Medicare Coverage Issues Manual

Department of Health & Human Services (DHHS)
Centers for Medicare & Medicaid Services (CMS)

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HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
Table of Contents	2 pp.	2 pp.
35-17 – 35-18	2 pp.	2 pp.
65-18 – 65-19 (Cont.)	4 pp.	2 pp.

NEW/REVISED MATERIAL--*EFFECTIVE DATE:* April 1, 2003
IMPLEMENTATION DATE: April 1, 2003

Section 35-20, Treatment of Motor Function Disorders with Electric Nerve Stimulation – Not Covered, has been amended to note that Medicare coverage for deep brain stimulation for essential tremor and Parkinson's disease can be found at section 65-19.

Section 65-19, Deep Brain Stimulation for Essential Tremor and Parkinson's Disease, is added to provide limited coverage for unilateral or bilateral thalamic ventralis intermedius nucleus (VIM) deep brain stimulation (DBS) for the treatment of essential tremor (ET) and/or Parkinsonian tremor and unilateral or bilateral subthalamic nucleus (STN) or globus pallidus interna (GPi) DBS for the treatment of Parkinson's disease.

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

These instructions should be implemented within your current operating budget.

DISCLAIMER: The revision date and transmittal number only apply to the redlined material. All other material was previously published in the manual and is only being reprinted.

COVERAGE ISSUES

Dialysis Equipment

Durable Medical Equipment

COVERAGE ISSUES

Prosthetic Devices

Braces - Trusses - Artificial Limbs and Eyes

Patient Education Programs

Nursing Services

See Medicare Intermediary Manual, §3212; Medicare Carriers Manual, §§2020 and 2470-2476.2; and Hospital Manual, §160.1.

35-15 POSTURAL DRAINAGE PROCEDURES AND PULMONARY EXERCISES

In most cases, postural drainage procedures and pulmonary exercises can be carried out safely and effectively by nursing personnel. However, in some cases patients may have acute or severe pulmonary conditions involving complex situations in which these procedures or exercises require the knowledge and skills of a physical therapist or a respiratory therapist. Therefore, if the attending physician determines as part of his/her plan of treatment that for the safe and effective administration of such services the procedures or exercises in question need to be performed by a physical therapist, the services of such a therapist constitute covered physical therapy when provided as an inpatient hospital service, extended care service, home health service, or outpatient physical therapy service.

NOTE: Physical therapy furnished in the outpatient department of a hospital is covered under the outpatient physical therapy benefit.

If the attending physician determines that the services should be performed by a respiratory therapist, the services of such a therapist constitute covered respiratory therapy when provided as an inpatient hospital service, outpatient hospital service, or extended care service, assuming that such services are furnished to the skilled nursing facility by a hospital with which the facility has a transfer agreement. Since the services of a respiratory therapist are not covered under the home health benefit, payment may not be made under the home health benefit for visits by a respiratory therapist to a patient's home to provide such services. Postural drainage procedures and pulmonary exercises are also covered when furnished by a physical therapist or a respiratory therapist as incident to a physician's professional service.

See Medicare Intermediary Manual, §§3112, §3116, and §3133.90 and Medicare Carriers Manual, §2050.2.

35-16 VITRECTOMY

Vitrectomy may be considered reasonable and necessary for the following conditions: vitreous loss incident to cataract surgery, vitreous opacities due to vitreous hemorrhage or other causes, retinal detachments secondary to vitreous strands, proliferative retinopathy, and vitreous retraction. See chapter 15 of the Medicare Carriers Manual for how to determine payment for physician vitrectomy services and §5243 of the Medicare Carriers Manual for how to determine payment for ASC facility vitrectomy services. Also, see §4630 of the Medicare Carriers Manual to identify when, for Medicare payment purposes, certain vitrectomy codes are included in other codes or when codes for other services include vitrectomy codes. The CPT codes for vitrectomy services are 67005, 67010, 67036, 67038, 67039, and 67040.

35-17 INDUCED LESIONS OF NERVE TRACTS

Surgically induced lesions of nerve tracts, which involve destruction of nerve tissue, are primarily indicated for controlling the chronic or acute pain arising from conditions such as terminal cancer or lumbar degenerative arthritis. Induced lesions of nerve tracts may be produced by surgical cutting of the nerve (rhizolysis), chemical destruction of the nerve, or by creation of a radio-frequency lesion (electrocautery). Accordingly, program payment may be made for these denervation procedures when used in selected cases (concurred in by contractor's medical staff) to treat chronic pain.

