Medicare Claims Processing Manual

Chapter 32 – Billing Requirements for Special Services

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(Rev. 261, 07-30-04)

10. - Diagnostic Blood Pressure Monitoring

(Rev. 109, 02-27-04)

10.1. - Ambulatory Blood Pressure Monitoring (ABPM) Billing Requirements

(Rev. 109, 02-27-04)

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

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, 14X, 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 and 14x 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.

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 OPPS hospital based RHC would be paid for the ABPM technical component services under the OPPS 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 124a, 03-19-04)

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% epithelialzed wound bed.

Coverage policy can be found in Medicare National Coverage Determinations Manual, Chapter 1, Section 270.1 (www.cms.hhs.gov/masnuals/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 hospitals, 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 1 payment will be made for the visit furnished to the RHC/FQHC patient to obtain the therapy service.

Payment Methodology for Critical Access Hospital (CAH) is payment is made on a reasonable cost basis unless the CAH has elected the Optional Method and pay 115% of the MPFS amount for the HCPCS code.

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*

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 the CMS 1500 or the electronic equivalent following instructions in Chapter 12 of this manual (www.cms.hhs.gov/manuals/104_claims/clm104index.asp)

D - Coinsurance and Deductible

The Medicare contractor 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.

11.2 - Electromagnetic Therapy

(Rev. 124a, 03-19-04)

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% epithelialzed wound bed.

Coverage policy can be found in Medicare National Coverage Determinations Manual, Chapter 1, Section 270.1. (www.cms.hhs.gov/masnuals/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	*ElectromagneticTherapy, 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 hospitals, (CORF), (ORF), (OPT) 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 1 payment will be made for the visit furnished to the RHC/FQHC patient to obtain the therapy service.

Payment Methodology for CAHs is payment is made on a reasonable cost basis unless the CAH has elected the Optional Method and pay 115% of the MPFS amount for the HCPCS code.

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*

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 the 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 July2004 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.

20 – Reserved

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. 187, 05-28-04)

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.*

HCPCS codes are shown in FL 44 of the Form CMS-1450 or the electronic equivalent.

***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 in FL 80 and 81.

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.

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 articulo o servicio para esta afeccion."*

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:

- Hospital outpatient departments - OPPS
- Critical Access Hospital (CAH) - Reasonable cost
- Comprehensive Outpatient Rehabilitation Facility - Medicare physician fee schedule (MPFS)
- 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 OPPS.

40.3 – Bill Types

(Rev. 125, 03-26-04)

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

RHCs and FQHCs bill you under bill type 71X and 73X for the professional component. The technical component is outside the scope of the RHC/FQHC benefit. The provider of that technical service bills their carrier on Form 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, 14X, 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.)

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.

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.

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 Procedural 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 (INR) Monitoring for Anticoagulation Management

(Rev. 130, 03-26-04)

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

60.1 – Coverage Requirements

(Rev. 130a, 03-26-04)

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

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

60.2 – Intermediary Payment Requirements

(Rev. 130a, 03-26-04)

60.2.1 – Part A Payment Methods

(Rev. 130a, 03-26-04)

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. 130a, 03-26-04)

60.3.1 – Bill Types

(Rev. 130a, 03-26-04)

The applicable bill types are 13X and 85X.

60.3.2 – Revenue Codes

(Rev. 130a, 03-26-04)

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. 130a, 03-26-04)

60.4.1 – Allowable Covered Diagnosis Codes

(Rev. 130a, 03-26-04)

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

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

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

(Rev. 130a, 03-26-04)

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

Short Description: Demonstrate use home INR mon

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

Short Description: Provide test material, equipm

60.5 – Carrier Billing Instructions

(Rev. 130a, 03-26-04)

60.5.1. - Healthcare Common Procedural Coding System (HCPCS) for Carriers

(Rev. 130a, 03-26-04)

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

Short Description: Demonstrate use home INR mon

G0249 TOS (Type of Service): 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 8 tests.

Short Description: Provide test material, equipm

G0250 TOS (Type of Service): 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 service)

Short Description: MD review interpret of test

60.5.2 – Applicable Diagnosis Code for Carriers

(Rev. 130a, 03-26-04)

ICD-9 V43.3, **Organ or tissue replaced by other means; heart valve, applies.**

60.6 – Carrier Claims Requirements

(Rev. 130a, 03-26-04)
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. Additionally, for G0250, since this code descriptor is per 4 tests, this code should only be billed no more than once every 4 weeks.

60.7 – Carrier Payment Requirements

(Rev. 130a, 03-26-04)

Payment and pricing information will be on the July update of 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. 130a, 03-26-04)

60.8.1 – Remittance Advice Notice

(Rev. 130a, 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 INR. If denying services as furnished before July 1, 2002, use existing ANSI X 12-835 claim adjustment reason code 26 "Expenses incurred prior to coverage" at the line level.

60.8.2 - Medicare Summary Notice (MSN) Messages

(Rev. 130a, 03-26-04)

Use the following MSN messages where appropriate:

If a claim for INR is being denied because the service was performed prior to July 1, 2002, 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 recibio`." (MSN Message 21.11)

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

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

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 service will remain non-covered.

70.1 - Healthcare Common Procedural 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. 261, Issued :07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

Carriers shall instruct physicians to bill using the above procedure code(s) with modifier ***QV*** *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. 261, Issued :07-30-04, Effective: 10-01-04, Implementation: 10-04-04)

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. The second diagnosis 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. 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.

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.