



Medicare News Update

Empire Medicare Services
A CMS Contracted Intermediary

❖ a publication for all Medicare Part A providers ❖

June 2002

<http://www.empiremedicare.com>



<http://www.cms.hhs.gov>

Issue # 2002-6

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Important Notice About Hardcopy Newsletters



We have received notification from the Centers for Medicare & Medicaid Services (CMS), that due to emerging priorities within the agency, monies from Provider Education and Training will be used to support the implementation of the Health Insurance Portability and Accountability Act (HIPAA).

As a way to minimize the impact of reduced funding, CMS has mandated a change in provider bulletin/newsletter activity.

Intermediaries and Carriers have been instructed to discontinue the printing and mailing of hardcopy bulletins and newsletters that are scheduled between July 1, 2002 and September 30, 2002. The bulletins/newsletters will continue to be posted on the Empire Medicare Services (EMS) Web site www.empiremedicare.com in both single article and PDF formats.

Subscribers to our Electronic Mailing List receive information regularly on topics such as billing, provider education and training, and other time-sensitive Medicare announcements. They also receive notification when our most recent *Medicare News Updates* are available online.

(Continued on next page)

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This bulletin should be shared with all health care practitioners and managerial members of the provider/supplier staff. Bulletins issued beginning October 1996 are available at no-cost from our Web site at www.empiremedicare.com

TELEPHONE NUMBERS

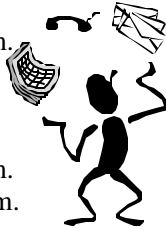
Provider Inquiries: 1 (877) 567-7205

Automated Response Unit:

Monday - Friday 7:00 a.m. to 6:15 p.m.
Saturdays 7:00 a.m. to noon

Customer Service Representatives:

Monday & Friday 9:00 a.m. to 4:00 p.m.
Tuesday - Thursday 7:30 a.m. to 4:00 p.m.



You will be able to transfer to a provider representative only during these hours. Please have your provider number, the HIC number and service dates available when you call.

Appeals: Tuesday - Thursday 9:00 a.m. to 3:00 p.m.

Beneficiary Inquiries:

English: 1 (800) 442-8430
Spanish: 1 (800) 492-6879
TTY for the Hearing-Impaired: 1 (877) 623-6190

Part A beneficiary representatives are available: Monday - Friday from 8:00 a.m. to 4:00 p.m.

Integrated Electronic Services (IES) Technical Help Desk:

Monday - Friday from 8:30 a.m. until 4:30 p.m.

1 (315) 448-0080

Medicare Fraud Hotline: To report fraud and abuse in the Medicare and Medicaid programs:

1 (800) HHS-TIPS
1 (800) 447-8477

The Hotline TTY Number for the Hearing-Impaired is:

1 (800) 223-4950

Medical Director:

Dr. Ted Triana 1 (315) 442-4893

Medicare Fraud Information Specialist - Region II:

Donald Sears 1 (315) 442-4126

Medicare policies can be found on our Web site in the Local Medical Review Policy section. You can access these policies by typing <http://www.empiremedicare.com/TRAINB/Lmpb.htm> Providers without access to the Internet can request hard copies from Empire Medicare Services.

(Continued from page 1)

Signing up is easy. Simply click on the "News" button from our homepage. Then click on the "Subscribe to the Mailing List!" link and fill in the requested information.



You will begin receiving notification as soon as bulletins, newsletters and important information are posted to the Internet.

Sign up now for our provider Electronic Mailing List on the Empire Web site (www.empiremedicare.com).

Clarification on DSMT Payment

The Centers for Medicare & Medicaid Services (CMS) has recently clarified that fiscal intermediary (FI) payment of outpatient diabetic self-management training (DSMT) services billed with HCPCS codes G0108 and G0109 are to be reimbursed based on the Medicare Physicians Fee Schedule (MPFS) for dates of service beginning February 27, 2002.

However, the system changes needed for fee rate application will not be in place until October 1, 2002. In the interim, DSMT services are being paid at reasonable cost. After system changes are implemented, claim adjustments may be made at the provider's discretion.

G0108 Diabetes outpatient self-management training services, individual session, per 30 minutes of training.

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



Inappropriate Use of Modifiers 73 and 74

A modifier is a two-position code that is added to the end of a HCPCS code. There is space for two modifiers per line on the hardcopy billing form (four of the nine positions). Accurate billing with modifiers is an integral part of the outpatient prospective payment system (OPPS). It has come to our attention that providers are using modifiers 73 and 74 inappropriately.

73 Discontinued Outpatient Hospital/Ambulatory Surgery Center (ASC) Procedure prior to the Administration of Anesthesia (Effective for dates of services July 1, 1998 and later)

This modifier is only used with surgical procedure codes.

Example: A patient is prepared for procedure 49590 (Repair spigelian hernia). Before anesthesia is administered, the physician decides the procedure should not be performed. This is billed as: 4959073.

Use modifier 73 for:

- ◆ an outpatient hospital/ambulatory surgery center procedure discontinued
 - after the patient has been prepared for the surgery (including sedation when provided) and taken to the room where the procedure is to be performed, but
 - before the induction of anesthesia (e.g., local, regional block(s), or general anesthesia)

On surgery claims, modifier 73 will price at 50 percent of the group rate.

74 Discontinued Outpatient Hospital/Ambulatory Surgery Center (ASC) Procedure after the Administration of Anesthesia (Effective for dates of services July 1, 1998 and later)

This modifier is only used for surgical codes.

Example: Procedure 61304 (Craniectomy or craniotomy, exploratory; supratentorial) has been started, but the physician terminates the procedure before it is completed. This is billed as: 6130474.

Use modifier 74 for:

- ◆ an outpatient hospital/ambulatory surgery center procedure discontinued
 - after the administration of anesthesia

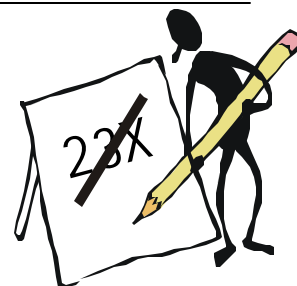
On ASC claims, modifier 74 will price at 100 percent of the group rate.

Additional Instructions for Coding Discontinued Surgical Services

When multiple procedures were planned and there was a termination:

- ◆ If one or more of the procedures was completed, report the completed procedure(s) as usual. The other(s) planned and not started are not reported.
- ◆ If none of the planned procedures were completed, report the first procedure that was planned with modifier 73 or modifier 74. The others are not reported.

Bill Types for Peripheral Neuropathy Claims



Medicare News Update 2002-5 included an article on Peripheral Neuropathy. We have received clarification from the Centers for Medicare & Medicaid Services (CMS) about the bill types included in that article.

Bill type 23X (outpatient skilled nursing facility) is not appropriate for billing peripheral neuropathy with loss of protective sensation in people with diabetes.

All other information and instructions in the *Medicare News Update* 2002-5 article remain in effect.

(Reference: Program Memorandum A-02-039)

Changes in Transitional Outpatient Payment (TOP) for 2002

Beginning January 1, 2002, TOPs are reduced for all providers except those hospitals that receive hold harmless TOPs (cancer hospitals, children's hospitals, and rural hospitals having 100 or fewer beds).

Revised TOPS Calculation effective July 1, 2002 for dates of service beginning January 1, 2002.

STEP 1

- A. Find the total charges for covered services for all OPSS services on claims paid during the month.
- B. Reduce the total charges to cost by multiplying them by the outpatient cost-to-charge ratio.
- C. Multiply this amount by the provider-specific payment-to-cost ratio (PSPCR).

STEP 2

- A. Find the total Medicare program payments, plus unreduced coinsurance, plus deductible applied for all APCs as well as all outlier payments (VC 17) and transitional pass-through payments for drugs (SI=H), biologicals and/or devices (SI=G) for those same claims paid during the month under OPSS.
- B. If the result is greater than the result of step 1, go to step 8. No transitional payment is due this month.

STEP 3

- A. If the hospital is a children's hospital, a small rural hospital with not more than 100 beds or a cancer hospital, go to step 4 only.
- B. If any other type of hospital:
 1. Divide the result of step 2 by the result of step 1, skip step 4 and perform step 5, 6, or 7 as appropriate.

STEP 4

- A. If the hospital is a children's hospital, a small rural hospital with not more than 100 beds or a cancer hospital:
 1. Subtract the result of step 2 from the result of step 1 and pay .85 times this amount. Do not perform steps 5-7.

STEP 5

- A. If the result of step 3 is greater than or equal to .9 and less than 1.0:
 1. Subtract the result of step 2 from the result of step 1
 2. Multiply the difference by .7
 3. Pay .85 times this amount.

STEP 6

- A. If the result of step 3 is greater than or equal to .8 and less than .9:
 1. Subtract .6 times the result of step 2 from .61 times the result of step 1
 2. Pay .85 times this amount.

STEP 7

- A. If the result of step 3 is less than .8:
1. Multiply the result of step 1 by .13
 2. Pay .85 times this amount.

STEP 8

When the result of step 2 is greater than the result of step 1 for the final month of a provider's cost report period, do nothing more. When the result of step 2 is greater than the result of step 1 for any other month, store all step 1 and step 2 totals and include these totals with the totals for the next month's TOP calculation.

Liability on Claims Submitted With Noncovered Charges



Effective for claims with dates of service beginning May 13, 2002, there are now four line level reject reason codes associated with noncovered charges submitted by the provider.

Beneficiary liable (outpatient claim contains occurrence code 32, and/or condition code 20 or condition code 21, -or - inpatient claim with noncovered charges):

31992 CHARGES ON THIS LINE WERE SUBMITTED AS NONCOVERED BY THE PROVIDER - ANSI adjustment reason code 46, group code PR

31993 CHARGES ON THIS LINE WERE SUBMITTED AS PARTIALLY NONCOVERED BY THE PROVIDER - ANSI adjustment reason code 46, group code PR

Provider liable (outpatient claim billed without occurrence code 32, condition code 20 or 21):

31947 CHARGES ON THIS LINE WERE SUBMITTED AS NONCOVERED BY THE PROVIDER - ANSI adjustment reason code 46, group code CO

31948 CHARGES ON THIS LINE WERE SUBMITTED AS PARTIALLY NONCOVERED BY THE PROVIDER - ANSI adjustment reason code 46, group code CO

Claim Processing Changes:

Outpatient claims

Noncovered claims will no longer be returned to the provider (RTP) with reason code 31023 if billed without condition code 20 or 21 or occurrence code 32. Claims will be processed according to criteria below:

- If occurrence code 32 is present without condition code 20 or 21, noncovered lines on an otherwise covered claim will be rejected with 31992 or 31993. Completely noncovered claims will be rejected with 31992.
- If there is no occurrence code 32 and no condition codes 20 or 21, noncovered lines on an otherwise covered claim will be rejected with 31947 or 31948. All lines on completely noncovered claims will be rejected with 31947.

Inpatient and SNF claims submitted with noncovered lines:

- All provider submitted noncovered lines will be rejected with 31992 or 31993.
- Current processing will continue for totally noncovered claims.

NOTE: If condition code 20 or 21 (Outpatient and SNF) is present, current processing will continue – claims will be denied with 52052 or 52054 as appropriate.



Reason Codes C7256 and C7252

Skilled nursing facility (SNF) consolidated billing (CB) edits to prevent duplicate payment for Part B services were installed in Common Working File (CWF) production on April 1, 2002.

We have become aware of some unanticipated consequences of some of these edits. Due to the high volume of outpatient hospital and other claims being rejected, the Centers for Medicare and Medicaid Services (CMS) has decided to deactivate CWF edit errors C7256 and C7252 for Medicare fiscal intermediary (FI) processed claims. These edits will remain deactivated until CMS is assured that there will be no unanticipated impact from activating the SNF CB and duplicate payment edits for FI processed claims.

Claims processed incorrectly as a result of the C7252 and C7256 edits after April 1, 2002 will be adjusted by Empire Medicare Services.

Policy for MSP Retirement Dates

(Effective June 10, 2002)

Occurrence Codes and Dates

Occurrence Code "25" has been developed for use on Medicare Secondary Payer (MSP) claims. The following occurrence codes must be completed for Medicare claims where applicable:

- 18 - Date of retirement (patient/beneficiary)
- 19 - Date of retirement (spouse)
- 24 - Date insurance denied
- 25 - Date benefits terminated by primary payer (date on which coverage, including workers' compensation benefits or no-fault coverage, is no longer available to patient)

In relation to the reporting of occurrence codes 18 and 19, referenced above, hospitals are now instructed in Section 301 of the Hospital Manual that when precise retirement dates cannot be obtained during the intake process, they should follow this policy:

Policy for MSP Retirement Dates

During the intake process, when a beneficiary cannot recall his/her precise retirement date as it relates to coverage under a group health plan as a policyholder or cannot recall the same information as it relates to his/her spouse, as applicable, follow the policies specified below.

When a beneficiary cannot recall his/her retirement date but knows it occurred prior to his/her Medicare entitlement dates, as shown on his/her Medicare card, report his/her Medicare A entitlement date as the date of retirement. If the beneficiary is a dependent under his/her spouse's group health insurance and the spouse retired prior to the beneficiary's Medicare Part A entitlement date, report the beneficiary's Medicare entitlement date as his/her retirement date.

If the beneficiary worked beyond his/her Medicare A entitlement date, had coverage under a group health plan during that time, and cannot recall his/her precise date of retirement but you determine it has been at least 5 years since the beneficiary retired, enter the retirement date as 5 years retrospective to the date of admission. (That is, if the date of admission is January 4, 2002, report the retirement date as January 4, 1997, in the format you are currently using.) As applicable, the same procedure holds for a spouse who had retired at least 5 years prior to the date of the beneficiary's hospital admission.

If a beneficiary's (or spouse's, as applicable) retirement date occurred less than 5 years ago, you must obtain the retirement date from appropriate informational sources, e.g., former employer or supplemental insurer.

Overpayment for Provider Services

Sections 3709-3714 of the Medicare Intermediary Manual (Pub. 13) contain instructions for the recovery of individual overpayment cases. Examples of individual overpayment cases are:

- Payment for provider services after benefits have been exhausted, or where the individual was not entitled to benefits.
- Incorrect application of the deductible or coinsurance.
- Payment for noncovered items and services, including medically unnecessary services or custodial care furnished an individual.
- Payment for items or services rendered after the beneficiary's date of death.



The identification of improperly paid claims started with fiscal year 2001 for beneficiaries who died the previous fiscal year. On an annual basis, contractors will conduct post-payment reviews to identify and recover payments with a billed date of service that is after the beneficiary's date of death. Claims paid after the beneficiary's date of death will be cancelled, and a notation will be entered in the "Remarks" section of the claim. Providers should submit a new claim with corrected dates of service if payment is due.

NOTE: The Hospital Manual (Pub. 10) has not yet been updated with the above information.

Reason Code File Updates May 21, 2002

NEW REASON CODES

10415

All line items have been rejected with C7251, C7252, C7253, C7254, C7255, C7256 or C7257. Resubmit if appropriate.

31638

For Bill Types 22X, 23X, 72X, 74X, and 75X, claim must be split between March and April 2002. Correct and resubmit if appropriate.

31992

Charges on this line were submitted as noncovered by the provider.

31993

Charges on this line were submitted as partially noncovered by the provider.

32066

Either the revenue code 510 (clinic) is missing or revenue code 510 (clinic) is present without units. Revenue code 510 is not billable on a 12X type of bill

unless the provider is a rural care hospital (3313XX) - or - For RPCH providers, either revenue code 510 is missing or revenue code 510 is present without units. Correct and resubmit if appropriate.

32429

Claim was submitted on TOB 13X, 22X, 23X, 71X, 73X, 75X or 85X with a HCPCS code of G0117 or G0118, and diagnosis code V801 is not present on the claim. Correct and resubmit if appropriate.

32430

HCPCS code G0117 or G0118 can only be billed with revenue code 770 on TOB 22X, 23X or 75X — OR — HCPCS code G0117 or G0118 can only be billed with revenue code 770 on TOB 85X that has a provider reimbursement method not equal to J. Correct and resubmit if appropriate.

32431

TOB must be 13X, 22X, 23X, 71X, 73X, 75X or 85X for a revenue code of 770 with a G0117 or G0118 HCPCS code. Correct and resubmit if appropriate.

34501

The intermediary's record indicates that this beneficiary has coverage thru a group health plan that is primary over Medicare. Therefore, we are denying this claim. Bill the beneficiary's primary payer and submit an MSP bill to Medicare upon receipt of the primary payment.

38200

This claim is an exact duplicate of a previously submitted claim where the following fields on the history and processing claim are the same:

- HIC Number
- Type of Bill (All three positions of any TOB)
- Provider Number
- Statement from date of service
- Statement through date of service
- Total Charges (0001 REVENUE LINE)
- Revenue Code
- HCPCS and Modifiers (If required by revenue code file)

Verify the information billed and resubmit a new claim, if appropriate.

54028

HCPCS code 84100 Phosphorus Inorganic. Refer to *Medicare News Update* issue # 2002-4 for coverage information.

76045

HCPCS codes for medical nutrition therapy are only payable when billed to the Part B Carriers. NO CLAIMS should be sent to fiscal intermediaries.

Medical nutrition therapy HCPCS codes are: 97802, 97803, 97804. Correct and resubmit claim if appropriate.

76046

Bill Type 11X billed with HCPCS code J7199 requires remarks describing the name of the antihemophilia drug given. Provide the trade and generic name of the drug given in addition to the dosage, dates and route of administration. Without this information we are unable to determine the correct add-on payment. Correct and resubmit if appropriate.

C7251

An outpatient claim (12X, 13X, 214X, 23X, 34X, 74X, 75X, 83X, or 85X) is submitted with a therapy HCPCS code and the dates of service are within the service dates of a SNF inpatient Part A Claim (21X)

or a SNF inpatient Part B claim (22X). Correct and resubmit if appropriate.

C7252

An outpatient claim (12X, 13X, 14X, 22X, 23X, 34X, 74X, 75X, 83X, or 85X) is submitted with a non-therapy service and the dates of service are within the admission and discharge date of a SNF inpatient Part A claim (21X). Correct and resubmit if appropriate.

C7253

An outpatient claim (23X) is submitted with revenue code 54X and the dates of service are equal to a Part B claim with HCPCS code(s) (A0380, A0390, A0425-A0436, and A0999). Correct and resubmit if appropriate.

C7254

An outpatient claim (12X, 13X, 14X, 23X, 34X, 74X, 75X, 83X, OR 85X) is submitted with the same HCPCS code(s), modifier(s), and detail line item date of service as a SNF inpatient Part B claim (22X). Correct and resubmit if appropriate.

C7255

A SNF inpatient Part B claim 22X is submitted with the same HCPCS code(s), modifier code(s), and the detail line item date of service as an outpatient claim (12X, 13X, 14X, 23X, 34X, 74X, 75X, 83X, OR 85X). Correct and resubmit if appropriate.

C7256

An outpatient claim (12X, 13X, 14X, 23X, 34X, 74X, 75X, 83X, or 85X) is submitted with the same HCPCS code(s), modifier code(s), and line item dates of service as a DMERC or Part B claim. Correct and resubmit if appropriate.

C7257

A SNF inpatient Part B claim 22X is submitted with the same HCPCS code(s), modifier code(s), and detail line item date of service as a DMERC or Part B claim. Correct and resubmit if appropriate.

OCE02

For fiscal intermediary use only; no provider action needed.

U0406

For mammography bills with a from date after 12/31/1990, the valid HCPCS code for mammography screening must equal 76085, 76092, G0202, or G0203, and after 01/01/2002, valid HCPCS code equals 76085. Correct and resubmit if appropriate.

U536A

The HCPCS code billed is for a Pap smear, but beneficiary master record shows that this is a male beneficiary. Correct and resubmit if appropriate.

W7049

Service on the same day as inpatient procedure the beneficiary is liable for the cost of the services. Only the beneficiary may appeal the denial. If the HCPCS code is incorrect and there is an appropriate outpatient code, you may request a reopen by submitting a corrected claim to the appeals department with a cover letter and a copy of the complete medical documentation for the services billed.

W7050

Noncovered based on statutory exclusion. Correct and resubmit if appropriate.

W7052

Observation does not meet criteria for separate payment. Correct and resubmit if appropriate.

W7053

HCPCS code G0244 is only allowed with bill type 13X. Correct and resubmit if appropriate.

W7054

Multiple platelet codes are on the claim for the same date of service. These HCPCS codes can't be billed together with dates of service after 040102:

C1012-P9033

C1013-P9031

C1014-P9035

Correct and resubmit if appropriate.

UPDATED REASON CODES**10410**

Revenue codes 631, 632 and 633 are not valid at this time. Verify the revenue code for drugs, correct and resubmit if appropriate.

13317

When occurrence span code 72 (in UB92 field 36), indicating the first/last visits for an outpatient bill type, the dates reported must be within the same calendar year. Correct and resubmit.

31023

Claim submitted with all noncovered charges or no total charges. Verify, correct and resubmit if appropriate. — or — A Medicare secondary claim has been submitted without covered charges and/or contains a condition code 20 or 21. Medicare secondary claims must contain covered charges and must be billed without condition code 20 or 21. Correct and resubmit if appropriate.

31387

Effective 8/1/00, professional components are not allowed on outpatient bill types, type of bill 34X with vaccine HCPCS code, non-OPPS bill types with dates of service on or after 04/01/02 with condition code 07 and an antigen, splint or cast HCPCS code payable under OPPS guidelines. This includes value code 05 or revenue codes 96X, 97X and 98X. Remove the professional component and resubmit the claim if appropriate.

31423

If billing revenue code(s) 331, 332 or 335, then revenue code 636 must also be present with a chemotherapeutic drug HCPCS code (J1440, J1441, J2820, Q0093, Q0094, Q0125, C1178, J1950, J2430, C9110 or J9000-J9999). Correct and resubmit if appropriate.

31439

For intermediary use only; no provider action is required.

31563

Occurrence code 36 is present and revenue code 636 is not present for dates of service on or after 04/01/2000 - or - bill type is not equal to 12X, 13X, 14X, 83X, or 85X - or - occurrence code 36 is present and revenue code 250 is not present for dates of service prior to 04/01/2000 - or - bill type is not 12x or 13x - or - occurrence code 36 is present and either revenue code 636 is not present for dates of service greater than or equal to 12/21/2000 - or - bill type is not equal to 12X, 13X, 14X, 22X, 83X, or 8X. Correct and resubmit if appropriate.

31591

A valid diagnosis code must be present when billing hemophilia clotting factor HCPCS codes.

31600

Either the revenue code 510 (clinic) is missing or revenue code 510 (clinic) is present without units. Revenue code 510 is not billable on a 12X type of bill unless the provider is a rural care hospital (3313XX) - or - for RPCH providers, either revenue code 510 is missing or revenue code 510 is present without units. Correct and resubmit if appropriate.

31608

Claim indicates HMO enrollment. HMO encounter data must be submitted to the HMO plan only for inpatient discharges greater than 06/30/98 or outpatient dates of service greater than 12/31/00. If the beneficiary is not enrolled in an HMO remove condition code 04.

31618

Effective with service dates on or after 01/01/01, revenue code 540 requires a value code of A0 with a valid zip code from the pickup origin of the ambulance service. Effective for service dates of 04/01/2002, foreign providers are now required to have a value code of A0 with a valid zip code from the pickup origin of the ambulance service when using revenue code 540. Correct and resubmit if appropriate.

31632

if billing for foreign claims (*) with ambulance services after 12/31/2000, then a value code of A0 WITH A valid ZIP code must be entered - Value of blank or 00000 is no longer valid. Correct and resubmit if appropriate.

(*) Mexican Providers = 56XXXXX
Canadian Providers = 59XXXXX

31947

Charges on this line were submitted as noncovered by the provider.

31948

Charges on this line were submitted as partially noncovered by the provider.

32054

Applicable to type bill: 11X, 18X, 21X, 41X, 51X. The admission date is less than the statement covers from date. The statement covers from date is equal to the statement covers to date, and the patient status is equal to 01, 02, 03, 04, 05, 06, 07, 50, 51, 61, 62, 63, 71 or 72; however, the number of covered days do not equal to zero. Correct and resubmit.

32081

There is no matching provider specific record (FISS screen 42-I) on file for an inpatient rehabilitation facility (IRF) PPS claim. IRF PPS claims are identified by:

- PPS indicator = Y
- Provider number XX3025-XX3099 or XXTXXX
- Statement covered to date equal to 1/01/02 or greater
- Statement covered to date equal to or greater than the PPS effective date on the provider file (MAP1101).

Correct and resubmit if appropriate.

32086

There is a revenue code 018X and occurrence code 74 span present on an inpatient rehabilitation facility (IRF) PPS claim indicating an interrupted stay, and the occurrence code 74 span dates are greater than 2 days. An interrupted stay greater than 2 days is not allowed on an IRF PPS claim.

32245

If PPS claim has revenue code 636 present, then the associated HCPCS code must be equal to J7190, J7191, J7192, J7193, J7194, J7195, J7196, J7198, J7199, Q0160, Q0161, Q0187, or Q0222.

***Note: Effective 01/01/00, J7196 is no longer allowed. Effective 01/01/02, J7193 REPLACES Q0160 and J7195 replaces Q0161. Correct and resubmit if appropriate

32428

Claim was submitted with TOB 71X OR 73X, revenue code equals 401 or 403 and revenue code 521 is not present on the claim — or — claim was submitted with TOB 71X or 73X, revenue code equals 770 and revenue code 520 or 521 is not present on the claim. Correct and resubmit if appropriate.

36428

Claim submitted with mammography services billed. Our provider file indicates either:

- > No mammography FDA certification on file for this provider number.
- > Claim statement from date is prior to FDA certification effective date.
- > Claim statement thru date is after the FDA certification termination date.

Verify bill type, provider number and service dates. Submit a copy of the current FDA certification to claims processing unit if appropriate.

37054

An invalid CMG code was entered for revenue line 0024. Correct and resubmit.

37537

UB92 provider submitted adjustment (XX7) is making an original no pay claim a payment claim. Nonpay code on original equals C, B, E, N, R, X, Y, or Z.

38106

This inpatient PPS claim has a patient status of 01, 05, 62, 63, 71 or 72 (and) the discharge date is equal to the admission date of another PPS inpatient claim. Correct and resubmit.

38005

This claim is a duplicate of a previously submitted inpatient claim. The first two positions of the TOB are 11X, 18X or 41X and the following fields on the history and processing claim are the same:

- HIC Number
- Provider Number
- Statement from DOS
- Statement thru DOS
- Revenue Code
- HCPCS and modifiers (if required by revenue code file)

Verify the information billed and resubmit a new claim, if appropriate.

38006

This claim is a duplicate of a previously submitted health maintenance organization (HMO), (HMO pay code is A1). The first two positions of the TOB are 11X, 18X, 21X, 41X or 51X and the following fields on the history and processing claim are the same:

- HIC Number
- Provider Number
- Statement from DOS
- Statement thru DOS
- Revenue Code
- HCPCS and modifiers (if required by revenue code file)

Verify the information billed and resubmit a new claim, if appropriate.

