

CMS Manual System

Pub 100-03 Medicare National Coverage Determinations

Transmittal 58

Department of Health &
Human Services (DHHS)

Centers for Medicare &
Medicaid Services (CMS)

Date: MAY 26, 2006

Change Request 5090

SUBJECT: Intestinal and Multi-Visceral Transplantation

I. SUMMARY OF CHANGES: CMS has been asked to reconsider our current requirements of an annual volume of 10 intestinal transplants per year with a 1-year actuarial survival of 65 percent as a condition of approval as an intestinal transplant facility. CMS previously determined that organ transplants are reasonable and necessary when performed on carefully selected patients in facilities that meet certain criteria. CMS has reviewed the evidence and concludes that the evidence supports the continued usage of the current requirements for facilities performing intestinal or multi-visceral transplants. Thus, we are making no change to current policy on intestinal/multi-visceral transplant facility requirements. Additionally, we have deleted the following reference to a defunct website: More specific criteria can be found at <http://cms.hhs.gov/providers/transplant/default.asp>. Clerical revisions have also been made to add section headings and effective dates.

This addition/revision of section 260.5 of Pub.100-03 is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, quality improvement organizations, qualified independent contractors, the Medicare Appeals Council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

NEW/REVISED MATERIAL

EFFECTIVE DATE: May 11, 2006

IMPLEMENTATION DATE: June 26, 2006

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revise information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R = REVISED, N = NEW, D = DELETED

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
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R

1/260.5/Intestinal and Multi-Visceral Transplantation

III. FUNDING:

No additional funding will be provided by CMS; Contractor activities are to be carried out within their FY 2006 operating budgets.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

**Medicare National Coverage
Determinations Manual
Chapter 1, Part 4 (Sections 200 – 310.1)
Coverage Determinations**

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(Rev. 58, 05-26-06)**

260.5 - Intestinal and Multi-Visceral Transplantation (*Effective May 11, 1006*)

260.5 Intestinal and Multi-Visceral Transplantation *(Effective May 11, 2006)*
(Rev. 58, Issued: 05-26-06; Effective: 05-11-06; Implementation: 06-26-06)

A. General

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.

B. Nationally Covered Indications

Effective for services performed on or after April 1, 2001, 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.

1. Failed TPN

The 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.

2. 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.

C. Nationally Non-covered Indications

All other indications remain non-covered.

D. Other

NA.

This NCD last reviewed May 2006.