Medicare Coverage Issues Manual

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

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REFER TO CHANGE REQUEST 1632

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
35-94 – 35-100	4 pp.	4 pp.

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

Section 35-96, Cryosurgery of the Prostate, regarding cryosurgery of the prostate has been expanded. Salvage cryosurgery of the prostate is medically necessary and appropriate for those patients who have failed a trial of radiation treatment and meet one of the limitations set forth in the policy.

This revision to the Coverage Issues Manual is a national coverage decision (NCD) made under §1862(a)(1) of the Social Security Act. NCDs are binding on all Medicare carriers, intermediaries, peer review organizations, and other contractors. 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 disregard, set aside, or otherwise review an NCD issued under §1862(a)(1). (See 42 CFR 405.732 and 405.860.)

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.

This study will consist of a registry of all patients referred to the participating clinical centers for LVRS. In addition, a subset of patients from the registry who meet specific inclusion criteria will be invited to participate in the randomized trial. All randomized patients will receive intensive medical therapy and pulmonary rehabilitation. Half will be selected randomly to undergo LVRS, which will be performed via median sternotomy or video-assisted thoracoscopy.

Medicare will provide coverage to those beneficiaries who may participate in the randomized trial for all services integral to the study and for which the Medicare statute does not prohibit. This includes tests performed to determine whether a beneficiary qualifies for randomization, LVRS, and follow-up tests that are necessary during participation in the randomized study. However, Medicare will not provide coverage for those services that are prohibited by the Act. For example, Medicare will provide coverage for pulmonary rehabilitation and pulmonary function testing, but will not provide coverage for oral steroids provided as part of a physician's service under §1862(s)(2) of the Act because they are self-administrable and thus statutorily excluded from coverage.

Payment for these services will be provided under the usual payment systems. For example, Part A services will be paid for according to the DRG system, and Part B physician services will be paid for according to the physician fee schedule.

The data from the randomized phase of the study will be analyzed and monitored continuously in order to determine any appropriate changes in Medicare coverage. These determinations will include if and how coverage will be continued.

35-94 TRANSMYOCARDIAL REVASCULARIZATION (TMR) FOR TREATMENT OF SEVERE ANGINA--COVERED (Effective for services performed on or after July 1, 1999)

Transmyocardial revascularization (TMR) is a surgical technique which uses a laser to bore holes through the myocardium of the heart in an attempt to restore perfusion to areas of the heart not being reached by diseased or clogged arteries. This technique is used as a late or last resort for relief of symptoms of severe angina in patients with ischemic heart disease not amenable to direct coronary revascularization interventions, such as angioplasty, stenting or open coronary bypass.

The precise workings of this technique are not certain. The original theory upon which the technique was based, that the open channels would result in increased perfusion of the myocardium, does not appear to be the major or only action at work. Several theories have been proposed, including partial denervation of the myocardium, or the triggering of the cascade of biological reactions which encourage increased development of blood vessels.

However, research at several facilities indicates that, despite this uncertainty, the technique does offer relief of angina symptoms for a period of time in patients for whom no other medical treatment offering relief is available. Studies indicate that both reduction in pain and reduction in hospitalizations are significant for most patients treated. Consequently, we have concluded that, for patients with severe angina (Class III or IV, Canadian Cardiovascular Society, or similar classification system) for whom all other medical therapies have been tried or evaluated and found insufficient, such therapy offers sufficient evidence of its medical effectiveness to treat the symptomatology. It is important to note that this technique does not provide for increased life expectancy, nor is it proven to affect the underlying cause of the angina. However, it appears effective in treating the symptoms of angina, and reducing hospitalizations and allowing patients to resume some of their normal activities of daily living.

We therefore cover TMR as a late or last resort for patients with severe (Canadian Cardiovascular Society classification Classes III or IV) angina (stable or unstable), which has been found refractory to standard medical therapy, including drug therapy at the maximum tolerated or maximum safe dosages. In addition, the angina symptoms must be caused by areas of the heart not amenable to surgical therapies such as percutaneous transluminal coronary angioplasty, stenting, coronary atherectomy or coronary bypass. Coverage is further limited to those uses of the laser used in performing the procedure which have been approved by the Food and Drug Administration for the purpose for which they are being used.

Patients would have to meet the following additional selection guidelines:

1. An ejection fraction of 25% or greater;

2. Have areas of viable ischemic myocardium (as demonstrated by diagnostic study) which are not capable of being revascularized by direct coronary intervention; and

3. Have been stabilized, or have had maximal efforts to stabilize acute conditions such as severe ventricular arrhythmias, decompensated congestive heart failure or acute myocardial infarction.

Coverage is limited to physicians who have been properly trained in the procedure. Providers of this service is performed must also document that all ancillary personnel, including physicians, nurses, operating room personnel and technicians, are trained in the procedure and the proper use of the equipment involved. Coverage is further limited to providers which have dedicated cardiac care units, including the diagnostic and support services necessary for care of patients undergoing this therapy. In addition, these providers must conform to the standards for laser safety set by the American National Standards Institute, ANSIZ1363.