38007

This is claim is a duplicate of a previously submitted SNF claim. the first two positions of the TOB are 21X or 51X and the following fields on the history and processing claim are the same:

- HIC Number
- Provider Number
- Statement from DOS
- Statement thru DOS
- Revenue Code
- HCPCS and modifiers (if required by revenue code file)

Verify the information billed and resubmit a new claim, if appropriate.

38030

This claim is a duplicate of a previously submitted outpatient claim that has been denied by the Peer Review Organization (PRO) (History PRO Approved indicator is C4). The first two positions of the TOB are 13X, 14X, 23X, 24X, 71X, 73X, 83X or 85X and the following fields on the history and processing claim are the same:

- HIC Number
- Provider Number
- Statement from DOS
- Statement thru DOS
- Revenue Code
- HCPCS and modifiers (if required by revenue code file)

Verify the information billed and resubmit a new claim, if appropriate.

38050

This claim is a duplicate of a previously submitted home health claim.

The first two positions of the TOB are 32X, 33X or 34X and the following fields on the history and processing claim are the same:

- HIC Number
- Provider Number
- Statement from DOS
- Statement thru DOS
- Revenue Code
- HCPCS and modifiers (if required by revenue code file)

Verify the information billed and resubmit a new claim, if appropriate.

38051

This claim is a duplicate of a previously submitted CORF claim. the first two positions of the TOB ARE 32X, 33X, 34X or 75X and the following fields on the history and processing claim are the same:

- HIC Number
- Provider Number
- Statement from DOS
- Statement thru DOS
- Revenue Code
- HCPCS and modifiers (if required by revenue code file)

Verify the information billed and resubmit a new claim, if appropriate.

38060

This claim is a duplicate of a previously submitted ESRD claim. The first two positions of the TOB are 13X, 72X or 85X and the following fields on the history and processing claim are the same:

- HIC Number
- Provider Number
- Statement from DOS
- Statement thru DOS
- Revenue Code
- HCPCS and modifiers (if required by revenue code file)

Verify the information billed and resubmit a new claim, if appropriate.

38075

This claim is a duplicate of a previously submitted inpatient ancillary claim. The first two positions of the TOB are 12X, 13X, 14X, 22X, 23X, 83X or 85X and the following fields on the history and processing

claim are the same:

- HIC Number
- Provider Number
- Statement from DOS
- Statement thru DOS
- Revenue Code
- HCPCS and modifiers (if required by revenue code file)

Verify the information billed and resubmit a new claim, if appropriate.

39929

If claim rejected with 39929, all lines have been rejected/and or denied with a line item reject code. Verify revenue codes, HCPCS codes and charges. - or- if adjustment returned to provider with 39929, all covered lines have been rejected with a line item reject code. Verify revenue codes, HCPCS codes and charges. Correct and resubmit if appropriate.

39933

This reason code will be assigned when a beneficiary is receiving home health benefits and all detail lines on an outpatient claim are noncovered due to home health PPS consolidated billing.

50535

J2500 Zemplar (Paricalcitol 5 mg) see *Medicare News Update* issue # 2001-5 for coverage information.

71020

Revenue code 636 is not allowed on type of bill 22X unless the associated HCPCS code is one of the following: FLU, PPV or Hepatitis Vaccine

Anticancer Type Drug (JXXXX)

Antiemetic Type Drug (QXXXX)

EPO (Q0136)

Immunosuppressive type drug (JXXXX) for claim dates of service on or after 12/21/00. Correct and resubmit if appropriate.

71202

Positron Emission Tomography (PET/PETT) scan billed without appropriate HCPCS code. revenue code 404 must be billed with HCPCS code G0030 - G0047, G0125, G0126 G0163 - G0165, or G0210 - G0234. Correct and resubmit if appropriate.

73007

For fiscal intermediary use only; no provider action needed.

75001

Unacceptable principal diagnosis. Correct the principal diagnosis code and resubmit. Resubmitting claims with false diagnosis codes is considered a fraudulent practice.

76036

HCPCS codes J2545 (*) should not be billed to the Part A fiscal intermediary. Verify the drug HCPCS code and correct as necessary. If the drug given is for inhalation administration, remove the revenue code line data and resubmit the claim for processing. Submit all durable medical equipment (DME) charges to the regional DMERC in your area. (*) This edit includes J7608-J7699 as inhalation drugs.

76044

For fiscal intermediary use only; no provider action needed.

76048

For fiscal intermediary use only; no provider action needed.

76206

For fiscal intermediary use only; no provider action needed.

76306

HCPCS code J9265 may only be billed for the diagnosis codes listed below:

1400-1499	1750-1759	1600-1619
1500-1509	1950	1960
1622-1629	1830, 1860, 1869	
1710-1719	1880-1889	
1730, 1731, 1733, 1734	19882	
1740-1749		
1800-1809 EFF. 7/2/98	1589	EFF. 02/11/99
1760-1769 EFF. 7/2/98	185	EFF. 02/11/99
1830-1839 EFF. 7/2/98	1891-1892	EFF. 02/11/99
1820-1828 EFF. 10/07/98	199.0-199.1	EFF. 06/05/01
1510-1519 EFF. 02/11/99		
1588	EFF. 02/11/99	

Correct and resubmit, if appropriate.

76369

New HCPCS code A0425 not allowed before 04/01/02. service dates before 04/01/02 use A0380/A0390. Correct and resubmit if appropriate.

76373

For fiscal intermediary use only; no provider action needed.

E51#6

A revenue code is shown, but total charges for the revenue code is zero.

-or- a revenue code is shown, but the revenue code is not on the revenue code file.

Correct and resubmit if appropriate.

E51#G

For fiscal intermediary use only; no provider action needed.

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E61#K

For fiscal intermediary use only; no provider action needed.

E61#R

For fiscal intermediary use only; no provider action needed.

E8301

Error has occurred on screening Pap smear HCPCS code (*). Check for the following conditions.

1. Required primary and secondary diagnoses codes for screening Pap smear are missing - V726 and V762 or V726 and V1589.
2. Bill type not equal to 13X, 14X, 22X, 23X, 24X, 71X, 75X or 85X.
3. Sex code is not consistent with the HCPCS code.
4. Screening Pap smear present on a 83X claim.

Remove Pap smear charges from 83X claim and resubmit a separate claim.

(*) Codes: P3000, P3001, G0123, G0124, G0143, G0144, G0145, G0147 or G0148.

Correct and resubmit if appropriate.

U5237

Claim indicates a Choices site, but the beneficiary does not have an HMO900 record or is not associated with a Choices site. Please verify that this is a Medicare choices beneficiary - or - claim indicates an ESRD managed care demonstration GHO site, but the beneficiary does not have a GHO record or is not associated with an ESRD managed care demonstration GHO site or there is an incorrect GHO pay code on the claim - or - the claim admit date does not fall within an ESRD managed care demonstration GHO period - or - the claim from and thru dates do not fall within an ESRD managed care demonstration GHO period. The claim cannot be processed until CWF files are updated with this information.

U5390

A therapy HCPCS code is present and the dates of service are within the start and end date of a home health PPS episode. These services must be billed to the home health agency only if you have a subcontracting agreement with that agency (and) the service is part of the plan of treatment.

W0235

Noncovered service. Line item denial. The provider is liable for the cost of the services. If the HCPCS code is incorrect and there is an appropriate outpatient code, you may request a reopen by submitting a corrected claim to the appeals department with a cover letter and a copy of the complete medical documentation for the services billed.

W7052

Observation does not meet criteria for separate payment. Correct and resubmit if appropriate.

Swing Bed PPS Transition Update

The Swing Bed Prospective Payment System (SB-PPS) is the latest Centers for Medicare & Medicaid Services (CMS) payment system for facility inpatient stays. Swing bed providers (provider numbers with U, W or Y as the third digit) nationwide will transition to SB-PPS on their cost report periods beginning on or after July 1, 2002. **None of the Swing bed providers that have Empire Medicare Services as their Fiscal Intermediary transition to Swing Bed PPS prior to January 1, 2003 due to their cost report period start dates.** (Critical Access Hospitals (CAHs) are exempt from Swing Bed PPS.)

In order to provide the most up-to-date and effective training for Swing Bed providers, CMS has allowed Empire Medicare Services to wait until late in the summer of this year to hold SB-PPS training sessions. This was requested so that the training will be closer to each provider's transition date. Session invitations and registration information will be mailed to the impacted facilities and posted on our Web site, www.empiremedicare.com, within the next few months.



For information on SB-PPS and the transition, please visit CMS's "Swing Bed Quick Reference Guide" on the Internet at www.cms.hhs.gov/medlearn/SBPPS.asp. CMS training materials, including a Question and Answer page, will be available on the Quick Reference Guide Web site by late May or early June 2002. In addition, look for upcoming articles in the *Medicare News Update* and News items regarding SB-PPS.

Reference: CR# 2147, A-02-028



Are Your SNF Demand Bills Being RTP for Claims Coding Corrections?

Is your facility continuing to have skilled nursing facility (SNF) demand bills returned to provider (RTP) for corrections to the health insurance prospective payment system (HIPPS) codes and modifiers?

Do you know why? Do you know how to fix the claim? Did you know that each time you “try” to fix the RTP and it is not correct, it will be returned to you again? Did you know that each time a demand bill is RTP - resubmission of that claim will generate another additional development request (ADR) for medical records - and your facility is obligated to send the records in AGAIN, even if you have already submitted the records?

The most common coding error on an SNF demand bill is when you automatically use the DEFAULT code (AAA00) for the dates of the claim. You are assuming that if the period of time is noncovered, it is acceptable to use the default code.

The Centers for Medicare & Medicaid Services (CMS) Central Office gave all fiscal intermediaries exact instructions for medical review in March 2000. Those instructions stated that:

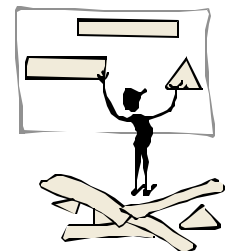
The demand bill must be coded with a resource utilization group (RUG III) if there was a minimum data set (MDS) in the medical record scored for Medicare, even if that RUG III group was in the top 26 group. The demand bill must also follow the assessment schedule payment block when applying a HIPPS code to the dates of the claim.

This correct coding requirement allows us to pay the claim appropriately if we find justification for covered care. Empire Medicare Services (EMS) has published this information at all seminars since March 2000.

If you have not completed an MDS for Medicare, the DEFAULT code is appropriate; otherwise you **MUST** use the valid RUG III score from your most recent assessment.

Example: The beneficiary was admitted on April 1, 2002.
Monthly covered claims were submitted for dates 4/01 - 5/19/02 (day 49).
The beneficiary was “cut” from Medicare on 5/19. The beneficiary remains in the SNF.
A valid MDS (30-day) was completed and is in the medical record. The HIPPS code was *CC102*.
It was used for covered days 5/01 - 5/19 in the 30-day payment block.
No 60-day assessment was done.

The beneficiary asks for a demand bill
You submit a 30-day demand bill for dates of service 5/20 - 6/18



Correct coding of Demand Bill:

CC102 for 11 days (5/20 - 5/30), the balance of the 30-day payment block
AAA01 for 19 days. Default is appropriate because no 60-day MDS assessment was completed for Medicare billing.

SNF facilities must follow these instructions if they wish to have their demand bills accepted for review on the first submission. Otherwise, the claims will continue to RTP. This is frustrating to all concerned, the SNF, the beneficiary, and the fiscal intermediary.

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EMPIRE MEDICARE SERVICES

MEDICARE PART A INTERMEDIARY

PROVIDER EDUCATION AND TRAINING SEMINARS

You are invited to attend our

Introduction to Skilled Nursing Facility Billing

COST: \$100 per person, including course materials and light refreshments. **Lunch is not included.** *This event is a discretionary education activity. As such, we must recoup all our development, delivery, printing, site, and travel costs through the fee. The fee was set with the express goal of being a zero-profit, zero-loss event. Any minor profits or losses will be used solely for provider education activities.*

PURPOSE: This course is designed to assist Skilled Nursing Facilities (SNFs) with basic Medicare billing. The primary audience for this course is someone who is **new** to Medicare SNF billing.

Attendees receive information on forms, systems, and concepts used in Medicare claim billing and processing. In addition, this session actively engages participants in the process of claim preparation by using interactive examples.

Upon completion of this course, the attendee will have the basic knowledge required to properly prepare and submit claims to Medicare. **Please be aware that clinical information will not be provided in this course.**

COURSE HIGHLIGHTS:

- | | |
|---|-------------------------------|
| ❖ Benefit Periods | ❖ Special Billing Situations |
| ❖ Eligibility Requirements for a Covered Stay | ◆ Demand Bills |
| ❖ Introduction to SNF PPS Billing | ◆ Benefits Exhausted |
| ❖ Appeal Information | ◆ Medicare as Secondary Payer |

DATES

& SITES: There are eight sessions during June and July 2002 throughout our service area. Please see the registration form on the reverse side for exact dates and locations.

TIMES: Registration starts at 8:00 a.m. Class starts at 9:00 a.m. and ends at approximately 4:00 p.m.

Seating is limited based on the location; therefore, we reserve the right to limit the number of attendees from each provider.

Preregistration, including prepayment, is required. Payment for this training will not be accepted at the door.

Classes will be filled on a "first-paid, first-accommodated" basis.

ADVANCED REGISTRATION SENT WITHOUT PAYMENT DOES NOT GUARANTEE PARTICIPATION IN THIS SESSION.

(Enclosed Empire Payment Authorization Form can be substituted for prepayment.)

The only acceptable form of payment is a check **from the facility**, made payable to Empire Medicare Services.

Confirmation cards will be sent to each registrant accepted for the session within five business days of registration receipt.

Confirmation will be required for entrance into the session.

Please send registration and check to:

Empire Medicare Services, c/o Jhadi Grace, P.O. Box 4846, Syracuse, NY 13221

315.442.4723 (telephone) 315.442.4525 (facsimile)

Online registration at www.empiremedicare.com



EMPIRE MEDICARE SERVICES
MEDICARE PART A INTERMEDIARY
PROVIDER EDUCATION AND TRAINING SEMINARS

Introduction to Skilled Nursing Facility Billing

CONFERENCE REGISTRATION FORM

Please check the session you will attend

NEW YORK CITY, NY
Tuesday, June 18, 2002
 Greater NY Hospital
 Association 555 West 57th
 Street, 15th Floor

TONAWANDA, NY
**Thursday, June 27,
 2002** Western NY
 Healthcare Association
 1876 Niagara Falls Blvd.

SYRACUSE, NY
Wednesday, July 23, 2002
 Empire Medicare Services
 400 South Salina Street

•Registration closes 5
 days prior to
 session.

LAKE SUCCESS, NY
Wednesday, June 19, 2002
 Island Peer Review Organization
 (IPRO) 1979 Marcus Avenue, 1st
 Floor

WALLINGFORD, CT
Tuesday, July 9, 2002
 Connecticut Hospital
 Association 110 Barnes Road

SYRACUSE, NY
Wednesday, July 24, 2002
 Empire Medicare Services
 400 South Salina Street

WILMINGTON, DE
Tuesday, June 25, 2002
 Wilmington Hospital 14th &
 Washington St. Conference Ctr.

WALLINGFORD, CT
Wednesday, July 10, 2002
 Connecticut Hospital Association
 110 Barnes Road

• Be sure to include a
 check or Payment
 Authorization Form

Sessions are scheduled from 9:00 a.m. to 4:00 p.m. We will begin collecting confirmation cards at 8:00 a.m.

The cost for this seminar is \$100 **per person**. Prepayment or Payment Authorization is required; checks will not be accepted at the door. Lunch is **not** included. Only **one** attendee is allowed per registration form. Please photocopy this registration form as needed for additional attendees.

*Please provide all of the information requested below. **Requests received that do not include your facility's Medicare provider number cannot be processed.***

MEDICARE PROVIDER NUMBER (REQUIRED)	PROVIDER NAME
FACILITY ADDRESS	PRIMARY PHONE
CITY STATE ZIP CODE	PRIMARY FAX
ATTENDEE NAME AND POSITION	PRIMARY E-MAIL

Confirmation cards for this seminar will be sent to the attention of the participant at your facility's main billing address.
Please contact the person receiving your facility's Medicare mail to obtain your confirmation card.

Please send registration and check to:
 Empire Medicare Services, c/o Jhadi Grace, P.O. Box 4846, Syracuse, NY 13221
 315.442.4723 (telephone) 315.442.4525 (facsimile)
 Online registration at www.empiremedicare.com



EMPIRE MEDICARE SERVICES
MEDICARE PART A INTERMEDIARY
PROVIDER EDUCATION AND TRAINING SEMINARS

Frequently Asked Questions About the Training Registration Process

Q *How do I know that I am included on the attendance list?*

A Participants whose registrations can be accommodated will receive a confirmation card for the training. The confirmation card contains information specific to the session including training date, location, and topic. The card also lists the attendee's name and confirmation number.

Note: Confirmation cards for this seminar will be sent to the attention of the participant at your facility's main billing address.

Q *How do I get directions to the session?*

A Directions to our seminars are available online. Many Web sites such as www.yahoo.com and www.mapquest.com offer free maps and printable directions. In addition, our Web-based registration form has links to printable directions.

Q *What happens if I can't make it to a session that I'm already confirmed for?*

A If you have already received confirmation for attendance at training and you cannot make the session, another person from your facility may present your confirmation card at the registration desk, and that person will be accommodated. If no one from your facility is able to attend training, contact Jhadi Grace to discuss refund opportunities, which may be available depending on several factors.

Q *What if I get "locked out" of a session?*

A **Registrations received in any of the following situations cannot be accommodated:** no check was received with registration (Completed Empire Payment Authorization Form can substitute for a check); registration received after the session is full or after the session is closed. The participant will be contacted and advised of the available options, if any.

Q *I don't want to get "locked out" of the session while my facility processes the check. Can you bill my facility for this training?*

A Yes. By having an authorized individual (other than the participant) fill out and return the following Empire Payment Authorization Form, you can request that Empire bill your facility for the training, or designate that the payment will come in the mail. Once the registration form and invoice are received, your participant will be registered (if space is available).

Q *I faxed/e-mailed my registration weeks ago. How did I get "locked out" of the session?*

A Classes are filled on a "first-paid, first-accommodated" basis. **Prepayment is required; payment cannot be accepted at the door on the day of training.** Registrations received via fax or e-mail are held until accompanying payment is received (Completed Empire Payment Authorization Form can substitute for a check). Seating is limited; early registration with payment is encouraged.

Please send registration and check to:
Empire Medicare Services, c/o Jhadi Grace, P.O. Box 4846, Syracuse, NY 13221
315.442.4723 (telephone) 315.442.4525 (facsimile)
Online registration at www.empiremedicare.com



EMPIRE MEDICARE SERVICES
MEDICARE PART A INTERMEDIARY
PROVIDER EDUCATION AND TRAINING SEMINARS

Date: _____

Dear Jhadi Grace:

My facility would like to participate in the Introduction to Skilled Nursing Facility Billing training. I understand that the cost for this seminar is \$100 per person and that prepayment is required.

In order to expedite the processing of my request and ensure participation at this training, I will have an authorized individual sign and return the form below, indicating that our facility understands and agrees to pay the cost of this education session. Empire will contact the person signing below in the event we have collection or other billing questions.

*This letter should be returned via fax to:

Empire Medicare Services
Attn: Jhadi Grace, Professional Relations
315.442.4525 (facsimile)
315.442.4723 (telephone)

I REALIZE THAT MY REGISTRATION WILL NOT BE PROCESSED UNTIL EITHER THE PAYMENT OR THIS SIGNED FORM HAS BEEN RECEIVED BY EMPIRE MEDICARE SERVICES.

Sincerely,

_____ Participant Name (*please print*)



Empire Payment Authorization Form

Provider Name: _____ Provider Number (required): _____

Number of Participants: _____ Total to be invoiced: \$ _____ .00

Company Address: _____

Authorized Payment Representative: _____ Title: _____ Phone: _____

Authorized Payment Representative Signature _____ Date _____

Providers are required to complete each field for the form to be acceptable.

- Please bill my facility for the full cost of training outlined above.
- Remittance for this training has already been sent via mail. (signature still required)

Implementation of the ANSI X12 270/271 Version 4010 Eligibility Inquiry & Response Transaction

The Centers for Medicare & Medicaid Services (CMS) has issued the following instructions regarding implementation of the ANSI X-12 270/271 version 4010 transaction.

- Medicare will implement the ANSI X-12 270/271 Eligibility Inquiry Response transaction in a real-time interactive environment. Batch transmissions will not be supported.
- Effective October 6, 2003, EDI requests for eligibility data must be submitted via a version 4010 270 query; each valid 270 inquiry will be issued a 271 version 4010 response.
- The Common Working File (CWF) will return 271 responses based on provider type:
 1. Hospitals/Skilled Nursing Facility Providers
 2. Psychiatric Providers
 3. Home Health Providers
 4. Managed Care Providers – HMO Eligibility Response
 5. Managed Care Providers – HMO Eligibility/Utilization Responses

Note: Empire Medicare Services does not service home health or managed care providers.

- CMS has instructed contractors to implement a new “inquiry to claim ratio” safeguard. If a provider has multiple provider numbers, the provider must make sure that the same number used to submit claims for a beneficiary is also used to submit eligibility inquiries; otherwise, the inquiry to claim ratio will be affected. Contractors are instructed to monitor provider inquiry to claim ratios. During the migration period, all sources of eligibility requests will be considered in calculating the inquiry to claim ratio.
- Current eligibility formats will continue to be supported until October 6, 2003. On October 6, these formats will be discontinued. Eligibility inquiry and response capability will continue to be supported through the Fiscal Intermediary Standard System (FISS) direct data entry (DDE) system.

- A provider that prefers to obtain eligibility data in an EDI format, but who does not want to use the 270/271 may contract with a clearinghouse to translate the information on its behalf; however, that provider would be liable for those clearinghouse costs.
- The version 4010 270/271 Implementation Guide can be downloaded without charge from the Washington Publishing Company Web site: www.wpc-edi.com/HIPAA.
- Providers who want to test to assure system compatibility of version 4010 of the 270/271 must schedule testing with their fiscal intermediary. There is no Medicare charge for this system testing.
- Although Medicare will furnish providers with basic information on the HIPAA standard transaction requirements to enable providers to make educated and timely decisions to plan for use of the HIPAA standard, Medicare will not furnish in-depth training on the use and interpretation of the standards implementation guides. Providers who feel they have a need to obtain such in-depth training for their staff are expected to obtain training of that nature from commercial vendors, their clearinghouses, or through standards compliance organizations.

Empire Medicare Services will develop a trading partner agreement with further instructions for implementing the ANSI X-12 version 4010 270/271 transactions. Trading partners will be notified when the agreement is available on the Empire Medicare Services (EMS) Web site.

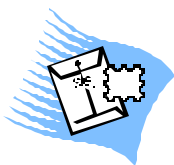
HIPAA Model Compliance Extension Plan and Instructions Now Available

In 1996, the Health Insurance Portability and Accountability Act (HIPAA) became law. It requires, among other things, that the Department of Health and Human Services (DHHS) establish national standards for electronic health care transactions and code sets. October 16, 2002 is the scheduled deadline for covered entities such as health plans, clearinghouses and providers (such as physicians, dentists, hospitals, nursing homes and others) to comply with these new standards. However, in December 2001, the Administrative Simplification Compliance Act (ASCA, Public Law 107-105) gave covered entities not compliant by October 16, 2002 the opportunity to extend their compliance deadline by 1 year – to October 16, 2003. This extension opportunity is applicable to all HIPAA covered entities other than small health plans (those with less than \$5 million in annual receipts whose compliance date is already set for October 16, 2003). In order to qualify for this extension, covered entities must submit a compliance plan by October 15, 2002.

A model compliance plan and instructions on how to complete and submit it are available on the Centers for Medicare & Medicaid Services (CMS) Web site, www.cms.hhs.gov/hipaa.



Providers can submit this on-line model plan electronically through the Web site or print and mail it. Providers can submit their own paper version of the plan as long as it provides equivalent information (covered entity and contact information; reasons for filing for the extension; HIPAA implementation budget information; and where you are in implementing and testing including whether or not you plan to use a vendor). The CMS strongly encourages electronic filing, but if you must file on paper, you should send your form to:



Attention: Model Compliance Plans
Centers for Medicare & Medicaid
Services (CMS)
P.O. Box 8040
Baltimore, MD 21244-8040

The deadline for both electronic and paper submissions is October 15, 2002.

If you file electronically through the Web site, you will receive an electronic confirmation number acknowledging and granting your extension. If you file a paper version, you won't receive a confirmation, but if your paper plan consists of the required equivalent information, you may consider your extension granted.

The instructions give more details on how to complete the form; explanation of who should file for an extension; data you need to include; and where to get more information on definitions, frequently asked questions, etc.



For more information, submit questions to askhipaa@cms.hhs.gov.

Providers Using Medicare Supplied Billing Software

Medicare contractors will continue to provide electronic billing software for providers to use to submit their Medicare claims. The HIPAA compliant version of this software may not be available until December 2002. As this is after the initial compliance deadline of October 16, 2002, any providers that plan to use the current version of this software after October 15, 2002 must submit a Compliance Extension Plan as described above.

Update to ANSI Adjustment Reason Codes and Provider Level Adjustment Code - Correction

Medicare News Update 2002-5 has a typographical error in the article "Update to ANSI Adjustment Reason Codes and Provider Level Adjustment Code."

The paragraph just below the table shows an incorrect date. That statement should have read:

"The changes are anticipated for June 3, 2002."

Techniques, Tidbits, & Tricks (FSS/DDE)

Claim Count Summary is selection (56) off the Empire Medicare Services inquiry menu. The information displayed can be used in monitoring the claims within the processing system by reviewing the status location categories. This option gives the user the total claim count and total dollar amount for each status location. From the OMNIPRO main menu, select 2 Medicare Part A. From the FSS/DDE main menu, then select 1 Inquiries. Key 56 (Claim Count Summary) from the menu selection. After the provider totals screen appears, key "Enter" again. The system will then display all status/location data for the primary provider. You have the capability to key the specific Status/Location and/or Category in the particular fields to display information for an individual status or location.

If your OMNIPRO™ logon is affiliated with other provider numbers, you can key over the provider number and press enter to display the next number's information.

The Status/Location (S/LOC) field identifies the condition of the claim. Status is a one-position alphanumeric field followed by the five-position alphanumeric location field that identifies where the claim resides in the system. Some common claim status and location codes can be referenced in the FISS Provider Online Manual, Chapter 1, Section C.

