

Molina Clinical Policy
Small Bowel Transplantation, Small Bowel and Liver
Transplantation and Multivisceral Transplantation: Policy No. 117

Last Approval: 10/13/2021

Next Review Due By: October 2022



DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. Policies are not a supplementation or recommendation for treatment; Providers are solely responsible for the diagnosis, treatment and clinical recommendations for the Member. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (e.g., will be paid for by Molina) for a particular Member. The Member's benefit plan determines coverage – each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their Providers will need to consult the Member's benefit plan to determine if there are any exclusion(s) or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a Member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid Members. CMS's Coverage Database can be found on the CMS website. The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this MCP and provide the directive for all Medicare members.¹ References included were accurate at the time of policy approval and publication.

OVERVIEW

Small bowel and multivisceral transplantation procedures are the surgical replacement of the small bowel alone or with other diseased organs with donor organs and can be a lifesaving procedure for patients with irreversible intestinal and/or multivisceral organ failure who can no longer be sustained on total parental nutrition (TPN). Patients can survive total intestinal failure with TPN therapy but frequently lose the ability to tolerate long term TPN therapy secondary to liver failure, thrombosis of central veins, infections from central lines and dehydration. The goals of the transplantation are the restoration of intestinal function and elimination or reduction in the need for TPN in patients with irreversible intestinal failure. Intestinal failure is defined as the loss of absorptive capacity of the small bowel so that macronutrient, water, electrolyte supplements, or a combination thereof are needed to maintain health or growth. Severe intestinal failure is when parenteral nutrition, fluid, or both are needed. Mild intestinal failure is when oral supplements or dietary modification suffice. Short bowel syndrome (SBS) is present when failure results from intestinal loss and failure to adapt by one month.⁴⁻⁶

Small bowel transplantation (SBT) involves either the whole small bowel or a bowel segment, and there are three different types: SBT alone, where the recipient receives part of or the entire small bowel; small bowel and liver transplant (SBLT) combined, which may be required if the patient with intestinal failure has irreversible end-stage liver disease; and multivisceral transplant (MVT), which may be required for patients with intestinal failure and disease or injury involving other gastrointestinal organs that may include the small bowel and liver with one or more of the following organs from the digestive system: stomach, pancreas, and/or colon. The majority of intestinal transplants are performed for short gut syndrome, a condition where the absorbing surface of the small intestine is inadequate due to extensive disease or surgical removal of a large portion of small intestine. Causes of short bowel syndrome include volvulus, atresias, necrotizing enterocolitis, Crohn's disease, gastroschisis, thrombosis of the superior mesenteric artery, desmoid tumors, and trauma. Patients with short gut syndrome are typically unable to obtain adequate nutrition from enteral feeding and become dependent upon total parenteral nutrition (TPN). Small bowel and concurrent liver transplants are performed for patients with short bowel syndrome and impending liver failure. Multivisceral transplantation is considered when patients have irreversible failure of three or more abdominal organs including the small bowel. The most common indications for multivisceral transplantation are total occlusion of the splanchnic circulation, extensive GI polyposis, hollow visceral myopathy or neuropathy, and some abdominal malignancies.⁴⁻⁶

The majority of SBT, SBLT and MVT procedures use cadaveric donors; however, a relatively small number of transplants have been performed in which the small bowel allograft is obtained from a healthy, living donor. At the current time, experience with living-donor segmental intestinal transplantation is limited. The potential advantages of living donor intestinal transplant include elimination of waiting time, better matching, the opportunity for preoperative donor and recipient optimization, elective surgery, minimal cold ischemia and expansion of the donor pool. However, this procedure will remain limited due to the risks associated for the donor.⁴⁻⁶

COVERAGE POLICY 1.7-16

All transplants require prior authorization from the Corporate Transplant Department. Solid organ transplant requests will be reviewed by the Corporate Senior Medical Director or qualified clinical designee. All other transplants will be reviewed by the Corporate Senior Medical Director or covering Medical Director. If the criteria are met using appropriate NCD and/or LCD guidelines, State regulations, and/or MCP policies the Corporate Senior Medical Director's designee can approve the requested transplant.

Members must meet United Network for Organ Sharing (UNOS) / Organ Procurement and Transplantation Network (OPTN) policies and guidelines for pre-transplantation evaluation and listing criteria and the diagnosis must be made by a specialist in the disease and/or a Transplant Surgeon.

Pre-Transplant Evaluation

Please see MCP-323 Pre-Transplant Evaluation for additional criteria and information.