35-95 PARTIAL VENTRICULECTOMY (ALSO KNOWN AS VENTRICULAR REDUCTION, VENTRICULAR REMODELING, OR HEART VOLUME REDUCTION SURGERY) - NOT COVERED

Partial ventriculectomy, also known as ventricular reduction, ventricular remodeling, or heart volume reduction surgery, was developed by a Brazilian surgeon and has been performed only on a limited basis in the United States. This procedure is performed on patients with enlarged hearts due to end-stage congestive heart failure. Partial ventriculectomy involves reducing the size of an enlarged heart by excising a portion of the left ventricular wall followed by repair of the defect. It is asserted that this procedure makes the failing heart pump better by improving the efficiency of the remaining left ventricle.

Since the mortality rate is high and there are no published scientific articles or clinical studies regarding partial ventriculectomy, this procedure cannot be considered reasonable and necessary within the meaning of §1862(a)(1) of the Act. Therefore, partial ventriculectomy is not covered by Medicare.

35-96 CRYOSURGERY OF PROSTATE (Effective for services performed on or after July 1, 1999)

Cryosurgery of the prostate gland, also known as cryosurgical ablation of the prostate (CSAP), destroys prostate tissue by applying extremely cold temperatures in order to reduce the size of the prostate gland. It is safe and effective, as well as medically necessary and appropriate, as primary treatment for patients with clinically localized prostate cancer, Stages T1-T3.

Cryosurgery of the prostate as a salvage therapy is not covered for any services performed prior to June 30, 2001.

SALVAGE CRYOSURGERY OF PROSTATE AFTER RADIATION FAILURE (Effective for services performed after July 1, 2001) Salvage cryosurgery of the prostate for recurrent cancer is medically necessary and appropriate only for those patients with localized disease who:

1. Have failed a trial of radiation therapy as their primary treatment; and

2. Meet one of the following conditions: Stage T2B or below, Gleason score < 9, PSA < 8 ng/mL.

Cryosurgery as salvage therapy is therefore not covered under Medicare after failure of other therapies as the primary treatment. Cryosurgery as salvage is only covered after the failure of a trial of radiation therapy, under the conditions noted above.

35-97 VERTEBRAL AXIAL DECOMPRESSION (VAX-D) - NOT COVERED

Vertebral axial decompression is performed for symptomatic relief of pain associated with lumbar disk problems. The treatment combines pelvic and/or cervical traction connected to a special table that permits the traction application. There is insufficient scientific data to support the benefits of this technique. Therefore, VAX-D is not covered by Medicare.

35-98 ELECTROSTIMULATION IN THE TREATMENT OF WOUNDS - NOT COVERED

Electrical stimulation (ES) has been used or studied for many different applications, one of which is accelerating wound healing. The types of ES used for healing chronic venous and arterial wound and pressure ulcers are direct current (DC), alternating current (AC), pulsed current (PC), pulsed electromagnetic induction (PEMI), and spinal cord stimulation (SCS). An example of AC is transcutaneous electrical stimulation (TENS). The PEMI includes Pulsed Electromagnetic Field (PEMF) and Pulsed Electromagnetic Energy (PEE) using pulsed radio frequency energy, both of which are nonthermal i.e., they do not produce heat. Some ES use generators to create energy in the radio frequency band, delivered in megahertz (MHz). They typically deliver energy by contacting means such as coils, rather than by leads or surface electrodes.

There is insufficient evidence to determine any clinically significant differences in healing rates. Therefore, ES cannot be covered by Medicare because its effectiveness has not been adequately demonstrated.

35-99 ABORTION

Abortions are not covered Medicare procedures except:

1. If the pregnancy is the result of an act of rape or incest; or

2. In the case where a woman suffers from a physical disorder, physical injury, or physical illness, including a life-endangering physical condition caused by or arising from the pregnancy itself, that would, as certified by a physician, place the woman in danger of death unless an abortion is performed.

This restricted coverage applies to CPT codes 59840, 59841, 59850, 59851, 59852, 59855, 59856, 59857, and 59866.

35-100 PHOTODYNAMIC THERAPY

Photodynamic therapy is a medical procedure which involves the infusion of a photosensitive (light-activated) drug with a very specific absorption peak. This drug is chemically designed to have a unique affinity for the diseased tissue intended for treatment. Once introduced to the body, the drug accumulates and is retained in diseased tissue to a greater degree than in normal tissue. Infusion is followed by the targeted irradiation of this tissue with a non-thermal laser, calibrated to emit light at a wavelength that corresponds to the drug's absorption peak. The drug then becomes active and locally treats the diseased tissue.

Ocular photodynamic therapy (OPT)

OPT is used in the treatment of ophthalmologic diseases. Effective July 1, 2001, OPT (CPT code 67221) is only covered when used in conjunction with verteporfin (see §45-30 PHOTOSENSITIVE DRUGS). For patients with age-related macular degeneration, OPT is only covered with a diagnosis of neovascular age-related macular degeneration (ICD-9-CM 362.52) with predominately classic subfoveal choroidal neovascular (CNV) lesions (where the area of classic CNV occupies ≥ 50% of

the area of the entire lesion) at the initial visit as determined by a fluorescein angiogram (CPT code 92235). Subsequent follow-up visits will require a fluorescein angiogram prior to treatment. There are no requirements regarding visual acuity, lesion size, and number of retreatments.