Note that these procedures differ from those employing implanted electrodes and associated equipment to control pain in that the nerve fibers are ablated rather than stimulated and no electronic equipment is required by the patient after the operation.

35-18 ELECTROSLEEP THERAPY--NOT COVERED

Electrosleep therapy consists of the application of short duration, low-amplitude pulses of direct current to the patient's brain via externally placed occipital electrodes. It is commonly used in the treatment of chronic insomnia, anxiety, and depression, but has also been used for psychosomatic disorders such as asthma, spastic colitis, or tension headache, and for organic disorders including essential hypertension. Until scientific assessment of this technique has been completed and its efficacy is established, no program payment may be made for electrosleep therapy.

35-19 INTRAVENOUS HISTAMINE THERAPY

The only accepted and scientifically valid medical use of histamine is diagnostic, including tests to assess:

- The ability of the stomach to secrete acid;
- The integrity of peripheral sensory nerves (e.g., in leprosy);
- The circulatory competency in limb extremities; and
- The presence of a pheochromocytoma.

However, there is no scientifically valid clinical evidence that histamine therapy is effective for any condition regardless of the method of administration, nor is it accepted or widely used by the medical profession. Therefore, histamine therapy cannot be considered reasonable and necessary, and program payment for such therapy is not made.

35-20 TREATMENT OF MOTOR FUNCTION DISORDERS WITH ELECTRIC NERVE STIMULATION-NOT COVERED

While electric nerve stimulation has been employed to control chronic intractable pain for some time, its use in the treatment of motor function disorders, such as multiple sclerosis, is a recent innovation, and the medical effectiveness of such therapy has not been verified by scientifically controlled studies. Therefore, where electric nerve stimulation is employed to treat motor function disorders, no reimbursement may be made for the stimulator or for the services related to its implantation since this treatment cannot be considered reasonable and necessary.

See §§35-27 and 65-8.

NOTE: For Medicare coverage of deep brain stimulation for essential tremor and Parkinson's disease, see §65-19.

35-21 INPATIENT HOSPITAL PAIN REHABILITATION PROGRAMS

Pain rehabilitation programs are a relatively new and innovative approach to the treatment of intractable pain. The goal of such programs is to give a patient the tools to manage and control his/her pain and thereby improve his/her ability to function independently.

A hospital level pain rehabilitation program is one that employs a coordinated multidisciplinary team to deliver, in a controlled environment, a concentrated program which is designed to modify pain behavior through the treatment of the physiological, psychological, and social aspects of pain. Such programs generally include diagnostic testing, skilled nursing, psychotherapy, structured progressive withdrawal from pain medications, physical therapy and occupational therapy to restore physical fitness (mobility and endurance) to a

65-16 TRACHEOSTOMY SPEAKING VALVE

A trachea tube has been determined to satisfy the definition of a prosthetic device, and the tracheostomy speaking valve is an add on to the trachea tube which may be considered a medically necessary accessory that enhances the function of the tube. In other words, it makes the system a better prosthesis. As such, a tracheostomy speaking valve is covered as an element of the trachea tube which makes the tube more effective.

65-17 URINARY DRAINAGE BAGS

Urinary collection and retention system are covered as prosthetic devices that replace bladder function in the case of permanent urinary incontinence. Urinary drainage bags that can be used either as bedside or leg drainage bags may be either multi-use or single use systems. Both the multi-use and the single use bags have a system that prevents urine backflow. However, the single use system is non-drainable. There is insufficient evidence to support the medical necessity of a single use system bag rather than the multi-use bag. Therefore, a single use drainage system is subject to the same coverage parameters as the multi-use drainage bags.

65-18 SACRAL NERVE STIMULATION FOR URINARY INCONTINENCE

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 three indications:

(1) 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.

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

(3) 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.

(4) 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.

65-19 DEEP BRAIN STIMULATION FOR ESSENTIAL TREMOR AND PARKINSON'S DISEASE

Effective for services furnished on or after April 1, 2003, Medicare will cover *unilateral or bilateral thalamic ventralis intermedius nucleus (VIM) deep brain stimulation (DBS)* for the treatment of essential tremor (ET) and/or Parkinsonian tremor and *unilateral or bilateral subthalamic nucleus (STN) or globus pallidus interna (GPi) DBS* for the treatment of Parkinson's disease (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 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:

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.

1. 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.

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

3. 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.