Criteria for transplant evaluation include **ALL** of the following:

1. History and physical examination; **AND**
2. Psychosocial evaluation and clearance:
 - a. No behavioral health disorder by history or psychosocial issues:
 - If history of behavioral health disorder, no severe psychosis or personality disorder;
 - Mood/anxiety disorder must be excluded or treated;
 - Member has understanding of surgical risk and post procedure compliance and follow-up required.
 - AND**
 - b. Adequate family and social support.

AND

3. EKG; **AND**
4. Chest x-ray; **AND**
5. Cardiac clearance in the presence of any of the following:
 - a. Chronic smokers; **OR**
 - b. Members > 50 years age; **OR**
 - c. Those with a clinical or family history of heart disease or diabetes.

AND

6. Pulmonary clearance if evidence of pulmonary artery hypertension (PAH) or chronic pulmonary disease; **AND**

AND

7. Lab studies that include:
 - a. Complete blood count; kidney profile (blood urea nitrogen, creatinine); electrolytes; calcium; phosphorous; albumin; liver function tests; and coagulation profile (prothrombin time, and partial thromboplastin time);*
 - b. Serologic screening for: HIV; Epstein Barr virus (EBV); Hepatitis virus B (HBV); Hepatitis C (HCV); cytomegalovirus (CMV); RPR and/or FTA:*
 - If HIV positive **ALL** of the following must be met:
 - CD4 count >200 cells/mm-3 for >6 months; **AND**
 - HIV-1 RNA undetectable; **AND**
 - On stable anti-retroviral therapy >3 months; **AND**
 - No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm).

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- If abnormal serology need physician plan to address and/or treatment as indicated
- c. Urine drug screen (UDS) if Member is current or gives a history of past drug abuse.

AND

8. Colonoscopy (if indicated or if Member is age ≥ 50) with complete workup and treatment of abnormal results as indicated; an initial screening colonoscopy after initial negative screening requires a follow-up colonoscopy every 10 years).*

AND

9. Gynecological examination with Pap smear for women ages ≥ 21 to ≤ 65 years of age or if indicated (not indicated in women who have had a total abdominal hysterectomy [TAH] or a total vaginal hysterectomy [TVH]) within the last three years with complete workup and treatment of abnormal results as indicated.

Within the last 12 months:

1. Dental examination or oral exam showing good dentition and oral care or no abnormality on panorex or plan for treatment of problems pre- or post-transplant; **AND**
 2. Mammogram (if indicated or $>$ age 40) with complete workup and treatment of abnormal results as indicated;*
- AND**
3. PSA if history of prostate cancer or previously elevated PSA with complete workup and treatment of abnormal results as indicated.*

* Participating Centers of Excellence may waive these criteria.

Adult & Pediatric Criteria

Small Bowel Organ Transplantation from a deceased or a living donor is **considered medically necessary** in adult and pediatric members that have met **ALL** of the following criteria:

1. All pre-transplant criteria are met; **AND**
2. Documentation that all medical, pharmaceutical and surgical alternatives to transplant have been utilized including, but not limited to the following, if applicable:
 - a. nutritional management of dehydration and electrolyte imbalance with oral and enteral feeding; **AND**
 - b. parental nutrition when oral and enteral management fails; **AND**
 - c. surgical enteroplasty, strictureplasty, or serosal patching to improve intestinal functioning if intestinal obstruction that requires correction is present.

AND

3. Diagnosis of irreversible intestinal failure caused by **ANY** of the following conditions:
 - a. Dysmotility disorders (Hirschsprung's disease, megacystis microcolon, or intestinal pseudo obstruction); **OR**
 - b. Genetic intestinal disorders of the mucosal cells (microvillus inclusion disease, tufting enteropathy); **OR**
 - c. Disease with a high potential for malignant degeneration including:
 - Familial Adenomatous Polyposis; **OR**
 - Neoplastic tumors of the gastrointestinal tract and pancreas that are limited to the abdominal cavity (e.g., neuroendocrine tumors); **OR**
 - Radiation-Induced Bowel Injury.

OR

4. Diagnosis of severe short bowel syndrome (gastrostomy, duodenostomy, and/or residual small bowel <10 cm in infants and <20 cm in adults) caused by **ANY** of the following conditions:
 - a. Crohn's disease; **OR**

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- b. Gastroschisis; **OR**
- c. Gardner's syndrome/familial polyposis; **OR**
- d. Necrotizing enterocolitis (NEC); **OR**
- e. Autoimmune enteritis; **OR**
- f. Small bowel atresia; **OR**
- g. Superior mesenteric artery thrombosis; **OR**
- h. Superior mesenteric vein thrombosis; **OR**
- i. Trauma; **OR**
- j. Volvulus.

