

Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

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10 - Diagnostic Blood Pressure Monitoring
(Rev. 109, 02-27-04)

10.1 - Ambulatory Blood Pressure Monitoring (ABPM) Billing Requirements

(Rev. 795, Issued: 12-30-05; Effective: 10-01-04; Implementation: 04-03-06)

A. Coding Applicable to Local Carriers & Fiscal Intermediaries (FIs)

Effective April 1, 2002, a National Coverage Decision was made to allow for Medicare coverage of ABPM for those beneficiaries with suspected "white coat hypertension" (WCH). ABPM involves the use of a non-invasive device, which is used to measure blood pressure in 24-hour cycles. These 24-hour measurements are stored in the device and are later interpreted by a physician. Suspected "WCH" is defined as: (1) Clinic/office blood pressure >140/90 mm Hg on at least three separate clinic/office visits with two separate measurements made at each visit; (2) At least two documented separate blood pressure measurements taken outside the clinic/office which are < 140/90 mm Hg; and (3) No evidence of end-organ damage. ABPM is not covered for any other uses. Coverage policy can be found in Medicare National Coverage Determinations Manual, Chapter 1, Section 20.19. (www.cms.hhs.gov/masnuals/103_cov_determ/ncd103index.asp).

The ABPM must be performed for at least 24 hours to meet coverage criteria. Payment is not allowed for institutionalized beneficiaries, such as those receiving Medicare covered skilled nursing in a facility. In the rare circumstance that ABPM needs to be performed more than once for a beneficiary, the qualifying criteria described above must be met for each subsequent ABPM test.

Effective dates for applicable Common Procedure Coding System (HCPCS) codes for ABPM for suspected WCH and their covered effective dates are as follows:

HCPCS	Definition	Effective Date
93784	ABPM, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; including recording, scanning analysis, interpretation and report.	04/01/2002
93786	ABPM, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; recording only.	04/01/2002
93788	ABPM, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; scanning analysis with report.	01/01/2004

HCPCS Definition Effective Date

93790	ABPM, utilizing a system such as magnetic tape and/or computer disk, for 24 hours or longer; physician review with interpretation and report.	04/01/2002
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In addition, the following diagnosis code must be present:

Diagnosis Code	Description
796.2	Elevated blood pressure reading without diagnosis of hypertension.

B. FI Billing Instructions

The applicable types of bills acceptable when billing for ABPM services are 13X, 23X, 71X, 73X, 75X, and 85X. Chapter 25 of this manual provides general billing instructions that must be followed for bills submitted to FIs. The FIs pay for hospital outpatient ABPM services billed on a 13X type of bill with HCPCS 93786 and/or 93788 as follows: (1) Outpatient Prospective Payment System (OPPS) hospitals pay based on the Ambulatory Payment Classification (APC); (2) non-OPPS hospitals (Indian Health Services Hospitals, Hospitals that provide Part B services only, and hospitals located in American Samoa, Guam, Saipan and the Virgin Islands) pay based on reasonable cost, except for Maryland Hospitals which are paid based on a percentage of cost. Effective 4/1/06, type of bill 14X is for non-patient laboratory specimens and is no longer applicable for ABPM.

The FIs pay for comprehensive outpatient rehabilitation facility (CORF) ABPM services billed on a 75x type of bill with HCPCS code 93786 and/or 93788 based on the Medicare Physician Fee Schedule (MPFS) amount for that HCPCS code.

The FIs pay for ABPM services for critical access hospitals (CAHs) billed on a 85x type of bill as follows: (1) for CAHs that elected the Standard Method and billed HCPCS code 93786 and/or 93788, pay based on reasonable cost for that HCPCS code; and (2) for CAHs that elected the Optional Method and billed any combination of HCPCS codes 93786, 93788 and 93790 pay based on reasonable cost for HCPCS 93786 and 93788 and pay 115% of the MPFS amount for HCPCS 93790.

The FIs pay for ABPM services for skilled nursing facility (SNF) outpatients billed on a 23x type of bill with HCPCS code 93786 and/or 93788, based on the MPFS.

The FIs accept independent and provider-based rural health clinic (RHC) bills for visits under the all-inclusive rate when the RHC bills on a 71x type of bill with revenue code 052x for providing the professional component of ABPM services. The FIs should not make a separate payment to a RHC for the professional component of ABPM services in

addition to the all-inclusive rate. RHCs are not required to use ABPM HCPCS codes for professional services covered under the all-inclusive rate.

The FIs accept free-standing and provider-based federally qualified health center (FQHC) bills for visits under the all-inclusive rate when the FQHC bills on a 73x type of bill with revenue code 052x for providing the professional component of ABPM services.

The FIs should not make a separate payment to a FQHC for the professional component of ABPM services in addition to the all-inclusive rate. FQHCs are not required to use ABPM HCPCS codes for professional services covered under the all-inclusive rate.

The FIs pay provider-based RHCs/FQHCs for the technical component of ABPM services when billed under the base provider's number using the above requirements for that particular base provider type, i.e., a OPSS hospital based RHC would be paid for the ABPM technical component services under the OPSS using the APC for code 93786 and/or 93788 when billed on a 13x type of bill.

Independent and free-standing RHC/FQHC practitioners are only paid for providing the technical component of ABPM services when billed to the carrier following the carrier instructions.

C. Carrier Claims

Local carriers pay for ABPM services billed with diagnosis code 796.2 and HCPCS codes 93784 or for any combination of 93786, 93788 and 93790, based on the MPFS for the specific HCPCS code billed.

D. Coinsurance and Deductible

The FIs and local carriers shall apply coinsurance and deductible to payments for ABPM services except for services billed to the FI by FQHCs. For FQHCs only co-insurance applies.

11 - Wound Treatments

(Rev 124a, 03-19-04)

11.1 - Electrical Stimulation

(Rev. 371, Issued 11-19-04, Effective: 04-01-05, Implementation: 04-04-05)

A. Coding Applicable to Carriers & Fiscal Intermediaries (FIs)

Effective April 1, 2003, a National Coverage Decision was made to allow for Medicare coverage of Electrical Stimulation for the treatment of certain types of wounds. The type of wounds covered are chronic Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers. All other uses of electrical stimulation for the

treatment of wounds are not covered by Medicare. Electrical stimulation will not be covered as an initial treatment modality.

The use of electrical stimulation will only be covered after appropriate standard wound care has been tried for at least 30 days and there are no measurable signs of healing. If electrical stimulation is being used, wounds must be evaluated periodically by the treating physician but no less than every 30 days by a physician. Continued treatment with electrical stimulation is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment. Additionally, electrical stimulation must be discontinued when the wound demonstrates a 100% epithelialized wound bed.

Coverage policy can be found in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 270.1 (http://www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp)

The applicable Healthcare Common Procedure Coding System (HCPCS) code for Electrical Stimulation and the covered effective date is as follows:

HCPCS	Definition	Effective Date
G0281	Electrical Stimulation, (unattended), to one or more areas for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care.	04/01/2003

Medicare will not cover the device used for the electrical stimulation for the treatment of wounds. However, Medicare will cover the service. Unsupervised home use of electrical stimulation will not be covered.

B. FI Billing Instructions

The applicable types of bills acceptable when billing for electrical stimulation services are 12X, 13X, 22X, 23X, 71X, 73X, 74X, 75X, and 85X. Chapter 25 of this manual provides general billing instructions that must be followed for bills submitted to FIs. FIs pay for electrical stimulation services under the Medicare Physician Fee Schedule for a hospital, Comprehensive Outpatient Rehabilitation Facility (CORF), Outpatient Rehabilitation Facility (ORF), Outpatient Physical Therapy (OPT) and Skilled Nursing Facility (SNF).

Payment methodology for independent Rural Health Clinic (RHC), provider-based RHCs, free-standing Federally Qualified Health Center (FQHC) and provider based FQHCs is made under the all-inclusive rate for the visit furnished to the RHC/FQHC patient to obtain the therapy service. Only one payment will be made for the visit furnished to the

RHC/FQHC patient to obtain the therapy service. As of April 1, 2005, RHCs/FQHCs are no longer required to report HCPCS codes when billing for these therapy services.

Payment Methodology for a Critical Access Hospital (CAH) is on a reasonable cost basis unless the CAH has elected the Optional Method and then the FI pays 15% of the MPFS amount for the professional component of the HCPCS code in addition to the technical component.

In addition, the following revenues code must be used in conjunction with the HCPCS code identified:

Revenue Code	Description
420	Physical Therapy
430	Occupational Therapy
520	Federal Qualified Health Center *
521	Rural Health Center *
977, 978	Critical Access Hospital- method II CAH professional services only

* **NOTE:** As of April 1, 2005, RHCs/FQHCs are no longer required to report HCPCS codes when billing for these therapy services.

C. Carrier Claims

Carriers pay for Electrical Stimulation services billed with HCPCS codes G0281 based on the MPFS. Claims for Electrical Stimulation services must be billed on Form CMS-1500 or the electronic equivalent following instructions in chapter 12 of this manual (http://www.cms.hhs.gov/manuals/104_claims/clm104c12.pdf).

D. Coinsurance and Deductible

The Medicare contractor shall apply coinsurance and deductible to payments for these therapy services except for services billed to the FI by FQHCs. For FQHCs, only coinsurance applies.

11.2 - Electromagnetic Therapy

(Rev. 371, Issued 11-19-04, Effective: 04-01-05, Implementation: 04-04-05)

A. HCPCS Coding Applicable to Carriers & Fiscal Intermediaries (FIs)

Effective July 1, 2004, a National Coverage Decision was made to allow for Medicare coverage of electromagnetic therapy for the treatment of certain types of wounds. The type of wounds covered are chronic Stage III or Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers. All other uses of electromagnetic therapy for the treatment of wounds are not covered by Medicare. Electromagnetic therapy will not be covered as an initial treatment modality.

The use of electromagnetic therapy will only be covered after appropriate standard wound care has been tried for at least 30 days and there are no measurable signs of healing. If electromagnetic therapy is being used, wounds must be evaluated periodically by the treating physician but no less than every 30 days by a physician. Continued treatment with electromagnetic therapy is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment. Additionally, electromagnetic therapy must be discontinued when the wound demonstrates a 100% epithelialized wound bed.

Coverage policy can be found in Pub. 100-03, Medicare National Coverage Determinations Manual, Chapter 1, Section 270.1.

(www.cms.hhs.gov/manuals/103_cov_determ/ncd103index.asp)

The applicable Healthcare Common Procedure Coding System (HCPCS) code for Electrical Stimulation and the covered effective date is as follows:

HCPCS	Definition	Effective Date
G0329	Electromagnetic Therapy, to one or more areas for chronic Stage III and Stage IV pressure ulcers, arterial ulcers, diabetic ulcers and venous stasis ulcers not demonstrating measurable signs of healing after 30 days of conventional care as part of a therapy plan of care.	07/01/2004

Medicare will not cover the device used for the electromagnetic therapy for the treatment of wounds. However, Medicare will cover the service. Unsupervised home use of electromagnetic therapy will not be covered.

B. FI Billing Instructions

The applicable types of bills acceptable when billing for electromagnetic therapy services are 12X, 13X, 22X, 23X, 71X, 73X, 74X, 75X, and 85X. Chapter 25 of this manual provides general billing instructions that must be followed for bills submitted to FIs. FIs pay for electromagnetic therapy services under the Medicare Physician Fee Schedule for a hospital, CORF, ORF, and SNF.

Payment methodology for independent (RHC), provider-based RHCs, free-standing FQHC and provider based FQHCs is made under the all-inclusive rate for the visit furnished to the RHC/FQHC patient to obtain the therapy service. Only one payment will be made for the visit furnished to the RHC/FQHC patient to obtain the therapy service. As of April 1, 2005, RHCs/FQHCs are no longer required to report HCPCS codes when billing for the therapy service.

Payment Methodology for a CAH is payment on a reasonable cost basis unless the CAH has elected the Optional Method and then the FI pays pay 115% of the MPFS amount for the professional component of the HCPCS code in addition to the technical component.

In addition, the following revenues code must be used in conjunction with the HCPCS code identified:

Revenue Code	Description
420	Physical Therapy
430	Occupational Therapy
520	Federal Qualified Health Center *
521	Rural Health Center *
977, 978	Critical Access Hospital- method II CAH professional services only

* **NOTE:** As of April 1, 2005, RHCs/FQHCs are no longer required to report HCPCS codes when billing for the therapy service.

C. Carrier Claims

Carriers pay for Electromagnetic Therapy services billed with HCPCS codes G0329 based on the MPFS. Claims for electromagnetic therapy services must be billed on Form CMS-1500 or the electronic equivalent following instructions in chapter 12 of this manual (www.cms.hhs.gov/manuals/104_claims/clm104index.asp).

Payment information for HCPCS code G0329 will be added to the July 2004 update of the Medicare Physician Fee Schedule Database (MPFSD).

D. Coinsurance and Deductible

The Medicare contractor shall apply coinsurance and deductible to payments for electromagnetic therapy services except for services billed to the FI by FQHCs. For FQHCs only co-insurance applies.

12 - Smoking and Tobacco-Use Cessation Counseling Services (Rev. 562, Issued: 05-20-05; Effective: 03-22-05; Implementation: 07-05-05)

Background: Effective for services furnished on or after March 22, 2005, a National Coverage Determination (NCD) provides for coverage of smoking and tobacco-use cessation counseling services. Conditions of Medicare Part A and Medicare Part B coverage for smoking and tobacco-use cessation counseling services are located in the Medicare National Coverage Determinations Manual, Publication 100-3, section 210.4.

12.1 - HCPCS and Diagnosis Coding (Rev. 1433, Issued: 02-01-08, Effective: 01-01-08, Implementation: 07-07-08)

The following HCPCS codes should be reported when billing for smoking and tobacco- use cessation counseling services:

99406 - Smoking and tobacco-use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes

99407 - Smoking and tobacco-use cessation counseling visit; intensive, greater than 10 minutes

Note the above codes are payable for dates of service on or after January 1, 2008. Codes G0375 and G0376, below, are not valid or payable for dates of service on or after January 1, 2008.

G0375 - Smoking and tobacco-use cessation counseling visit; intermediate, greater than 3 minutes up to 10 minutes

Short Descriptor: Smoke/Tobacco counseling 3-10

G0376 - Smoking and tobacco-use cessation counseling visit; intensive, greater than 10 minutes

Short Descriptor: Smoke/Tobacco counseling greater than 10

NOTE: The above G codes will NOT be active in contractors' systems until July 5, 2005. Therefore, contractors shall advise providers to use unlisted code 99199 to bill for smoking and tobacco- use cessation counseling services during the interim period of March 22, 2005, through July 4, 2005, and received prior to July 5, 2005.

On July 5, 2005, contractors' systems will accept the new G codes for services performed on and after March 22, 2005.

Contractors shall allow payment for a medically necessary E/M service on the same day as the smoking and tobacco-use cessation counseling service when it is clinically appropriate. Physicians and qualified non-physician practitioners shall use an appropriate HCPCS code,

such as HCPCS 99201– 99215, to report an E/M service with modifier 25 to indicate that the E/M service is a separately identifiable service from G0375 or G0376.

Contractors shall only pay for 8 Smoking and Tobacco-Use Cessation Counseling sessions in a 12-month period. The beneficiary may receive another 8 sessions during a second or subsequent year after 11 full months have passed since the first Medicare covered cessation session was performed. To start the count for the second or subsequent 12-month period, begin with the month after the month in which the first Medicare covered cessation session was performed and count until 11 full months have elapsed.

Claims for smoking and tobacco use cessation counseling services shall be submitted with an appropriate diagnosis code. Diagnosis codes should reflect: the condition the patient has that is adversely affected by tobacco use or the condition the patient is being treated for with a therapeutic agent whose metabolism or dosing is affected by tobacco use.

NOTE: This decision does not modify existing coverage for minimal cessation counseling (defined as 3 minutes or less in duration) which is already considered to be covered as part of each Evaluation and Management (E/M) visit and is not separately billable.

12.2 - Carrier Billing Requirements

(Rev. 1433, Issued: 02-01-08, Effective: 01-01-08, Implementation: 07-07-08)

Carriers shall pay for counseling services billed with codes 99406 and 99407 for dates of service on or after January 1, 2008. Carriers shall pay for counseling services billed with codes G0375 and G0376 for dates of service performed on and after March 22, 2005 through Dec. 31, 2007. The type of service (TOS) for each of the new codes is 1.

Carriers pay for counseling services billed based on the Medicare Physician Fee Schedule (MPFS). Deductible and coinsurance apply. Claims from physicians or other providers where assignment was not taken are subject to the Medicare limiting charge, which means that charges to the beneficiary may be no more than 115 percent of the allowed amount.

Physicians or qualified non-physician practitioners shall bill the carrier for smoking and tobacco-use cessation counseling services on the Form CMS-1500 or an approved electronic format.

12.3 - FI Billing Requirements

(Rev. 1593, Issued: 09-12-08; Effective Date: 07-01-08; Implementation Date: 12-12-08)

The FIs shall pay for Smoking and Tobacco-Use Cessation Counseling services with codes 99406 and 99407 for dates of service on or after January 1, 2008. FIs shall pay for counseling services billed with codes G0375 and G0376 for dates of service performed on or after March 22, 2005 through December 31, 2007.

A. Claims for Smoking and Tobacco-Use Cessation Counseling Services should be submitted on Form CMS-1450 or its electronic equivalent.

The applicable bill types are 12X, 13X, 22X, 23X, 34X, 71X, 73X, 83X, and 85X. Effective 4/1/06, type of bill 14X is for non-patient laboratory specimens and is no longer applicable for Smoking and Tobacco-Use Cessation Counseling services.

Applicable revenue codes are as follows:

Provider Type	Revenue Code
Rural Health Centers (RHCs)/Federally Qualified Health Centers (FQHCs)	052X
Indian Health Services (IHS)	0510
Critical Access Hospitals (CAHs) Method II	096X, 097X, 098X
All Other Providers	0942

NOTE: When these services are provided by a clinical nurse specialist in the RHC/FQHC setting, they are considered “incident to” and do not constitute a billable visit.

Payment for outpatient services is as follows:

Type of Facility	Method of Payment
Rural Health Centers (RHCs)/Federally Qualified Health Centers (FQHCs)	All-inclusive rate (AIR) for the encounter
Indian Health Service (IHS)/Tribally owned or operated hospitals and hospital- based facilities	All-inclusive rate (AIR)
IHS/Tribally owned or operated non-hospital-based facilities	Medicare Physician Fee Schedule (MPFS)
IHS/Tribally owned or operated Critical Access Hospitals (CAHs)	Facility Specific Visit Rate
Hospitals subject to the Outpatient Prospective Payment System (OPPS)	Ambulatory Payment Classification (APC)
Hospitals not subject to OPPS	Payment is made under current methodologies
Skilled Nursing Facilities (SNFs)	Medicare Physician Fee Schedule (MPFS)
NOTE: Included in Part A PPS for skilled patients.	
Home Health Agencies (HHAs)	Medicare Physician Fee Schedule (MPFS)

Critical Access Hospitals (CAHs)	Method I: Technical services are paid at 101% of reasonable cost. Method II: technical services are paid at 101% of reasonable cost, and Professional services are paid at 115% of the MMPFS Data Base
Maryland Hospitals	Payment is based according to the Health Services Cost Review Commission (HSCRC). That is 94% of submitted charges subject to any unmet deductible, coinsurance, and non-covered charges policies.

NOTE: Inpatient claims submitted with Smoking and Tobacco-Use Cessation Counseling Services are processed under the current payment methodologies.

12.4 - Remittance Advice (RA) Notices

(Rev. 605, Issued: 07-15-05, Effective: 10-01-05, Implementation: 10-03-05)

Contractors shall use the appropriate claim RA(s) when denying payment for smoking and tobacco-use cessation counseling services.

The following messages are used where applicable:

- If the counseling services were furnished before March 22, 2005, use an appropriate RA claim adjustment reason code, such as, 26, “Expenses incurred prior to coverage.”
- If the claim for counseling services is being denied because the coverage criteria are not met, use an appropriate reason code, such as, B5, “Payment adjusted because coverage/program guidelines were not met or were exceeded.”

