MEDICAL POLICY

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MEDICAL POLICY DETAILS	
Medical Policy Title	**Small Bowel and Multivisceral Transplants in Adults and Children**
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Product Disclaimer	• *Services are contract dependent; if a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.* • *If a commercial product (including an Essential Plan or Child Health Plus product), 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 STATEMENT

I. Small Bowel Transplant

A. Based upon our criteria and assessment of the peer-reviewed literature, small bowel (SB) transplantation has been medically proven to be effective and, therefore, 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. 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;
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. Based upon our criteria and the lack of peer-reviewed literature, SB transplant in adults has not been medically proven to be effective and, therefore, is considered **investigational** for adults who are able to tolerate TPN.

C. Based upon our criteria and the lack of peer-reviewed literature, living donations of SB for transplantation has not been medically proven to be effective and, therefore, is considered **investigational.**

II. Multivisceral Transplant

Based upon our criteria and assessment of the peer-reviewed literature, multivisceral (MV) transplantation has been medically proven to be effective and, therefore, 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.

IV. Currently, the United Network for Organ Sharing (UNOS) states that asymptomatic HIV-positive patients should not necessarily be excluded for candidacy for organ transplantation. In 2001, the Clinical Practice Committee of the American Society of Transplantation proposed that the presence of AIDS could be considered a contraindication to kidney transplant, unless the patient meets **ALL** of the following criteria:
   A. CD4 count greater than 200 cells/mm^3;
   B. Undetectable HIV-1RNA;
   C. On stable anti-retroviral therapy for greater than three months;
   D. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis; resistant fungal infections, Kaposi's sarcoma, or other neoplasm); **and**
   E. All other criteria for transplantation.

Refer to Corporate Medical Policy #11.01.03 Experimental or Investigational Services

POLICY GUIDELINES

I. Prior authorization requirements are contract dependent. Approvals for all transplants, including arrangements with an approved transplant center, may be required.

II. 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, a-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. https://uspreventiveservicestaskforce.org/uspstf/

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.

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.

RATIONALE

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.

There are limited long-term data on SB and MV transplants, due to the small numbers performed. International Intestinal Transplant Registry outcomes published in 1999 include overall patient and graft survival rates of 69% for isolated intestine recipients at one year, and 66% and 63%, respectively, for liver/bowel and MV graft recipients at one year. It is possible that some patient with severe TPN-associated complications face a higher probability of mortality with continued medical management than with transplantation. SB and MV transplantation are reserved for selected patients with life-threatening complications of TPN.

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. 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.

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. Furthermore, 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." In 2001, the Clinical Practice Committee of the American Society of Transplantation proposed that the presence of AIDS could be considered a contraindication to SB and MV transplants, unless the specific criteria were present (*refer to Policy Statement IV*).

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.

CODES

- *Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.*
- *CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.*
- *Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.*
- *Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).*

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

Code	Description
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

REFERENCES

*Benedetti E, et al. Progressive functional adaptation of segmental bowel graft from living related donor. Transplant 2001;71(4):569-71.

*Gangemi A, et al. Lessons learned in pediatric small bowel and liver transplantation from living-related donors. Transplantation 2009;87:1027-30.

*Horslen SP, et al. Isolated liver transplantation in infants with end-stage liver disease associated with short bowel syndrome. Ann Surg 2002 Mar;235(3):435-9.

Kaufman SS, et al. New insights into the indications for intestinal transplantation: consensus in the year 2019. Transplantation 2020 May;104(5):937-946.

Kesseli S and Sudan D. Small bowel transplantation. Surg Clinics of North America 2019;99:103-116.

Khan FA and Selvaggi G. Overview of intestinal and multivisceral transplantation. UpToDate [online serial]. Waltham, MA: UpToDate; reviewed May 2020.

Lee EJ, et al. Pediatric intestinal transplantation. Seminars in Pediatric Surgery 2022 Jun;31(3):151181.

*Sokal EM, et al. Liver and intestinal transplantation in children: working group report of the first world congress of pediatric gastroenterology, hepatology, and nutrition. J Ped Gastroenterol Nutrit 2002 Aug;35:S159-72.

Torres C, et al. Twelve year outcome of intestinal failure-associated liver disease in children with short bowel syndrome 97% transplant free survival and 81% enteral autonomy. Journal of Parenteral and Enteral Nutrition 2021 Apr;46(1):197-206.

*Key Article

KEY WORDS

Intestine, Multivisceral Small bowel, Transplant

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) 260.5 for Intestinal and Multi-Visceral Transplantation. Please refer to the following NCD website for Medicare Members: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=280&ncd ver=2&bc=BAABAAAAAAAA& accessed 02/13/24.