AND

- 5. Life-threatening complications attributable to intestinal failure and/or long-term TPN therapy that include **ANY** of the following:
 - a. Impending, progressive, but reversible, overt liver dysfunction (increased serum bilirubin and/or liver enzyme levels, splenomegaly, thrombocytopenia, gastroesophageal varices, coagulopathy, stomal bleeding, hepatic fibrosis or cirrhosis); **OR**
 - b. Multiple and prolonged hospitalizations to treat TPN-related complications; **OR**
 - c. Thrombosis of two or more major central venous channels (e.g., subclavian, jugular, or femoral veins) causing difficult venous access for TPN administration; **OR**
 - d. Repeated central line-related sepsis (defined as two episodes of systemic sepsis secondary to line infection per year, or one episode of line-related fungemia, septic shock, and/or acute respiratory distress syndrome); **OR**
 - e. Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN.

AND

- 6. The requesting transplant recipient should not have any of the following absolute contraindications:
 - a. Cardiac, pulmonary, and nervous system disease that cannot be corrected and is a prohibitive risk for surgery; **OR**
 - b. Malignant neoplasm with a high risk for reoccurrence, non-curable malignancy (excluding localized skin cancer); **OR**
 - c. Systemic and/or uncontrolled infection; **OR**
 - d. AIDS (CD4 count < 200cells/mm³); **OR**
 - e. Unwilling or unable to follow post-transplant regimen as documented by history of non-compliance and/or inability to follow through with medication adherence or office follow-up; **OR**
 - f. Chronic illness with one year or less life expectancy; **OR**
 - g. Limited, irreversible rehabilitation potential; **OR**
 - h. Active untreated substance abuse issues, requires documentation supporting free from addiction for minimally 6 months if previous addiction was present; **OR**
 - i. No adequate social/family support.

AND

- 7. The requesting transplant recipient should be evaluated carefully and potentially treated if any of the relative contraindications below are present. (Irreversible lung disease patients require consultation and clearance by a Pulmonologist prior to consideration of transplantation).
 - a. Smoking, documentation supporting free from smoking for 6 months; **OR**
 - b. Active peptic ulcer disease; **OR**
 - c. Active gastroesophageal reflux disease; **OR**
 - d. CVA with long term impairment that is not amendable to rehabilitation or a patient with CVA/transient ischemic attack within past 6 months; **OR**
 - e. Obesity with body mass index of >30 kg/m² may increase surgical risk; **OR**
 - f. Chronic liver disease such as Hepatitis B/C/D, or cirrhosis which increases the risk of death from sepsis and hepatic failure requires consultation by a gastroenterologist or hepatologist; **OR**
 - g. Gall bladder disease requires ultrasound of the gall bladder with treatment prior to transplantation.

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SMALL BOWEL AND LIVER SPECIFIC CRITERIA FOR ADULTS AND CHILDREN

Cadaver or living donor small bowel and liver transplantation **may be considered medically necessary** who meet above criteria and have irreversible end-stage liver disease evidenced by **ALL** of the following:

1. Irreversible intestinal failure; **AND**
2. TPN dependency established minimum of 2 years; **AND**
3. Evidence of impending liver failure, including **BOTH** of the following:
 - a. Prolonged prothrombin time (PT) >2 times the laboratory value (normal = 11 to 13.5 seconds); **AND**
 - b. Albumin decreasing to < 3.0 (normal range is 3.4 to 5.4 g/dL).

AND

4. Severe complications of TPN including at least **ONE** of the following:
 - a. Liver dysfunction; **OR**
 - b. Repeated infections; **OR**
 - c. Thrombosis; **OR**
 - d. Venous access difficulty with TPN.

CADAVER MULTIVISCERAL SPECIFIC CRITERIA FOR ADULTS AND CHILDREN

1. Cadaver Multivisceral transplantation (includes small bowel and liver; can include the stomach, duodenum, jejunum, ileum, pancreas, or colon) **may be considered medically necessary** who have met the above criteria and require 1 or more abdominal visceral organs to be transplanted due to concomitant organ failure or anatomical abnormalities that preclude a small bowel/liver transplant and **ANY** of the following:
 - a. Thromboses of the celiac axis, and the superior mesenteric artery; **OR**
 - b. Pseudo-obstruction, localized tumors or other causes of vascular occlusion affecting the arterial blood supply to stomach, liver, small bowel, and pancreas; **OR**
 - c. Massive gastrointestinal polyposis; **OR**
 - d. Generalized hollow visceral myopathy or neuropathy; **OR**
 - e. Pancreatic failure.