If the claim for counseling services is being denied because the maximum benefit has been reached, use an appropriate RA claim adjustment reason code, such as, 119, “Benefit maximum for this time period or occurrence has been reached.”

12.5 - Medicare Summary Notices (MSNs)

(Rev. 671, Issued: 09-09-05, Effective: 10-01-05, Implementation: 10-03-05)

When denying claims for counseling services that were performed prior to the effective date of coverage, contractors shall use an appropriate MSN, such as, MSN 21.11, “This service was not covered by Medicare at the time you received it.”

When denying claims for counseling services on the basis that the coverage criteria were not met, use an appropriate MSN, such as MSN 21.21, “This service was denied because Medicare only covers this service under certain circumstances.”

When denying claims for counseling services that have dates of service exceeding the maximum benefit allowed, use an appropriate MSN, such as MSN 16.25, “Medicare does not pay for this much equipment, or this many services or supplies.”

12.6 - Post-Payment Review for Smoking and Tobacco-Use Cessation Counseling Services

(Rev. 562, Issued: 05-20-05; Effective: 03-22-05; Implementation: 07-05-05)

As with any claim, Medicare may decide to conduct post-payment reviews to determine that the services provided are consistent with coverage instructions. Providers must keep patient record information on file for each Medicare patient for whom a Smoking and Tobacco-Use Cessation Counseling claim is made. These medical records can be used in any post-payment reviews and must include standard information along with sufficient patient histories to allow determination that the steps required in the coverage instructions were followed.

12.7 - Common Working File (CWF) Inquiry

(Rev. 818, Issued: 01-24-06; Effective: 04-01-06; Implementation: 04-03-06)

The Common Working File (CWF) maintains the number of smoking and tobacco-use cessation counseling sessions rendered to a beneficiary. By entering the beneficiary’s health insurance claim number (HICN), providers have the capability to view the number of sessions a beneficiary has received for this service via inquiry through CWF.

12.8 - Provider Access to Smoking and Tobacco-Use Cessation Counseling Services Eligibility Data

(Rev. 1000, Issued: 07-19-06; Effective: 10-01-06; Implementation: 10-02-06)

Providers may access coverage period remaining smoking and tobacco-use cessation counseling sessions and a next eligible date, when there are no remaining sessions, through the 270/271 eligibility inquiry and response transaction.

30 - Hyperbaric Oxygen (HBO) Therapy

(Rev. 187, 05-28-04)

30.1 - Billing Requirements for HBO Therapy for the Treatment of Diabetic Wounds of the Lower Extremities

(Rev. 1472, Issued: 03-06-08, Effective: 05-23-07, Implementation: 04-07-08)

Hyperbaric Oxygen Therapy is a modality in which the entire body is exposed to oxygen under increased atmospheric pressure. Effective April 1, 2003, a National Coverage Decision expanded the use of HBO therapy to include coverage for the treatment of diabetic wounds of the lower extremities. For specific coverage criteria for HBO Therapy, refer to the National Coverage Determinations Manual, chapter 1, section 20.29.

NOTE: Topical application of oxygen does not meet the definition of HBO therapy as stated above. Also, its clinical efficacy has not been established. Therefore, no Medicare reimbursement may be made for the topical application of oxygen.

I. Billing Requirements for Intermediaries

Claims for HBO therapy should be submitted on Form CMS-1450 or its electronic equivalent.

a. Applicable Bill Types

The applicable hospital bill types are 11X, 13X and 85X.

b. Procedural Coding

- 99183 – Physician attendance and supervision of hyperbaric oxygen therapy, per session.
- C1300 – Hyperbaric oxygen under pressure, full body chamber, per 30-minute interval.

NOTE: Code C1300 is not available for use other than in a hospital outpatient department. In skilled nursing facilities (SNFs), HBO therapy is part of the SNF PPS payment for beneficiaries in covered Part A stays.

For hospital inpatients and critical access hospitals (CAHs) not electing Method I, HBO therapy is reported under revenue code 940 without any HCPCS code. For inpatient services, show ICD-9-CM procedure code 93.59.

For CAHs electing Method I, HBO therapy is reported under revenue code 940 along with HCPCS code 99183.

c. Payment Requirements for Intermediaries

Payment is as follows:

Intermediary payment is allowed for HBO therapy for diabetic wounds of the lower extremities when performed as a physician service in a hospital outpatient setting and for inpatients. Payment is allowed for claims with valid diagnostic ICD-9 codes as shown above with dates of service on or after April 1, 2003. Those claims with invalid codes should be denied as not medically necessary.

For hospitals, payment will be based upon the Ambulatory Payment Classification (APC) or the inpatient Diagnosis Related Group (DRG). Deductible and coinsurance apply.

Payment to Critical Access Hospitals (electing Method I) is made under cost reimbursement. For Critical Access Hospitals electing Method II, the technical component is paid under cost reimbursement and the professional component is paid under the Physician Fee Schedule.

NOTE: Information regarding the form locator numbers that correspond to these data element names and a table to crosswalk UB-04 form locators to the 837 transaction is found in Chapter 25.

II. Carrier Billing Requirements

Claims for this service should be submitted on Form CMS-1500 or its electronic equivalent.

The following HCPCS code applies:

- 99183 – Physician attendance and supervision of hyperbaric oxygen therapy, per session.

a. Payment Requirements for Carriers

Payment and pricing information will occur through updates to the Medicare Physician Fee Schedule Database (MPFSDB). Pay for this service on the basis of the MPFSDB. Deductible and coinsurance apply. Claims from physicians or other practitioners where assignment was not taken, are subject to the Medicare limiting charge.

III. Medicare Summary Notices (MSNs)

Use the following MSN Messages where appropriate:

In situations where the claim is being denied on the basis that the condition does not meet our coverage requirements, use one of the following MSN Messages:

“Medicare does not pay for this item or service for this condition.” (MSN Message 16.48)

The Spanish version of the MSN message should read:

“Medicare no paga por este artículo o servicio para esta afección.”

In situations where, based on the above utilization policy, medical review of the claim results in a determination that the service is not medically necessary, use the following MSN message:

“The information provided does not support the need for this service or item.” (MSN Message 15.4)

The Spanish version of the MSN message should read:

“La informacion proporcionada no confirma la necesidad para este servicio o articulo.”

IV. Remittance Advice Notices

Use appropriate existing remittance advice and reason codes at the line level to express the specific reason if you deny payment for HBO therapy for the treatment of diabetic wounds of lower extremities.

40 – Sacral Nerve Stimulation (Rev. 125, 03-26-04)

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

40.1 – Coverage Requirements (Rev. 125, 03-26-04)

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

The following limitations for coverage apply to all indications:

- o Patient must be refractory to conventional therapy (documented behavioral, pharmacologic and/or surgical corrective therapy) and be an appropriate surgical candidate such that implantation with anesthesia can occur.

- o Patients with stress incontinence, urinary obstruction, and specific neurologic diseases (e.g., diabetes with peripheral nerve involvement) that are associated with secondary manifestations of the above three indications are excluded.

- o Patient must have had a successful test stimulation in order to support subsequent implantation. Before a patient is eligible for permanent implantation, he/she must demonstrate a 50% or greater improvement through test stimulation. Improvement is measured through voiding diaries.

- o Patient must be able to demonstrate adequate ability to record voiding diary data such that clinical results of the implant procedure can be properly evaluated.

40.2 – Billing Requirements **(Rev. 125, 03-26-04)**

40.2.1 – Healthcare Common Procedural Coding System (HCPCS) **(Rev. 125, 03-26-04)**

64561 - Percutaneous implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)

64581 - Incision for implantation of neurostimulator electrodes; sacral nerve (transforaminal placement)

64585 - Revision or removal of peripheral neurostimulator electrodes

64590 - Incision and subcutaneous placement of peripheral neurostimulator pulse generator or receiver, direct or inductive coupling

64595 - Revision or removal of peripheral neurostimulator pulse generator or receiver

A4290 - Sacral nerve stimulation test lead, each

E0752 - Implantable neurostimulator electrodes, each

E0756 - Implantable neurostimulator pulse generator

C1767 - Generator, neurostimulator (implantable)

C1778 - Lead, neurostimulator (implantable)

C1883 - Adaptor/extension, pacing lead or neurostimulator lead (implantable)

C1897 - Lead, neurostimulator test kit (implantable)

NOTE: The "C" codes listed above are only applicable when billing under the hospital outpatient prospective payment system (OPPS). They should be reported in place of codes A4290, E0752 and E0756.

40.2.2 – Payment Requirements for Test Procedures (HCPCS Codes 64585, 64590 and 64595) **(Rev. 125, 03-26-04)**

Payment is as follows:

- o Hospital outpatient departments – OPPS

- o Critical access hospital (CAH) - Reasonable cost
- o Comprehensive outpatient rehabilitation facility - Medicare physician fee schedule (MPFS)
- o Rural health clinics/federally qualified health centers (RHCs/FQHCs) - All inclusive rate, professional component only. The technical component is outside the scope of the RHC/FQHC benefit. Therefore, the provider of that technical service bills their carrier on Form CMS-1500 and payment is made under the MPFS. For provider-based RHCs/FQHCs payment for the technical component is made as indicated above based on the type of provider the RHC/FQHC is based with.

Deductible and coinsurance apply.

40.2.3 – Payment Requirements for Device Codes A4290, E0752 and E0756

(Rev. 125, 03-26-04)

Payment is made on a reasonable cost basis when these devices are implanted in a CAH.

40.2.4 – Payment Requirements for Codes C1767, C1778, C1883 and C1897

(Rev. 125, 03-26-04)

Only hospital outpatient departments report these codes. Payment is made under OPPTS.

40.3 – Bill Types

(Rev. 795, Issued: 12-30-05; Effective: 10-01-04; Implementation: 04-03-06)

The applicable bill types for test stimulation procedures are 13X, 71X, 73X, 75X and 85X.

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

The technical component for a provider-based RHC/FQHC is typically furnished by the provider. The provider of that service bills you under bill type 13X, or 85X as appropriate using their outpatient provider number (not the RHC/FQHC provider number since these services are not covered as RHC/FQHC services.) Effective 4/1/06, type of bill 14X is for non-patient laboratory specimens and is no longer applicable for test stimulation procedures.

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

40.4 – Revenue Codes **(Rev. 125, 03-26-04)**

The applicable revenue code for the test procedures is 920 except for RHCs/FQHCs who report these procedures under revenue code 521.

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

The applicable revenue code for the device codes C1767, C1778, C1883 and C1897, provided in a hospital outpatient department is 272, 274, 275, 276, 278, 279, 280, 289, 290 or 624 as appropriate. The applicable revenue code for device codes A4290, E0752 and E0756 provided in a CAH is 290.

40.5 – Claims Editing **(Rev. 125, 03-26-04)**

Nationwide claims processing edits for pre or post payment review of claim(s) for sacral nerve stimulation are not being required at this time. Contractors may develop local medical review policy and edits for such claim(s).

50 – Deep Brain Stimulation for Essential Tremor and Parkinson’s Disease **(Rev. 128, 03-26-04)**

Deep brain stimulation (DBS) refers to high-frequency electrical stimulation of anatomic regions deep within the brain utilizing neurosurgically implanted electrodes. These DBS electrodes are stereotactically placed within targeted nuclei on one (unilateral) or both (bilateral) sides of the brain. There are currently three targets for DBS -- the thalamic ventralis intermedius nucleus (VIM), subthalamic nucleus (STN) and globus pallidus interna (GPi).

Essential tremor (ET) is a progressive, disabling tremor most often affecting the hands. ET may also affect the head, voice and legs. The precise pathogenesis of ET is unknown. While it may start at any age, ET usually peaks within the second and sixth decades. Beta-adrenergic blockers and anticonvulsant medications are usually the first line treatments for reducing the severity of tremor. Many patients, however, do not adequately respond or cannot tolerate these medications. In these medically refractory ET patients, thalamic VIM DBS may be helpful for symptomatic relief of tremor.

Parkinson’s disease (PD) is an age-related progressive neurodegenerative disorder involving the loss of dopaminergic cells in the substantia nigra of the midbrain. The disease is characterized by tremor, rigidity, bradykinesia and progressive postural instability. Dopaminergic medication is typically used as a first line treatment for reducing

the primary symptoms of PD. However, after prolonged use, medication can become less effective and can produce significant adverse events such as dyskinesias and other motor function complications. For patients who become unresponsive to medical treatments and/or have intolerable side effects from medications, DBS for symptom relief may be considered.

50.1 – Coverage Requirements (Rev. 128, 03-26-04)

Effective on or after April 1, 2003, Medicare will cover unilateral or bilateral thalamic VIM DBS for the treatment of ET and/or Parkinsonian tremor and unilateral or bilateral STN or GPi DBS for the treatment of PD only under the following conditions:

1. Medicare will only consider DBS devices to be reasonable and necessary if they are Food and Drug Administration (FDA) approved devices for DBS or devices used in accordance with FDA approved protocols governing Category B Investigational Device Exemption (IDE) DBS clinical trials.

2. For thalamic VIM DBS to be considered reasonable and necessary, patients must meet all of the following criteria:

- a. Diagnosis of essential tremor (ET) based on postural or kinetic tremors of hand(s) without other neurologic signs, or diagnosis of idiopathic PD (presence of at least 2 cardinal PD features (tremor, rigidity or bradykinesia)) which is of a tremor- dominant form.
- b. Marked disabling tremor of at least level 3 or 4 on the Fahn-Tolosa-Marin Clinical Tremor Rating Scale (or equivalent scale) in the extremity intended for treatment, causing significant limitation in daily activities despite optimal medical therapy.
- c. Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

3. For STN or GPi DBS to be considered reasonable and necessary, patients must meet all of the following criteria:

- a. Diagnosis of PD based on the presence of at least 2 cardinal PD features (tremor, rigidity or bradykinesia).
- b. Advanced idiopathic PD as determined by the use of Hoehn and Yahr stage or Unified Parkinson's Disease Rating Scale (UPDRS) part III motor subscale.
- c. L-dopa responsive with clearly defined "on" periods.

- d. Persistent disabling Parkinson's symptoms or drug side effects (e.g., dyskinesias, motor fluctuations, or disabling "off" periods) despite optimal medical therapy.
- e. Willingness and ability to cooperate during conscious operative procedure, as well as during post-surgical evaluations, adjustments of medications and stimulator settings.

The DBS is not reasonable and necessary and is not covered for ET or PD patients with any of the following:

1. Non-idiopathic Parkinson's disease or "Parkinson's Plus" syndromes.
2. Cognitive impairment, dementia or depression which would be worsened by or would interfere with the patient's ability to benefit from DBS.
3. Current psychosis, alcohol abuse or other drug abuse.
4. Structural lesions such as basal ganglionic stroke, tumor or vascular malformation as etiology of the movement disorder.
5. Previous movement disorder surgery within the affected basal ganglion.
6. Significant medical, surgical, neurologic or orthopedic co-morbidities contraindicating DBS surgery or stimulation.

Patients who undergo DBS implantation should not be exposed to diathermy (deep heat treatment including shortwave diathermy, microwave diathermy and ultrasound diathermy) or any type of MRI which may adversely affect the DBS system or adversely affect the brain around the implanted electrodes.

The DBS should be performed with extreme caution in patients with cardiac pacemakers or other electronically controlled implants which may adversely affect or be affected by the DBS system.

For DBS lead implantation to be considered reasonable and necessary, providers and facilities must meet all of the following criteria:

1. Neurosurgeons must: (a) be properly trained in the procedure; (b) have experience with the surgical management of movement disorders, including DBS therapy; and (c) have experience performing stereotactic neurosurgical procedures
2. Operative teams must have training and experience with DBS systems, including knowledge of anatomical and neurophysiological characteristics for localizing

the targeted nucleus, surgical and/or implantation techniques for the DBS system, and operational and functional characteristics of the device.

3. Physicians specializing in movement disorders must be involved in both patient selection and post-procedure care.

4. Hospital medical centers must have: (a) brain imaging equipment (MRI and/or CT) for pre-operative stereotactic localization and targeting of the surgical site(s); (b) operating rooms with all necessary equipment for stereotactic surgery; and (c) support services necessary for care of patients undergoing this procedure and any potential complications arising intraoperatively or postoperatively.

50.2 – Billing Requirements (Rev. 128, 03-26-04)

50.2.1 – Part A Intermediary Billing Procedures (Rev. 128, 03-26-04)

This procedure can be two fold. Implantation of the electrodes is performed in a hospital inpatient setting. Implantation of the pulse generator can be performed in an outpatient department.

50.3 - Payment Requirements (Rev. 128, 03-26-04)

50.3.1 – Part A Payment Methods (Rev. 128, 03-26-04)

Payment for the inpatient procedure is under Diagnostic Related Group (DRG). The outpatient procedure is outpatient prospective payment system. For critical access hospitals (CAH), the inpatient stay is on reasonable cost and the outpatient procedures are also based on reasonable cost.

50.3.2 – Bill Types (Rev. 128, 03-26-04)

11X, 12X, 13X, 83X, 85X

50.3.3 – Revenue Codes (Rev. 128, 03-26-04)

Revenue codes for implementation can be performed in a number of revenue centers within a hospital such as operating room (360) or clinic (510). The codes to report the pulse generator and/or electrodes are 270, 278, 279.

For CAHs that choose method II, use revenue code 98X for the professional component only.

50.4 – Allowable Codes **(Rev. 128, 03-26-04)**

50.4.1 – Allowable Covered Diagnosis Codes **(Rev. 128, 03-26-04)**

Deep Brain Stimulation is covered for the following ICD-9-CM diagnosis codes:

332.0 - Parkinson's disease, with paralysis agitans

333.1 – Essential and other specified forms of tremor

50.4.2 – Allowable Covered Procedure Codes **(Rev. 128, 03-26-04)**

The following procedure codes may be present:

02.93 – Implantation of intracranial neurostimulator, encompasses the component parts of the surgery that include tunneling to protect the wiring and the initial creation of a pocket for the insertion of the electrical unit into the chest wall

86.09 – Other incision of skin and subcutaneous tissue, to reflect the creation of a pocket for the battery device

86.99 – Other operations on skin and subcutaneous tissue, for the tunneling of the wire connectors

50.4.3 – Healthcare Common Procedure Coding System (HCPCS) **(Rev. 128, 03-26-04)**

The following HCPCS codes are available for use when billing for covered deep brain stimulation:

E0752 Implantable Neurostimulator Electrode, Each

E0756 Implantable Neurostimulator Pulse Generator

61862 Twist drill, burr hole, craniectomy for stereotactic implantation of one neurostimulator array in subcortical site (e.g., thalamus, globus pallidus, subthalamic nucleus, periventricular, periaqueductal gray)

61880 Revision or removal of intracranial neurostimulator electrodes

- 61885 Incision and subcutaneous placement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array
- 61886 Incision and subcutaneous placement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to two or more electrode arrays
- 61888 Revision or removal of cranial neurostimulator pulse generator or receiver
- 95961 Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; initial hour of physician attendance
- 95962 Functional cortical and subcortical mapping by stimulation and/or recording of electrodes on brain surface, or of depth electrodes, to provoke seizures or identify vital brain structures; each additional hour of physician attendance (List separately in addition to code for primary procedure) (Use 95962 in conjunction with code 95961)
- 95970 Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple or complex brain, spinal cord, or peripheral (i.e., cranial nerve, peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, without reprogramming
- 95971 Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); simple brain, spinal cord, or peripheral (i.e., peripheral nerve, autonomic nerve, neuromuscular) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming
- 95972 Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex brain, spinal cord, or peripheral (except cranial nerve) neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, first hour
- 95973 Electronic analysis of implanted neurostimulator pulse generator system (e.g., rate, pulse amplitude and duration, configuration of wave form, battery status, electrode selectability, output modulation, cycling, impedance and patient compliance measurements); complex brain, spinal cord, or peripheral (except cranial nerve); complex brain, spinal cord, or peripheral (except cranial nerve)

neurostimulator pulse generator/transmitter, with intraoperative or subsequent programming, additional 30 minutes after hour (List separately in addition to code for primary procedure) (Use 95973 in conjunction with code 95972)

50.5 – Ambulatory Surgical Centers

(Rev. 128, 03-26-04)

The following HCPCS codes are approved for billing in Ambulatory Surgical Centers:

61885 Incision and subcutaneous placement of cranial neurostimulator pulse generator or receiver, direct or inductive coupling; with connection to a single electrode array - ASC Payment Group 02

61888 Revision or removal of cranial neurostimulator pulse generator or receiver - ASC Payment Group 01

NOTE: Pulse generator is payable in an ASC; implantation of electrodes are not.

