
Medicare Coverage Issues Manual

Department of Health and
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<u>HEADER SECTION NUMBERS</u>	<u>PAGES TO INSERT</u>	<u>PAGES TO DELETE</u>
35-50 – 35-61	6 pages	6 pages

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

Section 35-53, Adult Liver Transplantation, is revised to provide for coverage of adult liver transplantation for patients with hepatocellular carcinoma under certain circumstances. Liver transplantation for other forms of malignancies remains noncovered. Carriers need to advise providers of this new coverage provision via their web site or regularly scheduled bulletins. Fiscal intermediaries need not perform inpatient medical review on these claims as they are subject to review by the Peer Review Organization Payment Error Prevention Program.

This section of the coverage manual is a national coverage decision (NCD) made under §1862(a)(1) of the Social Security Act (the Act). National coverage determinations are binding on all Medicare carriers, fiscal intermediaries, Peer Review Organizations, Health Maintenance Organizations, Competitive Medical Plans, Health Care Prepayment Plans (§1862(a)(1)(A) of the Act). 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 a national coverage decision (42 CFR §405.860) issued under §1862(a)(1) of the 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.

Effective for services performed on or after September 15, 1980, nonunion of long bone fractures, for both noninvasive and invasive devices, is considered to exist only after 6 or more months have elapsed without healing of the fracture.

Effective for services performed on or after April 1, 2000, nonunion of long bone fractures, for both noninvasive and invasive devices, is considered to exist only when serial radiographs have confirmed that fracture healing has ceased for three or more months prior to starting treatment with the electrical osteogenic stimulator. Serial radiographs must include a minimum of two sets of radiographs, each including multiple views of the fracture site, separated by a minimum of 90 days.

B. Ultrasonic Osteogenic Stimulators.--An ultrasonic osteogenic stimulator is a non-invasive device that emits low intensity, pulsed ultrasound. The ultrasound signal is applied to the skin surface at the fracture location via ultrasound, conductive gel in order to stimulate fracture healing.

Effective for services performed on or after January 1, 2001, ultrasonic osteogenic stimulators are covered as medically reasonable and necessary for the treatment of non-union fractures. In demonstrating nonunion of fractures, we would expect :

1. A minimum of two sets of radiographs obtained prior to starting treatment with the osteogenic stimulator, separated by a minimum of 90 days. Each radiograph must include multiple views of the fracture site accompanied with a written interpretation by a physician stating that there has been no clinically significant evidence of fracture healing between the two sets of radiographs.

2. Indications that the patient failed at least one surgical intervention for the treatment of the fracture.

Non-unions of the skull, vertebrae, and those that are tumor-related are excluded from coverage. The ultrasonic osteogenic stimulator may not be used concurrently with other non-invasive osteogenic devices. The national non-coverage policy related to ultrasonic osteogenic stimulators for fresh fractures and delayed unions remains in place. This policy relates only to non-union as defined above.

35-49 HYPERTHERMIA FOR TREATMENT OF CANCER (Effective for services performed on or after December 31, 1984.)

Local hyperthermia for treatment of cancer consists of the use of heat to make tumors more susceptible to cancer therapy measures.

Local hyperthermia is covered under Medicare when used in connection with radiation therapy for the treatment of primary or metastatic cutaneous or subcutaneous superficial malignancies. It is not covered when used alone or in connection with chemotherapy.

35-50 COCHLEOSTOMY WITH NEUROVASCULAR TRANSPLANT FOR MENIERE'S DISEASE - NOT COVERED

Meniere's disease (or syndrome) is a common cause of paroxysmal vertigo. Meniere's syndrome is usually treated medically. When medical treatment fails, surgical treatment may be required.

While there are two recognized surgical procedures used in treating Meniere's disease (decompression of the endolymphatic hydrops and labyrinthectomy), there is no scientific evidence supporting the safety and effectiveness of cochleostomy with neurovascular transplant in treatment of Meniere's syndrome. Accordingly, Medicare does not cover cochleostomy with neurovascular transplant for treatment of Meniere's disease.

35-51 HEMODIALYSIS FOR TREATMENT OF SCHIZOPHRENIA - NOT COVERED

Scientific evidence supporting use of hemodialysis as a safe and effective means of treatment for schizophrenia is inconclusive at this time. Accordingly, Medicare does not cover hemodialysis for treatment of schizophrenia.

