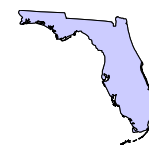


Medicare B Update!

A Newsletter for Florida Medicare Part B Providers



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Also...

HCFA Is Now CMS!

The Health Care Financing Administration is now the Centers for Medicare & Medicaid Services. For more information, see page 85.

Choose to Participate for 2002

The annual participation enrollment is now underway. For more information, see page 77.

The Medicare B Update! should be shared with all health care practitioners and managerial members of the provider/supplier staff. Issues published beginning in 1997 are available at no cost from our provider Web site, www.floridamedicare.com.

- Physician/Provider
- Office Manager
- Billing/Vendor
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- Other _____

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



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

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A PHYSICIAN'S FOCUS

"Be Hip With HIPAA"

If you have to ask, "What in the world is HIPAA?" then you're really behind the power curve. Congress passed the Health Insurance Portability and Accountability Act (HIPAA), in 1996. The two goals of this legislation are health insurance reform and administrative simplification.

Currently physicians have to use a different claim form for each patient with a different insurance company. This can often require the physician's office to manage multiple software programs in order to submit electronic claims. HIPAA will require all insurance companies to eventually adopt a single set of standards for electronic claims. Once the standards are adopted, physicians will be able to submit claims in the same standard format to any health plan. It is estimated that standardizing this form will eventually save the national health system 26 billion dollars. All health plans and physicians who submit or receive private health information electronically will be covered by the Act.



In addition to the new electronic data requirements, there are also extensive privacy issues that need to be implemented by all physicians who come under HIPAA. Physicians will be required to obtain an initial consent from all patients prior to using or disclosing Private Health Information (PHI). The definition of PHI is individually identifiable health information transmitted or maintained by the physician in any form. The basic patient consent will allow the physician to use the PHI for treatment, payment or health operations.. In other words, to care for the patient's medical needs. A good Web site for additional HIPAA information is <http://aspe.hhs.gov/admsimp/>. Releases concerning future changes will be posted on this site as they develop.

If you haven't already started the process to comply with HIPAA, you need to do so promptly. A more detailed article on the electronic claims requirements of HIPAA appeared in the November/December 1999 issue of the Florida *Medicare B Update!* (page 40). Other articles published in the *Update!* may be found in the 1st Quarter 2001 issue (page 82), the 3rd Quarter 2001 issue (page 79), and the 4th Quarter 2001 issue (page 74). Up to the minute information may be found on page 86 of this issue.

As with many things worthwhile, there will be difficulties implementing HIPAA. The sooner you start the journey, the sooner you will reap the benefits. Good luck.

Sincerely,

Sidney R. Sewell, MD
Medical Director

ADMINISTRATIVE

About the *Medicare B Update!*

The *Medicare B Update!* is a comprehensive magazine published quarterly for all Part B providers in the State of Florida. In accordance with notification requirements established by the Centers for Medicare & Medicare Services, 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, 2002
Third Quarter 2002	Mid-May 2002	July, 2002
Fourth Quarter 2002	Mid-August 2002	October 2002

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

Who Receives the *Update!*?

Distribution of the *Update!* is limited to individual providers and Professional Association (PA) groups who bill at least one Part B claim to Florida Medicare for processing during the twelve months prior to the release of each issue. Providers meeting these criteria are sent one complimentary copy of that issue. Production, distribution, and postage costs prohibit us from distributing copies to *all* practice settings. This primarily affects members of PA groups; one copy of each issue is sent to the group. The group is responsible for dissemination of each copy to its members. For additional copies, providers may purchase a separate annual subscription for \$75 (order form on page 90). Issues published since January 1997 may be downloaded from our Web site, free of charge.

Medicare Part B of Florida uses the same mailing address for *all* correspondence, and cannot designate that each issue of the *Update!* be sent to a specific person/department within a provider's office. To ensure continued receipt of all Medicare correspondence, providers must keep their addresses current with the Medicare Provider Registration Department.

What is in the *Update!*?

The *Update!* is divided into several sections, starting with a letter from the **Carrier Medical Director**. Following is **Administrative** information, then **Claims**, which provides claims submission requirements and tips. Correspondence (appeals and hearings) information is in

this section. **Coverage/Reimbursement** discusses *CPT* and *HCPCS* procedure codes. It is arranged by specialty *categories* (not *Specialties*). For example, "Mental Health" presents coverage information of interest to psychiatrists, clinical psychologists and clinical social workers, rather than listing articles separately under individual provider specialties. Also presented in this section are changes to the Medicare Physician Fee Schedule, and other pricing issues. **Local and Focused Medical Review Policies** follows, then **Electronic Media Claims**, and **General Information**, which includes **Fraud and Abuse**, **Medicare Registration**, and **Medicare Secondary Payer** topics, and more. **Educational Resources** provides seminar schedules and reproducible forms. **Important Addresses, Phone Numbers**, and **Web sites** are listed on the inside back cover.

The *Medicare B Update!* Represents Formal Notice of Coverage Policies

Articles included in each *Update!* represent formal notice that specific coverage policies either 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. Florida Medicare maintains copies of 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.

Advance Beneficiary Notice

The following information applies to all articles in this publication referencing services that must meet medical necessity requirements (e.g., services with specific diagnosis requirements). Refer to this information for articles that indicate advance notice applies.

Medicare Part B allows coverage for services and items deemed medically reasonable and necessary for the treatment/diagnosis of the patient. For some services, to ensure that payment is made only for medically necessary services or items, coverage may be limited based on one or more of the following factors (this list is not inclusive):

- Coverage for a service or item may be allowed only for specific diagnoses/conditions. Always code to the highest level of specificity.
- Coverage for a service or item may be allowed only when documentation supports the medical need for the service or item.
- Coverage for a service or item may be allowed only when its frequency is within the accepted standards of medical practice (utilization screen - i.e., a specified number of services in a specified timeframe for which the service may be covered).

If the provider believes that the service or item may not be covered as medically reasonable and necessary, the patient must be given an acceptable advance notice of Medicare's possible denial of payment if the provider does not want to accept financial responsibility for the service or item. The advance beneficiary notice (ABN) must meet the following requirements:

- The ABN must be given in writing, in advance of furnishing the service or item.
- The ABN must include the patient's name, date(s) and description of the service or item, and the reason(s) why the service or item may not be considered medically reasonable and necessary (e.g., the service is not covered based on the diagnosis of the patient, the frequency of the service was furnished in excess of the utilization screen, etc.).
- The notice must be signed and dated by the patient indicating that the patient assumes financial responsibility for the service if payment is denied as being not medically reasonable and necessary for the reason(s) indicated on the advance notice. The signature of the provider of service is not required.

When a patient is notified in advance that a service or item may be denied as not medically necessary, the provider must annotate this information on the claim (for both paper and electronic claims) by reporting procedure code modifier GA with the service or item. The ABN form should be maintained with the patient's medical record.

Failure to report modifier GA in cases where an appropriate advance notice was given to the patient may result in the provider having to assume financial responsibility for the denied service or item.

CLAIMS

Correct Coding Initiative

Version 8.0 of the Correct Coding Initiative (CCI) will be implemented January 1, 2002. Version 8.0 includes all previous versions and updates from January 1996 to the present.

The U.S. Department of Commerce, National Technical Information Service (NTIS) has developed a national correct coding policy manual to assist physicians in correctly coding services for reimbursement. Medicare carriers are prohibited from publishing specific correct coding edits. Concerns about correct coding edit pairs must be submitted in writing to:

The Correct Coding Initiative
AdminaStar Federal
P. O Box 50469
Indianapolis, IN 46250-0469

Information related to CCI may be obtained by ordering a national correct coding policy manual from NTIS.

- Single issues of the national correct coding policy manual may be requested by calling (703) 605-6000.
- Subscriptions to the national correct coding policy may be requested by calling (703) 605-6060 or (800) 363-2068.
- To receive information from NTIS by mail, call (800) 553-6847.
- Ordering and product information is also available on the Internet at www.ntis.gov/product/correct-coding.htm.

As a reminder, Florida Medicare is not liable for information provided and/or published by AdminaStar Federal and/or NTIS.

Source: CMS Transmittal B-01-55, CR 1833

Billing for Teaching Physician Services

Teaching physicians who involve residents in providing care to their patients and seek payment for their physician services must comply with the policy governing teaching physicians contained in section 15016 of the Medicare Carriers Manual (MCM). Effective January 1, 1997, services rendered by the teaching physicians involving a resident in the care of their patients must be identified when submitting the claim on Form HCFA-1500.

A. Teaching Physician Services That Meet the Requirement for Presence During the Key Portion of the Service: In item 24d of Form HCFA-1500, the GC modifier must be entered by the physician for teaching physician services rendered in compliance with all the requirements outlined in MCM section 15016. Providers who bill for teaching physician services are certifying by the use of this modifier that they have been present during the key portion of the service, and were immediately available during the other parts of the service.

B. Teaching Physician Services Under the Exception to the Requirement for Presence During the Key Portion of the Service: Certain teaching physicians are allowed an exception to the requirements outlined in MCM section 15016. The exception is for the requirement the teaching physician is present during the key portion of the service.

Teaching physicians who meet the requirements outlined for the exception to this policy in MCM section 15016 must provide their local carrier with an attestation that they meet those requirements.

Teaching physician services being billed under the exception to the policy governing presence during the key portion of the service must be identified when submitting the Part B bill for physician services. In Item 24d of Form HCFA-1500, enter the GE modifier for all teaching physicians services rendered under the policy exception requiring presence of the teaching physician during the key portion of the service.

Source: CMS Transmittal 1723, CR 1825

Billing for Procedure Codes with “Each” or “Each Additional” in Their Descriptors

Florida Medicare has noted discrepancies in the way providers are billing for services containing “each” or “each additional” in their descriptors. Some providers are billing these services using the number billed field; some are coding the additional services on a second line with modifier 76 (repeat procedure).

When a code descriptor contains the phrases “each,” “each additional,” or “each antibody,” the most appropriate way to bill these services is to indicate the correct number of services in the “days or units” field (field 24G of Form HCFA-1500, or electronic equivalent).

A notable example of such a service is CPT code 88312 [*special stains (list separately in addition to code for surgical pathology examination); group I for microorganisms (e.g., gridley, acid fast, methenamine silver), each*].

EXCEPTION: purchased diagnostic tests must be billed on separate claims, because a separate acquisition cost must be reported for each purchased test. Purchased diagnostic tests must be identified with modifier WU; additional purchased tests must also be billed with modifier 76.

In all other circumstances, billing additional lines for the same procedure code with modifier 76 may result in denials. Services for the same procedure billed on separate lines *without* modifier 76 will be denied as duplicates.

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Revised Guidelines for Processing Claims for Clinical Trial Routine Care Services

This article provides revised diagnosis reporting requirements for routine care clinical trial services billed on Form HCFA-1500 (or electronic claim equivalent) for services furnished on or after January 1, 2002. For services furnished on or between October 19, 2000 and December 31, 2001, continue to use the instructions published in the 1st Quarter 2001 *Medicare B Update!* (pages 6-7).

Effective for services furnished on or after January 1, 2002, providers are to use procedure code modifier QV to identify and report routine care for Medicare qualifying clinical trial services. The reporting of diagnosis code V70.5 as a secondary diagnosis on Form HCFA-1500 or the electronic claim equivalent will no longer be required for dates of service on or after January 1, 2002. For dates of service on or after January 1, 2002, the QV modifier constitutes the biller’s attestation that a service, supply, or equipment meets the Medicare qualifying coverage criteria for clinical trial services processed by carriers and DMERCs.

Exception for Healthy Control Group Volunteers

Routine care clinical trial services furnished on or after January 1, 2002 to healthy, control group volunteers participating in Medicare qualifying diagnostic clinical trials are to be coded and billed in the following manner:

- The QV modifier is reported at the line item level.
- Diagnosis code V70.7 (Examination of participant in clinical trial) is reported as the primary diagnosis for applicable line items on the Form HCFA-1500 or electronic claim equivalent.

If diagnosis code V70.7 is reported as a secondary rather than the primary diagnosis, the service is not considered as having been furnished to a healthy, control group, diagnostic trial volunteer.

Medical Documentation Requirements

Providers *do not* have to submit the trial name, sponsor, and sponsor-assigned control number with claims for routine items and services furnished in qualifying clinical trials. However, they must have this information in the beneficiaries’ medical records, and furnish the information to the carrier if requested for medical review activities.

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

COVERAGE/REIMBURSEMENT

MEDICARE PHYSICIAN FEE SCHEDULE

Allowance for Procedure Code 62311—Correction

The allowances for CPT code 62311 were updated effective July 1, 2001, in conjunction with the second update to the Medicare Physician Fee Schedule Database. The revised allowances were published in the June 2001 *Special Issue Medicare B Update!* (page 4). However, the allowances for localities 03 and 04 were inadvertently transposed. The correct allowances are as follows:

PAR			NONPAR			Limiting Charge		
Loc 01/02	Loc 03	Loc 04	Loc 01/02	Loc 03	Loc 04	Loc 01/02	Loc 03	Loc 04
203.60	217.83	227.31	193.42	206.94	215.94	222.43	237.98	248.34
76.43	80.59	84.43	72.61	76.56	80.21	83.50	88.04	92.24 *

* these amounts apply when performed in a facility setting

New Modifiers and Coding for Non-Covered Services and Services Not Reasonable and Necessary

This information supercedes all information found in CR 1371, Transmittal B-01-30, "Deletion of the HCFA Common Procedure Coding System (HCPCS) Codes A9160, A9170, and A9190 and the GX Modifier and Replacement with New Codes and Modifiers; Status Change to HCPCS Code A9270," that was published in the 4th Quarter 2001 Medicare B Update! (pages 14-15).

This article provides an explanation regarding the use of the new GY and GZ modifiers. These modifiers were developed to allow practitioners and suppliers to bill Medicare for items and services that are statutorily non-covered or do not meet the definition of a Medicare benefit and items and services not considered reasonable and necessary by Medicare. It also provides an explanation on the use of the GA modifier. The new modifiers will become effective for services provided on or after January 1, 2002, with the annual HCPCS update. The Q3015 and Q3016 described in CR 1371 will not be implemented.

Discontinued Codes/Modifier

A9160	Non-covered service by podiatrist
A9170	Non-covered service by chiropractor
A9190	Personal comfort item, (non-covered by Medicare statute)
GX	Service not covered by Medicare

New Modifiers

GY	Item or service statutorily excluded or does not meet the definition of any Medicare benefit.
GZ	Item or service expected to be denied as not reasonable and necessary.

Clarification on Use of A9270

HCPCS code A9270 (Non-covered item or service) will remain an active code and valid for Medicare, however a processing note will be added to the HCPCS file that states, **"Only for use on bills submitted by DMEPOS suppliers." HCPCS code A9270 will no longer be accepted for practitioner services billed to carriers.**

Use of the GY, GZ and GA Modifiers for Services Billed to Carriers

The new **GY** modifier must be used when practitioners want to indicate the item or service is statutorily non-covered (as defined in the Program Integrity Manual (PIM) Chapter 1, section 2.3.3.B) or is not a Medicare benefit (as defined in the PIM, Chapter 1, section 2.3.3.A).

The new **GZ** modifier must be used when practitioners want to indicate they expect that Medicare will deny an item or service as not reasonable and necessary and they **have not** had an advance beneficiary notice (ABN) signed by the beneficiary.

The **GA** modifier must be used when practitioners want to indicate they expect that Medicare will deny a service as not reasonable and necessary and they **do have** on file an ABN signed by the beneficiary.

The GY and GZ modifiers should be used with the specific, appropriate HCPCS code when one is available. In cases where there is no specific procedure code to describe services, a "Not Otherwise Classified code" (NOC) must be used with either the GY or GZ modifier.

If the GZ and GA modifiers are submitted for the same item or service, the item or service will be treated as having an invalid modifier and therefore will be returned as unprocessable.

Use of the GY, GZ and GA Modifiers for Items and Supplies Billed to Durable Medical Equipment Regional Carriers (DMERCs)

*This section applies **only** to items or supplies processed by the DMERC, and is published here solely as a convenience to suppliers who bill such services. Physicians **may not** use code A9270 to bill the local carrier.*

The new **GY** modifier must be used when suppliers want to indicate that the item or supply is statutorily non-covered (as defined in the PIM, Chapter 1, section 2.3.3.B) or is not a Medicare benefit (as defined in the PIM, Chapter 1, section 2.3.3.A).

The new **GZ** modifier must be used when suppliers want to indicate that they expect that Medicare will deny an item or supply as not reasonable and necessary and they **have not** had an ABN signed by the beneficiary.

The **GA** modifier must be used when suppliers want to indicate that they expect that Medicare will deny an item or supply as not reasonable and necessary and they **do have** on file an ABN signed by the beneficiary.

The **GY** and **GZ** modifiers should be used with the specific, appropriate HCPCS code when one is available. In cases where there is no specific procedure code to describe items or supplies, a NOC must be used with either the **GY** or **GZ** modifiers.

If the **GZ** and **GA** modifiers are submitted for the same item or service, the item or service will be treated as having an invalid modifier and therefore will be denied as unprocessable.

In cases where there is no specific procedure code for an item or supply and no appropriate NOC code is available, HCPCS code A9270 must be used by suppliers to bill for statutorily non-covered items and items that do not meet the definition of a Medicare benefit.

Explanatory Information to Be Included on Claims

Anytime a NOC code is used, providers and suppliers must include a description of the services or items provided. This information must be entered in item 19 on the Form HCFA-1500 or submitted as an attachment. For electronic claims, providers and suppliers must report this information in the claims level note.

Local Medical Review Policy

As a result of these changes, Florida Medicare is revising its local medical review policy (LMRP) "A9270: The List of Medicare Noncovered Services." The revised policy will be posted to our provider Web site, www.floridamedicare.com, and will be published in a future issue of the *Medicare B Update!*

Source: CMS Transmittal B-01-58, CR 1820

ALLERGY

Allergen Immunotherapy Doses

The local medical review policy (LMRP) for Allergen Immunotherapy was published in the 2nd Quarter 2001 *Medicare B Update!* (pages 96-97). A revision to that LMRP may be found on pages 75 of this issue. In addition, section 15050 of the Medicare Carriers Manual has been revised to clarify national Medicare policy regarding payment for doses of antigen. Florida Medicare's LMRP for Allergen Immunotherapy will be revised to reflect this clarification. The revised LMRP incorporating all of these changes will be published in a future issue of the *Update!*

CPT code 95165 represents preparation of vials of non-venom antigens. As in the case of venoms, some non-venom antigens cannot be mixed together, i.e., they must be prepared in separate vials. An example of this is mold and pollen. Therefore, some patients will be injected at one time from one vial - containing in one mixture all of the appropriate antigens - while other patients will be injected at one time from more than one vial. In establishing the practice expense component for mixing a multidose vial of antigens, The Centers for Medicare & Medicaid Services (CMS) observed the most common practice was to prepare a 10cc vial; CMS also observed the most common use was to remove aliquots with a volume of 1cc. Medicare practice expense (PE) computations were based on those facts. Therefore, a physician's removal of ten 1cc aliquot doses captures the entire PE component for the service.

This does not mean the physician must remove 1cc aliquot doses from a multidose vial. It means the practice expenses payable for preparation of a 10cc vial remain the same irrespective of the size or number of aliquots removed from the vial. Therefore, a physician may not

bill code 95165 for more than ten doses per vial; paying for more than ten doses per multidose vial would significantly overpay the practice expense component attributable to this service. (Note that this code does not include the injection of antigen(s); injections of antigen(s) is separately billable.)

When a multidose vial contains less than 10cc, physicians should bill Medicare for the number of 1cc aliquots that may be removed from the vial. That is, a physician may bill Medicare up to a maximum of ten doses per multidose vial, but should bill Medicare for fewer than ten doses per vial when there is less than 10cc in the vial.

If it is medically necessary, physicians may bill Medicare for preparation of more than one multidose vial.

Examples

1. If a 10cc multidose vial is filled to 6cc with antigen, the physician may bill Medicare for six doses since six 1cc aliquots may be removed from the vial.
2. If a 5cc multidose vial is filled completely, the physician may bill Medicare for five doses for this vial.
3. If a physician removes ½cc aliquots from a 10cc multidose vial for a total of 20 doses from one vial, he/she may only bill Medicare for ten doses. Billing for more than ten doses would mean that Medicare is overpaying for the practice expense of making the vial.
4. If a physician prepares two 10cc multidose vials, he/she may bill Medicare for 20 doses. However, he/she may remove aliquots of any amount from those vials. For example, the physician may remove ½cc aliquots from one vial, and 1cc aliquots from the other vial, but may bill no more than a total of 20 doses.

5. If a physician prepares a 20cc multidose vial, he/she may bill Medicare for 20 doses, since the practice expense is calculated based on the physician's removing 1cc aliquots from a vial. If a physician removes 2cc aliquots from this vial, thus getting only ten doses, he/she may nonetheless bill Medicare for 20 doses because the PE for 20 doses reflects the actual practice expense of preparing the vial.

6. If a physician prepares a 5cc multidose vial, he/she may bill Medicare for five doses, based on the way the practice expense component is calculated. However, if the physician removes ten ½cc aliquots from the vial, he/she may still bill only five doses because the practice expense of preparing the vial is the same, without regard to the number of additional doses that are removed from the vial.

Source: CMS Transmittal 1725, CR 1756

DIAGNOSTIC TESTS

ICD-9-CM Coding for Diagnostic Tests

The following clarifies reporting of the International Classification of Diseases, 9th 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 and 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 (CMS) agrees with this guideline.

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. 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 the 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, 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 Carriers Manual, an “order” is a communication from the treating physician/practitioner requesting that a diagnostic test be performed for a 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

Unrelated and co-existing conditions/diagnoses may be reported as additional diagnoses by the physician interpreting the diagnostic test.

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 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 the 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 the 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 the primary ICD-9-CM diagnosis code. The results of the test, 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 that address 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 the ordering of 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 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 the patient has diabetic complications or 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. One should be guided by the code book.

