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

Last Approval: 10/09/2024
Next Review Due By: October 2025

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. References included were accurate at the time of policy approval and publication.

OVERVIEW

Intestinal failure is defined as any gastrointestinal dysfunction that results in the inability of the body to meet nutritional demands, and therefore requiring exogenous nutrition and hydration ranging from oral supplements in mild intestinal failure to total parental nutrition therapy (TPN) in severe intestinal failure to sustain the life and health of the patient. Patients can survive severe intestinal failure with TPN therapy but can eventually lose the ability to tolerate long term TPN administration secondary to liver failure, central veins thromboses, central line infections, and/or chronic dehydration. There are multiple disease processes that can lead to intestinal failure including but not limited to volvulus, atresias, necrotizing enterocolitis, Crohn's disease, gastroschisis, thrombosis of the superior mesenteric artery, desmoid tumors, gastrointestinal malignancies, total occlusion of the splanchnic circulation, extensive GI polyposis, hollow visceral myopathy or neuropathy, and trauma.

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 TPN. The goals of the transplantation are the restoration of intestinal function and elimination or reduction in the need for TPN therapy in patients with irreversible intestinal failure. There are three types of transplantation: small bowel transplantation (SBT) alone where the recipient receives part of or the entire small bowel; small bowel and liver transplant (SBLT) for patients with intestinal failure and irreversible end-stage liver disease; and multivisceral transplant (MVT) for patients with irreversible failure of three or more abdominal organs including the small bowel.

The majority of SBT, SBLT, and MVT procedures use cadaveric donors; however, a relatively small number of transplants have been performed using small bowel allograft obtained from a healthy, living donor. 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. This procedure and associate research, however, will remain limited due to the risks associated for the donor.

COVERAGE POLICY

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.

Office visits with participating Providers do NOT require prior authorization. Providers should see the Member in office visits as soon as possible and without delay. Failure to see the Member in office visits may be considered a serious quality of care concern.

Please see *MCP-459 Pre-Transplant and Transplant Evaluation* for pre-transplant criteria and transplant

evaluation criteria that must be met prior to solid organ transplant.

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

1. All transplant evaluation criteria are met

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
   b. Parental nutrition when oral and enteral management fails
   c. Surgical enteroplasty, strictureplasty, or serosal patching to improve intestinal functioning if intestinal obstruction that requires correction is present

3. Diagnosis of irreversible intestinal failure **OR** severe short bowel syndrome (gastrostomy, duodenostomy, and/or residual small bowel <10 cm in infants and <20 cm in adults) **OR** abdominal malignancy

4. 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)
   b. Multiple and prolonged hospitalizations to treat TPN-related complications
   c. Thrombosis of two or more major central venous channels (e.g., subclavian, jugular, or femoral veins) causing difficult venous access for TPN administration
   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)
   e. Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN

Small Bowel and Liver Specific Criteria
Cadaver or living donor small bowel and liver transplantation **may be considered medically necessary** in adult and pediatric patients who meet above criteria and have irreversible end-stage liver disease as evidenced by **ALL** the following:

1. Irreversible intestinal failure

2. TPN dependency established minimum of 2 years

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)
   b. Albumin decreasing to < 3.0 (normal range is 3.4 to 5.4 g/dL)

4. Severe complications of TPN including at least **ONE** of the following:
   a. Liver dysfunction
   b. Repeated infections
   c. Thrombosis
   d. Volatile, poor, or inability to obtain proper venous access

Cadaver Multivisceral Specific Criteria
Cadaver Multivisceral transplantation (includes small bowel and liver; can include the stomach, duodenum, jejunum, ileum, pancreas, or colon) **may be considered medically necessary** in adult and pediatric patients 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, in addition to **ANY** of the following:

1. Thromboses of the celiac axis, and the superior mesenteric artery

2. Pseudo-obstruction, localized tumors or other causes of vascular occlusion affecting the arterial blood supply to stomach, liver, small bowel, and pancreas

3. Massive gastrointestinal polyposis

4. Generalized hollow visceral myopathy or neuropathy

5. Pancreatic failure

Re-transplantation Criteria

A second transplant **may be considered medically necessary** in adult and pediatric patients when **ALL** the above requirements for transplantation have been met **AND** when **ONE** of the following conditions are present:

1. Graft failure of an initial small bowel, small bowel/liver, or multi-visceral transplant, due to either technical reasons or acute rejection