35-52 LASER PROCEDURES

Medicare recognizes the use of lasers for many medical indications. Procedures performed with lasers are sometimes used in place of more conventional techniques. In the absence of a specific noncoverage instruction, and where a laser has been approved for marketing by the Food and Drug Administration, contractor discretion may be used to determine whether a procedure performed with a laser is reasonable and necessary and, therefore, covered.

The determination of coverage for a procedure performed using a laser is made on the basis that the use of lasers to alter, revise, or destroy tissue is a surgical procedure. Therefore, coverage of laser procedures is restricted to practitioners with training in the surgical management of the disease or condition being treated.

35-53 ADULT LIVER TRANSPLANTATION

A. **General.**--Effective July 15, 1996, adult liver transplantation when performed on beneficiaries with end stage liver disease other than hepatitis B or malignancies is covered under Medicare when performed in a facility which is approved by **CMS** as meeting institutional coverage criteria.

Effective December 10, 1999, adult liver transplantation when performed on beneficiaries with end stage liver disease other than malignancies is covered under Medicare when performed in a facility which is approved by **CMS** as meeting institutional coverage criteria.

Effective September 1, 2001, Medicare covers adult liver transplantation for hepatocellular carcinoma when the following conditions are met:

1. The patient is not a candidate for subtotal liver resection;
2. The patient's tumor(s) is less than or equal to 5 cm in diameter;
3. There is no macrovascular involvement;
4. There is no identifiable extrahepatic spread of tumor to surrounding lymph nodes, lungs, abdominal organs or bone; and
5. The transplant is furnished in a facility which is approved by **CMS** as meeting institutional coverage criteria for liver transplants (See 65 FR 15006).

Adult liver transplantation for other malignancies remains excluded from coverage.

Coverage of adult liver transplantation is effective as of the date of the facility's approval, but for applications received before July 13, 1991, can be effective as early as March 8, 1990. (See **Federal Register** 56 FR 15006 dated April 12, 1991.)

B. **Follow-up Care.**--Follow-up care or retransplantation (ICD-9-M 996.82, Complications of Transplanted Organ, Liver0 required as a result of a covered liver transplant is covered, provided such services are otherwise reasonable and necessary. Follow-up care is also covered for patients who have been discharged from a hospital after receiving noncovered liver transplant. Coverage for follow-up care is for items and services that are reasonable and necessary as determined by Medicare guidelines. (See Intermediary Manual, §3101.14 and Carriers Manual, §2300.1.)

C. **Immunosuppressive Drugs.**--See Intermediary Manual, §3600.8 and Carriers Manual; §§2050.5, 4471, and 5249.

35-53.1 PEDIATRIC LIVER TRANSPLANTATION

Effective for services performed on or after February 9, 1984, liver transplantation is covered for children (under age 18) with extrahepatic biliary atresia or any other form of end stage liver disease, except that coverage is not provided for children with a malignancy extending beyond the margins of the liver or those with persistent viremia.

Effective for services performed on or after April 12, 1991, liver transplantation is covered for Medicare beneficiaries when performed in a pediatric hospital that performs pediatric liver transplants if the hospital submits an application which CMS approves documenting that:

- o The hospital's pediatric liver transplant program is operated jointly by the hospital and another facility that has been found by CMS to meet the institutional coverage criteria in the *Federal Register* notice of April 12, 1991;
- o The unified program shares the same transplant surgeons and quality assurance program (including oversight committee, patient protocol, and patient selection criteria); and
- o The hospital is able to provide the specialized facilities, services, and personnel that are required by pediatric liver transplant patients.

35-54 REFRACTIVE KERATOPLASTY- NOT COVERED

Refractive keratoplasty is surgery to reshape the cornea of the eye to correct vision problems such as myopia (nearsightedness) and hyperopia (farsightedness). Refractive keratoplasty procedures include keratomileusis, in which the front of the cornea is removed, frozen, reshaped, and stitched back on the eye to correct either near or farsightedness; keratophakia, in which a reshaped donor cornea is inserted in the eye to correct farsightedness; and radial keratotomy, in which spoke-like slits are cut in the cornea to weaken and flatten the normally curved central portion to correct nearsightedness.

