MEDICAL POLICY

Excellus
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Medical Policy Title	**Small Bowel and Multivisceral Transplants in Adults and Children**
Policy Number	**07.02.05**
Current Effective Date	March 20, 2025
Next Review Date	March 2026

Our medical policies are based on the assessment of evidence based, peer-reviewed literature, and professional guidelines. Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract. (Link to Product Disclaimer)

POLICY STATEMENT(S)

I. Small Bowel Transplant

A. Small bowel (SB) transplantation is considered **medically appropriate** in pediatric and adult patients with short bowel syndrome (SBS) for **ANY** of the following indications:

1. Impending or overt liver failure due to total parenteral nutrition (TPN)-induced liver injury;
2. Thrombosis of two or more central veins;
3. Two or more episodes per year of systemic sepsis secondary to line infection that require hospitalization;
4. A single episode of line-related fungemia, septic shock, and/or acute respiratory distress syndrome; **or**
5. Frequent episodes of severe dehydration, despite intravenous fluid supplementation in addition to TPN.

B. SB transplant is considered investigational for adult and pediatric individuals with intestinal failure who can tolerate TPN.

C. SB transplant using live donor tissue is considered investigational.

II. Multivisceral Transplant

Multivisceral (MV) transplantation is considered **medically appropriate** in pediatric and adult patients with intestinal failure **AND** concurrent liver failure.

III. Candidates for SB or MV transplant must meet **ALL** of the following criteria:

A. Adequate cardiopulmonary status;

B. Absence of active infection;

C. Absence of malignancy (other than non-melanoma skin cancers), unless malignancy has been completely resected, or (upon medical review) it is determined that malignancy has been treated with small likelihood of recurrence and acceptable future risks; **and**

D. Documentation of patient compliance with medical management.

RELATED POLICIES

Corporate Medical Policy

11.01.03 Experimental or Investigational Services

POLICY GUIDELINE(S)

I. Pre-transplant evaluation documentation should include the following clinical information (if testing is unable to be performed, the rationale for not performing the testing should be included in the documentation):

   A. Clinical Evaluation:

      1. Confirmation of diagnosis;
      2. Identification of comorbidities;
      3. Treatment of co-morbidities;
      4. Current assessment of co-morbidities; and
      5. Consult notes (if applicable).

   B. Psycho-Social Evaluation:

      1. Karnofsky performance score; and/or Palliative Performance Scale (PPS) score.
      2. Identification of stressors (family support, noncompliance issues, motivational issues, alcohol, or substance abuse).

   C. Oral Health Evaluation

   D. Lab Tests:

      1. CBC, metabolic profile;
      2. Serologies: CMV, Hepatitis B and C; and
      3. HIV Testing.

   E. Cardiac Assessment:

      1. 12 Lead EKG; and
      2. Stress (exercise, nuclear, or dobutamine), and
      3. Echo or MUGA Scan

   F. Pulmonary Assessment:

      1. Chest x-ray;
      2. Pulmonary function tests (PFTs); for high-risk for respiratory failure (COPD, emphysema, alpha-1-antritrypsin deficiency, hepatopulmonary syndrome, or significant smoking history); and

3. Low-dose screening CT for individuals considered high-risk for lung cancer (e.g., 20- to 30-pack history of smoking).

G. Age-Appropriate Screening Tests: Please refer to the U.S Preventive Services Task Force (USPSTF) website for list of age appropriate screening guidelines. [accessed 2025 Feb 13]. Available from: https://uspreventiveservicestaskforce.org/uspstf/

II. Small Bowel and Multivisceral Transplants are considered a relative contraindication in human immunodeficiency virus (HIV) positive recipients, unless **ALL** of the following criteria are met:

A. Patient's CD4 count is greater than 200 cells/mm3;

B. HIV-1RNA is undetectable;

C. Patient has been on stable anti-retroviral therapy for greater than three months;

D. Patient has no other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis; resistant fungal infections, Kaposi's sarcoma, or other neoplasm); and

E. Patient meets all other criteria for transplantation.

DESCRIPTION

Small Bowel Transplant

The purpose of a small bowel (SB) transplant is to restore bowel function and allow for adequate nutrition in patients with short bowel syndrome (SBS). It may be an alternative to total parenteral nutrition (TPN) for selected patients who are predicted to have poor survival on TPN. SBS is a condition in which the absorbing surface of the small intestine is inadequate due to extensive disease or surgical removal of a large portion of the small intestine. The spectrum of clinical disease varies widely, from only single micronutrient malabsorption to complete intestinal failure, defined as the reduction of gut function below the minimum necessary for the absorption of macronutrients and/or water and electrolytes.

