Medicare Coverage Issues Manual

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

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CHANGE REQUEST 1881

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NEW/REVISED MATERIAL--*EFFECTIVE DATE: January 1, 2002*
IMPLEMENTATION DATE: January 1, 2002

Section 65-18, Sacral Nerve Stimulation for Urinary Incontinence is added to the section as the result of a national coverage decision.

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.

Dialysis Equipment

Durable Medical Equipment

COVERAGE ISSUES

Prosthetic Devices

Braces - Trusses - Artificial Limbs and Eyes

Patient Education Programs

Nursing Services

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.