be billed only once regardless of the number of sites being tested or included in the study (i.e., if the spine and hip are performed as part of the same study only one can be billed).

CPT/HCPCS Section & Benefit Category

Radiology/Diagnostic 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

32x Radiology Diagnostic
34x Nuclear Medicine

CPT/HCPCS Codes

G0130	Single energy X-ray absorptiometry (SEXA) bone density study, one or more sites, appendicular skeleton (peripheral) (e.g., radius, wrist, heel)
G0131	Computerized tomography bone mineral density study, one or more sites; axial skeleton (e.g., hips, pelvis, spine)
G0132	Computerized tomography bone mineral density study, one or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)
76075	Dual energy X-ray absorptiometry (DEXA), bone density study, one or more sites; axial skeleton (e.g., hips, pelvis, spine)
76076	Dual energy X-ray absorptiometry (DEXA), bone density study, one or more sites; appendicular skeleton (peripheral) (e.g., radius, wrist, heel)
76078	Radiographic absorptiometry (photodensitometry), one or more sites
76977	Ultrasound bone density measurement and interpretation, peripherial site(s), any method
78350	Bone density (bone mineral content) study, one or more sites; single photon absorptiometry

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

252.0	Hyperparathyroidism
256.2	Postablative ovarian failure
256.31-256.39	Other ovarian failure
627.2	Menopausal or female climacteric states
733.00	Osteoporosis, unspecified
733.01	Senile osteoporosis (Postmenopausal osteoporosis)
733.02	Idiopathic osteoporosis

76075: Bone Mineral Density Studies (continued)

733.09	Other osteoporosis (Drug-induced osteoporosis)
733.90	Disorder of bone and cartilage, unspecified (Osteopenia)
805.00-805.9	Fracture of vertebral column without mention of spinal cord injury
806.00-806.9	Fracture of vertebral column with spinal cord injury
E932.0	Adrenal cortical steroids

Diagnoses that Support Medical Necessity

N/A

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

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Reasons for Denials

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

Tests not ordered by the appropriate physician or qualified nonphysician practitioner who is treating the beneficiary are not reasonable and necessary. A physician or qualified nonphysician practitioner treating the beneficiary for purposes of this provision is one who furnishes a consultation or treats a beneficiary for a specific medical problem and who uses the results in the management of the patient.

Bone density studies of any type including DEXA scans are not covered under the portable X-ray benefit. The benefit allows for X-ray films of the skeleton, chest or abdomen. Although bone density studies are radiology procedures, they are not X-ray films. Also, to be a benefit of portable X-ray services the equipment must be portable to provide services in the home.

CPT 78351 (Dual Photon Absorptiometry) is noncovered by Medicare Coverage Issues Manual 50-44.

Noncovered ICD-9-CM Codes

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 performing bone mineral density studies, the CPT code that reflects the procedure that was performed should be billed. See the HCPCS section for the appropriate CPT code.

Dual photon absorptiometry (CPT code 78351) remains a noncovered service under Medicare and may not be reported under HCPCS codes (76075) or (76076).

Photodensitometry (a noninvasive radiological procedure that attempts to assess bone mass by measuring the optical density of extremity radiographs with a photodensitometer) is reported using code 76078. Since this procedure is performed by taking an X-ray of the hand simultaneous with an X-ray of a Aphantom@, the X-ray of the hand is not reimbursed separately.

One of the indications listed in this policy under the "Indications and Limitations of Coverage and/or Medical Necessity" section of this policy requires a dual diagnosis to be submitted. Refer to this section of the policy.

Providers are required to report the number of units on line item dates of service per revenue code line for each bone mass measurement reported. Line item date of service reporting is effective for dates of service on or after October 1, 1998.

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. If the service exceeds the frequency parameter listed in this policy, documentation of medical necessity must be submitted. This information is normally found in the office/progress notes, hospital notes, and/or procedure report.

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

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

Medicare may cover a bone mass measurement for a patient once every 2 years. However, if medically necessary, Medicare may cover a bone mass measurement for a patient more frequently than every 2 years.

Other Comments

N/A

Sources of Information and Basis for Decision

Black, Dennis M., Why Elderly Women Should Be Screened and Treated to Prevent Osteoporosis. *The American Journal of Medicine*, February 27, 1995, Volume 98 (suppl 2A) page 2A-67S.

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Ulrich, U., Browning, M., Gaffney, E.V., Schoter, K.-H., Chesnut III, C.H. (1997). Implementation of an osteoporosis research program with a mobile dual-energy X-ray absorptiometry unit: The Montana/Wyoming experience. *Osteoporosis International.*

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 carrier, this policy was developed in cooperation with advisory groups, which includes representatives from the Florida Obstetrics & Gynecologic Society.

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

11/01/2001

Revision History

Revision Number:	3
Start Date of Comment Period	N/A
Start Date of Notice Period	11/01/2001 1st Qtr 2002 *Bulletin*
Revised Effective Date:	10/01/2001
Explanation of Revision:	Annual ICD-9-CM Update

Revision Number:	2
Start Date of Comment Period	N/A
Start Date of Notice Period	02/25/2000 Special Issue 2000 *Bulletin*
Revised Effective Date:	02/25/2000
Explanation of Revision:	Outpatient PPS implementation

Revision Number:	1
Start Date of Comment Period	N/A
Start Date of Notice Period	08/01/1999 Aug/Sept *Bulletin*
Revised Effective Date:	08/01/2000
Explanation of Revision:	This policy is being revised to add an ICD-9-CM code based on provider correspondence.

Revision Number:	Original
Start Date of Comment Period	09/18/1998 *Bulletin* G-349
Start Date of Notice Period	01/21/1999 *Bulletin* G-360
Original Effective Date:	03/04/1999 ❖

78460: Myocardial Perfusion Imaging

Revision Overview: Policy has been revised to incorporate the 2002 Annual ICD-9-CM Update.

Policy Number
78460

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Myocardial Perfusion Imaging

AMA CPT Copyright Statement

CMS National Coverage Policy
Hospital Manual, Section 443
Intermediary Manual, Section 3631

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

CMS Region
Region IV

CMS Consortium
Southern

Original Policy Effective Date
01/21/1999

Original Policy Ending Date
N/A

Revision Effective Date
10/01/2001

Revision Ending Date
09/30/2001

LMRP Description
Myocardial perfusion imaging is a cardiac radionuclide imaging procedure that is usually performed with exercise electrocardiogram ECG/EKG testing for detecting coronary artery disease and determining prognosis. The SPECT (single-photon emission computed tomographic) technique is utilized to obtain multiple-angle images.

Indications and Limitations of Coverage and/or Medical Necessity
Myocardial perfusion imaging will be considered medically reasonable and necessary by Florida Medicare if any one of the following circumstances is present:

- The patient has chest pain, other symptoms, or signs suggestive of coronary artery disease, **and** the patient has an abnormal baseline EKG (RBBB, LBBB, IVCD, LVH, Atrial fibrillation, marked resting ST segment changes) which would make interpretation of a standard exercise test inaccurate.
- The patient has chest pain, other symptoms, or signs suggestive of coronary artery disease, **and** the patient is on a cardiac glycoside (Digoxin) or other medication which would impair the accuracy of interpretation of a standard exercise test.
- The patient has an abnormal or non-diagnostic standard exercise test and myocardial perfusion imaging is being performed in order to determine if the patient has myocardial ischemia.
- The patient has a condition, such as mitral valve prolapse, which would likely result in a non-diagnostic or inaccurate standard stress test.
- Patient has known coronary artery disease (or recent myocardial infarction) and myocardial perfusion imaging is being done to determine the significance of/ or the extent of myocardial ischemia (or scar) resulting from coronary artery disease or to assess myocardial viability.
- The patient has undergone cardiovascular re-perfusion (CABG, PTCA, thrombolysis) and perfusion imaging is being done to evaluate the effectiveness of the intervention.
- The patient has developed congestive heart failure and a silent MI is suspected.
- The patient has a ventricular wall motion abnormality demonstrated by another imaging modality and perfusion imaging is needed to further evaluate the abnormality.
- The patient has severe peripheral vascular disease and is a candidate for peripheral vascular reperfusion by balloon angioplasty or bypass surgery and myocardial perfusion imaging is being done pre-operatively because of concern about possible significant coronary artery disease.
- Follow-up within 48 hours of an abnormal multiple myocardial perfusion scan to determine whether the perfusion defect is related to myocardial scarring or myocardial ischemia. Usually only a single study is needed to evaluate this indication.

CPT/HCPCS Section & Benefit Category
Radiology/Nuclear Medicine

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

Revenue Code
34x Nuclear Medicine

CPT/HCPCS Codes

78460	Myocardial perfusion imaging; (planar) single study, at rest or stress (exercise and/or pharmacologic), with or without quantification
78461	multiple studies, (planar) at rest and/or stress (exercise and/or pharmacologic), and redistribution and/or rest injection, with or without quantification
78464	tomographic (SPECT), single study at rest or stress (exercise and/or pharmacologic), with or without quantification

78460: Myocardial Perfusion Imaging (continued)

78465	tomographic (SPECT), multiple studies, at rest and/or stress (exercise and/or pharmacologic), and redistribution and/or rest injection, with or without quantification
78478	Myocardial perfusion study with wall motion, qualitative or quantitative study (List separately in addition to code for primary procedure)
78480	Myocardial perfusion study with ejection fraction (List separately in addition to code for primary procedure)

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

411.0	Postmyocardial infarction syndrome
411.1	Intermediate coronary syndrome
411.81	Acute coronary occlusion without myocardial infarction
411.89	Other acute and subacute forms of ischemic heart disease
412	Old myocardial infarction
413.0	Angina decubitus
413.1	Prinzmetal angina
413.9	Other and unspecified 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	Aneurysm of heart (wall)
414.11	Aneurysm of coronary vessels
414.19	Other aneurysm of heart
414.8	Other specified forms of chronic ischemic heart disease
414.9	Chronic ischemic heart disease, unspecified
424.0	Mitral valve disorders
426.2	Left bundle branch hemiblock
426.3	Other left bundle branch block
426.4	Right bundle branch block
426.50	Bundle branch block, unspecified
426.51	Right bundle branch block and left posterior fascicular block
426.52	Right bundle branch block and left anterior fascicular block
426.53	Other bilateral bundle branch block
426.54	Trifascicular block
426.6	Other heart block
426.7	Anomalous atrioventricular excitation
427.31	Atrial fibrillation
428.0	Congestive heart failure
428.1	Left heart failure
428.9	Heart failure, unspecified
440.21-440.24	Atherosclerosis of native arteries of the extremities
794.31	Abnormal electrocardiogram [ECG] [EKG]
960.7	Poisoning by antineoplastic antibiotics
995.2	Unspecified adverse effect of drug, medicinal and biological substance
E942.0	Agents primarily affecting the cardiovascular system, cardiac rhythm regulators
E942.1	Agents primarily affecting the cardiovascular system, cardiotonic glycosides and drugs of similar action
V67.00	Follow-up examination following surgery, unspecified
V67.09	Follow-up examination following other surgery
V67.51	Follow-up examination following completed treatment with high-risk medication, not elsewhere classified
V67.59	Follow-up examination following other treatment

Diagnoses that Support Medical Necessity

N/A

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

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Reasons for Denials

Florida Medicare cannot provide coverage for myocardial perfusion imaging performed as a screening test for coronary artery disease.

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 Codes

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 performing both the rest and stress portions of the myocardial perfusion imaging for any one of the covered indications, a multiple study procedure code (78461, 78465) should be billed regardless of whether the imaging occurs on the same day or two different days.

Procedure codes 78478 and 78480 should be billed in conjunction with the appropriate primary procedure code: 78460, 78461, 78464, or 78465.

Documentation Requirements

Medical record documentation maintained by the ordering/referring physician must clearly indicate the medical necessity of myocardial perfusion imaging studies. Also, the results of myocardial perfusion studies must be

78460: Myocardial Perfusion Imaging (continued)

included in the patient's medical record. This information is normally found in the office/progress notes and/or test results.

If the provider of myocardial perfusion imaging 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.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

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Advisory Committee Notes

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

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

11/01/2001

Revision History

Revision Number:	4
Start Date of Comment Period	N/A
Start Date of Notice Period	11/01/2001 1st Qtr 2002 *Bulletin*
Revised Effective Date:	10/01/2001
Explanation of Revision:	Annual ICD-9-CM Update

Revision Number:	3
Start Date of Comment Period	N/A
Start Date of Notice Period	10/01/2000 Oct/Nov 2000 *Bulletin*
Revised Effective Date:	10/01/2000
Explanation of Revision:	Annual ICD-9-CM Update

Revision Number:	2
Start Date of Comment Period	N/A
Start Date of Notice Period	02/25/2000 Special Issue 2000 *Bulletin*
Revised Effective Date:	08/01/2000
Explanation of Revision:	Outpatient PPS implementation

Revision Number:	1
Start Date of Comment Period	N/A
Start Date of Notice Period	01/21/1999
Revised Effective Date:	01/01/1999
Explanation of Revision:	1999 HCPCS change occurred prior to implementation

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

80061: Lipid Profile/Cholesterol Testing

Revision Overview: Indications and Limitations of Coverage, and ICD-9-CM Codes that Support Medical Necessity sections of the policy have been revised to add coverage for patients with diabetes mellitus – ICD-9-CM code range 250.00-250.93 effective May 1, 2001, and ICD-9-CM diagnosis code 995.2 effective October 22, 2001.

Policy Number
A80061

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Lipid Profile/Cholesterol Testing

AMA CPT Copyright Statement

CMS National Coverage Policy
N/A

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

CMS Region
Region IV

CMS Consortium
Southern

Original Policy Effective Date
03/08/1999

Original Policy Ending Date
N/A

Revision Effective Date
10/22/2001

Revision Ending Date
10/21/2001

LMRP Description
Lipids are fatty substances made up of cholesterol, cholesterol esters (liquid compounds), triglycerides, nonesterized fatty acids, and phospholipids which provide energy for metabolism, serve as precursors of steroid hormones (adrenals, ovaries, and testes) and bile acids, and play an important role in cell membrane development. Very low density lipoproteins (VLDL) carry only a small amount of cholesterol. However, they are the predominant carriers of blood triglycerides. Lipoprotein measurements are diagnostic indicators for hyper- and hypolipidemia. A lipid profile usually includes cholesterol, triglycerides, LDL, HDL, and VLDL may also be included.

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will consider Lipid Profile/Cholesterol Testing to be medically reasonable and necessary for those patients undergoing the following current treatments:

Dietary Treatment:

Some patients may be managed during diet therapy on the basis of their total cholesterol levels. If the total cholesterol monitoring goal is met, the LDL cholesterol should be measured to confirm the desired LDL cholesterol level has been achieved.

Monitoring for adherence to dietary therapy would be expected at approximately 4 to 6 weeks from initiation and at 3 months. If the desired LDL and cholesterol levels have been achieved, quarterly monitoring for the first year and twice yearly thereafter, would be expected. In addition, triglyceride levels at the same frequency may also require monitoring to assess that desired levels have been achieved.

Drug Treatment:

After drug therapy is initiated, the serum cholesterol, serum triglyceride, LDL, VLDL and HDL level (as applicable to the drug therapy) would be expected to be measured at approximately 4 to 6 weeks and again at 3 months. If the drug therapy response is adequate (i.e., the LDL, serum cholesterol and triglyceride goal has been achieved), it would be expected that every 4 months or more frequently when drugs requiring closer follow-up are used to monitor the cholesterol response and possible side effects of therapy, would be required.

Lipid Profile/Cholesterol Testing for those patients with normal blood cholesterol, HDL, and LDL levels would be considered screening and not payable by Medicare.

Other Indications:

An annual fasting lipid panel (80061) is a recognized test utilized in the management of diabetes mellitus. Therefore, Florida Medicare will consider the performance of an annual fasting lipid panel (80061) medically reasonable and necessary for patients with diabetes mellitus (ICD-9-CM codes 250.00-250.93). If the lipid panel demonstrates dyslipidemia requiring dietary treatment, subsequent lipid panels should be billed utilizing ICD-9-CM codes 272.0-272.9. If the patient requires drug therapy due to dyslipidemia, subsequent lipid panels should be billed utilizing ICD-9-CM code E942.2.

Triglyceride testing (84478) can be performed on a patient to rule out hypertriglyceridemia as the cause of panceatitis.

Note: Once lipid profile testing is performed to rule out the cause of a condition and/or symptom (e.g., chest pain, thyroid disorder, etc.) it is not considered medically necessary to repeat the test(s) unless the results indicate a lipid disorder or the patient exhibits new symptomology.

A fasting lipid panel (80061) may be considered medically necessary for those patients receiving drug therapy with agents that are proven to significantly increase total cholesterol, HDL, and triglycerides (e.g., Bexarotene).

CPT/HCPCS Section & Benefit Category
Pathology and Laboratory/Organ or Disease Oriented Panels/Chemistry

80061: Lipid Profile/Cholesterol Testing (continued)

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 Chemistry

CPT/HCPCS Codes

80061	Lipid panel (this panel must include 82465, 83718 and 84478)
82172	Apolipoprotein, each
82465	Cholesterol, serum or whole blood, total
83715	Lipoprotein, blood; electrophoretic separation and quantitation
83716	high resolution fractionation and quantitation of lipoprotein cholesterols (eg, electrophoresis, nuclear magnetic resonance, ultracentrifugation)
83718	Lipoprotein, direct measurement; high density cholesterol (HDL cholesterol)
83719	direct measurement VLDL cholesterol
83721	direct measurement LDL cholesterol
84478	Triglycerides

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

240.0-246.9	Disorders of thyroid gland
250.00-250.93	Diabetes mellitus (for use with procedure code 80061)
272.0-272.9	Disorders of lipoid metabolism
401.0-405.99	Hypertensive disease
410.00-410.92	Acute myocardial infarction
411.0-411.89	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
414.8	Other specified forms of chronic ischemic heart disease
414.9	Chronic ischemic heart disease, unspecified
429.2	Cardiovascular disease, unspecified
431-437.9	Cerebrovascular disease
438.0-438.9	Late effects of cerebrovascular disease
440.0-440.9	Atherosclerosis
441.00-441.9	Aortic aneurysm and dissection
443.9	Peripheral vascular disease, unspecified
444.0-444.89	Arterial embolism and thrombosis
577.0-577.1	Acute and chronic pancreatitis (for use with procedure code 84478)
786.50	Chest pain, unspecified
995.2	Unspecified adverse effect of drug, medicinal and biological substance (for use with procedure code 80061)
E942.2	Agents primarily affecting the cardiovascular system, antilipemic and antiarteriosclerotic drugs

Diagnoses that Support Medical Necessity

N/A

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

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Reasons for Denials

Lipid Profile/Cholesterol Testing will not be covered on a routine or screening basis.

Apolipoprotein (82172) is considered to be a screening test and therefore, non-covered by Medicare.

Calculated LDL determination will be denied.

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 Codes

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

Noncovered Diagnosis

N/A

Coding Guidelines

Procedure code 83721 represents only those LDL cholesterol levels done by direct measurement. It is not appropriate to bill 83721 for LDL cholesterol levels done by the calculated method.

Documentation Requirements

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

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

N/A

Other Comments

The goal of diet and drug therapy is most often to lower LDL cholesterol.

