Medicare
Coverage Issues Manual

Department of Health & Human Services (DHHS)
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35-77 – 35-79	3 pp	2 pp

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

Section 35-77 Neuromuscular Electrical Stimulation (NMES) for Use by Spinal Cord Injured (SCI) Patients for Walking, new section on NMES. There are two broad categories of NMES. One type stimulates the muscle when the patient is in a resting state to treat patients with muscle atrophy. A second type is used to enhance functional activity in neurologically impaired patients. These devices use electrical impulses to activate paralyzed or weak muscles in precise sequence and have been utilized to provide SCI patients with the ability to walk. Based on the evidence that we have reviewed, we are issuing a positive national coverage determination for the use of NMES for walking, but we will maintain the existing national noncoverage policy for the treatment of disuse atrophy in SCI patients.

This revision is a national coverage decision (NCD). The NCDs are binding on all carriers, intermediaries, peer review organization, 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 reivew 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.**

Supplies - Drugs

Diagnostic Services

During diastole the three sets of air cuffs are inflated sequentially (distal to proximal) compressing the vascular beds within the muscles of the calves, lower thighs and upper thighs. This action results in an increase in diastolic pressure, generation of retrograde arterial blood flow and an increase in venous return. The cuffs are deflated simultaneously just prior to systole, which produces a rapid drop in vascular impedance, a decrease in ventricular workload and an increase in cardiac output.

The augmented diastolic pressure and retrograde aortic flow appear to improve myocardial perfusion, while systolic unloading appears to reduce cardiac workload and oxygen requirements. The increased venous return coupled with enhanced systolic flow appears to increase cardiac output. As a result of this treatment, most patients experience increased time until onset of ischemia, increased exercise tolerance, and a reduction in the number and severity of anginal episodes. Evidence was presented that this effect lasted well beyond the immediate post-treatment phase, with patients symptom-free for several months to two years.

This procedure must be done under direct supervision of a physician.

35-75 INTRAOPERATIVE VENTRICULAR MAPPING--(Effective for services rendered on or after 10/29/84.)

Intraoperative ventricular mapping is the technique of recording cardiac electrical activity directly from the heart. The recording sites are usually identified from an anatomical grid and may consist of epicardial, intramural, and endocardial sites. A probe with electrodes is used to explore these surfaces and generate a map that displays the sequence of electrical activation. This information is used by the surgeon to locate precisely the site of an operative intervention.

The intraoperative ventricular mapping procedure is covered under Medicare only for the uses and medical conditions described below:

- Localize accessory pathways associated with the Wolff-Parkinson-White (WPW) and other preexcitation syndromes;

- Map the sequence of atrial and ventricular activation for drug-resistant supraventricular tachycardias;

- Delineate the anatomical course of His bundle and/or bundle branches during corrective cardiac surgery for congenital heart diseases; and

- Direct the surgical treatment of patients with refractory ventricular tachyarrhythmias.

35-77 NEUROMUSCULAR ELECTRICAL STIMULATION (NMES)

Neuromuscular electrical stimulation (NMES) involves the use of a device that transmits an electrical impulse to activate muscle groups by way of electrodes. There are two broad categories of NMES. One type of device stimulates the muscle when the patient is in a resting state to treat muscle atrophy. The second type is used to enhance functional activity of neurologically impaired patients.

Treatment of Muscle Atrophy

Coverage of NMES to treat muscle atrophy is limited to the treatment of patients with disuse atrophy where the nerve supply to the muscle is intact, including brain, spinal cord and peripheral nerves and other non-neurological reasons for disuse atrophy. Examples include casting or splinting of a limb, contracture due to scarring of soft tissue as in burn lesions, and hip replacement surgery (until

orthotic training begins). (See CIM 45-25 for an explanation of coverage of medically necessary supplies for the effective use of NMES).

