Medicare Coverage Issues Manual

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

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CHANGE REQUEST 1535

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
Table of Contents	2pp.	2pp.
35-27 - 35-33	6pp.	6pp.

NEW/REVISED MATERIAL--*EFFECTIVE DATE:* July 1, 2001
***IMPLEMENTATION DATE:* July 1, 2001**

Section 35-27.1, Biofeedback Therapy for the Treatment of Urinary Incontinence, is added to delineate the coverage policy for biofeedback for the treatment of urinary incontinence.

This section of the Coverage Issues Manual is a national coverage decision made under §1862(a)(1) of the Social Security Act. National coverage determinations (NCDs) are binding on all Medicare carriers, intermediaries, peer review organizations, and other contractors. Under 42 CFR §422.256(b) a NCD that expands coverage is also binding on a Medicare+Choice organization. In addition, an administrative law judge may not disregard, set aside, or otherwise review a national coverage decision issued under §1862(a)(1), (see 42 CFR §§ 405.732, 405.860).

NOTE: The period between Jaunary 1, 2001 and the date of issue should be used to review any local medical review policies for biofeedback for the treatment of urinary incontinence for any adjustments and provider education.

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

Clinical Trials

Medical Procedures

Medical Procedures

35-26 TREATMENT OF OBESITY

Obesity itself cannot be considered an illness. The immediate cause is a caloric intake which is persistently higher than caloric output. Program payment may not be made for treatment of obesity alone since this treatment is not reasonable and necessary for the diagnosis or treatment of an illness or injury. However, although obesity is not in itself an illness, it may be caused by illnesses such as hypothyroidism, Cushing's disease, and hypothalamic lesions. In addition, obesity can aggravate a number of cardiac and respiratory diseases as well as diabetes and hypertension. Therefore, services in connection with the treatment of obesity are covered services when such services are an integral and necessary part of a course of treatment for one of these illnesses.

Cross refer: CIM 35-33 and 35-40

35-26.1 SUPPLEMENTED FASTING

Supplemented fasting is a type of very low calorie weight reduction regimen used to achieve rapid weight loss. The reduced calorie intake is supplemented by a mixture of protein, carbohydrates, vitamins and minerals. Serious questions exist about the safety of prolonged adherence for 2 months or more to a very low calorie weight reduction regimen as a general treatment for obesity, because of instances of cardiopathology and sudden death, as well as possible loss of body protein. Therefore, supplemented fasting is not covered as a general treatment for obesity.

In cases where weight loss is necessary before surgery in order to ameliorate the complications posed by obesity when it coexists with pathological conditions such as cardiac and respiratory diseases, diabetes or hypertension (and other more conservative techniques to achieve this end are not regarded as appropriate), supplemented fasting with adequate monitoring of the patient are covered under Medicare on a case-by-case basis, as determined by your medical consultant. The risks associated with the achievement of rapid weight loss must be carefully balanced against the risk posed by the condition requiring surgical treatment.

35-27 BIOFEEDBACK THERAPY

Biofeedback therapy provides visual, auditory or other evidence of the status of certain body functions so that a person can exert voluntary control over the functions, and thereby alleviate an abnormal bodily condition. Biofeedback therapy often uses electrical devices to transform bodily signals indicative of such functions as heart rate, blood pressure, skin temperature, salivation, peripheral vasomotor activity, and gross muscle tone into a tone or light, the loudness or brightness of which shows the extent of activity in the function being measured.

Biofeedback therapy differs from electromyography, which is a diagnostic procedure used to record and study the electrical properties of skeletal muscle. An electromyography device may be used to provide feedback with certain types of biofeedback.

Biofeedback therapy is covered under Medicare only when it is reasonable and necessary for the individual patient for muscle re-education of specific muscle groups or for treating pathological muscle abnormalities of spasticity, incapacitating muscle spasm, or weakness, and more conventional treatments (heat, cold, massage, exercise, support) have not been successful. This therapy is not covered for treatment of ordinary muscle tension states or for psychosomatic conditions. (See HCFA-Pub. 14-3, §§2200ff, 2215, and 4161; HCFA-Pub. 13-3, §§3133.3, 3148, and 3149; HCFA-Pub. 10, §§242 and 242.5 for special physical therapy requirements. See also §35-20 and 65-8.)