50.6 – Claims Editing for Intermediaries

(Rev. 128, 03-26-04)

We do not require nationwide standard system claims processing edits for pre and post payment review of claim(s) at this time. However, carriers and intermediaries may create local claims processing edits for the requirements listed above.

50.7 – Remittance Advice Notice for Intermediaries

(Rev. 128, 03-26-04)

Use appropriate existing remittance advice reason and remark codes at the line level to express the specific reason if you deny payment for DBS. If denying services as furnished before April 1, 2003, use existing ANSI X 12-835 claim adjustment reason code 26 "Expenses incurred prior to coverage" at the line level.

50.8 - Medicare Summary Notice (MSN) Messages for Intermediaries

(Rev. 128, 03-26-04)

Use the following MSN messages where appropriate:

If a claim for DBS is denied because the service was performed prior to April 1, 2003, use the MSN message:

"This service was not covered by Medicare at the time you received it." (MSN Message 21.11)

The Spanish version of the MSN message should read:

"Este servicio no estaba cubierto por Medicare cuando usted lo recibió." (MSN Message 21.11)

50.9 – Provider Notification **(Rev. 128, 03-26-04)**

Contractors should notify providers of this new national coverage in their next regularly scheduled bulletin, on their Web site within 2 weeks, and in routinely scheduled training sessions.

60 – Coverage and Billing for Home Prothrombin Time (PT/INR) Monitoring for Home Anticoagulation Management **(Rev. 1562, Issued: 07-25-08, Effective: 03-19-08, Implementation: 08-25-08)**

The prothrombin time (PT) test is an in-vitro test to assess coagulation. PT testing and its normalized correlate, the International Normalized Ratio (INR), are the standard measurements for therapeutic effectiveness of warfarin therapy. Warfarin, Coumadin®, and others, are self-administered, oral anticoagulant, or blood thinner, medications that affect a person's Vitamin K-dependent clotting factors.

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.

60.1 – Coverage Requirements **(Rev. 1562, Issued: 07-25-08, Effective: 03-19-08, Implementation: 08-25-08)**

For services furnished on or after July 1, 2002, Medicare will cover the use of home 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 3 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.

For services furnished on or after March 19, 2008, the Centers for Medicare & Medicaid Services revised its national coverage determination (NCD) on PT/INR Monitoring for Home Anticoagulation Management as follows:

Medicare will cover the use of home PT/INR monitoring for chronic, oral anticoagulation management for patients with mechanical heart valves, chronic atrial fibrillation, or venous thromboembolism (inclusive of deep venous thrombosis and pulmonary embolism) on warfarin. The monitor and the home testing must be prescribed by a treating physician as provided at 42 CFR 410.32(a), and all of the following requirements must be met:

1. The patient must have been anticoagulated for at least 3 months prior to use of the home INR device; and,
2. The patient must undergo a face-to-face educational program on anticoagulation management and must have demonstrated the correct use of the device prior to its use in the home; and,
3. The patient continues to correctly use the device in the context of the management of the anticoagulation therapy following the initiation of home monitoring; and,
4. Self-testing with the device should not occur more frequently than once a week.

NOTE: Porcine valves are not included in this NCD, so Medicare will not make payment on home INR monitoring for patients with porcine valves unless covered by local Medicare contractors.

60.2 – Intermediary Payment Requirements (Rev. 216, 06-25-04)

60.2.1 – Part A Payment Methods (Rev. 216, 06-25-04)

Payment is as follows:

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

Deductible and coinsurance apply.

60.3 – Intermediary Billing Procedures (Rev. 216, 06-25-04)

60.3.1 – Bill Types (Rev. 216, 06-25-04)

The applicable bill types are 13X and 85X.

60.3.2 – Revenue Codes

(Rev. 216, 06-25-04)

Hospitals may report these services under revenue code 920 or they may report HCPCS codes G0248 and G0249 under the revenue center where they are performed.

60.4 – Intermediary Allowable Codes

(Rev. 216, 06-25-04)

60.4.1 – Allowable Covered Diagnosis Codes

(Rev. 1663; Issued: 01-08-09; Effective Date: 03-19-08; Implementation Date: 02-09-09)

For services furnished on or after July 1, 2002, the applicable ICD-9-CM diagnosis code for this benefit is V43.3, organ or tissue replaced by other means; heart valve.

For services furnished on or after March 19, 2008, the applicable ICD-9-CM diagnosis codes for this benefit are:

V43.3 (organ or tissue replaced by other means; heart valve),

289.81 (primary hypercoagulable state),

451.0-451.9 (includes 451.11, 451.19, 451.2, 451.80-451.84, 451.89) (phlebitis & thrombophlebitis),

453.0-453.3 (other venous embolism & thrombosis),

453.40-453.49 (includes 453.40-453.42, 453.8-453.9) (venous embolism and thrombosis of the deep vessels of the lower extremity, and other specified veins/unspecified sites)

415.11-415.12, 415.19 (pulmonary embolism & infarction) or,

427.31 (atrial fibrillation (established) (paroxysmal)).

60.4.2 – Healthcare Common Procedure Coding System (HCPCS) for Intermediaries

(Rev. 1562, Issued: 07-25-08, Effective: 03-19-08, Implementation: 08-25-08)

For services furnished on or after July 1, 2002, and prior to March 19, 2008, the applicable HCPCS codes for this benefit are:

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's 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

For services furnished on or after March 19, 2008, the applicable HCPCS codes for this benefit are:

G0248: Demonstration, prior to initial use, of home INR monitoring for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria, under the direction of a physician; includes: face-to-face demonstration of 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 patient ability to perform testing prior to its use

Short Description: Demonstrate use home INR mon

G0249: Provision of test materials and equipment for home INR monitoring of patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; includes provision of materials for use in the home and reporting of test results to physician; not occurring more frequently than once a week

Short Description: Provide INR test mater/equip

60.5 – Carrier Billing Instructions

(Rev. 1562, Issued: 07-25-08, Effective: 03-19-08, Implementation: 08-25-08)

Effective for claims with dates of service on and after March 19, 2008, the descriptors of HCPCS Codes G0248, G0249, and G0250 were changed to reflect revised coverage policy.

60.5.1 - HCPCS for Carriers

(Rev. 1562, Issued: 07-25-08, Effective: 03-19-08, Implementation: 08-25-08)

For services furnished on or after July 1, 2002, and prior to March 19, 2008, the applicable HCPCS codes for this benefit are:

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's 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

G0250: Physician review; interpretation and patient management of home INR testing for a patient with mechanical heart valve(s) who meets other coverage criteria; per 4 tests (does not require face-to-face).

Short Description: MD review interpret of test

For services furnished on or after March 19, 2008, the applicable HCPCS codes for this benefit are:

G0248: Demonstration, prior to initial use, of home INR monitoring for patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria, under the direction of a physician; includes: face-to-face demonstration of 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 patient ability to perform testing prior to its use

Short Description: Demonstrate use home INR mon

G0249: Provision of test materials and equipment for home INR monitoring of patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; includes provision of materials for use in the home and reporting of test results to physician; not occurring more frequently than once a week

Short Description: Provide INR test mater/equip

G0250: Physician review, interpretation, and patient management of home INR testing for a patient with either mechanical heart valve(s), chronic atrial fibrillation, or venous thromboembolism who meets Medicare coverage criteria; includes face-to-face verification by the physician that the patient uses the device in the context of the management of the anticoagulation therapy following initiation of the home INR monitoring; not occurring more frequently than once a week

Short Description: MD INR test revie inter mgmt

60.5.2 – Applicable Diagnosis Codes for Carriers

(Rev. 1663; Issued: 01-08-09; Effective Date: 03-19-08; Implementation Date: 02-09-09)

For services furnished on or after July 1, 2002, the applicable ICD-9-CM diagnosis code for this benefit is V43.3, organ or tissue replaced by other means; heart valve.

For services furnished on or after March 19, 2008, the applicable ICD-9-CM diagnosis codes for this benefit are:

V43.3 (organ or tissue replaced by other means; heart valve),

289.81 (primary hypercoagulable state),

451.0-451.9 (includes 451.11, 451.19, 451.2, 451.80-451.84, 451.89) (phlebitis & thrombophlebitis),

453.0-453.3 (other venous embolism & thrombosis),

453.40-453.49 (includes 453.40-453.42, 453.8-453.9) (venous embolism and thrombosis of the deep vessels of the lower extremity, and other specified veins/unspecified sites)

415.11-415.12, 415.19 (pulmonary embolism & infarction) or,

427.31 (atrial fibrillation (established) (paroxysmal)).

60.6 – Carrier Claims Requirements

(Rev. 1562, Issued: 07-25-08, Effective: 03-19-08, Implementation: 08-25-08)

Note this test is not covered as durable medical equipment. Therefore, claims submitted to DMERCs will not be paid. It is covered under the physician fee schedule. Also note that the cost of the device and supplies is included in the payment for G0249 and therefore not separately billed to Medicare. G0249 continues to include materials for 4 tests. Additionally, G0250 continues to mean per 4 tests and should be billed no more frequently than once every 4 weeks.

60.7 – Carrier Payment Requirements

(Rev. 1562, Issued: 07-25-08, Effective: 03-19-08, Implementation: 08-25-08)

Payment and pricing information will be in the Medicare Physician Fee Schedule Database (MPFSDB). Pay for INR on the basis of the MPFS. Deductible and coinsurance apply.

60.8 – Carrier and Intermediary General Claims Processing Instructions

(Rev. 216, 06-25-04)

60.8.1 – Remittance Advice Notices

(Rev. 1562, Issued: 07-25-08, Effective: 03-19-08, Implementation: 08-25-08)

Use appropriate existing remittance advice reason and remark codes at the line level to express the specific reason for denying payment for PT/INR:

Remittance Advice Remark Code N386, “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at <http://www.cms.hhs.gov/mcd/search.asp>. If you do not have Web access, you may contact the contractor to request a copy of the NCD.”

If denying services furnished after July 1, 2002, use ANSI X 12-835 claim adjustment reason code 50, “These are non-covered services because this is not deemed a ‘medical necessity’ by the payer.”

60.8.2 - Medicare Summary Notice (MSN) Messages

(Rev. 1562, Issued: 07-25-08, Effective: 03-19-08, Implementation: 08-25-08)

If denying services furnished after July 1, 2002, use MSN message:

“The following policies [190.11] were used when we made this decision.” (MSN Message 15.20)

67 – No Cost Items

(Rev. 1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

On occasion, providers may receive an item (such as a device or drug) that is offered by a manufacturer/supplier free of charge. Such items, for purposes of these instructions, are considered “no cost items.” Providers are not to seek reimbursement for no cost items as noted in Section 1862(a)(2) of the Social Security Act.

67.1 – Practitioner Billing for No Cost Items

(Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)

Practitioners typically should not bill for no cost items as there is no non-covered charges field on the claim and there are also no system edits in place to require providers to do so. However, practitioners are required to report Category A IDE devices received at no cost on claims as specified in §68.3 of this chapter (although they will not receive payment).

67.2 – Institutional Billing for No Cost Items

(Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)

Generally speaking, institutional, providers should not have to report the usage of a no cost item. However, for some claims (e.g., hospital Outpatient Prospective Payment System (OPPS) claims), providers may be required to bill a no cost item due to claims processing

edits that require an item (even if received at no cost) to be billed along with an associated service (e.g., a specified device must be reported along with a specified implantation procedure).

For OPSS claims, providers must report a token charge of less than \$1.01 for the item in the covered charge field, along with the applicable HCPCS modifier (i.e., modifier –FB) appended to the procedure code that reports the service requiring a device. For more information on billing no cost items under the OPSS, refer to Chapter 4, §20.6.9 and 61.3.1 of this manual.

By billing in this way, the provider is accomplishing four things:

- 1) Communicating to the contractor that the provider is not seeking payment for the no cost item;
- 2) Reflecting, with completeness and accuracy, all services provided to the patient;
- 3) Preventing the line item or claim from being rejected/denied by system edits that require an item to be billed in conjunction with an associated procedure (such as implantation or administration procedures);
- 4) Assuring that the patient and provider are not held liable for any charges for the no cost item.

Future updates will be issued in a Recurring Update Notification.

67.2.1 – Billing No Cost Items Due to Recall, Replacement, or Free Sample

(Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)

Currently, institutional providers that use the Healthcare Common Procedural Coding System (HCPCS) bill device HCPCS codes for no cost or full credit items with token charges in order for claims to pass OPSS claims processing edits that require certain devices to be billed with their associated procedures so that payment can be made.

Effective January 1, 2006, modifier –FB is used to indicate that an item used in a procedure was furnished without cost to the provider, and, therefore, it is not being charged to Medicare or the beneficiary. More information on billing HCPCS modifier –FB can be located in Chapter 4, §20.6.9 and 61.3.1 of this manual.

Effective April 1, 2006, two new condition codes were created for institutional use: 49 and 50 (Table 1). These new codes are used to identify and track medical devices that are provided by a manufacturer at no cost or with full credit to the hospital due to warranty for a malfunction or recall.

Table 1: New Condition Codes and Descriptions
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Condition Code		Description
49	Product Replacement within Product Lifecycle	A medical device is replaced before "end-of-life" because there is an indication that the device is not functioning properly. (This is a warranty situation.)
50	Product Replacement for Known Recall of a Product	A medical device is replaced because of a manufacturer or FDA recall.

- Providers must use these condition codes to identify medical devices that are provided by a manufacturer at no cost or with full credit due to warranty or recall. These condition codes will be used to track no cost/full credit devices replaced due to recall or warranty.
- Providers must report these condition codes on any inpatient or outpatient institutional claim that includes a no cost/full credit replacement device when conditions of warranty or recall are met.

NOTE: OPPS hospitals billing no cost/full credit devices must append modifier –FB to the procedure code for implanting the no cost/full credit device, along with the appropriate condition code if applicable (in Table 1 above), in instances when claims processing edits require that certain devices be billed with their associated procedures. The modifier identifies the procedure code line for the no cost/full credit device, while the condition code explains if the device was provided free of cost due to warranty or recall.

68 – Investigational Device Exemption (IDE)

(Rev. 1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

68.1 – General

(Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)

CMS determines Medicare device coverage based on which category the FDA assigns the device. Devices are either designated as a Category A IDE or a Category B IDE.

NOTE: For purposes of these instructions, IDEs will be referred to as “studies” instead of “trials” to help distinguish clinical trial instructions from IDE study instructions.

Category A Devices

Category A IDE devices are considered experimental and, therefore, are not eligible for payment. Institutional providers should not bill for Category A IDE devices, while practitioners are required to report the Category A IDE number on the claim as specified in §68.3 of this chapter (although they will not receive payment). Practitioners must report the Category A IDE number on the claim because the contractor must validate that the IDE number is part of a current clinical trial by reviewing a monthly file provided by CMS.

Effective January 1, 2005, routine costs (as described in [The National Coverage Determinations Manual, section 310.1](#)) of clinical trials involving a Category A IDE device are covered when the Medicare contractors determine that the device is used in the trial for the diagnosis, monitoring, or treatment of an immediately life-threatening disease or condition. Both institutional providers and practitioners are required to bill for the routine costs of clinical trials involving Category A devices as specified in §68.3 of this chapter.

Category B Devices

Unlike Category A devices, Category B devices are newer generations of proven technologies that have had questions about its safety and effectiveness resolved. Category B devices may be covered under Medicare as long as it meets the billing requirements listed in section 68.2 below. If the device is billed under a Category B IDE study, and it meets the billing requirements for IDEs, the device itself and the routine costs associated with its use are eligible for payment (Payment for the device may not exceed the Medicare-approved amount for a comparable device that has been already FDA-approved).

More information regarding these two categories of IDEs can be located in [The Benefit Policy Manual, Chapter 14](#).

Future updates will be issued in a Recurring Update Notification.

68.2 – Notifying Contractors of an IDE Device Trial (Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)

Providers that participate in an IDE trial and anticipate filing Medicare claims must notify the Medicare contractor. The following information must be furnished prior to submission of a claim for payment:

- A copy of the FDA-approval letter provided to the sponsor or manufacturer of the device. The approved IDE code number must be on the letter;
- The name of the device (both trade, common or usual, and classification name);
- Any action taken to conform to any applicable IDE special controls;
- A narrative description of the device sufficient to make a payment determination;
- A statement indicating how the device is similar to and/or different from other comparable products;
- Indication of whether the device will be billed on an inpatient or outpatient claim;
- A brief summary of the study design or a copy of the actual trial protocol;

- The provider's protocol for obtaining informed consents for beneficiaries participating in the clinical trial.

NOTE: Potential Medicare coverage of Category B IDE devices is predicated, in part, on the device's status with the FDA. If a sponsor loses its Category B status for the device or violates relevant IDE requirements necessitating the FDA's withdrawal of approval, all payment will cease. Providers must notify their contractor within 30 days of any change in status for an IDE. By billing for an IDE, whether it is for a Category B IDE device or for the routine costs of clinical trials involving a Category A IDE device, the provider attests that the device was approved at the time the services were rendered.

68.3 – Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category A IDE

(Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)

Providers shall notify their contractor of the Category A IDE device trial before billing routine costs of the Category A IDE device trial, as listed in section 68.2 above. Upon receiving the required information for the trial, the contractor will determine if the Category A IDE device, as used in the trial, is intended for the diagnosis, monitoring, or treatment of an immediately life-threatening disease/condition. If the contractor determines that the device does, in fact, meet the requirements of coverage, then the provider may begin billing the routine costs of a clinical trial involving a Category A IDE device.

Institutional Inpatient Billing

Routine Costs

Institutional providers shall submit claims only for the routine costs of a clinical trial involving a Category A IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter. The Category A IDE device shall not be reported on institutional claims since it is non-covered by Medicare.

Institutional Outpatient Billing

Routine Costs

Institutional providers shall submit claims only for the routine costs of a clinical trial involving a Category A IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter. The Category A IDE device shall not be reported on institutional claims since it is non-covered by Medicare.

Practitioner Billing

Routine Costs

Practitioners shall submit claims for the routine costs of a clinical trial involving a Category A IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter.

Category A Device

Effective for dates of service on or before December 31, 2007, practitioners must place a QV modifier (Item or service provided as routine care in a Medicare qualifying clinical trial) on the line for the device along with the IDE number.

Effective for dates of service on or after January 1, 2008, practitioners will no longer bill a QV modifier to identify the device. Instead, practitioners will bill a Q0 (numeral 0 versus the letter o) modifier (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) along with the IDE number.

The following table shows the designated field locations to report the Category A IDE number on practitioner claims:

Data	CMS-1500	837i and 837p
IDE #	<u>Item 23</u>	Segment 2300, REF02(REF01=LX)

Contractors will validate the IDE number for the Category A device when modifier Q0 is submitted on the claim along with the IDE number. Claims containing an invalid IDE number will be returned to the provider. Remark code MA50 is used.

(Missing/incomplete/invalid Investigational Device Exemption Number for FDA approved clinical trial services), along with Reason Code 16 (Claim/service lacks information which is needed for adjudication).

68.4 – Billing Requirements for Providers Billing Routine Costs of Clinical Trials Involving a Category B IDE

(Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)

As noted above in section 68.2, of this chapter, providers shall first notify their contractor of the IDE device trial before submitting claims for Category B IDE devices and the routine costs of clinical trials involving Category B IDE devices. Once the contractor notifies the provider that all required information for the IDE has been furnished, the provider may bill Category B IDE claims.