Use for Walking in Patients with Spinal Cord Injury (SCI)

The type of NMES that is used to enhance the ability to walk of SCI patients is commonly referred to as functional electrical stimulation (FES). These devices are surface units that use electrical impulses to activate paralyzed or weak muscles in precise sequence. Coverage for the use of NMES/FES is limited to SCI patients, for walking, who have completed a training program, which consists of at least 32 physical therapy sessions with the device over a period of 3 months. The trial period of physical therapy will enable the physician treating the patient for his or her spinal cord injury to properly evaluate the person's ability to use these devices frequently and for the long term. Physical therapy sessions are only covered in the inpatient hospital, outpatient hospital, comprehensive outpatient rehabilitation facilities, and outpatient rehabilitation facilities. The physical therapy necessary to perform this training must be directly performed by the physical therapist as part of a one-on-one training program; this service cannot be done unattended.

The goal of physical therapy must be to train SCI patients on the use of NMES/FES devices to achieve walking, not to reverse or retard muscle atrophy.

Coverage for NMES/FES for walking will be limited to SCI patients with all of the following characteristics:

1) persons with intact lower motor units (L1 and below) (both muscle and peripheral nerve);

2) persons with muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently;

3) persons that demonstrate brisk muscle contraction to NMES and have sensory perception of electrical stimulation sufficient for muscle contraction;

4) persons that possess high motivation, commitment and cognitive ability to use such devices for walking;

5) persons that can transfer independently and can demonstrate independent standing tolerance for at least 3 minutes;

6) persons that can demonstrate hand and finger function to manipulate controls;

7) persons with at least 6-month post recovery spinal cord injury and restorative surgery;

8) persons without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis; and

9) persons who have demonstrated a willingness to use the device long-term.

NMES/FES for walking will not be covered in SCI patients with any of the following:

1) persons with cardiac pacemakers;
2) severe scoliosis or severe osteoporosis;
3) skin disease or cancer at area of stimulation;
4) irreversible contracture; or
5) autonomic dysreflexia.

The only settings where therapists with the sufficient skills to provide these services are employed, are inpatient hospitals, outpatient hospitals, comprehensive outpatient rehabilitation facilities and outpatient rehabilitation facilities. The physical therapy necessary to perform this training must be part of a one-on-one training program.

Additional therapy after the purchase of the DME would be limited by our general policies on coverage of skilled physical therapy.

All other uses of NMES remain non-covered.

(Also reference Medicare Carriers' Manual, Part 3, Claims-§2210 and Medicare Intermediary Manual, Part 3, Claims-§3653 – See - Maintenance Program 271.1)

35-78 DIAGNOSTIC ENDOCARDIAL ELECTRICAL STIMULATION (PACING)--(Effective for services performed on or after 12-03-84.)

Diagnostic endocardial electrical stimulation (EES), also called programmed electrical stimulation of the heart, is covered under Medicare when used for patients with severe cardiac arrhythmias.

Diagnostic endocardial electrical stimulation involves the detection and stimulation of cardiac electrical activity for the purpose of studying arrhythmias and abnormalities of the heart's conduction system. Intracardiac electrode catheters, intracardiac and extracardiac recordings and a stimulator device are required. From two to six multipolar electrode catheters are inserted percutaneously, usually through the femoral veins, and advanced to the heart under fluoroscopic control. Other venous or arterial routes may be employed as well. An intracardiac His bundle cardiogram is usually obtained during EES as are conventional electrocardiograms. No separate charge will be recognized for the His Bundle cardiogram. (See §50-3.)

EES is used to investigate the mechanisms, site of origin and pathways of cardiac arrhythmias as well as to select therapeutic approaches for their resolution. EES is also employed to identify patients at risk of sudden arrhythmic death. The principal use for EES is in the diagnosis and treatment of sustained ventricular tachycardia. However, it has also proven to be of value in the diagnosis and management of other complex arrhythmias, conduction defects, and after cardiac arrest.

35-79 ANESTHESIA IN CARDIAC PACEMAKER SURGERY (Effective for services performed on or after JULY 27, 1988.

The use of general or monitored anesthesia during transvenous cardiac pacemaker surgery may be reasonable and necessary and therefore covered under Medicare only if adequate documentation of medical necessity is provided on a case-by-case basis. Obtain advice from your medical consultants or from appropriate specialty physicians or groups in your locality regarding the adequacy of documentation before deciding whether a particular claim should be covered.

A second type of pacemaker surgery that is sometimes performed involves the use of the thoracic method of implantation, which requires open surgery. Where the thoracic method is employed, general anesthesia is always used and should not require special medical documentation.