For the latest ICD-9-CM coding guidelines, please refer to the following Web site: <http://www.cdc.gov/nchs/datawh/ftp/ftp9/ftp9.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 Qtr 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?

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

DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES

Change in Jurisdiction for Pessary Codes

Effective for dates of service on or after January 1, 2002, jurisdiction for processing claims for the following codes will change from the durable medical equipment regional carriers (DMERCs) to the local carriers:

A4561 Pessary, rubber, any type
A4562 Pessary, non rubber, any type

Source: CMS Transmittal B-01-53, CR 1788

Useful Lifetime Expectancy for Breast Prosthesis

Note: The information below applies only to services processed by Durable Medicare Equipment Regional Carriers (DMERCs) and Intermediaries, and is published here only as a convenience to our providers.

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, DMERCs have been allowed to determine the reasonable lifetime of breast prostheses but in no case could it be less than five years.

New 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. This program instruction lowers the useful lifetime expectancy for silicone breast prostheses to two years, the most common warranty period provided by manufacturers. For fabric, foam, or fiber filled breast prostheses, the useful lifetime expectancy is being lowered to six months. However, a

breast prosthesis can be replaced at any time if it is lost, irreparably damaged (this does not include 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 should document this by submitting 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 rendered on or after April 1, 2002.

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

EVALUATION AND MANAGEMENT SERVICES

Visits to Patients Residing in Various Places of Service—Clarification

An article was published in the 4th Quarter 2001 *Medicare B Update!* (pages 13-14) concerning the appropriate codes to use when billing for visits to patients residing in various places of service. Since then, the Centers for Medicare & Medicaid Services has provided clarification regarding the appropriate use of places of service (POS) 31 (Skilled Nursing Facility [SNF]) and 32 (Nursing Home/Nursing Facility) for procedure codes 99311-99313 and 99315-99316. The nursing facility codes should be used with POS 31 if the patient is in a

Part A SNF stay, and POS 32 if the patient *does not* have Part A SNF benefits.

In addition, a discrepancy has been noted in the table provided with the previous article. The *text* in the article is accurate; however, the table contained a duplicate reference to POS 32. The valid places of service for CPT codes 99311-99313 are 31, 32, 54, and 56. Florida Medicare apologizes for any inconvenience this error may have caused.

Source: CMS Transmittal 1725, CR 1756

END STAGE RENAL DISEASE/DIALYSIS

Coverage of Non-Invasive 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 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 non-invasive vascular studies such as duplex and Doppler flow scans and billing separately for these procedures. Non-invasive vascular studies are not covered as a separately billable service if used to monitor a patient's vascular access site. Medicare pays for the procedure's technical component 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 a patient's access site with a non-invasive 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 non-invasive 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 the clinical course of treatment for the patient.

The only *Current Procedural Terminology (CPT)* billing code for non-invasive vascular testing of a hemodialysis access site is 93990 (*Duplex scan of hemodialysis access (including arterial flow, body of access and venous outflow)*). 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.

The professional component of the procedure is included in the Monthly Capitation Payment (MCP) (see section 15060.1 of the Medicare Carriers Manual (MCM), Part 3). The professional component for code 93990 will be denied 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 (see sections 15060.1 and 15060.2 of the MCM, Part 3). Billing for monitoring of hemodialysis access using *CPT* codes for non-invasive vascular studies other than 93990 is considered a misrepresentation of the service actually provided.

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% or greater from previous study) and the physician requires an arteriogram to further define the extent 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. Florida Medicare's local medical review policy for Duplex Scan of Hemodialysis Access (93990) is being revised based on the information herein. Specific revisions will be published in a future issue of the *Medicare B Update!*

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

LABORATORY/PATHOLOGY

Attestation Option for Submission Requirement for Clinical Laboratories Billing the Technical Component of Physician Pathology Services to Hospital Patients

This is a clarification to a requirement in Program Memorandum (PM) AB-01-47, Change Request 1499, dated March 22, 2001, that gives details for implementing section 542 of the Benefits Improvement and Protection Act of 2000 (BIPA). This section allows carriers to continue to pay independent laboratories that bill the Technical Component (TC) of physician pathology for certain hospital patients. An article based on PM AB-01-47 was published in the 3rd Quarter 2001 *Medicare B Update!* (pages 29-30) and provides a full explanation of the requirements of BIPA section 542.

The basic requirement for a carrier to continue to pay an independent laboratory for the TC of a specimen for a hospital inpatient or outpatient is that the hospital must have had an agreement as of July 22, 1999, with an independent laboratory, for an independent laboratory to do the TC. If the hospital meets that requirement, it is called a "covered hospital."

AB-01-47 requires the independent laboratory to forward to its carrier(s) a copy of the agreement or other documentation to establish that there was an arrangement on or before July 22, 1999, between the laboratory and the hospital for processing of the TC by the independent lab.

Since release of AB-01-47, the Centers for Medicare & Medicaid Services (CMS) has received comments advising that not all such agreements were written; some were oral. Additional comments indicated that some of the original contracts could not be found.

Effective August 8, 2001, CMS amended the instruction in AB-01-47 regarding submission of an agreement or other documentation to clarify that an attestation will suffice to meet the requirement if no written agreement is available. An attestation that contains all the elements listed below would be considered sufficient.

- Legal name (and if necessary to ensure proper identification, the business name) of each entity;
- Mailing addresses for both entities;
- Medicare billing numbers for both entities and the Clinical Laboratory Improvements Amendments of 1988 (CLIA) number for the laboratory;
- Statement to the effect that on July 22, 1999, this arrangement existed between this laboratory (or a predecessor independent laboratory) and the hospital;
- Statement of any limitation to the agreement, e.g., only certain tests are covered under this agreement or certain time restrictions were imposed;
- Date of the attestation;
- Original signature of the representative of the laboratory (if the laboratory had the arrangement with the hospital as of July 22, 1999) or a representative of the hospital (if the hospital had an arrangement with a different laboratory as of July 22, 1999); and
- Statement that the signer is authorized to sign on behalf of the entity furnishing the attestation.

Attestation statements must clearly provide the identification of the independent laboratory, including the provider identification number, and must clearly identify the hospital with which the agreement exists. Send the attestation to:

Medicare Registration
P.O. Box 44021
Jacksonville, FL 32231-4021

Other than the submission of the agreement or attestation as described above, independent laboratories should not make any changes in their billing procedures for services provided in covered hospitals at this time. Providers will be advised of additional requirements as they become available in a future issue of the *Update!*

Source: CMS Transmittal B-01-50, CR 1781

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; and

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; and

83605QW for the KDK Corporation Lactate Pro System.

Newly Added Tests Granted Waived Status Under CLIA

TEST NAME	MANUFACTURER	CPT CODE(S)	USE
Wyntek OSOM® Strep A Test	Wyntek Diagnostics, Inc.	87880QW	Rapidly detects GAS Ultra 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 Test (Model 9073T)	Phamatech	80101QW	Screening test for the Drug presence/detection of cocaine metabolite in urine
Beckman Coulter Primary Care Diagnostics Flexsure HP Test for IgG Antibodies to <i>H. Pylori</i> in Whole Blood	Beckman Coulter, Inc.	86318QW	Immunoassay for rapid, qualitative detection of IgG antibodies specific to <i>Helicobacter pylori</i> in whole blood
Wampole PreVue™ <i>burgdorferi</i> Antibody Detection Assay	Wampole Laboratories	86618QW	Qualitative detection of <i>B. IgG/IgM</i> antibodies to <i>Borrelia burgdorferi</i> (causative agent of Lyme disease) in whole blood
Phamatech At Home Test (Model 9150T)	Phamatech	80101QW	Screening test for the Drug presence/detection of amphetamines, cannabinoids (THC), cocaine metabolites, methamphetamines, and opiates in urine
Phamatech At Home Test (Model 9078T)	Phamatech	80101QW	Screening test for the Drug presence/detection of cannabinoids (THC) in urine
KDK Corporation Lactate Pro System	KDK Corporation	83605QW	Quantitative measurement of lactate in whole blood

TEST NAME	MANUFACTURER	CPT CODE(S)	USE
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 Multisiteck 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 Multisiteck 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 Multisiteck 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 <i>pylori</i>	Medical Instruments Corporation	87077QW	Presumptive identification of <i>Helicobacter pylori</i> in <i>H.</i> gastric biopsy tissue, which has been shown to cause chronic active gastritis (ulcers)

This list includes updates through 9/13/2001

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

MEDICAL NUTRITION THERAPY

Medical Nutrition Therapy Services for Beneficiaries with Diabetes or Renal Disease

Beginning January 1, 2002, Medical Nutrition Therapy is a covered Medicare service when provided by a qualifying registered dietitian or nutrition professional. Other types of providers do not qualify for reimbursement for this service.

If you are a registered dietitian or nutrition professional and want to become a Medicare provider, please see <http://www.hcfa.gov/medicare/enrollment> to determine the local carrier for your area. The carrier will require you to submit a completed Form CMS-855. If you practice in the State of Florida, First Coast Service Options, Inc. (FCSO) is your local carrier.

Section 105 of the Benefits Improvement and Protection Act of 2000 permits Medicare coverage of Medical Nutrition Therapy (MNT) services when furnished by a registered dietitian or nutrition professional meeting certain requirements. The benefit is available for beneficiaries with diabetes or renal disease, when referral is made by a physician as defined in section 1861 (r) (1) of the Social Security Act (the Act). It also allows registered dietitians and nutrition professionals to receive direct Medicare reimbursement for the first time.

The benefit will consist of an initial visit for an assessment; follow-up visits for interventions; and reassessments as necessary during the 12-month period beginning with the initial assessment ("episode of care") to assure compliance with the dietary plan. For purposes of coverage, the benefit will be defined as a maximum number of hours that may be reimbursed in an episode of care. The maximum number of hours covered will be provided in a future issue of the *Medicare B Update!* when that requirement has been finalized by the Centers for Medicare & Medicaid Services (CMS). CMS will further define 'intervention' in the national coverage determination process. Please note; the number of hours covered for diabetes may be different than the number of hours covered for renal disease.

For the purposes of this benefit, renal disease means chronic renal insufficiency and the medical condition of a beneficiary who has been discharged from the hospital after a successful renal transplant within the last 6 months. Chronic renal insufficiency means a reduction in renal function not severe enough to require dialysis or transplantation (glomerular filtration rate 13-50 ml/min/1.73m²). Diabetes is defined as diabetes mellitus Type 1 (an autoimmune disease that destroys the beta cells of the pancreas, leading to insulin deficiency) and Type 2 (familial hyperglycemia). The diagnostic criterion for a diagnosis of diabetes is a fasting glucose greater than or equal to 126 mg/dl. These definitions come from the Institute of Medicare 2000 Report, *The Role of Nutrition in Maintaining Health in the Nation's Elderly*.

General Conditions of Coverage

The following are the general conditions of coverage:

- The treating physician must make a referral and indicate a diagnosis of diabetes or renal disease as described herein
- The number of hours covered in an episode of care may not be exceeded

- Services may be provided either on an individual or group basis without restrictions
- When follow-up Diabetes Self-Management Training (DSMT) and MNT services are provided within the same time period, hours from both benefits are counted toward the maximum number of covered hours allowed during the episode of care
- MNT services must be provided by a professional as defined below

Limitations on Coverage

The following limitations apply:

- MNT services are not covered for beneficiaries receiving maintenance dialysis for which payment is made under section 1881 of the Act.
- If a beneficiary has both renal disease and diabetes, they may receive only the number of hours covered under this benefit for either renal disease or diabetes, whichever is greater.
- A beneficiary cannot receive MNT if they have received initial DSMT within the last 12 months, unless:
 - The need for a reassessment and additional therapy has been documented by the referring physician as a result of a change in diagnosis or medical condition; or
 - The beneficiary receiving DSMT is subsequently diagnosed with renal disease.
- If a beneficiary diagnosed with diabetes has been referred for both follow-up DSMT and MNT services, the number of hours the beneficiary may receive is limited to the number of hours covered under either follow-up DSMT or MNT services annually, whichever is greater.

Referrals

Referral may only be made by the treating physician when the beneficiary has been diagnosed with diabetes or renal disease as defined herein with documentation maintained by the referring physician in the beneficiary's medical record. Referrals must be made for each episode of care and any reassessments prescribed during an episode of care because of a change in medical condition or diagnosis. The Unique Provider Identification Number (UPIN) of the referring physician must be on the Form HCFA-1500 claim form submitted by a registered dietitian or nutrition professional. Claims that do not contain the UPIN of the referring physician will be returned as unprocessable.

Additional Covered Hours for Reassessments and Interventions

Additional reassessments and interventions may be covered beyond the number of hours typically covered under an episode of care. The exact amount of hours that will be covered will be provided in the future, when that requirement has been finalized by CMS. Additional MNT reassessments and interventions are only covered within an episode of care when the referring physician determines there is a change of diagnosis or medical condition within such episode of care that makes a change in diet necessary.

Professional Standards for Dietitians and Nutritionists

For Medicare Part B coverage of MNT, only a registered dietitian or nutrition professional may provide the services. “Registered dietitian or nutrition professional” means a dietitian or nutritionist licensed or certified in a state as of December 21, 2000; or an individual whom, on or after December 22, 2000:

- Holds a bachelor’s or higher degree granted by a regionally accredited college or university in the United States (or an equivalent foreign degree) with completion of the academic requirements of a program in nutrition or dietetics, as accredited by an appropriate national accreditation organization recognized for this purpose,
- Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional, and
- Is licensed or certified as a dietitian or nutrition professional by the state in which the services are performed. In a state that does not provide for licensure or certification, the individual will be deemed to have met this requirement if he or she is recognized as a “registered dietitian” by the Commission on Dietetic Registration or its successor organization, or meets the requirements of the first two bullets of this section

Payment for MNT

Payment will be made under the physician fee schedule for dates of service on or after January 1, 2002, to a registered dietitian or nutrition professional that meets the above requirements. Deductible and coinsurance apply. As with the DSMT training benefit, payment is only made for MNT services actually attended by the beneficiary and documented by the provider, and for beneficiaries that are not inpatients of a hospital or skilled nursing facility.

Payment may be made under the following codes:

97802 *Medical nutrition therapy; initial assessment and intervention, individual, face-to-face with the patient, each 15 minutes.*

(NOTE: CPT code 97802 must *only* be used for the initial visit.)

97803 *Re-assessment and intervention, individual; face-to-face with the patient, each 15 minutes*

97804 *Group (2 or more individual(s)), each 30 minutes*

Instructions for Use of the Medical Nutrition Therapy Codes

Code 97802 is to be used only once a year, for initial assessment of a new patient. All subsequent individual visits (including reassessments and interventions) are to be coded as 97803. All subsequent group visits are to be billed as 97804.

Code 97803 is to be billed for all individual reassessments and all interventions after the initial visit (see 97802). This code should also be used when there is a change in the patient’s medical condition affecting his or her nutritional status (see “Additional Covered Hours for Reassessments and Interventions”).

Code 97804 is to be billed for all group visits, initial and subsequent. This code may also be used when there is a change in a patient’s condition affecting his or her nutritional status and the patient is attending in a group.

Note: The above codes can only be paid if submitted by a registered dietitian or nutrition professional who meets the specified requirements. These services cannot be paid “incident to” physician services.

General Claims Processing Information

Registered dietitians and nutrition professionals must accept assignment. If a claim is submitted as unassigned, the carrier will change the claim status to assigned. Since these new providers must accept assignment, the limiting charge does not apply.

Registered dietitians and nutrition professionals may be part of a group practice, in which case the provider identification number of the registered dietitian or nutrition professional that performed the service must be entered in item 24k of Form HCFA-1500.

Enrollment of Dietitians and Nutritionists

Registered dietitians and nutrition professionals are reimbursed for MNT services through local carriers. In order to file claims for MNT, a registered dietitian or nutrition professional must be enrolled as a provider in the Medicare program and meet the requirements outlined above. The new specialty code for “dietitians/nutritionists” is 71. Please see the italicized note at the beginning of this article for more information concerning enrollment of dietitians and nutritionists.

Source: CMS Transmittal B-01-48, CR 1776

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RADIOLOGY

Screening and Diagnostic Mammography

Section 4601 of the Medicare Carriers Manual, Screening Mammography and Diagnostic Mammography, has been updated based on section 104 of the Benefits Improvement and Protection Act of 2000. This amends section 1848(j)(3) of the Social Security Act to include screening mammography as a physician service for which payment is made under the Medicare Physician Fee Schedule (MPFS). The payment limitation for screening mammography no longer applies for claims with dates of service on or after January 1, 2002. Diagnostic mammography and screening mammography may both be paid when performed on the same day when provided to the same beneficiary.

New Computer-Aided Detection (CAD) Codes Used as Add-On Codes:

A new CPT code 76085, "Digitization of film radiographic images with computer analysis for lesion detection and further physician review for interpretation, screening mammography (List separately in addition to code for primary procedure)" for computer-aided detection conversion of standard film images to digital images has been established as an add-on code that may be billed only in conjunction with the primary service screening mammography code 76092.

A separate code, G0236, has been created for "Digitization of film radiographic images with computer analysis for lesion detection and further physician review for interpretation, diagnostic mammography (List separately in addition to code for primary procedure)" for computer-aided detection. This code is also an add-on code and must be used with diagnostic mammography codes (76090 and 76091).

Providers may not bill an add-on code without also billing for the appropriate mammography code. If just the add-on code is billed, the service will be denied. Both the add-on code and the appropriate mammography code should be on the same claim.

CPT/HCPCS Codes

Specific codes used for mammography claims on or after January 1, 2002, are listed below. Payment of *all* mammography tests (including screening mammography) is now made under the MPFS. The technical component, the professional component, and the global service will all be included on the MPFS. Part B deductible does not apply to screening mammography; however, coinsurance does apply. The non-participating provider reduction and the limiting charge provisions apply to *all* mammography tests (including screening mammography).

76092	<i>Screening mammography, bilateral (two view film study of each breast)</i>
76090	<i>Diagnostic mammography, unilateral</i>
76091	<i>Diagnostic mammography, bilateral</i>
G0202	Screening mammography, direct digital image, bilateral, all views
G0204	Diagnostic mammography, direct digital image, bilateral, all views
G0206	Diagnostic mammography, film processed to produce digital image analyzed for potential abnormalities, bilateral, all views
76085	<i>Computer-aided detection add-on code for screening mammography (use with 76092)</i>
G0236	Computer-aided detection add-on code for diagnostic mammography (use with 76090 or 76091)

Modifier GG Performance and payment of a screening mammography and diagnostic mammography on same patient same day.

Note: Use Modifier GG with a diagnostic mammography code to show the test changed from a screening test to a diagnostic test; contractors will pay both the screening and diagnostic mammography tests. This modifier is for tracking purposes only.

The following codes are not billable for claims with dates of service on or after January 1, 2002.

G0203	Screening mammography film processed to produce digital image, bilateral all views;
G0205	Diagnostic mammography, film processed to produce digital image, bilateral, all views;
G0207	Diagnostic mammography, film processed to produce digital image, unilateral

ICD-9-CM Codes

V76.12 Diagnosis code for screening mammography

ICD-9-CM codes for diagnostic mammography will vary according to diagnosis.

Source: CMS Transmittal 1724, CR 1837

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SURGERY

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 give the patient ability to void more properly. 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 appropriate candidates. Both the test and permanent implantation are covered.

Claims for sacral nerve stimulation will be reimbursed based on the Medicare physician fee schedule. Deductible and coinsurance apply. Claims from physicians, other practitioners, or suppliers where assignment was not taken are subject to the Medicare limiting charge. 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.
- Patient must have had successful test stimulation in order to support subsequent implantation. Before a patient is eligible for permanent implantation, he/she must demonstrate a 50 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.

CPT/HCPCS Coding

64555	<i>Percutaneous implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve).</i> This code applies to services performed prior to January 1, 2002
64561	<i>Percutaneous implantation of neurostimulator electrodes; sacral nerve. (transforaminal placement).</i> This code applies to services performed on or after January 1, 2002
64575	<i>Incision for implantation of neurostimulator electrodes; peripheral nerve (excludes sacral nerve).</i> This code applies to services performed prior to January 1, 2002
64581	<i>Incision for implantation of neurostimulator electrodes; sacral nerve; (transforaminal placement).</i> This code applies to services performed on or after January 1, 2002
64585	<i>Revision or removal of peripheral neurostimulator electrodes</i>
64590	<i>Incision and subcutaneous placement of peripheral neurostimulator pulse generator or receiver, direct or inductive coupling</i>
64595	<i>Revision or removal of peripheral neurostimulator pulse generator or receiver</i>
A4290	Sacral nerve stimulation test lead, each
E0752	Implantable neurostimulator electrodes
E0756	Implantable neurostimulator pulse generator

Ambulatory Surgical Centers (ASC)

ASC facility fees are payable for the following procedures:

64575	Group 1
64590	Group 2
64595	Group 1

Local Medical Review Policy

Based on this information, Florida Medicare is revising its local medical review policy (LMRP) for Sacral Neuromodulation (64555). The revised LMRP will be provided in a future issue of the *Medicare B Update!* and on our provider Web site, www.floridamedicare.com.

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

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VISION CARE

Coverage and Billing for Screening Glaucoma Services

Section 102 of the Benefits Improvements and Protection Act of 2000 provides coverage for annual 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 through future rulemaking 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: (1) a dilated eye examination with an intraocular pressure measurement; and (2) 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.**

HCPCS Codes

- | | |
|-------|--|
| G0117 | Glaucoma screening for high risk patients furnished by a physician |
| G0118 | Glaucoma screening for high risk patients furnished under the direct supervision of a physician. |

Providers should bill for glaucoma screening using screening ICD-9-CM code V80.1 (Special screening for neurological, eye, and ear diseases, glaucoma). **Claims submitted without this screening diagnosis code will be returned as unprocessable.**

Claims for screening for glaucoma should be submitted on Form HCFA-1500 or electronic equivalent. Payment for glaucoma screening will be made on the basis of the Medicare physician fee schedule; deductible and coinsurance apply. Claims from physicians or other providers where assignment was not taken are subject to the Medicare limiting charge.