Category (CAT) is a field that denotes the type of claims in a specific location by the first two positions of the type of bill and alpha categories:

GT = Grand Total	Total prints at the beginning of the listing including all categories in all Status/Locations
TC = Total Count	Total within each Status/Location excluding claims in AD, NM, or MP categories
AD = Adjustments	Adjustments within each Status/Location
NM = Non Medical	RTP claims in Status/Location TB9997 only where the first digit of the primary reason code <u>is not</u> 5.
MP = Medical Policy	RTP claims in Status/Location TB9997 only where the first digit of the primary reason code <u>is</u> 5.
XX = Type of Bill	First two positions of the specific type of bill

The total claim count for a specific status/location is the Claim Count field. The Total Charges field is the total dollar amount accumulated for the number of claims in the claim count. Total Payment represents the total Medicare reimbursement amount for claims in the related Bill category and status location.

NOTE: If the total charges are greater than \$1,000,000, the dollar amount is truncated for each category except GT (Grand Total). The Grand Total field displays all dollar amounts correctly.

The sample screens are for review to educate yourself before inquiring online data.

MAP1702

EMPIRE MEDICARE SERVICES INQUIRY MENU

BENEFICIARY/CWF	10	HCPC CODES	14
DRG (PRICER/GROUPER)	11	DX/PROC CODES	15
CLAIMS	12	ADJUSTMENT REASON CODES	16
REVENUE CODES	13	REASON CODES	17
CLAIM COUNT SUMMARY	56	ANSI REASON CODES	68
CHECK HISTORY	FI		

ENTER MENU SELECTION: 56

MEDICARE A ONLINE SYSTEM
CLAIM SUMMARY TOTALS INQUIRY

PROVIDER 999999		S/LOC	CAT		
S/LOC	CAT	CLAIM COUNT	TOTAL CHARGES	TOTAL PAYMENT	
	GT	1928	44,876,151.19	13,641.74	
P B7590	TC	3	211,759.10	0.00	
P B7590	11	3	211,759.10	0.00	
P B7591	TC	16	1,365.00	0.00	
P B7591	13	15	815.00	0.00	
P B7591	72	1	550.00	0.00	
P B9996	TC	4	24,232.10	13,641.74	
P B9996	11	3	17,474.97	11,082.81	
P B9996	13	1	6,757.13	2,558.93	
S B6099	TC	1	1.00	0.00	
S B6099	13	1	1.00	0.00	
S B0001	TC	8	2,325.00	0.00	
S B0001	13	8	2,325.00	0.00	
S B0095	TC	3	820.00	0.00	
S B0095	13	3	820.00	0.00	
S B0099	AD	2	15,928.72	0.00	

Announcing HIPAA Computer Based Training (CBT)



Now available for your learning pleasure, HIPAA Computer Based Training (CBT). This training course may be found on the Empire Medicare Services Web site at www.empiremedicare.com under the HIPAA selection. The course is designed to give the participant an overview and understanding of the Health Insurance Portability and Accountability Act (HIPAA). This course conveys highlights and gives an explanation of the Empire Medicare Services Trading Partner Agreement (TPA). The training course also addresses the purpose and usage of the ANSI ASC X12N Implementation Guide (IG) for the 837 claim transaction set. After taking this course, the participant will be knowledgeable about the process and terminology used for this implementation. Spread the word and tell your co-workers how easy and helpful this learning tool can be!

Instructions For Providers Using Network Service Vendors

The Centers for Medicare and Medicaid Services (CMS) has issued new instructions for providers using or changing network service vendors. A network service vendor has been defined by CMS as “any entity other than a billing service or clearinghouse engaged in EDI with a carrier or intermediary on behalf of Medicare providers.” Currently, network service vendors provide eligibility services to providers.

The CMS instructions for providers regarding changes in vendor contracts are as follows:

Providers must provide to their intermediaries written notice of any changes to their vendor contracts within 30 days of the effective date for the changes. Contractual changes include, but are not limited to:

- Change in vendors;
- Vendor ceases operations;
- Vendor is purchased by, or merged/aligned with another vendor or organization;
- Change in services provided by a vendor; and
- Discontinued use of vendor services by a provider.

When a new provider/vendor contract is initiated, or an existing contract changes for any of the above reasons or another reason, written notification must be submitted to the appropriate contractors within 30 days of the effective date of changes.

Notification needs to include vendor name and address identification and vendor tax identification number. Notification may consist of the following:

- A new contract with termination notification for prior contract;
- Addenda to existing contracts; and
- Contract termination.

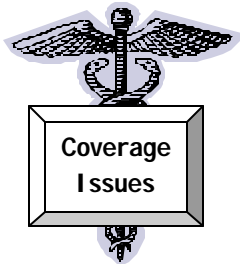
This instruction is **effective immediately**. All change notifications should be addressed as follows:



Institutional EDI Department
Empire Medicare Services
400 S. Salina Street
Syracuse, NY 13202

Important Information

In a continuing effort to improve provider communications, we have revised the format for Coverage Issues Manual Transmittals (CIM) and the corresponding Program Memorandums (PM) which contain billing instructions. Previously, we published two separate articles for the CIM transmittal and the PM. In this issue, you will find billing information from the program memorandum instructions at the end of each CIM topic.



Coverage Issues Manual Updates

Transmittal 154

Section 80-3, Medical Nutrition Therapy

New/Revised Material—Effective Date: October 1, 2002

Implementation Date: October 1, 2002

These sections of the Coverage Issues Manual are National Coverage Determinations (NCDs). NCDs are binding on all Medicare carriers, intermediaries, peer review organizations, Health Maintenance Organizations, Competitive Medical Plans, and Health Care Prepayment Plans. Under 42 CFR 422.256(b), an NCD that expands coverage is also binding on a Medicare+Choice Organization. In addition, an administrative law judge may not review an NCD. (See §1869 (f)(1)(A)(i) of the Social Security Act.)

Section 80-3 - Medical Nutrition Therapy

Section 1861(s)(2)(V) of the Social Security Act authorizes Medicare Part B coverage of medical nutrition therapy services (MNT) for certain beneficiaries who have diabetes or renal disease, effective for services furnished on or after January 1, 2002. Regulations for medical nutrition therapy (MNT) were established at 42 CFR §§410.130 – 410.134. This national coverage determination establishes the duration and frequency limits for the MNT benefit and coordinates MNT and diabetes outpatient self-management training (DSMT) as a national coverage determination.

Effective October 1, 2002, basic coverage of MNT for the first year a beneficiary receives MNT with either a diagnosis of renal disease or diabetes as defined at 42 CFR §410.130 is 3 hours. Also effective October 1, 2002, basic coverage in subsequent years for renal disease or diabetes is 2 hours. The dietitian/nutritionist may choose how many units are performed per day as long as all of the other requirements in this NCD and 42 CFR §§410.130-410.134 are met. Pursuant to the exception at 42 CFR §410.132(b)(5), additional hours are considered to be medically necessary and covered if the treating physician determines that there is a change in medical condition, diagnosis, or treatment regimen that requires a change in MNT and orders additional hours during that episode of care.

Effective October 1, 2002, if the treating physician determines that receipt of both MNT and DSMT is medically necessary in the same episode of care, Medicare will cover both DSMT and MNT initial and subsequent years without decreasing either benefit as long as DSMT and MNT are not provided on the same date of service. The dietitian/nutritionist may choose how many units are performed per day as long as all of the other requirements in the NCD and 42 CFR §§410.130-410.134 are met. Pursuant to the exception at 42 CFR 410.132(b)(5), additional hours are considered to be medically necessary and covered if the treating physician determines that there is a change in medical condition, diagnosis, or treatment regimen that requires a change in MNT and orders additional hours during that episode of care.

Medical Nutrition Therapy (MNT) Services (Additional Clarification from Program Memorandum (PM) AB-02-059)

Intermediaries

Claims for MNT are not billable to Medicare Part A intermediaries. All claims for this benefit must be submitted by the provider to their local Medicare carrier on a Form CMS-1500 or the appropriate electronic format. Payment will not be made for HCPCS codes 97802, 97803 or 97804 if billed by a provider on the UB92. There is no separate facility payment for this new benefit.

Background

Section 105 of BIPA 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 §1861 (r) (1) of the Social Security Act (the Act). Non-physician practitioners cannot make referrals for this service. 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 **is defined as a maximum of 3 hours that may be reimbursed in the initial episode of care. In subsequent years, beneficiaries may receive 2 hours of MNT with a physician referral. The number of hours covered for diabetes is the same as the number of hours covered for renal disease.**

For the purposes of this benefit, renal disease means chronic renal insufficiency; end-stage renal disease when dialysis is not received; and the medical condition of a beneficiary for 36 months after a kidney transplant. Chronic renal insufficiency means a reduction in renal function not severe enough to require dialysis or transplantation (glomerular filtration rate (GFR) 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), Type 2 (familial hyperglycemia), and gestational diabetes. Gestational diabetes is any degree of glucose intolerance with onset or first recognition during pregnancy. 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 Medicine 2000 Report, The Role of Nutrition in Maintaining Health in the Nation’s Elderly.

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 in this PM. A treating physician means the primary care physician or specialist coordinating care for the beneficiary with diabetes or renal disease.
- The number of hours covered in an episode of care may not be exceeded unless a second referral is received from the treating physician.
- Services may be provided either on an individual or group basis without restrictions.
- For a beneficiary with a diagnosis of diabetes, Diabetes Self-Management Training (DSMT) and MNT services can be provided within the same time period, and the maximum number of hours allowed under

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each benefit are covered. The only exception is that DSMT and MNT may not be provided on the same day to the same beneficiary. For a beneficiary with a diagnosis of diabetes who has received DSMT and is also diagnosed with renal disease in the same episode of care, the beneficiary may receive MNT services based on a change in medical condition, diagnosis, or treatment as stated in 42 CFR 410.132(b)(5).

- 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 §1881 of the Act.
- **A beneficiary may not receive MNT and DSMT on the same day.**

Referrals

Referrals may only be made by the treating physician when the beneficiary has been diagnosed with diabetes or renal disease as defined in this article 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 as a result of a change in medical condition or diagnosis. The UPIN number of the referring physician must be on the Form CMS-1500 claim submitted by a registered dietitian or nutrition professional. Return claims that do not contain the UPIN of the referring physician.

Additional Covered Hours for MNT Services

Additional hours of MNT services may be covered beyond the number of hours typically covered under an episode of care when the treating physician determines there is a change of diagnosis or medical condition within such episode of care that makes a change in diet necessary. Appropriate medical review for this provision should only be done on a postpayment basis. Outliers may be judged against nationally accepted dietary or nutritional protocols in accordance with 42 CFR 410.132(a).

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 (they are not required to meet any other requirements); 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. The academic requirements of a nutrition or dietetics program may be completed after the completion of the degree;
- Has completed at least 900 hours of supervised dietetics practice under the supervision of a registered dietitian or nutrition professional. Documentation of the supervised dietetics practice may be in the form of a signed document by the professional/facility that supervised the individual; 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 diabetes self-management 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 will be the lesser of the actual charge, or 85 percent of the physician fee schedule amount when rendered by a registered dietitian or nutrition professional. Coinsurance is based on 20 percent of the lesser of these two amounts. As required by statute, this same methodology will be used for services provided in the hospital outpatient department. (**NOTE:** This payment language change will be implemented on July 1, 2002.)

Payment will 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:** This CPT code must only be used for the initial visit.)
- 97803 Reassessment and intervention, individual, face-to-face with the patient, each 15 minutes
- 97804 Group (2 or more individual(s)), each 30 minutes

Use of the Medical Nutrition Therapy Codes

- 97802 This code 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.
- 97803 This code 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 that affects the nutritional status of the patient (see the heading, Additional Covered Hours for Reassessments and Interventions).
- 97804 This code is to be billed for all group visits, initial and subsequent. This code can also be used when there is a change in a patient's condition that affects the nutritional status of the patient 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 that meets the specified requirements. These services cannot be paid "incident to" physician services. The payments can be reassigned to the employer of a qualifying dietitian or nutrition professional.

Claims Processing Information

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

Registered dietitians and nutrition professionals can 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 CMS-1500.

As stated under "Conditions of Coverage," this benefit is payable for beneficiaries who have diabetes or renal disease. If the claim does not contain a diagnosis of diabetes or renal disease, the claim will be denied under §1862(a)(1)(A) of the Act.

Enrollment of Dietitians and Nutritionists

Registered dietitians and nutrition professionals are paid for MNT services through local carriers. In order to file claims for MNT, a registered dietitian/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. MNT services can be billed with the effective date of the provider’s license and the establishment of the practice location, but not before January 1, 2002.

Transmittal 155

Intravenous Immune Globulin (Program Memorandum AB-02-060)

We have requested clarification from the Centers for Medicare and Medicaid Services on a number of issues and will publish this Transmittal and the Program Memorandum when the clarification is received.

Transmittal 156

Section 50-56, Home Prothrombin Time International Normalized Ratio (INR) Monitoring for Anticoagulation Management

New/Revised Material—Effective Date: **July 1, 2002**

Implementation Date: July 1, 2002



Section 50-36, Positron Emission Tomography (PET) Scans

Section 50-57, Current Perception Threshold/Sensory Nerve Conduction Threshold test (sNCT)

Section 50-58, Single Photo Emission Tomography - Covered

New/Revised Material—Effective Date: **October 1, 2002**

Implementation Date: October 1, 2002

Section 50-56, Home Prothrombin Time International Normalized Ratio (INR) Monitoring for Anticoagulation Management

Effective for services furnished on or after July 1, 2002, this section is added to provide coverage for Home Prothrombin Time monitoring and management only for patients with mechanical heart valves when certain conditions have been met under the Medicare program.

Use of the International Normalized Ratio (INR) allows physicians to determine the level of anticoagulation in a patient independent of the laboratory reagents used. The INR is the ratio of the patient’s prothrombin time compared to the mean prothrombin time for a group of normal individuals. Maintaining patients within the therapeutic range minimizes adverse events associated with inadequate or excessive anticoagulation such as serious bleeding or thromboembolic events. Patient self-testing and self-management through the use of a home INR monitor may be used to improve the time in therapeutic rate (TTR) for select groups of patients. Increased TTR leads to improved clinical outcomes and reductions in thromboembolic and hemorrhagic events.

Home prothrombin monitoring with the use of INR devices is covered only for patients with mechanical heart valves. The monitor and the home testing must be prescribed by a treating physician as provided at 42 CFR 410.32 (a) and the following requirements must be met:

1. The patient must have been anticoagulated for at least three months prior to use of the home INR device;
2. The patient must undergo an educational program on anticoagulation management and the use of the device prior to its use in the home; and
3. Self-testing with the device should not occur more frequently than once a week.

Home Prothrombin Time International Normalized Ratio (INR) Monitoring for Anticoagulation Management

(Coverage and Billing Instructions from Program Memorandum AB-02-064)

Coverage

Use of the INR allows physicians to determine the level of anticoagulation in a patient independent of the laboratory reagents used. The INR is the ratio of the patient's prothrombin time compared to the mean prothrombin time for a group of normal individuals.

For services furnished on or after July 1, 2002, Medicare will cover the use of home prothrombin time INR monitoring for anticoagulation management for patients with mechanical heart valves on **warfarin**. The monitor and the home testing must be prescribed by a physician and the following patient requirements **must** be met:

- Must have been anticoagulated for at least three months prior to use of the home INR device;
- Must undergo an educational program on anticoagulation management and the use of the device prior to its use in the home; and
- Self-testing with the device is limited to a frequency of once per week.

Billing Instructions

HCPCS Codes

G0248 Demonstration, at initial use, of home INR monitoring for patient with mechanical heart valve(s) who meets Medicare coverage criteria, under the direction of a physician; includes: demonstration use and care of the INR monitor, obtaining at least one blood sample, provision of instructions for reporting home INR test results and documentation of a patient ability to perform testing.

Short Description: Demonstrate use home INR mon

G0249 Provision of test materials and equipment for home INR monitoring to patient with mechanical heart valve(s) who meets Medicare coverage criteria. Includes provision of materials for use in the home and reporting of test results to physician; per 4 tests.

Short Description: Provide test material, equipm

Bill Types - The applicable bill types are 13X (outpatient hospital) and 85X (Critical Access Hospital).

Revenue Codes - Hospitals may report these services under revenue code is 920 (Other Diagnostic Services) or they may report HCPCS codes G0248 and G0249 under the revenue center where they are performed.

Diagnosis Code - The applicable diagnosis code for this benefit is **V43.3**, organ or tissue replaced by other means; heart valve.

NOTE: Porcine valves are not covered so Medicare will not make payment on Home INR Monitoring for patients with porcine valves.

Payment Requirements - Payment is as follows:

- Hospital outpatient departments - Outpatient Prospective Payment System (OPPS)
- Critical Access Hospital (CAH) - Reasonable cost (Option 1) or Medicare Physician Fee Schedule (MPFS)

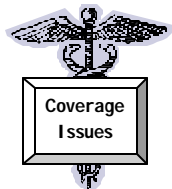
Deductible and coinsurance apply.

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Section 50-36 - Positron Emission Tomography (PET) Scans

General Description

Positron emission tomography (PET) is a noninvasive diagnostic imaging procedure that assesses the level of metabolic activity and perfusion in various organ systems of the [human] body. A positron camera (tomograph) is used to produce cross-sectional tomographic images, which are obtained from positron emitting radioactive tracer substances (radiopharmaceuticals) such as 2-[F-18] Fluoro-D-Glucose (FDG), that are administered intravenously to the patient.



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

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

Clinical Condition	Effective Date	Coverage
Solitary Pulmonary Nodules (SPNs)	January 1, 1998	Characterization
Lung Cancer (Non Small Cell)	January 1, 1998	Initial staging
Lung Cancer (Non Small Cell)	July 1, 2001	Diagnosis, staging and restaging
Esophageal Cancer	July 1, 2001	Diagnosis, staging and restaging
Colorectal Cancer	July 1, 1999	Determining location of tumors if rising CEA level suggests recurrence
Colorectal Cancer	July 1, 2001	Diagnosis, staging and restaging
Lymphoma	July 1, 1999	Staging and restaging only when used as an alternative to Gallium scan
Lymphoma	July 1, 2001	Diagnosis, staging and restaging
Melanoma	July 1, 1999	Evaluating recurrence prior to surgery as an alternative to a Gallium scan
Melanoma	July 1, 2001	Diagnosis, staging and restaging; Noncovered for evaluating regional nodes
Breast Cancer	October 1, 2002	As an adjunct to standard imaging modalities for staging patients with distant metastasis or restaging patients with locoregional recurrence or metastasis; as an adjunct to standard imaging modalities for monitoring tumor response to treatment for women with locally advanced and metastatic breast cancer when a change in therapy is anticipated.
Head and Neck Cancers (excluding CNS and thyroid)	July 1, 2001	Diagnosis, staging and restaging
Myocardial Viability	July 1, 2001 to September 30, 2002	Covered only following inconclusive SPECT
Myocardial Viability	October 1, 2002	Primary or initial diagnosis, or following an inconclusive SPECT prior to revascularization. SPECT may not be used following an inconclusive PET scan.

Refractory Seizures	July 1, 2001	Covered for pre-surgical evaluation only
Perfusion of the heart using Rubidium 82* tracer	March 14, 1995	Covered for noninvasive imaging of the perfusion of the heart

*Not FDG-PET.

General Conditions of Coverage for FDG PET

A. Allowable FDG PET Systems

1. Definitions: For purposes of this section,
 - a. “Any FDA approved” means all systems approved or cleared for marketing by the FDA to image radionuclides in the body.
 - b. “FDA approved” means that the system indicated has been approved or cleared for marketing by the FDA to image radionuclides in the body.
 - c. “Certain coincidence systems” refers to the systems that have all the following features:
 - crystal at least 5/8-inch thick,
 - techniques to minimize or correct for scatter and/or randoms, and
 - digital detectors and iterative reconstruction.

Scans performed with gamma camera PET systems with crystals thinner than 5/8-inch will not be covered by Medicare. In addition, scans performed with systems with crystals greater than or equal to 5/8-inch in thickness, but that do not meet the other listed design characteristics are not covered by Medicare.

2. Allowable PET systems by covered clinical indication:

Allowable Type of FDG PET System

Covered Clinical Condition	Prior to July 1, 2001	July 1, 2001 through December 31, 2001	On or after January 1, 2002
Characterization of single pulmonary nodules	Effective 1/1/1998, any FDA approved	Any FDA approved	FDA approved: Full ring Partial ring Certain coincidence systems
Initial staging of lung cancer (non small cell)	Effective 1/1/1998, any FDA approved	Any FDA approved	FDA approved: Full ring Partial ring Certain coincidence systems
Evaluating recurrence prior to surgery as an alternative to a gallium scan	Effective 7/1/1999, any FDA approved.	Any FDA approved	FDA approved: of melanoma Full ring Partial ring Certain coincidence systems
Diagnosis, staging, and restaging of colorectal cancer	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Diagnosis, staging, and restaging of esophageal cancer	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Diagnosis, staging, and restaging of head and neck cancers (excluding CNS and thyroid)	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Diagnosis, staging, and restaging of lung cancer (non small cell)	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring

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Diagnosis, staging, and restaging of lymphoma	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Diagnosis, staging, and restaging of melanoma (noncovered for evaluating regional nodes)	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Determination of myocardial viability only following an inconclusive SPECT	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Presurgical evaluation of refractory seizures	Not covered by Medicare	Full ring	FDA approved: Full ring Partial ring
Myocardial Viability Primary or initial diagnosis prior to revascularization	Not covered	Not covered Full and partial ring	Effective October 1, 2002,

- A. Regardless of any other terms or conditions, all uses of FDG PET scans, in order to be covered by the Medicare program, must meet the following general conditions prior to June 30, 2001:
1. Submission of claims for payment must include any information Medicare requires to assure that the PET scans performed: (a) were medically necessary, (b) did not unnecessarily duplicate other covered diagnostic tests, and (c) did not involve investigational drugs or procedures using investigational drugs, as determined by the Food and Drug Administration (FDA).
 2. The PET scan entity submitting claims for payment must keep such patient records as Medicare requires on file for each patient for whom a PET scan claim is made.
- B. Regardless of any other terms or conditions, all uses of FDG PET scans, in order to be covered by the Medicare program, must meet the following general conditions as of July 1, 2001:
1. The provider of the PET scan should maintain on file the doctor's referral and documentation that the procedure involved only FDA approved drugs and devices, as is normal business practice.
 2. The ordering physician is responsible for documenting the medical necessity of the study and that it meets the conditions specified in the instructions. The physician should have documentation in the beneficiary's medical record to support the referral to the PET scan provider.

Covered Indications for PET Scans and Limitations/Requirements for Usage

For all uses of PET relating to malignancies, the following **conditions** apply:

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

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

2. Staging and/or Restaging: PET is covered in clinical situations in which 1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient, and 2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.
3. Monitoring: Use of PET to monitor tumor response during the planned course of therapy (i.e., when no change in therapy is being contemplated) is not covered except for breast cancer. Restaging only occurs after a course of treatment is completed, and this is covered, subject to the conditions above.

NOTE: In the absence of national frequency limitations, contractors may, if necessary, develop frequency requirements on any or all of the indications covered on and after July 1, 2001.

Coverage of PET for Perfusion of the Heart Using Rubidium 82

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

Requirements:

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

- The PET scan, whether at rest alone or rest with stress, is used following a SPECT that was found to be inconclusive. In these cases, the PET scan must have been considered necessary in order to determine what medical or surgical intervention is required to treat the patient. (For purposes of this requirement, an inconclusive test is a test(s) whose results are equivocal, technically uninterpretable, or discordant with a patient's other clinical data and must be documented in the beneficiary's file.)
- For any PET scan for which Medicare payment is claimed for dates of services prior to July 1, 2001, the claimant must submit additional specified information on the claim form (including proper codes and/or modifiers), to indicate the results of the PET scan. The claimant must also include information on whether the PET scan was done after an inconclusive noninvasive cardiac test. The information submitted with respect to the previous noninvasive cardiac test must specify the type of test done prior to the PET scan and whether it was inconclusive or unsatisfactory. These explanations are in the form of special G codes used for billing PET scans using Rb 82. Beginning July 1, 2001, claims should be submitted with the appropriate codes.

Coverage of FDG PET for Lung Cancer

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

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

Beginning July 1, 2001, documentation should be maintained in the beneficiary's medical file at the referring physician's office to support the medical necessity of the procedure, as is normal business practice.

Requirements:

- There must be evidence of primary tumor. Claims for regional PET chest scans for characterizing SPNs should include evidence of the initial detection of a primary lung tumor, usually by computed tomography (CT). This should include, but is not restricted to, a report on the results of such CT or other detection method, indicating an indeterminate or possibly malignant lesion, not exceeding four centimeters (cm) in diameter.
- PET scan claims must include the results of concurrent thoracic CT (as noted above), which is necessary for anatomic information, in order to ensure that the PET scan is properly coordinated with other diagnostic modalities.
- In cases of serial evaluation of SPNs using both CT and regional PET chest scanning, such PET scans will not be covered if repeated within **90** days following a negative PET scan.

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

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

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

- The results of concurrent thoracic CT, necessary for anatomic information, and
- The results of any lymph node biopsy performed to

finalize whether the patient will be a surgical candidate. The ordering physician is responsible for providing this biopsy result to the PET facility.

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

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

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

- Diagnosis - PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal, and colorectal cancers as well as in melanoma should be rare.
- Staging and/or Restaging - PET is covered in clinical situations in which 1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient, and 2) clinical management of the patient would differ depending

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

Documentation should be maintained in the beneficiary's medical record at the referring physician's office to support the medical necessity of the procedure, as is normal business practice.

Coverage of FDG PET for Esophageal Cancer

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

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

- **Diagnosis** - PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal and colorectal cancers as well as in melanoma should be rare.
- **Staging and/or Restaging** - PET is covered in clinical situations in which 1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical

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

Documentation should be maintained in the beneficiary's medical record at the referring physician's office to support the medical necessity of the procedure, as is normal business practice.

Coverage of FDG PET for Colorectal Cancer

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

- A. Effective July 1, 1999, Medicare covers FDG PET for patients with recurrent colorectal carcinomas, which are suggested by rising levels of the biochemical tumor marker CEA.
1. **Frequency Limitations:** Whole body PET scans for assessment of recurrence of colorectal cancer cannot be ordered more frequently than once every 12 months unless medical necessity documentation supports a separate re-elevation of CEA within this period.
 2. **Limitations:** Because this service is covered only in those cases in which there has been a recurrence of colorectal tumor, claims for PET should include a statement or other evidence of previous colorectal tumor, through June 30, 2001.
- B. Beginning July 1, 2001, Medicare coverage has been expanded for colorectal carcinomas for diagnosis, staging and restaging. New medical evidence supports the use of FDG PET as a useful tool in determining the presence of hepatic/extrahepatic metastases in the primary staging of

colorectal carcinoma, prior to selecting a treatment regimen. Use of FDG PET is also supported in evaluating recurrent colorectal cancer beyond the limited presentation of a rising CEA level where the patient presents clinical signs or symptoms of recurrence.