RETRANSPLANTATION

1. A second transplant **may be considered medically necessary** when **ALL** of the above requirements for transplantation have been met **AND** when **ONE** of the following conditions are present:
 - a. Graft failure of an initial small bowel, small bowel/liver, or multi-visceral transplant, due to either technical reasons or acute rejection; **OR**
 - b. chronic rejection or recurrent disease.
2. Requests for a third or subsequent intestinal transplant **are considered not medically necessary**.

Continuation of Therapy

When extension of a previously approved transplant authorization is requested, review using updated clinical information is appropriate.

1. If Molina Healthcare has authorized prior requests for transplantation **ALL** of the following information is required for medical review:
 - a. Presence of no absolute contraindication as listed above; **AND**
 - b. History and physical within the last 12 months; **AND**
 - c. Kidney profile within the last 12 months; **AND**

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- d. Cardiac update if history of cardiac disease within two years (≥ 50 years of age); **AND**
 - e. Psychosocial evaluation or update within the last 12 months; **AND**
 - f. Per initial and updated history and physical, any other clinically indicated tests and/or scans as determined by transplant center physician or Molina Medical Director.
2. If authorized prior requests for transplantation were obtained from another insurer, **ALL** of the following information is required for medical review:
- a. Authorization letter/documentation from previous insurer; **AND**
 - b. Presence of no absolute contraindication as listed above; **AND**
 - c. History and physical within the last 12 months; **AND**
 - d. Cardiac update if history of cardiac disease within two years (≥ 50 years of age); **AND**
 - e. Psychosocial evaluation or update within the last 12 months; **AND**
 - f. Per initial and updated history and physical, any other clinically indicated tests and/or scans as determined by transplant center physician or Molina Medical Director.

Limitations and Exclusions

1. Intestinal transplantation in members who can tolerate TPN is considered not medically necessary.
2. Xenotransplantation: small bowel, small bowel-liver or multivisceral xenotransplantation (e.g., porcine xenografts) is considered experimental, investigational and unproven for any indication.

DOCUMENTATION REQUIREMENTS. Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

SUMMARY OF MEDICAL EVIDENCE ^{2,3,7-16}

The published medical evidence and outcomes for small bowel transplantation in children and adults in the United States consists of registry data obtained from transplant centers that perform adult and pediatric transplantation and is available from the United Network for Organ Sharing (UNOS) database. Registry data demonstrates graft survival rates and outcomes comparable to other organ transplants.

SUPPLEMENTAL INFORMATION

None.

CODING & BILLING INFORMATION

CPT Codes

CPT	Description
44132	Donor enterectomy (including cold preservation), open; from cadaver donor
44133	Donor enterectomy (including cold preservation), open; partial, from living donor
44135	Intestinal allotransplantation; from cadaver donor
44136	Intestinal allotransplantation; from living donor
44137	Removal of transplanted intestinal allograft, complete
47133	Donor hepatectomy (including cold preservation), from cadaver donor
47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age
47143-47147	Backbench procedure code range

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48550	Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation
48554	Transplantation of pancreatic allograft

HCPCS Codes

HCPCS	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

CODING DISCLAIMER. Codes listed in this policy are for reference purposes only and may not be all-inclusive. Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement. Listing of a service or device code in this policy does not guarantee coverage. Coverage is determined by the benefit document. Molina adheres to Current Procedural Terminology (CPT®), a registered trademark of the American Medical Association (AMA). All CPT codes and descriptions are copyrighted by the AMA; this information is included for informational purposes only. Providers and facilities are expected to utilize industry standard coding practices for all submissions. When improper billing and coding is not followed, Molina has the right to reject/deny the claim and recover claim payment(s). Due to changing industry practices, Molina reserves the right to revise this policy as needed.