CMS Transmittal B-01-46, CR 1717

LOCAL AND FOCUSED MEDICAL REVIEW POLICIES

This section of the *Medicare B Update!* features new and revised medical policies developed as a result of either the local medical review or focused medical review initiatives. Both initiatives are designed to ensure the appropriateness of medical care and that the carrier's medical policies and review guidelines are consistent with the accepted standards of medical practice.

LMRP Format

The local medical review policy (LMRP) format is consistent with the manner in which the carrier reports LMRPs to the Centers for Medicare & Medicaid Services.

Effective Dates

The effective dates are provided in each policy. Effective dates are based on the date claims are *processed*, not the date of service (unless otherwise noted in the policy).

More Information

Draft LMRPs and previously published final LMRPs may be obtained by accessing the Florida Medicare provider Web site at: www.floridamedicare.com

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FOCUSED MEDICAL REVIEW

Sacroiliac Joint Injection Procedures

The comprehensive data analysis team has uncovered an issue related to billing/coding for this service, during one of the routine studies of aberrant procedures in Florida. For a physician to bill for an injection procedure for sacroiliac joint, arthrography and/or anesthetic/steroid (CPT code 27096), he or she must be performing an injection into the joint, which requires the use of

fluoroscopic guidance or arthrography. This procedure should *not* be billed when a physician provides routine sacroiliac injections. Procedure 27096 represents an injection into the joint space. Please review the notations related to this procedure that may be found in the American Medical Association's *Current Procedural Terminology (CPT) Manual*.

Critical Care Services

Claims for critical care services (*CPT* codes 99291 and 99292) submitted to Florida Medicare were reviewed recently, and several coding issues appeared in the analysis. This is to serve as a reminder of the coding guidelines outlined in the American Medical Association's (*AMA*) *Current Procedural Terminology (CPT)* manual. This article is not designed to substitute for the *CPT* Book with respect to codes, coding advice, or guidelines for any user. *CPT* material may be ordered online from the *AMA* at www.ama-assn.org/catalog, or by calling 1-800-621-8335.

In the six-month period reviewed, some providers billed in excess of two additional 30-minute blocks (99292) of time on many patients. While this would not be uncommon, it would not be expected to occur with the majority of the patient population for particular providers. Be reminded, *"the time spent with the individual patient should be recorded in the patient's record. The time that can be reported as critical care is the time spent engaged in work directly related to the individual patient's care whether that time was spent at the immediate bedside or elsewhere on the floor or unit. For example, time spent on the unit or at the nursing station on the floor reviewing test results or imaging studies, discussing the critically ill patient's care with other medical staff or documenting critical care services in the medical record would be reported as critical care, even though it does not occur at the bedside. Also, when the patient is unable or clinically incompetent to participate in discussions, time spent on the floor or unit with family members or surrogate decision makers obtaining a medical history, reviewing the patient's condition or prognosis, or discussing the treatment may be reported as critical care, provided the conversation bears directly on the medical decision making. Time spent in activities that occur outside of the unit or off the floor (e.g., telephone calls, whether taken at home, in the office, or elsewhere in the hospital) may not be reported as critical care since the physician is not immediately available to the patient. Time spent in activities that do not directly contribute to the treatment of the patient may not be reported as critical care, even if they are performed in the critical care unit (e.g., participation in administrative meetings or telephone calls to discuss other patients)."*

Florida Medicare published guidelines for critical care services in the March/April 2000 issue to the *Medicare B Update!* (pages 7-10). In addition, CMS issued Program Memorandum (PM) AB-00-126 to clarify a number of issues related to the interpretation, reporting and payment of *CPT* critical care codes 99291 and 99292. The clarifications pertain mainly to the changes in critical care definitions in the *CPT* 2000. Several policies in this PM are already in effect and are mentioned here again.

Use of the Critical Care *CPT* Codes 99291 and 99292

(A) Definition of Critical Illness or Injury

The *AMA*'s *CPT* has redefined a critical illness or injury as follows:

"A critical illness or injury acutely impairs one or more vital organ systems such that the patient's survival is jeopardized."

*Note: the term "unstable" is no longer used in the *CPT* definition to describe critically ill or injured patients.*

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(B) Definition of Critical Care Services

CPT 2000 redefined critical care services as follows:

"Critical care is the direct delivery by a physician(s) of medical care for a critically ill or injured patient... the care of such patients involves decision making of high complexity to assess, manipulate, and support central nervous system failure, circulatory failure, shock-like conditions, renal, hepatic, metabolic, or respiratory failure, postoperative complications, overwhelming infection, or other vital system functions to treat single or multiple vital organ system failure or to prevent further deterioration. It may require extensive interpretation of multiple databases and application of advanced technology to manage the patient. Critical care may be provided on multiple days, even if no changes are made in the treatment rendered to the patient, provided that the patient's condition continues to require the level of physician attention described above."

"Critical care services include but are not limited to, the treatment or prevention of further deterioration of central nervous system failure, circulatory failure, shock-like conditions, renal, hepatic, metabolic or respiratory failure, post operative complications, or overwhelming infection. Critical care is usually, but not always, given in a critical care area, such as the coronary care unit, intensive care unit, pediatric intensive care unit, respiratory care unit, or the emergency care facility."

(C) Guidelines for Use Whenever Medical Review is Performed in Relation to Critical Illness and Critical Care Service

A clarification of Medicare policy concerning both payment for and medical review of critical care services is warranted, given the *CPT* redefinition of both critical illness/injury and critical care services.

In order to reliably and consistently determine that delivery of critical care services rather than other evaluation and management services is medically necessary, both of the following medical review criteria must be met in addition to the *CPT* definitions.

Clinical Condition Criterion

There is a high probability of sudden, clinically significant, or life threatening deterioration in the patient's condition which requires the highest level of physician preparedness to intervene urgently.

Treatment Criterion

Critical care services require direct personal management by the physician. They are life and organ supporting interventions that require frequent, personal assessment and manipulation by the physician. Withdrawal of, or failure to initiate these interventions on an urgent basis would likely result in sudden, clinically significant, or life threatening deterioration in the patient's condition.

Claims for critical care services must be denied if the services are not reasonable and medically necessary. If the services are reasonable and medically necessary but they do not meet the criteria for critical care services, then the services should be re-coded as another appropriate evaluation and management service (e.g., hospital visit).

Providing medical care to a critically ill patient should not be automatically determined to be a critical care service for the sole reason that the patient is critically ill. The physician service must be medically necessary and meet the definition of critical care services as described previously in order to be covered.

LOCAL MEDICAL REVIEW

2002 ICD-9-CM Coding Changes

The 2002 update to the ICD-9-CM diagnosis coding structure became effective October 1, 2001. Updated diagnosis codes *must* be used for all services billed on or after January 1, 2002. A 90-day grace period is provided during which Florida Medicare will accept both old and new ICD-9-CM codes, for claims received October 1 through December 31, 2001. This grace period is to allow providers sufficient time to obtain and integrate the updated ICD-9-CM codes into their billing systems. All claims for services rendered on or after January 1, 2002 *must* be billed with the updated 2002 ICD-9-CM codes.

Florida Medicare has reviewed all 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, the publication in which diagnosis criteria appeared, and the specific conditions revised as a result of the 2002 ICD-9-CM update:

2002 ICD-9 Part B LMRP Changes

LMRP Title	Publications Listing	2002 Changes
31231 Diagnostic Nasal Endoscopy	4 th QTR 2001 <i>Update!</i> (page 57) Sep/Oct 2000 <i>Update!</i> (page 29)	Change 464.0-464.4 to 464.00-464.51 for procedure codes 31231, 31233, and 31235
40000 Digestive System	Jan/Feb 2000 <i>Update!</i> (page 36)	Add 530.12 (Acute esophagitis) for procedure codes 91032 and 91033
44388 Colonoscopy	2 nd QTR 2001 <i>Update!</i> (page 51) Sep/Oct 2000 <i>Update!</i> (page 21) Nov/Dec 1998 <i>Update!</i> (page 7) Jul/Aug 1998 <i>Update!</i> (page 48)	Change descriptor for 558.1-558.9 to read Other <i>and unspecified</i> 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
64550 Application of Surface (Transcutaneous) Neurostimulator	1996	Add 718.70-718.79 (Developmental dislocation of joint) for procedure code 64550
70450 Computerized Tomography Scans	June 2001 Special Issue <i>Update!</i> (page 16) Sep/Oct 2000 <i>Update!</i> (page 22) Nov/Dec 1999 <i>Update!</i> (page 31) Sep/Oct 1999 <i>Update!</i> (page 31)	Change 772.1-772.2 to 772.10-772.2 for procedure codes 70450, 70460, and 70470
70551 Magnetic Resonance of the Brain	2 nd QTR 2001 <i>Update!</i> (page 69) Sep/Oct 2000 <i>Update!</i> (page 21) Nov/Dec 1997 <i>Update!</i> (page 5) May/Jun 1997 <i>Update!</i> (page 13) Mar/Apr 1997 <i>Update!</i> (page 55)	Change 772.1-772.2 to 772.10-772.2 for procedure codes 70551-70553
71010 Chest X-Ray	1 st QTR 2001 <i>Update!</i> (page 66) Sep/Oct 2000 <i>Update!</i> (page 21) Nov/Dec 1998 <i>Update!</i> (page 28) Nov/Dec 1997 <i>Update!</i> (page 5) Sep/Oct 1997 <i>Update!</i> (page 36) Mar/Apr 1997 <i>Update!</i> (page 56)	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	June 2001 Special Issue <i>Update!</i> (page 19)	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	Sep/Oct 1999 <i>Update!</i> (page 33) Sep/Oct 1998 <i>Update!</i> (page 35) Jan/Feb 1998 <i>Update!</i> (page 22)	Change 256.3 to 256.31-256.39 for procedure codes 76075, 76076, 76078, 76977, 78350, and G0130-G0132

LOCAL AND FOCUSED MEDICAL REVIEW POLICIES

LMRP Title	Publications Listing	2002 Changes
76090 Diagnostic Mammography	3 rd QTR 2001 <i>Update!</i> (page 62) Nov/Dec 1997 <i>Update!</i> (page 30)	Change 793.8 to 793.80-793.89 for procedure codes 76090, 76091, G0204-G0207
78460 Myocardial Perfusion Imaging	Sep/Oct 2000 <i>Update!</i> (page 21) Jan/Feb 1999 <i>Update!</i> (page 29)	Change descriptor for 411.81 to read <i>Acute</i> coronary occlusion without myocardial infarction for procedure codes 78460, 78461, 78464, 78465, 78478, and 78480
78472 Cardiac Blood Pool Imaging	Sep/Oct 2000 <i>Update!</i> (page 21) Mar/Apr 2000 <i>Update!</i> (page 38)	Change descriptor for 411.81 to read <i>Acute</i> coronary occlusion without myocardial infarction
82270 Fecal Occult Blood Testing	Sep/Oct 2000 <i>Update!</i> (page 21) Mar/Apr 1997 <i>Update!</i> (page 43) Nov/Dec 1998 <i>Update!</i> (page 7)	Change descriptor for 558.1-558.9 to read <i>Other and unspecified</i> noninfectious gastroenteritis and colitis; and Change 564.0-564.9 to 564.00-564.9 for procedure code 82270
82310 Total Calcium	3 rd QTR 2001 <i>Update!</i> (page 66)	Change 564.0 to 564.00-564.09 for procedure code 82310
84436 Thyroid Function Tests	Sep/Oct 2000 <i>Update!</i> (page 22) Mar/Apr 2000 <i>Update!</i> (page 40)	Change 564.0 to 564.00-564.09 for procedure codes 84436, 84437, 84439, 84443, 84479-84482
92980 Interventional Cardiology	Jan/Feb 1999 <i>Update!</i> (page 52)	Change descriptor for 411.81 to read <i>Acute</i> coronary occlusion without myocardial infarction for procedure codes 92980, 92981, 92982, 92984, 92995, and 92996
93224 Electrocardiographic Monitoring for 24 hours (Holter Monitoring)	Sep/Oct 2000 <i>Update!</i> (page 60)	Change descriptor for 411.81 to read <i>Acute</i> coronary occlusion without myocardial infarction for procedure codes 93224-93237
93303 Transthoracic and Doppler Echocardiography and Doppler Color Flow Velocity Mapping	4 th QTR 2001 <i>Update!</i> (page 71) June 2001 Special Issue <i>Update!</i> (page 23) Jan/Feb 2000 <i>Update!</i> (page 48)	Change descriptor for 411.81 to read <i>Acute</i> coronary occlusion without myocardial infarction for procedure codes 93307, 93308, 93320, 93321, and 93325
93312 Transesophageal Echocardiogram	2 nd QTR 2001 <i>Update!</i> (page 90)	Change descriptor for 411.81 to read <i>Acute</i> coronary occlusion without myocardial infarction for procedure codes 93312-93318
93350 Stress Echocardiography	Sep/Oct 2000 <i>Update!</i> (page 22) Jan/Feb 1998 <i>Update!</i> (page 30)	Change descriptor for 411.81 to read <i>Acute</i> coronary occlusion without myocardial infarction for procedure 93350
G0030 Positron Emission Tomography (PET) Scan	4 th QTR 2001 <i>Update!</i> (page 28) Jul/Aug 1999 <i>Update!</i> (page 18)	Change descriptor for 411.81 to read <i>Acute</i> coronary occlusion without myocardial infarction for procedure codes G0030-G0047
G0104 Colorectal Screening	4 th QTR 2001 <i>Update!</i> (page 34)	Change descriptor for 558.1-558.9 to read <i>Other and unspecified</i> noninfectious gastroenteritis and colitis for procedure codes G0105 and G0120

A0430: Air Ambulance Services

Please note the following changes to Florida Medicare’s local medical review policy for Air Ambulance Services that was published in the 4th Quarter 2001 *Medicare B Update!* (pages 20-22):

Original Policy Effective Date

09/28/2001

Start Date of Notice Period

08/01/2001

Revision History

Revision Number: Original PCR B2001-109
 Start Date of Comment Period: 02/16/2001
 Start Date of Notice Period: 08/01/2001
 4th QTR 2001 *Update!*
 Original Effective Date 09/28/2001

G0030: Positron Emission Tomography (PET) Scan

The local medical review policy (LMRP) for PET scans was published in the 4th Quarter 2001 *Medicare B Update!* (pages 28-34). Since then, the Centers for Medicare & Medicaid Services has advised carriers that HCPCS code G0219 (PET Imaging whole body; melanoma for non-covered indications) is not a covered service. Therefore, G0219 is deleted from the LMRP, effective for services provided on or after July 1, 2001.

J0150: Adenosine (Adenocard®, Adenoscan®)

Revision Overview: Original policy

Policy Number

J0150

Contractor Name

First Coast Service Options, Inc.

Contractor Number

00590

Contractor Type

Carrier

LMRP Title

Adenosine (Adenocard®, Adenoscan®)

AMA CPT Copyright Statement

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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

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.

CPT/HCPCS Section & Benefit Category

Drugs Administered Other than Oral Method

CPT/HCPCS Codes

J0150
J0151

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

Adenosine, 6 mg (procedure code J0150)

414.00-414.05	427.0	785.0
426.7	427.2	

Adenosine, 90 mg (procedure code J0151)

411.0	424.0	794.31
411.1	426.2	960.7
411.81	426.3	995.2
411.89	426.4	E942.0
412	426.50-426.54	E942.1
413.0-413.9	426.6	V67.00
414.00-414.05	426.7	V67.09
414.10-414.19	427.31	V67.51
414.8	428.0-428.9	V67.59
414.9	440.21-440.24	

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

Reason for Denial

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

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 Diagnoses

N/A

Coding Guidelines

HCPCS code J0150 should be used when a rapid intravenous/intracoronary bolus is being administered. When an intravenous infusion of adenosine is used, it is expected that HCPCS code J0151 be billed.

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

Sources of information may be found online under “Medical Policy” in the Part B 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 College of Cardiology.

Carrier Advisory Committee Meeting held on February 24, 2001.

Start Date of Comment Period

02/16/2001

End of Date of Comment Period

04/02/2001

Start Date of Notice Period

11/01/2001

Revision History

Revision Number Original PCR B2001-149
 Start Date of Comment Period: 02/16/2001
 Start Date of Notice Period: 11/01/2001
 1st QTR 2002 Update!
 Original Effective Date 01/01/2002

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

J7190: Hemophilia Clotting Factors

Revision Overview: Diagnoses 286.5 and 286.7 were added to the policy to ensure consistency with the Intermediary's policy.

Policy Number

J7190

Contractor Name

First Coast Service Options, Inc.

Contractor Number

00590

Contractor Type

Carrier

LMRP Title

Hemophilia Clotting Factors

AMA CPT Copyright Statement

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CMS National Coverage Policy

Medicare Carriers Manual, Sections 2049.5E, 5245
 Coverage Issues Manual, Section 45-24
 Program Memorandum AB-99-75 (Change request 913)

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

CMS Region

Region IV

CMS Consortium

Southern

Original Policy Effective Date

11/18/1996

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 physical 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 spontaneous 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

CPT/HCPCS Codes

J7190	J7192	J7198	Q0160	Q0187
J7191	J7194	J7199	Q0161	Q2022

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

286.0	286.2	286.4	286.7
286.1	286.3	286.5	

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 Diagnoses

N/A

Coding Guidelines

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).

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 (vWF), a protein that mediates platelet adhesion. The subtypes of von Willebrand’s disease are: type I, type IIa, type III, and pseudo-von Willebrand’s. This disorder affects both men and women, is usually mild, with most bleeding being mucosal (epistaxis, gingival bleeding, menorrhagia).

Sources of Information and Basis for Decision

Sources of information may be found online under “Medical Policy” in the Part B 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.

Carrier Advisory Committee meeting held on 2/19/2000.

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	PCR B2001-152
Start Date of Comment Period		NA
Start Date of Notice Period		11/01/2001
		1 st QTR 2002 <i>Update!</i>
Revised Effective Date:		10/01/2001

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

J9999: Antineoplastic Drugs

Revision Overview: J9310, Rituximab and J9390 Vinorelbine are added to the policy, and the code for Denileukin diffitox, Ontak® is changed from J9999 to J9160, effective January 1, 2002. Additional ICD-9-CM codes are added to various drugs, effective October 17, 2001.

Policy Number

J9999

Contractor Name

First Coast Service Options, Inc.

Contractor Number

00590

Contractor Type

Carrier

LMRP Title

Antineoplastic Drugs

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CMS National Coverage Policy

Medicare Carriers Manual, Sections 2049, 4630, and 15400

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

CMS Region

Region IV

CMS Consortium

Southern

Original Policy Effective Date

12/12/1997

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. Food and Drug Administration (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 the Centers for Medicare & Medicaid Services (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).

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
 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

Denileukin diftitox is a fusion protein designed to direct the cytotoxic 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 in patients 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-deacetylbaicatin 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 carcinoma (NSCLC), 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 (CUPs)

Fludarabine (Fludara®)-J9185

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

Fludarabine is FDA approved for treatment of chronic lymphocytic leukemia.

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

- Acute non-lymphocytic leukemia
- Non-Hodgkin's lymphoma

Gemcitabine (Gemzar®)-J9201

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

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

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

- Breast carcinoma
- Ovarian carcinoma
- Bladder carcinoma
- Transitional cell carcinoma of kidney and ureter
- Relapsed 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 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 (CUPs)
- 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 indications:

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

Trastuzumab (Herceptin®)-J9355

Trastuzumab is a monoclonal antibody, one of a group of drugs designed to attack specific cancer cells.

Transtuzumab's 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 (NSCLC).

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 photosensitizing agent that in combination with light, can cause cellular damage and tumor death.

Tumor selectivity occurs as a result of selective distribution and retention of Porfimer on tumor tissue, and by selective delivery of light. Illumination of target tissue with 630 nanometer wavelength laser light induces a photochemical reaction that activates Porfimer.

Porfimer photodynamic therapy causes the release of thromboxane A2, which results in vasoconstriction, activation and aggregation of platelets, and increased clotting. These factors contribute to ischemic necrosis which leads to tissue and tumor death.

