CHAPTER 4
SECTION 24.4

SMALL INTESTINE, COMBINED SMALL INTESTINE-LIVER, AND MULTIVISCERAL TRANSPLANTATION

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I. CPT[1] PROCEDURE CODES

44132, 44133, 44135, 44136

II. POLICY

A. Benefits are allowed for small intestine (SI), small intestine-liver (SI/L), and multivisceral transplantation.

NOTE: Multivisceral transplantation includes the en bloc graft of the stomach, pancreaticoduodenal complex, and small intestine. The liver is included for patients with irreversible liver disease. The kidney(s) is included for patients with renal failure.

1. A TRICARE Prime enrollee must have a referral from his/her Primary Care Manager (PCM) and an authorization from the contractor before obtaining transplant-related services. If network providers furnish transplant-related services without prior PCM referral and contractor authorization, penalties will be administered according to TRICARE network provider agreements. If Prime enrollees receive transplant-related services from non-network civilian providers without the required PCM referral and contractor authorization, Managed Care Support (MCS) contractors shall reimburse charges for the services on a Point of Service (POS) basis. Special cost-sharing requirements apply to POS claims.

2. For Standard and Extra patients residing in a MCS region, preauthorization authority is the responsibility of the MCS Medical Director or other designated utilization staff.

B. SI, SI/L, and multivisceral transplantation are covered for pediatric and adult patients who meet the following criteria:

1. Are suffering from 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.

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2. Have failed total parenteral nutrition (TPN). Indicators of failed TPN are liver failure, thrombosis, frequency of infection, and dehydration as demonstrated in the following clinical situations:

a. Impending or overt liver failure due to TPN induced liver injury.

b. Thrombosis of the major central venous channels, jugular, subclavian, and femoral veins.

c. Frequent line infection and sepsis.

d. Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN.

3. Pediatric patients have a parent or legal guardian who have a realistic understanding of the range of clinical outcomes that may be encountered for pediatric patients. Adult patients have a realistic understanding of the range of clinical outcomes that may be encountered.

4. Plans for long-term adherence to a disciplined medical regimen are feasible and realistic.

5. The transplant is performed at a TRICARE-certified SI transplantation center or TRICARE-certified pediatric consortium SI transplantation center or Medicare-certified SI transplantation center.

C. Services and supplies related to SI, SI/L, and multivisceral transplantation are covered for:

1. Evaluation of a potential candidate's suitability for SI, SI/L, and multivisceral transplantation whether or not the patient is ultimately accepted as a candidate for transplantation.

2. Pre- and post-transplantation inpatient hospital and outpatient services.

3. Surgical services and related pre- and postoperative services of the transplantation team.

4. Blood and blood products.

5. FDA approved immunosuppression drugs to include off-label uses when determined to be medically necessary for the treatment of the condition for which it is administered, according to accepted standards of medical practice.

6. Complications of the transplant procedure, including inpatient care, management of infection and rejection episodes.

7. Periodic evaluation and assessment of the successfully transplanted patient.

8. The donor acquisition team, including the costs of transportation to the location of the donor organ and transportation of the team and the donated organ to the location of the transplantation center.

9. The maintenance of the viability of the donor organ after all existing legal requirements for excision of the donor organ have been met.

10. Donor costs.

11. Hepatitis B and pneumococcal vaccines for patients undergoing transplantation.

12. DNA-HLA tissue typing in determining histocompatibility.

13. Transportation of the patient by air ambulance and the services of a certified life support attendant.

III. POLICY CONSIDERATIONS

A. For beneficiaries who fail to obtain preauthorization for SI, SI/L, or multivisceral transplantation, TRICARE benefits may be extended if the services or supplies otherwise would qualify for benefits but for the failure to obtain preauthorization. If preauthorization is not received, the appropriate preauthorizing authority is responsible for reviewing the claims to determine whether the beneficiary's condition meets the clinical criteria for the SI, SI/L, or multivisceral transplantation benefit. Charges for transplant and transplant-related services provided to TRICARE Prime enrollees who failed to obtain PCM referral and contractor authorization will be reimbursed only under POS rules.