35-27.1 BIOFEEDBACK THERAPY FOR THE TREATMENT OF URINARY INCONTINENCE

Biofeedback therapy for the treatment of urinary incontinence (Effective for services performed on or after July 1, 2001.) This policy applies to biofeedback therapy rendered by a practitioner in an office or other facility setting.

Biofeedback is covered for the treatment of stress and/or urge incontinence in cognitively intact patients who have failed a documented trial of pelvic muscle exercise (PME) training. Biofeedback is not a treatment, per se, but a tool to help patients learn how to perform PME. Biofeedback-assisted PME incorporates the use of an electronic or mechanical device to relay visual and/or auditory evidence of pelvic floor muscle tone, in order to improve awareness of pelvic floor musculature and to assist patients in the performance of PME.

A failed trial of PME training is defined as no clinically significant improvement in urinary incontinence after completing 4 weeks of an ordered plan of pelvic muscle exercises to increase periurethral muscle strength.

Contractors may decide whether or not to cover biofeedback as an initial treatment modality.

Home use of biofeedback therapy is not covered.

35-29 OXYGEN TREATMENT OF INNER EAR/CARBON THERAPY (Effective for services performed on and after August 1, 1978).--NOT COVERED

Oxygen (95 percent) and carbon dioxide (5 percent) inhalation therapy for inner ear disease, such as endolymphatic hydrops and fluctuant hearing loss, is not reasonable and necessary. The therapeutic benefit deriving from this procedure is highly questionable.

35-30 BLOOD PLATELET TRANSFUSIONS

Effective for services performed on or after **August 1, 1978**, blood platelet transplants are safe and effective for the correction of thrombocytopenia and other blood defects. It is covered under Medicare when treatment is reasonable and necessary for the individual patient.

35-30.1 STEM CELL TRANSPLANTATION

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. The transplant can 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.

A. Allogeneic Stem Cell Transplantation.--Allogeneic stem cell transplantation (ICD-9-CM procedure codes 41.02, 41.03, 41.05, and 41.08) is a procedure in which a portion of a healthy donor's stem cell or bone marrow is obtained and prepared for intravenous infusion.

1. Covered Conditions.--The following uses of allogeneic bone marrow transplantation are covered under Medicare:

- Effective for services performed on or after **August 1, 1978**, for the treatment of leukemia, leukemia in remission (ICD-9-CM codes 204.00 through 208.91), or aplastic anemia (ICD-9-CM codes 284.0 through 284.9) when it is reasonable and necessary; and

o Effective for services performed on or after June 3, 1985, for the treatment of severe combined immunodeficiency disease (SCID) (ICD-9-CM code 279.2), and for the treatment of Wiskott - Aldrich syndrome (ICD-9-CM 279.12).

2. Noncovered Conditions.--Effective May 24, 1996, allogeneic stem cell transplantation is not covered as treatment for multiple myeloma (ICD-9-CM codes 203.0 and 238.6).

B. Autologous Stem Cell Transplantation (Effective for Services Performed on or After 04/28/89).--Autologous stem cell transplantation (ICD-9-CM procedure codes 41.01, 41.04, 41.07, and 41.09) is a technique for restoring stem cells using the patient's own previously stored cells.

1. Covered Conditions.--Autologous stem cell transplantation (ICD-9-CM codes 41.01, 41.04, 41.07, 41.09, CPT-4 code 38241) is considered reasonable and necessary under §l862(a)(1)(A) of the Act for the following conditions and is covered under Medicare for patients with:

o Acute leukemia in remission (ICD-9-CM codes 204.01, lymphoid; 205.01, myeloid; 206.01, monocytic; 207.01, acute erythremia and erythroleukemia; and 208.01 unspecified cell type) who have a high probability of relapse and who have no human leucocyte antigens (HLA)-matched;

o Resistant non-Hodgkin's lymphomas (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, and 202.90-202.98) or those presenting with poor prognostic features following an initial response;

o Recurrent or refractory neuroblastoma (see ICD-9-CM Neoplasm by site, malignant); or

o Advanced Hodgkin's disease (ICD-9-CM codes 201.00-201.98) who have failed conventional therapy and have no HLA-matched donor;

o Effective October 1, 2000, multiple myeloma (ICD-9-CM 203.0 and 238.6) for beneficiaries less than age 78 who have Durie-Salmon stage II or III newly diagnosed or responsive multiple myeloma with adequate cardiac, renal, pulmonary and hepatic functioning. This includes those patients with previously untreated disease, those with at least a partial response to prior chemotherapy (partial response is defined as a 50% decrease either in measurable paraprotein [serum and/or urine] or in bone marrow infiltration, sustained for at least one month), and those in responsive relapse. Multiple rounds of autologous stem cell transplantation (known as tandem transplantation) will, however, remain non-covered.