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

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

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

CPT/HCPCS Section & Benefit Category

Chemotherapy Drugs

CPT/HCPCS Codes

J9000 J9001 J9015 J9045 J9160 J9170 J9181
J9182 J9185 J9201 J9206 J9265 J9280 J9290
J9291 J9310 J9350 J9355 J9390 J9600

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

J9000-Doxorubicin HCl

140.0-149.9	175.0-175.9	194.0-194.9
150.0-150.9	176.0-176.9	195.0
151.0-151.9	180.0-180.9	200.00-200.88
155.0	182.0	201.00-201.98
155.2	183.0	202.00-202.98
157.0-157.9	183.9	203.00-203.01
160.0-160.9	184.0	204.00-204.01
161.0-161.9	185	204.10-204.11
162.2-162.9	186.0-186.9	205.00-205.91
164.0	188.0-188.9	206.00-206.01
170.0-170.9	189.0	207.00-207.01
171.0-171.9	190.5	236.1
174.0-174.9	193	

J9001-Doxorubicin, Liposomal (Doxil)

174.0-174.9	176.0-176.9
175.0-175.9	183.0-183.9

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

172.0-172.9	189.1
189.0	205.10-205.11

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

140.0-149.9	174.0-174.9	189.0
150.0-150.9	175.0-175.9	190.5
158.8	180.0-180.9	191.0-191.9
160.0-160.9	182.0	194.0-194.9
161.0-161.9	183.0-183.9	195.0
162.2-162.9	186.0-186.9	199.0-199.1
172.0-172.9	188.0-188.9	

J9160-Denileukin diftitox (Ontak®)

202.10-202.18
202.20-202.28

J9170-Docetaxel (Taxotere®)

140.0-149.9	172.0-172.9	185
150.0-150.9	174.0-174.9	188.0-188.9
151.0-151.9	175.0-175.9	195.0
161.0-161.9	176.0-176.9	
162.2-162.9	183.0-183.9	

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

151.0-151.9	176.0-176.9	200.00-200.88
155.0	182.0-182.8	201.00-201.98
155.2	183.0	202.00-202.98
160.0-160.9	183.9	203.00-203.01
162.2-162.9	186.0-186	204.00-204.01
164.0	188.0-188.9	205.00-205.01
170.0-170.9	189.0	205.10-205.11
171.0-171.9	190.5	206.00-206.01
173.0-173.9	191.0-191.9	207.00-207.01
174.0-174.9	194.0-194.9	236.1
175.0-175.9	199.0-199.1	

J9185-Fludarabine (Fludara®)

200.00-200.88	204.10-204.11	206.00-206.01
202.00-202.98	205.00-205.01	207.00-207.01

J9201-Gemcitabine (Gemzar®)

157.0-157.9	183.0-183.9	201.00-201.98
162.2-162.9	188.0-188.9	202.00-202.98
174.0-174.9	189.0-189.2	
175.0-175.9	200.00-200.88	

J9206-Irinotecan (Camptosar®)

153.0-154.8	162.2-162.9	180.0-180.9
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J9265-Paclitaxel (Taxol®)

140.0-149.9	174.0-174.9	185
150.0-150.9	175.0-175.9	186.0-186.9
151.0-151.9	176.0-176.9	188.0-188.9
158.8	180.0-180.9	195.0
161.0-161.9	182.0-182.8	197.2
162.2-162.9	183.0-183.9	199.0-199.1

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

140.0-149.9	157.0-157.9	180.0-180.9
150.0-150.9	161.0-161.9	185
151.0-151.9	162.2-162.9	188.0-188.9
153.0-154.8	174.0-174.9	195.0
156.0-156.9	175.0-175.9	205.10-205.11

J9310-Rituximab (Rituximab®)

200.00-200.88	202.80-202.88
202.00-202.08	273.3

J9350-Topotecan Hydrochloride (Hycamtin®)

162.2-162.9	205.10	238.7
183.0-183.9	205.11	

J9355-Trastuzumab (Herceptin®)

174.0-174.9	198.0	198.5
175.0-175.9	198.1	198.6
196.0-196.9	198.2	198.7
197.0-197.8	198.4	198.82

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

J9390-Vinorelbine tartrate (Navelbine®)

162.2-162.9	175.0-175.9	183.0-183.9
174.0-174.9	180.0-180.9	

J9600-Porfimer (Photofrin®)

150.0-150.9	162.2-162.9
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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 Diagnoses

N/A

Coding Guidelines

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

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

When billing for Denileukin diftitox documentation which demonstrates that the patient’s malignant cells express CD25 must be maintained in the patient’s medical record.

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 Policy” in the Part B 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.

Carrier Advisory Committee Meeting held on May 19, 2001.

Start Date of Comment Period

05/11/2001

End Date of Comment Period

06/25/2001

Start Date of Notice Period

11/01/2001

Revision History

Revision Number:	14	PCR B2001-169
Start Date of Comment Period		05/11/2001
Start Date of Notice Period		11/01/2001
		1 st QTR 2002 Update!
Revised Effective Date:		01/01/2002

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

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

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

Policy Number

10060

Contractor Name

First Coast Service Options, Inc.

Contractor Number

00590

Contractor Type

Carrier

LMRP Title

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

AMA CPT Copyright Statement

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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

07/30/2001

Original Policy Ending Date

N/A

Revision Effective Date

10/23/2001

Revision Ending Date

10/22/2001

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

CPT/HCPCS Codes

10060 10061

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

528.5	680.0-680.9	705.83
607.2	681.10-681.11	
3611.0	682.0-682.9	

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 Diagnoses

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 ischio-rectal and/or perirectal abscess); an abscess of the finger should be billed with procedure codes 26010-26011 (Drainage of finger abscess).

Documentation Requirements

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

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

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

Utilization Guidelines

N/A

Other Comments

Terms Defined

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

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

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

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

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 Policy” in the Part B 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.

Carrier Advisory Committee Meeting held on February 24, 2001.

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	PCR B2001-163
Start Date of Comment Period		N/A
Start Date of Notice Period		11/01/2001
		1st QTR 2002 Update!
Revised Effective Date:		10/23/2001

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

11600: Excision of Malignant Skin Lesions

Revision Overview: Original policy.

Policy Number

11600

Contractor Name

First Coast Service Options, Inc.

Contractor Number

00590

Contractor Type

Carrier

LMRP Title

Excision of Malignant Skin Lesions

AMA CPT Copyright Statement

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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,
- Electrodesiccation (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. dysplastic 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

CPT/HCPCS Codes

11600	11606	11624	11643
11601	11620	11626	11644
11602	11621	11640	11646
11603	11622	11641	
11604	11623	11642	

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

Procedure Codes 11600-11606

172.5	173.6	232.6
172.6	173.7	232.7
172.7	195.1-195.8	232.8
173.5	232.5	238.2*

* 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	184.0-184.8	232.6
172.6	187.1-187.4	232.7
172.7	187.7	232.8
173.4	195.0	233.3
173.6	195.3-195.5	233.5-233.6
173.7	232.4	238.2*

* 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	173.8	232.8
172.0-172.3	195.0	238.2*
172.8	230.0	
173.0-173.3	232.0-232.3	

* 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 Diagnoses

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.

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 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

Sources of information may be found online under "Medical Policy" in the Part B 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.

Carrier Advisory Committee Meeting held on February 24, 2001.

Start Date of Comment Period

02/16/2001

End Date of Comment Period

04/02/2001

Start Date of Notice Period

11/01/2001

Revision History

Revision Number:	Original	PCR B2001-161
Start Date of Comment Period		02/16/2001
Start Date of Notice Period		11/01/2001
		1st QTR 2002 <i>Update!</i>
Original Effective Date:		01/01/2002

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

17000: Benign or Premalignant Skin Lesion Removal/Destruction— Changes to Policy

The local medical review policy (LMRP) for Benign or Premalignant Skin Lesion Removal/Destruction was last published in the January/February 1998 *Medicare B Update!* (pages 19-21). The indications for the removal of benign skin lesions have since been expanded. This change is effective for claims processed on or after November 6, 2001.

Generally, the removal of benign skin lesions such as seborrheic keratoses, cysts, and warts are done for cosmetic reasons, however, in certain instances it may be necessary to remove these types of lesions. Florida Medicare will consider the removal of these lesions as medically necessary when the medical record documentation supports any of the following:

- the lesion is symptomatic (e.g., inflamed, painful, tender)
- the lesion demonstrates evidence of bleeding
- the lesion is infected
- the lesion demonstrates evidence of enlargement

- the patient presents with a lesion (e.g., palmar or plantar warts) causing symptoms of such a severity that the patient's normal bodily functions/activities of daily living are impeded
- the lesion is likely to turn malignant as documented by medical peer-reviewed literature or medical textbooks
- the lesion is in an area such as the neck, bra line or waist and is constantly irritated and/or is located in an anatomical location of recurrent trauma and such trauma has in fact occurred
- the lesion obstructs and orifice or clinically obstructs vision (this would include any lesion)
- the patient presents with condylomata acuminata (venereal warts)

If the aforementioned signs and symptoms are not present, further treatment would be considered medically unnecessary and, therefore, not reimbursable by Florida Medicare.

22899: Coverage of Kyphoplasty

Balloon kyphoplasty is a minimally invasive operative procedure for the reduction and fixation of vertebral body compression fracture. The procedure is similar to vertebroplasty in that there is percutaneous placement of tools for insertion of the bone cement polymethylmethacrylate (PMMA). However, kyphoplasty involves the inflation of a balloon tamp which is intended to help restore vertebral body height and create a cavity into which the PMMA is injected under low pressure.

Florida Medicare has made a decision to remove the kyphoplasty procedure from our local medical review policy A9270 (The List of Medicare Noncovered Services) and begin providing local coverage for Kyphoplasty. **The effective date of local coverage for this procedure is July 1, 2001.**

Kyphoplasty must be billed to Florida Medicare using procedure code 22899 (Unlisted procedure, spine). Procedure code 22899 should only be billed one time per vertebra, regardless of the number of injections or balloon tamps into a single vertebra. The professional radiological

supervision and interpretation services associated with the performance of kyphoplasty must be billed using procedure code 76499 (Unlisted diagnostic radiologic procedure). Each of the claims for kyphoplasty will be reviewed on a prepayment basis; therefore, medical documentation must be submitted with each claim. The kyphoplasty procedure must be provided for the treatment of symptomatic osteoporotic or osteolytic compression fractures of the thoracic or lumbar vertebrae. It is inappropriate to bill for kyphoplasty using the following procedure codes: 22325-22328 (Open treatment and/or reduction of vertebral fractures) or 22851 (Application of intervertebral biomechanical devices).

Any kyphoplasty services performed prior to July 1, 2001 should be billed using HCPCS code A9270. Such services are considered locally noncovered and will continue to be denied. Any kyphoplasty services performed on or after July 1, 2001 that have been denied must be submitted through the written appeal process for reconsideration.

29540: Strapping

Revision Overview: 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.

Policy Number

29540

Contractor Name

First Coast Service Options, Inc.

Contractor Number

00590

Contractor Type

Carrier

LMRP Title

Strapping

AMA CPT Copyright Statement

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Applicable FARS/DFARS Clauses Apply.

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

06/18/2001

Original Policy Ending Date

N/A

Revision Effective Date

10/08/2001

Revision Ending Date

10/07/2001

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

CPT/HCPCS Codes

29540 29550 29580

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	734	824.2
718.87	735.0	825.0
719.27	735.1	825.20-825.29
726.70	735.3	826.0
726.71	735.4	837.0
726.72	735.5	838.00-838.09
726.73	735.8	845.00-845.19
726.79	736.70	924.20-924.21
727.06	736.79	924.3
728.71	824.0	

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

451.0-451.2	824.0-824.9	837.0-837.1
454.0	825.0	838.00-838.19
454.1	825.20-825.29	845.00-845.19
454.2	826.0	

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 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 Diagnoses

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 Policy" in the Part B 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.

Carrier Advisory Committee Meeting held on November 11, 2000.

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 PCR B2001-157
 Start Date of Comment Period NA
 Start Date of Notice Period 11/01/2001
 Revised Effective Date: 10/08/2001
 1st QTR 2002 Update!

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

40000: Digestive System

Revision Overview: Policy revised due to the 2002 ICD-9-CM update and to comply with CMS LMRP format.

Policy Number

40000

Contractor Name

First Coast Service Options, Inc.

Contractor Number

00590

Contractor Type

Carrier

LMRP Title

Digestive System

AMA CPT Copyright Statement

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CMS National Coverage Policy

Coverage Issues Manual, Sections 35-1, 35-26, 35-33, 35-34, 35-53, 35-65, 35-69, 35-80, 35-82, 35-83, 35-91, 50-51

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

CMS Region

Region IV

CMS Consortium

Southern

Original Policy Effective Date

1994

Original Policy Ending Date

N/A

Revision Effective Date

10/01/2001

Revision Ending Date

09/30/2001

LMRP Description

This policy lays out coding and payment guidelines for procedures performed on the digestive system.

Indications and Limitations of Coverage and/or Medical Necessity

Digestive System:

Any conditions that warrant surgical intervention.

Esophagus Acid Reflex Tests:

Esophagus acid reflex tests (91032-91033) are covered services for certain conditions.

CPT/HCPCS Section & Benefit Category

Surgery/Digestive System

Medicine/Gastroenterology

CPT/HCPCS Codes

40490-49999 91032-91033

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity (91032-91033)

530.0	530.6	531.01	531.50
530.10	530.7	531.10	531.51
530.11	530.81	531.11	531.60
530.12	530.82	531.20	531.61
530.19	530.83	531.21	531.70
530.2	530.84	531.30	531.71
530.3	530.89	531.31	531.90
530.4	530.9	531.40	531.91
530.5	531.00	531.41	

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

Colonic irrigation (A9270) is not medically indicated for any condition and has no evidence of therapeutic value.

Intestinal by-pass surgery (A9270) is not considered a safe procedure for treatment of obesity.

Fabric wrapping of abdominal aneurysms (M0301) is not considered reasonable and necessary. This procedure has not been proven to prevent eventual rupture.

Gastric freezing (M0100) was a nonsurgical treatment used nearly twenty years ago. Today, it is considered an obsolete problem.

Diagnostic breath analysis (A9270) are performed to diagnose certain gastrointestinal diseases. At this time, the lactose breath hydrogen test for diagnosing small bowel bacterial overgrowth and measuring small bowel transit time is excluded from coverage.

Excision, fatty apron panniculus adiposus (15831) for treatment of obesity is noncovered under the Medicare program.

Gastric balloon (A9270) for treatment of obesity is noncovered under the Medicare program.

Implantation of mesh or other prosthesis for incisional or ventral hernia repair (49568) is covered when billed separately with incisional or ventral hernia repairs (49560-49566). The use of mesh or other prosthetic devices are not reported separately with codes 49495-49557; 49570-49587.

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 Diagnoses

N/A

Coding Guidelines

CPT code 43259 upper gastrointestinal endoscopy including endoscopic ultrasound (EUS)

If the person doing the original endoscopy has access to the EUS and if the clinical situation is appropriate, the EUS may be done at the same time. The procedure, diagnostic and EUS, would be reported under the same code because the code, CPT code 43259, includes diagnostic endoscopy.

Therefore, when a diagnostic examination of the upper gastrointestinal tract "including esophagus, stomach, and either the duodenum or jejunum as appropriate," includes the use of endoscopic ultrasonography, the service should be reported by a single code, namely CPT code 43259. Interpretation, whether by a radiologist or endoscopist, is reported under CPT code 76975-26. These codes may both be reported on the same day.

Procedures for morbid obesity which include gastric bypass (43846, 43847, 43848) gastroplasty, (43842, 43843) and/or revision of gastric partition or other type of gastroplasty (43850, 43860, 43865, 43999) must be reviewed for medical necessity. The following information is required for medical review:

- operative report
- history and physical
- **Attachment A**, (Letter No. 415-416 or comparable information)

Implantation of an anti-gastroesophageal reflux device (43499) may be considered reasonable and necessary when a conventional valvuloplasty procedure is contraindicated.

The device is covered only for patients with documented severe or life-threatening gastroesophageal reflux disease whose conditions have been resistant to medical treatment. The following information is required for medical review:

- history and physical
- operative report

Twenty-four (24) hour esophageal PH monitoring (91033) is a covered service.

Reimbursement for removal of transplanted pancreatic allograft (48556) will be allowed on an individual consideration (I.C.) basis only.

Medical Documentation Required:

- operative report
- history and physical

Laparoscopic cholecystectomy is a surgical procedure in which a diseased gall bladder is removed through the use of instruments introduced via cannulae, with vision of the operative field maintained by use of a high-resolution television camera-monitor system (video laparoscope).

For all other claims use CPT codes 47562 for laparoscopy, surgical; cholecystectomy 47563 for laparoscopy, surgical; cholecystectomy with cholangiography, and 47564 for laparoscopy, surgical; cholecystectomy with exploration of common duct.

Omental flap (e.g., for reconstruction of sternal and chest wall defects) (list separately in addition to code for primary procedure) (49905) is a covered service.

Donor hepatectomy, with preparation and maintenance of allograft; partial, from living donor (47134), liver allotransplantation; orthoptic, partial or whole, from cadaver or living donor, any age (47135) and liver allotransplantation; heterotopic, partial or whole, from cadaver or living donor, any age (47136) are covered services when determined to be medically reasonable and necessary. Certain conditions and diagnosis criteria must be met before payment can be extended. In addition, the service must be furnished in a Medicare-approved facility. This procedure will be reviewed and reimbursed on an individual basis by the physician consultant.

The reimbursement for donor hepatectomy, with preparation and maintenance of allograft from cadaver donor (47133) is included in the organ acquisition charge of the Certified Transplant Center or the Independent Organ Procurement Organization which is covered under the Medicare Part A payment.

Documentation Requirements

Should a medical review be necessary the physician would be expected to maintain specific patient information in the medical record to justify the need for services (e.g., history, physical, office notes, and photographs, if necessary.)

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 Society of Internal Medicine, Florida G.I. Society and Florida Society of Colon and Rectal Surgeons.

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	PCR B2001-159
Start Date of Comment Period		N/A
Start Date of Notice Period		11/01/2001
		1 st QTR 2002 <i>Update!</i>
Revised Effective Date:		10/01/2001

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

ATTACHMENT A

Letter No. 415-416

Date of Service: _____

Reference: _____

Dear Doctor:

Benefits for the treatment of "obesity" are provided by Medicare B only under limited conditions. To assist us in evaluating the above beneficiary's claim, we require the following information for review:

1. Have the pressures of excess weight resulted in any physical trauma or disability:
Yes () No () If yes, please describe in detail:

2. Are either pulmonary or circulatory insufficiencies present?

- Have pulmonary function studies been done? If so, submit documented report.

3. Is arteriosclerosis, diabetes, coronary disease or endocrine disease present? If so, indicate current status and extent of condition(s). If condition(s) is under current treatment, please describe:

4. Have electrocardiograms or similar evaluations been performed? If so, submit copy of tracing and/or documented report.

5. Have any specific blood chemistries been done? If so, submit documented report.

6. Is the patient able to function normally in his/her work and/or home environment?
Comments: _____
7. Patient's Height _____, Weight _____, Age _____, Body Build (circle one): Small Frame () Medium Frame () Heavy Frame ()
8. How long has present level of obesity been present?
(years) _____
9. Has the patient attempted weight control through diet under the supervision of a physician? Yes () No (). If yes, please indicate data and results obtained. (If another attending physician, please give name.)

10. If surgery has been (or is to be) performed in an attempt to relieve the obesity, please describe the indications for surgical intervention:

11. General Comments:

PREPARED BY:

DATE:

Thank you for prompt attention to this matter.

Sincerely,
Special Claims

**WEIGHT IN POUNDS ACCORDING TO FRAME
MEN - AGES 25 AND OVER**
(With shoes on - 1 inch heels)

HEIGHT	SMALL FRAME	MEDIUM FRAME	LARGE FRAME
5 ft. 2"	112-120	118-129	126-141
5 ft. 3"	115-123	121-133	129-144
5 ft. 4"	118-126	124-136	132-148
5 ft. 5"	121-129	126-139	135-152
5 ft. 6"	124-133	130-143	138-156
5 ft. 7"	128-137	134-147	142-161
5 ft. 8"	132-141	138-152	147-166
5 ft. 9"	136-145	142-156	151-170
5 ft. 10"	140-150	146-160	155-174
5 ft. 11"	144-154	150-165	159-170
6 ft. 0"	148-158	154-170	164-184
6 ft. 1"	152-162	158-175	168-189
6 ft. 2"	156-167	162-180	173-194
6 ft. 3"	160-171	167-185	178-199
6 ft. 4"	164-175	172-190	182-204

**WEIGHT IN POUNDS ACCORDING TO FRAME
WOMEN AGES 25 AND OVER**
(Girls between 18 & 25 subtract one pound for each year under 25)

HEIGHT	SMALL FRAME	MEDIUM FRAME	LARGE FRAME
4 ft. 10"	92-98	96-107	104-119
4 ft. 11"	94-101	98-110	106-122
5 ft. 0"	96-104	101-113	109-125
5 ft. 1"	98-107	104-116	112-128
5 ft. 2"	102-110	107-119	115-131
5 ft. 3"	105-113	110-122	118-134
5 ft. 4"	108-116	113-126	121-138
5 ft. 5"	111-119	116-130	125-142
5 ft. 6"	114-123	120-135	129-146
5 ft. 7"	118-127	124-139	133-150
5 ft. 8"	122-131	128-143	137-154
5 ft. 9"	126-135	132-147	141-158
5 ft. 10"	130-140	136-151	145-163
5 ft. 11"	134-144	140-155	149-168
6 ft. 0"	138-148	144-159	153-173

Excerpt from "Four Steps to Weight Control", © Metropolitan Life Insurance Company (06/72)

64550: Application of Surface (Transcutaneous) Neurostimulator

Revision Overview: Policy is revised due to the 2002 ICD-9-CM update.

Policy Number

64550

CMS National Coverage Policy

Coverage Issues Manual, Sections 35-20, 35-46, 45-19, 60-20, 65-8

Contractor Name

First Coast Service Options, Inc.

Primary Geographic Jurisdiction

Florida

Contractor Number

00590

Secondary Geographic Jurisdiction

N/A

Contractor Type

Carrier

CMS Region

Region IV

LMRP Title

Application of Surface (Transcutaneous) Neurostimulator

CMS Consortium

Southern

AMA CPT Copyright Statement

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Original Policy Effective Date

11/18/1996

Original Policy Ending Date

N/A

Revision Effective Date

10/01/2001

Revision Ending Date

09/30/2001

LMRP Description

Transcutaneous electrical nerve stimulator (TENS) is a type of electrical nerve stimulator that is employed to treat chronic intractable pain and for the relief of acute post-operative pain. TENS is the application of electrical stimulation to skin electrodes which may be placed over a painful area. Placement in paravertebral locations as well as over nerves proximal, distal, and even contralateral to a site of pain may also be used. The electrical signals from the TENS interfere with the transmission of painful stimuli sent to the brain producing analgesia. TENS can produce analgesia for a wide range of medical conditions.

Indications and Limitations of Coverage and/or Medical Necessity

Florida Medicare will consider Application of Surface (Transcutaneous) Neurostimulator (TENS) medically reasonable and necessary for the following conditions: (See Covered ICD-9-CM Codes)

The TENS unit may be applied by the attending physician or an employee of the physician who has received the order from the physician. A patient must be taught how to employ the stimulator by the provider/supplier, and be able to use the TENS unit safely and effectively without direct medical supervision. Consequently, it would be inappropriate for a patient to visit his/her physician, physical therapist, or an outpatient clinic on a continuing basis for treatment of pain with electrical nerve stimulation. In addition, one would not expect to see Application of Surface (Transcutaneous) Neurostimulator (CPT code 64550) routinely billed with Electrical Stimulation (CPT codes 97014 or 97032) or other physical therapy services.