2. Chronic rejection or recurrent disease

Limitations and Exclusions

1. Requests for a third or subsequent intestinal transplant are **NOT considered medically necessary**

2. Intestinal transplantation in members who can tolerate TPN is **NOT considered medically necessary**

3. 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

Non-Randomized Studies, Retrospective Reviews, and Other Evidence

Ceulemans et al. (2023) conducted a propensity – match cohort analysis of the intestinal transplant registry to compare outcomes of living donor transplants versus deceased donor transplants. The primary outcomes were to compare acute rejection, and 1-/5-year patient/graft survival. Between January 1987 and April 2019, according to the Intestinal Transplant Registry, 4156 intestinal transplants (ITx) were performed, of which only 76 (1.8%) were living donor. The living donor transplants (5 combined liver-ITx, 7 ITx-colon, and 64 isolated ITx) were matched with 186 deceased donor intestinal transplants for recipient age/gender, weight, region, intestinal failure cause, re-transplant, pre-transplant status, ABO compatibility, immunosuppression, and transplant date. The results revealed 1-/5-year patient-survival for living donor and deceased donor was 74.2/49.8% versus 80.3/48.1%, respectively (P=0.826). One-/5-year graft survival was 60.3/40.6% versus 69.2/36.1%, respectively (P=0.733). Acute rejection was diagnosed in 47% of living donor versus 51% of deceased donor (P=0.723). In conclusion, there is no difference in the outcomes of living donor versus deceased donor.

Canovai et al. (2023) performed a single center retrospective case review from 2007 -2022. One hundred and thirty-four intestinal transplants in one hundred and twenty-seven patients were conducted at the institution, of those transplants 16 of the cases were for the indication of desmoid disease. The 16 transplants were as follows: 7 modified multivisceral transplants, 6 isolated intestinal transplants, and 3 liver-small bowel transplants. The median follow up was 50 months, and 11 out of 16 patients are alive (68%) without GI recurrence with no patients dying from desmoid recurrence. The review highlighted the complex issues specific to this population which include loss of abdominal domain (7/16), retroperitoneal involvement (6/16), pouch related issues (2/16) and the need for a

gastrectomy/duodenectomy due to dysplastic disease (7/16); despite which the authors conclude intestinal transplant is a viable treatment option in selected patients with desmoid disease.

Hind (2021) analyzed data from the intestinal transplant registry, recent publications, and in field reviews to compile mortality, morbidity, complications, nutritional, and psychosocial outcomes post intestinal transplantation. According to the intestinal transplant registered data the average long-term survival is 41% ten years post transplantation, with high volume experienced centers increasing their survival rates to 60-70% ten years post transplantation. Most recipients achieve enteral autonomy with an unrestricted diet, and quality of life improves post transplantation. Chronic rejection remains the largest obstacle for long term graft survival, however the medical fields understanding of humoral immunity is increasing and thus making progress towards reducing chronic rejection.

National and Specialty Organizations

The **American Gastroenterological Association (AGA)** (2022) published their recommendations in the Clinical Practice Update on Management of Short Bowel Syndrome. Topics include medical therapy, dietary management, parenteral nutrition, medical absorption, the role of surgery, intestinal transplantation, complications of long-term TPN that may necessitate intestinal transplantation, and current management strategies for patients. Referral for Intestinal Transplantation is recommended for patients with intestinal failure and onset of parenteral nutrition failure indicated by the occurrence of progressive intestinal failure–associated liver disease or catheter-related complications. The document highlights that presently around 50% of patients referred for intestinal failure are requiring simultaneous liver transplant, indicating late referral for intestinal failure. The document highlights best candidates for early transplantation referral and discusses short- and mid – term outcomes and complications.

The **American Society of Transplantation (AST)** (2020) published an update to their 2001 position paper to expand upon new insights into the indications for intestinal transplantation. The paper states patients with permanent intestinal failure should have a multidisciplinary team and be considered for intestinal transplantation in the presence of progressive intestinal failure associated liver disease, loss of central venous access, and repeated central line infections. Additionally, patients with large desmoid or other intra-abdominal tumors, extensive mesenteric vein thrombosis and intestinal infarction, total intestinal aganglionosis, and nonrecoverable congenital secretory diarrhea are indications for intestinal transplantation as well. The paper proceeds to cover topics such as quality of life considerations, referral to a transplant center, and considerations at the time of listing by a transplant center.

