

Subject: Small Bowel Transplantation, Small Bowel and Liver Transplantation and Multivisceral Transplantation		Original Effective Date: 8/30/12
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DISCLAIMER

This Molina Clinical Policy (MCP) is intended to facilitate the Utilization Management process. 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 (i.e., 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 Molina Clinical Policy (MCP) document and provide the directive for all Medicare members.¹

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DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

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.

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.

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.

RECOMMENDATION 1 18-25 27-29

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 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 UNOS guidelines for transplantation and the diagnosis must be made by a *Specialist in the Disease* and or 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:

- History and physical examination
- Psychosocial evaluation and clearance:
 - 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 understands that surgical risk and post procedure compliance and follow-up required
 - Adequate family and social support
- EKG
- Chest x-ray
- Cardiac clearance in the presence of any of the following:
 - chronic smokers
 - > 50 years age
 - those with a clinical or family history of heart disease or diabetes
- Pulmonary clearance if evidence of pulmonary artery hypertension (PAH) or chronic pulmonary disease
- Lab studies:
 - *Complete blood count, Kidney profile (blood urea nitrogen, creatinine), electrolytes, calcium, phosphorous, albumin, liver function tests, Coagulation profile (prothrombin time, and partial thromboplastin time)
 - *Serologic screening for HIV, Epstein Barr virus (EBV), Hepatitis virus B (HBV), and Hepatitis C(HCV), cytomegalovirus (CMV), RPR and/or FTA:
 - If HIV positive all of the following are met:
 - CD4 count >200 cells/mm-3 for >6 months
 - HIV-1 RNA undetectable
 - On stable anti-retroviral therapy >3 months
 - No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioides mycosis, resistant fungal infections, Kaposi's sarcoma, or other neoplasm)
 - If abnormal serology need physician plan to address and/or treatment as indicated
 - UDS (urine drug screen) if patient is current or gives a history of past drug abuse
- *Colonoscopy (if indicated or if patient is 50 ≥ older should have had an initial screening colonoscopy, after initial negative screening requires follow up colonoscopy every ten years) with complete workup and treatment of abnormal results as indicated
- *GYN examination with Pap smear for women ≥ 21 to ≤ 65 years of age or indicated (not indicated in women who have had a TAH or TVH) with in the last three year with complete workup and treatment of abnormal results as indicated

Within the last 12 months:

- 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
- *Mammogram (if indicated or > age 40) with complete workup and treatment of abnormal results as indicated

- *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: [ALL]

- All pre-transplant criteria are met; and
- Documentation that all medical, pharmaceutical and surgical alternatives to transplant have been utilized including but not limited to the following if applicable:
 - nutritional management of dehydration and electrolyte imbalance with oral and enteral feeding; and
 - parental nutrition when oral and enteral management fails; and
 - surgical enteroplasty, strictureplasty, or serosal patching to improve intestinal functioning if intestinal obstruction that requires correction is present; and
- Diagnosis of irreversible intestinal failure caused by any of the following conditions:[ONE]
 - Dysmotility disorders: [ONE]
 - Hirschsprung's disease
 - megacystis microcolon,
 - intestinal pseudo obstruction)
 - Genetic intestinal disorders of the mucosal cells: [ONE]
 - microvillus inclusion disease
 - tufting enteropathy
 - Disease with a high potential for malignant degeneration: [ONE]
 - familial adenomatous polyposis)
 - neoplastic tumors of the gastrointestinal tract and pancreas that are limited to the abdominal cavity (e.g., neuroendocrine tumors)
 - radiation-induced bowel injury

OR

- 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:[ONE]
 - Crohn's disease
 - Gastroschisis
 - Gardner's syndrome/familial polyposis
 - Necrotizing enterocolitis (NEC)
 - Autoimmune enteritis
 - Small bowel atresia
 - Superior mesenteric artery thrombosis
 - Superior mesenteric vein thrombosis
 - Trauma

- Volvulus

AND

- Life-threatening complications attributable to intestinal failure and/or long-term TPN therapy that include **any** of the following:
 - 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)
 - Multiple and prolonged hospitalizations to treat TPN-related complications
 - Thrombosis of two or more major central venous channels (e.g., subclavian, jugular, or femoral veins) causing difficult venous access for TPN administration
 - 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)
 - Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN

AND

The requesting transplant recipient should not have any of the following **absolute contraindications**:

- Cardiac, pulmonary, and nervous system disease that cannot be corrected and is a prohibitive risk for surgery
- Malignant neoplasm with a high risk for reoccurrence, non-curable malignancy (excluding localized skin cancer)
- Systemic and/or uncontrolled infection
- AIDS (CD4 count < 200cells/mm³)
- Unwilling or unable to follow post-transplant regimen
 - Documented history of non-compliance
 - Inability to follow through with medication adherence or office follow-up
- Chronic illness with one year or less life expectancy
- Limited, irreversible rehabilitation potential
- Active untreated substance abuse issues, requires documentation supporting free from addiction for minimally 6 months if previous addiction was present
- No adequate social/family support

The requesting transplant recipient should be evaluated carefully and potentially treated if the following **relative contraindications** are present:

- Irreversible lung disease patients require consultation and clearance by a Pulmonologist prior to consideration of transplantation, this includes the following:
 - Smoking, documentation supporting free from smoking for 6 months
 - Active peptic ulcer disease
 - Active gastroesophageal reflux disease
 - CVA with long term impairment that is not amendable to rehabilitation or a patient with CVA/transient ischemic attack within past 6 months

- Obesity with body mass index of $>30 \text{ kg/m}^2$ may increase surgical risk
- 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
- Gall bladder disease requires ultrasound of the gall bladder with treatment prior to transplantation

