Clinical Policy: Intestinal and Multivisceral Transplant

Reference Number: CP.MP.58 Coding Implications
Date of Last Revision: 04/26 Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
This policy describes the medical necessity criteria for the review of intestinal and multivisceral transplant requests.

Policy/Criteria
It is the policy of health plans affiliated with Centene Corporation® that any of the intestinal and/or multivisceral transplantation procedures listed in section **I** are **medically necessary** for pediatric and adult members/enrollees to restore function in those with irreversible intestinal failure when meeting the criteria in section **II**:

I. Transplantation Procedures
- A. Isolated *intestinal transplantation is indicated* for members/enrollees who have only isolated intestinal failure and no liver disease.
- B. Combined *intestinal and liver transplant is indicated* in those with intestinal failure and end stage liver disease.
- C. *Multivisceral transplant is indicated* in those with intestinal failure and gastrointestinal motility disorders (e.g., chronic idiopathic intestinal pseudo-obstruction, visceral myopathy, visceral neuropathy, total intestinal aganglionosis, and some forms of mitochondrial respiratory chain disorders that affect gastrointestinal motor function), or extensive mesenteric thrombosis.

II. Procedure Criteria: Members/enrollees must have one of the indications in **A** and none of the contraindications in **B**:
- A. Indications, any one of the following:
  1. Failure of total parenteral nutrition (TPN) as indicated by one or more of the following:
     - a. Impending or overt liver failure due to TPN induced liver injury, indicated by elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopenia, gastro-esophageal varices, coagulopathy, stomal bleeding, or hepatic fibrosis/cirrhosis;
     - b. Thrombosis of two or more central veins, including jugular, subclavian, and femoral veins;
     - c. Two or more episodes of systemic sepsis due to line infection, per year, that requires hospitalization;
     - d. One episode of septic shock, acute respiratory distress syndrome, and/or line related fungemia;
     - e. Frequent episodes of severe dehydration despite IV fluid supplementation in addition to TPN;
     - f. Other complications leading to loss of vascular access;
  2. High risk of death if transplant is not performed;

3. Severe short bowel syndrome (gastrostomy, duodenostomy, and/or residual small bowel <10 cm in infants and <20 cm in adults);
4. Frequent hospitalizations for complications directly related to intestinal failure (e.g. opioid dependency due to pain management for intestinal failure, or pseudo-obstruction);
5. Significant hepatic cirrhosis associated with diffuse portomesenteric thrombosis;
6. Large desmoid tumors and other intra-abdominal tumors with reasonable expectation of posttransplant cure;
7. Congenital secretory diarrheal disorders.

B. Does not have ANY of the following contraindications:
1. Malignancy with high risk of recurrence or death related to cancer;
2. Other severe uncontrolled medical condition expected to limit survival after transplant;
3. Glomerular filtration rate < 40 mL/min/1.73m^2 unless being considered for multi-organ transplant;
4. HIV infection with detectable viral load unless all of the following are noted:
   a. CD4 cell count >200 cells/mm3;
   b. Absence of active AIDS-defining opportunistic infection or malignancy;
   c. Member/enrollee is currently on effective ART (antiretroviral therapy);
5. Septic shock;
6. Progressive cognitive impairment;
7. Stroke, acute coronary syndrome, or myocardial infarction (excluding demand ischemia) within 30 days;
8. Chronic infection with highly virulent and/or resistant microbes that are poorly controlled pre-transplant;
9. Inability to adhere to the regimen necessary to preserve the transplant, even with caregiver support;
10. Active substance use or dependence including current tobacco use, vaping, marijuana use (unless prescribed by a licensed practitioner), or IV drug use without convincing evidence of risk reduction behaviors (unless urgent transplant timelines are present, in which case a commitment to reducing behaviors is acceptable). Serial blood and urine testing may be used to verify abstinence from substances that are of concern.

III. Retransplantation Criteria: A second transplant may be considered **medically necessary** in members/enrollees when all of the above criteria for transplantation have been met in addition to the following:

A. Indications, one of the following:
1. Graft failure following a primary small bowel, small bowel-liver, or multivisceral transplantation due to technical complications or acute rejection;
2. Graft failure attributable to chronic rejection or recurrence of the primary disease.

Background

Intestinal transplantation is a therapeutic option for patients with intestinal failure. Intestinal failure is the loss of absorptive capacity of the small bowel secondary to severe primary gastrointestinal disease or surgically induced short bowel syndrome (SBS). The typical small intestine length

varies widely, ranging from three to eight meters. SBS occurs when there is approximately < 200 cm of small bowel remaining.

Multi-visceral transplantation includes the stomach, duodenum, pancreas, liver, small intestine, and large intestine. A modified version excludes the liver if the recipient's liver is normal. A kidney transplant is occasionally included if the recipient has end-stage renal disease.[1]

Common indications for intestinal transplantation in children include[1]:

- Small bowel atresia
- Gastroschisis
- Aganglionosis (Hirschsprung's disease)
- Infections such as necrotizing enterocolitis and mesenteric ischemia
- Intestinal pseudo-obstruction
- Microvillus inclusion disease
- Short gut syndrome
- Trauma
- Crohn's disease
- Midgut volvulus
- Massive resection secondary to tumor

Common indications for intestinal transplantation in adults include:

- Short gut syndrome
- Mesenteric ischemia following thrombosis, embolism, volvulus, or trauma
- Crohn's disease
- Small bowel tumors
- Small bowel secretory disorders
- Tumors of mesenteric root and retroperitoneum
- Trauma
- Volvulus
- Pseudo-obstruction
- Radiation enteritis