When billing for Category B IDEs, providers shall bill for the device and all related procedures. The Category B IDE device and the routine costs associated with its use are eligible for payment under Medicare. (payment for the device may not exceed the Medicare-approved amount for a comparable device that has been already FDA-approved).

Institutional Inpatient Billing

Routine Costs

Institutional providers shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in §69.6 of this chapter.

Category B Device

Institutional providers must bill the Category B IDE number on a 0624 revenue code line with charges in the covered charges field. Hospital inpatient providers should not bill for the Category B IDE device if receiving the device free of charge.

Institutional Outpatient Billing

Routine Costs

Institutional providers shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in section 69.6 of this chapter.

Category B Device

On a 0624 revenue code line, institutional providers must bill the following for Category B IDE devices for which they incur a cost:

- Category B IDE device HCPCS code, if applicable.
- The appropriate HCPCS modifier:
 - Q0 (numeral 0 versus the letter o) modifier for claims with dates of service on or after January 1, 2008; or
 - QA modifier for claims with dates of service prior to January 1, 2008.
- The Category B IDE number.
- Charges for the device billed as covered charges.

NOTE: If the Category B IDE device is provided at no cost, OPSS providers must report a token charge in the covered charge field along with the applicable HCPCS modifier (i.e., modifier –FB) appended to the procedure code that reports the service to furnish the device, in instances when claims processing edits require that certain devices be billed with their associated procedures. For more information on billing no cost items under the OPSS, refer to Chapter 4, §§20.6.9 and 61.3.1 of this manual.

Practitioner Billing

Routine Costs

Practitioners shall submit claims for the routine costs of a clinical trial involving a Category B IDE device by billing according to the clinical trial billing instructions found in section 69.6 of this chapter.

Category B Device

Effective for dates of service on or before December 31, 2007, practitioners must bill the Category B IDE device on a line with a QA modifier (FDA IDE) along with the IDE number. However, effective for dates of service on or after January 1, 2008, practitioners will no longer bill a QA modifier to identify a Category B device. Instead, practitioners will bill a Q0 modifier (numeral 0 versus the letter o) (Investigational clinical service provided in a clinical research study that is in an approved clinical research study) along with the IDE number.

The following table shows the designated field locations to report the Category B IDE number on institutional and practitioner claims:

Data	CMS-1450	CMS-1500	837i and 837p
IDE #	<u>FL 43</u>	<u>Item 23</u>	Segment 2300, REF02(REF01=LX)

Contractors will validate the IDE number for the Category B device when modifier Q0 is submitted on the claim along with the IDE number. Claims containing an invalid IDE number will be returned to the provider. (Remark code MA50 is used (Missing/incomplete/invalid Investigational Device Exemption Number for FDA approved clinical trial services), along with Reason Code 16 (Claim/service lacks information which is needed for adjudication).

68.5 – Contractor Review of Category B IDEs

(Rev. 1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

When reviewing Category B IDE claims, Medicare contractors determine payment on a case-by-case basis. That is, contractors make local coverage determinations based on whether or not certain criteria are met. In addition to other national and local coverage policies, the following criteria are used by Medicare contractors to determine Medicare payment for Category B IDE trials:

- The use of the device must be part of an FDA-approved clinical trial;
- The device must be assigned to Category B as described by FDA regulations;

- The use of the device must be medically necessary for the patient for whom coverage is sought;
- The amount, duration, and frequency of the use of the device must be medically appropriate;

The device must be used in a setting appropriate for the patient's medical needs and condition.

69 - Qualifying Clinical Trials

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

69.1 – General

(Rev. 1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

The CMS has issued a National Coverage Determination (NCD) which allows Medicare coverage for the routine costs of qualifying clinical trial services as well as reasonable and necessary items and services used to diagnose and treat complications arising from participation in all clinical trials. The coverage requirements for routine costs of qualifying clinical trial services are contained in The National Coverage Determinations Manual, Section 310.1.

69.2 - Payment for Qualifying Clinical Trial Services

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

For dates of service on or after September 19, 2000, pay for covered services furnished to beneficiaries participating in qualifying clinical trials. Payment is based on the payment methodology applicable for the service that was furnished (e.g., physician fee schedule, lab fee schedule, DME fee schedule, reasonable charge, etc.). With the exception of managed care enrollees, applicable deductibles and coinsurance rules apply to clinical trial items and services. The Part A and Part B deductibles are assumed to be met for covered clinical trial services billed on a fee service basis for managed care enrollees.

69.3 - Medical Records Documentation Requirements

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

The billing provider must include in the beneficiary's medical record the following information: trial name, sponsor, and sponsor-assigned protocol number. This information does not need to be submitted with the claim but must be provided if requested for medical review.

69.4 - Local Medical Review Policy

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

Do not develop new or revised LMRPs for clinical trial services. Clinical trial services that meet the requirements of the NCD are considered reasonable and necessary.

69.5 - Billing Requirements – General

(Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)

Instruct practitioners and institutional providers to enter clinical trial and non-clinical trial services on separate line items when billing both types of services on the same claim. For services that require a Certificate of Medical Necessity (CMN), continue to require CMNs. Items and services provided free of charge by research sponsors generally may not be billed to be paid by Medicare, and providers are not required to submit the charge to Medicare. If it is necessary for a provider to show the items and services that are provided free of charge in order to receive payment for the covered routine costs (e.g. administration of a non-covered chemotherapeutic agent), providers are instructed to submit such charges as non-covered at the time of entry, while also assuring that the beneficiary is not held liable. This instruction applies to all hospitals including hospitals located in Maryland under the jurisdiction of the Health Services Cost Review Commission (HSCRC).

For OPPS claims, providers must report a token charge for a no cost item in the covered charge field along with the applicable HCPCS modifier (i.e., modifier –FB) appended to the procedure code that reports the service provided to furnish the no cost item, in instances when claims processing edits require that certain devices be billed with their associated procedures. For more information on billing no cost items under the OPPS, refer to Chapter 4, §§20.6.9 and 61.3.1 of this manual.

Future updates will be issued in a Recurring Update Notification.

69.6 - Requirements for Billing Routine Costs of Clinical Trials

(Rev. 1657, Issued: 12-31-08, Effective: 01-01-09, Implementation: 01-05-09)

Routine Costs Submitted by Practitioners

Claims with dates of service before January 1, 2008:

- HCPCS modifier ‘QV’
- Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the primary diagnosis

Claims with dates of service on or after January 1, 2008:

- HCPCS modifier ‘Q1’ (numeral 1 instead of the letter i); and
- Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the primary diagnosis.

If the QV or Q1 modifier is billed and diagnosis code V70.7 is submitted by practitioners as a secondary rather than the primary diagnosis, do not consider the service as having been

furnished to a diagnostic trial volunteer. Instead, process the service as a therapeutic clinical trial service.

Effective for clinical trial claims received after April 1, 2008, (regardless of the date of service) providers can begin to report an 8-digit clinical trial number. The reporting of this number is **voluntary** at this time. Refer to change request (CR) 5790 for more information regarding the 8-digit number. Below are the claim locators that providers should use to bill the 8-digit number:

- CMS-1500 paper form—place in Field 19 (preceded by ‘CT’); and
- 837 P—Loop 2300, REF02, REF01-P4 (do not use ‘CT’ on the electronic claim).

Routine Costs Submitted by Institutional Providers

All Institutional Clinical Trial Claims

Effective for clinical trial claims received after April 1, 2008, (regardless of the date of service) providers can begin to report an 8-digit clinical trial number. The reporting of this number is **voluntary** at this time. Refer to CR 5790 for more information regarding the 8-digit number. To bill the 8-digit clinical trial number, institutional providers shall code value code ‘D4’---where the value code amount equals the 8-digit clinical trial number. Below are the claim locators in which to bill the 8-digit number:

- CMS-1450—Form Locator 39-41
- 837I-Loop 2300 HI – VALUE INFORMATION segment (qualifier BE)

NOTE: The QV/Q1 modifier is line item specific and must be used to identify items and services that constitute medically necessary routine patient care or treatment of complications arising from a Medicare beneficiary’s participation in a Medicare-covered clinical trial. Items and services that are provided solely to satisfy data collection and analysis needs and that are not used in the clinical management of the patient are not covered and may not be billed using the QV/Q1 modifier. Items and services that are not covered by Medicare by virtue of a statutory exclusion or lack of a benefit category also may not be billed using the QV/Q1 modifier. When billed in conjunction with the V70.7 diagnosis code, the QV/Q1 modifier will serve as the provider’s attestation that the service meets the Medicare coverage criteria (i.e., was furnished to a beneficiary who is participating in a Medicare qualifying clinical trial and represents routine patient care, including complications associated with qualifying trial participation).

Inpatient Clinical Trial Claims

Institutional provider billing clinical trial service(s) must report a diagnosis code V70.7 and a condition code 30 regardless of whether all services are related to the clinical trial or not.

NOTE: HCPCS codes are not reported on inpatient claims. Therefore, the HCPCS modifier requirements (i.e., QV or Q1) as outlined in the outpatient clinical trial section immediately below, are not applicable to inpatient clinical trial claims.

Outpatient Clinical Trial Claims

A) All services on the claim related to the trial - Institutional providers billing clinical trial claims that contain only clinical trial line item services do not have to report the routine modifiers, QV or Q1. The presence of condition code 30, along with the absence of the QV or Q1 modifier, is the provider's attestation that all line item services on the claim are routine clinical trial services (with the exception of any investigational item on the claim that would be identified with a Q0 modifier on or after January 1, 2008, or a QA modifier before January 1, 2008).

B) Claim contains both services related and unrelated to the trial - Institutional providers billing clinical trial claims that contain both clinical trial line item services and non-clinical trial line item services, must bill the following elements:

Claims with dates of service before January 1, 2008:

- HCPCS modifier 'QV' only on line items related to the clinical trial;
- Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the secondary diagnosis; and
- Condition Code 30.

Claims with dates of service on or after January 1, 2008:

- HCPCS modifier 'Q1' only on line items related to the clinical trial; and
Diagnosis code V70.7 (Examination of participant in clinical trial) reported as the secondary diagnosis Condition Code 30.

69.7 - Reserved for Future Use

(Rev. 1418, Issued: 01-18-08, Effective: 01-01-08, Implementation: 04-07-08)

69.8 - Handling Erroneous Denials of Qualifying Clinical Trial Services

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

If a service Medicare covers was billed with the appropriate clinical trial coding but was inadvertently denied (e.g., for medical necessity or utilization) and is subsequently brought to your attention, adjust the denied claim. If the denied services weren't properly coded as clinical trial services, instruct the provider to resubmit the service on a new claim with appropriate clinical trial coding.

69.9 - Processing Fee for Service Claims for Covered Clinical Trial Services Furnished to Managed Care Enrollees

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

For dates of service on or after September 19, 2000, and until notified otherwise by CMS, Medicare contractors will pay for covered clinical trial services furnished to beneficiaries enrolled in managed care plans. Providers who furnish covered clinical trial services to managed care beneficiaries must be enrolled with Medicare in order to bill on a fee-for-service basis. Providers that wish to bill fee for service but have not enrolled with Medicare must contact their local carrier, intermediary, regional home health intermediary or National Supplier Clearinghouse, as appropriate, to obtain an enrollment application.

Determine payment for covered clinical trial services furnished to beneficiaries enrolled in managed care plans in accordance with applicable fee for service rules, except that beneficiaries are not responsible for the Part A or Part B deductibles (i.e., assume the Part A or Part B deductible has been met). Managed care enrollees are liable for the coinsurance amounts applicable to services paid under Medicare fee for service rules.

The clinical trial coding requirements for managed care enrollee claims are the same as those for regular Medicare fee for service claims.

69.10 - CWF Editing Of Clinical Trial Claims For Managed Care Enrollees

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

Submit clinical trial services for managed care enrollees to CWF for payment approval. CWF will not reject clinical trial claims for managed care enrollees when all services on the claim transaction record are coded as clinical trial services and the date(s) of service is (are) on or after September 19, 2000. In addition, CWF will not apply Part B deductible to clinical trial claims for managed care enrollees (i.e., CWF will process clinical trial services for managed care enrollees as if the Part B deductible has already been met).

69.11 - Resolution of CWF UR 5232 Rejects

(Rev. 487, Issued: 03-04-05, Effective and Implementation: N/A)

If you send a claim transaction to CWF that includes both clinical and non-clinical trial services for a managed care enrollee, the entire claim will be rejected with the UR 5232 error code. When you receive a UR 5232 error code split the claim and resubmit the clinical trial portion to CWF. Process the non-clinical trial portion of the rejected claims in the same manner that other non-clinical trial fee for service claims for managed care enrollees are handled.

70 - Billing Requirements for Islet Cell Transplantation for Beneficiaries in a National Institutes of Health (NIH) Clinical Trial

(Rev. 986, Issued: 06-16-06, Effective: 05-01-06, Implementation: 07-31-06)

For services performed on or after October 1, 2004, Medicare will cover islet cell transplantation for patients with Type I diabetes who are participating in an NIH sponsored

clinical trial. See Pub 100-04 (National Coverage Determinations Manual) section 260.3.1 for complete coverage policy.

The islet cell transplant may be done alone or in combination with a kidney transplant. Islet recipients will also need immunosuppressant therapy to prevent rejection of the transplanted islet cells. Routine follow-up care will be necessary for each trial patient. See Pub 100-04, section 310 for further guidance relative to routine care. All other uses for islet cell services will remain non-covered.

70.1 - Healthcare Common Procedure Coding System (HCPCS) Codes for Carriers

(Rev. 261, Issued: 07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

G0341: Percutaneous islet cell transplant, includes portal vein catheterization and infusion

Short Descriptor: Percutaneous islet cell trans

Type of Service: 2

G0342: Laparoscopy for islet cell transplant, includes portal vein catheterization and infusion

Short Descriptor: Laparoscopy islet cell trans

Type of Service: 2

G0343: Laparotomy for islet cell transplant, includes portal vein catheterization and infusion

Short Descriptor: Laparotomy islet cell transp

Type of Service: 2

70.2 - Applicable Modifier for Islet Cell Transplant Claims for Carriers

(Rev. 986, Issued: 06-16-06, Effective: 05-01-06, Implementation: 07-31-06)

Carriers shall instruct physicians to bill using the above procedure code(s) with modifier QR (Item or service provided in a Medicare-specified study) for all claims for islet cell transplantation and routine follow-up care related to this service.

70.3 - Special Billing and Payment Requirements for Carriers

(Rev. 261, Issued: 07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

Payment and pricing information will be on the October 2004 update of the Medicare Physician Fee Schedule Database (MPFSDB). Pay for islet cell transplants on the basis of the MPFS. Deductible and coinsurance apply for fee-for-service beneficiaries.

70.4 - Special Billing and Payment Requirements for Intermediaries (Rev. 1192, Issued: 03-02-07, Effective: 10-01-04, Implementation: 04-02-07)

This procedure (ICD-9-CM procedure code 52.85-heterotransplantation of islet cells of pancreas) is covered for the clinical trial in an inpatient hospital setting. The applicable TOB is 11X. A secondary diagnosis (diagnosis positions 2 – 9) of V70.7 (examination of participant or control in clinical research) must be present along with condition code 30 (qualifying clinical trial). V70.7 and condition code 30 alerts the claims processing system that this is a clinical trial. The procedure is paid under inpatient prospective payment system for hospitals with patients in the trial. Deductible and coinsurance apply for fee-for-service beneficiaries.

Inpatient hospitals participating in this trial are entitled to an add-on payment of \$18,848.00 for islet isolation services. This amount is in addition to the final IPPS payment made to the hospital. Should two infusions occur during the same hospital stay, Medicare will pay for two add-ons for isolation of the islet cells, but never for more than two add-ons for a hospital stay.

Inpatient hospitals shall report charges for organ acquisition in Revenue Code 0810, 0811, 0812, 0813, or 0819. This includes charges for the pre-transplant items and services related to the acquisition and delivery of the pancreatic islet cell transplants. As is Medicare's policy with other organ transplants, Medicare contractors deduct acquisition charges prior to processing through the IPPS Pricer. Pancreata procured for islet cell transplant are not included in the prospective payment. They are paid on a reasonable cost basis. This is a pass-through cost for which interim payments may be made.

Effective for services on or after May 1, 2006, contractors shall accept the QR modifier for islet cell transplantation follow up care when performed in an outpatient department of a hospital when the transplant was done in conjunction with an NIH-sponsored clinical trial, and when billed on type of bill 13X or 85X.

All other normal inpatient billing practices apply.

70.5 - Special Billing and Payment Requirements Medicare Advantage (MA) Beneficiaries (Rev. 261, Issued: 07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

CMS will make payment directly on a fee-for service basis for the routine costs of pancreatic islet cell transplants as well as transplantation and appropriate related items and services, for MA beneficiaries participating in an NIH-sponsored clinical trial. MA organizations will not be liable for payment for routine costs of this new clinical trial until MA payments can be appropriately adjusted to take into account the cost of this national coverage decision. Medicare contractors shall make payment on behalf of MA organizations directly to providers of these islet cell transplants in accordance with Medicare payment rules, except that beneficiaries are not responsible for the Part A and

Part B deductibles. MA enrollees will be liable for any applicable coinsurance amounts MA organizations have in place for clinical trial benefits.

80 - Billing of the Diagnosis and Treatment of Peripheral Neuropathy with Loss of Protective Sensation in People with Diabetes
(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

Coverage Requirements - Peripheral neuropathy is the most common factor leading to amputation in people with diabetes. In diabetes, peripheral neuropathy is an anatomically diffuse process primarily affecting sensory and autonomic fibers; however, distal motor findings may be present in advanced cases. Long nerves are affected first, with symptoms typically beginning insidiously in the toes and then advancing proximally. This leads to loss of protective sensation (LOPS), whereby a person is unable to feel minor trauma from mechanical, thermal, or chemical sources. When foot lesions are present, the reduction in autonomic nerve functions may also inhibit wound healing.

Peripheral neuropathy with LOPS, secondary to diabetes, is a localized illness of the feet and falls within the regulation's exception to the general exclusionary rule (see 42 C.F.R. §411.15(l)(1)(i)). Foot exams for people with diabetic peripheral neuropathy with LOPS are reasonable and necessary to allow for early intervention in serious complications that typically afflict diabetics with the disease.

Effective for services furnished on or after July 1, 2002, Medicare covers, as a physician service, an evaluation (examination and treatment) of the feet no more often than every 6 months for individuals with a documented diagnosis of diabetic sensory neuropathy and LOPS, as long as the beneficiary has not seen a foot care specialist for some other reason in the interim. LOPS shall be diagnosed through sensory testing with the 5.07 monofilament using established guidelines, such as those developed by the National Institute of Diabetes and Digestive and Kidney Diseases guidelines. Five sites should be tested on the plantar surface of each foot, according to the National Institute of Diabetes and Digestive and Kidney Diseases guidelines. The areas must be tested randomly since the loss of protective sensation may be patchy in distribution, and the patient may get clues if the test is done rhythmically. Heavily callused areas should be avoided. As suggested by the American Podiatric Medicine Association, an absence of sensation at two or more sites out of 5 tested on either foot when tested with the 5.07 Semmes-Weinstein monofilament must be present and documented to diagnose peripheral neuropathy with loss of protective sensation.

80.1 - General Billing Requirements - Follow the general bill review instructions in §3604.

(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

The following providers of service may bill you for these services:

- Hospitals;
- Rural Health Clinic;
- Free-Standing Federally Qualified Health Clinic (FQHC);

Outpatient Rehabilitation Facility (ORF);
Comprehensive Outpatient Rehabilitation Facility (CORF); and
Critical Access Hospitals

80.2 - Applicable HCPCS Codes

(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

G0245 - Initial physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) which must include:

1. The diagnosis of LOPS;
2. A patient history;
3. A physical examination that consists of at least the following elements:
 - (a) visual inspection of the forefoot, hindfoot, and toe web spaces,
 - (b) evaluation of a protective sensation,
 - (c) evaluation of foot structure and biomechanics,
 - (d) evaluation of vascular status and skin integrity,
 - (e) evaluation and recommendation of footwear, and
4. Patient education.