SMALL BOWEL AND LIVER SPECIFIC CRITERIA

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

- Irreversible intestinal failure; and
- TPN dependency established minimum of 2 years; and
- Evidence of impending liver failure, including both of the following:
 - Prolonged prothrombin time (PT) > 2 times the laboratory value (normal range is 11 to 13.5 seconds; and
 - Albumin decreasing to < 3.0 (normal range is 3.4 to 5.4 g/dL)
- Severe complications of TPN including at least one of the following: [ONE]
 - Liver dysfunction; or
 - Repeated infections; or
 - Thrombosis; or
 - Venous access difficulty with TPN

CADAVER MULTIVISCERAL SPECIFIC CRITERIA

1. Cadaver **Multivisceral** transplantation (includes the small bowel and liver and can include the stomach, duodenum, jejunum, ileum, pancreas, or colon) may be considered medically necessary in adults and children 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 conditions: [ONE]
 - Thromboses of the celiac axis, and the superior mesenteric artery; or
 - Pseudo-obstruction, localized tumors or other causes of vascular occlusion affecting the arterial blood supply to stomach, liver, small bowel, and pancreas; or
 - Massive gastrointestinal polyposis; or
 - Generalized hollow visceral myopathy or neuropathy; or
 - Pancreatic failure

RETRANSPLANTATION:

2. A second transplant may be considered medically necessary when all of the other requirements for transplantation outlined above have been met AND one of the following conditions are present: [ONE]
 - graft failure of an initial small bowel, small bowel/liver, or multi-visceral transplant, due to either technical reasons or acute rejection; or
 - chronic rejection or recurrent disease

3. 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.

- ❑ If Molina Healthcare has authorized prior requests for transplantation, the following information is required for medical review: [ALL]
 - Presence of no absolute contraindication as listed above;
 - History and physical within the last 12 months;
 - Kidney profile within the last 12 months;
 - Cardiac update if history of cardiac disease within two years (≥ 50 years of age);
 - Psychosocial evaluation or update within the last 12 months;
 - 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.

- ❑ If authorized prior requests for transplantation were obtained from another insurer, the following information is required for medical review: [ALL]
 - Authorization letter/documentation from previous insurer;
 - Presence of no absolute contraindication as listed above;
 - History and physical within the last 12 months;
 - Cardiac update if history of cardiac disease within two years (≥ 50 years of age);
 - Psychosocial evaluation or update within the last 12 months;
 - 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

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

SUMMARY OF MEDICAL EVIDENCE⁴⁻¹⁷

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.

CODING INFORMATION THE CODES LISTED IN THIS POLICY ARE FOR REFERENCE PURPOSES ONLY. LISTING OF A SERVICE OR DEVICE CODE IN THIS POLICY DOES NOT IMPLY THAT THE SERVICE DESCRIBED BY THIS CODE IS COVERED OR NON-COVERED. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

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

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 organ(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

ICD-10	Description: [For dates of service on or after 10/01/2015]
D12.6	Polyposis, familial
D237.1-D237.9	Neoplasm of uncertain behavior of stomach, intestines, colon and rectum
D48.1	Desmoid abdominal tumor
K50.00	Crohn's disease of small intestine without complications
K50.10	Crohn's disease
K50.80	Crohn's disease of both small and large intestine without complications
K55.0	Acute vascular disorders of intestine
K55.1	Chronic vascular disorders of intestine
K52.0	Gastroenteritis and colitis due to radiation
K56.2	Volvulus
K56.5	Intestinal adhesions [bands] with obstruction (postprocedural) (postinfection)
K56.69	Other intestinal obstruction
K58.9	Irritable bowel syndrome without diarrhea
K70-K77	Diseases of the liver
K91.92	Postsurgical malabsorption, not elsewhere classified

K90.9	Intestinal malabsorption, unspecified
Q41- Q41.9	Congenital absence, atresia and stenosis of small intestine
Q43.1	Hirschsprung's disease or megacolon
Q43.8	Other specified congenital malformations of intestine
Q79.3	Gastroschisis
Q87.89	Other specified congenital malformation syndromes, not elsewhere classified
P77.9	Necrotizing enterocolitis in newborn, unspecified
R19.7	Diarrhea, unspecified
S36.4- S36.59	Injury of small intestine and colon
D12.6	Polyposis, familial
D237.1- D237.9	Neoplasm of uncertain behavior of stomach, intestines, colon and rectum

RESOURCE REFERENCES

Government Agency

- Centers for Medicare & Medicaid Services. NCD for Intestinal and Multi-Visceral Transplantation (260.5). 2006. Accessed at: <http://www.cms.gov/medicare-coverage-database/>
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Other Resources

27. Advanced Medical Review (AMR):
 - Policy reviewed by MD board certified in Pediatrics, Pediatric Gastroenterology. August 2, 2012.
 - Policy reviewed by MD board certified in Internal Medicine, Gastroenterology. July 8th, 2020.
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Review/Revision History:

8/30/12: New Policy

5/26/15: This policy was reviewed and updated with new pretransplant criteria. The medical evidence section was condensed. One new indication was added to the multivisceral criteria for individuals with pancreatic failure.

12/14/16, 6/22/17, 9/13/18 & 9/18/19: Policy reviewed, no changes

9/16/2020: Policy reviewed, updated the diagnoses for small bowel transplant (alone), updated criteria for small bowel and liver transplant (simultaneous), updated references and coding table:

- Deleted CPT code 47136: Liver allotransplantation; heterotopic, partial or whole, from cadaver or living donor, any age
- Added CPT codes 47143-47147: Backbench procedure code range