Guideline Recommendations

The British Society of Gastroenterology recommends patients with SBS, including irreversible intestinal failure, expected to die prematurely on TPN, should be referred for consideration of short bowel transplant where appropriate.[2]

The American Society of Transplantation issued a position paper on indications for pediatric intestinal transplantation. The AST recommends intestinal transplantation only for TPN-dependent children with intestinal failure who have or are likely to develop life-threatening TPN-related complications such as liver disease, recurrent sepsis, and threatened loss of central venous access. The AST stated that intestinal transplantation should not be performed solely because of continued dependence on TPN.[3]

Coding Implications

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CPT® Codes	Description
44135	Intestinal allotransplantation; from cadaver donor
44136	Intestinal allotransplantation; from living donor
44137	Removal of transplanted intestinal allograft, complete
44715	Backbench standard preparation of cadaver or living donor intestine allograft prior to transplantation, including mobilization and fashioning of the superior mesenteric artery and vein
44720	Backbench reconstruction of cadaver or living donor intestine allograft prior to transplantation; venous anastomosis, each
44721	Backbench reconstruction of cadaver or living donor intestine allograft prior to transplantation; arterial anastomosis, each
47135	Liver allotransplantation, orthotopic, partial or whole, from cadaver or living donor, any age
47143	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; without trisegment or lobe split
47144	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with trisegment split of whole liver graft into two partial liver grafts (i.e., left lateral segment [segments II and III] and right trisegment [segments I and IV through VIII])
47145	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with lobe split of whole liver graft into two partial liver grafts (i.e., left lobe [segments II, III, and IV] and right lobe [segments I and V through VIII])
47146	Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; venous anastomosis, each
47147	Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; arterial anastomosis, each
48554	Transplantation of pancreatic allograft

HCPCS Codes	Description
S2053	Transplantation of small intestine and liver allografts
S2054	Transplantation of multivisceral organs
S2055	Harvesting of donor multivisceral organs, with preparation and maintenance of allografts; from cadaver donor

HCPCS Codes	Description
S2152	Solid organs(s), complete or segmental, single organ or combination of organs; deceased or living donor(s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre- and posttransplant care in the global definition

Reviews, Revisions, and Approvals	Revision Date	Approval Date
Policy developed Specialist review (Surgical Transplant)	02/14	02/14
References reviewed and updated. All instances of "member" changed to "member/enrollee."	04/21	05/21
Replaced contraindications of "severely limited functional status with poor rehabilitation potential" and those regarding past or current nonadherence to medical therapy, and psychological condition associated with the inability to comply with medical therapy with "Inability to adhere to the regimen necessary to preserve the transplant, even with caregiver support." Changed "review date" in header to "Date of Last Revision" and "Date" in the revision log header to "Revision Date."	08/21	08/21
Edited contraindications: Replaced "non-hepatic malignancy…" with malignancy with high risk of recurrence or death…"; added GFR restriction, added HIV infection with detectable viral load, added stroke, acute coronary syndrome, or MI; added acute renal failure…; added septic shock; added progressive cognitive impairment; replaced "untreatable significant dysfunction of another major organ system…" with "Other severe uncontrolled medical condition expected to limit survival after transplant;" slightly reworded substance use contraindication; removed "acute medical instability…"; removed "uncorrectable bleeding diathesis."	02/22	02/22
Annual review. References reviewed, updated, and reformatted. Specialist reviewed.	05/22	05/22
Annual review. Updated verbiage in II.B.13. to "Active substance use or dependence including current tobacco use, vaping, marijuana use (unless prescribed by a licensed practitioner), or IV drug use without convincing evidence of risk reduction behaviors (unless urgent transplant timelines are present, in which case a commitment to reducing behaviors is acceptable)." References reviewed and updated.	05/23	05/23
Annual review. Expanded criteria under II.A.4. to include (e.g. opioid dependency, or pseudo-obstruction). Updated contraindication under II.B.3. Glomerular filtration rate < 40 mL/min/1.73m^2 to <30mL/min/1.73m^2. Expanded contraindication under II.B.4.a-II.B.4.c. to include CD4 cell count >200 cells/mm3; Absence of active AIDS-	05/24	05/24

Reviews, Revisions, and Approvals	Revision Date	Approval Date
defining opportunistic infection (unless treated efficaciously or prevented, can be included on the heart transplant waiting list) or malignancy; Member/enrollee is currently on effective ART (antiretroviral therapy). References reviewed and updated. Reviewed by external specialist.		
Annual review. Added clarifying language in Policy/Criteria section and in Criteria II.A.1. Updated Criteria II.A.1.a. to include TPN induced liver injury for clarity and changed "peristomal" to "stomal." Added hospitalization requirement for clarity in Criteria II.A.1.c. Separated Criteria II.A.1.c. into two criteria points. Clarifying language added to Criteria II.A.1.d. Updated "post-mesenteric" to "portomesenteric" in Criteria II.A.2.5. Updated GFR from < 30 mL/min/1.73m^2 to < 40 mL/min/1.73m^2 in Criteria II.B.3. Removed information about heart transplant waiting list from Criteria II.B.4.b. Removed Criteria II.B.5. for other GI diseases. Removed Criteria II.B.6. for acute liver failure or cirrhosis…Removed Criteria II.B.12. contraindication regarding absence of an adequate support system. Background updated with no impact on criteria. Reviewed codes and descriptions. References reviewed and updated. Reviewed by internal specialist.	04/25	04/25
Annual review. Added criteria under II.A.6-II.A.7. Large desmoid tumors…Added retransplantation criteria under III. Added CPT codes 44137, 48554. References reviewed and updated. Reviewed by internal and external specialist.	04/26	05/26

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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted

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Note: For Medicaid members/enrollees, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take

precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members/enrollees, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.

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