Program Memorandum Intermediaries/Carriers

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

Transmittal AB-02-040 **Date: MARCH 27, 2002**

This Program Memorandum re-issues Program Memorandum AB-01-58, Change Request 1629 dated April 12, 2001. The only change is the discard date, contact person and contact person and address under completed applications; all other material remains the same.

CHANGE REQUEST 1629

SUBJECT: Intestinal and Multi-Visceral Transplantation

This Program Memorandum (PM) revises AB-00-130, Change Request 1436, dated December 22, 2000, on intestinal transplants. The entire PM is being reprinted so that AB-00-130 is superseded by this transmittal and may be discarded.

Coverage

The coverage section of this PM is a national coverage decision (NCD) made under §1862(a)(1) of the Social Security Act (the Act). NCDs are binding on all Medicare carriers, Medicare fiscal intermediaries (FIs), 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 NCD issued under §1862(a)(1). (See 42 CFR 405.732 and 405.860.)

Effective 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. Intestinal failure prevents oral nutrition and may be associated with mortality and profound morbidity. Multi-visceral transplantation includes organs in the digestive system (i.e., stomach, duodenum, pancreas, liver, intestine and colon).

This procedure is covered only when performed for patients who have failed total parenteral nutrition (TPN) and only when performed in facilities 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 is a 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.

Aged patients and those with significant co-morbidities, such as cardiopulmonary disease and systemic malignancies, generally do not survive as long as younger and healthier patients receiving intestinal transplantation. Nonetheless, some older patients who are free from other contraindications have received the procedure and are progressing well. The NCD does not include specific exclusions from coverage for advanced age or co-morbidities. You should base claim determinations regarding medical necessity considering the clinical condition of the individual patients.

There is no national coverage policy in effect for services furnished prior to April 1, 2001. In the absence of a national policy, you have discretion to make individual determinations regarding coverage on claims for intestinal transplantation services.

Approved Transplant Facilities

Medicare will cover intestinal transplantation 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. If 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 and 120 days before the fiducial date must be considered "lost to follow-up" if the patient 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 of 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 an intestinal or multi-visceral 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, and
- Number of retransplants.

In certain limited cases, exceptions to the volume and survival criteria may be warranted if there is justification and the facility ensures our objectives of safety and efficacy. For example, we might grant an exception to a facility that fails to meet the volume or survival criteria by a small number due to extraordinary circumstances. Also, we might consider an exception for a facility that has only minimally missed the volume criteria but has displayed exemplary survival performance.

Completed applications should be sent to:

Paul Olenick
Director
Centers for Medicare Management
Division of Integrated Delivery Systems
C4-01-26
7500 Security Boulevard
Baltimore, Maryland 21244-1850

A facility that submits a completed application to CMS 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.

A list of approved transplant facilities can be currently found at the following Web site: http://www.hcfa.gov/medicare/tranplan.htm. In the very near future, this Web site will change to: http://www.cms.hhs.gov/medicare/tranplan.htm.

Payment

Medicare will not pay transplant facilities on a reasonable cost basis for organ acquisition for intestinal or multi-visceral transplants. The diagnosis related group (DRG) payment will be paid in full for hospital services related to this procedure.

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,
- 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, and
- 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 intestinal transplantation and liver transplantation are performed simultaneously, or if a multi-visceral transplantation includes a liver, the case would be assigned to DRG 480 (Liver Transplant). If a multi-visceral transplantation that does not include a liver is performed, the case would be assigned to either DRG 148 or DRG 149.

Physicians will be paid for the transplant procedure using the fee schedule for CPT code 44135, intestinal transplantation from cadaver donor. The national coverage policy is silent with regard to coverage of living donor intestinal transplantation. Therefore, contractors have the discretion to determine coverage on CPT code 44136, intestinal allotransplantation from living donor.

Presently, the Medicare regulations do not authorize payment of organ acquisition costs on a reasonable cost basis for organs other than heart, liver, lung, kidney or pancreas. Hospitals should report any acquisition charges they incur for intestine, stomach, or colon on the bill for the transplant procedure. However, no interim pass-through acquisition payment will be made for these costs, and hospitals should not include the costs in the preparation of the schedule D-6 of their cost report. Acquisition costs for liver and pancreas may be paid on a reasonable cost basis and reported on the cost report.

For acquisition of organs for intestinal and multi-visceral transplantation, physicians should report one of the following CPT codes for the donor enterectomy as appropriate: 44132, open with preparation and maintenance of allograft from cadaver donor, or 44133, partial from living donor. These codes will be paid under the physician fee schedule until such time as the regulatory definition of "organ" is revised, which would allow payment to be made on a reasonable cost basis.

FI Processing Instructions

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

A. ICD-9-CM procedure code 46.97 is effective for discharges on or after April 1, 2001. The Medicare Code Editor (MCE) lists this code as a non-covered procedure with 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.

We recommend that you automate the diagnostic review for intestinal transplants and suggest that the MCE interface is the best place to do this. Where the procedure code is identified by the MCE, check the provider number and effective date to determine if the provider is an approved intestinal transplant facility. Check the effective date for Medicare approval. Suspend the claim for clerical review of the operative report to determine that the beneficiary has at least one of the covered conditions listed in the bullets in the Coverage section above, when the diagnosis code is for a covered condition. This review is not part of your medical review workload. Instead you should complete this review as part of your claims processing workload.

B. Charges for ICD-9-CM procedure code 46.97 should be billed under revenue code 360, Operating Room Services.

C. Bill the procedure used to obtain the donor's organ on the same claim, using appropriate ICD-9-CM procedure codes.

D. The 11X bill type should be used when billing for intestinal transplants.

E. You should bill for immunosuppressive therapy as stated in PM AB-01-10, CR 1513 dated January 24, 2001.

Carrier Processing Instructions

In block 24D of Form CMS-1500 or equivalent portions of the electronic claims, physicians should enter one of the following CPT codes for intestinal transplantation:

- 44135 - Intestinal allotransplantation; from cadaver donor, or
- 44136 - Intestinal allotransplantation; from living.

These codes were previously 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 have been incorporated in the April quarterly MFSDB update.

Physicians excising donor intestines for transplantation should billed one of the following CPT codes as appropriate:

- 44132 - donor enterectomy from cadaver donor, or
- 44133 - donor enterectomy, partial, from living donor.

These services should be billed with the recipient's health insurance number. Code 44132 is currently listed in the MPFSDB with an "E" indicator for non-covered services. We will be revising this to a "R" indicator in the July 2001 update of the MPFSDB. Until then, use the reconsideration process to pay any claims erroneously denied due to the status indicator.

Medicare Summary Notice (MSN), Remittance Advice Messages and Notice of Utilization (NOU) Messages

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

For Intermediaries Only

If an intestinal transplant is billed by an unapproved facility after April 1, 2001, deny the claim and use MSN message 21.6, "This item or service is not covered when performed, referred, or ordered by this provider;" 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 NOU 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 NOU messages used in this section are new. 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 for processing. 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 NCD.

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

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

These instructions should be implemented within your current operating budget.

This PM may be discarded after April 1, 2003.

If you have questions concerning any of the following issues, contact the appropriate individual(s) for assistance:

Applications, Claude Mone, 410-786-5666
Claims Processing, Part A, Sarah Shirey, 410-786-0187
Claims Processing, Part B, Yvette Cousar, 410-786-2160
Coverage, Samantha Richardson, 410-786-6940
Medicare + Choice, Patricia Thomas, 410-786-6372