Medicare Coverage Issues Manual

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

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This instruction manualizes expiring Program Memorandum AB-02-040 (CR 1629). There is no policy change.

HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
Table of Contents	2 pp.	2 pp.
35-103 - 35-104	2 pp.	1p.

MANUALIZATION--*EFFECTIVE DATE: Non-applicable*
IMPLEMENTATION DATE: Non-applicable

Section 35-104, Intestinal and Multi-Visceral Transplantation, is a new section which explains the coverage of intestinal and multi-visceral transplantation for the purpose of restoring intestinal function in patients with irreversible intestinal failure.

This revision to the Coverage Issues Manual is a national coverage decision (NCD). NCDs are binding on all Medicare carriers, intermediaries, peer review organizations, health maintanence organizations, competive 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 review 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

The use of electrical stimulation for the treatment of wounds is considered an adjunctive therapy. Electrical stimulation will be covered only after appropriate standard wound therapy has been tried for at least 30-days and there are no measurable signs of healing. This 30-day period can begin while the wound is acute. Measurable signs of improved healing include a decrease in wound size, either surface area or volume, decrease in amount of exudates and decrease in amount of necrotic tissue. Standard wound care includes: optimization of nutritional status; debridement by any means to remove devitalized tissue; maintenance of a clean, moist bed of granulation tissue with appropriate moist dressings; and necessary treatment to resolve any infection that may be present. Standard wound care based on the specific type of wound includes: frequent repositioning of a patient with pressure ulcers (usually every 2 hours); off-loading of pressure and good glucose control for diabetic ulcers; establishment of adequate circulation for arterial ulcers; and the use of a compression system for patients with venous ulcers.

Continued treatment with electrical stimulation is not covered if measurable signs of healing have not been demonstrated within any 30-day period of treatment. Electrical stimulation must be discontinued when the wound demonstrates 100 per-cent epithelialzed wound bed.

Any form of electromagnetic therapy for the treatment of chronic wounds will not be covered.

This service can only be covered when performed by a physician, physical therapist, or incident to a physician service. Evaluation of the wound is an integral part of wound therapy. When a physician, physical therapist, or a clinician incident to a physician, performs electrical stimulation, that practitioner must evaluate the wound and contact the treating physician if the wound worsens. If electrical stimulation is being used, wounds must be evaluated at least monthly by the treating physician.

Unsupervised use of electrical stimulation for wound therapy will not be covered, as this use has not been found to be medically reasonable and necessary.

35-103 Multiple Electroconvulsive Therapy (MECT) (Effective for services provided on or after April 1, 2003.)

The clinical effectiveness of the multiple-seizure electroconvulsive therapy has not been verified by scientifically controlled studies. In addition, studies have demonstrated an increased risk of adverse effects with multiple seizures. Accordingly, MECT cannot be considered reasonable and necessary and is not covered by the Medicare program.

35-104 INTESTINAL AND MULTI-VISCERAL TRANSPLANTATION (Effective for services performed on and after April 1, 2001)

Medicare covers intestinal and multi-visceral transplantation for the purpose of restoring intestinal function in patients with irreversible intestinal failure. Intestinal failure is defined as the loss of absorptive capacity of the small bowel secondary to severe primary gastrointestinal disease or surgically induced short bowel syndrome. It may be associated with both mortality and profound morbidity. Multi-visceral transplantation includes organs in the digestive system (stomach, duodenum, pancreas, liver and intestine).

The evidence supports the fact that aged patients generally do not survive as well as younger patients receiving intestinal transplantation. Nonetheless, some older patients who are free from other contraindications have received the procedure and are progressing well, as evidenced by the United Network for Organ Sharing (UNOS) data. Thus, it is not appropriate to include specific exclusions from coverage, such as an age limitation, in the national coverage policy.

This procedure is covered **only** when performed for patients who have failed total parenteral nutrition (TPN) and only when performed in centers that meet approval criteria.

Failed TPN

TPN delivers nutrients intravenously, avoiding the need for absorption through the small bowel. TPN failure includes the following:

- Impending or overt liver failure due to TPN induced liver injury. The clinical manifestations include elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopenia, gastroesophageal varices, coagulopathy, stomal bleeding or hepatic fibrosis/cirrhosis.

- Thrombosis of the major central venous channels; jugular, subclavian, and femoral veins. Thrombosis of two or more of these vessels is considered a life threatening complication and failure of TPN therapy. The sequelae of central venous thrombosis are lack of access for TPN infusion, fatal sepsis due to infected thrombi, pulmonary embolism, Superior Vena Cava syndrome, or chronic venous insufficiency.

- Frequent line infection and sepsis. The development of two or more episodes of systemic sepsis secondary to line infection per year that requires hospitalization indicates failure of TPN therapy. A single episode of line related fungemia, septic shock and/or Acute Respiratory Distress Syndrome are considered indicators of TPN failure.

- Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN. Under certain medical conditions such as secretory diarrhea and non-constructable gastrointestinal tract, the loss of the gastrointestinal and pancreatobiliary secretions exceeds the maximum intravenous infusion rates that can be tolerated by the cardiopulmonary system. Frequent episodes of dehydration are deleterious to all body organs particularly kidneys and the central nervous system with the development of multiple kidney stones, renal failure, and permanent brain damage.

Approved Transplant Facilities

Intestinal transplantation is covered by Medicare if performed in an approved facility. The criteria for approval of centers will be based on a volume of 10 intestinal transplants per year with a 1-year actuarial survival of 65 percent using the Kaplan-Meier technique. More specific criteria can be found at: http://cms.hhs.gov/providers/transplant/default.asp and in the Medicare Intermediary Manual §3615.7.