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

- Diagnosis - PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal, and colorectal cancers as well as in melanoma should be rare.
- Staging and/or Restaging - PET is covered in clinical situations in which 1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient, and 2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for detecting suspected recurrence, or to determine the extent of a known recurrence. Use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

Coverage of FDG PET for Lymphoma

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

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

Requirements:

- FDG PET is covered only for staging or follow-up restaging of lymphoma. Claims must include a statement or other evidence of previous diagnosis of lymphoma when used as an alternative to a Gallium scan.
- To ensure that the PET scan is properly coordinated with other diagnostic modalities, claims must include the results of concurrent computed tomography (CT) and/or other diagnostic modalities when they are necessary for additional anatomic information.
- In order to ensure that the PET scan is covered only as an alternative to a Gallium scan, no PET scan may be covered in cases where it is done within 50 days of a Gallium scan done by the same facility where the patient has remained during the 50-day period. Gallium scans done by another facility less than 50 days prior to the PET scan will not be counted against this screen. The purpose of this screen is to assure that PET scans are covered only when done as an alternative to a Gallium scan within the same facility. We are aware that, in order to assure proper patient care, the treating physician may conclude that previously performed Gallium scans are either inconclusive or not sufficiently reliable.

Frequency Limitation for Restaging: PET scans will be allowed for restaging no sooner than 50 days following the last staging PET scan or Gallium scan, unless sufficient evidence is presented to convince the Medicare contractor that the restaging at an earlier date is medically necessary. Since PET scans for restaging are generally done following cycles of

chemotherapy, and since such cycles usually take at least 8 weeks, we believe this screen will adequately prevent medically unnecessary scans while allowing some adjustments for unusual cases. In all cases, the determination of the medical necessity for a PET scan for restaging lymphoma is the responsibility of the local Medicare contractor.

Beginning July 1, 2001, documentation should be maintained in the beneficiary's medical record at the referring physician's office to support the medical necessity of the procedure, as is normal business practice.

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

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

- Diagnosis - PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal, and colorectal cancers as well as in melanoma should be rare.
- Staging and/or Restaging - PET is covered in clinical situations in which 1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient, and 2) clinical management of the patient would differ depending on the stage of the cancer identified. PET will be covered for restaging after the completion of treatment for the purpose of detecting residual disease, for

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

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

Coverage of FDG PET for Melanoma

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

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

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

Limitations: The FDG PET scan is covered only as an alternative to a Gallium scan. PET scans cannot be covered in cases where it is done within 50 days of a Gallium scan done by the same PET facility where the patient has remained under the care of the same facility during the 50-day period. Gallium scans done by another facility less than 50 days prior to the PET scan will not be counted against this screen. The purpose of this screen is to assure that PET scans are covered only when done as an alternative to a Gallium scan within the same facility. We are aware that, in order to assure proper patient care, the treating physician

may conclude that previously performed Gallium scans are either inconclusive or not sufficiently reliable to make the determination covered by this provision. Therefore, we will apply this 50-day rule only to PET scans done by the same facility that performed the Gallium scan.

Beginning July 1, 2001, documentation should be maintained in the beneficiary's medical file at the referring physician's office to support the medical necessity of the procedure, as is normal business practice.

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

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

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

- **Diagnosis** - PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal, and colorectal cancers as well as in melanoma should be rare.
- **Staging and/or Restaging** - PET is covered in clinical situations in which 1) (a) the stage of the cancer remains in doubt after completion of a standard diagnostic workup, including conventional imaging (computed tomography, magnetic resonance imaging, or ultrasound) or (b) the use of PET would also be considered reasonable and necessary if it could potentially replace one or more conventional imaging studies when it is expected that conventional study information is insufficient for the clinical management of the patient, and 2) clinical management of the patient

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

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical file, as is normal business practice.

Coverage of FDG PET for Head and Neck Cancers
(Cancers of the Central Nervous System (CNS) and thyroid are not covered)

Effective for services performed on or after July 1, 2001, Medicare will provide coverage for cancer of the head and neck, excluding the central nervous system (CNS) and thyroid. The head and neck cancers encompass a diverse set of malignancies of which the majority is squamous cell carcinomas. Patients may present with metastases to cervical lymph nodes but conventional forms of diagnostic imaging fail to identify the primary tumor. Patients that present with cancer of the head and neck are left with two options either to have a neck dissection or to have radiation of both sides of the neck with random biopsies. PET scanning attempts to reveal the site of primary tumor to prevent the adverse effects of random biopsies or unneeded radiation.

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

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

- **Diagnosis** - PET is covered only in clinical situations in which the PET results may assist in avoiding an invasive diagnostic procedure, or in which the PET results may assist in determining the optimal anatomical location to perform an invasive diagnostic procedure. In general, for most solid tumors, a tissue diagnosis is made prior to the performance of PET scanning. PET

scans following a tissue diagnosis are performed for the purpose of staging, not diagnosis. Therefore, the use of PET in the diagnosis of lymphoma, esophageal, and colorectal cancers as well as in melanoma should be rare.

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

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

Coverage of FDG PET for Myocardial Viability

The identification of patients with partial loss of heart muscle movement or hibernating myocardium is important in selecting candidates with compromised ventricular function to determine appropriateness for revascularization. Diagnostic tests such as FDG PET distinguish between dysfunctional but viable myocardial tissue and scar tissue in order to affect management decisions in patients with ischemic cardiomyopathy and left ventricular dysfunction.

FDG PET is covered for the determination of myocardial viability following an inconclusive SPECT from July 1, 2001 through September 30, 2002. Only full

ring PET scanners are covered from July 1, 2001 through December 31, 2001. However, as of January 1, 2002, full and partial ring scanners are covered.

Beginning October 1, 2002, Medicare covers FDG PET for the determination of myocardial viability as a primary or initial diagnostic study prior to revascularization, or following an inconclusive SPECT. Studies performed by full and partial ring scanners are covered.

Limitations: In the event that a patient has received a single photon computed tomography test (SPECT) with inconclusive results, a PET scan may be covered. However, if a patient received an FDG PET study with inconclusive results, a follow up SPECT is not covered.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice. (See §50-58 of the CIM for SPECT coverage.)

Coverage of FDG PET for Refractory Seizures

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

Limitations: Covered only for presurgical evaluation.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

Breast Cancer

Beginning October 1, 2002, Medicare covers FDG PET as an adjunct to other imaging modalities for staging patients with distant metastasis, or restaging patients with locoregional recurrence or metastasis. Monitoring treatment of a breast cancer tumor when a change in therapy is contemplated is also covered as an adjunct to other imaging modalities.

Limitations: Effective October 1, 2002, Medicare continues to have a national noncoverage determination for initial diagnosis of breast cancer and staging of axillary lymph nodes. Medicare coverage for staging patients with distant metastasis or restaging patients with locoregional recurrence or metastasis; and for monitoring tumor response to treatment for women with locally advanced and metastatic breast cancer when a change in therapy is anticipated, is only covered as an adjunct to other imaging modalities.

Documentation that these conditions are met should be maintained by the referring physician in the beneficiary's medical record, as is normal business practice.

Positron Emission Tomography (PET) Scans – for Breast Cancer and Revised Coverage Conditions for Myocardial Viability (Billing Instructions from Program Memorandum AB-02-065)

Coverage of FDG PET for Breast Cancer

Effective for dates of service on or after October 1, 2002, Medicare will cover FDG PET as an adjunct to other imaging modalities for staging and restaging for locoregional, recurrence or metastasis. Monitoring treatment of a locally advanced breast cancer tumor and metastatic breast cancer when a change in therapy is contemplated is also covered as an adjunct to other imaging modalities. The baseline PET study for monitoring should be done under the code for staging or restaging.

Limitations: Effective for dates of service on or after October 1, 2002, Medicare continues to have a national noncoverage determination for initial diagnosis of breast cancer and initial staging of axillary lymph nodes. Medicare coverage now includes PET as an adjunct to standard imaging modalities for staging patients with distant metastasis or restaging patients with locoregional recurrence or metastasis; as an adjunct to standard imaging modalities for monitoring for women with locally advanced and metastatic breast cancer when a change in therapy is contemplated.

Coverage for Myocardial Viability

FDG PET is covered for the determination of myocardial viability following an inconclusive single photon computed tomography test (SPECT) from July 1, 2001, through September 30, 2002. Only full ring scanners are covered as the scanning medium for this service from July 1, 2001 through December 31, 2001. However, as of January 1, 2002, full and partial ring scanners are covered for myocardial viability following an inconclusive SPECT.

Beginning October 1, 2002, Medicare will cover FDG PET for the determination of myocardial viability as a primary or initial diagnostic study prior to revascularization, and will continue to cover FDG PET when used as a follow-up to an inconclusive SPECT. However, if a patient received an FDG PET study with inconclusive results, a follow-up SPECT is not covered. FDA full and partial ring PET scanners are covered.

Limitations: In the event that a patient receives a SPECT with inconclusive results, a PET scan may be performed and covered by Medicare. However, a SPECT is not covered following an FDG PET with inconclusive results.

Documentation that these conditions are met should be maintained by the referring physician as part of the beneficiary's medical record.

Conditions and coverage guidelines for both conditions are summarized in the table on the next page.

Clinical Condition	Effective Date	Coverage
*Breast Cancer	October 1, 2002	As an adjunct to standard imaging modalities, staging distant metastasis or restaging patients with locoregional recurrence or metastasis; and as an adjunct to standard imaging modalities for monitoring response to treatment for locally advanced and metastatic disease to determine if therapy should be changed.
Myocardial Viability	July 1, 2001 to September 30, 2002	Covered only following inconclusive SPECT
Myocardial Viability	October 1, 2002	Primary or initial diagnosis prior to revascularization, or following an inconclusive SPECT.

* **NOTE:** For Breast Cancer, monitoring is allowed when a change in treatment is contemplated.

General Conditions of Coverage by Allowable Type of FDG PET Scanner

Covered Clinical Condition	Allowable Type of FDG PET System		
	Prior to July 1, 2001	July 1, 2001 through December 31, 2001	On or after January 1, 2002
Breast Cancer	Not covered	Not covered	Effective October 1, 2002, Full and partial ring
Myocardial Viability Primary or initial diagnosis prior to revascularization (Continued coverage following an inconclusive SPECT is also allowed)	Not covered	Not covered	Effective October 1, 2002, Full and partial ring

HCPCS Codes for Breast Cancer PET Scans Performed on or After October 1, 2002

- G0252 PET imaging, *full and partial-ring PET scanners only*, for initial diagnosis of breast cancer and/or surgical planning for breast cancer (e.g., initial staging of axillary lymph nodes), not covered by Medicare
Short Description: PET Imaging Initial dx
- G0253 PET imaging for Breast cancer, *full and partial-ring PET scanners only*, staging/restaging of local regional recurrence or distant metastases, i.e., Staging/restaging after or prior to course of treatment
Short Description: PET Image Brst Dection Recur
- G0254 PET imaging for Breast cancer, *full and partial-ring PET scanners only*, evaluation of response to treatment, performed during course of treatment
Short Description: PET Image Brst Eval to Tx

HCPCS Codes for Myocardial Viability PET Scans Performed on or After October 1, 2002

- G0230 (PET imaging; Metabolic assessment for myocardial viability following inconclusive SPECT study; full- and partial-ring PET scanners only) should continue to be billed following an inconclusive SPECT.
Short Description: PET myocard viability ring

78459 (Myocardial imaging, positron emission tomography (PET), metabolic evaluation) should be used for determination of myocardial viability as a primary or initial diagnostic study prior to revascularization.

Short Description: Heart muscle imaging (PET)

Billing Requirements

Claims for PET scan procedures must be billed on Form CMS-1450 (UB-92) or the electronic equivalent with the appropriate diagnosis HCPCS "G" codes to indicate the conditions under which a PET scan was done. These codes represent the technical component costs associated with these procedures when furnished to hospital outpatients, and are paid under the Outpatient Prospective Payment System.

Bill these codes under Revenue Code 404 (PET scan).

Applicable bill types include:

12X - Hospital, inpatient ancillary

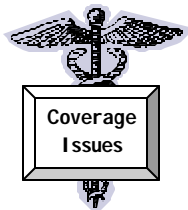
13X - Hospital, Outpatient

21X - SNF, inpatient

22X - SNF, inpatient ancillary

23X - SNF, Outpatient

85X - Critical Access Hospital



Section 50-57, Current Perception Threshold/Sensory Nerve Conduction Threshold Test (sNCT)

The Current Perception Threshold/Sensory Nerve Conduction Threshold (sNCT) test is a diagnostic test used to diagnose sensory neuropathies. The device is a noninvasive test that uses transcutaneous electrical stimuli to evoke a sensation. There is insufficient scientific or clinical evidence to consider this device as reasonable and necessary within the meaning of §1862(a)(1)(A) of the Social Security Act, and it will not be covered by Medicare. (Effective October 1, 2002)

A new code G0255 has been established for this test. The code descriptor is Current Perception Threshold/Sensory Nerve Conduction Threshold test (sNCT), per limb, any nerve (Not covered by Medicare).

The Current Perception Threshold/Sensory Nerve Conduction Threshold (sNCT) test is a diagnostic test used to diagnose sensory neuropathies. The device is a noninvasive test that uses transcutaneous electrical stimuli to evoke a sensation. There is insufficient scientific or clinical evidence to consider this device reasonable and necessary within the meaning of Section 1862(a)(1)(A) of the law, and it will **not** be covered by Medicare.

Perception Sensory Threshold/Nerve Conduction Threshold Test (sNCT)
(Billing Instructions from Program Memorandum AB-02-066)

Effective for dates of service **on or after October 1, 2002**, this test will not be covered by Medicare.

Billing/Claims Processing Instructions

Because Medicare has issued a national noncoverage decision for this service, existing local medical review policies for coverage of the Current Perception Sensory Nerve Conduction Threshold (sNCT) test are no longer valid.

Effective for dates of service **on or after October 1, 2002**, contractors will not pay for this test in any setting or under any code. HCPCS code G0255 applies for noncoverage:



Section 50-58, Single Photon Emission Tomography - Covered

This instruction implements the National Coverage Determinations (NCDs) for both PET scans for myocardial viability and PET scans for breast cancer under §1862 (a)(1)(A) of the Social Security Act. Section 50-56 regarding Single Photon Emission Computed Tomography has also been added as part of the determination regarding myocardial viability. (Effective October 1, 2002)

Single photon emission computed tomography (SPECT) acquires information on the concentration of radionuclides introduced into the patient's body. It is useful in the diagnosis of several clinical conditions including:

- stress fracture
- spondylosis
- infection (e.g., discitis)
- tumor (e.g., osteoid osteoma)
- analyze blood flow to an organ, as in the case of myocardial viability
- differentiate ischemic heart disease from dilated cardiomyopathy

Frequency limitations: Contractor discretion.

In the case of myocardial viability, FDG PET may be used following a SPECT that was found to be inconclusive. However, SPECT may not be used following an inconclusive FDG PET performed to evaluate myocardial viability.

There is no corresponding program memorandum with this topic.

June 2002 LMRP Updates

Allergy Immunotherapy AL001E03

Additions to "ICD-9-CM Diagnosis Codes That Support Medical Necessity":

- V14.0 Personal history of allergy to medicinal agents, penicillin
- V14.1 Personal history of allergy to medicinal agents, other antibiotic agent
- V14.2 Personal history of allergy to medicinal agents, sulfonamides
- V14.3 Personal history of allergy to medicinal agents, other anti-infective agent
- V14.4 Personal history of allergy to medicinal agents, anesthetic agent
- V14.7 Personal history of allergy to medicinal agents, serum or vaccine

Arthrocentesis, Aspiration and/or Injection of Joints, Bursa, or Ganglion Cyst SU001A01

Please note that the "ICD-9-CM Diagnosis Codes That Support Medical Necessity" section of this policy includes ICD-9-CM code 715.07 (Osteoarthritis of the foot and ankle) for CPT codes 20600 and 20605. ICD-9-CM code 715.07 is an invalid code and should not have been listed in the policy. Providers should utilize any of the other ICD-9-CM codes from those listed in the policy and based on the code that best describes the patient's condition.

Blood Counts LB007A06

The following were included in the “CPT/HCPCS” codes section:

- 85048 Blood count; white blood cell (WBC)
- 85590 Platelet; manual count
- 85595 Platelet; automated count

Noted in policy that the following codes may be used only as a secondary diagnosis when a more specific diagnosis code is used as a principal diagnosis.

- V72.81 Preoperative cardiovascular examination
- V72.82 Preoperative respiratory examination
- V72.83 Other specified preoperative examinations

Under “Documentation Requirements,” the following statement has been included:

ICD-9-CM codes V72.81, V72.82 and V72.83 may be used as a secondary diagnoses when a more specific principal diagnosis code is used. For example, a patient undergoing a preoperative respiratory examination prior to lung surgery due to lung cancer may require that the principal diagnosis is 162.2 (Malignant neoplasm of main bronchus) and the secondary diagnosis be V72.82 (Preoperative respiratory examination).

Breast Imaging: Mammography/Breast Echography (Sonography) Breast MRI Ductography RD001E02

Under section “ICD-9-CM Diagnosis Codes That Support Medical Necessity”:

- 793.8 Abnormal mammogram (**no longer valid as of 10/01/01**)

Please use the following:

- 793.80 Abnormal mammogram, unspecified
- 793.81 Mammographic microcalcification
- 793.89 Other abnormal findings on radiological examination of breast

Chloride LB009A01

Additions to “ICD-9-CM Diagnosis Codes That Support Medical Necessity”:

- 588.0 Renal Osteodystrophy
- 588.1 Nephrogenic diabetes insipidus
- 588.8 Other specified disorders resulting from impaired renal function
- 588.9 Unspecified disorder resulting from impaired renal function

Removed ICD-9-CM code 588 from section.

Computerized Axial Tomography (CT/CAT Scans) RD003E09

Under the “ICD-9-CM Diagnosis Codes That Support Medical Necessity” section of the policy for CPT codes **70450-70470 (Computerized axial tomography, head or brain)** the following code was terminated as of 09/30/2001:

- 772.1 Intraventricular hemorrhage

Please use the following ICD-9-CM codes:

- 772.10 Intraventricular hemorrhage unspecified grade
- 772.11 Intraventricular hemorrhage, Grade I
- 772.12 Intraventricular hemorrhage, Grade II
- 772.13 Intraventricular hemorrhage Grade III
- 772.14 Intraventricular hemorrhage, Grade IV

The following ICD-9-CM codes added to “ICD-9-CM Diagnosis Codes That Support Medical Necessity” section of the policy:

For 72192-72194 and 74150-74170 same day - (CT Scans of Abdomen/Pelvis on the Same Day)

- 599.7 Hematuria
- 789.1 Hepatomegaly

For CPT 76375 - Coronal sagittal, multiplanar, oblique, 3-Dimensional and/or holographic reconstruction of computerized tomography, magnetic resonance imaging, or other topographic modality

- 170.2 Malignant neoplasm of bone and articular cartilage, vertebral column, excluding sacrum and coccyx
- 170.6 ; pelvis bones, sacrum, and coccyx
- 170.7 ; long bones of lower limb
- 213.2 Benign neoplasm of bone and articular cartilage, vertebral column excluding sacrum and coccyx
- 213.6 ; pelvic bones, sacrum and coccyx
- 213.7 ; long bone of lower limb
- 721.0-721.91 Spondylosis and allied disorders
- 722.0-722.93 Intervertebral disc disorders
- 723.0-723.9 Other disorders of cervical region
- 724.00-724.9 Other and unspecified disorders of back
- 733.00-733.99 Other disorders of bone and cartilage
- 806.05-806.09 Fracture of vertebral column with spinal cord injury, cervical closed, C5-C7 level
- 806.15-806.19 Fracture of vertebral column with spinal cord injury, cervical, open, C5-C7 level
- 806.20-806.9 Fracture of vertebral column with spinal cord injury, dorsal (thoracic), closed or open, lumbar, closed or open, sacrum and coccyx, closed or open, or unspecified, closed or open
- 839.00-839.9 Other, multiple, and ill-defined dislocations

Hyperbaric Oxygen Therapy IM001A01

Correction of error in “ICD-9-CM Diagnosis Codes That Support Medical Necessity” section:

Should read 730.10-730.19 Chronic osteomyelitis

Incision and Drainage Services SU003A01

ICD-9-CM code 375.0 that is listed in the “ICD-9-CM Diagnosis Codes That Support Medical Necessity” should be listed as 375.00.

ICD-9-CM code 998.5 has become truncated. Please use the following:

- 998.51 Infected postoperative seroma
- 998.59 Other postoperative infection

Ultraviolet Light Therapy DM001A01

Clarification of statement under “Coding Guidelines.”

It should read as follows:

Use the appropriate CPT code with one of the ICD-9-CM codes listed under “ICD-9-CM Diagnosis Codes That Support Medical Necessity.”

MEDICARE LOCAL MEDICAL REVIEW POLICY

Contractor Policy Number: DR005A00
Contractor Name: Empire Medicare Services
Contractor Number: 00308
Contractor Type: Intermediary

LMRP Title: Cyclophosphamide (Cytosan)

AMA CPT Copyright Statement:

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CMS National Coverage Policy:

1. Title XVIII of the Social Security Act, Section 1862(a)(1)(A)
This section states that no Medicare payment shall be made for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury.
2. Title XVIII of the Social Security Act, Section 1833(e)
This section prohibits Medicare payment for any claim that lacks the necessary information to process the claim.
3. Medicare Carrier’s Manual, sections 2049, 2049.4C and 2050 outlines coverage for drugs and biologicals.

Primary Geographic Jurisdiction:

New York, Connecticut, Delaware, Massachusetts

CMS Region: 02

CMS Consortium: Northeast

Original Policy Effective Date: 07/01/2002

Original Policy Ending Date:

Revision Effective Date:

Revision Ending Date:

LMRP Description:

Cyclophosphamide is a nitrogen mustard-derivative that is used to treat several types of cancers, usually in combination with other antineoplastics. Cyclophosphamide has also been proven to be effective in nonmalignant diseases such as glomerulonephritis, Wegener’s granulomatosis, severe rheumatoid arthritis and systemic lupus erythematosus (SLE). The effect is related to its immunosuppressive properties. However, late-occurring toxicities such as, acute hemorrhage cystitis, transitional cell bladder carcinoma, and other bladder

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complications have been reported. The use of this drug in the treatment of nonmalignant conditions should be limited.	144.0-144.9*	Malignant neoplasm of floor of mouth
	145.0-145.9*	Malignant neoplasm of other unspecified parts of mouth
Indications and Limitations of Coverage and/or Medical Necessity:	146.0-146.9*	Malignant neoplasm of oropharynx
	147.0-147.9*	Malignant neoplasm of nasopharynx
	148.0-148.9*	Malignant neoplasm of hypopharynx
Indications	149.0*	Malignant neoplasm of pharynx, unspecified
Cyclophosphamide is covered for the indications listed in the "ICD-9-CM Codes That Support Medical Necessity" section of this policy.	149.1*	Malignant neoplasm of Waldeyer's ring
	149.8	Malignant neoplasm other sites
CPT/HCPCS Section & Benefit Category:	149.9	Malignant neoplasm of ill-defined sites
Drugs	153.0-153.9*	Malignant neoplasm of colon
	154.0-154.8*	Malignant neoplasm of rectum, rectosigmoid junction, and anus
Type of Bill Code:	157.0-157.9*	Malignant neoplasm of pancreas
13x Hospital Outpatient	160.0-160.9*	Malignant neoplasm of nasal cavities, middle ear, and accessory sinuses
22x SNF Inpatient Ancillary		
23x SNF Outpatient	162.0-162.9	Malignant neoplasm of trachea, bronchus, and lung
85x Critical Access Hospital	164.0	Malignant neoplasm of thymus
	170.0-170.9	Malignant neoplasm of bone and articular cartilage
Revenue Code(s):	171.0-171.9	Malignant neoplasm of connective and other soft tissue
0636 Drugs requiring detail coding	174.0-174.9	Malignant neoplasm of female breast
	175.0-175.9	Malignant neoplasm of male breast
CPT/HCPCS Code(s):	180.0-180.9	Malignant neoplasm of cervix uteri
J9070 Cyclophosphamide, [cytoxan], 100mg	182.0	Malignant neoplasm of corpus uteri, except isthmus
J9093 Cyclophosphamide, lyophilized, [lyophilized cytoxan], 100mg	182.1	Malignant neoplasm of isthmus
	182.8	Malignant neoplasm of other specified sites of body of uterus
ICD-9-CM Diagnosis Codes That Support Medical Necessity:	183.0	Malignant neoplasm of ovary
TRUNCATED DIAGNOSIS CODES ARE NOT ACCEPTABLE.	183.2	Malignant neoplasm of fallopian tube
ICD-9-CM code listings may cover a range and include truncated codes. It is the provider's responsibility to avoid truncated codes by selecting a code(s) carried out to the highest level of specificity and selected from the ICD-9-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.	183.3	Malignant neoplasm of broad ligament
	183.4	Malignant neoplasm of parametrium
It is not enough to link the procedure code to a correct, payable ICD-9-CM diagnosis code. The diagnosis or clinical suspicion must be present for the procedure to be paid.	183.5	Malignant neoplasm of round ligament
	183.8	Malignant neoplasm of other specified sites of uterine adnexa
140.0-140.9* Malignant neoplasm of lip	183.9	Malignant neoplasm of uterine adnexa, unspecified
141.0-141.9* Malignant neoplasm of tongue	185*	Malignant neoplasm of prostate
142.0-142.9* Malignant neoplasm of major salivary glands	186.0-186.9	Malignant neoplasm of testis
143.0-143.9* Malignant neoplasm of gum	188.0-188.9	Malignant neoplasm of bladder

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189.0*	Malignant neoplasm of kidney, except pelvis	446.29	Other specified hypersensitivity angiitis
189.1*	Malignant neoplasm of renal pelvis	446.3	Lethal midline granuloma
190.5	Malignant neoplasm of retina	446.4	Wegener's granulomatosis
191.0	Malignant neoplasm of cerebrum, except lobes and ventricles	446.5	Giant cell arteritis
		446.6	Thrombotic microangiopathy
194.0*	Malignant neoplasm of adrenal gland	446.7	Takayasu's disease
194.1*	Malignant neoplasm of parathyroid gland	447.6	Arteritis, unspecified
		581.0-581.9	Nephrotic syndrome
194.3*	Malignant neoplasm of pituitary gland and craniopharyngeal duct	710.0	Systemic lupus erythematosus
		710.1	Systemic sclerosis
194.4*	Malignant neoplasm of pineal gland	710.2	Sicca syndrome
194.5*	Malignant neoplasm of carotid body	710.3	Dermatomyositis
194.6*	Malignant neoplasm of aortic body and other paraganglia	710.4	Polymyositis
		710.5	Eosinophilia myalgia syndrome
194.8*	Malignant neoplasm of other [pluriglandular involvement NOS]	710.8	Other specified diffuse diseases of connective tissue
194.9*	Malignant neoplasm of endocrine gland, site unspecified	710.9	Unspecified diffuse connective tissue disease
200.00-200.88	Lymphosarcoma and reticulosarcoma	714.0	Rheumatoid arthritis
		714.1	Felty's syndrome
201.00-201.98	Hodgkin's disease	714.2	Other rheumatoid arthritis with visceral or systematic involvement
202.00-202.98	Other malignant neoplasms of lymphoid and histiocytic tissue	714.30	Polyarticular juvenile rheumatoid arthritis, chronic or unspecified
203.00	Multiple myeloma without mention of remission	714.31	Polyarticular juvenile rheumatoid arthritis, acute
203.01	Multiple myeloma with remission	714.33	Monoarticular juvenile rheumatoid arthritis
204.00-204.01	Acute lymphoid leukemia		
204.10-204.11	Chronic lymphoid leukemia		
205.00-205.01	Acute myeloid leukemia		
205.10-205.11	Chronic myeloid leukemia		
205.20-205.21	Myeloid leukemia, subacute		
205.30-205.31	Myeloid sarcoma		
205.80-205.81	Other myeloid leukemia		
205.90-205.91	Unspecified myeloid leukemia		
206.00-206.91	Monocytic leukemia, acute		
207.00-207.01	Acute erythremia and erythro leukemia		
236.1	Neoplasm of uncertain behavior of placenta		
283.0	Autoimmune hemolytic anemias		
287.3	Primary thrombocytopenia		
340	Multiple sclerosis		
356.4	Idiopathic progressive polyneuropathy		
357.9	Inflammatory/toxic neuropathy, unspecified		
446.0	Polyarteritis nodosa		
446.1	Mucocutaneous lymph node syndrome		
446.20	Hypersensitivity angiitis, unspecified		
446.21	Goodpasture's syndrome		

***Note:** There is evidence that treatment with Cyclophosphamide for these indications is no longer considered consistent with standards of chemotherapeutic medical practice.