The correction of common refractive errors by eyeglasses, contact lenses or other prosthetic devices is specifically excluded from coverage. The use of radial keratotomy and/or keratoplasty for the purpose of refractive error compensation is considered a substitute or alternative to eye glasses or contact lenses, which are specifically excluded by §1862 (a)(7) of the Act (except in certain cases in connection with cataract surgery). In addition, many in the medical community consider such procedures cosmetic surgery, which is excluded by section §1862 (a)(10) of the Act. Therefore, radial keratotomy and keratoplasty to treat refractive defects are not covered.

Keratoplasty that treats specific lesions of the cornea, such as phototherapeutic keratectomy that removes scar tissue from the visual field, deals with an abnormality of the eye and is not cosmetic surgery. Such cases may be covered under §1862(a)(1)(A) of the Act.

The use of lasers to treat ophthalmic disease constitutes ophthalmologic surgery. Coverage is restricted to practitioners who have completed an approved training program in ophthalmologic surgery.

35-55 TRANSVENOUS (CATHETER) PULMONARY EMBOLICTOMY - NOT COVERED

Transvenous (catheter) pulmonary embolictomy is a procedure for removing pulmonary emboli by passing a catheter through the femoral vein. It is not covered under Medicare because it is still experimental.

35-56 FLUIDIZED THERAPY DRY HEAT FOR CERTAIN MUSCULOSKELETAL DISORDERS

Fluidized therapy is a high intensity heat modality consisting of a dry whirlpool of finely divided solid particles suspended in a heated air stream, the mixture having the properties of a liquid. Use of fluidized therapy dry heat is covered as an acceptable alternative to other heat therapy modalities in the treatment of acute or subacute traumatic or nontraumatic musculoskeletal disorders of the extremities.

35-57 ELECTROENCEPHALOGRAPHIC MONITORING DURING SURGICAL PROCEDURES INVOLVING THE CEREBRAL VASCULATURE

Electroencephalographic (EEG) monitoring is a safe and reliable technique for the assessment of gross cerebral blood flow during general anesthesia and is covered under Medicare. Very characteristic changes in the EEG occur when cerebral perfusion is inadequate for cerebral function. EEG monitoring as an indirect measure of cerebral perfusion requires the expertise of an electroencephalographer, a neurologist trained in EEG, or an advanced EEG technician for its proper interpretation.

The EEG monitoring may be covered routinely in carotid endarterectomies and in other neurological procedures where cerebral perfusion could be reduced. Such other procedures might include aneurysm surgery where hypotensive anesthesia is used or other cerebral vascular procedures where cerebral blood flow may be interrupted.

35-57.1 ELECTROENCEPHALOGRAPHIC (EEG) MONITORING DURING OPEN-HEART SURGERY - NOT COVERED

The value of EEG monitoring during open heart surgery and in the immediate post-operative period is debatable because there are little published data based on well designed studies regarding its clinical effectiveness. The procedure is not frequently used and does not enjoy widespread acceptance of benefit.

Accordingly, Medicare does not cover EEG monitoring during open heart surgery and during the immediate post-operative period.

35-58 THORACIC DUCT DRAINAGE (TDD) IN RENAL TRANSPLANTS

Thoracic duct drainage (TDD) is an immunosuppressive technique used in renal transplantation. This procedure, which removes lymph from kidney transplant recipients as a means of achieving suppression of the immune mechanism, is currently being used both pre-transplant and post-transplant in conjunction with more conventional immunotherapy. TDD is performed on an inpatient basis, and the inpatient stay is covered for patients admitted for treatment in advance of a kidney transplant as well as for those receiving it post-transplant.

TDD is a covered technique when furnished to a kidney transplant recipient or an individual approved to receive kidney transplantation in a hospital approved to perform kidney transplantation.

35-59 ENDOSCOPY

Endoscopy is a technique in which a long flexible tube-like instrument is inserted into the body orally or rectally, permitting visual inspection of the gastrointestinal tract. Although primarily a diagnostic tool, endoscopy includes certain therapeutic procedures such as removal of polyps, and endoscopic papillotomy, by which stones are removed from the bile duct.

Endoscopic procedures are covered when reasonable and necessary for the individual patient.

35-60 APHERESIS (THERAPEUTIC PHERESIS)

A. General.--Apheresis (also known as pheresis or therapeutic pheresis) is a medical procedure utilizing specialized equipment to remove selected blood constituents (plasma, leukocytes, platelets, or cells) from whole blood. The remainder is retransfused into the person from whom the blood was taken.