Repeat training on the application of TENS (CPT code 64550) may be considered medically necessary if the patient presents with a new conditioning/injury and there has been an extended hiatus in treatment. Documentation would need to support the medical necessity for repeat training.

Claims submitted for Application of Surface (Transcutaneous) Neurostimulator performed at unusually frequent intervals will be reviewed by Medicare to make certain that the service was medically reasonable.

CPT/HCPCS Section & Benefit Category

Surgery/Nervous System

CPT/HCPCS Codes

64550

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

337.0-337.9	715.00-715.98	718.80-718.89
349.81-349.89	718.20-718.29	719.40-719.49
349.9	718.30-718.39	719.60-719.69
350.1-350.9	718.40-718.49	719.80-719.89
352.0-352.9	718.50-718.59	719.90-719.99
353.0-353.9	718.60	720.0-720.9
354.0-354.9	718.65	721.0-721.42
355.0-355.9	718.70-718.79	722.0-722.93

723.0	728.0	729.1
723.1	728.11	729.2
723.2	728.12	729.5
723.3	728.2	781.4
723.4	728.5	781.7
724.00-724.9	728.81	784.0
725	729.0	

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

The application of TENS (64550), is not payable for motor function disorders such as multiple sclerosis and Bell’s Palsy.

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 Diagnoses

N/A

Coding Guidelines

The physician may not be reimbursed for an office visit in conjunction with the procedure itself, unless there is a clear indication that the patient was seen for a different reason. The physician must utilize Modifier “25” to indicate that the office visit was for an unrelated condition.

Documentation Requirements

Medical record documentation maintained by the ordering/performing physician must indicate the medical necessity for the Application of TENS.

Required documentation in support of medical necessity would include:

- History and physical
- Office notes/progress notes
- Treatment records

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.

Carrier Advisory Committee Meeting held on July 20, 1996.

Start Date of Comment Period

N/A

End Date of Comment Period

N/A

Start Date of Notice Period

11/01/2001

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Start Date of Comment Period		N/A
Start Date of Notice Period		11/01/2001
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Revised Effective Date:		10/01/2001

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

70450: Computerized Tomography Scans

The local medical review policy for computerized tomography scans (70450) was published in the June 2001 Special *Medicare B Update!* (pages 16-17). Since that time, the ICD-9-CM diagnosis code for Visual field defect, unspecified (368.40) for CPT codes 70450, 70460 and 70470 has been expanded to include the diagnosis

code range for Visual field defects (368.40-368.47). This code range has been added to the “ICD-9-CM Codes that Support Medical Necessity (70450, 70460, 70470)” section of the policy, **effective for claims processed on or after October 29, 2001.**

71010: Chest X-Ray

Revision Overview: Policy revised due to 2002 ICD-9-CM update.

Policy Number

71010

Contractor Name

First Coast Service Options, Inc.

Contractor Number

00590

Contractor Type

Carrier

LMRP Title

Chest X-Ray

AMA CPT Copyright Statement

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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

06/01/1994

Original Policy Ending Date

N/A

Revision Effective Date

10/01/2001

Revision Ending Date

09/30/2001

LMRP Description

Radiologic examination of the chest (chest X-ray) facilitates the detection, diagnosis, staging and management of pathophysiologic processes involving thoracic, cardiovascular, pulmonary and mediastinal structures, contiguous coverings and the bony thorax. These examinations are covered by Florida Medicare when medically necessary and appropriate for evaluation and management of a specific symptom, sign, disease or injury.

Indications and Limitations of Coverage and/or Medical Necessity

Chest X-rays are utilized in a variety of clinical states. Generally accepted medical diagnoses are enunciated as Covered ICD-9-CM Codes (Covered Codes). This Carrier will utilize these Covered Codes, and medical consultation, to assess medical necessity and appropriate utilization. Routine, screening, pre-operative or periodic examinations in the absence of symptoms, signs or disease will not be reimbursed.

Florida Medicare will cover chest X-rays in instances of:

- injury to the chest area (heart, lungs, mediastinum, sternum, ribs);
- signs and symptoms suggestive of chest structure abnormalities (e.g., coughing, positive TB skin test, hemoptysis, shortness of breath, dyspnea);
- underlying medical conditions with possible manifestations involving chest structures in which a chest X-ray would be deemed necessary to fully evaluate the condition (e.g., cardiac, metastatic CA);
- preoperative clearance for medical conditions which may pose a risk factor with the administration of general anesthesia (e.g., congestive heart failure, COPD);
- follow-up of an invasive procedure such as thoracentesis or central venous line placement.

CPT/HCPCS Section & Benefit Category

Radiology/Diagnostic Radiology

CPT/HCPCS Codes

71010	71021	71030
71015	71022	71034
71020	71023	71035

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

Infectious and Parasitic Diseases:

010.00-011.96	074.20-074.23	115.13-115.15
012.00-012.86	075	115.93-115.95
015.70-015.76	080	116.0-116.2
015.80-015.86	081.0	117.1
018.01-018.96	084.0-084.8	117.3
020.2-020.5	086.0	117.5
021.2	093.0-093.9	120.0-120.2
022.1	095.1	121.0-121.8
025	098.83	122.0
027.0	098.84	122.1
027.2	098.85	130.3
031.0	100.0	130.4
033.0-033.9	112.4-112.5	135
039.1	114.0	136.1
039.8	114.1	136.3
042	114.3	137.0
052.1	114.4	
073.0	114.5	
074.1	115.03-115.05	

Neoplasms

141.0-141.9	189.0-189.9	201.92
142.0-142.9	191.0-191.9	201.98
143.0-143.9	193	202.00-202.92
144.0-144.9	194.3	202.94
145.0-145.9	195.0-195.2	203.00-203.81
146.0-146.9	195.4	212.2-212.9
147.0-147.9	195.8	213.3
148.0-148.9	196.0-196.1	213.4
149.0-149.9	196.8-196.9	214.2
150.0-150.9	197.0-197.3	215.2
151.0-151.9	198.0-198.1	215.4
153.0-153.9	198.3-198.6	227.6
154.0-154.8	198.81	228.00
162.0-162.9	199.0	228.09
163.0-163.9	200.00-200.88	228.1
164.0-164.9	201.02	230.1
165.0-165.9	201.04	231.1-231.2
170.3	201.08	231.8-231.9
171.0-171.9	201.12	233.0
172.0-172.9	201.14	235.7
174.0-174.9	201.18	235.8
175.0-175.9	201.22	235.9
176.4-176.5	201.24	236.0
180.1	201.28	236.2-236.3
180.8-180.9	201.42	236.9
182.0-182.8	201.44	237.2-237.4
183.0-183.9	201.48	238.0-238.1
184.4	201.62	238.3
185	201.68	239.1
186.0-186.9	201.72	239.3
188.0-188.9	201.78	

Endocrine, Nutritional and Metabolic Diseases, and Immunity Disorders:

254.0-254.9	276.6	277.3
276.2-276.4	277.00-277.01	277.5

Mental Disorders:

306.0-306.2

Diseases of the Nervous System and Sense Organs:

354.8

Diseases of the Circulatory System

391.0-391.9	412	441.1
392.0	413.0-413.9	441.2
393	414.00-414.9	441.6-441.7
394.0-394.9	415.0-415.19	442.81-442.82
395.0-395.9	416.0-416.9	442.89
396.0-396.9	417.0-417.9	444.0-444.1
397.0-397.9	420.0	446.1
398.0	420.90-420.99	446.4
398.90-398.99	421.0-421.9	446.5
401.0-401.9	422.0-422.99	446.6
402.00-402.91	423.0-423.9	446.7
403.00-403.91	424.0-424.99	447.0
404.00-404.01	425.0-425.9	447.2
404.03	427.0-427.9	451.89
404.11	428.0-428.9	453.2
404.13	429.0-429.1	453.8
404.91	429.3-429.6	456.0-456.1
404.93	429.71	456.20-456.21
405.01- 405.19	429.79	459.2
410.00-410.92	429.81-429.9	
411.0-411.89	441.00-441.03	

Diseases of the Respiratory System

464.10-464.11	486	505
464.20-464.21	487.0-487.1	506.0-506.9
464.30-464.31	490	507.0-507.8
464.4	491.0-491.9	508.0-508.9
466.0-466.19	492.0-492.8	510.0-510.9
476.1	493.00-493.92	511.0-511.9
478.31-478.32	494.0-494.1	512.0-512.8
480.0-480.9	495.0-495.9	513.0-513.1
481	496	514
482.0-482.9	500	515
483.0	501	516.0-516.9
483.8	502	517.1-517.8
484.1-484.8	503	518.0-518.89
485	504	519.00-519.9

Diseases of the Digestive System

530.0	551.3
530.10-530.89	552.3

Diseases of the Genitourinary System

611.71

Complications of Pregnancy, Childbirth, and the Puerperium

639.5-639.6	669.00-669.04	671.44
642.50-642.54	669.10-669.14	672.00
642.60-642.64	669.20-669.24	672.02
642.70-642.74	671.30-671.31	672.04
648.50-648.54	671.33	673.00-673.84
668.00-668.04	671.40	
668.10-668.14	671.42	

Diseases of the Skin and Subcutaneous Tissue
682.2

Diseases of the Musculoskeletal System and Connective Tissue

710.0-710.1	737.10-737.11	739.2
714.2	737.30-737.34	739.8
733.6	738.3	

Congenital Anomalies

745.0-745.9	748.3-748.5	756.2-756.3
746.00-746.7	748.60-748.69	756.6-756.79
746.81-746.84	748.8-748.9	756.81-756.83
746.87	750.3	759.3-759.4
746.89	750.4	759.7
746.9	750.6	759.82
747.0-747.49	754.81-754.82	

Certain Conditions Originating in the Perinatal Period

760.3	771.7	778.0
768.2-768.9	773.3	778.2
769	775.0	778.5
770.0-770.9	775.2	779.0
771.0-771.1	775.7	779.2
771.3	776.2	779.5

Symptoms, Signs and Ill-defined Conditions

780.01	785.50-785.59	794.2
780.6	786.00-786.9	794.30-794.39
781.5	787.2	795.5
782.5	790.91	799.0-799.1
783.21	793.1-793.2	
785.0-785.3	793.80-793.89	

Injury and Poisoning

807.00-807.09	926.11	958.7
807.10-807.19	926.8	959.1
807.2-807.3	927.01-927.02	972.9
807.4	933.0-933.1	980.3
807.5	934.0-934.9	981
807.6	935.1-935.2	983.0-983.9
810.00-810.03	942.00-942.02	986
810.10-810.13	942.04	987.0-987.9
828.0-828.1	942.10-942.12	991.6
839.61	942.14	992.1
839.71	942.20-942.22	992.3
847.1	942.24	993.2-993.9
848.3	942.30-942.32	994.0-994.1
848.40-848.49	942.34	994.7
860.0-860.5	942.40-942.42	995.0-995.2
861.00-861.32	942.44	996.00-996.2
862.0-862.9	942.50-942.52	996.60-996.63
869.0-869.1	942.54	996.69
874.10-874.12	947.0-947.2	996.71-996.72
875.0-875.1	948.10-948.11	996.74-996.75
879.1	948.20-948.22	996.79
879.7	948.30-948.33	996.83-996.84
901.0-901.9	948.40-948.44	997.00-997.09
903.00-903.02	948.50-948.55	997.1-997.3
905.1	948.60-948.66	998.0
906.0	948.70-948.77	998.2
908.0	948.80-948.88	998.4
908.2	948.90-948.99	998.81
908.4	958.0	999.1
909.0	958.1	999.2
909.2-909.5	958.2	999.3
922.0-922.1	958.4	999.4

Supplementary Classification of Factors Influencing Health Status and Contact with Health Services

V10.00-V10.09	V10.87	V45.00-V45.09
V10.11-V10.29	V12.01	V45.81
V10.3	V41.6	V47.0-V47.2
V10.40-V10.49	V42.1-V42.2	V58.81-V58.89
V10.50-V10.59	V42.6	V67.1-V67.2
V10.71-V10.79	V43.2-V43.3	V71.1-V71.2
V10.82	V43.81	

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 screening chest X-rays performed with routine physical evaluations. Such services should be submitted with the routine physical examination (health checkup) diagnosis code V70.0. This is a noncovered service.

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 Diagnoses

N/A

Coding Guidelines

Chest X-rays must be billed with a diagnosis relating to the chest rather than a routine diagnosis or unrelated diagnosis. Diagnosis V58.81-V58.89 should be billed when a chest X-ray is being performed as follow-up to an invasive procedure (e.g., insertion of central line, PICC, etc.).

Documentation Requirements

The medical record documentation must indicate the medical necessity of the test. In addition, documentation that the service was performed, including the test results, should be in the patient’s medical records. This information is usually found in the office/progress notes, hospital notes, and/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

Terms Defined:

COPD: chronic obstructive pulmonary disease: generalized airways obstruction, particularly of small airways, associated with varying combinations of chronic bronchitis, asthma, and emphysema.

Congestive Heart Failure (CHF): a common syndrome that may be caused by many different etiologies whose clinical manifestations reflect a fundamental abnormality—a decrease in the myocardial contractile state such that cardiac output is inadequate for the body’s needs.

Dyspnea: air hunger resulting in labored or difficult breathing, sometimes accompanied by pain.

Hemoptysis: expectoration of blood arising from hemorrhage of the larynx, trachea, bronchi, or lungs.

Pleural effusion: escape of fluid into the pleural cavity.

Sources of Information and Basis for Decision

Sources of information may be found online under “Medical Policy” in the Part B 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:	11	PCS B2001-159
Start Date of Comment Period		N/A
Start Date of Notice Period		11/01/2001
		1 st QTR 2002 <i>Update!</i>
Revised Effective Date:		10/01/2001

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

72192: Computerized Tomography of the Pelvis

The local medical review policy for computerized tomography of the pelvis (72192) was published in the 2nd Quarter 2001 *Medicare B Update!* (pages 71-73). Since that time, ICD-9-CM diagnosis codes 625.9,

789.00, and 789.39 have been added to the “ICD-9-CM Codes that Support Medical Necessity (CPT codes 72192, 72193, and 72194)” section of the policy, **effective for claims processed on or after October 29, 2001.**

76075: Bone Mineral Density Studies

Revision Overview: Policy is revised due to the 2002 ICD-9-CM update.

Policy Number

76075

Contractor Name

First Coast Service Options, Inc.

Contractor Number

00590

Contractor Type

Carrier

LMRP Title

Bone Mineral Density Studies

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CMS National Coverage Policy

HCFA-Pub. 60AB
Coverage Issues Manual 50-44 precludes Medicare payment for dual photon absorptiometry.
Code of Federal Regulations 410.32 A(3).

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

CMS Region

Region IV

CMS Consortium

Southern

Original Policy Effective Date

07/19/1993

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 a Food and Drug Administration (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.
- 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), 256.3[1-256.39] (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 practitioners include physician assistants, nurse practitioners, 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 FDA 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

CPT/HCPCS Codes

G0130	G0132	76076	76977
G0131	76075	76078	78350

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

252.0	733.00	733.90
256.2	733.01	805.00-805.9
256.31-256.39	733.02	806.00-806.9
627.2	733.09	E932.0

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” 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 dexta 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 Diagnoses

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 CPT/HCPCS section for the appropriate 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 “phantom”, 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.

Documentation Requirements

Medical record documentation maintained by the ordering/referring physician must indicate the medical necessity for performing the test and the test results. In addition, if the service exceeds the frequency parameter listed in this policy, documentation of medical necessity must be submitted. This information is usually found in the history and physical, office/progress notes, or test 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

N/A

Sources of Information and Basis for Decision

Sources of information may be found online under “Medical Policy” in the Part B 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 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:	13	PCR B2001-159
Start Date of Comment Period		N/A
Start Date of Notice Period		11/01/2001
		1 st QTR 2002 Update!
Revised Effective Date:		10/01/2001

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

78460: Myocardial Perfusion Imaging

Revision Overview: Policy revised due to the 2002 ICD-9-CM update.

Policy Number

78460

Contractor Name

First Coast Service Options, Inc.

Contractor Number

00590

Contractor Type

Carrier

LMRP Title

Myocardial Perfusion Imaging

AMA CPT Copyright Statement

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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

12/01/1994

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) testing for detecting coronary artery disease and determining prognosis. The single-photon emission computed tomographic (SPECT) technique is utilized to obtain multiple-angle images.

Florida Medicare has not previously published a specific coverage policy concerning myocardial perfusion imaging. This policy has been developed in order to define the circumstances for which myocardial perfusion imaging will be considered medically necessary by Florida Medicare.

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

CPT/HCPCS Codes

78460	78464	78478
78461	78465	78480

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

411.0	413.9	414.10
411.1	414.00	414.11
411.81	414.01	414.19
411.89	414.02	414.8
412	414.03	414.9
413.0	414.04	424.0
413.1	414.05	426.2

426.3	426.7	995.2
426.4	427.31	E942.0
426.50	428.0	E942.1
426.51	428.1	V67.00
426.52	428.9	V67.09
426.53	440.21-440.24	V67.51
426.54	794.31	V67.59
426.6	960.7	

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 Diagnoses

N/A

Coding Guidelines

Myocardial imaging agents used for cardiac perfusion studies *both* at rest and at stress are covered when billed with CPT codes 78460-78465, 78478, and 78480. Procedure code A4641 (supply of radiopharmaceutical diagnostic imaging agent) can be billed when a specific code does not exist for the agent used. Use code 93015 or 93016 as appropriate when billing for ECG (stress test supervision and interpretation) by a physician.

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 covered by the Medicare program. Also, the results of myocardial perfusion 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 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. When ordering myocardial perfusion imaging the ordering/referring physician must state the reason for the myocardial perfusion studies in his order for the test.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

Sources of information may be found online under “Medical Policy” in the Part B 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 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:	8	PCR B2001-159
Start Date of Comment Period		N/A
Start Date of Notice Period		11/01/2001
		1 st QTR 2002 <i>Update!</i>
Revised Effective Date:		10/01/2001

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

78472: Cardiac Blood Pool Imaging

Revision Overview: Policy revised due to the 2002 ICD-9-CM update.

Policy Number

78472

Contractor Name

First Coast Service Options, Inc.

Contractor Number

00590

Contractor Type

Carrier

LMRP Title

Cardiac Blood Pool Imaging

AMA CPT Copyright Statement

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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

04/17/2000

Original Policy Ending Date

N/A

Revision Effective Date

10/01/2001

Revision Ending Date

09/30/2001

LMRP Description

Radionuclide ventriculography is one of the most widely used techniques for evaluating ventricular function. This essentially noninvasive method of assessing ventricular function can be easily performed and provides a reproducible, accurate evaluation of both right ventricular and left ventricular function. Currently, there are two techniques for assessment of ventricular performance using radionuclides: the first-pass technique and gated blood pool imaging. Information that can be derived from these studies include assessment of left and/or right ventricular ejection fraction, regional wall motion, left ventricular volumes, and diastolic function.

Gated blood pool imaging (multigated acquisition, or MUGA), also known as equilibrium radionuclide angiography, is the most widely used technique to assess ventricular function. In this technique, the patient's erythrocytes are labeled with technetium-99m and the

imaging is performed by synchronizing acquisition to the R wave of the electrocardiogram (ECG). Sampling is performed repetitively over several hundred heartbeats with physiological segregation of nuclear data according to occurrence within the cardiac cycle.

First-pass radionuclide angiography utilizes a high-count-rate gamma camera and involves sampling for only seconds during the initial transient of the technetium-99m bolus through the central circulation. The high-frequency components of this radioactive passage are recorded and analyzed quantitatively. After data acquisition, right and left ventriculograms are constructed from which ejection fractions and ventricular volumes can be calculated.

Indications and Limitations of Coverage and/or Medical Necessity

Florida Medicare will consider cardiac blood pool imaging studies medically reasonable and necessary for the following indications:

- Evaluation of a patient with suspected or known coronary artery disease (CAD). A radionuclide ventriculogram assists in stratifying patients into low and high risk, thereby providing prognostic value. However, perfusion imaging is superior to exercise radionuclide ventriculograms. Therefore, current practice is to perform stress myocardial perfusion imaging in patients with suspected CAD.
- Evaluation of a patient after a Myocardial Infarction (MI). Assessment of the impact of the MI on ventricular function, identification of the physiologic importance of coronary stenosis outside the infarct distribution (i.e., extent in which viable myocardium is jeopardized), and risk stratification for future cardiac events is determined. Normally, a resting study is recommended.
- Assessment of right ventricular function, especially in patients with cor pulmonale or an acute inferior MI caused by right ventricular infarction.
- Evaluation and monitoring of a patient with dilated or hypertrophic cardiomyopathy. Restrictive cardiomyopathy is normally diagnosed with other noninvasive methods, therefore, radionuclide studies do not have a role in the diagnosis of restrictive cardiomyopathy.
- Evaluation of a patient with suspected or known valvular heart disease to determine ventricular function and estimate the degree of valvular regurgitation. Serial evaluations may be necessary in patients with asymptomatic aortic regurgitation to determine surgical timing. In addition to obtaining a resting left ventricular ejection fraction (usually by the gated blood pool technique) in the timing of surgery, exercise duration is also a key indicator.
- Evaluation and management of a patient with congestive heart failure. The most important imaging procedure is two-dimensional echocardiography, which can evaluate ventricular chamber size, regional and global wall motion, left ventricular wall thickness, and valvular function. Radionuclide angiography provides assessment of left ventricular ejection fraction and is quantified easier by a radionuclide rather than an echocardiographic technique.

