Program Memorandum Intermediaries/Carriers

Department of Health and Human Services (DHHS)

HEALTH CARE FINANCING ADMINISTRATION (HCFA)

Transmittal AB-00-130 **Date: DECEMBER 22, 2000**

CHANGE REQUEST 1436

SUBJECT: Intestinal Transplantation

This Program Memorandum (PM) is a national coverage decision made under §1862(a)(1) of the Social Security Act (the Act). National coverage determinations (NCDs) are binding on all Medicare Carriers, Medicare Fiscal 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 a national coverage decision issued under §1862(a)(1), (see 42 CFR 405.732 and 405.860).

Background

Effective April 1, 2001, Medicare covers intestinal 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. Intestinal failure prevents oral nutrition and may be associated with both mortality and profound morbidity.

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. TPN delivers nutrients intravenously, avoiding the need for absorption through the small bowel. Failed TPN for liver failure, thrombosis, frequency of infection, and dehydration are indicated in the following clinical situations:

- 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 central nervous system with the development of multiple kidney stones, renal failure, and permanent brain damage.

Approved Transplant Facilities

Intestinal transplantation will be 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. In addition, the following definitions and rules must also be used:

- The date of transplantation (or, if more than one transplantation is performed, the date of the first transplantation) must be the starting date for calculation of the survival rate.
- For those deceased, the date of death is used, if known. f the date of death is unknown, it must be assumed as 1 day after the date of the last ascertained survival.
- For those who have been ascertained as surviving within 60 days before the fiducial date (the point in time when the facility's survival rates are calculated and its experience is reported), survival is considered to be the date of the last ascertained survival. Any patient who receives an intestinal transplant between 61 to 120 days before the fiducial date must be considered "lost to follow-up" if he or she is known to be deceased and his or her survival has not been ascertained for at least 60 days before the fiducial date. Any patient transplanted within 60 days before the fiducial date must be considered as "lost to follow-up" if he or she is not known to be dead and his or her survival has not been ascertained on the fiducial date. Note: The fiducial date cannot be in the future; it must be within 90 days before the date we receive the application.
- Any patient who is not known to be deceased but whose survival cannot be ascertained to a date that is within 60 days before the fiducial date, must be considered as "lost to follow-up" for the purposes of this analysis.
- A facility must submit its survival analyses using the assumption that each patient in the "lost to follow-up" category died 1 day after the last date of ascertained survival. However, a facility may submit additional analyses that reflect each patient in the "lost to follow-up" category as alive at the date of the last ascertained survival.
- Survival is calculated based on patient survival, not graft survival. Consequently, facilities should not consider retransplantation as termination.

  In addition to reporting actuarial survival rates, the facility must also submit the following information on every Medicare and non-Medicare patient who received a transplantation.

- Patient transplant number
- Age
- Sex
- Clinical indication for transplant (diagnosis)
- Date of transplant
- Date of most recent ascertained survival
- Date of death
- Category of patient (living, dead, or "lost to follow-up")
- In days, survival after organ transplant
- Date of retransplant
- Number of retransplants

Completed applications should be sent to:

Bernadette Schumaker
Director
Division of Integrated Delivery Systems
C4-25-02
7500 Security Boulevard
Baltimore, Maryland 21244

A facility that submits a completed application to HCFA and meets all the requirements of this notice will be approved for intestinal transplants performed beginning on the date of the Administrator's approval letter, but no earlier than April 1, 2001.

Payment

Medicare will not pay a separate cost for organ acquisition to transplant facilities. The DRG payment will be payment in full.

This PM requires changes in the system and in the claims processing instructions. Immunosuppressive therapy for intestinal transplantation is covered. The ICD-9-CM procedure code for intestinal transplantation is 46.97. There is no specific ICD-9-CM diagnosis code for intestinal failure, although diagnosis codes exist to capture the causes of intestinal failure. Some examples of intestinal failure include, but are not limited to:

* Volvulus 560.2,
* Volvulus gastroschisis 756.79, other [congenital] anomalies of abdominal wall
* Volvulus gastroschisis 569.89, other specified disorders of intestine,
* Necrotizing enterocolitis 777.5, necrotizing enterocolitis in fetus or newborn
* Necrotizing enterocolitis 014.8, other tuberculosis of intestines, peritoneum, and mesenteric glands
* Necrotizing enterocolitis and splanchnic vascular thrombosis 557.0, acute vascular insufficiency of intestine
* Inflammatory bowel disease 569.9, unspecified disorder of intestine
* Radiation enteritis 777.5, necrotizing enterocolitis in fetus or newborn
* Radiation enteritis 558.1

If an intestinal transplantation alone is performed on a patient with an intestinal principal diagnosis, the case would be assigned to either DRG 148 (Major Small & Large Bowel Procedures With Complications or Comorbidities) or DRG 149 (Major Small & Large Bowel Procedures Without Complications or Comorbidities). If the intestinal transplantation and the liver transplantation are performed simultaneously, the case would be assigned to DRG 480 (Liver Transplant). If the intestinal transplantation and the pancreas transplantation are performed simultaneously, the case would be assigned to either DRG 148 (Major Small & Large Bowel Procedures With Complications or Comorbidities) or DRG 149 (Major Small & Large Bowel Procedures Without Complications or Comorbidities).