Sources of Information

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Advisory Committee Notes

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

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

11/01/2001

Revision History

Revision Number	4
Start Date of Comment Period	N/A
Start Date of Notice Period	11/01/2001 1st Qtr 2002 *Bulletin*
Revised Effective Date	10/22/2001

Explanation of Revision: Effective 05/01/2001, coverage for an annual lipid panel (80061) for patients with diabetes mellitus (ICD-9-CM codes 250.00-250.93) was added to the policy. Effective 10/22/2001, ICD-9-CM code 995.2 was added to the policy as a covered diagnosis.

Revision Number	3
Start Date of Comment Period	N/A
Start Date of Notice Period	12/22/2000 Special Issue 2000 Bulletin
Revised Effective Date	01/01/2001

Explanation of Revision: Annual 2001 HCPCS Update

Revision Number	2
Start Date of Comment Period	N/A
Start Date of Notice Period	01/21/1999
Revised Effective Date	01/21/1999

Explanation of Revision: To clarify that diagnosis range 577.0-577.1 is to be used for procedure code 84478.

Revision Number	1
Start Date of Comment Period	N/A
Start Date of Notice Period	01/21/1999
Revised Effective Date	01/21/1999

Explanation of Revision: 1999 HCPCS change occurred prior to implementation.

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

80162: Digoxin

Revision Overview: ICD-9-CM code V58.69 has been added to the ICD-9-CM Codes that Support Medical Necessity section of the policy.

Policy Number
80162

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Digoxin

AMA CPT Copyright Statement

CMS National Coverage Policy
N/A

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

CMS Region
Region IV

CMS Consortium
Southern

Original Policy Effective Date
11/24/1997

Original Policy Ending Date
N/A

Revision Effective Date
10/22/2001

Revision Ending Date
10/21/2001

LMRP Description
Therapeutic drug assays are performed on blood to determine levels of the drug systemically.

Indications and Limitations of Coverage and/or Medical Necessity
Digoxin assays are performed to monitor drug levels of individuals receiving digoxin therapy because the margin of safety between side effects and toxicity is narrow.

CPT/HCPCS Section & Benefit Category
Pathology and Laboratory/Therapeutic Drug Assays

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

Revenue Codes
300 General Classification
301 Chemistry

CPT/HCPCS Codes
80162 Digoxin

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity

368.16	Psychophysical visual disturbances
368.9	Unspecified visual disturbance
402.00-402.91	Hypertensive heart disease
413.0	Angina decubitus
425.3-425.9	Cardiomyopathy
426.0	Atrioventricular block, complete
426.10	Atrioventricular block, unspecified
426.4	Right bundle branch block
426.50-426.54	Bundle branch block, other and unspecified
426.6	Other heart block
426.7	Anomalous atrioventricular excitation
426.81-426.9	Other specified and unspecified conduction disorders
427.0-427.9	Cardiac dysrhythmias
428.0-428.9	Heart failure
514	Pulmonary congestion and hypostasis
783.0	Anorexia
787.01-787.03	Nausea and vomiting
972.1	Poisoning by cardiotonic glycosides and drugs of similar action
E942.1	Agents primarily affecting the cardiovascular system, cardiotonic glycosides and drugs of similar action (digoxin)
V58.69	Long-term (current) use of other medications (digoxin)
V72.84	Pre-operative examination, unspecified

Diagnoses that Support Medical Necessity
N/A

ICD-9-CM Codes that DO NOT Support Medical Necessity
N/A

Diagnoses that DO NOT Support Medical Necessity
N/A

Reasons for Denials
Diagnoses other than those listed as covered ICD-9-CM codes are considered not reasonable and necessary and will result in denial of coverage.

Coverage is not provided for this test when obtained for screening purposes.

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

80162: Digoxin (continued)

Noncovered ICD-9-CM Codes

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 digoxin, use revenue code 300 or 301. In addition to the revenue code, the following Type of Bill must also include HCPCS code 80162: Hospital - 13x, 14x; Rural Health Clinic - 71x; End Stage Renal Disease – 72x

Documentation Requirements

Documentation supporting the medical necessity of this procedure, such as ICD-9-CM codes, must be submitted with each claim. Claims submitted without such evidence will be denied as being not medically necessary.

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

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

N/A

Advisory Committee Notes

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

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

11/01/2001

Revision History

Revision Number:	3
Start Date of Comment Period	N/A
Start Date of Notice Period	11/01/2001 1st Qtr 2002 *Bulletin*
Revised Effective Date:	10/22/2001

Explanation of Revision: Received request from provider to add ICD-9-CM code V58.69.

Revision Number:	2
Start Date of Comment Period	N/A
Start Date of Notice Period	05/13/1998
Revised Effective Date:	05/28/1998
Revision Number:	1
Start Date of Comment Period	N/A
Start Date of Notice Period	01/23/1998
Revised Effective Date:	01/23/1998
Revision Number:	Original
Start Date of Comment Period	07/30/1997
Start Date of Notice Period	10/24/1997
Original Effective Date:	11/24/1997 ❖

82270: Fecal Occult Blood Testing

Revision Overview: Policy has been revised to incorporate the 2002 Annual ICD-9-CM Update.

Policy Number
82270

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Fecal Occult Blood Testing

AMA CPT Copyright Statement

CMS National Coverage Policy
N/A

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

CMS Region
Region IV

CMS Consortium
Southern

Original Policy Effective Date
06/21/1999 AI

Original Policy Ending Date
N/A

Revision Effective Date
10/01/2001

Revision Ending Date
09/30/2001

LMRP Description
Fecal Occult Blood Testing is a procedure involving chemical testing of a stool specimen for the purpose of detecting the presence of blood in the stool that cannot be seen or identified with the naked eye.

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare can provide coverage for Fecal Occult Blood Testing in any of the following circumstances (see Covered ICD-9-CM Codes):

- The patient has a disease or disorder of the digestive tract and testing for occult blood in the feces is required to properly evaluate and/or manage the patient.
- The patient has symptoms or signs suggestive of disease or disorder of the digestive tract and testing for fecal blood is necessary to evaluate the patient's complaint.
- The patient has sustained trauma to the trunk, abdomen, or gastrointestinal tract and fecal blood testing is necessary as part of the evaluation and management of the patient.
- The patient is under treatment with a medication known to be associated with gastrointestinal blood loss, and the patient is considered to be at high risk for gastrointestinal bleeding.

CPT/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
300 Laboratory General
301 Laboratory Chemistry
305 Laboratory Hematology

CPT/HCPCS Codes

82270	Blood, occult, by peroxidase activity (eg, guaiac); feces, 1-3 simultaneous determinations

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity

009.0-009.3	Ill-defined intestinal infections
042	Human immunodeficiency virus [HIV] disease
070.0-070.33	Viral hepatitis
070.41-070.49	Other specified viral hepatitis with hepatic coma
070.51-070.59	Other specified viral hepatitis without mention of hepatic coma
070.6	Unspecified viral hepatitis with hepatic coma
070.9	Unspecified viral hepatitis without mention of hepatic coma
129	Intestinal parasitism, unspecified
150.0-159.9	Malignant neoplasm of digestive organs and peritoneum
176.3	Kaposi's sarcoma of gastrointestinal sites
183.0-183.9	Malignant neoplasm of ovary and other uterine adnexa
197.0-197.8	Secondary malignant neoplasm of respiratory and digestive systems
199.0-199.1	Malignant neoplasm without specification of site
211.0-211.9	Benign neoplasm of other parts of digestive system
228.04	Hemangioma of intra-abdominal structures
228.09	Hemangioma of other sites
230.0-230.9	Carcinoma in situ of digestive organs
235.2	Neoplasm of uncertain behavior of stomach, intestines, and rectum

82270: Fecal Occult Blood Testing (continued)

235.3	Neoplasm of uncertain behavior of liver and biliary passages
235.4	Neoplasm of uncertain behavior of retroperitoneum and peritoneum
235.5	Neoplasm of uncertain behavior of other and unspecified digestive organs
239.0	Neoplasms of unspecified nature of digestive system
251.5	Abnormality of secretion of gastrin
263.9	Unspecified protein-calorie malnutrition
280.0-280.9	Iron deficiency anemias
281.0-281.9	Other deficiency anemias
282.0-282.9	Hereditary hemolytic anemias
283.0	Autoimmune hemolytic anemias
283.10-283.19	Non-autoimmune hemolytic anemias
283.2	Hemoglobulinuria due to hemolysis from external causes
283.9	Acquired hemolytic anemia, unspecified
284.0-284.9	Aplastic anemia
285.0-285.9	Other and unspecified anemias
286.0-286.9	Coagulation defects
287.0-287.9	Purpura and other hemorrhagic conditions
288.0-288.9	Diseases of white blood cells
289.0	Polycythemia, secondary
289.1	Chronic lymphadenitis
289.2	Nonspecific mesenteric lymphadenitis
289.3	Lymphadenitis, unspecified, except mesenteric
289.4	Hypersplenism
289.50-289.59	Other diseases of spleen
289.6	Familial polycythemia
289.7	Methemoglobinemia
289.8	Other specified diseases of blood and blood-forming organs
289.9	Unspecified diseases of blood and blood-forming organs
448.0	Hereditary hemorrhagic telangiectasia
455.0-455.9	Hemorrhoids
456.0-456.21	Esophageal varices
458.9	Hypotension, unspecified
530.0	Achalasia and cardiospasm
530.10-530.19	Esophagitis
530.2	Ulcer of esophagus
530.3	Stricture and stenosis of esophagus
530.4	Perforation of esophagus
530.5	Dyskinesia of esophagus
530.6	Diverticulum of esophagus, acquired
530.7	Gastroesophageal laceration-hemorrhage syndrome
530.81-530.89	Other specified disorders of the esophagus
530.9	Unspecified disorders of esophagus
531.00-531.91	Gastric ulcer
532.00-532.91	Duodenal ulcer
533.00-533.91	Peptic ulcer, site unspecified
534.00-534.91	Gastrojejunal ulcer
535.00-535.61	Gastritis and duodenitis
536.0-536.9	Disorders of function of stomach
537.0-537.6	Other disorders of stomach and duodenum
537.81-537.89	Other specified disorders of stomach and duodenum
537.9	Unspecified disorder of stomach and duodenum
555.0-555.9	Regional enteritis
556.0-556.9	Ulcerative colitis
557.0-557.9	Vascular insufficiency of intestine
558.1-558.9	Other and unspecified noninfectious gastroenteritis and colitis
560.0-560.2	Intestinal obstruction without mention of hernia
560.30-560.39	Impaction of intestine
560.81-560.89	Other specified intestinal obstruction
560.9	Unspecified intestinal obstruction
562.00-562.03	Diverticula of the small intestine
562.10-562.13	Diverticula of the colon
564.00-564.9	Functional digestive disorders, not elsewhere classified
565.0-565.1	Anal fissure and fistula
566	Abscess of anal and rectal regions
567.0-567.9	Peritonitis
568.0	Peritoneal adhesions (postoperative) (postinfection)
568.81-568.89	Other specified disorders of peritoneum
568.9	Unspecified disorder of peritoneum
569.0-569.3	Other disorders of intestine
569.41-569.49	Other specified disorders of rectum and anus
569.5	Abscess of intestine
569.60-569.69	Colostomy and enterostomy complications
569.81-569.89	Other specified disorders of intestine
569.9	Unspecified disorder of intestine
570	Acute and subacute necrosis of the liver
571.0-571.3	Chronic liver disease and cirrhosis
571.40-571.49	Chronic hepatitis
571.5	Cirrhosis of liver without mention of alcohol
571.6	Biliary cirrhosis
571.8	Other chronic nonalcoholic liver disease
571.9	Unspecified chronic liver disease without mention of alcohol
572.0-572.8	Liver abscess and sequelae of chronic liver disease
573.0-573.9	Other disorders of liver
574.00-574.91	Cholelithiasis
575.0-575.9	Other disorders of gallbladder
576.0-576.9	Other disorders of biliary tract
577.0-577.9	Diseases of pancreas
578.0-578.9	Gastrointestinal hemorrhage
579.0-579.9	Intestinal malabsorption
596.1	Intestinovesical fistula
751.0-751.5	Other congenital anomalies of digestive system
751.60-751.69	Anomalies of gallbladder, bile ducts, and liver
751.7	Anomalies of pancreas
751.8	Other specified anomalies of digestive system
751.9	Unspecified anomaly of digestive system
759.6	Other hamartoses, not elsewhere classified
772.4	Fetal and neonatal gastrointestinal hemorrhage
780.2	Syncope and collapse
780.4	Dizziness and giddiness

82270: Fecal Occult Blood Testing (continued)

780.6	Fever
780.79	Other malaise and fatigue
782.4	Jaundice, unspecified, not of newborn
783.0	Anorexia
783.2 1	Loss of weight
784.9	Other symptoms involving head and neck
787.01-787.03	Nausea and vomiting
787.1	Heartburn
787.2	Dysphagia
787.3	Flatulence, eructation, and gas pain
787.4	Visible peristalsis
787.5	Abnormal bowel sounds
787.6	Incontinence of feces
787.7	Abnormal feces
787.91	Diarrhea
787.99	Other symptoms involving digestive system
789.0-789.9	Other symptoms involving abdomen and pelvis
790.6	Other abnormal blood chemistry
792.1	Nonspecific abnormal findings in stool contents
793.3	Nonspecific abnormal findings on radiological and other examination of bilary tract
793.4	Nonspecific abnormal findings on radiological and other examination of gastrointestinal tract
793.6	Nonspecific abnormal findings on radiological and other examination of abdominal area, including retroperitoneum
794.8	Nonspecific abnormal results of function studies of liver
863.99	Injury to other gastrointestinal sites, with open wound into cavity
864.00-864.19	Injury to liver
865.00-865.09	Injury to spleen without mention of open wound into cavity
865.10-865.19	Injury to spleen with open wound into cavity
866.00-866.03	Injury to kidney without mention of open wound into cavity
866.10-866.13	Injury to kidney with open wound into cavity
867.0-867.9	Injury to pelvic organs
868.00-868.09	Injury to other intra-abdominal organs without mention of open wound into cavity
868.10-868.19	Injury to other intra-abdominal organs with open wound into cavity
869.0-869.1	Internal injury to unspecified or ill-defined organs
902.0	Injury to blood vessels of abdominal aorta
902.10-902.19	Injury to blood vessels of inferior vena cava
902.20-902.29	Injury to blood vessels of celiac and mesenteric arteries
902.31-902.39	Injury to blood vessels of portal and splenic veins
902.40-902.49	Injury to renal blood vessels
902.50-902.59	Injury to iliac blood vessels
902.81-902.89	Injury to other specified blood vessels of abdomen and pelvis
902.9	Injury to unspecified blood vessel of abdomen and pelvis
922.1-922.9	Contusion of trunk
926.0	Crushing injury to external genitalia
926.11	Crushing injury of back
926.12	Crushing injury of buttock
926.19	Crushing injury to other specified sites of trunk
926.8	Crushing injury to multiple sites of trunk
926.9	Crushing injury to unspecified site of trunk
935.0-935.2	Foreign body in mouth, esophagus, and stomach
936	Foreign body in intestine and colon
937	Foreign body in anus and rectum
938	Foreign body in digestive system, unspecified
995.2	Unspecified adverse effect of drug, medicinal and biological substance
V10.00-V10.09	Personal history of malignant neoplasm
V12.70-V12.79	Personal history of diseases of digestive system
V15.2	Personal history of surgery to other major organs (gastrectomy)
V67.51	Follow-up examination following completed treatment with high-risk medications, not elsewhere classified

Diagnoses that Support Medical Necessity

N/A

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

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Reasons for Denials

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 Codes

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 Fecal Occult Blood Testing **(82270)** includes payment for up to three (3) specimens. If three or less than three specimens are taken, the number billed should be reported as "1." Three specimens should not be fragmented and billed on separate days.

HCPCS code G0107 should be used to report screening fecal occult blood tests. See Local Medical Review Policy G0104 Colorectal Cancer Screening for more information regarding Medicare's screening benefit.

82270: Fecal Occult Blood Testing (continued)

Documentation Requirements

Medical record documentation maintained by the ordering physician must clearly indicate the medical necessity of fecal occult blood testing covered by the Medicare program. Also, the results of fecal occult blood testing covered by the Medicare program must be included in the patient's medical record.

If the provider of 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

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

N/A

Advisory Committee Notes

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

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

11/01/2001

Revision History

Revision Number: 5
Start Date of Comment Period N/A
Start Date of Notice Period 11/01/2001
1st Qtr 2002 *Bulletin*
Revised Effective Date: 10/01/2001
Explanation of Revision: Annual ICD-9-CM Update

Revision Number: 4
Start Date of Comment Period N/A
Start Date of Notice Period 12/22/2000
Special Issue 2000 *Bulletin*
Revised Effective Date: 01/01/2001
Explanation of Revision: Annual 2001 HCPCS Update

Revision Number: 3
Start Date of Comment Period N/A
Start Date of Notice Period 10/01/2000
Oct/Nov 2000 *Bulletin*
Revised Effective Date: 10/01/2000
Explanation of Revision: Annual ICD-9-CM Update

Revision Number: 2
Start Date of Comment Period N/A
Start Date of Notice Period 06/07/1999
Revised Effective Date: 02/03/1999
Explanation of Revision: Expand billable Revenue Codes, import language regarding screening services, update ICD-9-CM coding to 5th digit specificity

Revision Number: 1
Start Date of Comment Period N/A
Start Date of Notice Period 10/30/1998
Revised Effective Date: 10/01/1998
Explanation of Revision: Updating policy to 5th digit specificity to be in compliance with carrier, 1999 ICD-9-CM Update

Revision Number: Original
Start Date of Comment Period None needed
Start Date of Notice Period N/A
Original Effective Date: 06/21/1996 AI
Revised Effective Date: 02/25/1997
Explanation of Revision: Original effective date is based on Artificial Intelligence (AI) application implementation date. Revised to ensure ICD-9-CM list consistency between the intermediary and carrier. ❖

93224: Electrocardiographic Monitoring for 24 Hours (Holter Monitoring)

Revision Overview: Policy has been revised to incorporate the 2002 Annual ICD-9-CM Update

Policy Number
93224

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Electrocardiographic Monitoring for 24 hours (Holter Monitoring)

AMA CPT Copyright Statement

CMS National Coverage Policy
Coverage Issues Manual, Section 50-15
Hospital Manual, Section 443
Intermediary Manual 3, Section 3627.10, 3631.1b

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

CMS Region
Region IV

CMS Consortium
Southern

Original Policy Effective Date
07/22/1999

Original Policy Ending Date
N/A

Revision Effective Date
10/01/2001

Revision Ending Date
09/30/2001

LMRP Description
Electrocardiographic monitoring can be performed on ambulatory patients over a set period of time (usually twenty four hours). The monitoring device (holter monitor) allows the patient to resume their normal lifestyle and activities while recording episodes of arrhythmia. This gives the physician documented episodes of arrhythmias or absence of arrhythmias to correlate with the patient's symptoms.

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will consider twenty-four hour electrocardiographic monitoring to be medically necessary in any of the following circumstances (see "ICD-9-CM Codes that Support Medical Necessity):

The patient complains of palpitations, and physical examination and standard EKG have not satisfactorily explained the patient's complaints.