2. Noncovered Conditions.--Insufficient data exist to establish definite conclusions regarding the efficacy of autologous stem cell transplantation for the following conditions:

o Acute leukemia not in remission (ICD-9-CM codes 204.00, 205.00, 206.00, 207.00 and 208.00);

o Chronic granulocytic leukemia (ICD-9-CM codes 205.10 and 205.11);

o Solid tumors (other than neuroblastoma) (ICD-9-CM codes 140.0-l99.1);

o Up to October 1, 2000, multiple myeloma;

- Tandem transplantation (multiple rounds of autologous stem cell transplantation) for patients with multiple myeloma;

- Effective **October 1, 2000**, non-primary (AL) amyloidosis (ICD-9-CM 277.3);

- Effective **October 1, 2000**, primary (AL) amyloidosis (ICD-9-CM 277.3) for Medicare beneficiaries age 64 or older.

In these cases, autologous stem cell transplantation is not considered reasonable and necessary within the meaning of §1862(a)(1)(A) of the Act and is not covered under Medicare.

35-31 TREATMENT OF DECUBITUS ULCERS

An accepted procedure for healing decubitus ulcers is to remove dead tissue from the lesions and to keep them clean to promote the growth of new tissue. This may be accomplished by hydrotherapy (whirlpool) treatments. Hydrotherapy (whirlpool) treatment for decubitus ulcers is a covered service under Medicare for patients when treatment is reasonable and necessary. Some other methods of treating decubitus ulcers, the safety and effectiveness of which have not been established, are not covered under the Medicare program. Some examples of these types of treatments are: ultraviolet light, low intensity direct current, topical application of oxygen, and topical dressings with Balsam of Peru in castor oil.

35-32 VERTEBRAL ARTERY SURGERY

Obstructions which block the flow of blood through the vertebral artery can cause vertigo, visual or speech defects, ataxia, mental confusion, or stroke. These symptoms in patients result from reduction in blood flow to the brain and range from symptoms of transient basilar ischemia to mental deterioration or completed stroke.

Five types of surgical procedures are performed to relieve obstructions to vertebral artery blood flow. They are:

- Vertebral artery endarterectomy, a procedure which cleans out arteriosclerotic plaques which are inside the vertebral artery;

- Vertebral artery by-pass or resection with anastomosis or graft;

- Subclavian artery resection with or without endarterectomy;

- Removal of laterally located osteophytes anywhere in the C6(C7)-C2 course of the vertebral artery; and

- Arteriolysis which frees the artery from surrounding tissue, with or without arteriopexy (fixation of the vessel).

These procedures can be medically reasonable and necessary, but only if each of the following conditions is met:

- Symptoms of vertebral artery obstruction exist;

- Other causes have been considered and ruled out;

- There is radiographic evidence of a valid vertebral artery obstruction; and

- Contraindications to the procedure do not exist, such as coexistent obstructions of multiple cerebral vessels.

Angiograms documenting a valid obstruction should show not only the aortic arch with the vessels off the arch, but also show the vessels in the neck and head (providing biplane views of the carotid and vertebral vascular system). In addition, serial views are needed to diagnose "subclavian steal," the condition in which subclavian artery obstruction causes the symptoms of vertebral artery obstruction. Because the symptoms are not specific for vertebral artery obstruction, other causes must be considered. In addition to vertebral artery obstruction, the differential diagnosis should include various degenerative disorders of the brain, orthostatic hypotension, acoustic neuroma, labyrinthitis, diabetes mellitus and hypoglycemia related disorders.

Obstructions which can cause symptoms of blocked vertebral artery blood flow and which can be documented by an angiogram include:

- Intravascular obstructions - arteriosclerotic lesions within the vertebral artery or in other arteries.

- Extravascular obstructions -

- Bony tissue or osteophytes, located laterally in the C6(C7)-C2 cervical vertebral area course of the vertebral artery, most commonly at C5 -C6.