For purposes of Medicare coverage, apheresis is defined as an autologous procedure, i.e., blood is taken from the patient, processed, and returned to the patient as part of a continuous procedure (as distinguished from the procedure in which a patient donates blood preoperatively and is transfused with the donated blood at a later date).

B. Indications.--Apheresis is covered for the following indications:

- o Plasma exchange for acquired myasthenia gravis;
- o Leukapheresis in the treatment of leukemia;
- o Plasmapheresis in the treatment of primary macroglobulinemia (Waldenstrom);
- o Treatment of hyperglobulinemias, including (but not limited to) multiple myelomas, cryoglobulinemia and hyperviscosity syndromes;
- o Plasmapheresis or plasma exchange as a last resort treatment of thrombotic thrombocytopenic purpura (TTP);
- o Plasmapheresis or plasma exchange in the last resort treatment of life threatening rheumatoid vasculitis;
- o Plasma perfusion of charcoal filters for treatment of pruritis of cholestatic liver disease;
- o Plasma exchange in the treatment of Goodpasture's Syndrome;
- o Plasma exchange in the treatment of glomerulonephritis associated with antglomerular basement membrane antibodies and advancing renal failure or pulmonary hemorrhage;
- o Treatment of chronic relapsing polyneuropathy for patients with severe or life threatening symptoms who have failed to respond to conventional therapy;
- o Treatment of life threatening scleroderma and polymyositis when the patient is unresponsive to conventional therapy;
- o Treatment of Guillain-Barre Syndrome; and
- o Treatment of last resort for life threatening systemic lupus erythematosus (SLE) when conventional therapy has failed to prevent clinical deterioration.

C. Settings.--Apheresis is covered only when performed in the following settings:

o In a hospital setting (either inpatient or outpatient). Nonphysician services furnished to hospital patients are covered and paid for as hospital services. When covered services are provided to hospital patients by an outside provider/supplier, the hospital is responsible for paying the provider/supplier for the services.

o In a nonhospital setting, e.g., a physician directed clinic (see CMS Pub. 14-3, §2050.4) when the following conditions are met:

- A physician (or a number of physicians) is present to perform medical services and to respond to medical emergencies at all times during patient care hours;
- Each patient is under the care of a physician; and
- All nonphysician services are furnished under the direct, personal supervision of a physician.

35-61 TRANSSEXUAL SURGERY

Transsexual surgery, also known as sex reassignment surgery or intersex surgery, is the culmination of a series of procedures designed to change the anatomy of transsexuals to conform to their gender identity. Transsexuals are persons with an overwhelming desire to change anatomic sex because of their fixed conviction that they are members of the opposite sex. For the male-to-female, transsexual surgery entails castration, penectomy and vulva-vaginal construction. Surgery for the female-to-male transsexual consists of bilateral mastectomy, hysterectomy and salpingo-oophorectomy, which may be followed by phalloplasty and the insertion of testicular prostheses. Transsexual surgery for sex reassignment of transsexuals is controversial. Because of the lack of well controlled, long term studies of the safety and effectiveness of the surgical procedures and attendant therapies for transsexualism, the treatment is considered experimental. Moreover, there is a high rate of serious complications for these surgical procedures. For these reasons, transsexual surgery is not covered.

35-62 INVASIVE INTRACRANIAL PRESSURE MONITORING

Invasive intracranial pressure monitoring is a safe and effective therapeutic tool used to monitor intracranial pressure. It is usually used for patients suffering from head injuries, subarachnoid hemorrhage, intracerebral hemorrhage, Reye's syndrome, or posthypoxic, metabolic, and viral encephalopathies. It is usually performed in specialized intensive care units for neurosurgical and neurologic patients. It is a covered procedure when reasonable and necessary for the individual patient.

35-63 TINNITUS MASKING

A tinnitus masker is a device designed to be worn like a behind-the-ear hearing aid by persons seeking relief from tinnitus. Tinnitus is the perception of noise in the ear and/or head area. The masker produces external sounds to distract the person from the tinnitus.

By producing an external sound a few decibels above the person's audible threshold, tinnitus masking is thought to provide sufficient distraction from subjective idiopathic tinnitus to alleviate the discomfort and debilitation associated with endogenous sounds within the ear and/or head area.

Tinnitus masking is considered an experimental therapy at this time because of the lack of controlled clinical trials demonstrating effectiveness and the unstudied possibility of serious toxicity in the form of noise induced hearing loss. Therefore, it is not covered.