- Evaluation and management of a patient with a neoplastic disease who will be receiving an anthracycline like neoplastic drug. Doxorubicin (an example of an anthracycline) is associated with the development of irreversible cardiotoxicity when given in doses of 450 mg/m² or greater. Therefore, a resting left ventricular ejection fraction is recommended before starting therapy and again after receiving cumulative doses of 300 mg/m² and 450 mg/m². Other anthracyclines include drugs such as Daunorubicin, Epirubicin, Idarubicin, Mitoxantrone, and Valrubicin.
- Detection and quantification of intracardiac shunts for patients with congenital heart disease. The first pass technique is better than the gated technique for this indication.
- Evaluation of ventricular function during exercise to determine cardiac reserve in patients with congenital heart disease.
- To distinguish systolic from diastolic dysfunction in a patient with exertional dyspnea thought to be cardiac in etiology.
- Evaluation of a patient after cardiac surgery (e.g., coronary artery bypass graft) to determine the effect of the intervention on left ventricular function and the results are being used in the management of the patient (i.e., changes to patient’s medication regime or medical intervention will occur).

CPT/HCPCS Section & Benefit Category

Cardiovascular System/Radiology

CPT/HCPCS Codes

78472	78481	78494
78473	78483	78496

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

410.00-410.92	416.9	746.00-746.9
411.1	424.0	786.05
411.81	424.1	E930.7
413.0-413.9	425.1	E933.1
414.00-414.05	425.4	V58.83
414.8	428.0-428.9	V67.00
414.9	745.0-745.9	V67.09

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 Diagnoses

N/A

Coding Guidelines

Procedure code 78496 (cardiac blood pool imaging, gated equilibrium, single study, at rest, with right ventricular ejection fraction by first pass technique) is considered an add-on code, and therefore, should only be billed in conjunction with procedure code 78472 (cardiac blood pool imaging, gated equilibrium; planar, single study at rest or stress, wall motion plus ejection fraction, with or without additional quantitative processing).

In certain indications, it is common for a patient to undergo a myocardial perfusion imaging study (78460-78465, 78478-78480) and a cardiac blood pool imaging study during the same session. However, it is not expected that two different techniques (e.g., 78478 and 78472) be billed since the information such as wall motion and/or ejection fraction is obtained from the cardiac blood pool imaging technique. In this type of scenario, the billing of the lesser code is considered a duplicate of the cardiac blood pool imaging code.

It is not expected for a provider to bill for the multiple study procedure codes (78473 and 78483) on the same day, since the multiple study is performed using either the gated equilibrium method or the first pass technique.

Effective for services on or after 10/01/2000, diagnosis code V58.83 should be used when the imaging is being performed for the evaluation and management of a patient with a neoplastic disease who will be or is receiving an anthracycline like neoplastic drug. The E codes (E930.7 or E933.1) should be used when the patient is experiencing adverse events to the anthracycline like neoplastic drug.

Documentation Requirements

Medical record documentation maintained by the ordering/referring physician must clearly indicate the medical necessity of cardiac blood pool imaging studies. In addition, the results of the study must be included in the patient’s medical record. This information is normally found in the office/progress notes, hospital records, and/or test 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 service in his order for the test.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

Sources of information may be found online under “Medical Policy” in the Part B 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 College of Cardiology.

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 PCR B2001-159
 Start Date of Comment Period N/A
 Start Date of Notice Period 11/01/2001
 1st QTR 2002 *Update!*
 Revised Effective Date: 10/01/2001

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

80061: Lipid Profile/Cholesterol Testing

It was recently brought to the attention of Florida Medicare that certain drugs might significantly increase serum triglycerides and total cholesterol during the course of therapy. Therefore, for services processed on or after October 29, 2001, ICD-9-CM code 995.2 will be allowed for procedure code 80061.

80162: Digoxin

Revision Overview: ICD-9-CM code V58.69 was added to the list of codes that support medical necessity.

Policy Number
80162

Contractor Name
First Coast Service Options, Inc.

Contractor Number
00590

Contractor Type
Carrier

LMRP Title
Digoxin

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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
11/18/1996

Original Policy Ending Date
N/A

Revision Effective Date
10/29/2001

Revision Ending Date
10/28/2001

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

CPT/HCPCS Codes
80162

Not Otherwise Classified Codes (NOC)
N/A

ICD-9-CM Codes that Support Medical Necessity

368.16	426.4	514
368.9	426.50-426.54	783.0
402.00-402.91	426.6	787.01-787.03
413.0	426.7	972.1
425.3-425.9	426.81-426.9	E942.1
426.0	427.0-427.9	V58.69
426.10	428.0-428.9	V72.84

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.

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 Diagnoses

N/A

Coding Guidelines

Use CPT 80162 when performing a Digoxin blood level.

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.

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:	3	PCR B2001-164
Start Date of Comment Period		N/A
Start Date of Notice Period		11/01/2001
		1 st QTR 2002 <i>Update!</i>
Revised Effective Date:		10/29/2002

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

82270: Fecal Occult Blood Testing

Revision Overview: Policy revised due to 2002 ICD-9-CM update.

Policy Number

82270

Contractor Name

First Coast Service Options, Inc.

Contractor Number

00590

Contractor Type

Carrier

LMRP Title

Fecal Occult Blood Testing

AMA CPT Copyright Statement

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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

12/01/1994

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.

Florida Medicare has not previously published a specific policy concerning Fecal Occult Blood Testing. The policy below is being developed to delineate the circumstances where Fecal Occult Blood Testing will be considered medically necessary, and covered, by the Florida Medicare Carrier.

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 "ICD-9-CM Codes That Support Medical Necessity"):

- 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

CPT/HCPCS Codes

82270

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

009.0-009.3	530.81-530.89	780.4
042	530.9	780.6
070.0-070.33	531.00-531.91	780.79
070.41-070.49	532.00-532.91	782.4
070.51-070.59	533.00-533.91	783.0
070.6	534.00-534.91	783.2 1
070.9	535.00-535.61	784.9
129	536.0-536.9	787.01-787.03
150.0-159.9	537.0-537.6	787.1
176.3	537.81-537.89	787.2
183.0-183.9	537.9	787.3
197.0-197.8	555.0-555.9	787.4
199.0-199.1	556.0-556.9	787.5
211.0-211.9	557.0-557.9	787.6
228.04	558.1-558.9	787.7
228.09	560.0-560.2	787.91
230.0-230.9	560.30-560.39	787.99
235.2	560.81-560.89	789.0-789.9
235.3	560.9	790.6
235.4	562.00-562.03	792.1
235.5	562.10-562.13	793.3
239.0	564.00-564.9	793.4
251.5	565.0-565.1	793.6
263.9	566	794.8
280.0-280.9	567.0-567.9	863.99
281.0-281.9	568.0	864.00-864.19
282.0-282.9	568.81-568.89	865.00-865.09
283.0	568.9	865.10-865.19
283.10-283.19	569.0-569.3	866.00-866.03
283.2	569.41-569.49	866.10-866.13
283.9	569.5	867.0-867.9
284.0-284.9	569.60-569.69	868.00-868.09
285.0-285.9	569.81-569.89	868.10-868.19
286.0-286.9	569.9	869.0-869.1
287.0-287.9	570	902.0
288.0-288.9	571.0-571.3	902.10-902.19
289.0	571.40-571.49	902.20-902.29
289.1	571.5	902.31-902.39
289.2	571.6	902.40-902.49
289.3	571.8	902.50-902.59
289.4	571.9	902.81-902.89
289.50-289.59	572.0-572.8	902.9
289.6	573.0-573.9	922.1-922.9
289.7	574.00-574.91	926.0
289.8	575.0-575.9	926.11
289.9	576.0-576.9	926.12
448.0	577.0-577.9	926.19
455.0-455.9	578.0-578.9	926.8
456.0-456.21	579.0-579.9	926.9
458.9	596.1	935.0-935.2
530.0	751.0-751.5	936
530.10-530.19	751.60-751.69	937
530.2	751.7	938
530.3	751.8	995.2
530.4	751.9	V10.00-V10.09
530.5	759.6	V12.70-V12.79
530.6	772.4	V15.2
530.7	780.2	V67.51

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 Diagnoses

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.

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: 11 PCR B2001-159
 Start Date of Comment Period N/A
 Start Date of Notice Period 11/01/2001
 Revised Effective Date: 10/01/2001
 1st QTR 2002 *Update!*

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

82310: Total Calcium—Addition to Policy

The local medical review policy (LMRP) for Total Calcium was published in the 1st Quarter 2001 *Medicare B Update!* (pages 69-71). The diagnosis range for nephritis, nephritic syndrome, and nephrosis (580.0-

588.9) has since been added to the “ICD-9-CM Codes that Support Medical Necessity” section of the policy. This change is effective for claims processed on or after October 17, 2001.

84436: Thyroid Function Tests

Revision Overview: Policy revised due to 2002 ICD-9-CM update.

Policy Number

84436

Contractor Name

First Coast Service Options, Inc.

Contractor Number

00590

Contractor Type

Carrier

LMRP Title

Thyroid Function Tests

AMA CPT Copyright Statement

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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

03/08/1996

Original Policy Ending Date

N/A

Revision Effective Date

10/01/2001

Revision Ending Date

09/30/2001

LMRP Description

Thyroid function tests are standard tests used for the diagnosis of thyroid dysfunction, for investigation of conditions in which thyroid disease is in the differential diagnosis, and for the monitoring of treatment of diseases of the thyroid. Thyroid function tests include the total thyroxine (TT4), T3 resin uptake (T3 uptake), free thyroxine (FT4), triiodothyronine (TT3), free triiodothyronine (FT3), and thyroid stimulating hormone (TSH).

Indications and Limitations of Coverage and/or Medical Necessity

Florida Medicare will consider Thyroid Function Tests to be medically necessary under any of the following circumstances:

- A patient has signs and symptoms of hypothyroidism which can include the following:
 - ataxia
 - bradycardia and hypothermia
 - coarseness or loss of hair
 - constipation
 - decreased concentration
 - depression
 - dry skin and cold intolerance
 - fatigue
 - goiter
 - hoarseness
 - hyperlipidemia
 - irregular or heavy menses and infertility
 - memory and mental impairment
 - myalgias
 - myxedema, fluid infiltration of tissues
 - reflex delay, relaxation phase
 - weight gain
 - yellow skin
- A patient has signs and symptoms of hyperthyroidism which can include the following:
 - alterations in appetite
 - changes in vision, photophobia, eye irritation, diplopia, or exophthalmos (proptosis)
 - dependent lower extremity edema

- exertional intolerance and dyspnea	359.5	625.3	780.8
- fatigue and muscle weakness	368.2	626.0-626.2	781.3
- frequent bowel movements	374.41	626.4	782.3
- heat intolerance and increased sweating	376.21	648.10-648.14	783.1
- impaired fertility	376.30-376.31	701.1	783.21
- menstrual disturbance (decreased flow)	376.33-376.34	703.8	783.4
- mental disturbances	427.0	704.00	784.1
- nervousness and irritability	427.1	729.1	784.49
- palpitations and tachycardia	427.2	729.82	785.0
- pretibial myxedema (with Graves disease)	427.31	733.09	785.1
- sleep disturbances	427.32	759.2	786.03-786.09
- sudden paralysis	427.81-427.9	775.3	794.5
- thyroid enlargement/tenderness	560.1	780.09	799.2
- tremor	564.00-564.09	780.50	E939.8
- weight loss	564.7	780.79	

- Once thyroid levels have stabilized, testing would normally not be performed more than once every 6 months.
- More frequent testing may be medically necessary at the time of initial diagnosis of hyperthyroidism or hypothyroidism until desired thyroid levels are achieved.
- More frequent testing may also be medically necessary if there are acute changes in the patient’s condition, or if it is necessary to adjust a patient’s dosage.

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

- A Thyroid Function Test may be performed for the monitoring of a patient’s response to the administration of lithium. A Thyroid Function Test would normally be performed 6 months after the initiation of lithium and yearly thereafter for monitoring purposes.

Note: A Thyroid Function Test performed prior to the initiation of lithium in an asymptomatic patient is considered screening and is noncovered by Medicare.

CPT/HCPCS Section & Benefit Category

Pathology and Laboratory/Chemistry

CPT/HCPCS Codes

84436	84439	84479	84481
84437	84443	84480	84482

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

193	246.0-246.9	278.01
226	253.2	290.10-290.3
237.4	253.3-253.4	293.1
239.7	253.7	296.00-296.99
240.0-240.9	255.4	300.00-300.02
241.0-241.9	272.0	310.1
242.00-242.91	272.1	311
243	272.2	333.1
244.0-244.9	275.40-275.49	356.9
245.0-245.9	276.1	358.0

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 Diagnoses

N/A

Coding Guidelines

Separate payment will be made to physicians or independent clinical laboratories for drawing a blood sample through venipuncture (G0001).

ICD-9-CM code E939.8 is to be used for the monitoring of a patient’s response to the administration of Lithium.

Documentation Requirements

Medical record documentation maintained by the ordering/referring physician must indicate the medical necessity for performing thyroid function tests. Initially a comprehensive history and physical examination should be performed and documented that includes the following:

- cardiovascular examination
- neuromuscular examination
- patient’s complaints or symptoms
- pulse rate
- thyroid palpation
- weight and blood pressure

During follow-up visits, an appropriate interim history and physical examination should be performed in conjunction with appropriate laboratory tests. An interim history should assess response to therapy, changes in medication or therapy, and evaluation of the clinical improvement in symptoms, as well as possible side effects of the medication or therapy.

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

Sources of information may be found online under "Medical Policy" in the Part B 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:	9	PCR B2001-159
Start Date of Comment Period		N/A
Start Date of Notice Period		11/01/2001
		1 st QTR 2002 <i>Update!</i>
Revised Effective Date:		10/01/2001

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

85007: Complete Blood Count (CBC)

The Centers for Medicare & Medicaid Services Transmittal AB-01-135 (Change Request 1793) dated September 25, 2001 states 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, effective September 1, 2001, 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 local medical review policy for CBC.

Source: CMS Transmittal AB-01-135, CR 1793)

92136: Optical Coherence Biometry

Revision Overview: Original policy.

Policy Number

92136

Contractor Name

First Coast Service Options, Inc.

Contractor Number

00590

Contractor Type

Carrier

LMRP Title

Optical Coherence Biometry

AMA CPT Copyright Statement

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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

Optical Coherence Biometry (OCB) is a new ophthalmic diagnostic test to perform ophthalmic biometry and intraocular lens (IOL) calculation without ultrasound. The instrument utilized is a non-invasive, non-contact device that measures axial length, corneal curvature, and anterior chamber depth taking a series of measurements. All measurements are stored in a computer, as well as automatically transferred to the IOL calculation program, which allows the surgeon immediate and individualized computation of IOL implant options for his/her patient. The method takes about one minute per eye.

Indications and Limitations of Coverage and/or Medical Necessity

Florida Medicare will consider the performance of OCB medically reasonable and necessary if performed preoperatively by the operating surgeon or his/her designee for the purpose of determining intraocular lens power in a patient undergoing cataract surgery. Generally, it is expected that the provider that is performing the cataract surgery will perform OCB.

CPT/HCPCS Section & Benefit Category

Medicine/Ophthalmology

CPT/HCPCS Codes

92136

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

366.00-366.04	366.17	366.33
366.10	366.18	366.34
366.11	366.19	366.41-366.46
366.13	366.20	379.31-379.34
366.14	366.22	743.30-743.35
366.15	366.30	996.53
366.16	366.32	V43.1

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 Diagnoses

N/A

Coding Guidelines

Because this instrument employs partial coherence interferometry to determine the axial length of the eye, rather than ultrasound, it is not appropriate to bill procedure code 76519 (Ophthalmic biometry by ultrasound echography, A-scan; with intraocular lens power calculation) for this device.

It is not considered medically reasonable or necessary to perform both an A-scan and OCB. Therefore, procedure code 76519 will not be paid in addition to OCB.

Documentation Requirements

Medical record documentation maintained by the performing provider 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 record. This information is normally found in the office/progress notes and/or procedure report.

Documentation should support the criteria 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 Policy” in the Part B 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 Society of Ophthalmology.

Carrier Advisory Committee Meeting held on May 19, 2001.

Start Date of Comment Period

05/11/2001

End Date of Comment Period

06/25/2001

Start Date of Notice Period

11/01/2001

Revision History

Revision Number	Original	PCR B2001-167
Start Date of Comment Period:		05/11/2001
Start Date of Notice Period:		11/01/2001
		1 st QTR 2002 <i>Update!</i>
Original Effective Date		01/01/2002

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

92980: Interventional Cardiology

Revision Overview: Policy revised due to the 2002 ICD-9-CM update and to comply with CMS LMRP format.

Policy Number

92980

Contractor Name

First Coast Service Options, Inc.

Contractor Number

00590

Contractor Type

Carrier

LMRP Title

Interventional Cardiology

AMA CPT Copyright Statement

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CMS National Coverage Policy

Coverage Issues Manual, Section 50-32

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

CMS Region

Region IV

CMS Consortium

Southern

Original Policy Effective Date

1993

Original Policy Ending Date

N/A

Revision Effective Date

10/01/2001

Revision Ending Date

09/30/2001

LMRP Description

Percutaneous transluminal coronary interventions have, since Gruentzig's 1979 report of coronary balloon angioplasty, substantively altered the management of individuals with symptomatic arteriosclerotic heart disease. Balloon angioplasty rapidly expanded from single to multiple vessels and simple to complex anatomic substrates. Transluminal interventions now encompass balloon dilation, a variety of atherectomy devices and two stents approved for coronary placement. Complementing medical therapy and aortocoronary bypass, transluminal interventions have emerged as a third therapeutic option for the management of patients with chronic angina, acute coronary insufficiency and evolving myocardial infarction.

In this policy, the Carrier relates existing procedural descriptors, defines indications for coverage and provides documentation and submission instructions. These definitions and instructions are provided to emphasize the Centers for Medicare & Medicaid Services' policy and philosophic intent, and to provide a flexible framework to meet the challenges of evolving technology and advances in physician experience and expertise. Much of this information has been previously published. It is repeated for clarification and coherence.

Indications and Limitations of Coverage and/ or Medical Necessity

Interventional Cardiology (92980, 92981, 92982, 92984, 92995, 92996):

Transluminal coronary interventions are appropriately considered in those patients who manifest either acute or chronic signs and symptoms of coronary insufficiency, who have not responded adequately to optimize medical therapy, for whom a probative alternative is aortocoronary bypass, who have objective evidence of myocardial ischemia and have lesions amenable to transluminal intervention. Medicare recognizes only three coronary arteries when considering first and additional vessel interventions; the left anterior descending, the left circumflex and the right coronary arteries.

Intravascular Ultrasound (Coronary Vessel or Graft) (92978, 92979):

Intravascular ultrasound takes the ultrasound transducer directly to the inside of the more distant vessels, and by using high frequencies is able to provide the most exquisite detail of these structures.

Codes 92978 and 92979 are add-on codes that should

be reported in addition to the specifically listed therapeutic intervention procedures when ultrasound is being performed. Codes 92978 and 92979 will only be allowed when billed in conjunction with the following therapeutic services:

92975, 92980, 92981, 92982, 92984, 92995, 92996

Intravascular ultrasound services include all transducer manipulations and repositioning within the specific vessel being examined, both before and after therapeutic intervention, (stent placement).

CPT/HCPCS Section & Benefit Category

Cardiovascular /Medicine

CPT/HCPCS Codes

92978	92980	92982	92995
92979	92981	92984	92996

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

(92980, 92981, 92982, 92984, 92995, 92996)

410.00-410.02	410.60-410.62	411.89
410.10-410.12	410.70-410.72	413.0
410.20-410.22	410.80-410.82	413.9
410.30-410.32	410.90-410.92	414.01-414.03
410.40-410.42	411.1	414.11
410.50-410.52	411.81	414.8

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

Use of an interventional device, or technologic modification, that has not received FDA approval.

Additional vessel codes applied to vessels other than the named major coronary arteries as recognized by Medicare and defined above.

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 Diagnoses

N/A

Coding Guidelines

When a single interventional modality is utilized in more than one of these three vessels, the first vessel is to be identified using the respective "single vessel" code. Each additional major coronary instrumented is to be identified using the "each additional vessel" code. Branch vessels are considered an integral part of these three parent,

major, named coronary arteries. Interventions in branch vessels are considered a part of and included with intervention in the named parent vessel.

Anatomic variants, (large ramus or marginal branches, unbalanced circulatory patterns, etc.), should be referenced as precisely as possible to a corresponding named vessel. Bypass conduits are considered, for nomenclature and coding purposes, integral to the vessel of distal anastomosis. Special consideration will be provided when multiple bypass conduits have a common named vessel distal anastomosis and when transluminal interventions are performed on both native vessels and bypass conduits. In the presence of bypass conduits, for purposes of these definitions, the left main coronary artery is considered a part of the major left system vessel receiving antegrade flow.

Medicare also recognizes a hierarchical scheme in technical complexity when multiple types of coronary intervention are employed in a single session. Generally, stent placement supersedes atherectomy which supersedes angioplasty. The *CPT-95* explanatory notes accompanying the instant codes define further this hierarchical ordering. When multiple transluminal interventions are combined during a single setting, coding should reflect this ranking order; the most complex intervention is identified by using that intervention's "single vessel" code and other interventions using the appropriate "each additional vessel" code. This same format is applicable when multiple interventions are performed in bypass conduits and/or native vessels and bypass conduits.

Three modifiers were added effective 1/1/97.

- LC-Left circumflex coronary artery
- LD-Left anterior descending coronary artery
- RC-Right coronary artery

These modifiers will be needed to identify treatment of multiple arteries.

Documentation Requirements

The provider has the responsibility to ensure medical necessity for all services and must maintain documentation for the possibility of a postpayment audit.

If medical necessity is in question or for postpayment review, submit the following:

- History and physical, and
- Operative 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 Policy" in the Part B section on our provider Web site - www.floridamedicare.com.

Advisory Committee Notes

N/A

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	PCR 2001-159
Start Date of Comment Period		N/A
Start Date of Notice Period		11/01/2001
		1 st QTR 2002 <i>Update!</i>
Revised Effective Date:		10/01/2001

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

93224: Electrocardiographic Monitoring for 24 hours (Holter Monitoring)

Revision Overview: Policy revised due to 2002 ICD-9-CM update and to comply with CMS' LMRP format.

Policy Number

93224

Contractor Name

First Coast Service Options, Inc.