Reasons for Denial:

1. A claim submitted without a valid ICD-9-CM diagnosis code will be returned as an incomplete claim under 1833(e).
2. A claim submitted without one of the ICD-9-CM diagnosis codes listed in the "ICD-9-CM Diagnosis Codes That Support Medical Necessity" section of this policy will be denied under 1862(a)(1)(A).
3. Claims submitted for an unusual frequency of any of these services or services ordered for a diagnosis not listed as covered in this policy will be denied as not medically necessary in the absence of supportive documentation in the patient's record.

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4. A claim for cyclophosphamide, submitted without the UPIN number of the referring/ordering physician or qualified non-physician practitioner, will be returned as an incomplete claim under 1833(e).
5. Claims submitted with diagnosis codes not listed above will be denied as not medically reasonable and necessary. The drug must be recognized in one of the established reference compendia, peer review professional journals, or scientific literature as being effective in the treatment for the type of cancer it has been prescribed.

Noncovered ICD-9-CM Code(s):

- Use of any ICD-9-CM diagnosis code not listed in the “ICD-9-CM Diagnosis Codes That Support Medical Necessity” section of this policy will be considered noncovered.

Coding Guidelines:

1. All claims billed to Medicare must contain an appropriate diagnosis code for each service, procedure or supply billed. All coding on the claim, i.e., ICD-9-CM, HCPCS, etc., must be accurate and specific for the service rendered to the beneficiary.
2. This policy does not take precedence over the Correct Coding Initiative (CCI), and CCI does not interfere with the Indications and Limitations within this policy.

Documentation Requirements:

1. Documentation supporting the medical necessity, such as ICD-9-CM diagnosis codes, must be submitted with each claim. Claims submitted without such evidence will be denied as not medically necessary.
2. Documentation must be available to Medicare upon request.
3. When a portion of the drug is discarded, the medical record must clearly document the amount administered and the amount wasted. This documentation must be available to the intermediary upon request.

Other Comments:

For services that exceed the accepted standard of medical practice and may be deemed not medically necessary, the provider/supplier must provide the patient with an acceptable advance notice of Medicare’s possible denial of payment. A waiver of liability should thus be signed when a provider/supplier does not want to accept the financial responsibility for the service.

Financial Responsibility:

Provider Liable

The provider of the service or the ordering physician must have notified the patient in writing, prior to the service, and obtained a signature verifying Advance Beneficiary Notice. Without prior notice, services denied as not medically necessary cannot be billed to the beneficiary. The provider is liable.

Beneficiary Liable

If there is clear evidence that the beneficiary was issued and signed a notice of noncoverage prior to the service, the liability rests with the beneficiary. The UB-92 Medicare bill should contain the condition code 20 and occurrence code 32, with date, to signify that notice of noncoverage was given to the beneficiary. Absence of these codes will result in a provider liable determination.

Sources of Information and Basis for Decision:

1. Copyright© 2001, Physicians’ Current Procedural Terminology, American Medical Association.
2. Copyright© 2000, International Classification of Diseases, 9th Revision, Clinical Modification, Medicode Inc.
3. Other Medicare Policies: Georgia
4. Ferri, F.F. Clinical Advisor, 2001 Edition, Mosby
5. Noble, J. Textbook of Primary Care Medicine, Third Edition, Mosby

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6. Compendia-Based Drug Bulletin, August 2001, Vol. 10, No. 3
7. Internal Medicine Archive, February 1998
8. Patient Care Archive, July 1, 1999
9. Drug Topics Archive, June 19, 2000

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 include representatives from all specialty societies and the Medical Society of the State of New York.

Start Date of Comment Period: 03/11/2002

End Date of Comment Period: 04/25/2002

Start Date of Notice Period: 06/01/2002

Revision History:

Revision Number	Effective Date	Reason for Revision

MEDICARE LOCAL MEDICAL REVIEW POLICY

Contractor Policy Number: RD003A00
Contractor Name : Empire Medicare Services
Contractor Number: 00308
Contractor Type: Intermediary

LMRP Title: Dialysis Shunt Maintenance

AMA CPT Copyright Statement:

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CMS National Coverage Policy:

- Title XVIII of the Social Security Act, Section 1862(a)(7)
This section excludes routine physical checkups and prohibits Medicare payment for routine screening services.
- Title XVIII of the Social Security Act, Section 1862(a)(1)(A)
This section states that no Medicare payment shall be made for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1833(e)
This section prohibits Medicare payment for any claim that lacks the necessary information to process the claim.
- Coverage Issue Manual, Section 50-32
This section allows for coverage for a (PTA) of Arteriovenous Dialysis Fistula and Grafts.

Primary Geographic Jurisdiction:

New York, Connecticut, Delaware, Massachusetts

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CMS Region: 02
CMS Consortium: Northeast

Policy Effective Date: 07/01/2002
Policy Ending Date:

Revision Effective Date:
Revision Ending Effective Date:

LMRP Description:

Arteriovenous fistula (cannula, shunt) declotting or interventions to restore and/or maintain functional patency may encompass a number of open surgical or percutaneous procedures. A fistula may either demonstrate compromised flow presaging occlusion, or it may have recently thrombosed. The objective is to restore appropriate flow, preserve the fistula's functional integrity, and avoid the need to create a new fistula.

Definitions:

1. **Arteriovenous (AV) fistula:** An abnormal communication between an artery and a vein; in this instance, a surgically created communication to facilitate chronic hemodialysis. The interposed conduit may be autogenous vessel or synthetic material. (Brescia-Cimino, polytetrafluoroethylene [PEFE], straight or loop, etc.)
2. **Percutaneous Transluminal Angioplasty (PTA):** An invasive procedure which, when successful, culminates in the enlargement of a vascular lumen. Typically, a balloon-tipped catheter is introduced into the stenosed vessel. Inflation of the balloon at the site of vascular narrowing can result in sustained luminal enlargement.
3. **Thrombolysis:** Pharmacologic and/or mechanical dissolution of a thrombus or blood clot.
4. **Infusion:** Continuous intravenous administration of a medication containing solution lasting longer than thirty (30) minutes. Bolus injections are not considered infusions, regardless of the time required to inject the solution.
5. **Shunt:** An arteriovenous conduit.

Percutaneous interventions to enhance or reestablish patency of a hemodialysis AV fistula have proven useful in extending the life of the fistula, reducing the need for open repair, reconstruction or replacement. The longevity and quality of life of the ESRD patient are positively impacted.

Percutaneous AV fistula declotting, maintenance or reestablishment of appropriate and adequate flow may encompass the following procedures:

- Access by introduction of either needle or vascular sheath into the AV shunt (e.g., 36145).
- Mechanical and/or pharmacologic maneuvers to promote dissolution, fragmentation and/or removal of obstructing thrombotic materials (e.g., 36860, 36861).
- PTA may be necessary if, after removal of thrombotic material, flow remains inadequate and examination and/or angiography demonstrates residual, hemodynamically significant, impediment to flow that is caused by other than thrombotic material. Residual hemodynamically significant flow impairment may be demonstrated with the AV fistula, at either anastomotic junction or more remotely in the artery or vein providing the fistula's inflow and outflow (e.g., 35475, 35476).
- Therapeutically directed angiography (e.g., 75710, 75790). These need not all be performed on every dysfunctional shunt. Each may, under unique circumstances, be considered reasonable and medically necessary (Social Security Act, Section 1862.a.1.A).

Open surgical therapy for thrombosed dialysis cannula or hemodynamically significant flow impediment utilizes direct access to the conduit and contiguous vessels. Mechanical fragmentation and surgical removal of occlusive thrombotic material is effected under direct visualization. Adjunctive thrombolytic pharmacotherapy may be employed. Residual vascular stenoses or obstructive lesions are removed and corrected using standard vascular surgical techniques (e.g., 36832, 36834). Angiography is adjunctively employed, when appropriate and medically necessary, to assess the functional integrity of afferent and efferent vessels remote from the surgical field.

Indications and Limitations of Coverage and/or Medical Necessity:

Indications

1. Typically, the clinical examination provides adequate information to determine whether there is hemodynamically significant dialysis shunt dysfunction. The following clinical findings are considered diagnostically specific and appropriate

indications to initiate therapies to reestablish physiologically appropriate flow in the dialysis fistula.

- a. Venous outflow impediment:
 - i. elevated venous pressure in the graft
 - ii. elevated venous/arterial ratio (above 40%)
 - iii. prolonged bleeding following needle removal
 - iv. inefficient dialysis
 - v. recirculation percentage greater than 10-15%
 - vi. development of pseudoaneurysms
 - vii. swelling of extremity
 - viii. large collateral venous channels
 - ix. loss of “machine-like” bruit, i.e., short shard bruit
 - x. abnormal physical findings, specifically pulsatile graft or loss of thrill
- b. Arterial inflow impediment:
 - i. low pressure in graft even when outflow is manually occluded
 - ii. ischemic changes of the extremity (steal syndrome)
 - iii. diminished intra-access flow

2. PTA of the dialysis conduit and/or afferent and efferent vessels is not necessary in all shunt dysfunction situations. Coverage will be considered if there is documentation supporting the presence of residual, hemodynamically significant flow restriction after any previous interventions. There must be clear documentation of the site and extent of any hemodynamically significant stenosis. This documentation may be subjected to medical necessity review.

3. Subject to FDA approval of specific devices, stents are covered if used as a last resort to salvage a graft or fistula. Placement of an intra-vascular stent (e.g., 37205-37206) and the associated supervision and interpretation (75960) may be appropriated in selected clinical scenarios. The following clinical scenarios are examples where a stent may be considered for payment:

- Failure of percutaneous transluminal angioplasty (PTA) of central veins (two failed procedures in a three month period),
- There is a PTA induced rupture,
- For graft salvage,
- For central veins stenosis or occlusion,

- Surgical revision is not a viable option,
- There is contraindication to surgery,
- There are limited residual access sites,
- There are surgically inaccessible lesions.

Stents used under experimental protocols are not covered unless used within the Category B Device protocol.

Limitations

1. The dispersing, maceration, and removal of thrombotic material are an integral part of cannula/shunt/fistula declotting or revision (36860, 36861, 36831, 36832, 36833 and 36870). It is not to be interpreted or coded as thrombectomy.
2. Intermittent boluses of anticoagulant or thrombolytic agents are integral to and included in the percutaneous thrombectomy of a dialysis access (36870) and are not separately coded. However, if thrombus is present outside the graft and requires thrombolytic therapy (e.g., thrombus is extending into the central veins or embolized into a distal artery), this portion of the procedure would be separately coded using 37201 and 75896 plus the appropriate catheterization code(s). This therapy typically involves additional selection of the vessel involved, negotiation of an infusion catheter into the thrombus and prolonged infusion of drug to dissolve the clot.
3. In the absence of clinical findings suggesting the need to reestablish appropriate flow in a dialysis fistula, it is seldom reasonable and necessary to perform diagnostic angiography or sonographic confirmatory studies as part of the decision to treat (i.e., 75710, 75790, 75820, 93990). When diagnostic noninvasive vascular studies are performed to evaluate an AV Shunt on a routine basis in the absence of signs and symptoms, the services are considered monitoring, and are not covered separately by Medicare. These procedures are reasonable and necessary in the presence of signs and symptoms of impending failure of the access sites and when the result may impact the clinical course of the patient.
4. Noncovered conditions:
 - a. Total occlusion of graft due to thrombus of more than one year in duration (for percutaneous interventions).

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- b. Medical records (e.g., procedure report) that do not verify that the services described by the submitted CPT codes were provided and/or medically necessary.
 - c. Services that are screening examinations (that are not providing clinically relevant information).
 - d. The placement of stent(s) in a vessel(s) for which there has been no objective symptoms or limitations of function is considered to be preventive, and therefore not covered by Medicare.
5. Declotting of shunts in a dialysis setting is included in the composite rate.
6. Declotting of shunts is separately reimbursed if the documentation indicates the following:
- a. That the patient's shunt is compromised and causing severe symptoms such as pain; and
 - b. The situation is such that without immediate intervention, the patient may experience:
 1. Serious impairment of bodily functions;
 2. Serious dysfunction of any organ; and
 3. Increased morbidity and mortality.

*The above conditions must be clearly documented in the medical records in order for the shunt declotting to be considered reasonable and necessary.

CPT/HCPCS Section & Benefit Category:
Surgery, Cardiovascular System; Radiology

Type of Bill:

- 13x Hospital Outpatient
- 72x Renal Dialysis Center (ESRD) (See Coding Guidelines #8)
- 85x Critical Access Hospital

Revenue Code(s):

- 032x Radiology-Diagnostic
- 033x Radiology Therapeutic
- 036x Operating Room
- 045x Emergency Room
- 049x Ambulatory Surgery

CPT/HCPCS Codes:Ó

- 35473 Transluminal balloon angioplasty percutaneous, iliac
- 35474 ; femoral-popliteal

- 35475 Transluminal balloon angioplasty, percutaneous; brachiocephalic trunk or branches, each vessel
- 35476 Transluminal balloon angioplasty, percutaneous; venous
- 35903 Excision of infected graft, extremity
- 36005 Injection procedure for contrast venography (including introduction of needle or intracatheter)
- 36010 Introduction of catheter, superior or inferior vena-cava
- 36120 Introduction of needle or intracatheter; retrograde brachial artery
- 36140 Introduction of needle or intracatheter; extremity artery
- 36145 Introduction of needle or intracatheter; arteriovenous shunt created for dialysis (cannula, fistula, or graft)
- 36215 Selective catheter placement arterial system; each first order thoracic or brachiocephalic branch, within a vascular family
- 36216 ; initial second order thoracic or brachiocephalic branch, within a vascular family
- 36217 Selective catheter placement, arterial system; initial third order or more selective thoracic or brachiocephalic branch, within a vascular family
- 36218 ; additional second order, third order, and beyond, thoracic or brachiocephalic branch, within a vascular family
- 36245 Selective catheter placement, arterial system; each first order abdominal, pelvic, or lower extremity artery branch, within a vascular family
- 36246 ; initial second order abdominal, pelvic, or lower extremity artery branch, with a vascular family
- 36247 ; initial third order or more selective abdominal, pelvic or lower extremity artery branch, within a vascular family
- 36831 Thrombectomy, open, arteriovenous fistula without revision, autogenous or nonautogenous dialysis graft (separate procedure)
- 36832 Revision, arteriovenous fistula; without thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure)
- 36833 Revision, arteriovenous fistula; with thrombectomy, autogenous or nonautogenous dialysis graft (separate procedure)

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36834 Plastic repair of arteriovenous aneurysm (separate procedure)

36860 External cannula declotting (separate procedure); without balloon catheter

36861 External cannula declotting (separate procedure); with balloon catheter

36870 Thrombectomy, percutaneous, arteriovenous fistula, autogenous or nonautogenous graft (includes mechanical thrombus extraction and intra-graft thrombolysis)

37201 Transcatheter therapy, infusion for thrombolysis other than coronary

37205 Transcatheter placement of an intravascular stent(s), (non-coronary) vessel, percutaneous; initial vessel

37206 Transcatheter placement of an intravascular stent(s), (non-coronary) vessel, percutaneous; each additional vessel

75710 Angiography, extremity, unilateral, radiological supervision and interpretation

75790 Angiography, arteriovenous shunt (e.g., dialysis patient) radiological supervision and interpretation

75820 Venography, extremity, unilateral, radiological supervision and interpretation

75822 Venography, extremity, bilateral, radiological supervision and interpretation

75825 Venography, caval, inferior, with serialography, radiological supervision and interpretation

75827 Venography, caval, superior, with serialography, radiological supervision

75896 Transcatheter therapy, infusion, any method (e.g., thrombolysis other than coronary), radiological supervision and interpretation

75960 Transcatheter introduction of intravascular stent(s), (non-coronary vessel), percutaneous and/or open, radiological supervision and interpretation, each vessel

75962 Transluminal balloon angioplasty, peripheral artery, radiological supervision and interpretation

75964 Transluminal balloon angioplasty, each additional peripheral artery, radiological supervision and interpretation

75978 Transluminal balloon angioplasty, venous (e.g., subclavian stenosis), radiological supervision and interpretation

90939 Hemodialysis access flow study to determine blood flow in grafts and arteriovenous fistula by an indicator dilution method, hook up;

93990 Duplex scan of hemodialysis access (including arterial inflow, body of access and venous outflow)

J0350 Injection, antistreptase, per 30 units

J2993 Injection, reteplase, 18.1 mg

J2997 Injection, alteplase recombinant, per 1 mg

ICD-9-CM Diagnosis Codes That Support Medical Necessity:

TRUNCATED DIAGNOSIS CODES ARE NOT ACCEPTABLE.

ICD-9-CM code listings may cover a range and include truncated codes. It is the provider's responsibility to avoid truncated codes by selecting a code(s) carried out to the highest level of specificity and selected from the ICD-9-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

It is not enough to link the procedure code to a correct, payable ICD-9-CM diagnosis code. The diagnosis or clinical suspicion must be present for the procedure to be paid.

440.31	Atherosclerosis, of autologous vein bypass graft
440.32	Atherosclerosis, nonautologous biological bypass graft
442.0	Aneurysm, upper extremity artery
442.3	Aneurysm, lower extremity
444.21-444.22	Thrombus/embolus, upper/lower extremity artery
447.1	Stricture of artery
451.82	Phlebitis of superficial veins-upper extremities
453.8	Thrombus/embolus, specified vein
459.2	Compression of vein
729.81	Swelling of limb
996.1	Mechanical complications of other vascular device, implant, and graft
996.62	Infection and inflammatory reaction due to internal prosthetic device, implant and graft
*996.73	Mechanical complications due to renal dialysis implant and graft

* The appropriate code that describes a malfunctioning dialysis shunt is 996.73 that should be used with the secondary diagnosis 585 (chronic renal failure).

Reasons for Denial:

1. A claim submitted without a valid ICD-9-CM diagnosis code will be returned as an incomplete claim under 1833(e).
2. A claim submitted without one of the ICD-9-CM diagnosis codes listed in the “ICD-9-CM Diagnosis Codes That Support Medical Necessity” section of this policy will be denied under 1862(a)(1)(A).
3. Claims submitted for an unusual frequency of any of these services or services ordered for a diagnosis not listed as covered in this policy will be denied as not medically necessary in the absence of supportive documentation in the patient’s record.
4. Section 1821(a)(7) of the Social Security Act does not extend Medicare coverage for screening procedures.
5. Placement of a stent (CPT codes 37205-37206) and the associated radiological supervision and interpretation service (CPT code 75960) in an A-V shunt when there are no objective symptoms or limitation or function are considered preventative and therefore not covered.
6. If a particular stent device is FDA approved, but is not used as a means of salvaging angiographic induced rupture, the placement of the stent (CPT codes 37205-37206) and the associated radiological supervision and interpretation service (CPT code 75960) are not covered.
7. Use of a particular device that is not FDA approved will be denied as investigational.
8. Services performed with excessive frequency will be denied as not medically necessary. Frequency is considered excessive when services are performed more frequently than generally accepted by peers and reasons for additional services are not justified by documentation.
9. Services performed for percutaneous interventions to treat total occlusion of graft due to thrombus of more than one year in duration will be denied as not reasonable and medically necessary.
10. Services that are not supported by the patient’s medical record (e.g., procedure report) will be denied.
11. Angioplasty of vessels not documented to be significantly stenosed by angiography or ultrasound will be denied.
12. Dilatation of both limbs of the fistula will be denied unless significant obstruction is documented in both limbs.
13. Dilation of the graft anastomotic site will be considered either arterial or venous but not both.
14. Procedure codes 35475 and 35476 performed on the same day will be denied without documentation of anatomically separate lesions. Code 35475 may be reported for angioplasty of an inflow lesion that is proximal to the graft while 35476 may be reported for PTA of the venous anastomosis and/or venous outflow. 35475 and 35476 should not be reported on the same day for the graft alone since it is considered a single vessel for the purposes of this policy.

Noncovered ICD-9-CM Code(s):

- Use of any ICD-9-CM diagnosis code not listed in the “ICD-9-CM Diagnosis Codes That Support Medical Necessity” section of this policy will be denied.
- Use of ICD-9-CM diagnosis code V82.9 (Special screening of other conditions, unspecified condition) will result in the denial of claims as noncovered screening services.

Coding Guidelines:

1. Claims reporting maintenance of malfunctioning dialysis shunts for patients with end stage renal disease (ESRD) should be coded with the appropriate CPT code(s) and ICD-9-CM code 996.73 (and not 585).
2. CPT 37201 may only be used for infusions as defined in the policy.
3. Code 35475 may be reported for angioplasty of an inflow lesion that is proximal to the graft while 35476 may be reported for PTA of the venous anastomosis and/or venous outflow. 35475 and 35476 should not be reported on the same day for the graft alone since it is considered a single vessel for the purposes of this policy.
4. Intermittent boluses of anticoagulant or thrombolytic agents are integral to and included with percutaneous

thrombectomy of a dialysis access (36870) and are not separately coded. However, if a thrombus is present outside the graft and requires separately identifiable thrombolytic therapy, this portion of the procedure would be separately coded using 37201 and 75896 plus the appropriate catheterization code(s). This therapy typically involves selection of the vessel, negotiation of an infusion catheter into the thrombus and prolonged infusion of the drug to dissolve the clot.

5. Procedure codes 36831, 36832 and 36833 are open procedures and should not be reported when percutaneous procedures are performed.
6. The Correct Coding Initiative (CCI) precludes the billing of the following combination of codes on the same date of service:
 - 35476 same day as 36860 or 36861
 - 36005 same day as 36145
 - 36120 same day as 36215
 - 36215 same day as 36140
 - 36216 same day as 36140 or 36215
 - 37217 same day as 36140, 36215 or 36216
 - 36246 same day as 36140
 - 36247 same day as 36140, 36245 or 36246
 - 36831 same day as 36145 or 36870
 - 36831 same day as 36832, 36833 or 36834
 - 36832 same day as 36870
 - 36832 same day as 36833 or 36834
 - 36833 same day as 36870
 - 36834 same day as 36833
 - 36860 same day as 36145
 - 36860 same day as 36831, 36832, 36833, or 36834
 - 36861 same day as 36145
 - 36861 same day as 36831, 36832, 36833, 36834 or 36870
 - 36870 same day as 36140 or 37210
 - 36870 same day as 36834
 - 37201 same day as 37205
 - 37205 same day as 36831, 36832, 36833, 36860 or 36861
 - 75822 same day as 75820
7. The following add-on codes must be reported in conjunction with the primary codes:
 - Procedure code 37206 must be used in conjunction with procedure code 37205.
 - Procedure code 75964 must be used in conjunction with procedure code 75962.
 - Procedure code 36218 must be used in conjunction with procedure code 36217.
 - Procedure code 36248 must be used in conjunction with procedure code 36246 or 36247.
8. Modifier LT or RT must accompany the appropriate CPT codes.

Documentation Requirements:

1. Documentation supporting the medical necessity, such as ICD-9-CM diagnosis codes, must be submitted with each claim. Claims submitted without such evidence will be denied as not medically necessary.
2. Angiographic/ultrasound report studies may be required to document the need for angioplasty of arterial and venous vessels at the same setting.
3. The operative report must document the services reported.
4. Documentation must be available to Medicare upon request.

Other Comments:

- For services that exceed the accepted standard of medical practice and may be deemed not medically necessary, the provider/supplier must provide the patient with an acceptable advance notice of Medicare's possible denial of payment. A waiver of liability should thus be signed when a provider/supplier does not want to accept the financial responsibility for the service.
- Reason for the creation of this policy:
To provide and clarify the availability of services to beneficiaries in view of recent coding changes, and to address the high volumes of renal angioplasties for ESRD patients.

Financial Responsibility:

Provider Liable

The provider of the service or the ordering physician must have notified the patient in writing, prior to the service, and obtained a signature verifying Advance Beneficiary Notice. Without prior notice, services denied as not medically necessary cannot be billed to the beneficiary. The provider is liable.

Beneficiary Liable

If there is clear evidence that the beneficiary was issued and signed a notice of noncoverage prior to the service, the liability rests with the beneficiary. The UB-92 Medicare bill should contain the condition code 20 and occurrence code 32, with date, to signify that notice of noncoverage was given to the beneficiary. Absence of these codes will result in a provider liable determination.