In adults, etiologies of short bowel syndrome include ischemia, trauma, volvulus, and tumors. In children, gastroschisis, volvulus, necrotizing enterocolitis, and congenital atresia are predominant causes of short bowel syndrome. The actual prevalence of short bowel syndrome is not clear primarily due to under-reporting and a lack of reliable patient databases.

Multivisceral Transplant

Candidates for MV transplant have SBS and terminal liver failure or other gastrointestinal problems, such as pancreatic failure, thromboses of the celiac axis and the mesenteric artery, or pseudo-obstruction affecting the entire gastrointestinal tract. Due to anatomic or other medical problems, patients with these conditions require a more extensive transplant procedure than an SB and liver. In addition to the SB and liver, MV transplantation may include the stomach, duodenum, jejunum, ileum, pancreas, and/or colon.

MV transplantation is an infrequently performed procedure, but, without this procedure, most patients who are candidates for it face 100% mortality.

Progressive thrombocytopenia and cholestasis are the most reliable indicators of developing liver dysfunction. Complications of portal hypertension, such as variceal bleeding, ascites, and hepatorenal syndrome, do not arise until late in the course of disease. Timely referral may allow salvage of the native liver with the more accessible intestinal allograft. Given the higher patient survival rates with this single-organ transplant, patients should be identified and considered for transplant before development of irreversible liver dysfunction.

Total parenteral nutrition (TPN) is the only established treatment that can produce long-term survival, once the small intestine is dysfunctional, and oral nutrition is ineffective. TPN requires placement of a permanent venous access device. There are some serious, life-threatening complications that can occur as a result of TPN, including hepatobiliary disease, thrombosis due to the venous catheter, or sepsis from the venous access line.

SUPPORTIVE LITERATURE

There are limited long-term data on SB and MV transplants, due to the small numbers of transplantations performed. Intestinal transplants (including multivisceral and bowel/liver) represent a small minority of all solid organ transplants. In 2024, 80 intestinal transplants were performed in the U.S. according to the U.S. Department of Health and Human Services (DHHS) Organ Procurement and Transplantation Network National Data 2024. The number of new patients added to the intestinal transplant waiting list as of February 14, 2025, was 183.

Sudan (2010) published a review of the literature on long-term outcomes after intestinal transplantation. Sudan noted that intestinal transplantation had become standard therapy for patients with life-threatening complications from parenteral nutrition therapy. Data from current single center series have indicated 1-year patient survival rates between 78% and 85% and 5-year or more survival rates between 56% and 61%.

Pediatric intestinal transplant patients, most achieve normal growth velocity at 2 years posttransplant. However, oral aversion is common; tube feedings are necessary for 45% of children. Sudan also reported on parental surveys of quality of life for pediatric transplant patients in which intestinal transplant patients appear to have modestly improved quality of life compared with those remaining on TPN and slightly worse than matched school-age controls without intestinal disease.

Living donor isolated or combined liver/intestinal transplants have been studied in very small case studies. Typically, living donor transplants have been reserved for children who are at high risk for premature death while on the cadaveric waiting list and who have no central venous access, or for children with impending TPN-related liver failure (Gangemi 2009). A living donor liver transplant may be performed first, followed by an intestinal transplant from the same donor later. Advantages to living donors' transplants include better human leukocyte antigen (HLA) matching, reduction of cold ischemia time, and no waitlisting for a transplant; thus, the patient is less likely to die while waiting for an organ. Results from the studies showed few or no complications for the donor after transplant. Most complications for the recipient, such as diarrhea, weight loss, and nausea, were resolved within

a few weeks of surgery. However, these small studies are lacking long-term follow up of the donors. Patient survival and graft survival for recipients of living donor combined liver/intestinal or isolated intestinal transplants has been favorable. More large studies are needed, to determine whether patient survival rate is comparable to or better than the survival rate for patients receiving cadaveric organs. Most studies suggest that living donor-transplanted organs are to be reserved for circumstances in which there is high risk for death, and no cadaveric donors are available.

PROFESSIONAL GUIDELINE(S)

In 2001, the American Society of Transplantation issued a position paper on indications for pediatric intestinal transplantation (Iyer 2022). The Society listed the following disorders in children as being potentially treatable by intestinal transplantation: short bowel syndrome, defective intestinal motility, and impaired enterocyte absorptive capacity. Contraindications for intestinal transplant to treat pediatric patients with intestinal failure are similar to those of other solid organ transplants: profound neurologic disabilities, life-threatening comorbidities, severe immunologic deficiencies, nonresectable malignancies, autoimmune diseases, and insufficient vascular patency.

In 2003, the American Gastroenterological Association (AGA) published a position statement on short bowel syndrome and intestinal transplantation. The statement noted that only patients with life-threatening complications due to intestinal failure or long-term total parenteral nutrition (TPN) have undergone intestinal transplantation. The AGA published an expert review update in 2022. The update made the same statements as the 2003 position statement in their best practice advice for referral for intestinal transplantation.