The patient has experienced an unexplained syncopal episode or the patient has experienced a transient episode of cerebral ischemia which is felt to possibly be secondary to a cardiac rhythm disturbance.

The patient has been found to have a significant cardiac arrhythmia or conduction disorder (see list below) and holter monitoring is necessary as part of the evaluation and management of the patient:

Complete Heart Block
Second Degree AV Block
New Left Bundle Branch Block
New Right Bundle Branch Block
Bifasicular Block
Paroxysmal SVT
Paroxysmal VT
Atrial Fib/Flutter
Ventricular Fib/Flutter
Cardiac Arrest
SA Node Dysfunction
Frequent PAC's
Frequent PVC's
Wandering Atrial Pacemaker
Unspecified Cardiac Arrhythmia

The patient has a heart condition (see list below) associated with a high incidence of serious cardiac arrhythmia and/or myocardial ischemia, and holter monitoring is being done as part of the evaluation and management of the patient:

Dressler's Syndrome
History of Myocardial Infarction
Angina Pectoris
Prinzmetals's Angina
Aneurysm of Heart Wall
Chronic Ischemic Heart Disease
Pericarditis
Mitral Valve Disease
Cardiomyopathy
Anomalus AV Excitation
Cardiomegaly
Post Heart Surgery
Prolonged QT Interval

The patient has a cardiac arrhythmia or other cardiac condition and a cardiac medication which affects the electrical conduction system of the heart has been prescribed, and holter monitoring is necessary to evaluate the effect of the cardiac medication on the patient's cardiac rhythm and/or conduction system.

The patient has a pacemaker and clinical findings (history or physical examination) suggest possible pacemaker malfunction.

Claims submitted for holter studies performed at unusually frequent intervals will be reviewed by Medicare to make certain that the services were medically reasonable and necessary.

93224: Electrocardiographic Monitoring for 24 hours (Holter Monitoring) (continued)

CPT/HCPCS Section & Benefit Category

Medicine/Cardiovascular

Type of Bill

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

Revenue Code

730 EKG/ECG (Electrocardiogram), General Classification
731 Holter Monitor

CPT/HCPCS Codes

93224-93237 ECG monitoring for 24 hours

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

410.00-410.02	Acute myocardial infarction of anterolateral wall
410.10-410.12	Acute myocardial infarction of other anterior wall
410.20-410.22	Acute myocardial infarction of inferolateral wall
410.30-410.32	Acute myocardial infarction of inferoposterior wall
410.40-410.42	Acute myocardial infarction of inferior wall
410.50-410.52	Acute myocardial infarction of other lateral wall infarction
410.60-410.62	Acute myocardial infarction of true posterior wall infarction
410.70-410.72	Acute myocardial infarction of subendocardial infarction
410.80-410.82	Acute myocardial infarction of other specified sites
410.90-410.92	Acute myocardial infarction of unspecified site
411.0	Postmyocardial infarction syndrome
411.1	Intermediate coronary syndrome
411.81	Acute 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 vessel
414.01	Coronary atherosclerosis of native coronary
414.02	Coronary atherosclerosis of autologous vein bypass graft
414.03	Coronary atherosclerosis of nonautologous biological bypass graft
414.10	Aneurysm of heart (wall)
414.11	Aneurysm of coronary vessels
414.19	Other aneurysm of heart
414.8	Other specified forms of chronic ischemic heart disease
414.9	Chronic ischemic heart disease, unspecified
423.1	Adhesive pericarditis
423.2	Constrictive pericarditis
424.0	Mitral valve disorders
425.0-425.9	Cardiomyopathy
426.0	Artrioventricular block, complete
426.12	Mobitz (type) II atriioventricular block
426.13	Other second degree atrioventricular block
426.2	Left bundle branch hemiblock
426.4	Right bundle branch block
426.53	Other bilateral bundle branch block
426.7	Anomalous atrioventricular excitation
426.9	Conduction disorder, unspecified
427.0	Paroxysmal supraventricular tachycardia
427.1	Paroxysmol ventricular tachycardia
427.31	Atrial fibrillation
427.32	Atrial flutter
427.41	Ventricular fibrillation
427.42	Ventricular flutter
427.5	Cardiac arrest
427.61	Supraventricular premature beats
427.69	Other premature beats
427.81	Sinoatrial node dysfunction
427.89	Other specified cardiac dysrhythmias
427.9	Cardiac dysrhythmia, unspecified
429.3	Cardiomegaly
429.4	Functional disturbances following cardiac surgery
429.9	Heart disease, unspecified
780.2	Syncope and collapse
785.1	Palpitations
E942.0	Cardiac rhythm regulators
E942.1	Cardiotonic glycosides and drugs of similar action
V45.00	Unspecified cardiac device
V45.01	Cardiac pacemaker
V45.02	Automatic implantable cardiac defibrillator
V45.09	Other specified cardiac device
V67.51	Followup examination following treatment with high-risk medication, not elsewhere classified

Diagnoses that Support Medical Necessity

N/A

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

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Reasons for Denials

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

Noncovered Diagnosis

N/A

93224: Electrocardiographic Monitoring for 24 hours (Holter Monitoring) (continued)

Coding Guidelines

The following HCPCS codes are not reportable by hospitals: 93224, 93227, 93230, 93233, 93235, and 93237.

Revenue code 730 should only be reported by CORFs for holter monitoring. All other TOBs should use revenue code 731 to report these services.

Documentation Requirements

Medical record documentation maintained by the ordering/referring physician must clearly indicate the medical necessity of holter monitor studies covered by the Medicare program. Also, the results of holter studies covered by the Medicare program must be included in the patient's medical record.

If the provider of holter 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 study. When ordering holter studies from an independent physiological lab or other provider, the ordering/referring physician must state the reason for the holter study in his order for the test.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

N/A

Advisory Committee Notes

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

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

11/01/2001

Revision History

Revision Number:	1
Start Date of Comment Period	N/A
Start Date of Notice Period	11/01/2001 1st Qtr 2002 *Bulletin*
Revised Effective Date:	10/01/2001
Explanation of Revision:	Annual ICD-9-CM Update

Revision Number:	Original
Start Date of Comment Period	02/08/1999
Start Date of Notice Period	
Original Effective Date:	07/22/1999 ❖

93350: Stress Echocardiography

Revision Overview: Policy has been revised to incorporate the 2002 Annual ICD-9-CM Update.

Policy Number
93350

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Stress Echocardiography

AMA CPT Copyright Statement

CMS National Coverage Policy
Coverage Issues Manual, Section 50-7
Hospital Manual, Section 443
Intermediary Manual, Sections 3627, 3631

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

CMS Region
Region IV

CMS Consortium
Southern

Original Policy Effective Date
05/27/1999

Original Policy Ending Date
N/A

Revision Effective Date
10/01/2001

Revision Ending Date
09/30/2001

LMRP Description
Echocardiography is used to image cardiac structures and function as well as 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.

Florida Medicare has not previously published a specific policy concerning stress echocardiography. The purpose of this policy is to define the circumstances for which this service will be considered medically necessary by Florida Medicare

Indications and Limitations of Coverage and/or Medical Necessity
Stress echocardiography will be considered medically reasonable and necessary and therefore covered by Florida Medicare if any one of the following circumstances is present (see Covered ICD-9-CM Codes):

- The patient has symptoms which require further investigation via stress testing and the patient has a significantly abnormal baseline EKG which would make interpretation of a standard exercise test (without imaging) inaccurate.
- The patient has abnormal or non-diagnostic standard exercise test and stress echocardiography is being performed to evaluate stress induced cardiac abnormality.
- The patient has symptoms which require further investigation by stress testing and the patient is on a medication (such as digoxin) which would interfere with the interpretation of a standard exercise test.
- The patient has a cardiac condition, such as mitral valve prolapse or other anatomic abnormality of the heart, which would interfere with the interpretation of a standard exercise stress test.
- The patient has confirmed coronary artery disease or congestive heart failure and stress echocardiography is necessary to evaluate the extent or significance of disease.

CPT/HCPCS Section & Benefit Category
Medicine/Cardiovascular

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

Revenue Code
480 Cardiology, General Classification

CPT/HCPCS Codes

93350	Echocardiography, transthoracic, real-time with image documentation (2D), with or without M-mode recording, during rest and cardiovascular stress test using treadmill, bicycle exercise and/or pharmacologically induced stress, with interpretation and report

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity

411.1	Intermediate coronary syndrome
411.81	Acute coronary occlusion without myocardial infarction
411.89	Other acute and subacute forms of ischemic heart disease
412	Old myocardial infarction
413.0	Angina decubitus
413.1	Prinzmetal angina
413.9	Other and unspecified angina pectoris
414.00-414.03	Coronary atherosclerosis
414.10	Aneurysm of heart (wall)
414.11	Aneurysm of coronary vessels
414.19	Other aneurysm of heart
414.8	Other specified forms of chronic ischemic heart disease
414.9	Chronic ischemic heart disease, unspecified

93350: Stress Echocardiography (continued)

424.0	Mitral valve disorders
426.2	Left bundle branch hemiblock
426.3	Other left bundle branch block
426.4	Right bundle branch block
426.50	Bundle branch block, unspecified
426.51	Right bundle branch block and left posterior fascicular block
426.52	Right bundle branch block and left anterior fascicular block
426.53	Other bilateral bundle branch block
426.54	Trifascicular block
426.6	Other heart block
426.7	Anomalous atrioventricular excitation
427.31	Atrial fibrillation
428.0	Congestive heart failure
428.1	Left heart failure
428.9	Heart failure, unspecified
440.21-440.24	Atherosclerosis of the extremities with intermittent claudication, rest pain, ulceration or gangrene
794.31	Abnormal electrocardiogram [ECG] [EKG]
960.7	Poisoning by antineoplastic antibiotics
995.2	Unspecified adverse effect of drug, medicinal and biological substance
E942.0	Agents primarily affecting the cardiovascular system, cardiac rhythm regulators
E942.1	Agents primarily affecting the cardiovascular system, cardiotonic glycosides and drugs of similar action
V67.00	Follow-up examination following surgery, unspecified
V67.09	Follow-up examination following other surgery
V67.51	Follow-up examination following treatment with high-risk medication, not elsewhere classified
V67.59	Follow-up examination following other treatment

Diagnoses that Support Medical Necessity

N/A

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

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Reasons for Denials

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 Codes

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

Noncovered Diagnosis

N/A

Coding Guidelines

N/A

Documentation Requirements

Medical record documentation maintained by the ordering/referring physician must clearly indicate the medical necessity of echocardiography studies covered by the Medicare program. Also, the results of echocardiography studies covered by the Medicare program must be included in the patient's medical record. This information is normally found in the office/progress notes, hospital notes, and/or test results.

If the provider of echocardiography 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.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

N/A

Advisory Committee Notes

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

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

11/01/2001

Revision History

Revision Number:	2
Start Date of Comment Period	N/A
Start Date of Notice Period	11/01/2001 1st Qtr 2002 *Bulletin*
Revised Effective Date:	10/01/2001
Explanation of Revision:	Annual ICD-9-CM Update

Revision Number:	1
Start Date of Comment Period	N/A
Start Date of Notice Period	10/01/2000 Oct/Nov 2000 *Bulletin*
Revised Effective Date:	10/01/2000
Explanation of Revision:	Annual ICD-9-CM Update

Revision Number:	Original
Start Date of Comment Period	12/07/98
Start Date of Notice Period	03/18/99
Original Effective Date:	05/27/99 ❖

94010: Spirometry

Revision Overview: The diagnosis range 516.0-516.9 has been added to the "ICD-9-CM Codes that Support Medical Necessity" section. The "Utilization Guidelines" section of the policy has been revised.

Policy Number
94010

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Spirometry

AMA CPT Copyright Statement

CMS National Coverage Policy
Hospital Manual, Section 443

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

CMS Region
Region IV

CMS Consortium
Southern

Original Policy Effective Date
01/21/1999

Original Policy Ending Date
N/A

Revision Effective Date
10/01/2001

Revision Ending Date
09/30/2001

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% is 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
PFTs 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.
- Initial diagnostic workup for a patient with chronic cough. It is not expected that a patient would have a

94010: Spirometry (continued)

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.
- 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 sensitivity 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: pre-operative 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.

CPT/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 Codes

460 Pulmonary Function, General Classification
469 Other Pulmonary Function

CPT/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
446.20	Hypersensitivity angiitis, unspecified
466.0-466.19	Acute bronchitis and bronchiolitis

94010: Spirometry (continued)

486	Pneumonia, organism unspecified
490	Bronchitis, not specified as acute or chronic
491.0-491.9	Chronic bronchitis
492.0-492.8	Emphysema
493.00-493.92	Asthma
494.0-494.1	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
516.0-516.9	Other alveolar and parietoalveolar pneumonopathy
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

Diagnoses that Support Medical Necessity

N/A

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

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Reasons for Denials

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 Codes

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.

CPT code 94150, in accordance with OP PPS implementation, is packaged. Separate reimbursement will not be made.

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

It is expected that these services are performed as indicated by current medical literature and/or standards of practice. Services performed in excess of established utilization parameters may be reviewed for medical necessity.

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

94010: Spirometry (continued)

serve as an index of dynamic function. These flow rates are determined by a spirometer.

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 and Basis for Decision

1998 Physician Desk Reference

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Advisory Committee Notes

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

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

11/01/2001

Revision History

Revision Number	6
Start Date of Comment Period	N/A
Start Date of Notice Period	11/01/2001 1st Qtr 2002 *Bulletin*
Revised Effective Date	10/01/2001

Explanation of Revision: Addition of diagnosis range 516.0-516.9

Revision Number	5
Start Date of Comment Period	N/A
Start Date of Notice Period	05/01/2001 3rd Qtr 2001 *Bulletin*
Revised Effective Date	08/08/2000

Explanation of Revision: Revision was made to correct Revenue Code 461 to 469.

Revision Number	4
Start Date of Comment Period:	N/A
Start Date of Notice Period:	10/01/2000 Oct/Nov 2000 *Bulletin*
Original Effective Date	10/01/2000

Explanation of Revision: Annual ICD-9-CM Update

Revision Number	3
Start Date of Comment Period	N/A
Start Date of Notice Period	08/01/2000 Aug/Sept 2000 *Bulletin*
Revised Effective Date	08/01/2000

Explanation of Revision: Outpatient PPS implementation

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	05/11/2000

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

Explanation of Revision: 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 ❖

94240: Functional Residual Capacity or Residual Volume

Revision Overview: The diagnosis range 516.0-516.9 has been added to the "ICD-9-CM Codes that Support Medical Necessity" section. The "Utilization Guidelines" section of the policy has been revised.

Policy Number
94240

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Functional Residual Capacity or Residual Volume

AMA CPT Copyright Statement

CMS National Coverage Policy
N/A

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

CMS Region
Region IV

CMS Consortium
Southern

Original Policy Effective Date
01/21/1999

Original Policy Ending Date
N/A

Revision Effective Date
10/01/2001

Revision Ending Date
09/30/2001

LMRP Description
The functional residual capacity (FRC) and residual volume (RV) are pulmonary tests that cannot be measured directly using spirometry because these volumes and capacities include air that cannot be expelled from the lungs. 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.

Indications and Limitations of Coverage and/or Medical Necessity
Pulmonary function tests (PFTs) are performed to detect abnormalities in respiratory function and to determine the extent of any pulmonary abnormalities. The PFT will be considered medically necessary by Florida Medicare for the following conditions:

- Preoperative evaluation of the lungs and pulmonary reserve when:
  - thoracic surgery will result in loss of functional pulmonary tissue (e.g., 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 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 (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.
- Re-evaluation of a patient with or without underlying lung disease that presents with increasing SOB (from previous evaluation) and related qualifying factors such as abnormal breath sounds or decreasing endurance to perform activities of daily living.
- Initial diagnostic workup for a patient with chronic cough. It is not expected that a patient would have a repeat spirometry without new symptomology.
- 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, pleuriter chest pain) may suggest the possibility of pulmonary toxicity.

The FRC is most frequently measured by one of the four different methods:

94240: Functional Residual Capacity or Residual Volume (continued)

- Closed circuit helium equilibration,
- Open circuit nitrogen washout,
- Whole body plethysmograph, or
- Radiologic techniques.

The residual volume can be determined by subtracting the expiratory reserve volume (obtained during simple spirometry) from the FRC.

CPT/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 Codes

46x Pulmonary Function

CPT/HCPCS Codes

94240	Functional residual capacity or residual volume: helium method, nitrogen open circuit method, or other method

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
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
493.00-493.92	Asthma
494.0-494.1	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
516.0-516.9	Other alveolar and parietoalveolar pneumonopathy
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

Diagnoses that Support Medical Necessity

N/A

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

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Reasons for Denials

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 Codes

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 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.

94240: Functional Residual Capacity or Residual Volume (continued)

Utilization Guidelines

It is expected that these services are performed as indicated by current medical literature and/or standards of practice. Services performed in excess of established utilization parameters may be reviewed for medical necessity.

Other Comments

N/A

Sources of Information and Basis for Decision

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 advisory groups, which includes representatives from the Pulmonary Society.

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

11/01/2001

Revision History

Revision Number	4
Start Date of Comment Period	N/A
Start Date of Notice Period	11/01/2001 1st Qtr 2002 *Bulletin*
Revised Effective Date	10/01/2001
Explanation of Revision:	Addition of diagnosis range 516.0-516.9

Revision Number	3
Start Date of Comment Period	N/A
Start Date of Notice Period	10/01/2000
Revised Effective Date	10/01/2000
Explanation of Revision:	Annual ICD-9-CM Update

Revision Number	2
Start Date of Comment Period	N/A
Start Date of Notice Period	02/25/2000 Special Issue 2000 *Bulletin*
Revised Effective Date	08/01/2000
Explanation of Revision:	Outpatient PPS Implementation

Revision Number	1
Start Date of Comment Period	
Start Date of Notice Period	
Revised Effective Date	01/01/1999
Explanation of Revision:	1999 HCPCS

Revision Number	Original	
Start Date of Comment Period:	07/17/1998	
Start Date of Notice Period:	12/07/1998	G-354
Original Effective Date	01/21/1999 ❖	

95115: Allergen Immunotherapy

Revision Overview: Diagnosis code 995.0 has been added to the "ICD-9-CM Codes that Support Medical Necessity" section for procedure codes 95115 and 95117. The "Indications and Limitations of Coverage and/or Medical Necessity" section of the policy has been revised.

Policy Number
95115

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Allergen Immunotherapy

AMA CPT Copyright Statement

CMS National Coverage Policy
Medicare Hospital Manual, Section 442

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

CMS Region
Region IV

CMS Consortium
Southern

Original Policy Effective Date
11/15/2000

Original Policy Ending Date
N/A

Revision Effective Date
10/01/2001

Revision Ending Date
10/30/2001

LMRP Description
Allergen immunotherapy (desensitization), also referred to as specific immunotherapy, is the subcutaneous introduction of increasing doses of allergens to which the patient is sensitive. Allergen immunotherapy is antigen-specific; thus the sensitivity of the patient must be known before formulating extracts for therapy. The antigenic cross-reactivity of extracts should be known by the physician to optimize use of the minimum number of separate extracts given per single injection. In this way, the maximum amount of protein antigen can be given.