G0246 - Follow-up physician evaluation and management of a diabetic patient with diabetic sensory neuropathy resulting in a loss of protective sensation (LOPS) to include at least the following:

1. a patient history;
2. a physical examination that includes:
 - (a) visual inspection of the forefoot, hindfoot, and toe web spaces,
 - (b) evaluation of protective sensation,
 - (c) evaluation of foot structure and biomechanics,
 - (d) evaluation of vascular status and skin integrity,
 - (e) evaluation and recommendation of footwear, and

3. patient education.

G0247 - Routine foot care by a physician of a diabetic patient with diabetic sensory neuropathy resulting in a LOPS to include if present, at least the following:

- (1) local care of superficial (i.e., superficial to muscle and fascia) wounds;
- (2) debridement of corns and calluses; and
- (3) trimming and debridement of nails.

NOTE: Code G0247 must be billed on the same date of service with either G0245 or G0246 in order to be considered for payment.

The short descriptors for the above HCPCS codes are as follows:

G0245 – INITIAL FOOT EXAM PTLOPS

G0246 – FOLLOWUP EVAL OF FOOT PT LOP

G0247 – ROUTINE FOOTCARE PT W LOPS

80.3 - Diagnosis Codes

(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

Diagnosis Codes.--Providers should report one of the following diagnosis codes in conjunction with this benefit: 250.60, 250.61, 250.62, 250.63, and 357.2.

80.4 - Payment

(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

- Hospital outpatient departments – OPPS
- Critical Access Hospital (CAH) - Method I -- Reasonable cost; Method II -- Technical - reasonable cost, Professional -- 115 percent of the fee schedule
- Comprehensive Outpatient Rehabilitation Facility - Medicare physician fee schedule (MPFS)
- Skilled Nursing Facility – MPFS
- Rural Health Clinics/Federally Qualified Health Centers (RHCs/FQHCs) - All inclusive rate.

Deductible and coinsurance apply.

Examples of Payment calculation:

Part B Deductible Met: \$900 (MPFS allowed amount) x 20 percent (co-insurance) = \$720 (Medicare reimbursement). Beneficiary is responsible for \$180.

Part B Deductible Not met: \$900 (MPFS allowed amount) - \$100 (Part B deductible) = \$800 x 20 percent (co-insurance) = \$640 (Medicare reimbursement). Beneficiary is responsible for \$260.

Part B Deductible Met: \$800 (actual charged amount) x 20 percent (co-insurance) = \$640 (Medicare Reimbursement), beneficiary is responsible for \$160 co-insurance.

Part B Deductible Not Met: \$800 (actual charged amount) - \$100 (Part B deductible) = \$700 x 20 percent (co-insurance) = \$560 (Medicare reimbursement). Beneficiary is responsible for \$240, (\$100 Part B deductible and \$140 co-insurance).

Services are paid at 80 percent of the lesser of the fee schedule amount or the actual charges.

This service, when furnished in an RHC/FQHC by a physician or non-physician, is considered an RHC/FQHC service. RHCs/FQHCs bill you under bill type 71X or 73X with revenue code 940 and HCPCS G0245, G0246, and G0247.

Payment should not be made for this service unless the claim contains a related visit code. Therefore, install an edit in your system to assure payment is not made for revenue code 940 unless the claim also contains a visit revenue code (520 or 521).

Applicable Revenue Codes

The applicable revenue code is 940, except for hospitals.

This service can be performed in other revenue centers such as a clinic (510) for hospitals. Therefore, instruct your hospitals to report these procedures under the revenue center where they are performed.

80.5 - Applicable Revenue Codes

(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

The applicable revenue code is 940, except for hospitals.

This service can be performed in other revenue centers such as a clinic (510) for hospitals. Therefore, instruct your hospitals to report these procedures under the revenue center where they are performed.

80.6 - Editing Instructions for Fiscal Intermediaries (FIs)

(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

Edit 1 - Implement diagnosis to procedure code edits to allow payment only for the LOPS codes, G0245, G0246, and G0247 when submitted with one of the diagnosis codes 250.60, 250.61, 250.62, 250.63, or 357.2. Deny these services when submitted without one of the appropriate diagnoses.

Use the same messages you currently use for procedure to diagnosis code denials.

Edit 2 – Deny G0247 if it is not submitted on the same claim as G0245 or G0246.

Use MSN 21.21 - This service was denied because Medicare only covers this service under certain circumstances.

Use RA claim adjustment reason code 107 - Claim/service denied because the related or qualifying claim/service was not paid or identified on the claim.

80.7 - CWF General Information

(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

Though G0245 and G0246 have no technical or professional components, for these codes, CWF will post FI claims for bill types 13X, 74X, and 75X as technical, and carrier claims as professional. For bill type 85X with revenue code 940, CWF will post as technical. For 85X bill type with revenue code 98X, (Method II), CWF will post as technical and professional. This will allow both the facility and professional service payments to be approved by CWF for payment when the code and date of service match. Therefore, should a claim from a carrier and an FI be received with the same code and same date of service for the same beneficiary, the second claim submitted will not be rejected as a duplicate.

Due to the billing and payment methodology of Rural Health Clinics - bill type 71X and Federally Qualified Health Centers - bill type 73X, CWF will post these claims as usual, which will correctly allow claims from these entities that are billed to the FI to reject as duplicates when the HCPCS code, date of service, and beneficiary Health Insurance Claim number are an exact match with a claim billed to a carrier.

Carriers and FIs must react to these duplicate claims as they currently do for any other duplicates.

80.8 - CWF Utilization Edits

(Rev. 498, Issued: 03-11-05, Effective/Implementation: N/A)

Edit 1 - Should CWF receive a claim from an FI for G0245 or G0246 and a second claim from a carrier for either G0245 or G0246 (or vice versa) and they are different dates of service and less than 6 months apart, the second claim will reject. CWF will edit to allow G0245 or G0246 to be paid no more than every 6 months for a particular beneficiary, regardless of who furnished the service. If G0245 has been paid, regardless of whether it

was posted as a facility or professional claim, it must be 6 months before G0245 can be paid again or G0246 can be paid. If G0246 has been paid, regardless of whether it was posted as a facility or professional claim, it must be 6 months before G0246 can be paid again or G0245 can be paid. CWF will not impose limits on how many times each code can be paid for a beneficiary as long as there has been 6 months between each service.

The CWF will return a specific reject code for this edit to the carriers and FIs that will be identified in the CWF documentation. Based on the CWF reject code, the carriers and FIs must deny the claims and return the following messages:

MSN 18.4 -- This service is being denied because it has not been __ months since your last examination of this kind (NOTE: Insert 6 as the appropriate number of months.)

RA claim adjustment reason code 96 – Non-covered charges, along with remark code M86 – Service denied because payment already made for similar procedure within set time frame.

Edit 2

The CWF will edit to allow G0247 to pay only if either G0245 or G0246 has been submitted and accepted as payable on the same date of service. CWF will return a specific reject code for this edit to the carriers and FIs that will be identified in the CWF documentation. Based on this reject code, carriers and FIs will deny the claims and return the following messages:

MSN 21.21 - This service was denied because Medicare only covers this service under certain circumstances.

RA claim adjustment reason code 107 - Claim/service denied because the related or qualifying claim/service was not paid or identified on the claim.

Edit 3

Once a beneficiary's condition has progressed to the point where routine foot care becomes a covered service, payment will no longer be made for LOPS evaluation and management services. Those services would be considered to be included in the regular exams and treatments afforded to the beneficiary on a routine basis. The physician or provider must then just bill the routine foot care codes along with the appropriate modifier.

The CWF will edit to reject LOPS codes G0245, G0246, and/or G0247 when on the beneficiary's record it shows that one of the following routine foot care codes were billed and paid within the prior 6 months: 11055, 11056, 11057, 11719, 11720, and/or 11721.

The CWF will return a specific reject code for this edit to the carriers and FIs that will be identified in the CWF documentation. Based on the CWF reject code, the carriers and FIs must deny the claims and return the following messages:

MSN 21.21 - This service was denied because Medicare only covers this service under certain circumstances.

The RA claim adjustment reason code 96 – Non-covered charges, along with remark code M86 – Service denied because payment already made for similar procedure within set time frame.

90 - Stem Cell Transplantation

(Rev. 776, Issued: 12-06-05, Effective: 11-28-05, Implementation: 01-03-06)

Stem cell transplantation is a process in which stem cells are harvested from either a patient's or donor's bone marrow or peripheral blood for intravenous infusion. Autologous stem cell transplantation (AuSCT) must be used to effect hematopoietic reconstitution following severely myelotoxic doses of chemotherapy (HDCT) and/or radiotherapy used to treat various malignancies. Allogeneic stem cell transplant may also be used to restore function in recipients having an inherited or acquired deficiency or defect.

Bone marrow and peripheral blood stem cell transplantation is a process which includes mobilization, harvesting, and transplant of bone marrow or peripheral blood stem cells and the administration of high dose chemotherapy or radiotherapy prior to the actual transplant. When bone marrow or peripheral blood stem cell transplantation is covered, all necessary steps are included in coverage. When bone marrow or peripheral blood stem cell transplantation is non-covered, none of the steps are covered.

Allogeneic and autologous stem cell transplants are covered under Medicare for specific diagnoses. See Pub. 100-03, National Coverage Determinations Manual, section 110.8.1, for a complete description of covered and noncovered conditions. The following sections contain claims processing instructions for carrier claims. For institutional claims processing instructions, please refer to Pub. 100-04, chapter 3, section 90.3.

90.1 - General

(Rev. 486, Issued: 03-04-05, Effective Date/Implementation Date: N/A)

Allogeneic Stem Cell Transplantation.

Allogeneic stem cell transplantation is a procedure in which a portion of a healthy donor's stem cells is obtained and prepared for intravenous infusion to restore normal hematopoietic function in recipients having an inherited or acquired hematopoietic deficiency or defect.

Expenses incurred by a donor are a covered benefit to the recipient/beneficiary but, except for physician services, are not paid separately. Services to the donor include physician services, hospital care in connection with screening the stem cell, and ordinary follow-up care.

Autologous Stem Cell Transplantation

Autologous stem cell transplantations is a technique for restoring stem cells using the patient's own previously stored cells. Autologous stem cell transplants are covered for certain specified diagnoses for services rendered on or after April 28, 1989.

90.2 - HCPCS and Diagnosis Coding

(Rev. 526, Issued: 04-15-05, Effective: 03-15-05, Implementation: 05-16-05)

Allogeneic Stem Cell Transplantation

- Effective for services performed on or after August 1, 1978:
 - For the treatment of leukemia or leukemia in remission, providers shall use ICD-9-CM codes 204.00 through 208.91 and HCPCS code 38240.
 - For the treatment of aplastic anemia, providers shall use ICD-9-CM codes 284.0 through 284.9 and HCPCS code 38240.
- Effective for services performed on or after June 3, 1985:
 - For the treatment of severe combined immunodeficiency disease, providers shall use ICD-9-CM code 279.2 and HCPCS code 38240.
 - For the treatment of Wiskott-Aldrich syndrome, providers shall use ICD-9-CM code 279.12 and HCPCS code 38240.
- Effective for services performed on or after May 24, 1996:
 - Allogeneic stem cell transplantation, HCPCS code 38240 is not covered as treatment for the diagnosis of multiple myeloma ICD-9-CM codes 203.00 or 203.01.
- Autologous Stem Cell Transplantation.--Is covered under the following circumstances effective for services performed on or after April 28, 1989:
 - For the treatment of patients with acute leukemia in remission who have a high probability of relapse and who have no human leucocyte antigens (HLA) matched, providers shall use ICD-9-CM code 204.01 lymphoid; ICD-9-CM code 205.01 myeloid; ICD-9-CM code 206.01 monocytic; or ICD-9-CM code 207.01 acute erythremia and erythroleukemia; or ICD-9-CM code 208.01 unspecified cell type and HCPCS code 38241.
 - For the treatment of resistant non-Hodgkin's lymphomas for those patients presenting with poor prognostic features following an initial response, providers shall use ICD-9-CM codes 200.00 - 200.08, 200.10-200.18, 200.20-200.28, 200.80-200.88, 202.00-202.08, 202.80-202.88 or 202.90-202.98 and HCPCS code 38241.

- For the treatment of recurrent or refractory neuroblastoma, providers shall use ICD-9-CM codes Neoplasm by site, malignant, the appropriate HCPCS code and HCPCS code 38241.

- For the treatment of advanced Hodgkin's disease for patients who have failed conventional therapy and have no HLA-matched donor, providers shall use ICD-9-CM codes 201.00 - 201.98 and HCPCS code **38241**.

- Autologous Stem Cell Transplantation.--Is covered under the following circumstances effective for services furnished on or after October 1, 2000:

- For the treatment of multiple myeloma (only for beneficiaries who are less than age 78, have Durie-Salmon stage II or III newly diagnosed or responsive multiple myeloma, and have adequate cardiac, renal, pulmonary and hepatic functioning), providers shall use ICD- 9-CM code 203.00 or 238.6 and HCPCS code 38241.

- For the treatment of recurrent or refractory neuroblastoma, providers shall use appropriate code (see ICD-9-CM neoplasm by site, malignant) and HCPCS code 38241.

- Effective for services performed on or after March 15, 2005, when recognized clinical risk factors are employed to select patients for transplantation, high-dose melphalan (HDM) together with autologous stem cell transplantation (HDM/AuSCT) is reasonable and necessary for Medicare beneficiaries of any age group for the treatment of primary amyloid light chain (AL) amyloidosis, ICD-9-CM code 277.3 who meet the following criteria:

- Amyloid deposition in 2 or fewer organs; and,
- Cardiac left ventricular ejection fraction (EF) greater than 45%.

90.3 - Non-Covered Conditions

(Rev. 526, Issued: 04-15-05, Effective: 03-15-05, Implementation: 05-16-05)

Autologous stem cell transplantation is not covered for the following conditions:

- Acute leukemia not in remission (ICD-9-CM codes 204.00, 205.00, 206.00, 207.00 and 208.00);
- Chronic granulocytic leukemia (ICD-9-CM codes 205.10 and 205.11);
- Solid tumors (other than neuroblastoma) (ICD-9-CM codes 140.0 through 199.1);
or
- Effective for services rendered on or after May 24, 1996 through September 30, 2000, multiple myeloma (ICD-9-CM code 203.00 and 203.01).

- Effective for services on or after October 1, 2000, through March 14, 2005, for Medicare beneficiaries age 64 or older, all forms of amyloidosis, primary and non-primary (ICD-9-CM code 277.3)
- Effective for services on or after 10/01/00, for all Medicare beneficiaries, non-primary amyloidosis (ICD-9-CM code 277.3).

NOTE: Coverage for conditions other than those specifically designated as covered in 90.2 or specifically designated as non-covered in this section will be at the discretion of the individual carrier.

90.4 - Edits

(Rev. 486, Issued: 03-04-05, Effective Date/Implementation Date: N/A)

NOTE: Coverage for conditions other than those specifically designated as covered in 80.2 or specifically designated as non-covered in this section will be at the discretion of the individual carrier.

Appropriate diagnosis to procedure code edits should be implemented for the covered conditions and services in 90.2

As the ICD-9-CM code 277.3 for amyloidosis does not differentiate between primary and non-primary, carriers should perform prepay reviews on all claims with a diagnosis of ICD-9-CM code 277.3 and a HCPCS procedure code of 38241 to determine whether payment is appropriate.

90.5 - Suggested MSN and RA Messages

(Rev. 486, Issued: 03-04-05, Effective Date/Implementation Date: N/A)

The contractor shall use an appropriate MSN and RA message such as the following:

MSN - 15.4, The information provided does not support the need for this service or item;

RA - 150, Payment adjusted because the payer deems the information submitted does not support this level of service.

100 – Billing Requirements for Expanded Coverage of Cochlear Implantation

(Rev. 601, Issued: 07-01-05; Effective: 04-04-05; Implementation: 07-25-05)

Effective for dates of services on and after April 4, 2005, the Centers for Medicare & Medicaid Services (CMS) has expanded the coverage for cochlear implantation to cover moderate-to-profound hearing loss in individuals with hearing test scores equal to or less than 40% correct in the best aided listening condition on tape-recorded tests of open-set sentence recognition and who demonstrate limited benefit from amplification. (See Publication 100-03, chapter 1, section 50.3, for specific coverage criteria).

In addition CMS is covering cochlear implantation for individuals with open-set sentence recognition test scores of greater than 40% to less than or equal to 60% correct but only when the provider is participating in, and patients are enrolled in, either:

- A Food and Drug Administration (FDA)-approved category B investigational device exemption (IDE) clinical trial; or
- A trial under the CMS clinical trial policy (see Pub. 100-03, section 310.1); or

A prospective, controlled comparative trial approved by CMS as consistent with the evidentiary requirements for national coverage analyses and meeting specific quality standards.

100.1 – Intermediary Billing Procedures

(Rev. 601, Issued: 07-01-05; Effective: 04-04-05; Implementation: 07-25-05)

100.1.1 – Applicable Bill Types

(Rev. 601, Issued: 07-01-05; Effective: 04-04-05; Implementation: 07-25-05)

11X, 12X (see note below), 13X, 83X, 85X

NOTE: Surgical procedures are not acceptable on 12x bill types.

100.1.2 – Special Billing Requirements for Intermediaries

(Rev. 601, Issued: 07-01-05; Effective: 04-04-05; Implementation: 07-25-05)

For inpatient billing:

- The second or subsequent diagnosis code must be V70.7 (examination of participant or control in clinical research). V70.7 alerts the claims processing system that this is a clinical trial.

For inpatient Part B and outpatient bills:

- For patients in an approved clinical trial with hearing test scores greater than 40% to less than or equal to 60% hearing, the QR modifier must be reported with the cochlear implantation device and all other related costs or; (see note below)
- For patients in an approved clinical trial under the clinical trial policy with hearing test scores greater than 60% hearing, the QV modifier must be billed for routine costs.

NOTE: The QR or QV modifier does not need to be applied to HCPCS 92601-92604 or any applicable audiology codes.

100.2 – Intermediary Payment Requirements

(Rev. 601, Issued: 07-01-05; Effective: 04-04-05; Implementation: 07-25-05)

There are no special payment methods. Existing payment methods shall apply.

100.3 – Carrier Billing Procedures

(Rev. 601, Issued: 07-01-05; Effective: 04-04-05; Implementation: 07-25-05)

Effective for dates of service performed on and after April 4, 2005, the following applies:

Carriers shall accept claims for cochlear implantation devices and services for beneficiaries with moderate-to-profound hearing loss with hearing test scores equal to or less than 40%.

Carriers shall accept claims for cochlear implantation devices and all related costs for beneficiaries with hearing test scores of greater than 40% to less than or equal to 60% hearing provided in an FDA-approved category B IDE clinical trial, a trial under the CMS Clinical Trial policy, or a prospective, controlled comparative trial approved by CMS that is billed with the QR modifier. The definition of the QR modifier is, “Item or service provided in a Medicare specified study.”

Carriers shall accept claims for routine costs pertaining to beneficiaries with hearing test scores of greater than 60% hearing who are in a clinical trial under the clinical trial policy that is billed with the QV modifier. The definition of the QV modifier is, “Item or service provided as routine care in a Medicare qualifying clinical trial.”

Carriers shall accept claims for evaluation and therapeutic services related to cochlear implantation.

NOTE: Modifiers QR or QV do not need to be applied to these services (92601– 92604 or any applicable audiology codes).

These services should be billed on an approved electronic claim form or a paper CMS Form 1500.

100.4 – Healthcare Common Procedural Coding System (HCPCS)

(Rev. 601, Issued: 07-01-05; Effective: 04-04-05; Implementation: 07-25-05)

The following HCPCS codes are some of those available for use when billing for cochlear implantation services and devices provided by audiologists or physicians, and for the services of 92506 and 92507, by speech language pathologists.

