

# Clinical Policy: Intestinal and Multivisceral Transplant

Reference Number: CP.MP.58 Date of Last Revision: 05/24 Coding Implications Revision Log

# See <u>Important Reminder</u> 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<sup>®</sup> that any of the intestinal and/or multivisceral transplantation procedures listed in **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 of the following:
      - a. Impending or overt liver failure due to TPN, indicated by elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopenia, gastro-esophageal varices, coagulopathy, peristomal 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, or one episode of septic shock, acute respiratory distress syndrome, and/or line related fungemia;
      - d. Frequent episodes of dehydration despite IV fluid supplementation;
      - e. 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 post-mesenteric thrombosis;
- 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 < 30 mL/min/1.73m<sup>2</sup> 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 (unless treated efficaciously or prevented, can be included on the heart transplant waiting list) or malignancy;
    - c. Member/enrollee is currently on effective ART (antiretroviral therapy);
  - 5. Presence of other GI diseases;
  - 6. Acute liver failure, or cirrhosis with portal hypertension or synthetic dysfunction unless being considered for multi-organ transplant;
  - 7. Septic shock;
  - 8. Progressive cognitive impairment;
  - 9. Stroke, acute coronary syndrome, or myocardial infarction (excluding demand ischemia) within 30 days;
  - 10. Chronic infection with highly virulent and/or resistant microbes that are poorly controlled pre-transplant;
  - 11. Inability to adhere to the regimen necessary to preserve the transplant, even with caregiver support;
  - 12. Absence of an adequate or reliable social support system;
  - 13. 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.

#### 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 normal 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, and small 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.<sup>4</sup>

Common indications for intestinal transplantation in children include:



- 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.<sup>13</sup>

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.<sup>8</sup>

#### **Coding Implications**

This clinical policy references Current Procedural Terminology (CPT<sup>®</sup>). CPT<sup>®</sup> is a registered trademark of the American Medical Association. All CPT codes and descriptions are copyrighted 2023, American Medical Association. All rights reserved. CPT codes and CPT descriptions are from the current manuals and those included herein are not intended to be all-inclusive and are included for informational purposes only. Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

CPT <sup>®</sup> Codes	Description
44135	Intestinal allotransplantation; from cadaver donor
44136	Intestinal allotransplantation; from living donor
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



CPT®	Description
Codes	
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
47144	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

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
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 post-transplant 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.		06/18
References reviewed and updated. Added CPT 47135. Specialist review	06/18 06/19	06/19
Edited malignancy contraindication to not specify within two years, and	05/20	05/20
added exceptions early stage prostate cancer, cancer that has been completely resected, or that has been treated and poses acceptable future risk. Clarified in I.C that multivisceral transplants are indicated in gastrointestinal motility disorders, along with examples of such. Added ICD 10 Q43.1 References reviewed and updated.	03/20	00/20
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 <sup>2</sup> to <30mL/min/1.73m <sup>2</sup> . Expanded contraindication under II.B.4.a-II.B.4.c. to include CD4 cell count >200 cells/mm3; Absence of active AIDS-defining opportunistic infection (unless treated efficaciously or	05/24	05/24



Reviews, Revisions, and Approvals	Revision Date	Approval Date
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.		