This therapy is generally reserved for patients with significant relapsing, subacute to chronic symptoms, where the symptoms are likely caused by allergic pathology, and in situations where other means of conservative therapy (including avoidance) have failed to control the symptoms adequately, or avoidance of the relevant allergen (e.g., dust mites, pollen, mold) is impractical.

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will provide coverage for allergen immunotherapy for patients with allergic rhinitis, allergic conjunctivitis, asthma, or a previous anaphylactic reaction to a stinging/biting insect or other arthropod when **all four** of the following criteria are met:

(1) the patient must have significant exposure to an allergen;
(2) the patient must have demonstrated a significant level of sensitivity to the allergen;
(3) the pattern of symptoms must conform to the pattern of exposure; and
(4) other means of conservative therapy (including avoidance) have failed to control the symptoms, or avoidance of the relevant antigen (e.g., dust mites, pollen, mold) is impractical.

Generally, the course of allergen immunotherapy, if successful, should be continued until the patient has been symptom-free or has had substantially reduced symptoms for 1 to 2 years and in most cases from 3 to 5 years. If no response has occurred after 1 year at maintenance dose, the patient's sensitivities should be reviewed. All patients on immunotherapy should be encouraged to maintain environmental control and may have to use concomitant medication, such as antihistamines.

CPT/HCPCS Section & Benefit Category
Medicine/Allergy and Clinical Immunology

Type of Bill Code
Hospital – 13x

Revenue Code
924 Allergy Test

CPT/HCPCS Codes

95115	Professional services for allergen immunotherapy not including provision of allergenic extracts; single injection
95117	two or more injections
95165	Professional services for the supervision and provision of antigens for allergen immunotherapy; single or multiple antigens (specify number of doses)

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity

372.05	Acute atopic conjunctivitis
372.14	Other chronic allergic conjunctivitis
477.0	Allergic rhinitis due to pollen
477.8	Allergic rhinitis due to other allergen
493.00-493.02	Extrinsic asthma (allergic asthma)

95115: Allergen Immunotherapy (continued)

493.90-493.92	Asthma, unspecified (allergic bronchial asthma)
989.5	Toxic effect of other substances, venom (not applicable to procedure code 95165)
995.0	Other anaphylactic shock (not applicable to procedure code 95165)

Diagnoses that Support Medical Necessity

N/A

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

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Reasons for Denials

Allergen immunotherapy 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 Codes

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

You may choose to use HCPCS code 95115 to report all allergy therapies provided during a visit, without regard to the type or number of antigens, or you may report each of the HCPCS codes in this policy separately.

A dose of code 95165 is defined as one cc aliquot from a single multidose vial.

Documentation Requirements

Medical record documentation maintained by the treating physician must clearly document the medical necessity to initiate allergen immunotherapy and the continued need thereof. The documentation should include:

- A history and physical that documents the following: a complete allergic history and physical examination; correlation of symptoms; occurrence of symptoms; exposure profile; documentation of allergic sensitization by accepted means and where attempts at avoidance have proven unsuccessful (or the impracticality of avoidance exists); and a copy of the sensitivity results.
- Progress notes that document physician management during the course of the allergic disease, anticipated length of treatment, and explanation of any deviations from normal treatment frequency.

Utilization Guidelines

N/A

Other Comments

Terms Defined:

Allergen – any substance that indicates a state of, or brings on manifestations of, allergy.

Allergy – an altered reaction of body tissues to a specific substance (allergen) which in nonsensitive persons will, in similar amounts, produce no effect.

Asthma – a reversible obstructive lung disorder characterized by increased responsiveness of the airways.

Immunotherapy – the production or enhancement of immunity.

Rhinitis – inflammation of the nasal mucosa.

Sources of Information and Basis for Decision

American Medical Association. (1996). Allergy immunotherapy update. *cpt Assistant*, (6)5, 1-2 and 11.

American Medical Association. (2000). Allergy immunotherapy – Provision of antigens. *cpt Assistant*, 10(4), 4.

Middleton, Jr., E., Reed, C., Ellis, E.F., Adkinson, Jr., N.F., Yunginger, J.W., & Busse, W.W. (Eds.). (1998). *Allergy principles and practice*. (Vol II). St. Louis: Mosby.

Theodoropoulos, D.S. & Lockey, R.F. (2000). Allergen immunotherapy: Guidelines, update, and recommendations of the World Health Organization. *Allergy Asthma Proc. 2000*, 21(3), 159-166.

Advisory Committee Notes

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

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

11/01/2001

Revision History

Revision Number:	2
Start Date of Comment Period	N/A
Start Date of Notice Period	11/01/2001 1st Qtr 2002 *Bulletin*
Revised Effective Date:	10/01/2001

Explanation of Revision: The addition of ICD-9-CM code 995.0 (other anaphylactic shock) to the policy.

Revision Number:	1
Start Date of Comment Period	N/A
Start Date of Notice Period	02/01/2001 2nd Qtr 2001 *Bulletin*
Revised Effective Date:	01/01/2001

Explanation of Revision: Annual 2001 HCPCS Update

Revision Number:	Original
Start Date of Comment Period	06/01/2000
Start Date of Notice Period	10/01/2000 Oct/Nov 2000 *Bulletin*
Original Effective Date:	11/15/2000 ❖

J0150: Adenosine (Adenocard®, Adenoscan®)

Policy Number
J0150

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Adenosine (Adenocard®, Adenoscan®)

AMA CPT Copyright Statement

CMS National Coverage Policy
Hospital Manual, Section 443
Intermediary Manual, Section 3631

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

CMS Region
Region IV

CMS Consortium
Southern

Original Policy Effective Date
01/01/2002

Original Policy Ending Date
N/A

Revision Effective Date
N/A

Revision Ending Date
N/A

LMRP Description
Adenosine is a naturally occurring nucleoside that is not chemically related to other antiarrhythmic agents. Adenosine slows conduction time through the AV node, can interrupt the re-entry pathways through the AV node and can restore normal sinus rhythm in patients with paroxysmal supraventricular tachycardia (PSVT), including PSVT associated with Wolff-Parkinson-White (W-P-W) syndrome. Adenosine is also used as a diagnostic aid in noninvasive testing in conjunction with myocardial perfusion scans for patients with suspected or known coronary artery disease.

Indications and Limitations of Coverage and/or Medical Necessity
Florida Medicare will consider Adenosine medically reasonable and necessary when performed for the following indications:

- As an adjunct to noninvasive testing in conjunction with myocardial perfusion scans to produce pharmacologic stress in those patients who are unable to exercise adequately (i.e., the inability to obtain 75-100% of their age-predicted heart rate through exercise). Examples of patients that may be unable to exercise include, but are not limited to the following: patients with musculoskeletal abnormalities, severe peripheral vascular disease, patients receiving medications such as beta blockers and calcium channel blockers that decrease heart rate, etc. The infusion rate for Adenosine is based on the patients weight and is typically administered at 140 mcg/kg/min over 6 minutes (total dose of 0.84 mg/kg).
- To convert a patient with PSVT, including PSVT associated with W-P-W syndrome to normal sinus rhythm. Normally, an initial dose of 6 mg as a rapid intravenous bolus (over a 1 to 2 second period) is administered. If the first dose does not eliminate the supraventricular tachycardia within 1 to 20 minutes, then a 12 mg rapid IV bolus is administered and can be followed by a second dose. Doses > 12 mg are not recommended.
- To briefly cause AV block to identify atrial fibrillation or atrial flutter waves when the patient presents with rapid atrial tachycardia. Normally, an initial dose of 6 mg rapid IV bolus is given with the dose doubled within 2 minutes if no response.
- As a trial dose in stable patients with wide-complex tachycardia based on advanced cardiac life support (ACLS) protocol. Normally the trial dose includes a bolus of 6 mg, followed either with another 6 mg dose or 12 mg dose.
- As a diagnostic and/or therapeutic agent for patients undergoing electrophysiology studies. The administration of Adenosine is given as a bolus.
- Measurement of fractional flow reserve (FFR) during cardiac catheterization to assess ischemic potential of a moderately stenosed (50-80%) coronary artery. A FFR index of 0.75 or less is considered a functionally ischemic lesion. The administration of adenosine is either given intravenously and/or intracoronary. It is expected that the FFR obtained is used in the clinical decision making of future treatments (e.g., revascularization).

Adenosine is contraindicated in patients with second- or third-degree AV block or sick sinus syndrome (except in patients with a functional artificial pacemaker); atrial flutter (except as indicated above), atrial fibrillation (except as indicated above), ventricular tachycardia (except as indicated above), suspected bronchoconstrictive or bronchospastic lung disease (e.g., asthma), and hypersensitivity to adenosine.

Note: The myocardial perfusion imaging test must meet the medical necessity requirements as identified in the local medical review policy “Myocardial Perfusion Imaging” (78460). Please refer to this policy for the coverage indications.

J0150: Adenosine (Adenocard®, Adenoscan®) (continued)

CPT/HCPCS Section & Benefit Category
Drugs Requiring Other Than Oral Method

Type of Bill Code
Hospital – 12x, 13x, 14x

Revenue Codes
636 Drugs Requiring Detailed Coding

CPT/HCPCS Codes
J0150	Injection, adenosine, 6 mg (not to be used to report any adenosine phosphate compounds; instead use A9270)

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity
411.0	Postmyocardial infarction syndrome
411.1	Intermediate coronary syndrome
411.81	Acute 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
414.8	Other specified forms of chronic ischemic heart disease
414.9	Chronic ischemic heart disease, unspecified
424.0	Mitral valve disorders
426.2	Left bundle branch hemiblock
426.3	Other left bundle branch block
426.4	Right bundle branch block
426.50-426.54	Bundle branch block, other and unspecified
426.6	Other heart block
426.7	Anomalous atrioventricular excitation
427.0	Paroxysmal supraventricular tachycardia
427.2	Paroxysmal tachycardia, unspecified
427.31	Atrial fibrillation
428.0-428.9	Heart failure
440.21-440.24	Atherosclerosis of native arteries of the extremities
785.0	Tachycardia, unspecified
794.31	Abnormal electrocardiogram [ECG] [EKG]
960.7	Poisoning by antineoplastic antibiotics
995.2	Unspecified adverse effect of drug, medicinal and biological substance
E942.0	Agents primarily affecting the cardiovascular system, cardiac rhythm regulators
E942.1	Agents primarily affecting the cardiovascular system, cardiotonic glycosides and drugs of similar action
V67.00	Follow-up examination following surgery, unspecified
V67.09	Follow-up examination following other surgery
V67.51	Follow-up examination following completed treatment with high-risk medication, not elsewhere classified
V67.59	Follow-up examination following other treatment

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
Based on the outpatient prospective payment system, HCPCS code J0151 is not valid. Therefore, type of bills 12x, 13x, and 14x must bill J0150 with the number of units adjusted to reflect the dosage administered. J0150 is paid via an APC rate.

Documentation Requirements
Medical record documentation must support the medical necessity for the use of Adenosine. If the Adenosine is used as a pharmacologic stress agent, then the documentation must support the medical condition that prohibits the patient from exercising adequately. For all indications, the documentation must indicate the strength and amount of Adenosine administered to the patient. This information is usually found in the office/progress notes, history and physical, and/or procedure report.

Utilization Guidelines
N/A

Other Comments
Terms defined

Fractional flow reserve – maximum blood flow to the myocardium in the presence of a stenosis in the supplying coronary artery divided by the theoretical normal maximum flow in the same distribution. The index represents the fraction of the normal maximal myocardial flow that can be achieved despite the coronary stenosis.

Sources of Information and Basis for Decision
Atkins, D., Dorian, P., Gonzalez, E., Gorgels, A., Kudenchuk, P., Lurie, K., Morley, P., Robertson, C., Samson, R., Silka, M., & Singh, B. (2001). Treatment of

J0150: Adenosine (Adenocard®, Adenoscan®) (continued)

tachyarrhythmias. [On-line]. Available: http://home.mdconsult.com. Supported use of adenosine for PSVT and atrial tachycardia.

Facts and Comparisons. (2000, January). Adenosine. *Drugs Facts and Comparisons*, 436-437, 1987-1988. Supported labeled indications for Adenosine.

Fearon, W., Takagi, A., Jeremias, A., Yeung, A., Joye, J., Cohen, D., Chou, T., Kern, M., & Yock, P. (2000). Use of fractional myocardial flow reserve to assess the functional significance of intermediate coronary stenoses. *The American Journal of Cardiology*, 86, 1013-1014. Supported predictive accuracy and specificity of FFR.

Fulton, S., & Jackimczyk, K. (2000). Pharmacologic advances in emergency medicine. [On-line]. Available: http://home.mdconsult.com. Supported adenosine for SVT and to differentiate between SVT and atrial tachycardiac (afib/flutter).

Herbert, M., & Votey, S. (1997). Adenosine in wide-complex tachycardia. [On-line]. Available: http://home.mdconsult.com. Supported use of adenosine for wide-complex tachycardiac as part of ACLS protocol.

Jeremias, A., Whitbourn, A., Filardo, S., Fitzgerald, P., Cohen, D., Tuzcu, E., Anderson, W., Abizaid, A., Mintz, G., Yeung, A., Kern, M., & Yock, P. (2000). Adequacy of intracoronary versus intravenous adenosine-induced maximal coronary hyperemia for fractional flow reserve measurements. [On-line]. Available: http://home.mdconsult.com. Discussed the use of both IV and IC adenosine.

Pijls, N., Bruyne, B., Peels, K., Van Der Voort, P., Bonnier, H., Bartunek, J., & Koolen, J. (1996). Measurement of fractional flow reserve to assess the functional severity of coronary-artery stenosis. *New England Journal of Medicine*, 334(26), 1703-1708. Supported indication for FFR during cardiac cath.

Advisory Committee Notes

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

Start Date of Comment Period

02/28/2001

End Date of Comment Period

04/14/2001

Start Date of Notice Period

11/01/2001

Revision History

Revision Number	Original
Start Date of Comment Period:	02/28/2001
Start Date of Notice Period:	11/01/2001
	1st Qtr 2002 *Bulletin*
Original Effective Date	01/01/2002 ❖

J7190: Hemophilia Clotting Factors

Revision Overview: Diagnoses 286.5 and 286.7 have been added to the "ICD-9-CM Codes that Support Medical Necessity" section.

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

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

Primary Geographic Jurisdiction
Florida

Secondary Geographic Jurisdiction
N/A

CMS Region
Region IV

CMS Consortium
Southern

Original Policy Effective Date
07/17/2000

Original Policy Ending Date
N/A

Revision Effective Date
10/01/2001

Revision Ending Date
09/30/2001

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 80% 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 5% to 40% of normal coagulation factor activity) experience complications only after having undergone surgery or experiencing a major physicial trauma. Those with moderate hemophilia (from 1% to 5% of coagulation factor activity) experience some spontaneous hemorrhage but normally exhibit bleeding provoked by trauma. Those with severe hemophilia (less than 1% 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-inhibitors to 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.

CPT/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

CPT/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
Q2022	von Willebrand factor complex, human, per IU

J7190: Hemophilia Clotting Factors (continued)

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM-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
286.5	Hemorrhagic disorder due to circulating anticoagulants
286.7	Acquired coagulation factor deficiency

Diagnoses that Support Medical Necessity

N/A

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

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Reasons for Denials

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 Codes

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 are administered to hemophilia inpatients. The add-on payment is calculated based on the pharmaceutical average wholesale price.

One hundred international units 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 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).

J7199 is non-covered for dates of service on or after August 1, 2000 in accordance with OP PPS implementation.

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 1%, moderate if levels are 1-5%, and mild if levels are greater than 5%. Approximately one in 10,000 males are affected. The most common sites of bleeding are into joints (knees, ankles, 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, 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 and Basis for Decision

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

Advisory Committee Notes

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

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

11/01/2001

Revision History

Revision Number:	3
Start Date of Comment Period	N/A
Start Date of Notice Period	11/01/2001
	1st Qtr 2002 *Bulletin*
Revised Effective Date:	10/012001

Explanation of Revision: Based on change request 1695 (transmittal A-01-89, dated 08/01/01), diagnoses 286.5 and 286.7 were added to the policy. ❖

J9999: Antineoplastic Drugs

Revision Overview: Coverage for Rituximab – J9310 and Vinorelbine – J9390 have been added to the policy. HCPCS code for denileukin diffitox, (Ontak®) has been changed from J9999 to J9160/C1084, effective January 1, 2002. Effective October 23, 2001, additional ICD-9CM diagnosis codes are added to various antineoplastic drugs.

Number
J9999

Contractor Name
First Coast Service Options, Inc.

Contractor Number
090

Contractor Type
Intermediary

LMRP Title
Antineoplastic Drugs

AMA CPT Copyright Statement

CMS 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

CMS Region
Region IV

CMS Consortium
Southern

Original Policy Effective Date
11/02/1997

Original Policy Ending Date
N/A

Revision Effective Date
01/01/2002

Revision Ending Date
12/31/2001

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. The Food and Drug Administrtion (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 CMS, 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.
- 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).

J9999: Antineoplastic Drugs (continued)

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; or
- Leukemia.

The carrier 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, osteosarcoma and AIDS related Kaposi's sarcoma.

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 hepatocellular carcinoma
- Hepatoblastoma
- Thymoma
- Gestational trophoblastic tumors
- Retinoblastoma
- Esophageal carcinoma
- Adrenocortical carcinoma
- Vaginal carcinoma
- Testicular carcinoma

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.

Florida Medicare will cover Liposomal Doxorubicin for its FDA approved uses, as well as for the treatment of the off-labeled indication, breast carcinoma.

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:

- 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

J9999: Antineoplastic Drugs (continued)

- Wilms' tumor
- Esophageal carcinoma
- Cervical carcinoma
- Cancer of unknown primary site (CUPs)
- Fallopian and peritoneal carcinomas of ovarian origin when used in combination with Paclitaxel

Denileukin diftitox (Ontak®) – J9160/C1084

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.

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 breast cancer, 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
- Head and neck carcinoma
- Bladder carcinoma
- Ovarian carcinoma
- Gastric carcinoma
- Melanoma
- Prostatic carcinoma
- Breast carcinoma, first-line therapy for locally advanced or metastatic
- Non-small cell lung (NSCLC) carcinoma, first-line
- Esophageal carcinoma
- Gastric carcinomas, alone or in combination for the treatment of advanced and/or metastatic esophageal, gastric, and/or gastroesophageal (GE) junction carcinomas which includes adenocarcinomas and squamous cell carcinomas

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
- Hepatoblastoma
- Neuroblastoma
- Non-small cell lung carcinoma
- Thymoma
- Osteosarcoma
- Ewing's sarcoma
- Soft tissue sarcomas
- Cutaneous T cell lymphomas
- Breast carcinoma
- Kaposi's sarcoma
- Endometrial carcinoma
- Ovarian carcinoma
- Bladder carcinoma
- Wilms' Tumor
- Retinoblastoma
- Adrenocortical carcinoma
- Acute lymphocytic leukemia
- Acute nonlymphocytic leukemia
- Chronic myelocytic leukemia
- Hodgkin's lymphoma
- Non-Hodgkin's lymphoma
- Multiple myeloma
- Primary brain tumor
- Gestational trophoblastic tumor
- Cancer of unknown primary site

Fludarabine (Fludara®) – J9185

Fludarabine phosphate is a nucleotide analog that 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
- Transitional cell carcinoma of kidney and ureter
- Relasped Hodgkin's and non-Hodgkin's lymphoma

Irinotecan (Camptosar®) – J9206

Irinotecan, also known as CPT-11, is an analog of camptothecin, a plant alkaloid. It inhibits the enzyme, topoisomerase I, which is necessary for DNA replication.