69930 – Cochlear device implantation, with or without mastoidectomy

L8614 – Cochlear Device/System

L8619 – Cochlear implant external speech processor, replacement

L7500 – Repair of prosthetic device, hourly rate (excludes V5335 repair of oral laryngeal prosthesis or artificial larynx)

L7510 – Repair of prosthetic device, repair or replace minor parts

92506 – Evaluation of speech, language, voice, communication, auditory processing, and/or aural rehabilitation status

92507 – Treatment of speech, language, voice, communication, and/or auditory processing disorder (includes aural rehabilitation); individual

92601 – Diagnostic analysis of cochlear implant, patient under 7 years of age; with programming

(Codes 92601 and 92603 describe post-operative analysis and fitting of previously placed external devices, connection to the cochlear implant, and programming of the stimulator. Codes 92602 and 92604 describe subsequent sessions for measurements and adjustment of the external transmitter and re-programming of the internal stimulator.)

92602 – Diagnostic analysis of cochlear implant, patient under 7 years of age; subsequent programming. (Do not report 92602 in addition to 92601.)

92603 – Diagnostic analysis of cochlear implant, age 7 years or older; with programming

92604 – Diagnostic analysis of cochlear implant, age 7 years or older; subsequent reprogramming

A complete list of audiology codes can be found in Pub 100-4, chapter 12, section 30.3.

110 – Coverage and Billing for Ultrasound Stimulation for Nonunion Fracture Healing

(Rev. 597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)

An ultrasonic osteogenic stimulator is a non-invasive device that emits low intensity, pulsed ultrasound. This device is applied to the surface of the skin at the fracture site and ultrasound waves are emitted via a conductive coupling gel to stimulate fracture healing. The ultrasonic osteogenic stimulators are not to be used concurrently with other non-invasive osteogenic devices.

110.1 – Coverage Requirements

(Rev. 597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)

Effective for dates of service on and after April 27, 2005, ultrasonic osteogenic stimulators are covered as medically reasonable and necessary for the treatment of nonunion bone fractures prior to surgical intervention. In demonstrating nonunion fractures, CMS expects:

- A minimum of 2 sets of radiographs, obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days. Each radiograph set must include multiple views of the fracture site accompanied with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the 2 sets of radiographs.

For further coverage information, please refer to the National Coverage Determinations Manual, Pub. 100-03, chapter 1, section 150.2.

110.2 – Intermediary Billing Requirements

(Rev. 597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)

The RHHIs will pay for ultrasonic osteogenic stimulators only when services are submitted on type of bills (TOBs) listed under Pub. 100-04, Medicare Claims Processing Manual, chapter 32, section 100.3.

Fiscal intermediaries (FIs) must educate hospitals that there are no covered services for Ultrasonic Osteogenic Stimulation for which hospitals can be paid by the FI.

NOTE: Hospitals can not bill for Ultrasonic Osteogenic Stimulators.

110.3 – Bill Types

(Rev. 597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)

Only the following TOBs can bill for Ultrasonic Osteogenic Stimulators: 32X, 33X, 34X, which is payable under the DMEPOS Fee Schedule.

NOTE: Ultrasonic Osteogenic Stimulators must be in the patient's home health plan of care if billed on TOBs 32X or 33X.

110.4 – Carrier and Intermediary Billing Instructions

(Rev. 597, Issued: 06-24-05, Effective: 04-27-05, Implementation: 08-01-05)

Effective for dates of service on or after April 27, 2005, contractors shall allow payment for ultrasonic osteogenic stimulators with the following current procedural terminology (CPT) code:

- 20979 - Low intensity ultrasound stimulation to aid bone healing, noninvasive (nonoperative)

110.5 – DMERC Billing Instructions

(Rev. 816, Issued: 01-20-06, Effective: 04-27-05, Implementation: 04-03-06)

Effective for dates of service on or after April 27, 2005, DMERCs shall allow payment for ultrasonic osteogenic stimulators with the following HCPCS codes:

E0760 for low intensity ultrasound (include modifier “KF”), or;
E1399 for other ultrasound stimulation (include modifier “KF”)

120 - Presbyopia-Correcting (P-C IOLS) and Astigmatism-Correcting Intraocular Lenses (A-C IOLS) (General Policy Information)
(Rev. 1228; Issued: 04-27-07; Effective: 01-22-07; Implementation: 05-29-07)

Per CMS Ruling 05-01, issued May 3, 2005, Medicare will allow beneficiaries to pay additional charges associated with insertion of a P-C IOL following cataract surgery.

- Presbyopia is a type of age-associated refractive error that results in progressive loss of the focusing power of the lens of the eye, causing difficulty seeing objects at near distance, or close-up. Presbyopia occurs as the natural lens of the eye becomes thicker and less flexible with age.
- A presbyopia-correcting IOL is indicated for primary implantation in the capsular bag of the eye for the visual correction of aphakia (absence of the lens of the eye) following cataract extraction that is intended to provide near, intermediate and distance vision without the need for eyeglasses or contact lenses.

Per CMS-1536-Ruling, effective for services on and after January 22, 2007, Medicare will allow beneficiaries to pay additional charges (which are non-covered by Medicare as these additional charges are not part of a Medicare benefit category) for insertion of an A-C IOL.

- Regular astigmatism is a visual condition where part of an image is blurred due to uneven corneal curvature. A normal cornea has the same curvature at all axes, whereas the curvature of an astigmatic cornea differs in two primary axes, resulting in vision that is distorted at all distances.
- The A-C IOL is intended to provide what is otherwise achieved by two separate items; an implantable conventional IOL (one that is not astigmatism-correcting) that is covered by Medicare, and the surgical correction, eyeglasses or contact lenses that are not covered by Medicare.

A list of A-C IOLs and P-C IOLs can be accessed online at
http://www.cms.hhs.gov/HospitalOutpatientPPS/01_overview.asp

120.1 - Payment for Services and Supplies
(Rev. 1430; Issued: 02-01-08; Effective: 01-01-08; Implementation: 03-03-08)

For an IOL inserted following removal of a cataract in a hospital, on either an outpatient or inpatient basis, that is paid under the hospital Outpatient Prospective Payment System (OPPS) or the Inpatient Prospective Payment System (IPPS), respectively; or in a Medicare-approved ambulatory surgical center (ASC) that is paid under the ASC fee schedule:

- Medicare does not make separate payment to the hospital or ASC for an IOL inserted subsequent to extraction of a cataract. Payment for the IOL is packaged into the payment for the surgical cataract extraction/lens replacement procedure.
- Any person or ASC, who presents or causes to be presented a bill or request for payment for an IOL inserted during or subsequent to cataract surgery for which payment is made under the ASC fee schedule, is subject to a civil money penalty.
- For a P-C IOL or A-C IOL inserted subsequent to removal of a cataract in a hospital, on either an outpatient or inpatient basis, that is paid under the OPSS or the IPPS, respectively; or in a Medicare-approved ASC that is paid under the ASC fee schedule:
- The facility shall bill for the removal of a cataract with insertion of a conventional IOL, regardless of whether a conventional, P-C IOL, or A-C IOL is inserted. When a beneficiary receives a P-C or A-C IOL following removal of a cataract, hospitals and ASCs shall report the same CPT code that is used to report removal of a cataract with insertion of a conventional IOL. Physicians, hospitals and ASCs may also report an additional HCPCS code, V2788, to indicate any additional charges that accrue when a P-C IOL or A-C IOL is inserted in lieu of a conventional IOL until January 1, 2008. Effective for A-C IOL insertion services on or after January 1, 2008, physicians, hospitals and ASCs should use V2787 to report any additional charges that accrue. On or after January 1, 2008, physicians, hospitals, and ASCs should continue to report HCPCS code V2788 to indicate any additional charges that accrue for insertion of a P-C IOL. See Section 120.2 for coding guidelines.
- There is no Medicare benefit category that allows payment of facility charges for services and supplies required to insert and adjust a P-C or A-C IOL following removal of a cataract that exceed the facility charges for services and supplies required for the insertion and adjustment of a conventional IOL.
- There is no Medicare benefit category that allows payment of facility charges for subsequent treatments, services and supplies required to examine and monitor the beneficiary who receives a P-C or A-C IOL following removal of a cataract that exceeds the facility charges for subsequent treatments, services and supplies required to examine and monitor a beneficiary after cataract surgery followed by insertion of a conventional IOL.

A - For a P-C IOL or A-C IOL inserted in a physician's office

- A physician shall bill for a conventional IOL, regardless of whether a conventional, P-C IOL, or A-C IOL is inserted (see section 120.2, General Billing Requirements)

- There is no Medicare benefit category that allows payment of physician charges for services and supplies required to insert and adjust a P-C or A-C IOL following removal of a cataract that exceed the physician charges for services and supplies for the insertion and adjustment of a conventional IOL.

- There is no Medicare benefit category that allows payment of physician charges for subsequent treatments, service and supplies required to examine and monitor a beneficiary following removal of a cataract with insertion of a P-C or A-C IOL that exceed physician charges for services and supplies to examine and monitor a beneficiary following removal of a cataract with insertion of a conventional IOL.

B - For a P-C IOL or A-C IOL inserted in a hospital

- A physician may not bill Medicare for a P-C or A-C IOL inserted during a cataract procedure performed in a hospital setting because the payment for the lens is included in the payment made to the facility for the surgical procedure.

- There is no Medicare benefit category that allows payment of physician charges for services and supplies required to insert and adjust a P-C or A-C IOL following removal of a cataract that exceed the physician charges for services and supplies required for the insertion of a conventional IOL.

C - For a P-C IOL or A-C IOL inserted in an Ambulatory Surgical Center

- Refer to Chapter 14, Section 40.3 for complete guidance on payment for P-C IOL or A-C IOL in Ambulatory Surgical Centers.

120.2 - Coding and General Billing Requirements

(Rev. 1430; Issued: 02-01-08; Effective: 01-01-08; Implementation: 03-03-08)

Physicians and hospitals must report one of the following Current Procedural Terminology (CPT) codes on the claim:

66982 - Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification), complex requiring devices or techniques not generally used in routine cataract surgery (e.g., iris expansion device, suture support for intraocular lens, or primary posterior capsulorrhexis) or performed on patients in the amblyogenic development stage.

- 66983 - Intracapsular cataract with insertion of intraocular lens prosthesis (one stage procedure)
- 66984 - Extracapsular cataract removal with insertion of intraocular lens prosthesis (one stage procedure), manual or mechanical technique (e.g., irrigation and aspiration or phacoemulsification)

- 66985 - Insertion of intraocular lens prosthesis (secondary implant), not associated with concurrent cataract extraction
- 66986 - Exchange of intraocular lens

In addition, physicians inserting a P-C IOL or A-C IOL in an office setting may bill code V2632 (posterior chamber intraocular lens) for the IOL. Medicare will make payment for the lens based on reasonable cost for a conventional IOL. Place of Service (POS) = 11.

Effective for dates of service on and after January 1, 2006, physician, hospitals and ASCs may also bill the non-covered charges related to the P-C function of the IOL using HCPCS code V2788. Effective for dates of service on and after January 22, 2007 through January 1, 2008, non-covered charges related to A-C function of the IOL can be billed using HCPCS code V2788. The type of service indicator for the non-covered billed charges is Q. (The type of service is applied by the Medicare carrier and not the provider). Effective for A-C IOL insertion services on or after January 1, 2008, physicians, hospitals and ASCs should use V2787 rather than V2788 to report any additional charges that accrue.

When denying the non-payable charges submitted with V2787 or V2788, contractors shall use an appropriate Medical Summary Notice (MSN) such as 16.10 (Medicare does not pay for this item or service) and an appropriate claim adjustment reason code such as 96 (non-covered charges) for claims submitted with the non-payable charges.

Hospitals and physicians may use the proper CPT code(s) to bill Medicare for evaluation and management services usually associated with services following cataract extraction surgery, if appropriate.

A - Applicable Bill Types

The hospital applicable bill types are 12X, 13X, 83X and 85X.

B - Other Special Requirements for Hospitals

Hospitals shall continue to pay CAHs method 2 claims under current payment methodologies for conditional IOLs.

120.3 - Provider Notification Requirements

(Rev. 1228; Issued: 04-27-07; Effective: 01-22-07; Implementation: 05-29-07)

When a beneficiary requests insertion of a P-C or A-C IOL instead of a conventional IOL following removal of a cataract:

- Prior to the procedure to remove a cataractous lens and insert a P-C or A-C lens, the facility and the physician must inform the beneficiary that Medicare will not make

payment for services that are specific to the insertion, adjustment or other subsequent treatments related to the P-C or A-C functionality of the IOL.

- The P-C or A-C functionality of a P-C or A-C IOL does not fall into a Medicare benefit category, and, therefore, is not covered. Therefore, the facility and physician are not required to provide an Advanced Beneficiary Notice to beneficiaries who request a P-C or A-C IOL.
- Although not required, CMS strongly encourages facilities and physicians to issue a Notice of Exclusion from Medicare Benefits to beneficiaries in order to clearly identify the non-payable aspects of a P-C or A-C IOL insertion. This notice may be found in English at http://cms.hhs.gov/medicare/bni/20007_English.pdf
- Spanish language at: http://cms.hhs.gov/medicare/bni/20007_Spanish.pdf.

120.4 - Beneficiary Liability

(Rev. 1228; Issued: 04-27-07; Effective: 01-22-07; Implementation: 05-29-07)

When a beneficiary requests insertion of a P-C or A-C IOL instead of a conventional IOL following removal of a cataract and that procedure is performed, the beneficiary is responsible for payment of facility and physician charges for services and supplies attributable to the P-C or A-C functionality of the P-C or A-C IOL:

- In determining the beneficiary's liability, the facility and physician may take into account any additional work and resources required for insertion, fitting, vision acuity testing, and monitoring of the P-C or A-C IOL that exceed the work and resources attributable to insertion of a conventional IOL.
- The physician and the facility may not charge for cataract extraction with insertion of a P-C or A-C IOL unless the beneficiary requests this service.
 - The physician and the facility may not require the beneficiary to request a P-C or A-C IOL as a condition of performing a cataract extraction with IOL insertion.

130 - External Counterpulsation (ECP) Therapy

(Rev. 898, Issued: 03-31-06; Effective/Implementation Dates: 03-31-06)

Commonly referred to as enhanced external counterpulsation, is a non-invasive outpatient treatment for coronary artery disease refractory medical and/or surgical therapy. Effective for dates of service July 1, 1999, and after, Medicare will cover ECP when its use is in patients with stable angina (Class III or Class IV, Canadian Cardiovascular Society Classification or equivalent classification) who, in the opinion of a cardiologist or cardiothoracic surgeon, are not readily amenable to surgical intervention, such as PTCA or cardiac bypass, because:

- Their condition is inoperable, or at high risk of operative complications or post-operative failure;
- Their coronary anatomy is not readily amenable to such procedures; or
- They have co-morbid states that create excessive risk.

(Refer to Publication 100-03, section 20.20 for further coverage criteria.)

130.1 - Billing and Payment Requirements
(Rev. 898, Issued: 03-31-06; Effective/Implementation Dates: 03-31-06)

Effective for dates of service on or after January 1, 2000, use HCPCS code G0166 (External counterpulsation, per session) to report ECP services. The codes for external cardiac assist (92971), ECG rhythm strip and report (93040 or 93041), pulse oximetry (94760 or 94761) and plethysmography (93922 or 93923) or other monitoring tests for examining the effects of this treatment are not clinically necessary with this service and should not be paid on the same day, unless they occur in a clinical setting not connected with the delivery of the ECP. Daily evaluation and management service, e.g., 99201-99205, 99211-99215, 99217-99220, 99241-99245, cannot be billed with the ECP treatments. Any evaluation and management service must be justified with adequate documentation of the medical necessity of the visit. Deductible and coinsurance apply.

130.2 - Special Intermediary Billing and Payment Requirements
(Rev. 898, Issued: 03-31-06; Effective/Implementation Dates: 03-31-06)

Payment is made to hospitals for the facility costs it incurs under Part B on a reasonable cost basis. Payment is also made to PPS-exempt hospitals for the facility costs it incurs on a reasonable cost basis. Deductible and coinsurance apply.

Applicable bill types are 12X, 13X, 83X or 85X.

140 - Cardiac Rehabilitation Programs
(Rev. 909, Issued: 04-21-06, Effective: 03-22-06, Implementation: 06-21-06)

Medicare covers cardiac rehabilitation exercise programs for patients who meet the following criteria:

- Have a documented diagnosis of acute myocardial infarction within the preceding 12 months; or
- Have had coronary bypass surgery; or
- Have stable angina pectoris; or
- Have had heart valve repair/replacement; or

- Have had percutaneous transluminal coronary angioplasty (PTCA) or coronary stenting; or
- Have had a heart or heart-lung transplant.

Effective for dates of services on or after March 22, 2006, services provided in connection with a cardiac rehabilitation exercise program may be considered reasonable and necessary for up to 36 sessions. Patients generally receive 2 to 3 sessions per week for 12 to 18 weeks. The contractor has discretion to cover cardiac rehabilitation services beyond 18 weeks. Coverage must not exceed a total of 72 sessions for 36 weeks.

Cardiac rehabilitation programs shall be performed incident to physician's services in outpatient hospitals, or outpatient settings such as clinics or offices. Follow the policies for services incident to the services of a physician as they apply in each setting. For example, see Pub. 100-02, chapter 6, section 2.4.1, and Pub. 100-02, chapter 15, section 60.1.

(Refer to Publication 100-03, section 20.10 for further coverage guidelines.)

140.1 - Coding Requirements

(Rev. 909, Issued: 04-21-06, Effective: 03-22-06, Implementation: 06-21-06)

The following are applicable HCPCS codes:

- 93797 - Physician services for outpatient cardiac rehabilitation; without continuous ECG monitoring (per session)
- 93798 - Physician services for outpatient cardiac rehabilitation; with continuous ECG monitoring (per session)

150 - Billing Requirements for Bariatric Surgery for Treatment of Morbid Obesity

(Rev. 931, Issued: 04-28-06, Effective: 02-21-06, Implementation: 05-30-06 Carrier/10-02-06 FI)

150.1 - General

(Rev. 1233, Issued: 04-27-07, Effective: 02-21-06, Implementation: 05-29-07)

A. Covered Bariatric Surgery Procedures

Effective for services on or after February 21, 2006, Medicare has determined that the following bariatric surgery procedures are reasonable and necessary under certain conditions for the treatment of morbid obesity. The patient must have a body-mass index (BMI) ≥ 35 , have at least one co-morbidity related to obesity, and have been previously unsuccessful with medical treatment for obesity. This medical information must be

documented in the patient's medical record. In addition, the procedure must be performed at an approved facility. A list of approved facilities may be found at <http://www.cms.hhs.gov/MedicareApprovedFacilitie/BSF/list.asp#TopOfPage>.

- Open Roux-en-Y gastric bypass (RYGBP).
- Laparoscopic Roux-en-Y gastric bypass (RYGBP).
- Laparoscopic adjustable gastric banding (LAGB).
- Open biliopancreatic diversion with duodenal switch (BPD/DS).
- Laparoscopic biliopancreatic diversion with duodenal switch (BPD/DS).

B. Non-Covered Bariatric Surgery Procedures

Effective for services on or after February 21, 2006, Medicare has determined that the following bariatric surgery procedures are not reasonable and necessary for the treatment of morbid obesity.

- Open vertical banded gastroplasty.
- Laparoscopic vertical banded gastroplasty.
- Open sleeve gastrectomy.
- Laparoscopic sleeve gastrectomy.
- Open adjustable gastric banding.

Complete coverage guidelines can be found in the National Coverage Determination Manual (Publication 100-03), Sections 40.5 and 100.1.

150.2 - HCPCS Procedure Codes for Bariatric Surgery (Rev. 1233, Issued: 04-27-07, Effective: 02-21-06, Implementation: 05-29-07)

A. Covered HCPCS Procedure Codes

For services on or after February 21, 2006, the following HCPCS procedure codes are covered for bariatric surgery:

- 43770 - Laparoscopy, surgical, gastric restrictive procedure; placement of adjustable gastric band (gastric band and subcutaneous port components).
- 43644 - Laparoscopy, surgical, gastric restrictive procedure; with gastric bypass and Roux-en-Y gastroenterostomy (roux limb 150 cm or less).
- 43645 - Laparoscopy with gastric bypass and small intestine reconstruction to limit absorption. (Do not report 43645 in conjunction with 49320, 43847.)