#### References

- Buchman AL, Iyer K, Fryer J. Parenteral nutrition-associated liver disease and the role for isolated intestine and intestine/liver transplantation. *Hepatology*. 2006;43(1):9-19. doi:10.1002/hep.20997
- 2. National coverage determination: intestinal and multi-visceral transplantation (260.5). Centers for Medicare and Medicaid Services Web site. <u>https://www.cms.gov/medicare-coverage-database/search.aspx</u>. Published May 11, 2006. Accessed March 26, 2024.
- 3. Khan FA, Selvaggi G. Overview of intestinal and multivisceral transplantation. UpToDate. <u>www.uptodate.com</u>. Published August 17, 2022. Accessed March 26, 2024.
- Gilroy RK. Intestinal and multivisceral transplantation. Medscape. <u>https://reference.medscape.com/</u>. Published May 24, 2018 (updated November 1, 2023). Accessed March 26, 2024.
- 5. Andacoglu, OM. Intestinal transplantation. Medscape. <u>https://reference.medscape.com/</u>. Published January 18, 2017 (updated March 16, 2021). Accessed March 26, 2024.
- 6. Kato T, Tzakis AG, Selvaggi G, et al. Intestinal and multivisceral transplantation in children. *Ann Surg.* 2006;243(6):756-766. doi:10.1097/01.sla.0000219696.11261.13
- Kaufman SS, Atkinson JB, Bianchi A, et al. Indications for pediatric intestinal transplantation: a position paper of the American Society of Transplantation. *Pediatr Transplant*. 2001;5(2):80-87. doi:10.1034/j.1399-3046.2001.005002080.x
- 8. Kubal CA, Mangus RS, Tector AJ. Intestine and multivisceral transplantation: current status and future directions. *Curr Gastroenterol Rep*. 2015;17(1):427. doi:10.1007/s11894-014-0427-8
- Levitsky J, Doucette K; AST Infectious Diseases Community of Practice. Viral hepatitis in solid organ transplantation. *Am J Transplant*. 2013;13 Suppl 4:147-168. doi:10.1111/ajt.12108
- Lladó L, Fabregat J, Castellote J, et al. Management of portal vein thrombosis in liver transplantation: influence on morbidity and mortality. *Clin Transplant*. 2007;21(6):716-721. doi:10.1111/j.1399-0012.2007.00728.x
- Mangus RS, Tector AJ, Kubal CA, Fridell JA, Vianna RM. Multivisceral transplantation: expanding indications and improving outcomes. *J Gastrointest Surg.* 2013;17(1):179-p.187. doi:10.1007/s11605-012-2047-7
- 12. Nightingale J, Woodward JM; Small Bowel and Nutrition Committee of the British Society of Gastroenterology. Guidelines for management of patients with a short bowel. *Gut*. 2006;55 Suppl 4(Suppl 4):iv1-iv12. doi:10.1136/gut.2006.091108
- 13. Holzheimer RG, Mannick JA, eds. *Surgical Treatment: Evidence-Based and Problem-Oriented*. Munich: Zuckschwerdt; 2001.
- 14. Tzakis AG, Kato T, Levi DM, et al. 100 multivisceral transplants at a single center. *Ann Surg.* 2005;242(4):480-493. doi:10.1097/01.sla.0000183347.61361.7a



- 15. U.S. Department of Veteran Affairs. HIV. Laboratory Tests and HIV: Entire Lesson. https://www.hiv.va.gov/patient/diagnosis/labtests-single-page.asp. Accessed March 26, 2024.
- Vianna RM, Mangus RS, Kubal C, Fridell JA, Beduschi T, Tector AJ. Multivisceral transplantation for diffuse portomesenteric thrombosis. *Ann Surg.* 2012;255(6):1144-1150. doi:10.1097/SLA.0b013e31825429c0
- 17. Wu G, Cruz RJ. Liver inclusion improves outcomes of intestinal retransplantation in adults. [Corrected] [published correction appears in Transplantation. 2015 Aug;99(8):e118]. *Transplantation*. 2015;99(6):1265-1272. doi:10.1097/TP.00000000000488
- 18. Bharadwaj S, Tandon P, Gohel TD, et al. Current status of intestinal and multivisceral transplantation. *Gastroenterol Rep (Oxf)*. 2017;5(1):20-28. doi:10.1093/gastro/gow045
- Pironi L, Arends J, Bozzetti F, et al. ESPEN guidelines on chronic intestinal failure in adults [published correction appears in Clin Nutr. 2017 Apr;36(2):619]. *Clin Nutr.* 2016;35(2):247-307. doi:10.1016/j.clnu.2016.01.020
- 20. Hawksworth JS, Desai CS, Khan KM, et al. Visceral transplantation in patients with intestinal-failure associated liver disease: Evolving indications, graft selection, and outcomes. *Am J Transplant*. 2018;18(6):1312-1320. doi:10.1111/ajt.14715
- 21. Camilleri M. Chronic intestinal pseudo-obstruction: Etiology, clinical manifestations, and diagnosis. UpToDate. <u>www.uptodate.com</u>. Published February 17, 2022. Accessed March 26, 2024.
- 22. Roest S, Hesselink DA, Klimczak-Tomaniak D, et al. Incidence of end-stage renal disease after heart transplantation and effect of its treatment on survival. *ESC Heart Fail*. 2020;7(2):533-541. doi:10.1002/ehf2.12585
- 23. Harbell J, Terrault NA, Stock P. Solid organ transplants in HIV-infected patients. *Curr HIV/AIDS Rep.* 2013;10(3):217-225. doi:10.1007/s11904-013-0170-z

#### **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 standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

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This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members/enrollees. This clinical policy is not intended to recommend treatment for members/enrollees. Members/enrollees should consult with their treating physician in connection with diagnosis and treatment decisions.

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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 <u>prior to</u> applying the criteria set forth in this clinical policy. Refer to the CMS website at <u>http://www.cms.gov</u> for additional information.

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