Irinotecan is FDA approved for the treatment of colorectal carcinoma.

Florida Medicare will cover Irinotecan for its FDA approved use, as well as for the treatment of the following

J9999: Antineoplastic Drugs (continued)

off-labeled indications:
- Small-cell lung carcinoma
- Cervical 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
- Malignant pleural effusion
- Cancer of unknown primary site
- Fallopian and peritoneal carcinomas of ovarian origin when used in combination with Carboplatin or Cisplatin
- Testicular germ cell 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.

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

Rituximab (Rituxan ®) – J9310

Rituximab is FDA approved for the treatment of relapsed or refractory low grade or follicular CD20-positive, B-cell non-Hodgkin's lymphoma.

Florida Medicare will consider the use of Rituximab as medically reasonable and necessary for the FDA approved uses as well as for the first-line treatment of the following off-labeled indications:
- low grade B-cell non-Hodgkin's lymphomas (NHL)
- intermediate and high grade NHL when used in combination with a CHOP (Cyclophosphamide, Doxorubicin, Vincristine, and Prednisone) chemotherapy regimen.

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 and small cell carcinoma of the lung.

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 carcinoma of the lung
- Myelodysplastic syndrome
- Chronic myelomonocytic leukemia

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.

Vinorelbine tartrate (Navelbine®) – J9390

Vinorelbine is FDA approved for use as a single agent or in combination with Cisplatin for the treatment of patients with advanced (stage III or IV) non-small cell lung carcinoma.

Florida Medicare will consider Vinorelbine medically reasonable and necessary when provided for its FDA approved uses, as well as for the treatment of the following off-labeled indications:
- Cervical carcinoma
- Epithelial ovarian carcinoma
- Metastatic breast carcinoma that did not respond to standard first-line chemotherapy. It is also indicated for patients with metastatic breast cancer who have relapsed within 6 months of anthracycline-based adjuvant therapy.

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,

J9999: Antineoplastic Drugs (continued)

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 for whom surgery and radiotherapy are not indicated.

CPT/HCPCS Section & Benefit Category

Chemotherapy Drugs

Type of Bill Code

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

Revenue Codes

636 Drugs Requiring Detailed Coding

CPT/HCPCS Codes

J9000	Doxorubicin HCl, 10 mg
J9001	Doxorubicin hydrochloride, all lipid formulations, 10 mg
J9015	Aldesleukin, per single use vial
J9045	Carboplatin, 50mg
J9160/ C1084	Denileukin diftitox, 300 mcg,
J9170	Docetaxel, 20 mg
J9181	Etoposide, 10 mg
J9182	Etoposide, 100 mg
J9185	Fludarabine phosphate, 50 mg
J9201	Gemcitabine HCl, 200 mg
J9206	Irinotecan, 20 mg
J9265	Paclitaxel, 30mg
J9280	Mitomycin, 5mg
J9290	Mitomycin, 20mg
J9291	Mitomycin, 40mg
J9310	Rituximab, 100mg
J9350	Topotecan, 4 mg
J9355	Trastuzumab, 10 mg
J9390	Vinorelbine tartrate, per 10 mg
J9600	Porfimer sodium, 75 mg

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

J9000 – Doxorubicin HCl

140.0-149.9	Malignant neoplasm of lip, oral cavity, and pharynx (carcinoid tumors)
150-0-150.9	Malignant neoplasm of esophagus
151.0-151.9	Malignant neoplasm of stomach
155.0	Malignant neoplasm of liver, primary
155.2	Malignant neoplasm of liver, not specified as primary or secondary
157.0-157.9	Malignant neoplasm of pancreas
160.0-160.9	Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses
161.0-161.9	Malignant neoplasm of larynx
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
183.9	Malignant neoplasm of uterine adnexa, unspecified
184.0	Malignant neoplasm of vagina
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
190.5	Malignant neoplasm of retina (retinoblastoma)
193	Malignant neoplasm of thyroid gland
194.0-194.9	Malignant neoplasm of other endocrine glands and related structures (adrenal cortex)
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
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)

J9001 – Doxorubicin, Liposomal (Doxil)

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
183.0-183.9	Malignant neoplasm of ovary and other uterine adnexa

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

J9999: Antineoplastic Drugs (continued)

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
150.0-150.9	Malignant neoplasm of esophagus
158.8	Malignant neoplasm of specified parts of peritoneum
160.0-160.9	Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses (neuroblastoma)
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
180.0-180.9	Malignant neoplasm of cervix uteri
182.0	Malignant neoplasm of corpus uteri, except isthmus
183.0-183.9	Malignant neoplasm of ovary and other uterine adnexa
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
199.0-199.1	Malignant neoplasm without specification of site

J9160/C1084 – Denileukin diftitox (Ontak®)

202.10-202.18	Mycosis fungoides
202.20-202.28	Sezary's disease

J9170 – Docetaxel (Taxotere®)

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 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
183.0-183.9	Malignant neoplasm of ovary and other uterine adnexa
185	Malignant neoplasm of prostate
188.0-188.9	Malignant neoplasm of bladder
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 (hepatoblastoma)
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)
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
182.0-182.8	Malignant neoplasm of body of uterus
183.0	Malignant neoplasm of ovary (germ and nongerm cell)
183.9	Malignant neoplasm of uterine adnexa, unspecified
186.0-186	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)
199.0-199.1	Malignant neoplasm without specification of site
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 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)

J9999: Antineoplastic Drugs (continued)

174.0-174.9	Malignant neoplasm of female breast
175.0-175.9	Malignant neoplasm of male breast
183.0-183.9	Malignant neoplasm of ovary and other uterine adnexa
188.0-188.9	Malignant neoplasm of bladder
189.0-189.2	Malignant neoplasm of kidney, renal pelvis, and ureter
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

J9206 – Irinotecan (Camptosar®)

153.0-154.8	Malignant neoplasm of colon, rectum, rectosigmoid juction, and anus
162.2-162.9	Malignant neoplasm of lung (small-cell lung carcinoma)
180.0-180.9	Malignant neoplasm of cervix uteri

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
158.8	Malignant neoplasm of specified parts of peritoneum
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
182.0-182.8	Malignant neoplasm of body of uterus
183.0-183.9	Malignant neoplasm of ovary and other uterine adnexa
185	Malignant neoplasm of prostate
186.0-186.9	Malignant neoplasm of testis
188.0-188.9	Malignant neoplasm of bladder
195.0	Malignant neoplasm of head, face, and neck
197.2	Secondary malignant neoplasm of pleura (malignant pleural effusion)
199.0-199.1	Malignant neoplasm without specification of site

J9280, J9290, & 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

J9310–-Rituximab (Rituximab®)

200.00-200.88	Lymphosarcoma and reticulosarcoma
202.00-202.08	Other malignant neoplasms of lymphoid and histiocytic tissue, nodular lymphoma
202.80-202.88	Other malignant neoplasms of lymphoid and histiocytic tissue, other lymphomas
273.3	Macroglobulinemia (Waldenstrom's macroglobulinemia)

J9350 – Topotecan Hydrochloride (Hycamtin®)

162.2-162.9	Malignant neoplasm of lung (non-small/ small cell lung carcinoma)
183.0-183.9	Malignant neoplasm of ovary and other uterine adnexa
205.10	Chronic myeloid leukemia without mention of remission
205.11	Chronic myeloid leukemia in remission
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
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., ICD9 code 174.0 and 198.5).

J9390 – Vinorelbine tartrate (Navelbine®)

162.2-162.9	Malignant neoplasm of lung (non-small lung carcinoma)
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
183.0-183.9	Malignant neoplasm of ovary and other uterine adnexa

J9999: Antineoplastic Drugs (continued)

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)

Diagnoses that Support Medical Necessity

N/A

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

N/A

Diagnoses that DO NOT Support Medical Necessity

N/A

Reasons for Denials

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 Codes

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 that 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 that 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, 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.

OP PPS implementation has identified J9182, J9290, J9291, and J9999 as non-covered items and services. For services provided on or after August 1, 2000, bill Etoposide under HCPCS code J9181 and adjust the units billed field. Mitomycin should be billed utilizing HCPCS code J9280 and adjust the units billed field. In addition, Denileukin diftitox should be billed using C1094.

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 might include the type of cancer, staging, if applicable, prior therapy and the patient's response to that therapy. 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.

For patients receiving Rituximab, an explanation of lymphoma type and previous treatment(s) should be maintained in the patient's medical record.

Utilization Guidelines

N/A

Other Comments

Terms used to describe low-grade B-cell NHL might include small lymphocytic, plasmacytoid lymphocytic, small cleaved, mixed or large cell follicular, nodular or diffuse mantle cell.

Intermediate and high-grade lymphomas may be referred to as diffuse large or mixed cell lymphoma.

Sources of Information and Basis for Decision

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

Advisory Committee Notes

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

Start Date of Comment Period

05/18/2001

End Date of Comment Period

07/02/2001

Start Date of Notice Period

11/01/2001

Revision History

Revision Number:	10
Start Date of Comment Period	05/18/2001
Start Date of Notice Period	11/01/2001 1st Qtr 2002 *Bulletin*
Revised Effective Date:	01/01/2002

Explanation of Revision: J9310, Rituximab and J9390 Vinorelbine are added to the policy, and the code for Denileukin diffitox, Ontak® is changed from J9999 to J9160/C1084, effective January 1, 2002. Effective October 23, 2001, additional ICD-9CM codes are added to various drugs.

Complete history revision may be found online under "Medical Policies" in the Part A section on our provider Web site – **www.floridamedicare.com.** ❖

70450: Computerized Tomography Scans—Addition to Policy

The local medical review policy for Computerized Tomography Scans – 70450 was published in the Third Quarter *Medicare A Bulletin* (pages 38-41). Since that time, diagnosis code 368.40 for visual field defects has been expanded to include diagnosis code range 368.40-368.47 for visual field defects. This diagnosis code range has been added to the "ICD-9-CM Codes that Support Medical Necessity" section of the policy for coverage with the following CPT codes:

70450 Computerized axial tomography, head or brain; without contrast material
70460 with contrast material(s)
70470 without contrast material, followed by contrast material(s) and further sections

This addition is effective for claims processed **on or after October 22, 2001.** ❖

82310: Total Calcium—Addition to Policy

The local medical review policy for Total Calcium – 82310 was published in the Second Quarter 2001 *Medicare A Bulletin* (pages 43-45). Since that time, the diagnosis range 580.0-588.9 for nephritis, nephritic syndrome, and nephrosis has since been added to the "ICD-9-CM Codes that Support Medical Necessity" section of the policy.

This addition is effective for claims processed **on or after October 23, 2001.** ❖

93501: Cardiac Catheterization—Addition to Policy

The local medical review policy for Cardiac Catheterization – 93501 was published in the February/March 2000 *Medicare A Bulletin* (pages 26-29). Since that time, the word "dyspnea" has been added to the descriptor for ICD-9-CM diagnosis code 786.05 – Shortness of breath (dyspnea) in the "ICD-9-CM Codes that Support Medical Necessity" section of the policy.

This addition is effective for claims processed **on or after October 18, 2001.** ❖

G0030: Positron Emission Tomography (PET) Scan—Revision to Policy

The local medical review policy for Positron Emission Tomography (PET) scan – G0030 was published in the Fourth Quarter 2001 *Medicare A Bulletin* (pages 57-64). Since then, the Centers for Medicare & Medicaid Services has advised the Medicare contractors that HCPCS code G0219 (PET Imaging whole body; melanoma for non-covered indications) is not a covered service. Therefore, G0219 is deleted from the local medical review policy, effective for services provided **on or after July 1, 2001.** ❖

72192: Computerized Tomography of the Pelvis—Addition to Policy

The local medical review policy for Computerized Tomography of the Pelvis – 72192 was published in the Second Quarter 2001 *Medicare A Bulletin* (pages 34-37). Since that time, the following diagnosis codes have been added to the "ICD-9-CM Codes that Support Medical Necessity" section of the policy.

625.9 Unspecified symptom associated with genital organs
789.0 Abdominal pain, unspecified site
789.39 Abdominal or pelvic swelling, mass, or lump, other specified site

This addition is effective for claims processed **on or after October 22, 2001.** ❖

85007: Complete Blood Count—Revision to Policy

The local medical review policy (LMRP) for Complete Blood Count – 85007 was published in the Fourth Quarter 2001 *Medicare A Bulletin* (pages 38-41). Since then, the Centers for Medicare & Medicaid Services has advised the Medicare contractors that "Contractors may not install edits that result in the automatic denial of services based solely on the ICD-9-CM codes for dementia." Therefore, ICD-9-CM codes 290.0-290.9, 295.00-295.95, 331.0, and 331.1 have been removed from the "Noncovered ICD-9-CM Codes" section of the policy. This revision is effective **September 1, 2001.** ❖

C1300: Hyperbaric Oxygen (HBO) Therapy—Clarification Regarding Physician Supervision

The Medicare contractor has received numerous inquiries regarding the article published in the Fourth Quarter 2001 *Medicare A Bulletin* page 86, regarding the physician supervision requirement for Hyperbaric Oxygen (HBO) therapy – C1300. The article states "National coverage policy for HBO therapy no longer requires a physician to be present during an HBO therapy session." This is not an accurate statement regarding the national coverage policy for HBO therapy physician supervision.

The national coverage policy for HBO therapy does not currently comment on physician supervision for HBO therapy. Therefore, this contractor has established a local coverage decision with regard to the physician supervision requirement. Florida Medicare has made a local decision to deny HBO therapy services performed in the absence of a physician (HCPCS code G0167 – Hyperbaric oxygen treatment not requiring physician attendance, per treatment session). ❖

2002 ICD-9-CM Part A Local Medical Review Policy Changes

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

Florida Medicare has revised local medical review policies (LMRPs), for procedure codes with specific diagnosis criteria that are affected by the 2002 ICD-9-CM update. The following table lists the LMRPs affected and the specific conditions revised as a result of the 2002 ICD-9-CM update:

LMRP Title	Publication Listings	2002 Changes
44388: Colonoscopy	2nd Quarter 2001 *Bulletin* (page 91) Oct/Nov 2000 *Bulletin* (page 18) *Bulletin* G-333, 5/19/1998	Change descriptor for 558.1-558.9 to read Other *and unspecified* noninfectious gastroenteritis and colitis; and Change 564.0 to 564.00-564.09 for procedure codes 44388-44394, 44397, 45355, 45378-45380, 45382-45385, and 45387
70450: Computerized Tomography Scans	3rd Quarter 2001 *Bulletin* (page 38) Aug/Sep 1999 *Bulletin* (page 15) *Bulletin* G-363, 2/8/1999 *Bulletin* G-354, 12/7/1998	Change 772.1-772.2 to 772.10-772.2 for procedure codes 70450, 70460, and 70470
70551: Magnetic Resonance of the Brain	2nd Quarter 2001 *Bulletin* (page 31) *Bulletin* G-354, 12/7/1998	Change 772.1-772.2 to 772.10-772.2 for procedure codes 70551-70553
71010: Chest X-Ray	1st Quarter 2001 *Bulletin* (page 19) Aug/Sep 2000 *Bulletin* (page 24) *Bulletin* G-348, 9/18/1998	Change 793.8 to 793.80-793.89 for procedure codes 71010, 71015, 71020-71023, 71030, 71034, and 71035
74150: Computerized Axial Tomography of the Abdomen	4th Quarter 2001 *Bulletin* (page 31)	Change descriptor for 558.1-558.9 to read Other *and unspecified* noninfectious gastroenteritis and colitis; change 256.3 to 256.31-256.39; and change 564.0-564.9 to 564.00-564.9 for procedure codes 74150, 74160, and 74170
76075: Bone Mineral Density Studies	*Bulletin* G-360, 1/21/1999	Change 256.3 to 256.31-256.39 for procedure codes 76075, 76076, 76078, 76977, 78350, and G0130-G0132
76090: Diagnostic Mammography	3rd Quarter 2001 *Bulletin* (page 42) *Bulletin* G-333, 5/29/1998 *Bulletin* G-317, 1/23/1998	Change 793.8 to 793.80-793.89 for procedure codes 76090, 76091, G0204-G0207
78460: Myocardial Perfusion Imaging	*Bulletin* G-360, 1/21/1999 *Bulletin* G-354, 12/7/1998	Change descriptor for 411.81 to read *Acute* coronary occlusion without myocardial infarction for procedure codes 78460, 78461, 78464, 78465, 78478, and 78480
78472: Cardiac Blood Pool Imaging	Oct/Nov 2000 *Bulletin* (page 22) Feb/Mar 2000 *Bulletin* (page 21)	Change descriptor for 411.81 to read *Acute* coronary occlusion without myocardial infarction for procedure codes 78472, 78473, 78481, 78483, 78494, and 78496
82270: Fecal Occult Blood Testing	June/July 1999 *Bulletin* (page 47) *Bulletin* G-291, 7/2/97	Change descriptor for 558.1-558.9 to read Other *and unspecified* noninfectious gastroenteritis and colitis; and Change 564.0-564.9 to 564.00-564.9 for procedure code 82270
82310: Total Calcium	2nd Quarter 2001 *Bulletin* (page 43)	Change 564.0 to 564.00-564.09 for procedure code 82310
84436: Thyroid Function Tests	April/May 2000 *Bulletin* (page 21) Feb/Mar 2000 *Bulletin* (page 20) 2000 HCPCS December 1999 Special *Bulletin* (page 29)	Change 564.0 to 564.00-564.09 for procedure codes 84436, 84437, 84439, 84443, 84479-84482

2002 ICD-9-CM Part A Local Medical Review Policy Changes (continued)

LMRP Title	Publication Listings	2002 Changes
93224: Electrocardiographic Monitoring for 24 hours (Holter Monitoring)	Jun/Jul 1999 *Bulletin* (page 80)	Change descriptor for 411.81 to read *Acute* coronary occlusion without myocardial infarction for procedure codes 93224-93237
93303: Transthoracic and Doppler Echocardiography and Doppler Color Flow Velocity Mapping	4th Quarter 2001 *Bulletin* (page 49) Jun/Jul 2000 *Bulletin* (page 32)	Change descriptor for 411.81 to read *Acute* coronary occlusion without myocardial infarction for procedure codes 93307, 93308, 93320, 93321, and 93325
93312: Transesophageal Echocardigram	2nd Quarter 2001 *Bulletin* (page 53) *Bulletin* G-367, 3/18/1999	Change descriptor for 411.81 to read *Acute* coronary occlusion without myocardial infarction for procedure codes 93312-93318
93350: Stress Echocardiography	*Bulletin* G-367, 3/18/1999	Change descriptor for 411.81 to read *Acute* coronary occlusion without myocardial infarction for procedure 93350
G0030: Positron Emission Tomography (PET) Scan	4th Quarter 2001 *Bulletin* (page 57) Jun/Jul 1999 *Bulletin* (page 80) *Bulletin* G-348, 9/18/1998	Change descriptor for 411.81 to read *Acute* coronary occlusion without myocardial infarction for procedure codes G0030-G0047
G0104: Colorectal Screening	4th Quarter 2001 *Bulletin* (page 65) *Bulletin* G-367, 3/18/1999	Change descriptor for 558.1-558.9 to read Other *and unspecified* noninfectious gastroenteritis and colitis for procedure codes G0105 and G0120

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

HealthCare Consultants of America	Medicode Publications	St. Anthony's Publishing
(800) 253-4945	(800) 999-4600	(800) 632-0123

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

In addition, detailed information regarding the 2002 ICD-9-CM update is available by accessing Florida Medicare Web site – **www.floridamedicare.com.** ❖

Change in Effective Date for Local Medical Review Policies

The following local medical review policies were published in the 4th Quarter 2001 *Medicare A Bulletin* (pages 23-85).