- 43845 - Gastric restrictive procedure with partial gastrectomy, pylorus-preserving duodenoileostomy and ileoieostomy (50 to 100 cm common channel) to limit absorption (biliopancreatic diversion with duodenal switch).
- 43846 - Gastric restrictive procedure, with gastric bypass for morbid obesity; with short limb (150 cm or less Roux-en-Y gastroenterostomy. (For greater than 150 cm, use 43847.) (For laparoscopic procedure, use 43644.)
- 43847 - With small intestine reconstruction to limit absorption.

B. Noncovered HCPCS Procedure Codes

For services on or after February 21, 2006, the following HCPCS procedure codes are non-covered for bariatric surgery:

- 43842 - Gastric restrictive procedure, without gastric bypass, for morbid obesity; vertical banded gastroplasty.
- NOC code 43999 used to bill for:
- Laparoscopic vertical banded gastroplasty.
- Open sleeve gastrectomy.
- Laparoscopic sleeve gastrectomy.
- Open adjustable gastric banding.

150.3 - ICD-9 Procedure Codes for Bariatric Surgery (FIs only) (Rev. 1233, Issued: 04-27-07, Effective: 02-21-06, Implementation: 05-29-07)

A. Covered ICD-9 Procedure Codes

For services on or after February 21, 2006, the following ICD-9 procedure codes are covered for bariatric surgery:

- 44.38 - Laparoscopic gastroenterostomy (laparoscopic Roux-en-Y).
- 44.39 - Other gastroenterostomy (open Roux-en-Y).
- 44.95 - Laparoscopic gastric restrictive procedure (laparoscopic adjustable gastric band and port insertion).
- Open and laparoscopic BPD with DS.
 - 43.89 - Other partial gastrectomy.
 - 45.51 - Isolation of segment of small intestine.
 - 45.91 - Small to small intestinal anastomosis.

Note: There is no distinction between open and laparoscopic BPD with DS for the inpatient setting. For either approach, all three codes must appear on the claim to be covered.

B. Noncovered ICD-9 Procedure Codes

For services on or after February 21, 2006, the following ICD-9 procedure codes are non-covered for bariatric surgery:

- 44.68 - Laparoscopic gastroplasty (vertical banded gastroplasty).
- 44.69 - Other. Inversion of gastric diverticulum. Repair of stomach NOS.
- 43.89 - Other partial gastrectomy.

NOTE: 44.68 is non-covered when used to bill for open adjustable gastric banding and laparoscopic vertical banded gastroplasty. 44.69 is non-covered when used to bill for open vertical banded gastroplasty. 43.89 is non-covered when used to bill for open and laparoscopic sleeve gastrectomy.

150.4 - ICD-9 Diagnosis Codes for Bariatric Surgery

(Rev. 1233, Issued: 04-27-07, Effective: 02-21-06, Implementation: 05-29-07)

For services on or after February 21, 2006, the following ICD-9 diagnosis code is covered for bariatric surgery if certain other conditions are met:

278.01 - Morbid obesity; severe obesity.

150.5 - ICD-9 Diagnosis Codes for BMI \geq 35

(Rev.1233, Issued: 04-27-07, Effective: 02-21-06, Implementation: 05-29-07)

The following ICD-9 diagnosis codes identify BMI \geq 35:

- V85.35 - Body Mass Index 35.0-35.9, adult.
- V85.36 - Body Mass Index 36.0-36.9, adult.
- V85.37 - Body Mass Index 37.0-37.9, adult.
- V85.38 - Body Mass Index 38.0-38.9, adult.
- V85.39 - Body Mass Index 39.0-39.9, adult.
- V85.4 - Body Mass Index 40 and over, adult.

150.6 - Claims Guidance for Payment

(Rev. 1233, Issued: 04-27-07, Effective: 02-21-06, Implementation: 05-29-07)

A. Covered Bariatric Surgery Procedures

Process covered bariatric surgery claims as follows:

1. Identify bariatric surgery claims.

- FIs identify bariatric surgery claims by the presence of ICD-9-CM diagnosis code 278.01 for morbid obesity and one of the covered ICD-9-CM procedure codes listed in §150.3.
 - Carriers identify bariatric surgery claims by the presence of ICD-9-CM diagnosis code 278.01 for morbid obesity and one of the covered HCPCS procedure codes listed in §150.2.
2. Perform facility certification validation for all bariatric surgery claims on a pre-pay basis.
 - A list of approved facilities may be found at:
<http://www.cms.hhs.gov/MedicareApprovedFacilities/BSF/list.asp#TopOfPage>.
 3. Contractors should review bariatric surgery claims data and determine whether a pre- or post-pay sample of bariatric surgery claims need further review to assure that the beneficiary has a BMI ≥ 35 (V85.35 - V85.4) and at least one co-morbidity related to obesity.
 - The carrier/FI/A/B MAC medical director may define the appropriate method for addressing the obesity-related co-morbid requirement.

NOTE: If ICD-9-CM diagnosis code 278.01 and one of the covered ICD-9-CM procedure codes listed in §150.3 (for FIs) or HCPCS procedure codes listed in §150.2 (for carriers) are not present, the claim is not for bariatric surgery and should be processed under normal procedures.

B. Non-Covered Bariatric Surgery Procedures

Carriers are to process non-covered bariatric surgery claims according to the conditions outlined below:

1. Deny claims billed with HCPCS procedure code 43842 when used for:
 - Open vertical banded gastroplasty.
2. Deny claims billed with HCPCS NOC code 43999 when used for:
 - Laparoscopic vertical banded gastroplasty.
 - Open sleeve gastrectomy.
 - Laparoscopic sleeve gastrectomy.
 - Open adjustable gastric banding.

FIs are to process non-covered bariatric surgery claims according to the conditions outlined below:

1. Reject claims billed with principal ICD-9 CM diagnosis code 278.01 and ICD-9 procedure code 44.68 when used for:
 - Open adjustable gastric banding.
 - Laparoscopic vertical banded gastroplasty.
2. Reject billed with principal ICD-9 CM diagnosis code 278.01 and ICD-9 procedure code 44.69 when used for:
 - Open vertical banded gastroplasty.
3. Reject claims billed with principal ICD-9 CM diagnosis code 278.01 and ICD-9 procedure code 43.89 when used for:
 - Open sleeve gastrectomy.
 - Laparoscopic sleeve gastrectomy.

NOTE: If ICD-9 procedure code 43.89 appears on the claim along with 45.51 and 45.91 to describe open or laparoscopic BPD/DS, process as a covered procedure according to §150.6.A.

150.7 - Medicare Summary Notices (MSNs) and Claim Adjustment Reason Codes

(Rev. 1233, Issued: 04-27-07, Effective: 02-21-06, Implementation: 05-29-07)

When rejecting/denying claims because bariatric surgery procedures were performed in an unapproved facility use:

- MSN 16.2 - "This service cannot be paid when provided in this location/facility."
- Claim Adjustment Reason Code 58 - "Payment adjusted because treatment was deemed by the payer to have been rendered in an inappropriate or invalid place of service."

When rejecting/denying claims for noncovered bariatric surgery procedures use:

- MSN16.10 - Medicare does not pay for this item or service.
- Claim Adjustment Reason Code 50 - "These are noncovered services because this is not deemed a "medical necessity" by the payer."

When rejecting/denying claims for covered bariatric surgery procedures because the patient did not meet the conditions for coverage use:

- MSN 15.4 - "The information provided does not support the need for this service or item."

- Claim Adjustment Reason Code 167 - "This (these) diagnosis(es) is (are) not covered"

In addition to the codes listed above, afford appeal rights to all parties.

150.8 - Fiscal Intermediary Billing Requirements

(Rev. 1233, Issued: 04-27-07, Effective: 02-21-06, Implementation: 05-29-07)

The FI will pay for bariatric surgery only when the services are submitted on the following type of bill (TOB): 11X.

Type of facility and setting determines the basis of payment:

- For services performed in IHS inpatient hospitals, TOB 11X under IPPS payment is based on the DRG.
- For services performed in inpatient hospitals, TOB 11X under IPPS payment is based on the DRG.
- For services performed in IHS critical access hospitals, TOB 11X, payment is based on 101% facility specific per diem rate.

For services performed in CAH inpatient hospitals, TOB 11X, payment is based on 101% of reasonable cost.

150.9 - Advance Beneficiary Notice and HINN Information

(Rev. 1233, Issued: 04-27-07, Effective: 02-21-06, Implementation: 05-29-07)

Physicians must be advised that the physician is liable for charges if the surgery is performed in an unapproved facility, unless the beneficiary was informed that he or she would be financially responsible prior to performance for the procedure. The provider must have the beneficiary sign an advance beneficiary notice (ABN) if the bariatric surgery is performed in an unapproved facility. Note that the ABN is the appropriate notice for Part B services.

The HINN model language should be adapted to this situation in the sections addressing: description of the care at issue if the surgery is performed on an inpatient basis, in an unapproved facility, to avoid being liable, the provider must issue a HINN. Other content requirements of HINN still apply. Use the HINN letter most appropriate to the overall situation.

160 – PTA for Implanting the Carotid Stent

(Rev. 1042, Issued: 08-25-06; Effective: 03-17-05; Implementation: 10-02-06)

160.1 – Category B IDE Study Coverage

(Rev. 1042, Issued: 08-25-06, Effective: 03-17-05, Implementation: 10-02-06)

CR 1660 (Effective July 1, 2001)

Medicare covers PTA of the carotid artery concurrent with stent placement when furnished in accordance with the FDA protocols governing Category B Investigational Device Exemption (IDE) studies.

The billing for this procedure is based upon how the service is delivered. There are several CPT codes that may be billed depending upon how the procedure is performed. Contractor medical directors should consider what provider education information is needed to assist providers on the billing for this service.

Contractors must review their local medical review policies to ensure that payment is provided for claims for PTA in a FDA approved clinical study and deny any claims for services for PTA of the carotid artery when provided outside of a FDA approved clinical study.

As a requirement for Category B IDE coverage, providers must bill a six-digit IDE Number that begins with a “G” (i.e., G123456). To identify the line as an IDE line, providers billing FIs must bill this IDE Number on a 0624 Revenue Code line while providers billing carriers must bill this IDE Number along with a QA modifier.

160.2 – Post Approval Study Coverage

(Rev. 1042, Issued: 08-25-06, Effective: 03-17-05, Implementation: 10-02-06)

CR 3489 (Effective October 12, 2004)

Medicare covers PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing post-approval studies. Billing Post Approval Studies is similar to normal Category B IDEs billing procedures, except that under Post Approval coverage, providers must bill the Pre-Market Approval (PMA) number assigned to the stent system by the FDA. PMA numbers are like typical IDE Numbers in that they have six-digits, but they begin with a “P” (i.e., P123456) instead of “G.”

160.2.1 – Carotid Artery Stenting (CAS) for Post-Approval Studies

(Rev. 951, Issued: 05-12-06, Effective: 02-28-06, Implementation: 06-12-06)

A. Background

As explained above in §160.2, CMS issued Change Request (CR) 3489, Transmittal 314 to provide contractors with instructions for processing claims for carotid artery stenting procedures performed in Food and Drug Administration (FDA)-approved post-approval studies. As the post-approval studies began to end, CMS received requests to extend coverage for the post-approval studies. CMS has reviewed the extension requests and has

determined that patients participating in post-approval extension studies are also included in the currently covered population of patients participating in FDA-approved post-approval studies.

B. Policy

To grant approval for post-approval studies, the FDA reviews each study protocol. Once approval is granted, the FDA issues a formal approval letter to the study sponsor. Extensions of post-approval studies are not subject to approval by the FDA because they surpass the post-approval study requirements identified in the conditions of approval for post-approval studies. Since the FDA cannot approve these extension studies, individual Post-Market Approval (PMA) numbers cannot be issued to separately identify each study. Currently, in order to receive reimbursement for procedures performed as part of a carotid artery stenting post-approval study, providers must include the FDA-issued PMA number on each claim to indicate participation in a specific study.

CMS has determined that all extension studies must be reviewed by the FDA. The FDA will issue an acknowledgement letter stating that the extension study is scientifically valid and will generate clinically relevant post-market data. Upon receipt of this letter and review of the extension study protocol, CMS will issue a letter to the study sponsor indicating that the study under review will be covered by Medicare. Since an individual PMA number cannot be assigned by the FDA to each extension study, these studies will use the PMA number assigned to the original FDA-approved post-approval study (i.e., CAPTURE 2 shall use the PMA number assigned to CAPTURE 1).

C. Billing

In order to receive Medicare coverage for patients participating in post-approval extension studies, providers shall follow the process for informing contractors of their participation as established in CR 3489, Transmittal 314. Providers shall submit both the FDA acknowledgement letter and the CMS letter providing coverage for the extension study to their contractor. Additionally, providers shall submit any other materials contractors would require for FDA-approved post-approval studies.

In response, contractors will issue a letter assigning an effective date for each facility's participation in the extension study. Providers may bill for procedures performed in the extension study for dates of service on and after the assigned effective date. Providers shall follow the billing instructions from CR 3489, Transmittal 314. Providers billing FIs must bill using the most current ICD-9 CM procedure codes. For example, when billing a CAS extension study with dates of service July 1, 2006, through July 15, 2006, the provider should bill ICD-9 CM procedure codes 00.61 and 00.63 (instead of the 39.50 and 39.90 procedure codes published in CR 3489).

160.3 – Carotid Artery Stenting (CAS) With Embolic Protection Coverage

(Rev. 1315, Issued: 08-10-07, Effective: 03-17-05, Implementation: 10-01-07)

CR 3811 (Effective March 17, 2005)

Medicare covers PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent under specific patient indications found in The National Coverage Determinations Manual, chapter 1, part 1, section 20.7. In addition to the specific patient indications, CMS determined that CAS with embolic protection is reasonable and necessary only if performed in facilities meeting specified facility requirements and are, therefore, determined to be competent in performing the evaluation, procedure, and follow-up necessary to ensure optimal patient outcomes. Facilities meeting facility standards for coverage are deemed “approved” for receiving Medicare payment for CAS with embolic protection and are viewable on the following Web site:
<http://www.cms.hhs.gov/MedicareApprovedFacilitie/CASF/list.asp>.

CR 5667 (Effective March 17, 2005)

As stated in the NCD, patients who experience non-disabling strokes (modified Rankin scale <3) are considered to be symptomatic and therefore eligible for coverage; however, patients who experience disabling strokes (modified Rankin scale ≥3) are not eligible for coverage. Prior to the implementation of CR 5667, there are no codes that distinguish between non-disabling and disabling strokes. To ensure claims for all eligible patients can be paid, CR 5667 adds the ICD-9-CM diagnosis code 433.11, occlusion of the carotid artery with infarct, to the list of payable claims for CAS. Patients who experience disabling strokes remain ineligible for coverage.

161 - Intracranial Percutaneous Transluminal Angioplasty (PTA) With Stenting

(Rev. 1147, Issued: 01-05-07, Effective: 11-06-06, Implementation: 02-05-07)

A. Background

In the past, PTA to treat obstructive lesions of the cerebral arteries was non-covered by Medicare because the safety and efficacy of the procedure had not been established. This national coverage determination (NCD) meant that the procedure was also non-covered for beneficiaries participating in Food and Drug Administration (FDA)-approved investigational device exemption (IDE) clinical trials.

B. Policy

On February 9, 2006, a request for reconsideration of this NCD initiated a national coverage analysis. CMS reviewed the evidence and determined that intracranial PTA with stenting is reasonable and necessary under §1862(a)(1)(A) of the Social Security Act for the treatment of cerebral vessels (as specified in The National Coverage Determinations Manual, chapter 1, part 1, section 20.7) only when furnished in accordance with FDA-approved protocols governing Category B IDE clinical trials. All other indications for intracranial PTA with stenting remain non-covered.

C. Billing

Providers of covered intracranial PTA with stenting shall use Category B IDE billing requirements, as listed above in section 68.4. In addition to these requirements, providers must bill the appropriate procedure and diagnosis codes to receive payment. That is, under Part A, providers must bill intracranial PTA using procedure codes 00.62 and 00.65, along with a diagnosis code of 437.0. Under Part B, providers must bill procedure code 37799 along with a diagnosis code of 437.0.

NOTE: ICD-9CM codes are subject to modification. Providers must always ensure they are using the latest and most appropriate codes.

170 - Billing Requirements for Lumbar Artificial Disc Replacement (Rev. 992, Issued: 06-23-06, Effective: 05-16-06, Implementation: Carriers 07-17-06/FIs 10-01-06)

170.1 - General

(Rev. 1340, Issued: 09-21-07, Effective: 08-14-07, Implementation: 10-01-07)

Effective for services performed from May 16, 2006 through August 13, 2007, the Centers for Medicare & Medicaid Services (CMS) made the decision that lumbar artificial disc replacement (LADR) with the Charite™ lumbar artificial disc is non-covered for Medicare beneficiaries over 60 years of age. See Pub. 100-03, Medicare National Coverage Determinations Manual, section 150.10, for more information about the non-covered determination.

Effective for services performed on or after August 14, 2007, CMS made the decision that LADR with any lumbar artificial disc is non-covered for Medicare beneficiaries over 60 years of age, (i.e., on or after a beneficiary's 61st birthday).

For Medicare beneficiaries 60 years of age and younger, there is no national coverage determination for LADR, leaving such determinations to continue to be made by the local contractors.

170.2 - Carrier Billing Requirements

(Rev. 1340, Issued: 09-21-07, Effective: 08-14-07, Implementation: 10-01-07)

Effective for services performed on or after May 16, 2006 through December 31, 2006, carriers shall deny claims, for Medicare beneficiaries over 60 years of age, submitted with the following Category III Codes:

- 0091T Single interspace, lumbar; and
- 0092T Each additional interspace (List separately in addition to code for primary procedure.)

Effective for services performed on or after January 1, 2007 through August 13, 2007, for Medicare beneficiaries over 60 years of age, LADR with the Charite™ lumbar artificial disc, carriers shall deny claims submitted with the following codes:

- 22857 Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, single interspace; and
- 0163T Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, each additional interspace.

Carriers shall continue to follow their normal claims processing criteria for IDEs for LADR performed with an implant eligible under the IDE criteria.

For dates of service May 16, 2006 through August 13, 2007, Medicare coverage under the investigational device exemption (IDE) for LADR with a disc other than the Charite™ lumbar disc in eligible clinical trials is not impacted.

Effective for services performed on or after August 14, 2007, carriers shall deny claims for LADR surgery, for Medicare beneficiaries over 60 years of age, (i.e., on or after a beneficiary's 61st birthday) submitted with the following codes:

- 22857 Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, single interspace; and
- 0163T Total disc arthroplasty (artificial disc), anterior approach, including discectomy to prepare interspace (other than for decompression), lumbar, each additional interspace

170.3 - Fiscal Intermediary (FI) Billing Requirements

(Rev. 1340, Issued: 09-21-07, Effective: 08-14-07, Implementation: 10-01-07)

The FI/A/B MAC will pay for LADR when approved under the IDE/clinical trial criteria only when submitted with ICD-9-CM procedure code 84.65 with condition code 30 and diagnosis code V70.7 when submitted on type of bill (TOB) 11X from May 16, 2006 through August 13, 2007.

Special Billing instructions:

For services performed on TOB 11X in critical access hospitals (CAH), the payment will be 101% of reasonable cost.

For services performed on TOB 11X Indian Health Services (IHS) inpatient hospitals will pay under the inpatient prospective payment system (IPPS) based on the DRG.

For services performed on TOB 11X, IHS CAHs will pay under 101% facility specific per diem rate.

NOTE: ICD-9-CM procedure code 84.65 is never payable for beneficiaries over 60 years of age, with the Charite™ lumbar artificial disc, which is the only one that is FDA approved for any diagnosis. If a different manufacture's disc is used in one of the approved clinical trials or is an approved IDE, then condition code 30 and diagnosis code V70.7 must be on the claim for it to be payable.