Contractor Number

00590

Contractor Type

Carrier

LMRP Title

Electrocardiographic Monitoring for 24 hours (Holter Monitoring)

AMA CPT Copyright Statement

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CMS National Coverage Policy

Coverage Issues Manual, Section 50-15
Medicare Carriers Manual, Section 7506.5G

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

CMS Region

Region IV

CMS Consortium

Southern

Original Policy Effective Date

12/01/1994

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.

This coverage policy is being developed to clearly define the circumstances for which twenty-four hour continuous electrocardiographic monitoring is considered to be medically reasonable and necessary, and therefore covered, by Florida Medicare.

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 electrocardiogram 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
- Bifascicular 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
- Anomalous 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 Florida Medicare to make certain that the services were medically reasonable and necessary.

CPT/HCPCS Section & Benefit Category

Medicine/Cardiovascular

CPT/HCPCS Codes

93224-93237

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

410.00-410.02	414.11	427.42
410.10-410.12	414.19	427.5
410.20-410.22	414.8	427.61
410.30-410.32	414.9	427.69
410.40-410.42	423.1	427.81
410.50-410.52	423.2	427.89
410.60-410.62	424.0	427.9
410.70-410.72	425.0-425.9	429.3
410.80-410.82	426.0	429.4
410.90-410.92	426.12	429.9
411.0	426.13	780.2
411.1	426.2	785.1
411.81	426.4	E942.0
411.89	426.53	E942.1
412	426.7	V45.00
413.0-413.9	426.9	V45.01
414.00	427.0	V45.02
414.01	427.1	V45.09
414.02	427.31	V67.51
414.03	427.32	
414.10	427.41	

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

Screening tests performed on asymptomatic patients without medical problems, cannot be covered by Florida Medicare

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 Diagnoses

N/A

Coding Guidelines

These procedures can be performed in the following places of service:

- 11 Office
- 12 Home
- 21 Inpatient Hospital
- 22 Outpatient Hospital
- 31 Skilled Nursing Facility
- 32 Nursing Facility
- 33 Custodial Care Facility
- 51 Inpatient Psychiatric Facility
- 54 Intermediate Care Facility/Mentally Retarded
- 55 Residential Substance Abuse Treatment Facility
- 56 Psychiatric Residential Treatment Center
- 61 Comprehensive Inpatient Rehabilitation Facility

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

The most common specialties one would expect to see performing these services are:

- 01 General Practice
- 06 Cardiovascular Disease
- 08 Family Practice
- 11 Internal Medicine
- 78 Cardiac Surgery

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 Cardiology Society.

Carrier Advisory Committee Meeting held on July 23, 1994.

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	PCR B2001-159
Start Date of Comment Period		N/A
Start Date of Notice Period		11/01/2001
		1 st QTR 2002 <i>Update!</i>
Revised Effective Date:		10/01/2001

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

93350: Stress Echocardiography

Revision Overview: Policy revised due to 2002 ICD-9-CM update and to comply with CMS’ LMRP format.

Policy Number

93350

Contractor Name

First Coast Service Options, Inc.

Contractor Number

00590

Contractor Type

Carrier

LMRP Title

Stress Echocardiography

AMA CPT Copyright Statement

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CMS National Coverage Policy

Coverage Issues Manual, Section 50-7

Primary Geographic Jurisdiction

Florida

Secondary Geographic Jurisdiction

N/A

CMS Region

Region IV

CMS Consortium

Southern

Original Policy Effective Date

04/17/1995

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 and also flow direction and velocities within cardiac chambers and vessels. Usually these images are obtained from several positions on the chest wall and abdomen using a hand-held transducer.

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 “ICD-9-CM Codes that Support Medical Necessity”)

- 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

CPT/HCPCS Codes

93350

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

411.1	424.0	428.1
411.81	426.2	428.9
411.89	426.3	440.21-440.24
412	426.4	794.31
413.0	426.50	960.7
413.1	426.51	995.2
413.9	426.52	E942.0
414.00-414.03	426.53	E942.1
414.10	426.54	V67.00
414.11	426.6	V67.09
414.19	426.7	V67.51
414.8	427.31	V67.59
414.9	428.0	

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 stress echocardiography 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 Diagnoses

N/A

Coding Guidelines

These procedures can be performed in the following places of service:

- 11 Office
- 21 Inpatient Hospital
- 22 Outpatient Hospital
- 23 Emergency Room-Hospital
- 51 Inpatient Psychiatric Facility
- 61 Comprehensive Inpatient Rehabilitation Facility

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.

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. When ordering echocardiography studies from an independent physiological lab or other provider, the ordering/referring physician must state the reason for the echocardiography studies 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 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:	3	PCR B2001-159
Start Date of Comment Period		N/A
Start Date of Notice Period		11/01/2001
		1 st QTR 2002 <i>Update!</i>
Revised Effective Date:		10/01/2001

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

93501: Cardiac Catheterization

Florida Medicare has noted some confusion regarding the use of ICD-9-CM diagnosis code 786.05 (Shortness of breath). To help alleviate this, the local medical review policy for cardiac catheterization is being revised to add the word *dyspnea* to the descriptor for ICD-9-CM code 786.05.

94010: Spirometry

Revision Overview: Addition of diagnosis range 516.0-516.9

Policy Number

94010

Contractor Name

First Coast Service Options, Inc.

Contractor Number

00590

Contractor Type

Carrier

LMRP Title

Spirometry

AMA CPT Copyright Statement

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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

08/19/1996

Original Policy Ending Date

N/A

Revision Effective Date

10/08/2001

Revision Ending Date

10/07/2001

LMRP Description

Spirometry, a component of pulmonary function tests (PFT's) consists of the performance of a set of maneuvers to detect and quantitate disorders of pulmonary ventilation and gas exchange. PFT's 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

Pulmonary function tests are performed to detect abnormalities in respiratory function and to determine the extent of any pulmonary abnormalities. The PFT will be considered 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 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 patient's being treated with pulmonary toxic regimens (e.g., Amiodarone).
- To monitor patient's being treated with pulmonary toxic regimens when any new respiratory symptoms (e.g., exertional dyspnea, non-productive 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 utilized 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

CPT/HCPCS Codes

94010	94070	94200	94375
94060	94150	94360	

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

135	491.0-491.9	519.8
162.0-162.9	492.0-492.8	780.51
197.0	493.00-493.92	780.53
197.3	494.0-494.1	780.57
212.2	495.0-495.9	786.02-786.09
212.3	496	786.2
231.2	508.0-508.9	786.3
415.0	515	793.1
415.11-415.19	516.0-516.9	799.1
446.20	517.1-517.8	E942.9
466.0-466.19	518.0-518.89	E945.8
486	519.1	V72.82
490	519.4	

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 Diagnoses

N/A

Coding Guidelines

When a physician who is in attendance for a pulmonary function study, obtains a limited history, and performs a limited examination referable specifically to the pulmonary function testing, separately coding for an evaluation and management service is not appropriate. If a significant, separately identifiable service is performed unrelated to the technical performance of the pulmonary function test, an evaluation and management service may be billed.

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.

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 Comment

Terms Defined:

Tidal Volume (TV or VT) - the 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 (FEV1, FEV2, FEV3) are airway flow rates that provide information about the severity of airway obstruction in terms of air trapping and serve as an index of dynamic function. These flow rates are determined by a spirometer.

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

Sources of information may be found online under "Medical Policy" in the Part B 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 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:	12	PCR B2001-151
Start Date of Comment Period		NA
Start Date of Notice Period		11/01/2001
		1 st QTR 2002 Update!
Revised Effective Date:		10/08/2001

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

94240: Functional Residual Capacity or Residual Volume

Revision Overview: Addition of diagnosis range 516.0-516.9

Policy Number

94240

Contractor Name

First Coast Service Options, Inc.

Contractor Number

00590

Contractor Type

Carrier

LMRP Title

Functional Residual Capacity Or Residual Volume

AMA CPT Copyright Statement

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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

08/19/1996

Original Policy Ending Date

N/A

Revision Effective Date

10/08/2001

Revision Ending Date

10/07/2001

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 (PFT's) 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 (ADL's).
- 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, pleuritic chest pain) may suggest the possibility of pulmonary toxicity.

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

- 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

CPT/HCPCS Codes

94240

Not Otherwise Classified Codes (NOC)

N/A

ICD-9-CM Codes that Support Medical Necessity

135	491.0-491.9	519.8
162.0-162.9	492.0-492.8	780.51
197.0	493.00-493.92	780.53
197.3	494.0-494.1	780.57
212.2	495.0-495.9	786.02-786.09
212.3	496	786.2
231.2	508.0-508.9	786.3
415.0	515	793.1
415.11-415.19	516.0-516.9	799.1
446.20	517.1-517.8	E942.9
466.0-466.19	518.0-518.89	E945.8
486	519.1	V72.82
490	519.4	

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

Procedure code 94240 can be billed in addition to spirometry testing (94010, 94060, or 94070).

Documentation Requirements

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

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

Utilization Guidelines

N/A

Other Comments

N/A

Sources of Information and Basis for Decision

Sources of information may be found online under "Medical Policy" in the Part B 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 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: 8 PCR B2001-150
 Start Date of Comment Period NA
 Start Date of Notice Period 11/01/2001
 1st QTR 2002 *Update!*
 Revised Effective Date: 10/08/2001

Advance Notice Statement

Advance Beneficiary Notice (ABN) is required in the event the service may be denied or reduced for reasons of medical necessity. See page 5 for details concerning ABNs.

95115: Allergen Immunotherapy

The local medical review policy (LMRP) for allergen immunotherapy was published in the 2nd Quarter 2001 *Medicare B Update!* (pages 96-97). Since then, ICD-9-CM code 995.0 (other anaphylactic shock) has been added to the policy for CPT codes 95115 and 95117, effective for services processed on or after October 15, 2001. In addition, please note a change to the “Indications and Limitations of Coverage and/or Medical Necessity” section, highlighted below:

“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.”

This change is also effective for services processed on or after October 15, 2001. The remainder of the LMRP continues as published in the 2nd Quarter 2001 *Update!*

99183: HBO Physician Supervision—Clarification

Florida Medicare has received inquiries regarding an article concerning the physician supervision requirement for Hyperbaric Oxygen (HBO) therapy published in the 4th Quarter 2001 *Medicare B Update!* (page 73). 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).

Silicone Oil Injections

There is no separate procedure code or reimbursement for silicone oil injections. Silicone oil injections are included in the basic allowance of procedure code 67108 (*Repair of retinal detachment; with vitrectomy, any method, with or without air or gas tamponade, focal*

endolaser photocoagulation, cryotherapy, drainage of subretinal fluid, scleral buckling, and/or removal of lens by same technique). Therefore, it is inappropriate to bill for silicone oil injections in addition to procedure code 67108.

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ELECTRONIC MEDIA CLAIMS

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.

TRANSACTION NUMBER

837
835
270/271
276/277

TRANSACTION DESCRIPTION

Health Care Claim
Health Care Claim Payment Advice
Health Care Eligibility Benefit Inquiry and Response
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 1.04, 2.0, 3.01) or older versions of ANSI (3032 2.B.00 and 3051 3B.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 B of Florida will begin accepting production claims in the ANSI ASC X12N 837 Version 4010 format on or about February 4, 2002, at which time *new* electronic submitters will be required to submit claims in this format.

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.**

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/admsimp	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) 354-5977.

GENERAL INFORMATION

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 their Medicare contractor after becoming suspicious of the two individuals and alerting the police. The two 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 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 (866) 454-9007 to report suspected fraud.

Source: CMS Central Office Medicare Fraud Alert

MEDICARE REGISTRATION

Choose to Participate for 2002!

It's time again for Medicare providers to choose whether to participate in the Medicare program for the upcoming calendar year. Medicare offers the following benefits to participating providers:

Access to Patient Eligibility Data. Participating providers who file their claims electronically using a national standard format can obtain information about a patient's benefit eligibility. Contact Provider Electronic Services Marketing at (904) 791-8767 for more information.

Claim Filing Advantages. Participating providers who file paper claims use a separate post office box established specifically for these claims.

Higher Payment Rates. Participating providers are reimbursed directly by Medicare Part B at rates five percent higher than those that are paid to non-participating providers (for most services).

Automatic Medigap Claim Filing. In most cases, Florida Medicare will automatically file claims to a patient's Medigap insurer (responsible for the 20 percent not covered by Medicare), eliminating the need to submit separate claims to both Medicare and the insurer.

Inclusion in Participating Provider Directory. All independently participating providers and groups are eligible for inclusion in the MEDPARD, a directory of participating providers made available to Medicare beneficiaries. To be included in this directory, independently practicing physicians and groups must elect to participate during the upcoming year, actively file claims to Florida Medicare, and provide us with their physical office address (where the office is located) and telephone number for patients to use when scheduling appointments.

Enrollment Information

Enrollment materials for 2002 will be released in mid-November, in conjunction with the 2002 Medicare Part B Physician and Non-Physician Practitioner Fee Schedule. We encourage you to register as a participating Medicare provider and to take advantage of these benefits. However, don't wait too long to decide: your decision must be received by December 31, 2001, and will apply to services provided from January 1, 2002, through December 31, 2002.

Some providers believe they are participating simply because they enrolled and obtained a provider number. This is not the case; a Medicare participation agreement must be signed and submitted during the enrollment period to become participating (providers who are already participating and want to remain so do not need to sign a new agreement). Providers who are unsure of their Medicare participation status may call customer service at 1 (866) 454-9007. A representative will be able to provide this information.

New Enrollment Applications

The Centers for Medicare & Medicaid Services (CMS) has revised all provider enrollment applications. The new applications will be available for distribution beginning the first week of November 2001. The new applications are available for downloading from our provider Web site, www.floridamedicare.com.

The new applications are categorized by provider type as follows:

Form Number	Available From	Provider Type
CMS 855A	Fiscal Intermediaries CMS Regional Offices	All providers that will bill Medicare intermediaries
CMS 855B	Carriers CMS Regional Offices	Suppliers that will bill Medicare carriers, including entities and organizations
CMS 855I	Carriers CMS Regional Offices	Individual health care practitioners
CMS 855R	Carriers CMS Regional Offices	Individual health care practitioners to reassign Medicare benefits
CMS 855S	National Supplier Clearinghouse CMS Regional Offices	Suppliers of durable medical equipment, prosthetics, orthotics, and supplies <i>only</i>

Form HCFA-855C is being eliminated. Any changes to a provider's business structure should be reported within 30 days on the applicable Form CMS-855 outlined above.

CMS has instructed contractors to destroy any remaining stock of Form HCFA-855 (1/98 version) on November 1, 2001, and begin utilizing the new forms. We will process change requests on the 1/98 version of Form HCFA 855, if they are postmarked prior to January 1, 2002. Requests submitted on the 1/98 version that are postmarked on or after January 1, 2002, will be returned with instruction to complete the new CMS application.

All applications *must* have an original signature with the date the application was signed. Applications that are not signed and dated cannot be processed and will be returned. Resubmission of these applications will *not* receive priority.

Requests for additional information will include a gold form indicating the name of the person processing your application and his or her telephone number. The form will also indicate the date we must have the requested information in order for the request to receive priority. Please ensure the gold form is returned with the requested information. Failure to return the information timely will delay processing of the application.

Source: CMS Transmittal AB-01-146, CR 1835; Medicare Registration

New Specialty Code for Pain Management

Effective January 1, 2002, a new physician specialty code has been established for pain management. The new code is "72" which was previously listed as reserved. A physician choosing this specialty code is not required to accept assignment unless he/she enters into a participating supplier agreement. Carriers will enroll these physicians, if they are not already enrolled, using the general enrollment instructions.

Carriers will change a current physician specialty code to pain management *only* if the physician requests the change. Requests must be submitted on the appropriate Form CMS-855 to:

Medicare Registration
P.O. Box 44021
Jacksonville, FL 32231-4021

Source: CMS Transmittal B-01-57, CR 1872

FINANCIAL SERVICES

Medicare Checks Must Be Cashed Timely

In accordance with the Code of Federal Regulations (42 CFR 424.352) and Medicare guidelines, First Coast Service Options, Inc. (FCSO) will not reissue checks that are older than one year unless the following circumstances are met:

1. The check can be physically presented; and
2. FCSO can prove that the check was not previously reissued.

Please monitor any payment due your office. If you determine a check has been lost, stolen, defaced, destroyed or mutilated, please contact Florida Medicare toll-free at (866) 454-9007, or write to:

Medicare Part B
P.O. Box 2360
Jacksonville, FL 32231-0018

This revises information published in the September/October 2000 *Medicare B Update!* (page 75).

Source: CMS Transmittal AB-01-122, CR 1364

Notice of Interest Rate for Medicare Overpayments and Underpayments

Medicare Regulation 42 CFR section 405.378 provides for the assessment of interest at the higher of the Private Consumer Rate (PCR) or the current value of funds rate (5 percent) for calendar year 2001. The Secretary of the Treasury has notified the Department of Health and Human Services that the PCR has been revised to 13.25 percent. The notice of the PCR was published in the Federal Register (see Vol. 66, No. 152 dated 08/07/01). Therefore, the PCR will remain in effect until a new rate change is published. In addition, this reaffirms interest rates for prior periods.

Period	Interest Rate
August 7, 2001 -	13.25%
April 26, 2001 - August 6, 2001	13.75%
February 7, 2001 – April 25, 2001	14.125%
October 24, 2000 – February 6, 2001	13.875%
August 1, 2000 – October 23, 2000	13.875%
May 3, 2000 - July 31, 2000	13.75%
February 2, 2000 - May 2, 2000	13.5%
October 28, 1999 - February 1, 2000	13.375%
August 04, 1999 - October 27, 1999	13.25%
May 05, 1999 - August 03, 1999	13.375%
February 01, 1999 - May 04, 1999	13.75%
October 23, 1998 - January 31, 1999	13.50%
July 31, 1998 - October 22, 1998	13.75%
May 13, 1998 - July 30, 1998	14.00 %
January 28, 1998 - May 12, 1998	14.50%
October 24, 1997 - January 27, 1998	13.875%
July 25, 1997 - October 23, 1997	13.75%
April 24, 1997 - July 24, 1997	13.50%
January 23, 1997 - April 23, 1997	13.625%
October 24, 1996 - January 22, 1997	13.375%

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

Timely Receipt of Overpayment Refunds

Overpayment refunds must be received within 30-days from the date of the initial refund request letter to be timely. In accordance with Section 1833(j) of the Act and 42 CFR 405.378, First Coast Service Options, Inc., must charge interest on Medicare overpayments. Interest accrues from the date of the initial request for refund and is assessed for each 30-day period, or portion thereof, that payment is delayed after the first 30-day period.

Based on Medicare guidelines, "A refund is received as of the date of a legible U.S. Postal Service postmark or dated shipping label from a commercial carrier." If the postmark date on the envelope is not legible or there is no postmark date, the carrier uses the date received at the carrier location.

Source: Financial Services Department

COORDINATION OF BENEFITS

Current Status of Coordination of Benefits Contractor Operations

The following article is being provided at the request of 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
Voluntary Agreement Project
P.O. Box 660
New York, N.Y. 10274-0660

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

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.

Source: CMS Letter Dated September 28, 2001

HOME HEALTH CONSOLIDATED BILLING

Home Health Prospective Payment System (HH PPS) Consolidated Billing Enforcement

Information concerning editing for Home Health Prospective Payment System (HH PPS) Consolidated Billing was published in the 4th Quarter 2001 *Medicare B Update!* (page 78). In that article, providers were advised of a new remark code (N88) that gives notification of conditional payment for services provided to beneficiaries for whom a Home Health Agency has filed an episode of care notice.

Effective January 1, 2002, new edits will be created to address situations in which a therapy or non-routine supply claim subject to HH PPS consolidated billing has been paid prior to the posting on the Common Working File (CWF) of a claim for a HH PPS episode. These edits will identify claims that contain line items paid during a home health episode that are subject to consolidated billing. The edits will use the list of procedure codes provided below. The Centers for Medicare & Medicaid Services will update the list of codes annually.

Recovery of Payments Made Before the Posting of a HH PPS Episode

For services processed on or after January 1, 2002, carriers and intermediaries will initiate recovery of payments for services subject to consolidated billing that are paid within an HH PPS episode period.

To capture services subject to consolidated billing with dates of service on or after October 1, 2000, paid prior to January 1, 2002, Medicare will identify therapy and supply claims that were paid prior to the posting of home health claims on CWF. Overpayment recovery procedures will then be applied. It is anticipated that this will occur shortly after January 1, 2002.

Modifying Consolidated Billing Edits on Institutional Claims

Concerns have been raised regarding claims for certain services being affected by HH PPS consolidated billing editing in an unintended manner. Claims for

certain emergency, surgical, diagnostic, and End Stage Renal Disease (ESRD) services have been subject to consolidated billing edits based on the presence of a medical supply procedure code in addition to the other services provided. Because these supplies are either bundled into the rate paid for the primary service or are otherwise incident to the primary service(s) being

rendered, CMS does not believe they fall within the bundling provisions of home health prospective payment. In order to allow claims for these supplies to process unaffected by HH PPS consolidated billing edits, CWF editing will be revised to no longer apply to institutional claim types. This change will apply to claims processed on or after January 1, 2002.