The publication indicated the effective date for these policies as September 21, 2001, it has been changed to **September 28, 2001.**

- Incision and Drainage of Abscess of Skin, Subcutaneous and Accessory Structures – 10060
- Computerized Axial Tomography of the Thorax – 71250
- Computerized Axial Tomography of the Abdomen – 74150
- Serum Protein – 84155
- Air Ambulance Service – A0430
- Intravenous Immune Globulin – J1561
- Interferon – J9212
- Cardiac Output by Electrical Bioimpedance – M0302 ❖

SKILLED NURSING FACILITY SERVICES

Respiratory Services under Skilled Nursing Facility Prospective Payment System (SNF PPS)

This article addresses issues raised by respiratory therapists concerning the billing of respiratory therapy services under skilled nursing facility prospective payment system (SNF PPS). This notification restates definitions of respiratory services that can be provided under SNF PPS and medical review of claims that include these services. Respiratory therapy is defined as those services prescribed by a physician for assessment, diagnostic evaluation, treatment, management, and monitoring of patients with deficiencies and abnormalities of cardiopulmonary function.

SNF Manual section 230.10C, describes respiratory services provided by the SNF. Respiratory therapy services include but are not limited to:

1. The application of techniques for support of oxygenation and ventilation in the acutely ill patient. These techniques include, but are not limited to:
   a) establishment and maintenance of artificial airways,
   b) ventilator therapy and other means of airway pressure manipulation,
   c) precise delivery of oxygen concentration, and
   d) techniques to aid removal of secretions from the pulmonary tree.
2. The therapeutic use and monitoring of medical gases (especially oxygen), bland and pharmacologically active mists and aerosols, and such equipment as resuscitators and ventilators.
3. Bronchial hygiene therapy, including deep breathing and coughing exercises, IPPB, postural drainage, chest percussion and vibration, and nasotracheal suctioning.
4. Diagnostic tests for evaluation by a physician, e.g., pulmonary function tests, spirometry, and blood gas analyses.
5. Pulmonary rehabilitation techniques which include:
   a) exercise conditioning,
   b) breathing retraining, and
   c) patient education regarding the management of the patient's respiratory problems, and
6. Periodic assessment and monitoring of the acute and chronically ill patients for indications for, and the effectiveness of, respiratory therapy services.

Respiratory therapists or technicians, physical therapists, nurses and other qualified personnel perform these services. It is the responsibility of the SNF to ensure the appropriate personnel perform the services within their scope of practice as licensed by the state(s) in which the services are performed. ❖

Fee Schedule for Additional Part B Services Furnished by a Skilled Nursing Facility (SNF) or Another Entity under Arrangements with the SNF

Effective April 1, 2001, fee schedule payment was implemented for type of bills 22x and 23x for the following services:

- Clinical diagnostic laboratory services, for which 23x was paid on the fee schedule, and 22x was paid on a cost basis.
- Durable medical equipment, prosthetic and orthotic devices, supplies, surgical dressings, etc, which have historically been paid on cost to the limited extent these services/items were payable in a SNF.
- Therapy services, which have been paid on a fee schedule basis, using the Medicare physician fee schedule (MPFS) since 01/01/1999.

Fee Schedule Payment for Part B Services

Effective for services furnished **on and after January 1, 2002,** radiology, other diagnostic, and other services included in the MPFS will be paid under a fee schedule when rendered to patients of a SNF. Payment is the lower of the billed charges or fee schedule amount. In either case, any applicable deductible and coinsurance amounts are subtracted from the payment amount prior to payment. Coinsurance is calculated on the Medicare payment amount after subtraction of any applicable deductible amount.

Services Not Paid Through a Fee Schedule

The following services are not paid under a fee schedule system since the fee schedules have not yet been developed or implemented:

- Some medical supplies
- Dialysis supplies and equipment
- Therapeutic shoes
- Blood products
- Transfusion medicine
- Drugs
- Ambulance

Note: The ambulance fee schedule is currently scheduled for implementation January 1, 2002.

Since January 1, 1999, SNFs were instructed to begin reporting all Part B services with a CPT/HCPCS code, if one exists, for type of bills 22x and 23x.

Effective for services furnished **on or after January 1. 2002,** any claim for type of bills 22x and 23x will be returned for the provider as incomplete if the claim is not reported with the appropriate revenue code for the services furnished and the CPT/HCPCS code, if one exists. Denial appeal rights are not applicable, and the provider may not charge the beneficiary for services reported incorrectly. The provider may correct and resubmit the claim with appropriate HCPCS coding and a new filing date.

Fee Schedule for Additional Part B Services Furnished by a SNF ... (continued)

Revenue Codes Requiring HCPCS Codes on Type of Bills 22x and 23x

27x	**Medical/Surgical Supplies. (Also see 62x)**
271	Nonsterile Supply
272	Sterile Supply
273	Take Home Supplies
274	Prosthetic/Orthotic Devices
279	Other Supplies/Devices
30x	**Laboratory**
301	Chemistry
302	Immunology
305	Hematology
306	Bacteriology & Microbiology
307	Urology
309	Other Laboratory
32x	**Radiology – Diagnostic**
321	Angiocardiography
322	Arthrography
323	Arteriography
324	Chest X-Ray
329	Other
33x	**Radiology – Therapeutic**
330	Radiology – Therapeutic, General Classification
332	Chemotherapy – Oral
333	Radiation Therapy
339	Other
34x	**Nuclear Medicine**
340	General Classification (NUC MED)
341	Diagnostic
342	Therapeutic
349	Other
40x	**Other Imaging Services**
400	General Classification
401	Diagnostic Mammography
402	Ultrasound
403	Screening Mammography
404	Positron Emission Tomography
409	Other Imaging Services
41x	**Respiratory Services**
410	General Classification
412	Inhalation Services
413	Hyperbaric Oxygen Therapy
419	Other Respiratory Services
42x	**Physical Therapy**
420	General Classification
421	Visit Charge
422	Hourly Charge
423	Group Rate
424	Evaluation or Re-evaluation
429	Other Physical Therapy
43x	**Occupational Therapy**
430	General Classification
43	Visit Charge
432	Hourly Charge
433	Group Rate
434	Evaluation or Re-evaluation
439	Other Occupational Therapy (may include restorative therapy)
44x	**Speech – Language Pathology**
440	General Classification
441	Visit Charge
442	Hourly Charge
443	Group Rate
444	Evaluation or Re-evaluation
449	Other Speech – Language Pathology
46x	**Pulmonary Function**
460	General Classification
469	Other Pulmonary Function
47x	**Audiology**
470	General Classification
471	Diagnostic
472	Treatment
479	Other Audiology
48x	**Cardiology**
480	General Classification
481	Cardiac Cath Lab
482	Stress Test
483	Echocardiology
489	Other Cardiology
54x	**Ambulance**
540	General Classification
542	Medical Transport
548	Telephone Transmission EKG
549	Other Ambulance
62x	**Medical/Surgical Supplies – Extension of 27x**
621	Supplies Incident to Radiology
622	Supplies Incident to Other Diagnostic Services
623	Surgical Dressings
63X	**Drugs Requiring Specific Identification**
634	Erythroepoetin (EPO) less than 10,000 units
635	Erythroepoetin (EPO) 10,000 or more units
636	Drugs Requiring Detailed Coding (HCPCS)
637	Self-administrable Drugs
73X	**EKG/ECG (Electrocardiogram)**
730	General Classification
731	Holter Monitor
732	Telemetry
739	Other EKG/ECG
74X	**EEG (Electroencephalogram)**
740	General Classification
749	Other EEG
75X	**Gastro-Intestinal Services**
750	General Classification
759	Other Gastro-Intestinal
77X	**Preventative Care Services**
771	Vaccine Administration
92X	**Other Diagnostic Services**
920	General Classification
921	Peripheral Vascular Lab
922	Electromyelogram
923	Pap Smear
924	Allergy test
925	Pregnancy test
929	Other Diagnostic Service ❖

Source: CMS Transmittal A-01-119, CR 1878

CRITICAL ACCESS HOSPITAL SERVICES

Outpatient Code Editor Specifications Version 17.0 for Bills from Hospitals not Paid Under the Outpatient Prospective Payment System (OPPS)

The Outpatient Code Editor (OCE) has been updated with new additions, changes, and deletions to Healthcare Common Procedure Coding System/Current Procedural Terminology, Fourth Edition (HCPCS/CPT-4) codes and International Classification of Diseases, 9th Revision, Clinical Modification (ICD-9-CM) diagnosis codes. The majority of these codes are effective for dates of service on or after October 1, 2001. This OCE is used to process bills from Indian health service hospitals, critical access hospitals, Maryland hospitals, and hospitals located in American Samoa, Guam, and Saipan. Below are the Centers for Medicare & Medicaid Services' requirements.

New ICD-9-CM Diagnosis Codes

The following new diagnosis codes were added to the list of valid ICD-9-CM diagnosis, **effective October 1, 2001** (OCE v17.0)

256.31	256.39	277.7	464.00	464.01
464.50	464.51	521.00	521.01	521 02
521.03	521.04	521.05	521.09	525.10
525.11	525.12	525.13	525.19	530.12
564.00	564.01	564.02	564.09	602.3
608.82	608.87	692.76	692.77	718.70
718.71	718.72	718.73	718.74	718.75
718.76	718.77	718.78	718.79	733.93
733.94	733.95	772.10	772.11	772.12
772.13	772.14	77.97	793.80	793.81
793.89	840.7	997.71	997.72	997.79
V10.53	V45.84	V49.82	V83.01	V83.02
E88.80	E88.81	E88.88	E888.9	E917.3
E917.4	E917.5	E917.6	E917.7	E917.8

Deleted ICD-9-CM Diagnosis Codes

The following diagnosis codes were deleted from the list of valid ICD-9-CM diagnosis codes, **effective October 1, 2001.**

256.3	464.0	521.0	525.1	564.0
772.1	793.8	E88.8		

Revised ICD-9-CM Diagnosis Code Descriptors

411.81	493.00	493.10	493.20	493.90
V707	E9170	E9171	E9172	E9179

New HCPCS/CPT Procedure Codes

The following new HCPCS codes were added to the list of valid codes for the OCE, **effective October 1, 2001** (OCE v17.0).

C9110 C9506 C9711 Q3014 Q4001 – Q4051

Deleted HCPCS/CPT Procedure Codes

The following HCPCS codes were deleted from the list of valid codes for the OCE, **effective April 1, 2001** (OCE v16.1.1).

C8500 – C8514	C8516	C8518 – C8526
C8528 – C8536	C8539 – C8543	C8550 – C8552
C8597 – C8600	C8650	C8724
C8725	C8748 – C8750	C8775 – C8777
C8800 – C8802	C8830	C8890
C8891		

The following HCPCS codes were deleted from the list of valid codes for the OCE, **effective July 1, 2001** (OCE v16.2).

C1024 C1059 C1086 C1205 C9107

The following HCPCS codes were deleted from the list of valid codes for the OCE, **effective October 1, 2001** (OCE v17.0).

C9017 A4570 A4580 L2102 L2104 L2122 L2124

Medicare Outpatient Code Edits

Newborn Diagnoses – Age 0 years

The following new codes were added to the list of newborn diagnoses:

772.10 772.11 772.12 772.13 772.14 779.7

The following existing code was deleted from the list of newborn diagnoses:

770.7

Adult Diagnoses – Age greater than 14

The following new codes were added to the list of adult diagnoses:

256.31 277.7

Diagnoses for Females Only

The following new codes were added to the list of diagnoses allowed for females only:

256.31 256.39

The following existing codes were added to the list of diagnoses allowed for females only:

V764.6 V764.7

Diagnoses for Males Only

The following codes were added to the list of diagnoses allowed for males only:

602.3 608.82 608.87

Outpatient Code Editor Specifications Version 17.0 ... (continued)

Ambulatory Surgical Center (ASC) Procedures

The following codes were added to the list of ASC procedures, **effective January 1, 2001** (OCE v16.1).

Code	Payment Group
19102	2
19103	2
58353	4
66982	8

The following code was added to the list of ASC procedures, **effective July 1, 2001** (OCE v16.2).

Code	Payment Group
G0121	2

Non-Covered Procedures

The following code was added to the list of Non-Covered Procedures, **effective August 1, 2000** (OCE v15.2):

G0122

The following code was added to the list of Non-Covered Procedures, **effective July 1, 2001** (OCE v16.2):

Q0181

Source: CMS Transmittal A-01-103, CR 1816

Non-Reportable Procedures

All HCPCS codes beginning with C that were in the valid list for August 1, 2000 were added to the Non-Reportable list **retroactive to August 1, 2000** (OCE v15.2).

All HCPCS codes beginning with C that were in the valid list for October 1, 2000 were added to the Non-Reportable list **retroactive to October 1, 2000** (OCE v16.0).

All HCPCS codes beginning with C that were in the valid list for January 1, 2001 were added to the Non-Reportable list **retroactive to January 1, 2001** (OCE v16.1).

All HCPCS codes beginning with C that were in the valid list for April 1, 2001 were added to the Non-Reportable list **retroactive to April 1, 2001** (OCE v16.1.1).

Note: All HCPCS codes beginning with C that were in the valid list for July 1, 2001 were added to the Non-Reportable list for OCE v16.2.

The following codes were added to the list of Non-Reportable codes, **effective October 1, 2001** (OCE v17.0).

71555	73725	74185	76093	76094
C9110	C9506	K0008	K0013	

The following codes were removed from the list of Non-Reportable codes, **effective January 1, 2001** (OCE v16.1).

G0107 J1441 ❖

HOSPITAL OUTPATIENT PROSPECTIVE PAYMENT SYSTEM

Removal of Category Code C1723 from the Pass-Through Device Category

The Outpatient Prospective Payment System section of the Third Quarter 2001 *Medicare A Bulletin* provided several articles with information on categories for pass-through devices under the hospital OPPS. One article (pages 84-85) contained a list of categories eligible for pass-through status effective April 1, 2001. Another article (pages 85-106) provided a list of specific devices mapped to the new category codes.

C1723 (catheter, ablation, non-cardiac) was one of the categories approved for pass-through status effective April 1, 2001. Only one device was mapped to this category code, specifically the Gynecare Thermachoice II catheter.

Based on a subsequent review of the application for pass-through status that was submitted on behalf of the Gynecare Thermachoice II catheter, Medicare has determined that this specific item does not meet the pass-through criteria set forth in the Federal Register on August 3, 2000 and November 13, 2000. As provided in 42 CFR 419.43(e)(4)(iv), a device must be surgically implanted or inserted, whether or not it remains with the patient when the patient is released from the hospital outpatient department. The November 13, 2000, Federal Register (65 FR 67805) explained that Medicare considers a device to be surgically implanted or inserted "if it is introduced into the human body through a surgically created incision." The Gynecare Thermachoice II catheter does not meet this pass-through criterion.

As provided in the Benefits Improvement and Protection Act of 2000, in order for a device to be a category code effective April 1, 2001, the device must have met the pass-through criteria and the Centers for Medicare & Medicaid Services (CMS) must have received the application by December 1, 2000. Because CMS has now determined that the Gynecare Thermachoice II catheter did not meet the criteria for eligibility as a pass-through device and because CMS is not aware of any other device described by category code C1723 that does meet the criteria, C1723 will be removed from the list of eligible category codes effective January 1, 2002.

Device manufacturers are encouraged to submit applications if they believe they have non-cardiac ablation catheters that meet the established criteria for pass-through payment eligibility.

Although Medicare generally allows a 90-day grace period when a code is removed, a grace period is not granted when the eligibility for a code is terminated. In this case, **there will be no grace period for category code C1723 beyond the January 1, 2002 termination date.** ❖

Source: CMS Transmittal AB-01-120; CR 1827

Clarification of Same Day Rule Billing Requirements under the Outpatient Prospective Payment System (OPPS)

The Centers for Medicare & Medicaid Services (CMS) has provided instructions to clarify billing requirements for services furnished on the same day, and clarification to questions and answers numbers 103 to 105 on the CMS Web site **www.hcfa.gov** regarding bill submittal requirements under OPPS. These instructions also clarify billing of observation services.

Same Day Rule

Hospitals and community mental health centers are required to report all OPPS services provided on the same day on the same claim with the exception of claims containing condition codes 20, 21 or G0 (zero). If an individual OPPS service is provided on the same day as an OPPS repetitive service, the individual OPPS service must be billed on the OPPS monthly repetitive claim. The policy for repetitive services continues under OPPS for all providers. If a non-OPPS repetitive service is provided on the same day as an OPPS service, separate claims may be submitted. In addition, if a type of bill 13x and 14x contains OPPS services that were performed on the same day for the same beneficiary, the services must be reported on the same claim. Providers must submit one claim in this situation utilizing the type of bill 13x.

Note: Hospitals should continue to submit screening mammography services on separate claims. This billing practice continues under OPPS.

The following revenue codes are considered to be repetitive services and must be billed monthly or at the conclusion of treatment. Please note that all repetitive services with the exception of physical, occupational and speech therapy are subject to OPPS.

Type of Service	Revenue Code(s)
Therapeutic Radiology	330-339
Therapeutic Nuclear Medicine	342
Respiratory Therapy	410-419
Physical Therapy	420-429
Occupational Therapy	430-439
Speech Pathology	440-449
Cardiac Rehabilitation Services	482, 493
Psychological Services	910-919

See section 3603.B of the Part A Medicare Intermediary Manual and section 402 of the Medicare Hospital Manual for a list of outpatient repetitive services that are required to be billed monthly.

Clarification of Same Day Rule Billing Requirements under the Outpatient PPS (continued)

Example I

If a patient receives a laboratory service on May 1 and has an emergency room (ER) visit on the same day, two separate bills may be submitted since the laboratory service is paid under the clinical diagnostic laboratory fee schedule and not subject to OPPS. In this situation, the laboratory service was not related to the ER visit or done in conjunction with the ER visit.

Example II

If a patient was seen in the ER and the same patient received non-partial hospitalization psychological services on the same day, as well as, several other days in the month, the provider should report the ER visit on the monthly repetitive claim along with the psychological services, since both services are paid under OPPS.

Example III

If a patient has an ER visit on the same day as a chemotherapy visit, the provider should report both of these services on the monthly chemotherapy repetitive claim since both services are paid under OPPS.

Example IV

If the patient receives chemotherapy on July 7, 29, and 30 and receives services in the ER on July 28, the provider may submit separate claims since the isolated individual service (ER visit) did not occur on the same day as the repetitive services (chemotherapy services). In this situation, it does not matter whether the services are reimbursed under OPPS or not.