B. Benefits will only be allowed for transplants performed at a TRICARE-certified SI or Medicare-certified SI transplantation center. Benefits are also allowed for transplants performed at a pediatric facility that is TRICARE-certified as an SI transplantation center on the basis that the center belongs to a pediatric consortium program whose combined experience and survival data meet the TRICARE criteria for certification. The contractor is the certifying authority for transplant centers within its region. Refer to Chapter 11, Section 7.1 for organ transplant center certification requirements.

C. Effective for admissions on or after October 1, 2001, SI, SI/L, and multivisceral transplantations shall be reimbursed under the assigned DRG based on the patient's diagnosis. Claims for admissions prior to October 1, 2001, shall be reimbursed based on billed charges.

D. Claims for transportation of the donor organ and transplantation team shall be adjudicated on the basis of billed charges, but not to exceed the transport service's published schedule of charges, and cost-shared on an inpatient basis. Scheduled or chartered transportation may be cost-shared.

E. Charges made by the donor hospital will be cost-shared on an inpatient basis and must be fully itemized and billed by the transplantation center in the name of the TRICARE patient.

F. Acquisition and donor costs are not considered to be components of the services covered under the DRG and will be reimbursed based on billed charges. These costs must be billed separately on a standard CMS 1450 UB-04 claim form in the name of the TRICARE patient.

G. When a properly preauthorized transplantation candidate is discharged less than 24 hours after admission because of extenuating circumstances, such as the available organ is found not suitable or other circumstances which prohibit the transplantation from being timely performed, all otherwise authorized services associated with the admission shall be cost-shared on an inpatient basis, since the expectation at admission was that the patient would remain more than 24 hours.

H. SI, SI/L, or multivisceral transplants performed on an emergency basis in an unauthorized SI facility may be cost shared only when the following conditions have been met:

1. The unauthorized center must consult with the nearest TRICARE-certified or Medicare-certified SI transplantation center regarding the transplantation case; and

2. It must be determined and documented by the transplant team physician(s) at the certified SI transplantation center that transfer of the patient (to the certified SI transplantation center) is not medically reasonable, even though transplantation is feasible and appropriate.

IV. EXCLUSIONS

A. SI, SI/L, or multivisceral transplantation is excluded when any of the following contraindications exist:

1. Ability to ingest oral nutrition.

2. Serious, uncontrolled psychiatric illness that would hinder compliance with any stage of the transplant process.

3. Significant cardiopulmonary insufficiency.

4. History or presence of aggressive and/or incurable malignancy.

5. Persistent abdominal or systemic infection.

6. Severe autoimmune disease.

7. Severe immunodeficiency disease.

8. Active alcohol or chemical dependency that interferes with compliance to strict treatment regimen.

9. Inability or unwillingness of the patient or legal guardian to give signed consent and to comply with regular follow-up requirements.

B. Also excluded are:

1. Expenses waived by the transplantation center (e.g., beneficiary/sponsor not financially liable).

2. Services and supplies not provided in accordance with applicable program criteria (i.e., part of a grant or research program; unproven procedure).

3. Administration of an unproven immunosuppressant drug that is not FDA approved or has not received approval as an appropriate “off-label” drug indication.

4. Pre- or post-transplantation nonmedical expenses (e.g., out-of-hospital living expenses, to include hotel, meals, privately owned vehicle for the beneficiary or family members).

5. Transportation of an organ donor.

V. EFFECTIVE DATES

A. January 1, 1996, for small intestine alone transplants for patients under the age of 16 and combined small intestine-liver transplants for pediatric and adult patients.

B. February 1, 1998, for multivisceral transplants.

C. October 4, 2000, for small intestine alone transplants for patients age 16 and older.

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