Solid organ transplantation for candidates who are HIV-positive has long been controversial, due to the long-term prognosis for HIV positivity, and the impact of immunosuppression on HIV disease. Although HIV-positive transplant recipients may be a research interest of some transplant centers, the minimal data regarding long-term outcome in these patients consist primarily of case reports and abstract presentations of liver and kidney recipients. Nevertheless, some transplant surgeons argue that HIV positivity is no longer an absolute contraindication to transplant, due to the advent of highly active anti-retroviral therapy (HAART), which has markedly changed the natural history of the disease.

In 2001, the United Network for Organ Sharing (UNOS) has indicated that asymptomatic HIV-positive patients should not necessarily be excluded from candidacy for organ transplantation, stating, "A potential candidate for organ transplantation whose test for HIV is positive but who is in an asymptomatic state should not necessarily be excluded from candidacy for organ transplantation, but should be advised that he or she may be at increased risk of morbidity and mortality because of immunosuppressive therapy."

The HIV Organ Policy Equity (HOPE) Act was enacted in June 2013. The HOPE act would permit donated, HIV-positive organs to be used for transplantation in HIV-positive patients, a medical procedure currently prohibited by federal law. The HOPE Act directs the Department of Health and Human Services and the Organ Procurement Transplant Network (OPTN) to develop and institute standards for research on HIV-positive organ transplantation and permits the Secretary to permit positive-to-positive transplantation if it is determined that the results of research warrant such a

change. The Secretary would be required to direct OPTN to develop standards to ensure that positive-to-positive transplantation does not impact the safety of the organ transplantation network. In addition, the Act amends federal criminal law regarding HIV transmission to clarify that such organ donations are not barred.

REGULATORY STATUS

The U.S. Food and Drug Administration (FDA) regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation Title 21, parts 1270 and 1271. Solid organs used for transplantation are subject to these regulations.

CODE(S)

- Codes may not be covered under all circumstances.
- Code list may not be all inclusive (AMA and CMS code updates may occur more frequently than policy updates).
- (E/I)=Experimental/Investigational
- (NMN)=Not medically necessary/appropriate

CPT Codes

Code	Description
44120	Enterectomy, resection of small intestine; single resection and anastomosis
44121	Enterectomy; each additional resection and anastomosis (List separately in addition to code for primary procedure)
44125	Enterectomy, resection of small intestine; with enterostomy
44135	Intestinal allotransplantation from a cadaver donor
44136 (E/I)	Intestinal allotransplantation from a living donor
44137	Removal of transplanted intestinal allograft, complete
47135	Liver allotransplantation; orthotopic, partial or whole from cadaver or living donor, any age

HCPCS Codes

Code	Description
S2053	Transplantation of small intestine, and liver allografts
S2054	Transplantation of multivisceral organs

ICD10 Codes

Code	Description
K72.10	Chronic hepatic failure without coma
K72.11	Chronic hepatic failure with coma
K72.90	Hepatic failure, unspecified without coma
K72.91	Hepatic failure, unspecified with coma
K91.2	Postsurgical malabsorption, not elsewhere classified

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SEARCH TERMS

Intestine, Multivisceral, Small Bowel, Transplant

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

NCD - Intestinal and Multi-Visceral Transplantation (260.5) [accessed 2025 Feb 13]

PRODUCT DISCLAIMER

- Services are contract dependent; if a product does not cover a service, medical policy criteria do not apply.
- If a commercial product (including an Essential Plan or Child Health Plus product) covers a specific service, medical policy criteria apply to the benefit.
- If a Medicaid product covers a specific service, and there are no New York State Medicaid guidelines (eMedNY) criteria, medical policy criteria apply to the benefit.
- If a Medicare product (including Medicare HMO-Dual Special Needs Program (DSNP) product) covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.
- If a Medicare HMO-Dual Special Needs Program (DSNP) product DOES NOT cover a specific service, please refer to the Medicaid Product coverage line.

POLICY HISTORY/REVISION

Committee Approval Dates

07/19/01, 06/20/02, 04/24/03, 02/19/04, 02/17/05, 02/16/06, 03/15/07, 03/20/08, 03/19/09, 03/18/10, 03/17/11, 03/15/12, 02/21/13, 02/20/14, 02/19/15, 03/17/16, 03/16/17, 03/15/18, 03/21/19, 10/22/20, 03/18/21, 03/24/22, 03/23/23, 03/21/24, 03/20/25

Date	Summary of Changes
03/20/25	• Annual review; policy intent unchanged.
01/01/25	• Summary of changes tracking implemented.
02/16/00	• Original effective date