Example V

If a patient has an ER visit (OPPS service) on May 15 and also received a physical therapy visit (non-OPPS service) on the same day, (as well as other physical therapy visits provided May 1 through May 31) the services may be billed on separate claims. The provider would bill the ER service on one claim and the therapy services on the monthly repetitive claim. Please note, as stated above, the procedures for billing of repetitive services remain in effect under OPPS. Therefore, in this example, it would not be appropriate to submit one therapy claim for services provided May 1 through May 15, a second claim for the ER visit provided on May 15, and a third claim for therapy visits provided on May 16 through May 31.

Providers should not split repetitive services in mid-month when another outpatient service occurs.

Claims submitted for the same date of service (except exact duplicates or those containing condition codes 20, 21, or G0) will be returned to the provider with a notification that an adjustment bill should be submitted.

Proper Billing of Observation Services

To properly capture cost data for future updates, hospitals are required to report observation charges under revenue code 762 – observation room. HCPCS codes do not have to be reported. The appropriate CPT codes, if reported, are 99217 through 99220 and 99234 through 99236. The number of hours a patient is in observation status must be reported in the units field.

When ancillary services are furnished while the patient is in observation status, the hospital reports these services under revenue code 760 – treatment/observation room. Hospitals should not report these services under revenue code 762. In addition, hospitals should report any laboratory, radiology, etc. services under revenue codes 30x, 31x, 32x, etc., as appropriate. ❖

Source: CMS Transmittal A-01-91, CR 1768

Clarification on "Inpatient Only" Services

The Centers for Medicare & Medicaid Services (CMS) has been informed that in some cases, Medicare beneficiaries are being charged for "inpatient only" services that were furnished in a hospital outpatient setting.

The outpatient prospective payment system (OPPS) requires that "inpatient only" services must be furnished on an inpatient basis in order for the claim to be paid by Medicare. If "inpatient only" services are furnished in an outpatient basis, then the Medicare Part A fiscal intermediary rejects the claim. In some cases, the beneficiary is then being billed by the hospital for the "inpatient only" procedure rendered in the outpatient setting.

This fiscal intermediary may remind providers that "inpatient only" services are to be furnished only in the hospital inpatient setting in order to be paid by Medicare. The "inpatient only" list consists solely of complicated procedures requiring more than 24 hours of recovery time.

Currently, CMS lacks the authority to require beneficiaries in this type of circumstance sign an advanced beneficiary notice. The fiscal intermediary will review OPPS claims to determine any problems that may exist in billing Medicare for this services in accordance with the OPPS requirements. ❖

Technical Corrections under the Hospital Outpatient Prospective Payment System (OPPS)

This article contains a list of corrected category designations for devices published in previous publications. This article also provides additional information on Lomustine, as well as, additional clarifications/corrections to other specific items.

The outpatient code editor (OCE) and PRICER currently contain the codes included in this document. All of the C-codes included in this document are used exclusively for services paid under the OPPS and may **not** be used to bill services paid under other Medicare payment systems.

The listing of HCPCS codes contained in this instruction does not assure coverage of the specific item or service in a given case. To be eligible for pass-through payments, the items contained in this document must be considered reasonable and necessary.

Technical Corrections Under the Hospital Outpatient Prospective Payment System (OPPS) (continued)

Category Re-designation for Pass-Through Devices Effective April 1, 2001

The category designations for the specific devices listed below have been revised and supercedes the previous category designations previously published.

Current C-Code	Long Descriptor	New Category C-code
C1003	Livewire TC Ablation Catheter 402205, 402006, 402207, 402208 (formerly listed as Livewire TC Compass Ablation Catheter)	C1733
C1008	Stent, urethral, UroLume	C1876
C1025	Marinr CS	C1730
C1035	Catheter, intracardiac echocardiography, Ultra ICE 6F, 12.5 MHz Catheter with Disposable Sheath, Ultra ICE 9F, 9 MHz Catheter with Disposable Sheath NOTE: To appropriately bill for these pass-through devices, report two categories. The catheter is reported with category code C1759 and the introducer/sheath is reported with category code C1893.	C1759/ C1893
C1036	Bard Port Implanted Port, Bard Rosenblatt Lumen Port, Bard Ultra Low Profile Port, BardPort Titanium Implanted Port, BardPort X-Port Implanted Port, BardPort M.R.I. Dual Implanted Port, BardPort M.R.I. Hard-Base Implanted Port	C1788
C1101	Zuma Guide Catheter, Medtronic AVE Vector Guide Catheter, Medtronic AVE Vector X Guide Catheter	C1887
C1115	Lead, pacemaker 2188 Coronary Sinus Lead	C1898
C1143	Paragon III (models 2314L, 2315 M/S)	C2619
C1319	Wallstent Esophageal Prosthesis (Double) With Permalume Covering, UltraFlex Esophageal Stent System With Permalume Covering	C1874
C1319	Wallstent Esophageal Prosthesis (Double) Non-Covered, UltraFlex Esophageal Stent System, Non-Covered	C1876
C1362	Stent, biliary, RX HERCULINK 14 Biliary Stent, OTW MEGALINK SDS Biliary Stent	C1876
C1365	Hi-Torque Balance (this was previously listed as Hi-Torque Extra Balance)	C1769
C1370	Tension-Free Vaginal Tape Single Use Device	C1771
C1371	Nir Biliary Stent (this was previously listed as Nir Biliary Stent System)	C1877
C1420	TransFix Bone Anchor System with Dermis, StapleTac2 Bone Anchor System with Dermis	C1771
C1421	TransFix Bone Anchor System without Dermis, Staple Tac2 Bone Anchor System without Dermis	C1771
C1811	Biomet Repicci II Unicondylar Knee System	C1776
C1932	Dispatch Coronary Infusion Catheter, AngioDynamics Pulse Spray Infusion Catheter, AngioDynamics Unifuse Infusion Catheter	C1751
C2001	Catheter, Constellation Diagnostic Catheter	C1732
C2002	Catheter, Marinr	C1730
C2010	Response Fixed Curve Catheter, Supreme Fixed Curve Catheter, TorqrCS	C1730
C2012	Catheter, ablation, Biosense Webster Celsius 5mm Temperature Ablation Catheter, Biosense Webster Celsius Temperature Sensing Diagnostic/Ablation Tip Catheter	C1733
C2019	Cardima Naviport Deflectable Tip Guiding Catheter, Cardima Venaport Guiding Catheter	C1887
C5009	Stent, biliary, Biliary VistaFlex Stent	C1876
C5012	IntraStent Double Strut Para Mount Biliary Stent	C1876
C5016	Wallstent Single-Use Covered Biliary Endoprosthesis with Unistep Plus Delivery System	C1874
C5030	BiodivYsio AS PC Coated Coronary Stent Delivery System (11mm)	C1874
C5031	BiodivYsio AS PC Coated Coronary Stent Delivery System (15mm)	C1874
C5039	IntraCoil Peripheral Stent (40mm stent length)	C1876
C5040	IntraCoil Peripheral Stent (60mm stent length)	C1876
C5281	Wallgraft Tracheobronchial Endoprosthesis with Unistep Delivery System (70mm in length)	C1874
C5282	Wallgraft Tracheobronchial Endoprosthesis with Unistep Delivery System (20mm, 30mm, 50mm in length)	C1874
C6650	Introducer, guiding, Fast-Cath Two-Piece Guiding Introducer (models 406869, 406892, 406893, 406904)	C1766*

Technical Corrections Under the Hospital Outpatient Prospective Payment System (OPPS) (continued)

*See "New Pass-through Device Category C-codes and Revision of a Category C-code Descriptor" in the Fourth Quarter *Medicare A Bulletin* (page 88) for information on this category.

Pass-Through Item No Longer Eligible for Pass-Through Status Effective April 1, 2001

The Centers for Medicare & Medicaid Services have determined that Lomustine – C9017 is **not** a drug that qualifies for coverage as an oral chemotherapeutic agent under 1861(s)(2)(Q). Therefore, Medicare does **not** cover this oral anti-cancer drug. (Lomustine – C9017 was previously published as a drug approved for transitional pass-through status effective April 1, 2001.) As a result of this revision:

- HCPCS code C9017 and APC 9017 have been deleted from the October 1, 2001, release of the OCE.
- The July 1, 2001, release of PRICER was updated to reflect these determinations.

Additional Clarifications/Corrections

The following codes were assigned to new APCs effective July 1, 2001 and October 1, 2001. The information below supercedes the information previously published related to these specific codes. The OCE for the October 2001 reflects these changes.

HCPCS	Short Descriptor	Old APC	New APC (as of 7/1/01)	New APC (as of 10/1/01)
70486	Ct maxillofacial w/o dye	0282		0332
73206	Ct angio upr extrm w/o&w dye	0283	0332	0333
73700	Ct lower extremity w/o dye	0283	0332	
75554	Cardiac mri/function	0284		0335
75555	Cardiac mri/limited study	0284		0335
75635	Ct angio abdominal arteries	0283		0333
76390	Mr spectroscopy	0284		0335
76400	Magnetic image, bone marrow	0284		0335

Source: CMS Transmittal A-01-97, CR 1743

Clarification of Activity Therapy and Patient Education/Training Services

This article provides information for hospitals related to the treatment of activity therapy and patient education and training under the outpatient prospective payment system (OPPS).

Currently, activity therapy (G0176) and patient education and training (G0177) are not paid separately under OPPS. The definition of these codes limits coverage to services provided as a component of a partial hospitalization program. Activity therapy services include music, dance, art, or play therapies not for recreation, related to the care and treatment of patient's disabling mental health problems. Patient education and training services include training and educational services related to the care and treatment of patient's disabling mental health problems. Patient education and training services have been packaged into the overall costs associated with hospital outpatient psychiatric services; it is not a separately paid service. However, both of these services (activity therapy and patient education and training) will continue to be covered and paid when furnished as a component of a partial hospitalization program.

Activity Therapy

Activity therapy services are not covered outside of partial hospitalization programs because it is the policy of CMS that activity therapy should be utilized only within the context of a structured and intensive treatment program, such as an inpatient treatment program or a partial hospitalization program.

Providers should **not** report G0176 or revenue code 904 **unless** billing under the partial hospitalization program. Non-partial hospitalization bills (those bills **not** containing condition code 41) submitted with revenue code 904 will be returned to the provider. The revenue code 904 and/or HCPCS G0176 should be removed and the bill re-submitted for payment.

Patient Education and Training for Psychiatric Purposes

Hospitals should continue to bill for patient education and training services, as they are a packaged service. It is paid as part of covered **psychological services** furnished in OPPS. Hospitals must bill for patient education and training services, **only for psychiatric purposes,** using revenue code 942 and HCPCS code G0177. Medicare recognizes that reporting HCPCS code G0177 on a non-partial hospitalization bill is not consistent with the definition for this HCPCS code, however, reporting is necessary for the purpose of data analysis. When both the revenue code and G0177 are reported, it allows Medicare to know that a psychological service is included in the services furnished and that it might be part of a partial hospitalization per diem day. Additionally, sections 3651 and 3661 of the Medicare Intermediary Manual require that providers report revenue code 942 and HCPCS code G0177 when specifying the service for psychiatric purposes only.

It is important for hospitals to continue to bill their charges for patient education and training for psychiatric purposes because these charges will be taken into account in determining outlier payments, transitional corridor payments, and future updates of the ambulatory payment classification payment rates for the services with which the education and training are furnished.

See sections 3651 and 3661 of the Medicare Intermediary Manual for billable codes under the partial hospitalization program. ❖

Source: CMS Transmittal A-01-111, CR 1798

ELECTRONIC DATA INTERCHANGE

The Health Insurance Portability and Accountability Act - Administrative Simplification (HIPAA-AS)

The Health Insurance Portability and Accountability Act of 1996 (P.L. 104-191 known as HIPAA) includes provisions for Administrative Simplification, which directed the Secretary of Health and Human Services to adopt national standards for electronic transactions and for code sets to be used in those transactions. The Transaction and Code Set Final Rule, the first HIPAA Administrative Simplification provision, was published in the Federal Register on August 17, 2000.

As published in the Transaction and Code Set Final Rule, the Secretary of Health and Human Services has adopted standards for eight administrative transactions.

This correspondence highlights only those transactions applicable to Medicare Electronic Data Interchanges with us. ANSI ASC X12N Version 4010 was adopted as the single electronic standard format for Health Care Claims, Electronic Remittance, Electronic Eligibility and Electronic Claim Status.

Ultimately this will make electronic submission of claims and use of other transactions (Eligibility, Claim Status and Electronic Remittance) easier and more efficient to use because all health care payers are required to use the same electronic standards. **NOTE: This Act affects electronic exchange of health care data with any health plan, not just Medicare.**

TRANSACTION NUMBER	TRANSACTION DESCRIPTION
837	Health Care Claim
835	Health Care Claim Payment Advice
270/271	Health Care Eligibility Benefit Inquiry and Response
276/277	Health Care Claim Status Request and Response

How This Affects Providers

Once the HIPAA transaction standards are fully implemented, Medicare will no longer accept National Standard Format (NSF 6.0) or older versions of ANSI (3051 3A.01) for electronic claims submission. You need to consider what steps need to be taken to upgrade your software to conform to the new standards.

All non-HIPAA standard health care formats and versions will become obsolete no later than October 16, 2002, the legislatively defined deadline. Medicare A of Florida will begin accepting production claims in the ANSI ASC X12N 837 Version 4010 format on or about October 1, 2001, at which time *new* electronic submitters will be required to submit claims in this format.

What Providers Need To Do Now

Consider what steps you need to take to upgrade your software so it will conform to the new standards. This can be done either independently or through commercial vendors. You can also contract with a clearinghouse to translate your claim data into the ANSI ASC X12N 837 4010 format. Providers who contract with a clearinghouse for translation services are liable for these costs. Additionally, you will need to furnish them all data required by the ANSI ASC X12N 837 version 4010 Implementation Guide.

If you currently use a commercial vendor, talk to your vendor about when the upgraded software will be available for you and to determine what tests you may need to perform before you can submit your claims to the various health plans you interact with.

Where to Get Additional Information

Refer to the list of Web sites below for additional Administrative Simplification information.

WEB SITE ADDRESS	WHAT'S THERE
http://aspe.os.dhhs.gov/admnsimp	This is the Department of Health and Human Services Web site regarding information dealing with the Administrative Simplification provisions of HIPAA. A copy of the Transaction and Code Set Final Rule, Frequently Asked Questions, and information regarding other Administrative Simplification provisions can be obtained from this site.
http://www.wpc-edi.com/hipaa/	This is the Washington Publishing Company Web site. This site contains the HIPAA X12N Version 4010 Implementation guides.
http://www.wedi.org	This is the Workgroup for Electronic Data Interchange (WEDI) Web site.
http://www.wedi.org/snip/	SNIP is a sub-group of WEDI. Their mission is to develop a Strategic National Implementation Process to help ensure the successful implementation of the HIPAA requirements throughout the health care industry.
http://www.cms.hhs.gov	This is the Centers for Medicare & Medicaid Services Web site where one may find detailed information on the National Provider Identifier and PAYERID.
http://www.sharpworkgroup.com/	The Southern HIPAA Administrative Regional Process (SHARP) is established to meet the immediate need of assessing regional HIPAA Administrative Simplification implementation readiness to bring about regional coordination for successful HIPAA compliance by all stakeholders in the southern regional healthcare industry.

If you have any questions, please contact EDI Support at (904) 791-6865.

EDUCATIONAL RESOURCES

Introducing CMS

As of July 1, 2001, the Health Care Financing Administration (HCFA) is now the Centers for Medicare & Medicaid Services (CMS). It's more than just a new name - it's an increased emphasis on responsiveness to beneficiaries and providers, and quality improvement.

Health and Human Services Secretary Tommy G. Thompson made the announcement on June 14, 2001. "We're making quality service the number one priority in this agency," Thompson said. "These sweeping reforms will strengthen our programs and enable our dedicated employees to better serve Medicare and Medicaid beneficiaries, as well as health care providers. We're going to encourage innovation, better educate consumers about their options, and be more responsive to the health care needs of Americans."

Three new business centers are being established as a part of the reform: the Center for Beneficiary Choices, the Center for Medicare Management, and the Center for Medicaid and State Operations.

The new CMS will launch a national media campaign to educate seniors and other Medicare beneficiaries about their options, allowing them to make better decisions.

Beginning October 1, 2001, the Medicare 800 number (1-800-633-4227) is being enhanced to provide service to beneficiaries 24 hours a day, seven days a week.

"More changes are on the way," Secretary Thompson stated. "We're going to keep fine-tuning this department so Americans are receiving the highest quality health care possible."

Source: CMS Web site - http://www.cms.hhs.gov

The Ultimate Medicare Expo

Interactive Sessions Evoke Strong Emotion

The recent Ultimate Medicare Expo held in Jacksonville, Florida, incorporated many new offerings: the combination of beneficiaries and providers, entertainment, an empowerment session, physician speakers and interactive plays to illustrate areas of concern between the beneficiary and provider communities.

The plays, one each day of the expo, took the form of two acts: one to illustrate all the wrong things to do and one to illustrate the right things. After each act, the audience was invited to give comments.

On the first day, the play tackled the issue of advance beneficiary notices (ABNs). These notices are a source of contention between providers and beneficiaries because they have to do with responsibility of payment. If a generally covered service may not be reimbursed by Medicare, providers give one of these notices to a beneficiary to sign. This indicates the beneficiary will be responsible for payment. If a provider does not get a notice signed, he or she may be responsible for the payment. Naturally, no one wants this responsibility. This play, therefore, brought out strong emotions in both communities. Many of the comments had to do with communication. Beneficiaries felt that this process was not explained clearly, if at all. In most cases, they were asked to sign a document that appeared to take away some rights…with no explanation at all! Typical comments were "I'm not signing anything unless I know what it is", and "Somebody needs to explain why I need to sign this". Providers mentioned feeling overwhelmed with all they had to do and little time for explanations. There did not seem to be an easy solution for anyone but, clearly, better communication would be a big help.

The second day's play tackled the issue of Medicare Secondary Payer (MSP). MSP occurs when there is other insurance that can pay first, thereby making Medicare secondary. An example of such a situation is a Medicare-eligible beneficiary who works full time and is covered by a large group health plan. The problem arises in identifying those situations. Most comments resulting from this enactment asked for more communication from the other party. Beneficiaries felt providers should ask more questions such as "Has your insurance changed?" or give them a form to fill out. Providers felt that patients should take some responsibility to be forthcoming with information about themselves. Many voiced concern that patient information changed rapidly and it was too difficult being constantly asked about changes. Clearly, there needs to be better communication on both sides to make the system work for everyone.