The AST (2001) published the Position Paper titled *Indications for Pediatric Intestinal Transplantation*. This includes a subset of children with intestinal failure who are dependent on parenteral nutrition and develop life-threatening complications due to therapy. Complications include parenteral nutrition-associated liver disease, recurrent sepsis, and threatened loss of central venous access. Wait times for this type of transplantation is longer due to a shortage of donor organs – children with life-threatening complications of should therefore be identified early to receive suitable donor organs prior to illness becoming critical.

The **European Society for Clinical Nutrition and Metabolism (ESPEN)** (2023) published updated guidelines for Chronic Intestinal Failure in Adults. The guidelines covered the topics management of home parenteral nutrition (HPN); parenteral nutrition formulation; intestinal rehabilitation, medical therapies, and non-transplant surgery, for short bowel syndrome, chronic intestinal pseudo-obstruction, and radiation enteritis; intestinal transplantation; prevention/treatment of CVC-related infection, CVC-related occlusion/thrombosis; intestinal failure-associated liver disease, gallbladder sludge and stones, renal failure, and metabolic bone disease. New chapters were added focusing on costs, pregnancy, and transition of care from pediatric to adult centers. An updated guideline 149 recommendations and 16 statements for the management of chronic intestinal failure in adults.

The **European Society for Paediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN)** (2015) published a position paper on Intestinal Failure – Associated Liver Disease. The paper tackled the most prevalent complication affecting the pediatric population with intestinal failure receiving parenteral nutrition, intestinal failure associate liver disease. The paper guides diagnostic criteria, and highlights prevalence, pathogenesis, and risk factors. The guidelines lay out recommendations for nutrition in premature infants, enteral nutrition, probiotic use, parenteral nutrition, and surgical treatment options. The paper stipulates indications for isolated small bowel transplant, combined liver, and small bowel transplant, multivisceral transplant, and isolated liver transplant.

CODING & BILLING INFORMATION

CPT (Current Procedural Terminology)

Code	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
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
47133	Donor hepatectomy (including cold preservation), from cadaver donor
47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age
47140	Donor hepatectomy (including cold preservation), from living donor; left lateral segment only (segments II and III)
47141	Donor hepatectomy (including cold preservation), from living donor; total left lobectomy (segments II, III and IV)
47142	Donor hepatectomy (including cold preservation), from living donor; total right lobectomy (segments V, VI, VII and VIII)
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 2 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 2 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
48550	Donor pancreatectomy (including cold preservation), with or without duodenal segment for transplantation
48554	Transplantation of pancreatic allograft

HCPCS (Healthcare Common Procedure Coding System)

Code	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

10/09/2024	Policy reviewed**,** no changes to coverage criteria. Updated Summary of Medical Evidence and References.
06/12/2024	Coverage criteria revised with removal of transplant evaluation, continuation of therapy, and general contraindication coverage criteria as it is now stipulated in MCP 459 Pre-Transplant and General Transplant Evaluation. Annual Review Scheduled for October 2024.
10/12/2023	Policy reviewed, changes to criteria include age for colonoscopy reduced to 45 years, addition of non-life limiting neurological impairment criteria, removal of abnormal serology criteria and daily cannabis use section, removal of specific disease criteria, and addition of active pregnancy and substance abuse statement under absolute contraindications. Updated Overview, Summary of Medical Evidence, and References. IRO Peer Review by a practicing physician board certified in transplant hepatology September 2023.
10/12/2022	Policy reviewed, no changes to criteria, included section on marijuana use, updated Summary of Medical Evidence section.
10/13/2021	Policy reviewed, no changes to criteria, updated references.
09/16/2020	Policy reviewed, updated diagnoses for small bowel transplant (alone) and for small bowel and liver transplant (simultaneous). Updated references and coding. IRO peer reviewed by board certified Gastroenterology and Internal Medicine physician.
09/18/2019	Policy reviewed, no changes to criteria, updated references.
09/13/2018	Policy reviewed, no changes to criteria, updated references.
06/22/2017	Policy reviewed, no changes to criteria, updated references.
12/14/2016	Policy reviewed, no changes to criteria, updated references.
05/26/2015	Policy reviewed, updated with new pretransplant criteria. Medical Evidence section condensed; added 1 new indication to the multivisceral criteria for individuals with pancreatic failure.
08/30/2012	New policy.

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