Sources of Information and Basis for Decision:

1. Other Carriers' policies:
 - Nationwide (Ohio), policy number SURGCV-002, effective May 1, 1999
 - Noridian (ND, SD, CO, WY, IA), policy number 98.26, effective July 1, 1999
 - Upstate Medicare (Upstate NY), policy number S-97-4, effective October 1, 1998
 - Group Health Incorporated, (Queens County, New York), policy number SUR-1188, effective January 31, 1998
2. "Standard of Practice, Quality Improvement Guidelines for Percutaneous Management of the Thrombosed or Dysfunctional Dialysis Access," The Society of Cardiovascular & Interventional Radiology as reported in *JVIR*, April 1999. <http://www.scvir.org/clinical>
3. "Percutaneous Intervention to Support Failing Hemodialysis Fistulas and Grafts," *Kidney Blood Press Res* 1997; 20:145-47 by Dierk Vorwerk, MD.
4. "Percutaneous Intervention for Permanent Hemodialysis Access: A Review," by Richard Gray, MD, *SCVIR*, May-June 1997
5. "Reporting Standards for Percutaneous Intervention in Dialysis Access," special communication by R.J. Gray, MD, D. Sacks, MD, L.G. Martin, MD, and the member of Technology Assessment Committee, November-December 1999 *JVIR*.
6. "Intervention Based on Monthly Monitoring Decreases Hemodialysis Access Thrombosis," Jeffrey J. Sands, Patti A Jabyac, Carol L Miranda and Brian Kapsick, *ASAIO Journal* 1999; 45:147-150.
7. "Patency of Wallstents Placed Across the Venous Anastomosis of Hemodialysis Grafts after Percutaneous Recanalization," by R. Patel, MD, S. Peck, MD, S. Cooper, MD, D. Epstein, MD, C.T. Sofocleous, MD, I Schur, MD, A. Falk, MD, November 1998.
8. "Treatment of Hemodialysis-Related Central Venous Stenosis or Occlusion: Results of Primary Wallstent Placement and Follow-up in 50 patients," by P. Haage, MD, D. Vorwerk, MD, W. Piroth, MD, K. Schuermann, MD, R. Guenther, MD, July 1999.
9. "Endovascular Stent Placement for Angioplasty-Induced Venous Rupture Related to the Treatment of Hemodialysis Grafts," by A. Welber, MD, MS, I. Schur, MD, C. Sofocleous, MD, S. Cooper, MD, S. Peack, MD, *SCVIR* 1999.

10. "Surgical Care of the Arteriovenous Graft: Issues for the Interventionalist," by Gary A. Gelfish, MD, FACS, *Techniques in Vascular and Interventional Radiology*, Vol. 2, No. 4, (December), 1999: pages 179-185.
11. "Assessing the Adequacy of Vascular Access and Its Relationship to Patient Outcome," by Steve J. Schwab, MD in *American Journal of Kidney Diseases*, Vol. 24, No. 2 (August), 1994: pages 316-320.

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 include representatives from all specialty societies and the Medical Society of the State of New York.

Start Date of Comment Period: 03/11/2002

Ending Date of Comment Period: 04/25/2002

Start Date of Notice Period: 06/01/2002

Revision History:

Revision Number	Effective Date	Reason for Revision

MEDICARE LOCAL MEDICAL REVIEW POLICY

Contractor Policy Number: LB008A00

Contractor Name: Empire Medicare Services

Contractor Number: 00308

Contractor Type: Intermediary

LMRP Title: Magnesium (Serum)

AMA CPT Copyright Statement:

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CMS National Coverage Policy:

1. Title XVIII of the Social Security Act, Section 1862(a)(7)
This section excludes routine physical checkups and prohibits Medicare payment for routine screening services.
2. Title XVIII of the Social Security Act, Section 1862(a)(1)(A)
This section states that no Medicare payment shall be made for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury.
3. Title XVIII of the Social Security Act, Section 1833(e)
This section prohibits Medicare payment for any claim that lacks the necessary information to process the claim.
4. Medicare Intermediary Manual, Section 3171.2
5. Renal Dialysis Facility Manual, Sections 240.3 and 318.1

Primary Geographic Jurisdiction:

New York, Connecticut, Delaware, Massachusetts

CMS Region: 02
CMS Consortium: Northeast

Policy Effective Date: 07/01/2002
Policy Ending Date:

Revision Effective Date:
Revision Ending Effective Date:

LMRP Description:

Magnesium (Mg) is an essential cofactor for many different enzymatic reactions involved in the transfer of high-energy phosphate groups from Adenosine Triphosphate (ATP). Mg is the fourth most abundant cation in the body. About 50 percent is sequestered in bone and is not readily exchangeable with other compartments. Approximately one percent is in the extracellular fluid, and the rest is found in the intracellular compartment.

The serum concentration is approximately 1.7-2.6 mg/dl. Mg deficiency is a common problem caused primarily by renal or gastrointestinal losses and a decrease in intestinal magnesium absorption. Drugs associated with low levels of Mg include diuretics, aminoglycosides, cisplatin, cyclosporine A and amphotericin B.

Hypermagnesemia is most commonly caused by renal failure and can be worsened by the use of Mg-containing antacids. Other causes of this condition include untreated ketoacidosis, volume depletion and Lithium intake.

Indications and Limitations of Coverage and/or Medical Necessity:

Indications

Serum Mg levels may be medically necessary for the following conditions:

1. When there are signs or symptoms of hypomagnesemia which include weakness, muscle cramping, irritability, tetany, delirium, anorexia, nausea, vomiting and/or electrocardiographic changes. Conditions which may produce these signs and symptoms include, but are not limited to:
 - cardiac arrhythmias
 - malabsorption syndromes
 - alcoholism

- chronic diarrhea
- parenteral alimentation with inadequate Mg content
- diabetic ketoacidosis
- diuretic therapy
- hyperaldosteronism
- hyperthyroidism
- hypoparathyroidism
- chronic renal failure
- prolonged I.V. therapy
- prolonged nasogastric suction
- cis-platinum therapy
- aminoglycoside toxicity
- amphotericin toxicity

2. When there are signs or symptoms of hypermagnesemia, which may include muscle weakness, confusion, hypotension, respiratory muscle paralysis, or cardiac arrest. Conditions which may produce these signs and symptoms include but are not limited to:
 - adrenal insufficiency
 - renal insufficiency
 - ingestion of drugs containing Mg (ex., antacids and laxatives)
 - rhabdomyolysis

Policy Type:

Local medical necessity policy
Local coding instructions

CPT/HCPCS Section & Benefit Category:

Pathology and Laboratory

Type of Bill:

- 12x Hospital Inpatient Ancillary
- 13x Hospital Outpatient
- 14x Hospital Referred Diagnostic Services
- 22x SNF Inpatient Ancillary
- 23x SNF Outpatient
- 72x Renal Dialysis Center (ESRD)
- 85x Critical Access Hospital

Revenue Code(s):

- 030x Laboratory Clinical Diagnostic
- 031x Laboratory Pathology

CPT/HCPCS Code(s):

83735 Magnesium

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ICD-9-CM Diagnosis Codes That Support Medical Necessity:	070.51	Acute or unspecified hepatitis C without mention of hepatic coma
TRUNCATED DIAGNOSIS CODES ARE NOT ACCEPTABLE.	070.52	Hepatitis delta without mention of active hepatitis B disease or hepatic coma
ICD-9-CM code listings may cover a range and include truncated codes. It is the provider's responsibility to avoid truncated codes by selecting a code(s) carried out to the highest level of specificity and selected from the ICD-9-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.	070.53	Hepatitis E without mention of hepatic coma
	070.54	Chronic hepatitis C without mention of hepatic coma
	070.59	Other specified viral hepatitis without mention of hepatic coma
	070.6	Unspecified viral hepatitis with hepatic coma
It is not enough to link the procedure code to a correct, payable ICD-9-CM diagnosis code. The diagnosis or clinical suspicion must be present for the procedure to be paid.	070.9	Unspecified viral hepatitis without mention of hepatic coma
	153.0-153.9	Malignant neoplasm of colon
	242.00-242.91	Thyrotoxicosis, with or without goiter
008.45 Intestinal infection due to clostridium difficile	243	Congenital hypothyroidism
040.2 Whipple's disease	244.0-244.9	Acquired hypothyroidism
070.0 Viral hepatitis A with hepatic coma	250.00	Diabetes mellitus without mention of complication
070.1 Viral hepatitis A without mention of hepatic coma	250.10-250.13	Diabetes with ketoacidosis
070.20 Viral hepatitis B acute or unspecified without mention of hepatic delta	250.20-250.23	Diabetes with hyperosmolarity
070.21 Viral hepatitis B with hepatic coma or unspecified, with hepatitis delta	250.30-250.33	Diabetes with other coma
070.22 Viral hepatitis B chronic, without mention of hepatitis delta	250.40-250.43	Diabetes with renal manifestations
070.23 Viral hepatitis B with hepatic coma, chronic with hepatitis delta	250.50-250.53	Diabetes with ophthalmic manifestations
070.30 Viral hepatitis B without mention of hepatic coma acute or unspecified, without mention of hepatitis delta	250.60-250.63	Diabetes with neurological manifestations
070.31 Viral hepatitis B without mention of hepatic coma with hepatitis delta	250.70-250.73	Diabetes with peripheral circulatory disorders
070.32 Viral hepatitis B without mention of hepatic coma chronic, without mention of hepatitis delta	250.80-250.83	Diabetes with other specified manifestations
070.33 Viral hepatitis B without mention of hepatic coma chronic, with hepatitis delta	250.90-250.93	Diabetes with unspecified complication
070.41 Acute or unspecified hepatitis C with hepatic coma	252.0	Hyperparathyroidism
070.42 Hepatitis delta without mention of active hepatitis B disease with hepatic coma	252.1	Hypoparathyroidism
070.43 Hepatitis E with hepatic coma	252.8	Other specified disorders of parathyroid gland
070.44 Chronic hepatitis C with hepatic coma	252.9	Unspecified disorder of parathyroid gland
070.49 Other specified viral hepatitis with hepatic coma	253.6	Other disorders of neurohypophysis (syndrome of inappropriate antidiuretic hormone [SIADH])
	255.1	Hyperaldosteronism
	255.4	Corticoadrenal insufficiency
	259.3	Ectopic hormone secretion, not elsewhere classified
	260	Kwashiorkor

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261	Nutritional marasmus	359.8	Other myopathies
262	Other severe protein-calorie malnutrition	359.9	Myopathy, unspecified
263.0	Malnutrition of moderate degree	402.00	Malignant hypertensive heart disease without congestive heart failure
263.1	Malnutrition of mild degree		
263.8	Other protein-calorie malnutrition	402.01	Malignant hypertensive heart disease with congestive heart failure
263.9	Unspecified protein-calorie malnutrition	402.10	Benign hypertensive heart disease without congestive heart failure
272.0	Pure hypercholesterolemia		
272.1	Pure hyperglyceridemia	402.11	Benign hypertensive heart disease with congestive heart failure
272.2	Mixed hyperlipidemia		
275.2	Disorders of magnesium metabolism	402.90	Hypertensive heart disease unspecified
275.40	Unspecified disorder of calcium metabolism	402.91	Hypertensive heart disease with congestive heart failure
275.41	Hypocalcemia		
275.42	Hypercalcemia	403.00	Malignant hypertensive renal disease without mention of renal failure
275.49	Other disorders of calcium metabolism		
276.2	Acidosis	403.01	Malignant hypertensive renal disease with renal failure
276.4	Mixed acid-base balance disorder		
276.5	Volume depletion	403.10	Benign hypertensive renal disease
276.7	Hyperpotassemia	403.11	Benign hypertensive renal disease with renal failure
276.8	Hypopotassemia		
276.9	Electrolyte and fluid disorders not elsewhere classified	403.90	Unspecified hypertensive renal disease without mention of renal failure
277.1	Disorders of porphyrin metabolism		
278.8	Other specified disorders of metabolism	404.00	Hypertensive heart and renal disease without mention of congestive heart failure or renal failure
286.9	Other and unspecified coagulation defects	404.01	Hypertensive heart and renal disease with congestive heart failure
289.59	Other diseases of spleen		
293.0-293.1	Transient acute and subacute delirium	404.02	Hypertensive heart and renal disease with renal failure
298.9	Unspecified psychosis	404.03	Hypertensive heart and renal disease with congestive heart failure and renal failure
303.00-303.93	Alcohol dependence syndrome		
305.00-305.03	Alcohol abuse		
305.90-305.93	Other mixed or unspecified drug abuse	404.10	Benign hypertensive heart and renal disease
307.1	Anorexia nervosa		
307.20	Tic disorder, unspecified	404.11	Benign hypertensive heart and renal disease with congestive heart failure
307.22	Chronic motor tic disorder		
307.50	Eating disorder, unspecified	404.12	Benign hypertensive heart and renal disease with renal failure
307.51	Bulimia		
307.52	Pica	404.90	Unspecified hypertensive heart and renal disease without mention of congestive heart failure or renal failure
307.59	Other disorders of eating		
331.3	Communicating hydrocephalus		
333.2	Myoclonus	410.00	Acute myocardial infarction anterolateral, unspecified
333.3	Tics of organic origin		
336.1	Vascular myelopathies	410.01	Acute myocardial infarction anterolateral, initial
345.60-345.61	Infantile spasms		
359.5	Myopathy in endocrine diseases classified elsewhere	410.02	Acute myocardial infarction anterolateral, subsequent

410.10	Acute myocardial infarction anterior wall, unspecified	424.0	Mitral valve disorders
		426.0	Atrioventricular block, complete
410.11	Acute myocardial infarction anterior wall, initial	426.10	Atrioventricular block, unspecified
		426.11	First degree atrioventricular block
410.12	Acute myocardial infarction anterior wall, subsequent	426.12	Mobitz (type) II atrioventricular block
		426.13	Other second degree atrioventricular block
410.20	Acute myocardial infarction inferolateral, unspecified	426.2	Left bundle branch hemiblock
410.21	Acute myocardial infarction inferolateral, initial	426.3	Other left bundle branch block
		426.4	Right bundle branch block
410.22	Acute myocardial infarction inferolateral, subsequent	426.50	Bundle branch block, unspecified
		426.51	Right bundle branch block and left posterior fascicular block
410.30	Acute myocardial infarction inferoposterior, unspecified	426.52	Right bundle branch block and left anterior fascicular block
410.31	Acute myocardial infarction inferoposterior, initial	426.53	Other bilateral bundle branch block
410.32	Acute myocardial infarction inferoposterior, subsequent	426.54	Trifascicular block
		426.6	Other heart block
410.40	Acute myocardial infarction inferior wall, unspecified	426.7	Anomalous atrioventricular excitation
		426.81	Lown-Ganong-Levine syndrome
410.41	Acute myocardial infarction inferior wall, initial	426.89	Other specified conduction disorder
		426.9	Conduction disorder, unspecified
410.42	Acute myocardial infarction inferior wall, subsequent	427.0	Paroxysmal atrial tachycardia
		427.1	Paroxysmal ventricular tachycardia
410.50	Acute myocardial infarction lateral NEC, unspecified	427.2	Paroxysmal tachycardia NOS
		427.31	Atrial fibrillation
410.51	Acute myocardial infarction lateral NEC, initial	427.32	Atrial flutter
		427.41	Ventricular fibrillation
410.52	Acute myocardial infarction lateral NEC, subsequent	427.42	Ventricular flutter
		427.5	Cardiac arrest
410.60	True posterior infarction, unspecified	427.60	Premature beats NOS
410.61	True posterior infarction, initial	427.61	Atrial premature beats
410.62	True posterior infarction, subsequent	427.69	Premature beats NEC
410.70	Subendocardial infarction, unspecified	427.81	Sinoatrial node dysfunction
410.71	Subendocardial infarction, initial	427.89	Cardiac dysrhythmias NEC
410.72	Subendocardial infarction, subsequent	427.9	Cardiac dysrhythmia, unspecified
410.80	Acute myocardial infarction NEC, unspecified	428	Congestive heart failure
		428.1	Left heart failure
410.81	Acute myocardial infarction NEC, initial	428.9	Heart failure unspecified
410.82	Acute myocardial infarction NEC, subsequent	429.79	Other certain sequelae of myocardial infarction, not elsewhere classified
410.90	Acute myocardial infarction NOS, unspecified	429.89	Other ill-defined heart disease
		458.0-458.8	Hypotension
410.91	Acute myocardial infarction NOS, initial	458.9	Hypotension, unspecified
410.92	Acute myocardial infarction NOS, subsequent	493.90-493.92	Asthma, unspecified
		536.2	Persistent vomiting
411.81	Coronary occlusion without myocardial infarction	555.0-555.9	Regional enteritis
		556.0-556.9	Ulcerative colitis
415.11	Iatrogenic pulmonary embolism and infarction	557.0	Acute vascular insufficiency of intestine
415.19	Other pulmonary embolism and infarction		

557.1	Chronic vascular insufficiency of intestine	634.80-634.82	With unspecified complications
558.1	Gastroenteritis and colitis due to radiation	635.10-635.12	Legally induced abortion, complicated by delay or excessive hemorrhage
560.1	Paralytic ileus	635.30-635.32	Complicated by renal failure
564.2	Postgastric surgery syndromes	635.40-635.42	Complicated by metabolic disorder
569.81	Fistula of intestine, excluding rectum and anus	635.50-635.52	Complicated by shock
		635.60-635.62	Complicated by embolism
		635.70-635.72	With other specified complications
571.0-571.9	Chronic liver disease and cirrhosis	635.80-635.82	With unspecified complications
572.0-572.8	Liver abscess and sequelae of chronic liver disease	636.10-636.12	Illegally induced abortion, complicated by delay or excessive hemorrhage
573.0	Chronic passive congestion of liver		
576.4	Fistula of bile duct	636.30-636.32	Complicated by renal failure
577.0-577.9	Diseases of pancreas	636.40-636.42	Complicated by metabolic disorder
579.0	Celiac disease	636.50-636.52	Complicated by shock
579.1	Tropical sprue	636.60-636.62	Complicated by embolism
579.2	Blind loop syndrome	636.70-636.72	With other specified complications
579.3	Other and unspecified postsurgical malabsorption	636.80-636.82	With unspecified complications
		637.10-637.12	Unspecified abortion, complicated by delay or excessive hemorrhage
579.4	Pancreatic steatorrhea		
579.8	Other specified intestinal malabsorption	637.30-637.32	Complicated by renal failure
		637.40-637.42	Complicated by metabolic disorder
579.9	Unspecified intestinal malabsorption	637.50-637.52	Complicated by shock
584.5-584.9	Acute renal failure	637.60-637.62	Complicated by embolism
585	Chronic renal failure	637.70-637.72	With other specified complications
586	Renal failure, unspecified	637.80-637.82	With unspecified complications
587	Renal sclerosis, unspecified	638.1- 638.9	Failed attempted abortion
588.1	Nephrogenic diabetes insipidus	639.1	Delayed or excessive hemorrhage
588.8	Other specified disorders resulting from impaired renal function	639.3	Renal failure
		639.4	Metabolic disorders
588.9	Unspecified disorder resulting from impaired renal function	639.5	Shock
		639.6	Embolism
590.00-590.9	Infections of kidney	639.8	Other and unspecified complications following abortion or ectopic and molar pregnancy
592.0	Calculus of kidney		
592.1	Calculus of ureter		
593.81	Vascular disorders of kidney	639.9	Unspecified complication following abortion or ectopic and molar pregnancy
593.89	Other specified disorder of kidney and ureter		
593.9	Unspecified disorder of kidney and ureter	640.00-640.93	Hemorrhage in early pregnancy
		641.00-641.93	Antepartum hemorrhage, abruptio placentae, and placenta previa
594.0	Calculus in diverticulum of bladder		
594.1	Other calculus in bladder	642.00-642.94	Hypertension complicating pregnancy, childbirth, and the puerperium
594.2	Calculus in urethra		
632	Missed abortion	643.10-643.93	Excessive vomiting in pregnancy
634.10-634.12	Spontaneous abortion, complicated by delay or excessive hemorrhage	646.20-646.24	Unspecified renal disease in pregnancy, without mention of hypertension
634.30-634.32	Complicated by renal failure	646.80-646.84	Other specified complications of pregnancy
634.40-634.42	Complicated by metabolic disorder		
634.50-634.52	Complicated by shock	646.90-646.93	Unspecified complications of pregnancy
634.60-634.62	Complicated by embolism		
634.70-634.72	With other specified complications		

648.00-648.94	Other current conditions in the mother classifiable elsewhere, but complicating pregnancy, childbirth, or the puerperium	763.9	Unspecified complications of labor and delivery affecting fetus or newborn
655.80-655.83	Other known or suspected fetal abnormality, not elsewhere classified	764.10-764.19	"Light-for-dates" with signs of fetal malnutrition
655.90-655.93	Unspecified fetal abnormality	764.20-764.29	Fetal malnutrition without mention of "light-for-dates"
656.00-656.03	Fetal-maternal hemorrhage	775.4	Hypocalcemia and hypomagnesemia of newborn
656.30-656.33	Fetal distress	780.01	Alterations of consciousness, coma
656.40-656.43	Intrauterine death	780.02	Transient alteration of awareness
659.70-659.73	Abnormality in fetal heart rate or rhythm	780.09	Other alterations of consciousness
666.00-666.24	Postpartum hemorrhage	780.2	Syncope and collapse
668.10-668.14	Cardiac complications	780.31	Febrile convulsions
668.80-668.84	Other complications of anesthesia or other sedation in labor and delivery	780.39	Other convulsions
668.90-668.94	Unspecified complication of anesthesia and other sedation	780.71	Chronic fatigue syndrome
669.10-669.14	Shock during or following labor and delivery	780.79	Other malaise and fatigue
669.20-669.24	Maternal hypotension syndrome	781.0	Abnormal involuntary movements
669.30-669.34	Acute renal failure following labor and delivery	781.7	Tetany
669.40-669.44	Other complications of obstetrical surgery and procedures	781.99	Other symptoms involving nervous and musculoskeletal systems
669.80-669.84	Other complications of delivery	783.0	Anorexia
669.90-669.94	Unspecified complication of labor and delivery	783.21	Abnormal loss of weight
673.20-673.24	Obstetrical blood-clot embolism	783.22	Underweight
710.1	Systemic sclerosis	783.3	Feeding difficulties and mismanagement
728.5	Hypermobility syndrome	783.41	Failure to thrive, failure to gain weight
728.85	Spasm of muscle	783.7	Adult failure to thrive
728.86	Necrotizing fasciitis	783.9	Other symptoms concerning nutrition, metabolism, and development
728.89	Other disorders of muscle, ligament, and fascia (rhabdomyolysis)	785.0	Tachycardia, unspecified
728.9	Unspecified disorders of muscle, ligament, and fascia	785.50-785.59	Shock without mention of trauma
760.0	Maternal hypertensive disorders	787.01	Nausea and vomiting
760.1	Maternal renal and urinary tract disease	787.02	Nausea alone
760.4	Maternal nutrition disorders	787.03	Vomiting alone
760.71	Alcohol affecting fetus via placenta or breast milk	787.91	Diarrhea
760.8	Other specified maternal conditions affecting fetus or newborn	790.6	Other abnormal blood chemistry
763.8	Other specified complications of labor and delivery affecting fetus or newborn	794.31	Abnormal electrocardiogram
763.81-763.89	Other specified complications of labor and delivery affecting fetus or newborn	794.4	Nonspecific abnormal results of function studies, kidney
		796.1	Abnormal reflex
		796.2	Elevated blood pressure reading without diagnosis of hypertension
		799.4	Cachexia
		941.00-949.5	Burns
		958.4	Traumatic shock
		958.5	Traumatic anuria
		960.8	Poisoning other specified antibiotics
		963.1	Antineoplastic agents (poisoning)
		989.5	Toxic effect of venom

994.0	Effects of lightning
994.8	Electrocution and nonfatal effects of electric current
995.2	Unspecified adverse effect of drug, medicinal and biological substance (amphotericin B and digitalis)
995.4	Shock due to anesthesia, not else where classified
995.50-995.59	Child maltreatment syndrome
995.81	Adult maltreatment syndrome
997.1	Cardiac complications
998.0	Postoperative shock
998.9	Unspecified complication of procedure, not elsewhere classified
999.9	Other and unspecified complications of medical care, not elsewhere classified
V10.43	Personal history of malignant neoplasm, ovary
V42.0	Organ or tissue replaced by transplant, kidney
V42.7	Organ or tissue replaced by transplant, liver
V56.0	Extracorporeal dialysis
V56.8	Other dialysis
V58.1	Chemotherapy (Cis-platinum)
V58.2	Blood transfusion, without reported diagnosis
V58.62	Long-term (current) use of antibiotics
V58.69	Long-term (current) use of high-risk medications

Reasons for Denial:

1. A claim submitted without a valid ICD-9-CM diagnosis code will be returned as an incomplete claim under 1833(e).
2. A claim submitted without one of the ICD-9-CM diagnosis codes listed in the “ICD-9-CM Diagnosis Codes That Support Medical Necessity” section of this policy will be denied under 1862(a)(1)(A).
3. Claims submitted for an unusual frequency of any of these services or services ordered for a diagnosis not listed as covered in this policy will be denied as not medically necessary in the absence of supportive documentation in the patient’s record.
4. Section 1821(a)(7) of the Social Security Act does not extend Medicare coverage for screening procedures.

5. A claim for Magnesium Levels, submitted without the UPIN number of the referring/ordering physician or qualified non-physician practitioner, will be returned as an incomplete claim under 1833(e).

Noncovered ICD-9-CM Code(s):

- Use of any ICD-9-CM diagnosis code not listed in the “ICD-9-CM Diagnosis Codes That Support Medical Necessity” section of this policy will be denied.
- Use of ICD-9-CM diagnosis code V82.9 (Special screening of other conditions, unspecified condition) will result in the denial of claims as noncovered screening services.

Coding Guidelines:

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

Documentation Requirements:

1. Medical record documentation (i.e., office notes/progress notes) maintained by the ordering/referring physician must indicate the medical necessity for performing the test. Additionally, a copy of the test results should be maintained in the medical records.
2. When ICD-9-CM code **427.1** is used, the documentation in the medical records must indicate “Polymorphic Ventricular Tachycardia.”
3. When ICD-9-CM code **427.31** is used, the documentation in the medical records must indicate “Symptomatic Atrial Fibrillation.”
4. When Magnesium levels are billed outside of the composite rate, the medical justification must be submitted on the claim and noted in the medical record.

Other Comments:

- For services that exceed the accepted standard of medical practice and may be deemed not medically necessary, the provider/supplier must provide the patient with an acceptable advance notice of Medicare’s possible denial of payment. A waiver of liability should thus be signed when a provider/supplier does not want to accept the financial responsibility for the service.
- This policy supersedes a previous policy dated December 1997.

Financial Responsibility:

Provider Liable

The provider of the service or the ordering physician must have notified the patient in writing, prior to the service, and obtained a signature verifying Advance Beneficiary Notice. Without prior notice, services denied not medically necessary cannot be billed to the beneficiary. The provider is liable.

Beneficiary Liable

If there is clear evidence that the beneficiary was issued and signed a notice of noncoverage prior to the service, the liability rests with the beneficiary. The UB-92 Medicare bill should contain the condition code 20 and occurrence code 32, with date, to signify that notice of noncoverage was given to the beneficiary. Absence of these codes will result in a provider liable determination.