The CPT code for donor enterectomy from a cadaver donor is 44132, 44133 for partial, from living donor, 44135 for intestinal allotransplantation from cadaver donor, and 44136 for living donor.

FI Processing Instructions

In addition to the above listed payment implications, the following also apply:

A. Effective for discharges on or after October 1, 2000, ICD-9-CM Procedure Code 46.97, Transplant of Intestine was created. The Medicare Code Editor (MCE) lists this code as a non-covered procedure, no exceptions. You are to override the MCE when this procedure code is listed and the above coverage criteria are met in an approved transplant facility.
B. Have your system generate an ADR for medical records.
C. Upon receipt of medical records, MR staff must review the bill and the supporting documentation to determine if the coverage criteria are met.
D. Charges for ICD-9-CM Procedure Code 46.97 should be billed under Revenue Center 360, Operating Room Services.
E. Bill the procedure used to obtain the donor's organ on the same claim, using appropriate ICD-9-CM procedure codes.
F. The 11X bill type should be used when billing for intestinal transplants.
G. You should bill for immunosuppressive therapy as stated in PM AB-99-98 (CR 1069), dated December 1999.

Carrier Processing Instructions

Effective for services performed on or after April 1, 2001, in block 24D of the form HCFA 1500, physicians should enter the following CPT codes for intestinal transplantation:

- 44133 - partial, from living donor
- 44135 - Intestinal allotransplantation; from cadaver donor
- 44136 - Intestinal allotransplantation; from living

These codes are currently listed in the Medicare Physician Fee Schedule Database (MPFSDB) with an "N" indicator for non-covered services. Changes for these codes to the "R" indicator will be incorporated in the April quarterly MFSDB update.

NOTE: CPT code 44132 is not paid by carriers and should be denied if billed. Payment for this CPT code is made to the facility where the organ is procured.

Medicare Summary Notice (MSN), Remittance Advice Messages and Explanation of Medicare Benefits (EOMB)

The following messages can be used to notify beneficiaries and providers of denial situations that may occur:

For Intermediaries and Carriers

1. If an intestinal transplant is performed prior to April 1, 2001, deny the claim and use MSN message 21.11 or 16.13 or EOMB message 9.54, "This service was not covered by Medicare at the time you received it, The code(s) your provider used is/are not valid for the date of service billed," and Remittance Advice Message, Claim Adjustment Reason Code 26, "Expenses incurred prior to coverage."

2. If a facility bills organ acquisition costs separately from the intestinal transplant or if a physicians bills for 44132, deny the claim and use MSN 16.29 or EOMB message 9.55. "Payment is included in another service you have received," and Remittance Advice Message, Claim Adjustment Reason Code 97, "Payment is included in the allowance for another service/procedure."

For Intermediaries Only

3. If an intestinal transplant is billed by an unapproved facility, deny the claim and use MSN message 21.6, "This item or service is not covered when performed, referred, or ordered by this provider," or 21.18, "This item or service is not covered when performed or ordered by this provider," or 16.2, "This service cannot be paid when provided in this location/facility," or EOMB message 16.99, "This service cannot be paid when provided in this location/facility," and Remittance Advice Message, Claim Adjustment Reason Code 52, "The referring/prescribing/rendering provider is not eligible to refer/prescribe/order/perform the service billed."

NOTE: The EOMB messages used in this section are new. Please update your files accordingly.

DMERC Processing Instructions

DMERCs will receive claims for immunosuppressive drugs for intestinal transplants. Suppliers must submit claims and the DMERC Information Form (DMERC 08.02) to the DMERC to process. Suppliers should submit the DMERC Information Form utilizing Block # 5/Item # 7 and write "intestinal transplant" in the blank space.

These changes are required in order to implement this National Coverage Decision.

The *effective date* for this PM is April 1, 2001.

The *implementation date* for this PM is April 1, 2001.

These instructions should be implemented within your current operating budget.

This PM may be discarded after April 1, 2002.

If you have any questions, contact Jennifer Doherty at 410-786-2462.