APPROVAL HISTORY

10/13/2021	Policy reviewed, no changes to criteria, updated references.
9/16/2020	Policy reviewed, updated diagnoses for small bowel transplant (alone) and for small bowel and liver transplant (simultaneous). Updated references and coding (deleted CPT 47136; added CPT codes 47143-47147).
12/14/2016, 6/22/2017, 9/13/2018, 9/18/2019	Policy reviewed, no changes.
5/26/2015	Policy reviewed, updated with new pretransplant criteria. Medical Evidence section condensed; added 1 new indication to the multivisceral criteria for individuals with pancreatic failure.
8/30/2012	New policy.

REFERENCES

Government Agency

- Centers for Medicare and Medicaid Services (CMS). Medicare coverage database: National coverage determination (NCD) for intestinal and multi-visceral transplantation (260.5). <http://www.cms.gov/mcd/search.asp>. Effective June 26, 2006. Accessed August 15, 2021.
- Organ Procurement and Transplantation Network (OPTN). Policy 7: Allocation of intestine. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf. Effective July 27, 2021. Accessed August 15, 2021.
- Organ Procurement and Transplantation Network (OPTN). Policy 9: Allocation of liver-intestine. https://optn.transplant.hrsa.gov/media/1200/optn_policies.pdf. Effective July 27, 2021. Accessed August 15, 2021.

Peer Reviewed Publications

- Bharadwaj S, Tandon P, Gohel TD, et al. Current status of intestinal and multivisceral transplantation. *Gastroenterol Rep (Oxf)*. 2017 Feb;5(1):20-28. doi: 10.1093/gastro/gow045. Accessed August 15, 2021.
- Pironi L, Arends J, Bozzetti F, et al. ESPEN guidelines on chronic intestinal failure in adults. *Clin Nutr*. 2016 Apr;35(2):247-307. doi: 10.1016/j.clnu.2016.01.020. Accessed August 15, 2021.
- Hawthornthwaite JS, Desai CS, Khan KM, et al. Visceral transplantation in patients with intestine-failure associated liver disease: evolving indications, graft selection, and outcomes. *Am J Transplant*. 2018 Jun;18(6):1312-1320. doi: 10.1111/ajt.14715. Accessed Aug. 15, 2021.

National and Specialty Organizations

- American Gastroenterological Association (AGA). American Gastroenterological Association medical position statement: Short Bowel Syndrome and Intestinal Transplantation. *Gastroenterology*. 2003. 124(4); P1105-1110. doi: <https://doi.org/10.1053/gast.2003.50139>. Accessed August 15, 2021.
- Kaufman SS, Atkinson JB, Bianchi A, Goulet OJ, Grant D, Langanas AN, et al. Indications for pediatric intestinal transplantation: a position paper of the American Society of Transplantation. *Pediatr Transplant*. 2001 Apr;5(2):80-7. doi: 10.1034/j.1399-3046.2001.005002080.x. Accessed August 15, 2021.
- Ontario Medical Advisory Secretariat. Small bowel transplant: an evidence-based analysis. *Ont Health Technol Assess Ser*. 2003; 3(1): 1-72. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3387750/>. Accessed August 15, 2021.

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10. Steinman TI, Becker BN, et al., Clinical Practice Committee, American Society of Transplantation. Guidelines for the referral and management of patients eligible for solid organ transplantation. Transplantation. 2001 May 15;71(9):1189-204. doi: 10.1097/00007890-200105150-00001. Accessed August 15, 2021.

Other Peer Reviewed Resources

11. AMR Peer Review. Policy reviewed on August 2, 2012 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the areas of Pediatrics and Pediatric Gastroenterology.
12. AMR Peer Review. Policy reviewed on July 8, 2020 by an Advanced Medical Reviews (AMR) practicing, board-certified physician in the areas of Internal Medicine and Gastroenterology.
13. Kaplan MM. Approach to the Patient with Abnormal Liver Function Tests. <http://www.uptodate.com>. Updated June 10, 2020. Accessed August 15, 2021. Registration and login required.
14. Khan FA et al. Overview of intestinal and multivisceral transplantation. <http://www.uptodate.com>. Updated September 16, 2020. Accessed August 15, 2021. Registration and login required.
15. Stamm DA, Duggan C. Management of short bowel syndrome in children. <http://www.uptodate.com>. Updated May 13, 2021. Accessed August 15, 2021. Registration and login required.
16. Camilleri M. Chronic intestinal pseudo-obstruction. <http://www.uptodate.com>. Updated February 4, 2021. Accessed August 15, 2021. Registration and login required.

APPENDIX

Reserved for State specific information (to be provided by the individual States, not Corporate). Information includes, but is not limited to, State contract language, Medicaid criteria and other mandated criteria.