Sources of Information and Basis for Decision:

1. Knochel, J.P. (1998), Disorders of Magnesium Metabolism. K.J. Isselbacher, E. Braunwald, J. Wilson, J.B. Martin, A.S. Fauci & D.L. Kasper (Vol. Eds.), Harrison’s Principles of Internal Medicine: Vol. 1 (14th Edition, pages 2263-2266), New York: McGraw-Hill.
2. Textbook of Primary Care Medicine; John Noble
3. The Merck Manual; 17th Edition
4. Tierney, L.M., Jr., McPhee, S.J., and Papadakis, M.A. (Eds). (1997). Current Medical Diagnosis and Treatment. Stamford, CT.: Appleton and Lange.
5. Other Medicare Contractors: Empire Medicare Services, New Jersey; Trailblazers

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 include representatives from all specialty societies and the Medical Society of the State of New York.

Start Date of Comment Period: 03/11/2002

Ending Date of Comment Period: 04/25/2002

Start Date of Notice Period: 06/01/2002

Revision History:

Revision Number	Effective Date	Reason for Revision

MEDICARE LOCAL MEDICAL REVIEW POLICY

Contractor Policy Number: DR006A00
Contractor Name: Empire Medicare Services
Contractor Number: 00308
Contractor Type: Intermediary

LMRP Title: Mitoxantrone Hydrochloride (Novantrone®)

AMA CPT Copyright Statement:

CPT codes, descriptions, and other data only are copyright 2001 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS clauses apply.

CMS National Coverage Policy:

1. Title XVIII of the Social Security Act, Section 1862(a)(7)
This section excludes routine physical examinations.
2. Title XVIII of the Social Security Act, Section 1862(a)(1)(A)
This section states that no Medicare payment shall be made for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury.
3. Title XVIII of the Social Security Act, Section 1833(e)
This section prohibits Medicare payment for any claim that lacks the necessary information to process the claim.
4. Medicare Carriers Manual section 15400.
This section addresses coverage of chemotherapy administration.
5. Medicare Carriers Manual sections 2049 and 2050.
These sections address coverage of drugs and biologicals/services and supplies.

Primary Geographic Jurisdiction:

New York, Connecticut, Delaware, Massachusetts

CMS Region: 02

CMS Consortium: Northeast

Original Policy Effective Date: 07/01/2002

Original Policy Ending Date:

Revision Effective Date:

Revision Ending Date:

LMRP Description:

Mitoxantrone (Novantrone) is a parenteral, synthetic antineoplastic drug. Its structure is similar to that of the anthracyclines, doxorubicin, daunorubicin and idarubicin. The FDA approved this drug in 1987, and in October 2000, it approved its use to slow the worsening of neurologic disability and to reduce relapse rates in patients with clinically worsening forms of relapsing-remitting and secondary progressive multiple sclerosis.

Indications and Limitations of Coverage and/or Medical Necessity:

The following are FDA-approved indications for Mitoxantrone:

1. To treat pain related to advanced hormone-refractory prostate cancer.
2. To reduce neurologic disability and/or the frequency of clinical relapses in patients with secondary (chronic) progressive, progressive relapsing, or worsening relapsing-remitting multiple sclerosis, for example, in patients whose neurologic status is significantly abnormal between relapses. Mitoxantrone is **not** indicated for primary progressive multiple sclerosis.
3. In the initial therapy of acute non-lymphocytic leukemia (ANLL) in adults. This includes myelogenous, promyelocytic, and erythroid acute leukemias.

The following compendia-supported indications will also be covered:

1. Hepatomas in adults.
2. Recurrent acute lymphocytic leukemias in adults.
3. Breast carcinoma, including locally advanced and metastatic disease.
4. Non-Hodgkin's lymphomas.

CPT/HCPCS Section & Benefit Category:

Drugs

Type of Bill:

- 13x Hospital Outpatient
- 22x SNF Inpatient Ancillary
- 23x SNF Outpatient
- 85x Critical Access Hospital

Revenue Code(s):

- 0636 Drugs requiring detail coding

CPT/HCPCS Code(s):

- J9293 Injection, Mitoxantrone Hydrochloride, per 5 mg

ICD-9-CM Diagnosis Codes That Support Medical Necessity:

TRUNCATED DIAGNOSIS CODES ARE NOT ACCEPTABLE. ICD-9-CM code listings may cover a range and include truncated codes. It is the provider's responsibility to avoid truncated codes by selecting a code(s) carried out to the highest level of specificity and selected from the ICD-9-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

It is not enough to link the procedure code to a correct, payable ICD-9-CM diagnosis code. The diagnosis or clinical suspicion must be present for the procedure to be paid.

- 155.0-155.2 Malignant neoplasm of liver and intrahepatic bile ducts
- 158.8 Malignant neoplasm of specified parts of peritoneum
- 158.9 Malignant neoplasm peritoneum unspecified
- 162.2 Malignant neoplasm main bronchus
- 162.3 Malignant neoplasm upper lobe, bronchus or lung
- 162.4 Malignant neoplasm middle lobe, bronchus or lung
- 162.5 Malignant neoplasm lower lobe, bronchus or lung
- 162.8 Malignant neoplasm other parts of bronchus or lung
- 162.9 Malignant neoplasm bronchus and lung, unspecified
- 173.5 Malignant neoplasm skin of trunk, except scrotum
- 174.0-174.9 Malignant neoplasm of female breast
- 175.0-175.9 Malignant neoplasm of male breast
- 183.0 Malignant neoplasm of ovary
- 185 Malignant neoplasm of prostate
- 188.0 Malignant neoplasm bladder-trigone
- 188.1 Malignant neoplasm bladder-dome
- 188.2 Malignant neoplasm bladder-lateral wall
- 188.3 Malignant neoplasm bladder-anterior wall
- 188.4 Malignant neoplasm bladder-posterior wall
- 188.5 Malignant neoplasm bladder neck
- 188.6 Malignant neoplasm ureteric orifice
- 188.7 Malignant neoplasm urachus
- 188.8 Malignant neoplasm other specified sites of bladder
- 188.9 Malignant neoplasm bladder, part unspecified
- 189.1 Malignant neoplasm renal pelvis
- 189.2 Malignant neoplasm ureter
- 195.2 Malignant neoplasm abdomen
- 198.1 Secondary malignant neoplasm other urinary organs
- 198.2 Secondary malignant neoplasm skin
- 198.6 Secondary malignant neoplasm ovary
- 198.81 Secondary malignant neoplasm breast

200.00-200.88	Lymphosarcoma and reticulosarcoma	206.11	Chronic monocytic leukemia in remission
201.00-201.98	Hodgkin's disease		
202.00-202.98	Other malignant neoplasm of lymphoid and histiocytic tissue	206.20	Subacute monocytic leukemia without mention of remission
203.00	Multiple myeloma without mention of remission	206.21	Subacute monocytic leukemia in remission
203.01	Multiple myeloma in remission	206.80	Other monocytic leukemia without mention of remission
204.00	Acute lymphoid leukemia without mention of remission	206.81	Other monocytic leukemia in remission
204.01	Acute lymphoid leukemia in remission	206.90	Unspecified monocytic leukemia without mention of remission
204.10	Chronic lymphoid leukemia without mention of remission	206.91	Unspecified monocytic leukemia in remission
204.11	Chronic lymphoid leukemia in remission	207.00	Acute erythremia and erythroleukemia without mention of leukemia
204.20	Subacute lymphoid leukemia without mention of remission	207.01	Acute erythremia and erythroleukemia in remission
204.21	Subacute lymphoid leukemia in remission	207.10	Chronic erythremia without mention of leukemia
204.80	Other lymphoid leukemia without mention of remission	207.11	Chronic erythremia in remission
204.81	Other lymphoid leukemia in remission	207.20	Megakaryocytic leukemia without mention of remission
204.90	Unspecified lymphoid leukemia without mention of remission	207.21	Megakaryocytic leukemia in remission
204.91	Unspecified lymphoid leukemia in remission	207.80	Other specified leukemia without mention of remission
205.00	Acute myeloid leukemia without mention of remission	207.81	Other specified leukemia in remission
205.01	Acute myeloid leukemia in remission	208.00	Acute leukemia of unspecified cell type without mention or remission
205.10	Chronic myeloid leukemia without mention of remission	208.01	Acute leukemia of unspecified cell type in remission
205.11	Chronic myeloid leukemia in remission	208.10	Chronic leukemia of unspecified cell type without mention of remission
205.20	Subacute myeloid leukemia without mention of remission	208.11	Chronic leukemia of unspecified cell type in remission
205.21	Subacute myeloid leukemia in remission	208.20	Subacute leukemia of unspecified cell type without mention of remission
205.30	Myeloid sarcoma without mention of remission	208.21	Subacute leukemia of unspecified cell type in remission
205.31	Myeloid sarcoma in remission	208.80	Other leukemia of unspecified cell type without mention of remission
205.80	Other myeloid leukemia without mention of remission	208.81	Other leukemia of unspecified cell type in remission
205.81	Other myeloid leukemia in remission	208.90	Unspecified leukemia without mention of remission
205.90	Unspecified myeloid leukemia without mention of remission	208.91	Unspecified leukemia in remission
205.91	Unspecified myeloid leukemia in remission	232.5	Carcinoma in situ of skin of trunk, except scrotum
206.00	Acute monocytic leukemia without mention of remission	233.0	Carcinoma in situ of breast
206.01	Acute monocytic leukemia in remission	238.3	Neoplasm uncertain behavior breast
206.10	Chronic monocytic leukemia without mention of remission	239.2	Bone/skin neoplasm NOS
		340*	Multiple sclerosis

*Note ICD-9-CM code **340** is effective for dates of service on and after **11/01/2000**.

Reasons for Denial:

- Claims submitted with diagnosis codes that are not listed above will be denied as investigational. The drug must be recognized in one of the established reference compendia, peer review professional journals, or scientific literature as being effective in the treatment for the type of cancer it has been prescribed.
- If the diagnosis is progressive multiple sclerosis.

Noncovered ICD-9-CM Code(s):

- Use of any ICD-9-CM diagnosis code not listed in the “ICD-9-CM Diagnosis Codes That Support Medical Necessity” section of this policy will be denied.

Coding Guidelines:

1. The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.
2. When used for FDA-approved indications, the frequency of administration should not exceed that specified in the package insert.
3. When used for compendia-approved indications, the frequency of administration should not exceed that specified by the compendia.

Documentation Requirements:

1. Documentation supporting the medical necessity, such as ICD-9-CM diagnosis codes, must be submitted with each claim. Claims submitted without such evidence will be denied as not medically necessary.
2. Documentation must be available to Medicare upon request.
3. When a portion of the drug is discarded, the medical record must clearly document the amount administered and the amount wasted. This documentation must be available to the intermediary upon request.
4. When Mitoxantrone Hydrochloride is used to treat multiple sclerosis, the documentation must support that the patient has secondary chronic progressive, relapsing, or worsening relapsing-remitting multiple sclerosis.

Other Comments:

For services that exceed the accepted standard of medical practice and may be deemed not medically necessary, the provider/supplier must provide the patient with an acceptable advance notice of Medicare’s possible denial of payment. A waiver of liability should thus be signed when a provider/supplier does not want to accept the financial responsibility for the service.

Financial Responsibility:

Provider Liable

The provider of the service or the ordering physician must have notified the patient in writing, prior to the service, and obtained a signature verifying Advance Beneficiary Notice. Without prior notice, services denied as not medically necessary cannot be billed to the beneficiary. The provider is liable.

Beneficiary Liable

If there is clear evidence that the beneficiary was issued and signed a notice of noncoverage prior to the service, the liability rests with the beneficiary. The UB-92 Medicare bill should contain the condition code 20 and occurrence code 32, with date, to signify that notice of noncoverage was given to the beneficiary. Absence of these codes will result in a provider liable determination.

Sources of Information and Basis for Decision:

1. Physicians’ Current Procedural Terminology 2002, American Medical Association.
2. ICD-9-CM Expert 2002, Vol. 1 & 2, 6th Edition, Medicode Inc.
3. Other Medicare Policies: New York Part B, Florida
4. Ferri, F.F. Clinical Advisor, 2001 Edition, Mosby.
5. Noble, J. Textbook of Primary Care Medicine, Third Edition, Mosby.
6. Physicians’ Desk Reference, 56th Edition, 2002.
7. Clinical Pharmacology©2001, Gold Standard Multimedia Inc.
8. Drug Topics Archive, June 19, 2000

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 include representatives from all specialty societies and the Medical Society of the State of New York.

Start Date of Comment Period: 03/11/2002

End Date of Comment Period: 04/25/2002

Start Date of Notice Period: 06/01/2002

Revision History:

Revision Number	Effective Date	Reason for Revision

**MEDICARE
LOCAL MEDICAL REVIEW POLICY**

Contractor Policy Number: LB011A00
Contractor Name : Empire Medicare Services
Contractor Number: 00308
Contractor Type: Intermediary

LMRP Title: Potassium (Serum) Levels

AMA CPT Copyright Statement:

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CMS National Coverage Policy:

- Title XVIII of the Social Security Act, Section 1862(a)(7)
This section excludes routine physical checkups and prohibits Medicare payment for routine screening services.
- Title XVIII of the Social Security Act, Section 1862(a)(1)(A)
This section states that no Medicare payment shall be made for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1833(e)
This section prohibits Medicare payment for any claim that lacks the necessary information to process the claim.

Primary Geographic Jurisdiction:

New York, Connecticut, Delaware, Massachusetts

CMS Region: 02

CMS Consortium: Northeast

Policy Effective Date: 07/01/2002

Policy Ending Date:

Revision Effective Date:

Revision Ending Effective Date:

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LMRP Description:

Potassium (K) is the most abundant cation found primarily in the intracellular fluid. Under normal conditions, 90 percent of the ingested potassium is excreted in the urine and 10 percent in the stools. Potassium homeostasis is regulated mainly by the kidneys and is essential for proper neuromuscular function.

Indications and Limitations of Coverage and/or Medical Necessity:**Indications**

Periodic monitoring of serum potassium levels may be medically necessary for patients taking potassium-depleting diuretics and in patients with renal failure or acidosis. Levels may also be appropriate when a patient presents with signs and symptoms of:

1. Hypokalemia (K less than 3.5mEq/L) which may include:

- Moderate muscle weakness
- Decreased reflexes
- Respiratory depression
- Paralysis
- Palpitations
- Abnormal EKG findings such as wide QRS, depressed ST segment or U-waves
- Heart failure
- Polyuria
- Polydipsia
- Nocturia

2. Hyperkalemia (K greater than 5 mmol/L) which may include:

- Muscle weakness
- Respiratory depression
- Abnormal EKG findings such as prolonged PR interval, atrial asystole, etc.

Those at risk for hypokalemia include those with persistent vomiting or diarrhea and those taking laxatives or diuretics on a chronic basis. Those at risk for hyperkalemia include those with acute renal failure and less commonly, those with chronic renal failure.

Policy Type:

Local medical necessity policy

An operational statement of national coverage policy

Local coding instructions

CPT/HCPCS Section & Benefit Category:

Laboratory

Type of Bill:

12x Hospital Inpatient Ancillary
 13x Hospital Outpatient
 14x Hospital Referred Diagnostic Services
 22x SNF Inpatient Ancillary
 23x SNF Outpatient
 72x Renal Dialysis Center (ESRD)
 85x Critical Access Hospital

Revenue Code(s):

0301 Laboratory - Chemistry
 0310 Laboratory - Pathology

CPT/HCPCS Code(s):

84132 Potassium

ICD-9-CM Diagnosis Codes That Support Medical Necessity:

TRUNCATED DIAGNOSIS CODES ARE NOT ACCEPTABLE.

ICD-9-CM code listings may cover a range and include truncated codes. It is the provider's responsibility to avoid truncated codes by selecting a code(s) carried out to the highest level of specificity and selected from the ICD-9-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

It is not enough to link the procedure code to a correct, payable ICD-9-CM diagnosis code. The diagnosis or clinical suspicion must be present for the procedure to be paid.

001.0-001.9	Cholera
002.0-002.9	Typhoid and paratyphoid fevers
003.0-003.9	Other salmonella infections
004.0-004.9	Shigellosis
005.0-005.9	Other food poisoning (bacterial)
006.0-006.9	Amebiasis
007.0-007.9	Other protozoal intestinal diseases
008.0-008.8	Intestinal infections due to other organisms
009.0-009.3	Ill-defined intestinal infections
188.9	Malignant neoplasm of bladder part unspecified
198.1	Secondary malignant neoplasm other urinary organs

204.00	Acute lymphoid leukemia without mention of remission	207.00	Acute erythremia and erythroleukemia without mention of remission
204.01	Acute lymphoid leukemia in remission	207.01	Acute erythremia and erythroleukemia in remission
204.10	Chronic lymphoid leukemia without mention of remission	207.10	Chronic erythremia without remission
204.11	Chronic lymphoid leukemia in remission	207.11	Chronic erythremia in remission
204.20	Subacute lymphoid leukemia	207.20	Megakaryocytic leukemia without mention of remission
204.21	Subacute lymphoid leukemia	207.21	Megakaryocytic leukemia in remission
204.80	Other lymphoid leukemia without mention of leukemia	207.80	Other specified leukemia without mention of remission
204.81	Other lymphoid leukemia in remission	207.81	Other specified leukemia in remission
204.90	Unspecified lymphoid leukemia without mention of remission	208.00	Acute leukemia of unspecified cell type without remission
204.91	Unspecified lymphoid leukemia in remission	208.01	Acute leukemia of unspecified cell type in remission
205.00	Acute myeloid leukemia without mention of remission	208.10	Chronic leukemia of unspecified cell type without remission
205.01	Acute myeloid leukemia in remission	208.11	Chronic leukemia of unspecified cell type in remission
205.10	Chronic myeloid leukemia without mention of remission	208.20	Subacute leukemia of unspecified cell type without remission
205.11	Chronic myeloid leukemia in remission	208.21	Subacute leukemia of unspecified cell type in remission
205.20	Subacute myeloid leukemia without mention of remission	208.80	Other leukemia of unspecified cell type without mention of remission
205.21	Subacute myeloid leukemia in remission	208.81	Other leukemia on unspecified cell type in remission
205.30	Myeloid sarcoma without mention of remission	208.90	Unspecified leukemia without mention of remission
205.31	Myeloid sarcoma in remission	208.91	Unspecified leukemia with remission
205.80	Other myeloid leukemia without mention of remission	223.3	Benign neoplasm bladder
205.81	Other myeloid leukemia in remission	227.0	Benign neoplasm adrenal gland
205.90	Unspecified myeloid leukemia without mention of remission	227.3	Benign neoplasm pituitary gland
205.91	Unspecified myeloid leukemia in remission	233.7	Carcinoma in situ bladder
206.00	Acute monocytic leukemia without mention of remission	236.7	Uncertain behavior neoplasm bladder
206.01	Acute monocytic leukemia in remission	239.4	Bladder neoplasm unspecified
206.10	Chronic monocytic leukemia without mention of remission	250.00-250.93	Diabetes mellitus
206.11	Chronic monocytic leukemia in remission	251.0	Hypoglycemic coma
206.20	Subacute monocytic leukemia without remission	251.1	Other specified hypoglycemia
206.21	Subacute monocytic leukemia in remission	251.2	Hypoglycemia, unspecified
206.80	Other monocytic leukemia without mention of remission	251.3	Post surgical hypoinsulinemia
206.81	Other monocytic leukemia in remission	251.4	Abnormal secretion glucagon
206.90	Unspecified monocytic leukemia without mention of remission	251.5	Abnormal secretion gastrin
206.91	Unspecified monocytic leukemia in remission	251.8	Other specified disorders of pancreatic internal secretion
		251.9	Unspecified disorder of pancreatic internal secretion pancreatic disorder
		252.0	Hyperparathyroidism
		252.1	Hypoparathyroidism
		252.8	Parathyroid disorder NEC

252.9	Parathyroid disorder NOS	276.9	Electrolyte and fluid disorders NEC
253.0	Acromegaly and gigantism	277.00	Cystic fibrosis without mention of meconium ileus
253.1	Anterior pituitary hyperfunction		Cystic fibrosis with meconium ileus
253.2	Panhypopituitarism	277.01	Unspecified deficiency anemia
253.3	Pituitary dwarfism	281.9	Hemoglobinuria due to hemolysis from external causes
253.4	Other anterior pituitary disorders	283.2	Unspecified diseases of blood and blood-forming organs
253.5	Diabetes insipidus		Acute delirium
253.6	Neurohypophysis disease NEC	289.9	Unspecified psychosis
253.7	Iatrogenic pituitary disease		Other and unspecified alcohol dependence
253.8	Pituitary disorder NEC	293.0	Psychogenic gastrointestinal disease
253.9	Pituitary disorder NOS	298.9	Anorexia nervosa
254.0	Persistent hyperplasia thymus	303.90-303.93	Pica
254.1	Abscess of thymus		Familial periodic paralysis
254.8	Other specified diseases of thymus gland	306.4	Malignant hypertension
254.9	Unspecified disease of thymus gland	307.1	Benign hypertension
255.0	Cushing's syndrome	307.52	Hypertension unspecified
255.1	Hyperaldosteronism	359.3	Malignant hypertensive heart disease without congestive heart failure
255.2	Adrenogenital disorders	401.0	Malignant hypertensive heart disease with congestive heart failure
255.3	Corticoadrenal overactivity	401.1	Benign hypertensive heart disease without congestive heart failure
255.4	Corticoadrenal insufficiency	401.9	Benign hypertensive heart disease with congestive heart failure
255.5	Other adrenal hypofunction	402.00	Hypertensive heart disease without congestive heart failure
255.6	Medulloadrenal hyperfunction		Hypertensive heart disease with congestive heart failure
255.8	Other specified disorders of adrenal glands	402.01	Malignant hypertensive renal disease without renal failure
255.9	Unspecified disorder of adrenal glands	402.10	Malignant hypertensive renal disease with renal failure
259.0	Delay sexual development and puberty NEC	402.11	Benign hypertensive renal disease without renal failure
259.1	Precocious sexual development and puberty, not elsewhere classified	402.90	Benign hypertensive renal disease with renal failure
259.2	Carcinoid syndrome		Hypertensive renal disease NOS without renal failure
259.3	Ectopic hormone secretion NEC	402.91	Hypertensive renal disease NOS with renal failure
259.4	Dwarfism NEC		Malignant hypertensive heart disease and renal disease without mention of congestive heart failure or renal failure
259.8	Endocrine disorder NEC	403.00	Malignant hypertensive heart and renal disease with renal failure
259.9	Endocrine disorder NOS		Malignant hypertensive heart and renal disease with renal failure
262	Other severe malnutrition	403.01	
263.9	Unspecified protein-calorie malnutrition		
269.2	Unspecified vitamin deficiency	403.10	
269.9	Nutritional deficiency, unspecified		
270.0	Disturbances of amino-acid transport	403.11	
273.8	Other disorders of plasma protein metabolism	403.90	
275.2	Disorders of magnesium metabolism		
276.0	Hyperosmolality	403.91	
276.1	Hyposmolality		
276.2	Acidosis	404.00	
276.3	Alkalosis		
276.4	Mixed acid-base balance disorder		
276.5	Hypovolemia	404.01	
276.6	Fluid overload		
276.7	Hyperpotassemia	404.02	
276.8	Hypopotassemia		

404.03	Malignant hypertensive heart and renal disease with congestive heart failure and renal failure	410.41	Acute myocardial infarction inferior wall, initial
404.10	Benign hypertensive heart and renal disease without mention of congestive heart failure or renal failure	410.42	Acute myocardial infarction inferior wall, subsequent
404.11	Benign hypertensive heart and renal disease with congestive heart failure	410.50	Acute myocardial infarction lateral NEC, unspecified
404.12	Benign hypertensive heart and renal disease with renal failure	410.51	Acute myocardial infarction lateral NEC, initial
404.13	Benign hypertensive heart and renal disease with congestive heart failure and renal failure	410.52	Acute myocardial infarction lateral NEC, subsequent
404.90	Unspecified hypertensive heart and renal disease without mention of congestive heart failure or renal failure	410.60	True posterior infarction, unspecified
404.91	Unspecified hypertensive heart and renal disease with congestive heart failure	410.61	True posterior infarction, initial
404.92	Unspecified hypertensive heart and renal disease with renal failure	410.62	True posterior infarction, subsequent
404.93	Unspecified hypertensive heart and renal disease with congestive heart failure and renal failure	410.70	Subendocardial infarction, unspecified
405.01-405.99	Secondary hypertension	410.71	Subendocardial infarction, initial
410.00	Acute myocardial infarction anterolateral, unspecified	410.72	Subendocardial infarction, subsequent
410.01	Acute myocardial infarction anterolateral, initial	410.80	Acute myocardial infarction NEC, unspecified
410.02	Acute myocardial infarction anterolateral, subsequent	410.81	Acute myocardial infarction NEC, initial
410.10	Acute myocardial infarction anterior wall, unspecified	410.82	Acute myocardial infarction NEC, subsequent
410.11	Acute myocardial infarction anterior wall, initial	410.90	Acute myocardial infarction NOS, unspecified
410.12	Acute myocardial infarction anterior wall, subsequent	410.91	Acute myocardial infarction NOS, initial
410.20	Acute myocardial infarction inferolateral, unspecified	410.92	Acute myocardial infarction NOS, subsequent
410.21	Acute myocardial infarction inferolateral, initial	426.0-426.9	Conduction disorders
410.22	Acute myocardial infarction inferolateral, subsequent	427.0-427.9	Cardiac dysrhythmias
410.30	Acute myocardial infarction inferoposterior, unspecified	428.0	Congestive heart failure
410.31	Acute myocardial infarction inferoposterior, initial	428.1	Left heart failure
410.32	Acute myocardial infarction inferoposterior, subsequent	428.9	Heart failure, unspecified
410.40	Acute myocardial infarction inferior wall, unspecified	491.20	Chronic emphysema
		537.4	Fistula of stomach or duodenum
		555.9	Regional enteritis unspecified site
		556.9	Ulcerative colitis, unspecified
		560.0-560.9	Intestinal obstruction without mention of hernia
		564.0	Constipation
		564.2	Postgastric surgery syndromes
		571.5	Cirrhosis of liver without mention of alcohol
		576.4	Fistula of bile duct
		577.8	Other specified diseases of pancreas
		579.3	Other and unspecified postsurgical nonabsorption
		579.9	Unspecified intestinal malabsorption
		580.0-580.9	Acute glomerulonephritis
		581.0-581.9	Nephrotic syndrome
		582.0-582.9	Chronic glomerulonephritis

583.0-583.9	Nephritis and nephropathy, not specified as acute or chronic	949.0	Burn unspecified degree
584.5-584.9	Acute renal failure	949.1	Erythema [first degree]
585	Chronic renal failure	949.2	Blisters, epidermal loss [second degree]
586	Renal failure, unspecified	949.3	Full thickness skin loss [third degree NOS]
587	Renal sclerosis, unspecified	949.4	Deep necrosis of underlying tissues [deep third degree] without mention of loss of a body part
588.0	Renal osteodystrophy	949.5	Deep necrosis of underlying tissues [deep third degree] with loss of a body part
588.1	Nephrogenic diabetes insipidus	960.0	Poisoning by penicillins
588.8	Impaired renal function NEC	960.1	Poisoning by antifungal antibiotics
588.9	Impaired renal function NOS	960.8	Poisoning by unspecified antibiotics
589.0	Unilateral small kidney	961.0	Poisoning by sulfonamides
589.1	Bilateral small kidneys	962.0	Poisoning by adrenal cortical steroids
589.9	Small kidney NOS	962.3	Poisoning by insulins and antidiabetic agents
590.00	Chronic pyelonephritis	964.1	Poisoning by liver preparations and other antianemic agents
593.9	Unspecified disorder of kidney and ureter	973.3	Poisoning by other cathartics, including intestinal atonia drugs
728.89	Other disorders of muscles, ligament and fascia	974.0	Poisoning by mercurial diuretics
728.9	Unspecified disorder of muscle, ligament, and fascia	974.1	Poisoning by purine derivative diuretics
729.82	Other musculoskeletal symptoms referable to limbs, cramp	974.2	Poisoning by carbonic acid anhydrase inhibitors
780.71	Chronic fatigue syndrome	974.3	Poisoning by saluretics
780.79	Other malaise and fatigue	974.4	Poisoning by other diuretics
785.1	Palpitations	975.2	Poisoning by skeletal muscle relaxants
783.0	Anorexia	977.8	Poisoning by other specified drugs and medicinal substances
787.01	Nausea and vomiting	985.8	Toxic effect of other specified metals
787.03	Vomiting alone	994.2	Effects of hunger and starvation
787.91	Diarrhea	995.0	Other anaphylactic shock
790.6	Other abnormal blood chemistry	995.2	Unspecified adverse effect of drug, medicinal and biological substance
925.1-929.9	Crush injuries	V56.0	Extracorporeal dialysis
934.8	Foreign body in trachea, bronchus and lung NEC	V56.8	Other dialysis
940.0-940.9	Burn confined to eye and adnexa	V58.1	Encounter or admission for chemotherapy
941.20-941.59	Burns of face, head or neck	V58.69	Long-term (current) use of other (high-risk) medications
942.20-942.59	Burn of trunk	V58.83	Encounter for therapeutic drug monitoring
943.20-943.59	Burn of upper limb, except wrist and hand	V67.51	Following completed treatment with high-risk medications
944.00-944.58	Burn of wrist(s) and hand(s)		
945.20-945.59	Burn of lower limb(s)		
946.2	Second degree burn multiple sites		
946.3	Third degree burn multiple sites		
946.4	Deep third degree burn multiple sites		
946.5	Third degree burn with loss of a body part		
947.1	Burn larynx/trachea/lung		
947.2	Burn of esophagus		
947.3	Burn of gastrointestinal tract		
947.9	Burn of internal organ unspecified site		
948.10-948.99	Burns classified according to extent of body surface involved		

Reasons for Denial:

1. A claim submitted without a valid ICD-9-CM diagnosis code will be returned as an incomplete claim under 1833(e).
2. A claim submitted without one of the ICD-9-CM diagnosis codes listed in the "ICD-9-CM Diagnosis Codes That Support Medical Necessity" section of this policy will be denied under 1862(a)(1)(A).
3. Claims submitted for an unusual frequency of any of these services or services ordered for a diagnosis not listed as covered in this policy will be denied as not medically necessary in the absence of supportive documentation in the patient's record.
4. Section 1821(a)(7) of the Social Security Act does not extend Medicare coverage for screening procedures.
5. A claim for Potassium Testing, submitted without the UPIN number of the referring/ordering physician or qualified non-physician practitioner, will be returned as an incomplete claim under 1833(e).