The purpose of these plays was twofold: to bring an awareness of issues and concerns of both providers and beneficiaries to each other and to explore possible solutions. The beneficiaries and providers who attended the session definitely left with a better appreciation of the problems facing the other side and it seemed that both sides agreed that everyone needed to communicate more often and fully. If this is the case, we at First Coast Service Options, Inc. feel the effort put into the plays was worth it. We welcome your comments and suggestions regarding solutions to these issues, and whether you feel this format is an effective method of surfacing and solving those issues. Please fax or email comments to:

Gloria Steinberg
Senior Provider Relations Representative
First Coast Service Options, Inc.
Fax: 904-791-6035
E-mail: gloria.steinberg@fcso.com

Overview of HIPAA-AS Privacy Regulations

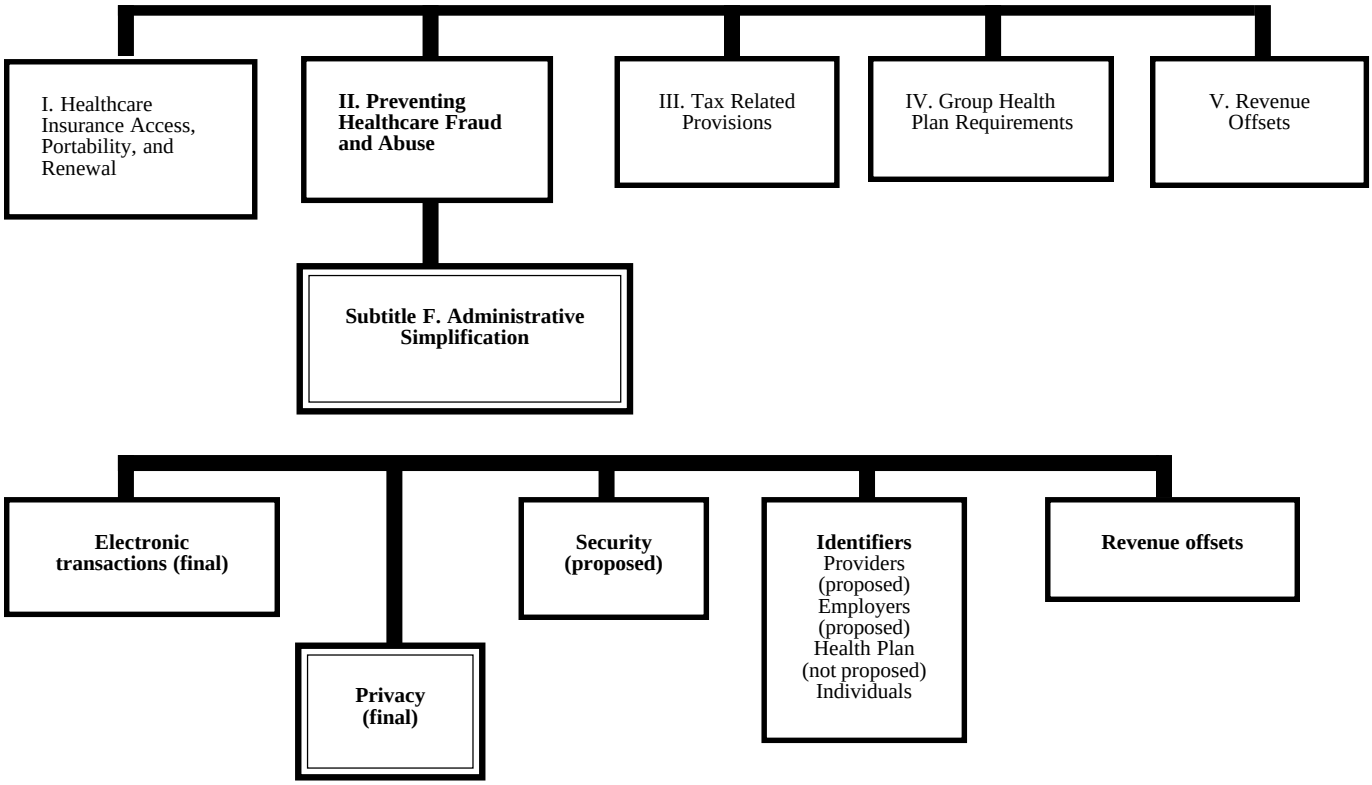
The Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191), also known as HIPAA, was enacted as part of a broad Congressional attempt at incremental healthcare reform. The Administrative Simplification (AS) aspect of that law requires the United States Department of Health and Human Services to develop standards and requirements for the maintenance and transmission of health care information that identifies, or may identify, individual patients.

The privacy regulations are located at 45 C.F.R. Part 164. The privacy regulations and other HIPAA information are available at: **aspe.hhs.gov/admnsimp/index.htm**.

The final privacy regulations were issued on December 28, 2000 (65 Federal Register 82, 462). The privacy regulations were ratified on April 14, 2001, and the compliance date for the privacy regulations is April 14, 2003, except for small health plans (under $5 million annual revenue), which have until April 14, 2004, to comply.

The AS portion of the law (subtitle F) has five parts: electronic transactions, privacy, security, identifiers, and enforcement (revenue offsets). These parts all deal with setting and enforcing guidelines for the electronic transmission, use, and disclosure of health information that identifies individual patients. The following chart illustrates (as of June, 2001), the location of the privacy portion in relation to the entire Act.

HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT CHART



Even before privacy considerations, there was a need for standardization of the electronic transmission of health care information as there are currently over 400 Electronic Data Interchange (EDI) formats. The cost of paperwork in healthcare is enormous. HIPAA is the nation's strategy to eliminate much of that paperwork and make processes more efficient, accurate, secure and patient service oriented. A by-product of these improvements should eventually be higher financial return.

The restructuring of electronic transactions was addressed in the first AS regulation. However, Congress recognized the fact that administrative simplification cannot succeed without protecting the privacy and confidentiality of personal health information. Because the provision of high quality health care requires the exchange of personal, often-sensitive information, the patient's ability to trust that the information shared will be protected and kept confidential is vital to the interaction. Evolving technology can be a great benefit to reducing costs and promoting efficiency, but unless public fears are allayed and more individuals have a level of comfort concerning privacy, the health care system will be unable to obtain the full benefits of electronic technologies.

In an effort to allay that fear, Congress enacted regulations to protect individual privacy in order to convince patients to entrust their personal information to technology systems. The HIPAA-AS privacy regulations outline those protections and are far-reaching: All health plans, all health care clearinghouses and health care providers who transmit Individually Identifiable Health Information (IIHI) electronically must comply. From the date of the ratification of the final rule on April 14, 2001, covered entities have 24 months to comply with the standards (until April 14, 2003). Small health plans have 36 months, until April 14, 2004. All health care participants stand to benefit from HIPAA through cost

reduction, error reduction, and service improvement. Although the initial cost will be high, the eventual benefits will far outweigh that investment. The savings over a ten-year period are estimated to be approximately $9 billion for health care providers and $26 billion for the national health system. The following are highlights of major changes that will affect covered entities.

HIPAA Consent Form:

The final rule states that a special consent form must be obtained by covered entities prior to disclosing Protected Health Information (PHI) for purposes of "Treatment, Payment or Operations" (TPO). A consent form must be in plain language, must be signed and dated by the patient, and must state:

- Your PHI may be disclosed to carry out TPO
- Additional information on the covered entity's privacy procedures is available from the entity's comprehensive *notice*, which the individual may review prior to providing consent.
- The individual has the right to request restriction of how PHI is used or disclosed, and the covered entity may agree or refuse said request.
- The individual has the right to revoke the consent in writing except to the extent that the covered entity has already acted on the consent.
- A consent may not be combined into a single document with the covered entity's comprehensive notice but may be combined with other types of written legal permissions if organizationally and separately signed and dated.
- A provider may make signing a consent a condition of treatment. A plan may make signing a consent form a condition of enrollment.

Authorization

For a use or disclosure of PHI for purposes other than for TPO, the individual (patient) must provide written authorization, except under special circumstances (e.g., authorization is generally required for the use of PHI for marketing purposes). An authorization must be written in plain language and contain at a minimum the following:

- A description of the information to be used or disclosed
- The name of the person or class of persons authorized to make the use or disclosure
- The name of the person, or class of persons, to whom the covered entity may make the requested use or disclosure
- An expiration date or expiration event (e.g., the date the research project ends)
- A statement in which the individual acknowledges that he or she understands his or her right to revoke the authorization in writing, and how revocation may be accomplished
- A statement that the information used or disclosed may be subject to re-disclosure by the recipient and may no longer be protected by HIPAA
- Signature and date.
- If the authorization is executed by a personal representative, a description of his or her authority to act on behalf of the individual or his or her relationship to the individual.

Note: Signing an authorization may not be a condition of treatment.

> *Minimum Disclosure Rule: When using or disclosing PHI, or when requesting PHI from another covered entity, a covered entity must make "reasonable efforts to limit PHI to the minimum necessary to accomplish the intended purpose." This means that the entity must identify the persons and classes of its workforce who need access to specific categories of PHI.*

Business Associates

A "business associate" is defined as a person who, *on behalf of* a covered entity or Organized Healthcare Arrangement (OHCA) in which the covered entity participates, performs or assists in performing a function or activity involving the use of or disclosure of IIHI. A covered entity may disclose PHI to a "business associate", and may allow the business associate to create or receive PHI if the covered entity obtains "satisfactory assurance" the business associate will safeguard the information appropriately. This assurance needs to take the form of a written contract, called a "business associate agreement," between the covered entity and its business associates

Notice of Individual Rights (referred to in consent form)

The notice must be written in plain language under the following header:

> **THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.**

The body of the notice must contain:

- A detailed description and one example of each of the permitted uses and disclosures of PHI under the HIPAA privacy regulations for purposes of TPO
- A statement that all other uses and disclosures will be made with the individual's written, revocable authorization
- A separate statement if the covered entity intends to engage in certain alternative activities (such as appointment reminders)
- A brief description of the individual's rights to: request restrictions on uses and disclosures of PHI for TPO, to receive confidential communications of PHI by alternative means and/or alternative locations, to inspect, copy and/or amend PHI, to receive an accounting of disclosures of PHI, to obtain a paper copy of this notice if notice is given electronically

- A statement that the covered entity is required to:
  - Maintain the privacy of PHI
  - Provide this notice and abide by the terms of the notice currently in effect

A provider that has a "direct treatment relationship" (i.e., not based on orders provided by another provider) must provide this notice no later than the date of the first service delivery after the compliance date (April 14, 2003). For a provider that maintains a physical delivery site, copies of the notice must be available for the individuals to take with them. In addition, the notice must be posted in a clear and prominent location.

Elements of Compliance

Although there is no official list or document outlining a compliance program, the following requirements are listed under: 45 C.F.R. 154.530.

- *Privacy official:* A covered entity must designate a privacy official responsible for the development and implementation of privacy policies and procedures.
- *Complaints:* A covered entity must have in place a process for individuals to make complaints concerning the covered entity's privacy policies and procedures.
- *Contact person for complaints:* A covered entity must designate a contact person or office to receive complaints and receive further information about matters covered by the notice.
- *Training:* A covered entity must train all workforce members no later than the covered entity's HIPAA compliance date.
- *Safeguards:* A covered entity must have in place appropriate administrative, technical and physical safeguards to protect the privacy of PHI.
- *Sanctions:* A covered entity must have and apply appropriate sanctions to members of the workforce who violate the entity's privacy policies and procedures, except for the whistleblowers and crime.
- *Mitigation:* A covered entity must mitigate "to the extent practicable", any harmful effect known to the entity of an inappropriate use or disclosure of PHI.
- *Intimidating or retaliatory acts:* A covered entity may not engage in any intimidating or retaliatory acts against any individual for exercising any right under HIPAA or participating in a compliance review, proceeding or hearing.
- *Waiver of rights:* A covered entity must not require an individual to waive any HIPAA right as a condition of receiving treatment, payment, enrollment or eligibility.
- *Policies and procedures:* A covered entity must develop and implement policies and procedures to comply with the HIPAA privacy regulations.
- *Documentation:* A covered entity must maintain its policies and procedures and any required communications, actions, activities or designations in written or electronic form for 6 years from the date of creation, or last effective date whichever is later.

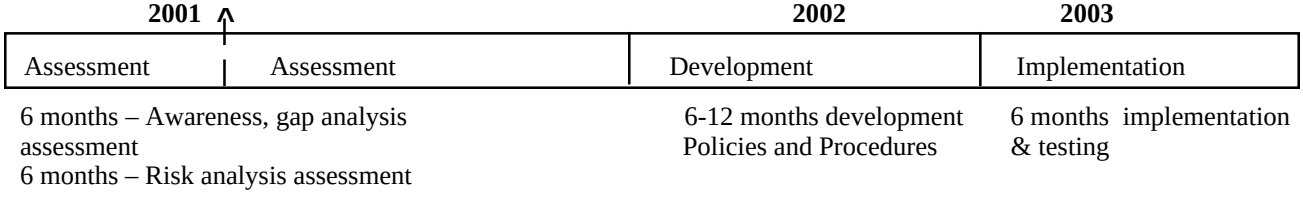
Penalties

DHHS may impose penalties on covered entities for non-compliance to the privacy rules, as follows:

- Civil: Up to $100 per person per violation, and up to $25,000 per person per violation for a calendar year
- Criminal:
  - For knowing misuse of health identifiers or individually health identifiable information, a fine shall be imposed of up to $50,000 and/or imprisonment for up to one year
  - If the above mentioned offense is committed under "false pretenses," the fine may be up to $100,000 and/or imprisonment of up to five years.
  - If the above mentioned offense is committed with the intent to sell, transfer or use IIHI for commercial advantage, personal gain or malicious harm, the fine may be up to $250,000 and/or imprisonment of up to ten years.

Preparation

In conclusion, privacy compliance will be a large task, involving administrative operations from document storage to medical procedures to customer service. The timeline is short for such a complicated task, but it can be accomplished if organized and taken in steps. Here is a suggested timeline and an outline of logical steps to take to achieve compliance by April 14, 2003.



FREE!
INPATIENT REHABILITATION FACILITY PROSPECTIVE PAYMENT SYSTEM (IRF/PPS) SEMINAR

Presented by First Coast Service Options, Inc.
Your Florida Medicare Contractor

Why Attend This Seminar?

☑ You'll receive a comprehensive overview of the *NEW* IRF/PPS guidelines. Topics will include: Patient Assessment Instrument, Case Mix Group classifications, co-morbidity codes and their affect on payment rates.

☑ You'll learn how to correctly submit IRF claims to prevent rejects or denials.

Seminar dates and locations (CHECK ONE)

Jacksonville **November 26, 2001, First Coast Service Options, Inc., 532 Riverside Ave.**

☐ 9:00 a.m. – 11:30 a.m. **OR** ☐ 1:00 p.m. – 3:30 p.m.

Miami **November 27, 2001, Hilton Miami Airport, 5101 Blue Lagoon Drive**

☐ 9:00 a.m. – 11:30 a.m.

OR

Ft. Lauderdale **November 27, 2001, Hilton Hotel, 1870 Griffin Road, Dania, FL**

☐ 1:30 p.m. – 4:00 p.m.

Orlando **November 28, 2001, Florida Hospital Assoc., 307 Park Lake Circle**

☐ 9:00 a.m. – 11:30 a.m. **OR** ☐ 1:00 p.m.– 3:30 p.m.

Registrant's Name: _____

Provider's Name: _____

Medicare Billing Provider/Group Number: _____

Address: _____

City, State, Zip Code _____

Phone Number: ( ) _____ **Fax: ( )** _____

E-mail: _____

Fax completed form to (904) 791-6035, attention: Michelle Jackson

UPCOMING 2001 MEDICARE PART A EVENTS

Presented by First Coast Service Options, Inc.
Your Florida Medicare Contractor

Provider Education & Training Advisory Meeting

December 7, 2001

Time: 9:00 a.m. to 12 noon

Place: First Coast Service Options, Inc.
532 Riverside Ave.
Jacksonville, FL

The Medicare Education and Outreach team is happy to announce the first PET Advisory Council Meeting for Fiscal Year 2002.

The PET Advisory Group is a panel of representatives from state medical societies, provider offices, billing organizations and consulting firms that meets every quarter to:

- Review new and existing Medicare education programs
- Recommend changes to these programs
- Alert Medicare to problems or concerns affecting providers
- Network with other professionals interested in Medicare
- Disseminate information from the advisory group to the organizations represented

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Teleconference

Date: December 11, 2001

Time: 12:15 p.m. to 1:45 p.m. (eastern standard time)

Description: One hour presentation to include Hot Topics and Changes for 2002, and a thirty-minute question and answer period. This session is conducted during the primary lunch hour to maximize the number of participants and use of your time.

Please see www.floridamedicare.com for more details.

ORDER FORM - PART A MATERIALS

The following materials are available for purchase. To order, 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
_____	***Medicare A Bulletin* Subscriptions** - One subscription of the Medicare A Bulletin is sent free of charge to all providers with an active status with the Medicare Part A program. Non-providers (e.g., billing agencies, consultants, software vendors, etc.) or providers who need additional copies at other office facility locations may purchase an annual subscription. This subscription includes all Medicare bulletins published during calendar year 2002 (back issues sent upon receipt of the order). Please check here if this will be a: [ ] Subscription Renewal or [ ] New Subscription	756134	$75.00

Subtotal $ _____

Tax **(7.0%)** $ _____

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:_____

Please make check/money order payable to: BCBSFL- FCSO Account #756134

(CHECKS MADE TO "PURCHASE ORDERS" NOT ACCEPTED)

ALL ORDERS MUST BE PREPAID -

DO NOT FAX - PLEASE PRINT

NOTE: *The Medicare A Bulletin is available* ***free of charge*** *online at www.FloridaMedicare.com.*

A

B

C

C (continued)

D

E

F

F (continued)

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P

P (continued)

R

R (continued)

S

T

U

V

W

Y

Procedure Codes

CPT Codes

Anesthesia/Surgery, 00100-69979

Diagnostic Tests, 70010-89399

Diagnostic Tests, 70010-89399 (continued)

Medicine, 90281-99199

Medicine, 90281-99199 (continued)

HCPCS Codes

HCPCS Codes (continued)

Special *Bulletins*

* This special issue is available only on the provider Web site ***www.floridamedicare.com***

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

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

FRAUD AND ABUSE

Medicare Anti-fraud Branch
P. O. Box 45087
Jacksonville, FL 32231
(904) 355-8899

REVIEW REQUEST

Denied claims that may have been payable under the Medicare Part A program
Medicare Part A Reconsiderations
P. O. Box 45053
Jacksonville, FL 32232

OVERPAYMENT COLLECTIONS

Repayment Plans for Part A Participating Providers
Cost Reports (original and amended)
Receipts and Acceptances
Tentative Settlement Determinations
Provider Statistical and Reimbursement (PS&R) Reports
Cost Report Settlement (payments due to provider or Program)
Interim Rate Determinations
TEFRA Target Limit and Skilled Nursing Facility Routine Cost Limit Exceptions
Freedom of Information Act Requests (relative to cost reports and audits)
Provider Audit and Reimbursement Department (PARD)
P.O. Box 45268
Jacksonville, FL 32232-5268
(904) 791-8430

Phone Numbers

PROVIDERS

Customer Service Representatives:
1-877-602-8816

BENEFICIARY

1-800-333-7586

ELECTRONIC MEDIA CLAIMS

EMC Start-Up:
904-791-8767

Electronic Eligibility
904-791-8131

Electronic Remittance Advice
904-791-6865

Direct Data Entry (DDE) Support:
904-791-8131

PC-ACE Support
904-355-0313

Testing:
904-791-6865

Help Desk (Confirmation/ Transmission)
904-905-8880

Medicare Web sites

PROVIDERS

Florida Medicare Contractor
www.floridamedicare.com
Centers for Medicare & Medicaid Services
www.hcfa.gov

BENEFICIARIES

Florida Medicare Contractor
www.medicarefla.com
Centers for Medicare & Medicaid Services
www.medicare.gov

MEDICARE A BULLETIN

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