Effective for discharges on or after August 14, 2007, CMS has found that LADR is not reasonable and necessary for the Medicare population over 60 years of age. Therefore, LADR is non-covered for Medicare beneficiaries over 60 years of age as identified in section 150.10, of Pub.100-03, the NCD Manual. FIs/A/B MACS shall deny claims with ICD-9-CM procedure code 84.65 for Medicare beneficiaries over 60 years of age.

For Medicare beneficiaries 60 years of age and younger, there is no NCD, leaving such determinations to continue to be made by the local contractors.

170.4 – Reasons for Denial and Medicare Summary Notice (MSN), Claim Adjustment Reason Code Messages, and Remittance Advice Remark Code

(Rev. 1340, Issued: 09-21-07, Effective: 08-14-07, Implementation: 10-01-07)

Contractors shall use the following messages when denying claims for Medicare beneficiaries over 60 years of age (i.e. on or after a beneficiary's 61st birthday).

21.24 "This service is not covered for patients over age 60."

"Este servicio no está cubierto en pacientes mayores de 60 años."

Use an appropriate Claim Adjustment Reason Code:

96 "Non-covered charge(s)."

Use an appropriate Remittance Advice Remark Code:

N386 "This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A copy of this policy is available at <http://www.cms.hhs.gov/mcd/search.asp>. If you do not have Web access, you may contact the contractor to request a copy of the NCD."

170.5 - Advance Beneficiary Notice (ABN) and Hospital Issued Notice of Noncoverage (HINN) Information

(Rev. 1340, Issued: 09-21-07, Effective: 08-14-07, Implementation: 10-01-07)

Providers must be advised that the provider is liable for charges if the lumbar artificial disc replacement is used in the surgery, unless the beneficiary was informed that he/she would be financially responsible prior to performance of the procedure. To avoid this liability the provider should have the beneficiary sign an ABN.

The HINN model language should be adapted to this situation in the sections addressing description of the care at issue if the surgery is performed on an inpatient basis. Unless the beneficiary was informed prior to the admission that he/ she would be financially liable for the admission, the provider is liable. To avoid this liability the provider must issue a HINN. Other content requirements of a HINN still apply. Use the HINN letter most appropriate to the overall situation.

180 – Cryosurgery of the Prostate Gland

(Rev. 1111, Issued: 11-09-06, Effective: 04-01-07, Implementation: 04-02-07)

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

180.1 - Coverage Requirements

(Rev. 1111, Issued: 11-09-06, Effective: 04-01-07, Implementation: 04-02-07)

Medicare covers cryosurgery of the prostate gland effective for claims with dates of service on or after July 1, 1999. The coverage is for:

1. Primary treatment of patients with clinically localized prostate cancer, Stages T1 – T3 (diagnosis code is 185 – malignant neoplasm of prostate).
2. Salvage therapy (effective for claims with dates of service on or after July 1, 2001 for patients:
 - a. Having recurrent, localized prostate cancer;
 - b. Failing a trial of radiation therapy as their primary treatment; and
 - c. Meeting one of these conditions: State T2B or below; Gleason score less than 9 or; PSA less than 8 ng/ml.

180.2 - Billing Requirements

(Rev. 1111, Issued: 11-09-06, Effective: 04-01-07, Implementation: 04-02-07)

Claims for cryosurgery for the prostate gland are to be submitted on the ANSI X12 ASC 837, or, in exceptional circumstances, on a hard copy Form CMS – 1450. This procedure can be rendered in an inpatient or outpatient hospital setting (types of bill (TOBs) 11x 13x, 83x, and 85x).

The FI will look for the following when processing claims with cryosurgery services:

- Diagnosis Code 185 (must be on all cryosurgical claims);
- For outpatient claims HCPCS 55873 and revenue codes 0360, 0361, or 0369 Cryosurgery ablation of localized prostate cancer, stages T1- T3 (includes ultrasonic guidance for interstitial cryosurgery probe placement, postoperative irrigations and aspiration of sloughing tissue included) must be on all outpatient claims; and
- For inpatient claims procedure code 60.62 (perineal prostatectomy- the definition includes cryoablation of prostate, cryostatectomy of prostate, and radical cryosurgical ablation of prostate) must be on the claim.

180.3 – Payment Requirements

(Rev. 1111, Issued: 11-09-06, Effective: 04-01-07, Implementation: 04-02-07)

This service may be paid as a primary treatment for patients with clinically localized prostate cancer, Stages T1 – T3. The ultrasonic guidance associated with this procedure will not be paid for separately, but is bundled into the payment for the surgical procedure. When one provider has furnished the cryosurgical ablation and another the ultrasonic guidance, the provider of the ultrasonic guidance must seek compensation from the provider of the cryosurgical ablation.

Effective July 1, 2001, cryosurgery performed as salvage therapy, will be paid only according to the coverage requirements described above.

Type of facility and setting determines the basis of payment:

- For services performed on an inpatient or outpatient basis in a CAH, TOBs 11x and 85x: the FI will pay 101 percent of reasonable cost minus any applicable deductible and coinsurance.
- For services performed on an inpatient basis in short term acute care hospitals, (including those in Guam, American Samoa, Virgin Islands, Saipan, and Indian Health Services Hospitals) TOB 11x: the FI will pay the DRG payment minus any applicable deductible and coinsurance.
- For services performed on an outpatient basis in hospitals subject to the Outpatient PPS, TOB 13x: the FI will pay the assigned APC minus any applicable deductible and coinsurance.
- For outpatient services in hospitals that are exempt from OPPS (such as in American Samoa, Virgin Islands, Guam, and Saipan) TOBs 13x: the FI will pay reasonable cost, minus any applicable deductible and coinsurance.

- For outpatient services in Indian Health Service hospitals TOBs 13x and 83x: the FI will pay the ASC payment amount for TOB 83x. minus any applicable deductible and coinsurance.
- For inpatient or outpatient services in hospitals in Maryland, make payment according to the State Cost Containment system.

For services performed on an inpatient basis: the hospitals exempt from inpatient acute care PPS shall be paid on reasonable cost basis, minus any applicable deductible and coinsurance.

190 – Billing Requirements for Extracorporeal Photopheresis

(Rev. 1206; Issued: 03-16-07; Effective: December 19, 2006; Implementation: 04-02-07)

Effective for dates of services on and after December 19, 2006, Medicare has expanded coverage for extracorporeal photopheresis for patients with acute cardiac allograft rejection whose disease is refractory to standard immunosuppressive drug treatment and patients with chronic graft versus host disease whose disease is refractory to standard immunosuppressive drug treatment. (See Pub. 100-03, chapter 1, section 110.4, for complete coverage guidelines).

190.1 – Applicable Intermediary Bill Types

(Rev. 1206; Issued: 03-16-07; Effective: December 19, 2006; Implementation: 04-02-07)

11X, 13X, or 85X

190.2 – Healthcare Common Procedural Coding System (HCPCS), Applicable Diagnosis Codes and Procedure Code

(Rev. 1206; Issued: 03-16-07; Effective: December 19, 2006; Implementation: 04-02-07)

The following HCPCS procedure code is used for billing extracorporeal photopheresis

- 36522 - Photopheresis, extracorporeal

The following are the applicable ICD-9-CM diagnosis codes for the new expanded coverage:

- 996.83 - Complications of transplanted heart, or
- 996.85 - Complications of transplanted bone marrow.

The following is the applicable ICD-9-CM procedure code for the new expanded coverage:

- 99.88 - Therapeutic photopheresis.

NOTE: Contractors shall edit for an appropriate oncological and autoimmune disorder diagnosis for payment of extracorporeal photopheresis according to the National Coverage Determination

190.3 – Medicare Summary Notices (MSNs), Remittance Advice Remark Codes (RAs) and Claim Adjustment Reason Code (Rev. 1206; Issued: 03-16-07; Effective: December 19, 2006; Implementation: 04-02-07)

Contractors shall continue to use the appropriate existing messages that they have in place when denying claims submitted that do not meet the Medicare coverage criteria for extracorporeal photopheresis.

Contractors shall deny claims when the service is not rendered to an inpatient or outpatient of a hospital, including critical access hospitals (CAHs) using the following codes:

- Claim Adjustment Reason code: 58 – “Claim/service denied/reduced because treatment was deemed by payer to have been rendered in an inappropriate or invalid place of service.”
- MSN 16.2 - “This service cannot be paid when provided in this location/facility.” Spanish translation: "Este servicio no se puede pagar cuando es suministrado en esta sitio/facilidad." (Include either MSN 36.1 or 36.2 dependant on liability.)
- RA MA 30 - "Missing/incomplete/invalid type of bill." (FIs and A/MACs only)
- Group Code - CO (Contractual Obligations) or PR (Patient Responsibility) dependant on liability.

190.4 – Advance Beneficiary Notice and Hospital Issued Notice of Noncoverage Information (Rev. 1206; Issued: 03-16-07; Effective: December 19, 2006; Implementation: 04-02-07)

If this service is not reasonable and necessary under 1862(a)(1)(A) of the Act (falls outside the scope of the revised NCD found in Pub. 100-03, chapter 1, section 110.4), contractors shall advise physicians and/or hospital outpatient departments, including critical access hospitals (CAHs), that they will be held liable for charges unless the physician and/or hospital has the beneficiary sign an Advance Beneficiary Notice in advance of providing the service.

If this service is provided to a hospital inpatient, including CAHs, for a reason unrelated to the admission (outside of the bundled payment) contractors shall advise hospitals billing for inpatient services that they will be held liable for charges unless the hospital has the beneficiary sign a Hospital Issued Notice of Noncoverage letter 11 in advance of providing the service.

200 - Billing Requirements for Vagus Nerve Stimulation (VNS)

(Rev. 1271, Issued: 06-22-07; Effective: 05-04-07; Implementation: 07-23-07)

200.1 - General

(Rev. 1271, Issued: 06-22-07; Effective: 05-04-07; Implementation: 07-23-07)

VNS is a pulse generator, similar to a pacemaker, that is surgically implanted under the skin of the left chest and an electrical lead (wire) is connected from the generator to the left vagus nerve. Electrical signals are sent from the battery-powered generator to the vagus nerve via the lead. These signals are in turn sent to the brain. FDA approved VNS for treatment of refractory epilepsy in 1999. Further coverage guidelines can be found in the National Coverage Determination Manual (Publication 100-03), Chapter 1, Section 160.18. Since the HCPCS codes for VNS can also be used for other indications, contractors must determine if the service being billed are for VNS and make a determination to pay or deny. CMS guidance on payment is listed below.

200.2 - ICD-9 Diagnosis Codes for Vagus Nerve Stimulation (Covered since DOS on and after July 1, 1999)

(Rev. 1271, Issued: 06-22-07; Effective: 05-04-07; Implementation: 07-23-07)

One of the following diagnosis codes must be reported, as appropriate, when billing for Vagus Nerve Stimulation:

- 345.41 Localization-related (focal) (partial) epilepsy and epileptic syndromes with complex partial seizures with intractable epilepsy
- 345.51 Localization-related (focal) (partial) epilepsy and epileptic syndromes with simple partial seizures with intractable epilepsy

200.3 - Carrier/MAC Billing Requirements

(Rev. 1271, Issued: 06-22-07; Effective: 05-04-07; Implementation: 07-23-07)

Effective for services performed on or after July 1, 1999, contractors are accepting claims submitted for vagus nerve stimulation for epilepsy and recurrent seizures.

Effective for services performed on or after July 1, 1999, CMS determined that vagus nerve stimulation is not reasonable and necessary for all other types of seizures which are refractory and for whom surgery is not recommended or for whom surgery has failed.

Effective for services performed on or after May 4, 2007, contractors will deny claims submitted for vagus nerve stimulation for resistant depression. Contractors need to update their local coverage determination policy to include this new NCD determination. There is no coverage for vagus nerve stimulation for patient with resistant depression.

200.4 - Fiscal Intermediary Billing Requirements

(Rev. 1271, Issued: 06-22-07; Effective: 05-04-07; Implementation: 07-23-07)

Effective for services performed on or after July 1, 1999, contractors are accepting claims submitted for vagus nerve stimulation for epilepsy and recurrent seizures.

Effective for services performed on or after July 1, 1999, CMS determined that vagus nerve stimulation is not reasonable and necessary for all other types of seizures which are refractory and for whom surgery is not recommended or for whom surgery has failed.

Effective for services performed on or after May 4, 2007, contractors will reject claims submitted for vagus nerve stimulation for resistant depression.

200.5 - Medicare Summary Notice (MSN), Remittance Advice Remark Code (RARC) and Claim Adjustment Reason Code (CARC) Messages

(Rev. 1271, Issued: 06-22-07; Effective: 05-04-07; Implementation: 07-23-07)

The following messages are used by Medicare contractors when denying non-covered VNS services:

- MSN: 16.10 "Medicare does not pay for this item or service."
- CARC: 50 "These are non-covered services because this is not deemed a "medical necessity" by the payer."

The following R.ARC messages can be used depending on liability:

- M27 Alert: The patient has been relieved of liability of payment of these items and services under the limitation of liability provision of the law. You, the provider, are ultimately liable for the patient's waived charges, including any charges for coinsurance, since the items or services were not reasonable and necessary or constituted custodial care, and you knew or could reasonably have been expected to know, that they were not covered.

You may appeal this determination. You may ask for an appeal regarding both the coverage determination and the issue of whether you exercised due care. The appeal request must be filed within 120 days of the date you receive this notice. You must make the request through this office.

Or

- M38 The patient is liable for the charges for this service as you informed the patient in writing before the service was furnished that we would not pay for it, and the patient agreed to pay.

Contractors will also include group code CO (contractual obligation) or PR (patient responsibility) depending on liability.

200.6 - Advance Beneficiary Notice and HINN Information (Rev. 1271, Issued: 06-22-07; Effective: 05-04-07; Implementation: 07-23-07)

Physicians are liable for non-covered VNS procedures unless they issue an appropriate advance beneficiary notice (ABN). The following language should be included in the ABN:

Items or Service Section:
“Vagus Nerve Stimulation”.

Because Section:
“As specified in section 160.18 of Pub.100-03, Medicare National Coverage Determination Manual, Medicare will not pay for this procedure as it is not a reasonable and necessary treatment for (select either “your type of seizure disorder” or “resistant depression.”)

Note that the ABN is the appropriate notice for Part B services and is valid whether the language above is inserted or not.

210 - Billing Requirements for Continuous Positive Airway Pressure (CPAP) for Obstructive Sleep Apnea (OSA) (Rev.)

220 - Billing Requirements for Thermal Intradiscal Procedures (TIPs) (Rev. 1646, Issued: 12-09-08, Effective: 09-29-08, Implementation: 01-05-09)

220.1 - General

(Rev. 1646, Issued: 12-09-08, Effective: 09-29-08, Implementation: 01-05-09)

Effective for services on or after September 29, 2008, the Center for Medicare & Medicaid Services (CMS) made the decision that Thermal Intradiscal Procedures (TIPS) are not reasonable and necessary for the treatment of low back pain. Therefore, TIPS are non-covered. Refer to Pub.100-03, Medicare National Coverage Determination (NCD) Manual Chapter 1, Part 2, Section 150.11, for further information on the NCD.

220.2 - Contractors, A/B Medicare Administrative Contractors (MACs)

(Rev. 1646, Issued: 12-09-08, Effective: 09-29-08, Implementation: 01-05-09)

The following Healthcare Common Procedure Coding System (HCPCS) codes will be nationally non-covered by Medicare effective for dates of service on and after September 29, 2008:

22526: Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; single level

22527: Percutaneous intradiscal electrothermal annuloplasty, unilateral or bilateral including fluoroscopic guidance; one or more additional levels

0062T: Percutaneous intradiscal annuloplasty, any method except electrothermal, unilateral or bilateral including fluoroscopic guidance; single level

0063T: Percutaneous intradiscal annuloplasty, any method except electrothermal, unilateral or bilateral including fluoroscopic guidance; one or more additional levels

NOTE: The change to add the non-covered indicator for the above HCPCS codes will be part of the January 2009 Medicare Physician Fee Schedule Update. The change to the status indicator to non-cover the above HCPCS will be part of the January Integrated Outpatient Code Editor (IOCE) update.

Claims submitted with the non-covered HCPCS codes on or after September 29, 2008, will be denied by Medicare contractors.

220.3 - Medicare Summary Notice (MSN), Claim Adjustment Reason Code (CARC), and Remittance Advice Remark Code (RARC)

(Rev. 1646, Issued: 12-09-08, Effective: 09-29-08, Implementation: 01-05-09)

The following messages are used by Medicare contractors when denying non-covered TIP services:

- MSN: 21.11 “This service was not covered by Medicare at the time you received it.”
- CARC: 96 “Non-covered charge(s)”

N386 “This decision was based on a National Coverage Determination (NCD). An NCD provides a coverage determination as to whether a particular item or service is covered. A

copy of this policy is available at <http://www.cms.hhs.gov/med/search.asp>. If you do not have web access, you may contact the contractor to request a copy of the NCD.”

220.4 - Advance Beneficiary Notice (ABN)

(Rev. 1646, Issued: 12-09-08, Effective: 09-29-08, Implementation: 01-05-09)

Providers are liable for charges if TIPS is used in surgery, unless the beneficiary was informed that he/she would be financially responsible prior to performance of the procedure. To avoid this liability the provider should have the beneficiary sign an ABN.

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R1663CP	01/08/2009	Correction to Prothrombin Time (PT/INR) Monitoring for Home Anticoagulation Management	02/09/2009	6313
R1657CP	12/31/2008	January 2009 Update of the Hospital Outpatient Prospective Payment System (OPPS)	01/05/2009	6320
R1646CP	12/09/2008	Thermal Intradiscal Procedures (TIPs)	01/05/2009	6291
R1593CP	09/12/2008	Smoking and Tobacco Use Cessation Counseling Billing Update for Comprehensive Outpatient Rehabilitation Facilities (CORFs) and Outpatient Physical Therapy Providers (OPTs)	12/12/2008	6163
R1592CP	09/10/2008	Artificial Hearts	12/01/2008	6185
R1583CP	08/29/2008	Artificial Hearts - Replaced by Transmittal 1592	10/06/2008	6185
R1562CP	07/25/2008	Prothrombin Time (PT/INR) Monitoring for Home Anticoagulation Management - Rescinded and replaced by CR 6313	08/25/2008	6138
R1509CP	05/16/2008	Adjusting Inpatient Prospective Payment System (IPPS) Reimbursement for Replaced Devices Offered Without Cost or With a Credit	10/06/2008	5860
R1498CP	05/02/2008	Adjusting Inpatient Prospective Payment System (IPPS) Reimbursement for Replaced Devices Offered Without Cost or With a Credit – Replaced by Transmittal 1509	10/06/2008	5860
R1472CP	03/06/2008	Update of Institutional Claims References	04/07/2008	5893
R1433CP	02/01/2008	Smoking and Tobacco Use Cessation Counseling Billing Code Update	07/07/2008	5878
R1430CP	02/01/2008	Use of HCPCS V2787 When Billing Approved Astigmatism-Correcting Intraocular Lens (A-CIOLs) in Ambulatory Surgery Centers (ASCs), Physician Offices, and Hospital Outpatient Departments (HOPDs)	03/03/2008	5853
R1421CP	01/25/2008	Update of Institutional Claims References - Rescinded and Replaced by Transmittal 1472	04/07/2008	5893
R1418CP	01/18/2008	New HCPCS Modifiers When Billing for Patient Care in Clinical Research Studies	04/07/2008	5805
R1340CP	09/21/2007	Lumbar Artificial Disc Replacement (LADR)	10/01/2007	5727
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<u>R130aCP</u>	03/26/2004	Manualization of Instructions for INR Monitoring	N/A	2323
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<u>R109CP</u>	02/27/2004	Updated Policy and Claims Processing Instructions for Ambulatory Blood Pressure Monitoring (AMPM)	04/05/2004	2726