Noncovered ICD-9-CM Code(s):

- Use of any ICD-9-CM diagnosis code not listed in the "ICD-9-CM Diagnosis Codes That Support Medical Necessity" section of this policy will be denied.
- Use of ICD-9-CM diagnosis code V82.9 (Special screening of other conditions, unspecified condition) will result in the denial of claims as noncovered screening services.

Coding Guidelines:

1. CPT code 84132 should not be billed if the serum potassium test is included as part of a chemistry panel billed on the same day.
2. V58.1, V58.69 and V67.51 require a primary diagnosis. For example, if potassium levels are obtained in a patient who presents with symptoms of hypokalemia and is taking laxatives on a chronic basis, use the code for chronic constipation (564.0) as the primary code and V58.69 as the secondary code.

Documentation Requirements:

1. Documentation supporting the medical necessity, such as ICD-9-CM diagnosis codes, must be submitted with each claim. Claims submitted

without such evidence will be denied as not medically necessary.

2. Documentation must be available to Medicare upon request.
3. For Potassium serum levels billed outside of the composite rate, medical justification must be in the medical records.

Other Comments:

For services that exceed the accepted standard of medical practice and may be deemed not medically necessary, the provider/supplier must provide the patient with an acceptable advance notice of Medicare's possible denial of payment. A waiver of liability should thus be signed when a provider/supplier does not want to accept the financial responsibility for the service.

Financial Responsibility:Provider Liable

The provider of the service or the ordering physician must have notified the patient in writing, prior to the service, and obtained a signature verifying Advance Beneficiary Notice. Without prior notice, services denied as not medically necessary cannot be billed to the beneficiary. The provider is liable.

Beneficiary Liable

If there is clear evidence that the beneficiary was issued and signed a notice of noncoverage prior to the service, the liability rests with the beneficiary. The UB-92 Medicare bill should contain the condition code 20 and occurrence code 32, with date, to signify that notice of noncoverage was given to the beneficiary. Absence of these codes will result in a provider liable determination.

Sources of Information and Basis for Decision:

1. Copyright© 2001, Physicians' Current Procedural Terminology, American Medical Association.
2. Copyright© 2000, International Classification of Diseases, 9th Revision, Clinical Modification, Medicode Inc.
3. Other Medicare Policies: New Mexico, Oklahoma.
4. Ferri, F.F., Clinical Advisor, 2001 Edition, Mosby.
5. Noble, J., Textbook of Primary Care Medicine, Third Edition, Mosby.

6. Wallach, J., Interpretation of Diagnostic Tests, 7th Edition, Lippincott Williams & Wilkins.
7. Physicians' Desk Reference, 56th Edition, 2002.

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 include representatives from all specialty societies and the Medical Society of the State of New York.

Start Date of Comment Period: 03/11/2002

Ending Date of Comment Period: 04/25/2002

Start Date of Notice Period: 06/01/2002

Revision History:

Revision Number	Effective Date	Reason for Revision

**MEDICARE
LOCAL MEDICAL REVIEW POLICY**

Contractor Policy Number: PM001A00
Contractor Name : Empire Medicare Services
Contractor Number: 00308
Contractor Type : Intermediary

LMRP Title: Visual Rehabilitation Services

AMA CPT Copyright Statement:

CPT codes, descriptions, and other data only are copyright 2001 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply.

CMS National Coverage Policy:

- Title XVIII of the Social Security Act, Section 1862(a)(7)
This section excludes routine physical checkups and prohibits Medicare payment for routine or screening services.
- Title XVIII of the Social Security Act, Section 1862(a)(1)(A)
This section states that no Medicare payment shall be made for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury.
- Title XVIII of the Social Security Act, Section 1833(e)
This section prohibits Medicare payment for any claim that lacks the necessary information to process the claim.

Primary Geographic Jurisdiction:

New York, Connecticut, Delaware, Massachusetts

CMS Region: 02

CMS Consortium: Northeast

Policy Effective Date: 07/01/2002

Policy Ending Date:

Revision Effective Date:

Revision Ending Effective Date:

LMRP Description:

The purpose of rehabilitative therapy is to maximize the use of residual vision and provide patients with many practical adaptations for activities of daily living. In doing so, it builds the confidence that is necessary for ongoing creative problem solving. Rehabilitation appears to be more effective if it is started as soon as functional visual difficulties are identified.

Indications and Limitations of Coverage and/or Medical Necessity:

Coverage of low vision rehabilitation services is considered reasonable and necessary only for patients with a clear medical need.

1. Patients must have a moderate or severe or visual impairment not correctable by conventional refractive means.
2. Patients must have a clear potential for significant improvement in function following rehabilitation over a reasonable period of time.

Services provided in connection with visual rehabilitation may be considered reasonable and necessary as follows:

Moderate Impairment	Maximum of six one-hour sessions
Severe Impairment	Maximum of eight one-hour sessions

Sessions are generally conducted over a three-month period of time with intervals appropriate to the patient's rehabilitative needs. If additional sessions are necessary, medical record documentation must indicate the need for the additional sessions.

The level of vision impairment is described as:

Moderate	Best corrected visual acuity is less than 20/60 in the better eye (including 20/70 to 20/160)
Severe visual impairment	Best corrected visual acuity is less than 20/160 including 20/200 to 20/400); or visual field diameter is 20° or less (largest field diameter for Goldmann isopter III4e, 1/100 white test object or equivalent) in the better eye.

Policy Type:

Local medical necessity

CPT/HCPCS Section & Benefit Category:

Physical Medicine and Rehabilitation

Type of Bill:

12x	Hospital Inpatient Ancillary
13x	Hospital Outpatient
22x	SNF Inpatient Ancillary

23x SNF Outpatient
 74x Outpatient Rehabilitation Facility
 75x Comprehensive Outpatient Rehabilitation Facility
 85x Critical Access Hospital

Revenue Codes:

043x Occupational Therapy

CPT/HCPCS Codes:Ó

97112 Therapeutic procedure, one or more areas, each 15 minutes; neuromuscular reeducation of movement, balance, coordination, kinesthetic sense, posture, and proprioception

97116 Gait training (includes stair climbing)

97530 Therapeutic activities, direct (one on one) patient contact by the provider (use of dynamic activities to improve functional performance), each 15 minutes

97535 Self care/home management training (e.g., activities of daily living (ADL) and compensatory training, meal preparation, safety procedures, and instructions in use of adaptive equipment) direct one on one contact by provider, each 15 minutes

97537 Community/work reintegration training (e.g., shopping, transportation, money)

ICD-9-CM Diagnosis Codes That Support Medical Necessity:

TRUNCATED DIAGNOSIS CODES ARE NOT ACCEPTABLE.

ICD-9-CM code listings may cover a range and include truncated codes. It is the provider’s responsibility to avoid truncated codes by selecting a code(s) carried out to the highest level of specificity and selected from the ICD-9-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

It is not enough to link the procedure code to a correct, payable ICD-9-CM diagnosis code. The diagnosis or clinical suspicion must be present for the procedure to be paid.

368.46 Homonymous bilateral field defects
 368.47 Heteronymous bilateral filed defects

369.01 Better eye: total impairment; lesser eye: total impairment

369.03 Better eye: near-total impairment; lesser eye: total impairment

369.04 Better eye: near-total impairment; lesser eye: near-total impairment

369.06 Better eye: profound impairment; lesser eye: total impairment

369.07 Better eye: profound impairment; lesser eye: near-total impairment

369.08 Better eye: profound impairment; lesser eye: profound impairment

369.12 Better eye: severe impairment; lesser eye: total impairment

369.13 Better eye: severe impairment; lesser eye: near-total impairment

369.14 Better eye: severe impairment; lesser eye: profound impairment

369.16 Better eye: moderate impairment; lesser eye: total impairment

369.17 Better eye: moderate impairment; lesser eye: near-total impairment

369.18 Better eye: moderate impairment; lesser eye: profound impairment

369.22 Better eye: severe impairment; lesser eye: severe impairment

369.24 Better eye: moderate impairment; lesser eye: severe impairment

369.25 Better eye: moderate impairment; lesser eye: moderate impairment

Reasons for Denial:

1. A claim submitted without a valid ICD-9-CM diagnosis code will be returned as an incomplete claim under 1833(e).
2. A claim submitted without one of the ICD-9-CM diagnosis codes listed in the “ICD-9-CM Diagnosis Codes That Support Medical Necessity” section of this policy will be denied under 1862(a)(1)(A).
3. Claims submitted for an unusual frequency of any of these services or services ordered for a diagnosis not listed as covered in this policy will be denied as not medically necessary in the absence of supportive documentation in the patient’s record.
4. Section 1821(a)(7) of the Social Security Act does not extend Medicare coverage for screening procedures.

5. A claim for Visual Rehabilitation Services, submitted without the UPIN number of the referring/ordering physician or qualified non-physician practitioner, will be returned as an incomplete claim under 1833(e).
 6. The provision of conventional refraction aids and the immediate instruction in their use are not covered, unless related to the treatment following cataract surgery.
 7. A patient, who has poor rehabilitative potential, unable to cooperate in the program, or where no clear goals are definable, will not be covered.
 8. "Maintenance," where a patient has reached a steady state in his or her rehabilitation and is seen at intervals to maintain that state, is a noncovered service.
 8. A reasonable estimate of when the goals will be reached and the frequency at which the services will be provided;
 9. Progress notes describing the treatment and time for each treatment;
 10. Discharge summary documenting the extent to which each goal in the plan of care was achieved, which is to be reviewed and signed by the physician;
 11. Physician certification and recertification.
- B. It is not expected that the rehabilitative sessions will extend beyond four weeks. If they do, a monthly written progress report must be provided by the person performing the service that has been reviewed and signed by the physician.

Noncovered ICD-9-CM Code(s):

- Use of any ICD-9-CM diagnosis code not listed in the "ICD-9-CM Diagnosis Codes That Support Medical Necessity" section of this policy will be denied.
- Use of ICD-9-CM diagnosis code V82.9 (special screening of other conditions, unspecified condition) will result in the denial of claims as noncovered screening services.

Coding Guidelines:

- Effective for dates of service January 1, 2000, optometrists may refer patients for visual outpatient rehabilitation services as well as establish and review the plan of treatment.

Documentation Requirements:

- A. Written documentation by the person conducting the sessions shall include:
1. Dated order from the referring physician or provider;
 2. Approximate exacerbation date of the patient's condition;
 3. The patient's level of cognition and motivation;
 4. The initial assessment which includes the level of visual impairment;
 5. Any treatments previously attempted;
 6. The plan of care with the specific goals to be fulfilled during rehabilitation;
 7. Definition of specific rehabilitative services to be provided during the course of rehabilitation;

Utilization Guidelines:

Services provided in connection with visual rehabilitation may be considered reasonable and necessary as follows:

Moderate Impairment

Maximum of six one-hour sessions

Severe Impairment

Maximum of eight one-hour sessions

Sessions are generally conducted over a three-month period of time with intervals appropriate to the patient's rehabilitative needs. If additional sessions are necessary, medical record documentation must indicate the need for the additional sessions.

- In accordance with CMS ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.

Other Comments:

- For services that exceed the accepted standard of medical practice and may be deemed not medically necessary, the provider/supplier must provide the patient with an acceptable advance notice of Medicare's possible denial of payment. A waiver of liability should thus be signed when a provider/supplier does not want to accept the financial responsibility for the service.
- The program of rehabilitation will be judged as completed when the treatment goals have been attained. Any subsequent services would be considered maintenance.

Financial Responsibility:

Provider Liable

The provider of the service or the ordering physician must have notified the patient in writing, prior to the service, and obtained a signature verifying Advance Beneficiary Notice. Without prior notice, services denied not medically necessary cannot be billed to the beneficiary. The provider is liable.

Beneficiary Liable

If there is clear evidence that the beneficiary was issued and signed a notice of noncoverage prior to the service, the liability rests with the beneficiary. The UB-92 Medicare bill should contain the condition code 20 and occurrence code 32, with date, to signify that notice of noncoverage was given to the beneficiary. Absence of these codes will result in a provider liable determination.

Sources of Information and Basis for Decision:

1. The American Academy of Ophthalmology Rehabilitation: "The Management of Adult Patients with Low Vision." Prepared by the American Academy of Ophthalmology Quality of Care Committee. 1994.
2. Beaver, Kathleen A., "Overview of Technology for Low Vision." *The American Journal of Occupational Therapy*, " October 1995: pages 913-921.
3. Colenbrander, August, "Basic Concepts and Terms for Low Vision Rehabilitation." *The American Journal of Occupational Therapy*, October 1995: pages 865-869
4. Lampert, Jessica, "Functional Considerations in Evaluation and Treatment of the Client with Low Vision." *The American Journal of Occupational Therapy*, October 1995, pages 885-890.
5. Massof, Robert W., "A Systems Model for Low Vision Rehabilitation," Optometry and Vision Science, Vol. 72, No. 10, pages 725-736.
6. Raasch, Thomas W., "Evaluating the Value of Low-Vision Services," *Journal of the American Optometric Association*, May 1997: pages 287-294.
7. Other Carriers' Policies (Michigan, Illinois)
8. Carrier Advisory Committee
9. Carrier Advisory Committee Members in the Specialty of Ophthalmology
10. CMS Program Memorandum AB-00-39

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 include representatives from all specialty societies and the Medical Society of the State of New York.

Start Date of Comment Period: 05/29/2001

Ending Date of Comment Period: 07/11/2001

Start Date of Notice Period: 06/01/2002

Revision History:

Revision Number	Effective Date	Reason for Revision

MEDICARE LOCAL MEDICAL REVIEW POLICY

Contractor Policy Number: DR007A00
Contractor Name: Empire Medicare Services
Contractor Number: 00308
Contractor Type: Intermediary

LMRP Title: Zoledronic Acid (Zometa®)

AMA CPT Copyright Statement:

CPT codes, descriptions, and other data only are copyright 2001 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS clauses apply.

CMS National Coverage Policy:

1. Title XVIII of the Social Security Act, Section 1862(a)(7)
This section excludes routine physical checkups and prohibits Medicare payment for routine screening services.
2. Title XVIII of the Social Security Act, Section 1862(a)(1)(A)
This section states that no Medicare payment shall be made for items or services that are not reasonable and necessary for the diagnosis or treatment of illness or injury.
3. Title XVIII of the Social Security Act, Section 1833(e)
This section prohibits Medicare payment for any claim that lacks the necessary information to process the claim.
4. Medicare Carrier's Manual, Section 2049

Primary Geographic Jurisdiction:

New York, Connecticut, Delaware, Massachusetts

CMS Region: 02

CMS Consortium: Northeast

Original Policy Effective Date: 07/01/2002

Original Policy Ending Date:

Revision Effective Date:

Revision Ending Date:

LMRP Description:

Zoledronic acid is an FDA-approved intravenous bisphosphonate for the treatment of hypercalcemia of malignancy (HCM). HCM is a life-threatening metabolic complication associated with cancer characterized by increased levels of calcium. The drug has been shown in clinical trials to normalize the serum calcium levels in approximately 88 percent of the patients tested. The recommendation is that Zoledronic acid be given as a single dose, intravenous infusion, over no less than 15 minutes. The patients must be well hydrated prior to administration of the drug. Their renal function must be closely monitored.

Indications and Limitations of Coverage and/or Medical Necessity:

Indications:

1. Zoledronic acid is covered for FDA-approved indication of hypercalcemia of malignancy (HCM).

- Based on the current literature, this policy will allow coverage for the treatment of patients with bone metastases secondary to breast cancer, prostate cancer or multiple myeloma.
- To treat patients with osteolytic lesions due to metastatic cancer.

Limitations:

- For purposes of this policy, HCM is defined as an albumin-corrected serum calcium level of >12mg/dl.
- Infusion time for zoledronic acid is usually 15 minutes. Therefore, the administration time reported should not exceed one hour. If other agents or fluids are infused at the same time, the administration may go beyond one hour.

CPT/HCPCS Section & Benefit Category:

Drugs

Type of Bill Code:

13x Hospital Outpatient
85x Critical Access Hospital

Revenue Codes:

0636 Drugs requiring detail coding

CPT/HCPCS Code(s):

C9115 Injection, zoledronic acid, per 2 mg

ICD-9-CM Diagnosis Codes That Support Medical Necessity:

TRUNCATED DIAGNOSIS CODES ARE NOT ACCEPTABLE.

ICD-9-CM code listings may cover a range and include truncated codes. It is the provider's responsibility to avoid truncated codes by selecting a code(s) carried out to the highest level of specificity and selected from the ICD-9-CM code book appropriate to the year in which the service is rendered for the claim(s) submitted.

It is not enough to link the procedure code to a correct, payable ICD-9-CM diagnosis code. The diagnosis or clinical suspicion must be present for the procedure to be paid.

- Situation 1 (must have a primary and a secondary diagnosis)**

Primary diagnosis:

275.42 Hypercalcemia
or
733.90 Bone pain

With secondary diagnosis:

174.0-174.9 Malignant neoplasm of female breast
175.0-175.9 Malignant neoplasm of male breast
185 Malignant neoplasm of prostate
198.5 Secondary malignant neoplasm of bone and bone marrow
198.81 Secondary malignant neoplasm of breast

- Situation 2 (no secondary diagnosis required)**

198.5 Secondary malignant neoplasm of bone and bone marrow

- Situation 3 (off-label indications-no secondary diagnosis required)**

174.0-174.9 Malignant neoplasm of female breast
175.0-175.9 Malignant neoplasm of male breast
203.00-203.01 Multiple myeloma

Reasons for Denial:

- A claim submitted without a valid ICD-9-CM diagnosis code will be returned as an incomplete claim under 1833(e).
- A claim submitted without one of the ICD-9-CM diagnosis codes listed in the "ICD-9-CM Diagnosis Codes That Support Medical Necessity" section of this policy will be denied under 1862(a)(1)(A).
- Claims submitted for an unusual frequency of any of these services or services ordered for a diagnosis not listed as covered in this policy will be denied as not medically necessary in the absence of supportive documentation in the patient's record.
- A claim for Zoledronic acid submitted without the UPIN number of the referring/ordering physician or qualified non-physician practitioner, will be returned as an incomplete claim under 1833(e).
- Claims that do not report the administration code on the same claim will be denied.

Noncovered ICD-9-CM Code(s):

- Use of any ICD-9-CM diagnosis code not listed in the “ICD-9-CM Diagnosis Codes That Support Medical Necessity” section of this policy will be denied.

Coding Guidelines:

1. This policy does not take precedence over the Correct Coding Initiative (CCI).
2. Infusion of fluids for hydration (e.g., saline) can be reported on the same day as zoledronic acid, using the appropriate hydrating solution and infusion codes. All codes must be reported on the same claim.
3. Claims for zoledronic acid must report the primary and secondary diagnoses as required.

Documentation Requirements:

1. Documentation supporting the medical necessity, such as ICD-9-CM diagnosis codes, must be submitted with each claim. Claims submitted without such evidence will be denied as not medically necessary.
2. Documentation must be available to Medicare upon request.
3. When a portion of the drug is discarded, the medical record must clearly document the amount administered and the amount wasted. This documentation must be available to the intermediary upon request.

Other Comments:

1. For services that exceed the accepted standard of medical practice and may be deemed not medically necessary, the provider/supplier must provide the patient with an acceptable advance notice of Medicare’s possible denial of payment. A waiver of liability should thus be signed when a provider/supplier does not want to accept the financial responsibility for the service.
2. The normal dosage for zoledronic acid is 4 mg. The expected administration of this agent is generally twice in 60 days.
3. In accordance with CMS Ruling 95-1 (V), utilization of these services should be consistent with locally acceptable standards of practice.
4. When used for FDA-approved indications, the frequency of administration should not exceed that specified in the package insert. When used for compendia or peer review supported literature, the frequency should not exceed that specified in the supported compendia/literature.

5. This policy is effective for dates of service on or after January 1, 2002

Financial Responsibility:Provider Liable

The provider of the service or the ordering physician must have notified the patient in writing, prior to the service, and obtained a signature verifying Advance Beneficiary Notice. Without prior notice, services denied as not medically necessary cannot be billed to the beneficiary. The provider is liable.

Beneficiary Liable

If there is clear evidence that the beneficiary was issued and signed a notice of noncoverage prior to the service, the liability rests with the beneficiary. The UB-92 Medicare bill should contain the condition code 20 and occurrence code 32, with date, to signify that notice of noncoverage was given to the beneficiary. Absence of these codes will result in a provider liable determination.

Sources of Information and Basis for Decision:

1. Berenson, James, M.D. et al, “Zoledronic Acid Reduces Skeletal-Related Events in Patients with Osteolytic Metastases.” *Cancer*, April 1, 2001, Vol. 91, Number 7
2. Major, P et al, “Zoledronic Acid is Superior Pamidronate in the Treatment of Hypercalcemia of Malignancy: A Pooled Analysis of Two Randomized, Controlled Clinical Trials,” *Journal of Clinical Oncology*, January 15, 2001, Vol. 19, No. 2.
3. Novartis Corporation press release, “FDA Approves Novartis Agent Zometa® for Treatment of Hypercalcemia of Malignancy,” August 20, 2001
4. Yarbrow, John, M.D., Mastrandello, Michael, M.D., “Advances in the Treatment of Malignant Metastatic Bone Disease with Zoledronic Acid (Zometa),” *Seminars in Oncology*, April, 2001, Vol. 28, No. 2, Suppl. 6
5. Rosen, Lee S., M.D. et al, “Zoledronic Acid versus Pamidronate in the Treatment of Skeletal Metastases in Patients with Breast Cancer or Osteolytic Lesions of Multiple Myeloma: A Phase III, Double-Blind, Comparative Trial,” *The Cancer Journal*, September/October 2001, Vol. 7, No. 5
6. Package insert for Zometa from Novartis Pharmaceuticals Corporation
7. New Products Newswire, Drug Topics 2001; 17:65.

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 include representatives from all specialty societies and the Medical Society of the State of New York.

Start Date of Comment Period: 03/11/2002

End Date of Comment Period: 04/25/2002

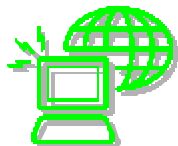
Start Date of Notice Period: 06/01/2002

Revision History:

Revision Number	Effective Date	Reason for Revision

New Source of Provider Information Available on the CMS Web Site

The Centers for Medicare and Medicaid Services (CMS) released the first issue of *The CMS Quarterly Provider Update* on April 22, 2002. Future issues will be released the first work day of each subsequent calendar quarter. These quarterly *Updates* will include all changes to Medicare instructions that affect providers, or may be of interest to them. They will provide a single source for national Medicare provider information and give providers advance notice of upcoming instructions and regulations.



The first release is a Web-based document and is available at <http://www.cms.hhs.gov/providerupdate>. For ease of use by individual providers, regulations and instructions are collated and sorted based on the interests of the user.

Each *Update* will include the full text of instructions to be implemented 90 or more days after its release. For example, instructions included in the April *Update* will have an implementation date of July 1, 2002 or later. The listings of regulations will be presented in two parts. One part will list all regulations CMS plans to publish within the next 90 days. The second part will include hyperlinks to the text of all regulations published in the previous quarter.

CMS's goal is to make it easier for providers to understand and comply with Medicare regulations and instructions and to give them time to review and react to upcoming program changes. To improve future issues of the *Update* and ensure they are responsive to provider needs, a feedback form will be included with each issue. CMS encourages anyone accessing the *Update* to use the feedback form to forward comments on its utility, organization and format.

EMPIRE MEDICARE SERVICES

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