Non-Routine Supply Codes

A4212	A4338	A4373	A4398	A5073	A6200	A6231	A6258
A4310	A4340	A4374	A4399	A5081	A6201	A6232	A6259
A4311	A4344	A4375	A4400	A5082	A6202	A6233	A6261
A4312	A4346	A4376	A4402	A5093	A6203	A6234	A6262
A4313	A4347	A4377	A4404	A5102	A6204	A6235	A6266
A4314	A4348	A4378	A4421	A5105	A6205	A6236	A6402
A4315	A4351	A4379	A4455	A5112	A6206	A6237	A6403
A4316	A4352	A4380	A4460	A5113	A6207	A6238	A6404
A4319	A4353	A4381	A4462	A5114	A6208	A6239	A6405
A4320	A4354	A4382	A4481	A5119	A6209	A6240	A6406
A4321	A4355	A4383	A4622	A5121	A6210	A6241	A7501
A4322	A4356	A4384	A4623	A5122	A6211	A6242	A7502
A4323	A4357	A4385	A4625	A5123	A6212	A6243	A7503
A4324	A4358	A4386	A4626	A5126	A6213	A6244	A7504
A4325	A4359	A4387	A4649	A5131	A6214	A6245	A7505
A4326	A4361	A4388	A5051	A6020	A6215	A6246	A7506
A4327	A4362	A4389	A5052	A6021	A6219	A6247	A7507
A4328	A4364	A4390	A5053	A6022	A6220	A6248	A7508
A4329	A4365	A4391	A5054	A6023	A6221	A6251	A7509
A4330	A4367	A4392	A5055	A6024	A6222	A6252	
A4331	A4368	A4393	A5061	A6154	A6223	A6253	
A4332	A4369	A4394	A5062	A6196	A6224	A6254	
A4333	A4370	A4395	A5063	A6197	A6228	A6255	
A4334	A4371	A4396	A5071	A6198	A6229	A6256	
A4335	A4372	A4397	A5072	A6199	A6230	A6257	

Therapy Codes

G0193	64550	92597	97001	97022	97039	97504	97546
G0194	90901	92598	97002	97024	97110	97520	97601
G0195	90911	95831	97003	97026	97112	97530	97602
G0196	92506	95832	97004	97028	97113	97532	97703
G0197	92507	95833	97012	97032	97116	97533	97750
G0198	92508	95834	97014	97033	97124	97535	97799
G0199	92510	95851	97016	97034	97139	97537	
G0200	92525	95852	97018	97035	97140	97542	
G0201	92526	96105	97020	97036	97150	97545	

GENERAL INFORMATION

Coordination of Part A Denials From Intermediaries (A/B Link)

Intermediaries refer to carriers all Part A inpatient hospital denials based on determinations of medical necessity, appropriateness, or reasonableness. They are the results of either Peer Review Organization (PRO) or intermediary denial determinations.

Denied Physicians' Services

Information is referred for an in-depth medical review and denial of physicians' services where appropriate because there is a strong assumption that physicians' services rendered in conjunction with denied care or services are also not medically necessary.

This may include:

- Invasive or surgical procedures that are not medically necessary
- Nonmedically necessary cost outlier service(s) with a physician component

Hospital Data

Part A denial information may indicate:

- an entire inpatient stay was denied,
- the denial was for a portion of the stay (e.g., after a particular date or certain specific dates), or
- certain hospital ancillary services were denied.

When the data reveals a hospital stay or certain days of a stay have been denied, the carrier will review the physician's claim using appropriate medical records. Additional documentation (i.e., the medical records from either the PRO or intermediary) will be requested when necessary before adjudication of the claim.

Overpayments

If a postpayment review results in the finding of an overpayment, the carrier will initiate recovery of the inappropriately paid funds, following procedures outlined in section 7100 of the Medicare Carriers Manual (MCM).

Source: MCM section 4169

Comprehensive Error Rate Testing (CERT) Program

An article was published on the cover of the 4th Quarter 2001 *Medicare B Update!* concerning requests for medical records for therapy services from DynCorp TRP. The following provides additional information regarding this initiative.

In order to improve the processing and medical decision making involved with payment of Medicare claims, the Centers for Medicare & Medicaid Services (CMS) initiated a new program effective August 2000. This program is called Comprehensive Error Rate Testing (CERT) and is being implemented in order to achieve goals of the Government Performance and Results Act of 1993, which sets performance measurements for Federal agencies.

Under CERT, an independent contractor (DynCorp of Richmond, Virginia) will select a random sample of claims processed by each Medicare contractor. DynCorp's medical review staff (to include nurses, physicians, and other qualified healthcare practitioners) will then verify that contractor decisions regarding the claims were accurate and based on sound policy. CMS will use the DynCorp findings to determine underlying reasons for errors in claims payments or denials, and to implement appropriate corrective actions aimed toward improvements in the accuracy of claims and systems of claims processing.

Eventually, all Medicare contractors will undergo CERT review by DynCorp. On a monthly basis, DynCorp will request a small sample of claims—approximately 200—from each contractor, as the claims are entered into

their system. DynCorp will follow the claims until they are adjudicated, and then compare the contractor's final claims decision with its own. Instances of incorrect processing (e.g., due to questions of medical necessity, inappropriate application of medical review policy, etc.) become targets for correction or improvement, in appropriate ways. Consequently, it is CMS' intent that the Medicare Trust Fund benefits from improved claims accuracy and payment processes.

How else are providers and suppliers impacted by CERT? Providers and suppliers of the sampled claims will be asked during the course of the DynCorp review, to provide additional information (e.g., medical records, certificates of medical necessity, etc.) for DynCorp staff to verify:

- services billed were delivered,
- were medically necessary, and
- appropriate claims processing procedures were followed.

If contacted, you will be provided with the details regarding the needed information and the name of a contact person.

General questions regarding the CERT initiative may be directed to Laura Castelli, DynCorp Project Director for the CERT Program, at 804-264-1778. Otherwise, providers and suppliers will be contacted *only* if their claim(s) is selected and additional information is required by DynCorp.

Source: CMS Transmittal B-00-61, CR 1338

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

Information was published in the 3rd Quarter 2001 *Medicare B Update!* (pages 34-35) concerning a National Coverage Decision (NCD) for intestinal and multivisceral transplantation. 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 meeting the Medicare coverage criteria specified in Program Memorandum AB-01-58 (and published in the 3rd Quarter 2001 *Update!*). Physician services will be paid based on the physician fee schedule. No payment will be made to a managed care organization unless it is an enrolled provider or supplier.

Source: CMS Transmittal AB-01-73, CR 1564

Introduction to Medicare's Multi-Carrier System

The Centers for Medicare & Medicaid Services (CMS) awarded the contract to provide a standard Medicare claims processing system for all Medicare Part B carriers to Electronic Data Systems, Inc. (EDS). This new system is called the Multi-Carrier System (MCS), and it is currently used to process over 50% of the Medicare Part B claims in the United States.

On February 4 2002, First Coast Service Options, Inc. (FCSO) will convert from the Verizon (formerly GTE) Medicare B claims processing system to the Multi-Carrier System. To successfully accomplish this, FCSO

has developed a comprehensive plan to convert from the current processing system to MCS. FCSO is dedicated to making a smooth transition to the new system with minimal impact to our valued customers. Conversion information is being provided as early as possible so providers, vendors, and senders may take the necessary actions to adjust processing and/or cash flow needs.

FCSO is committed to keeping you informed about the upcoming conversion and encourages you to watch for MCS updates in future issues of the *Medicare B Update!* and on the Florida provider Web site at www.floridamedicare.com.

THE PATIENT FRIENDLY ADVISORY

Remind your Patients to Get their Flu and PPV Shots!

Flu season is almost here. Physicians, clinicians, and practitioners know the importance of having senior and high-risk patients receive a flu shot. First Coast Service Options, Inc., along with the Centers for Medicare & Medicaid Services (CMS) and the Florida Flu Coalition, is asking providers to help us increase Florida's vaccination rates by encouraging patients to receive influenza and Pneumococcal Pneumonia Vaccines (PPV) as appropriate.

You can promote the vaccines in your offices in several simple ways.

- Use patient reminders, such as the one on the next page. Post the reminders or copy and distribute them to your patients. Patient reminders and other promotional information can be obtained at Web sites such as the following:
 - Florida Flu and Pneumonia Coalition (www.ffpcoalition.org)
 - Centers for Disease Control's National Immunization Program (www.cdc.gov/nip)
 - National Coalition for Adult Immunization (www.nfdi.org/ncai)
 - Immunization Action Coalition (www.immunize.org)
- Have your reception or nursing staff ask patients as they check in if they have received their flu and PPV vaccines.
- Put a note in patient's charts prompting you to talk to them about the and PPV shots.
- Establish "standing orders" so your staff can automatically vaccinate senior patients against the flu and PPV diseases.
- Double-check with patients who are in Florida for the winter. These "snowbirds" from other states such as New York may or may not have received their vaccinations prior to their visit to Florida. By asking these patients about their vaccination history, you can help assure they do not miss their flu shot.

Billing and claims processing instructions for influenza and PPV vaccines were included in the 4th Quarter 2001 *Medicare B Update!* (pages 6-9) You may obtain additional flu and PPV information and resources targeted to people with Medicare by accessing CMS' Medicare Web site at www.medicare.gov/health/fludetails.asp or by calling 1-800-MEDICARE.

Why should I get the flu shot?

Here are five reasons why:

- **The flu is serious business.**

Influenza (commonly called the flu) is not just a runny nose or upset stomach. It is a serious illness that can lead to pneumonia. At least 45,000 Americans die each year from influenza and pneumonia, the sixth leading cause of death in the United States. Ninety percent of these deaths are among people 65 years of age or over.

- **The flu can be very dangerous for people 50 and older.**

People 50 years of age or over should get a flu shot, unless they are allergic to eggs. The flu shot's also important for those with a chronic illness, and for those who spend a lot of time around sick or elderly people.

- **A flu shot is safe and helps you protect others.**

Flu shots are safe and effective. And when you get a flu shot you help yourself and those around you. By avoiding the flu, you avoid giving it to friends and family.

- **The flu can make you “blue.”**

Even if you don't develop serious problems, the flu can make you feel bad for days. It can cause fever, chills, headache, cough and sore muscles.

- **Medicare Part B pays for it.**

When you have Medicare Part B and you get your flu shot from a Medicare provider, you pay no “coinsurance or deductible.” Also, if the person giving the shot agrees not to charge more than the amount Medicare pays, you pay nothing. Medicare Part B also pays for the pneumococcal vaccination. Ask your health care provider about both of these vaccines. (Note: HMO members may be required to get shots from their HMO. Ask your HMO for more information.)

Ask your doctor if the flu shot is right for you.

EDUCATIONAL RESOURCES

Introducing CMS

As of July 1, 2001, the Health Care Financing Administration 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, or 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/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. 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 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

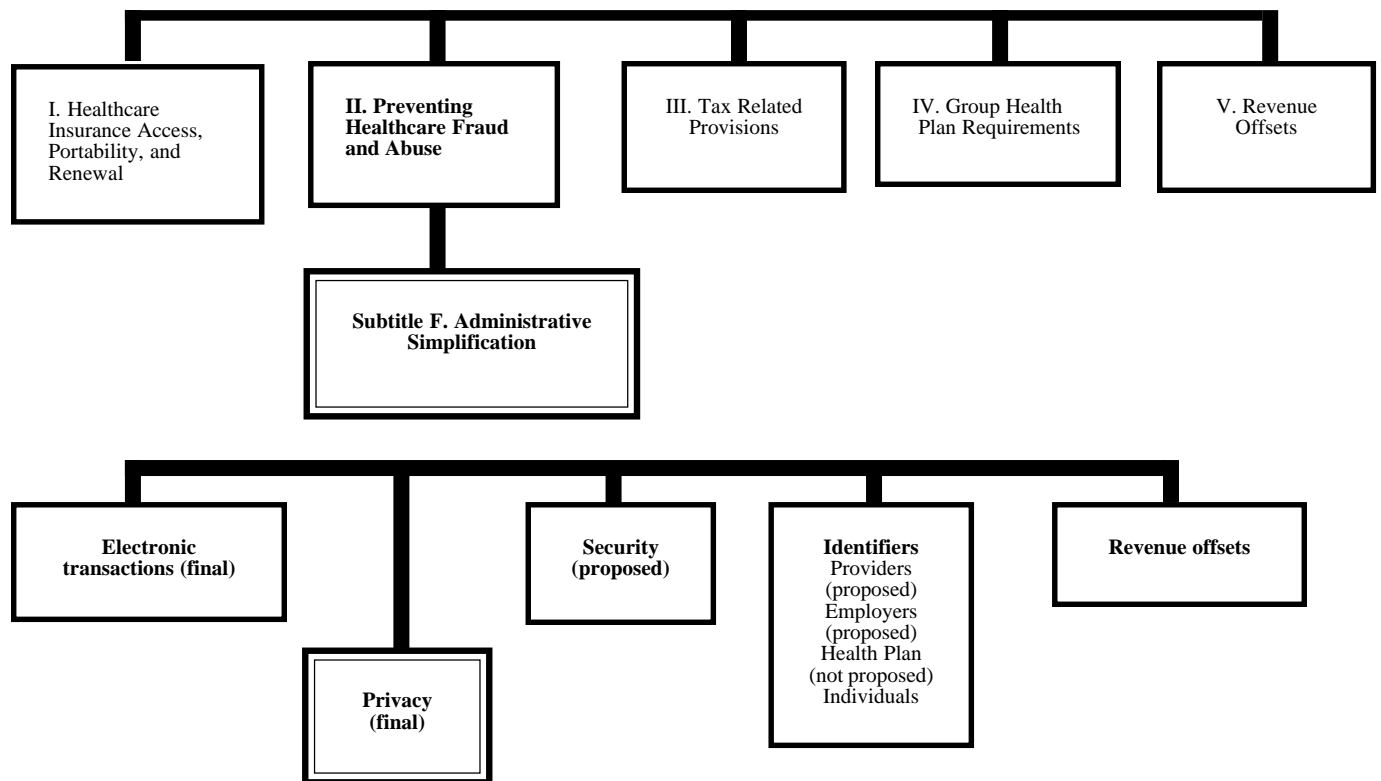
The Health Insurance Portability and Accountability Act of 1996 (Public Law 104-191), also known as HIPAA, was enacted as part of a broad Congressional attempt at incremental healthcare reform. The Administrative Simplification (AS) aspect of that law requires the United States Department of Health and Human Services (DHHS) to develop standards and requirements for the maintenance and transmission of healthcare 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 healthcare 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 healthcare 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 healthcare 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 healthcare clearinghouses and healthcare 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 healthcare 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 healthcare 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 PHI. 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 IIII 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.

2001		2002	2003
Assessment	Assessment	Development	Implementation
6 months – Awareness, gap analysis assessment 6 months – Risk analysis assessment		6-12 months development Policies and Procedures	6 months implementation & testing

Free Provider Enrollment Workshops

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Seminar location and dates (check one)

December 13, 2001
1:00 P.M. – 4:00 P.M.

December 14, 2001
8:30 A.M. – 11:30 A.M.

OR

Radisson Riverwalk Hotel
1515 Prudential Drive
Jacksonville, Florida

Radisson Riverwalk Hotel
1515 Prudential Drive
Jacksonville, Florida

Registrant's Name: _____

Provider's Name: _____

Medicare Billing Provider/Group Number: _____

Address: _____

City, State, Zip Code: _____

Phone Number: () _____ Fax: () _____

E-mail: _____

Register early. Seating is limited.

ORDER FORM – 2002 PART B MATERIALS

The following materials are available for purchase. To order these items, please complete and submit this form along with your check/money order payable to First Coast Service Options, Inc. with the account number listed by each item.

PLEASE NOTE: Payment for fee schedules cannot be combined with payment for other items; separate payments are required for purchases of items from different accounts.

NUMBER ORDERED	ITEM	ACCOUNT NUMBER	COST PER ITEM
<input type="checkbox"/>	Medicare B Update! Subscription – One copy of the <i>Update!</i> is sent free of charge to individual providers and Professional Association (PA) groups who bill at least one claim to Medicare Part B of Florida for processing during the twelvemonths prior to the release of each issue. Non-provider entities or providers who need additional copies at other office locations may purchase an annual subscription. This subscription includes all issues published during calendar year 2002 (back issues sent upon receipt of order).	756245	\$75.00
<input type="checkbox"/>	2002 Fee Schedule – One copy of the <i>Medicare Part B Physician and Non-Physician Practitioner Fee Schedule</i> is sent free of charge in mid-November to individual providers and Professional Association (PA) groups who bill at least one claim to Medicare Part B of Florida for processing during the preceding six months. The Fee Schedule contains calendar year 2002 payment rates for all Florida localities. These fees apply to services performed between January 1 and December 31, 2002. These items include the payment rates for injectable drugs, but <i>do not</i> include payment rates for clinical lab services, mammography screening, or DMEPOS items. Note also that revisions to fees may occur; these revisions will be published in future editions of the <i>Medicare B Update!</i> Non-provider entities or providers who need additional copies at other office locations may purchase additional copies.	756250	\$20.00
<input type="checkbox"/>	Procedure-to-Diagnosis Relationship Report – This is a listing of the most current file used during claims processing to determine coverage for procedures subject to specific diagnosis criteria. This document is designed to assist providers by outlining diagnosis criteria in order to limit their financial liability for these procedures.	756245	\$20.00

Subtotal \$ _____

Tax (7%) \$ _____

Total \$ _____

Mail this form with payment to:

**First Coast Service Options, Inc.
Medicare Publications
P.O. Box 45280
Jacksonville, FL 32232-5280**

Contact Name: _____

Provider/Office Name: _____

Phone : _____ FAX Number: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

**Please make check/money order payable to: BCBSFL- FCSO Account # (fill in from above)
(CHECKS MADE TO "PURCHASE ORDERS" NOT ACCEPTED)
ALL ORDERS MUST BE PREPAID - DO NOT FAX - PLEASE PRINT**

Note: The *Medicare B Update!* and *2002 Medicare Part B Physician and Non-Physician Practitioner Fee Schedule* are available **free of charge** online at www.floridamedicare.com .

IMPORTANT ADDRESSES

CLAIMS SUBMISSIONS

Routine Paper Claims

Medicare Part B
P. O. Box 2525
Jacksonville, FL 32231-0019

Participating Providers

Medicare Part B Participating Providers
P. O. Box 44117
Jacksonville, FL 32231-4117

Chiropractic Claims

Medicare Part B Chiropractic Unit
P. O. Box 44067
Jacksonville, FL 32231-4067

Ambulance Claims

Medicare Part B Ambulance Dept.
P. O. Box 44099
Jacksonville, FL 32231-4099

Medicare Secondary Payer

Medicare Part B Secondary Payer Dept.
P. O. Box 44078
Jacksonville, FL 32231-4078

ESRD Claims

Medicare Part B ESRD Claims
P. O. Box 45236
Jacksonville, FL 32232-5236

COMMUNICATIONS

Review Requests

Medicare Part B Claims Review
P. O. Box 2360
Jacksonville, FL 32231-0018

Fair Hearing Requests

Medicare Part B Fair Hearings
P. O. Box 45156
Jacksonville, FL 32232-5156

Administrative Law Judge Hearing

Administrative Law Judge Hearing
P. O. Box 45001
Jacksonville, FL 32231-5001

Status/General Inquiries

Medicare Part B Correspondence
P. O. Box 2360
Jacksonville, FL 32231-0018

Overpayments

Medicare Part B Financial Services
P. O. Box 44141
Jacksonville, FL 32231-0048

DURABLE MEDICAL EQUIPMENT (DME)

DME, Orthotic or Prosthetic Claims

Palmetto GBA Medicare
DMERC Operations
P. O. Box 100141
Columbia, SC 29202-3141

ELECTRONIC MEDIA CLAIMS (EMC)

EMC Claims, Agreements and Inquiries

Medicare EDI
P. O. Box 44071
Jacksonville, FL 32231-4071

MEDICARE PART B ADDITIONAL DEVELOPMENT

Within 40 days of initial request:

Medicare Part B Claims
P. O. Box 2537
Jacksonville, FL 32231-2537

Over 40 days of initial request:

Submit the charge(s) in question, including information requested, as you would a new claim, to:

Medicare Part B Claims
P. O. Box 2525
Jacksonville, FL 32231-0019

MISCELLANEOUS

Provider Participation and Group Membership Issues; Written Requests for UPINs, Profiles & Fee Schedules:

Medicare Registration
P. O. Box 44021
Jacksonville, FL 32231-4021

Provider Change of Address:

Medicare Registration
P. O. Box 44021
Jacksonville, FL 32231-4021

and

Provider Registration Department
Blue Cross Blue Shield of Florida
P. O. Box 41109
Jacksonville, FL 32231-1109

Provider Education:

For Educational Purposes and Review of Customary/Prevailing Charges or Fee Schedule:

Medicare Part B
Medicare Education and Outreach
P. O. Box 2078
Jacksonville, FL 32231-0048

For Seminar Registration:

Medicare Part B
Medicare Education and Outreach
P. O. Box 45157
Jacksonville, FL 32231

Limiting Charge Issues:

For Processing Errors:

Medicare Part B
P. O. Box 2360
Jacksonville, FL 32231-0048

For Refund Verification:

Medicare Part B
Compliance Monitoring
P. O. Box 2078
Jacksonville, FL 32231-0048

Medicare Claims for Railroad Retirees:

MetraHealth RRB Medicare
P. O. Box 10066
Augusta, GA 30999-0001

Fraud and Abuse

Medicare Fraud Branch
P. O. Box 45087
Jacksonville, FL 32231

PHONE NUMBERS

BENEFICIARY

Toll-Free:
(800) 333-7586
Hearing Impaired:
(800) 754-7820

Note: The toll-free customer service lines are reserved for Medicare beneficiaries only. Use of this line by providers is not permitted and may be considered program abuse.

PROVIDERS

Toll-Free
Customer Service:
(866) 454-9007
Interactive Voice Response (IVR):
(877) 847-4992

EMC

Format Issues & Testing:

(904) 354-5977

Start-Up & Front-End Edits/Rejects:

(904) 791-8767

Electronic Remittance Advice, Electronic Claim Status, & Electronic Eligibility:

(904) 791-6895

PC-ACE Support:

(904) 355-0313

Help Desk

(Confirmation/Transmission):
(904) 905-8880

OCR

Printer Specifications/Test Claims:

(904) 791-8132

DME, Orthotic or Prosthetic Claims

Palmetto GBA Medicare
(803) 735-1034

MEDICARE PART A

Toll-Free:
(877) 602-8816

WEB SITES

PROVIDER

Florida
www.floridamedicare.com

Centers for Medicare & Medicaid Services
www.hcfa.gov

BENEFICIARY

Florida
www.medicarefla.com

Centers for Medicare & Medicaid Services
www.medicare.gov



MEDICARE B UPDATE!

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