- Anatomical variations - Anomalous location of the origin of the vertebral artery, a congenital aberration, and tortuosity and kinks of the vertebral artery.

- Fibrous tissue - Tissue changed as a result of manipulation of the neck for neck pain or injury associated with hematoma; external bands, tendinous slings, and fibrous bands.

The most controversial obstructions include vertebral artery tortuosity and kinks and connective tissue along the course of the vertebral artery, and variously called external bands, tendinous slings and fibrous bands. In the absence of symptoms of vertebral artery obstruction, vascular surgeons feel such abnormalities are insignificant. Vascular surgery experts, however, agree that these abnormalities in very rare cases do cause symptoms of vertebral artery obstruction and do necessitate surgical correction.

Vertebral artery construction and vertebral artery surgery are phrases which most physicians interpret to include only surgical cleaning (endarterectomy) and bypass (resection) procedures. However, some physicians who use these terms mean all operative manipulations which remove vertebral artery blood flow obstructions. Also, some physicians use general terms of vascular surgery, such as endarterectomy when vertebral artery related surgery is performed. Use of the above terminology specifies neither the surgical procedure performed nor its relationship to the vertebral artery. Therefore, in developing claims for this type of procedure, require specific identification of the obstruction in question and the surgical procedure performed. Also, in view of the specific coverage criteria given, develop all claims for vertebral artery surgery on a case-by-case basis.

Make payment for a surgical procedure listed above if: (1) it is reasonable and necessary for the individual patient to have the surgery performed to remove or relieve an obstruction to vertebral artery flow, and (2) the four conditions noted are met.

In all other cases, these procedures cannot be considered reasonable and necessary within the meaning of §1862(a)(1) of the Act and are not reimbursable under the program.

35-33 INTESTINAL BY-PASS SURGERY--NOT COVERED

The safety of intestinal bypass surgery for treatment of obesity has not been demonstrated. Severe adverse reactions such as steatorrhea, electrolyte depletion, liver failure, arthralgia, hypoplasia of bone marrow, and avitaminosis have sometimes occurred as a result of this procedure. It does not meet the reasonable and necessary provisions of §1862(a)(1) of the Act and is not a covered Medicare procedure.

Cross-refer: §§ 35-26, 35-40

35-34 FABRIC WRAPPING OF ABDOMINAL ANEURYSMS--NOT COVERED

Fabric wrapping of abdominal aneurysms is not a covered Medicare procedure. This is a treatment for abdominal aneurysms which involves wrapping aneurysms with cellophane or fascia lata. This procedure has not been shown to prevent eventual rupture. In extremely rare instances, external wall reinforcement may be indicated when the current accepted treatment (excision of the aneurysm and reconstruction with synthetic materials) is not a viable alternative, but external wall reinforcement is not fabric wrapping. Accordingly, fabric wrapping of abdominal aneurysms is not considered reasonable and necessary within the meaning of §1862(a)(1) of the Act.

35-35 THERAPEUTIC EMBOLIZATION
(Effective for services performed on or after April 15, 1982.)

Therapeutic embolization is covered when done for hemorrhage, and for other conditions amenable to treatment by the procedure, when reasonable and necessary for the individual patient. Renal embolization for the treatment of renal adenocarcinoma continues to be covered, effective December 15, 1978, as one type of therapeutic embolization, to:

- Reduce tumor vascularity preoperatively;
- Reduce tumor bulk in inoperable cases; or
- Palliate specific symptoms.

35-37 EXTRACRANIAL-INTRACRANIAL (EC-IC) ARTERIAL BYPASS SURGERY
(Effective for services performed on or after March 27, 1991)

Extracranial-Intracranial (EC-IC) arterial bypass surgery is not a covered procedure when it is performed as a treatment for ischemic cerebrovascular disease of the carotid or middle cerebral arteries, which includes the treatment or prevention of strokes. The premise that this procedure which bypasses narrowed arterial segments improves the blood supply to the brain and reduces the risk of having a stroke has not been demonstrated to be any more effective than no surgical intervention. Accordingly, EC-IC arterial bypass surgery is not considered reasonable and necessary within the meaning of §1862(a)(1) of the Act when it is performed as a treatment for ischemic cerebrovascular disease of the carotid or middle cerebral arteries.