

Small Bowel, Small Bowel/Liver and Multivisceral Transplant

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Disclaimer

Highmark Health Options medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

POLICY STATEMENT

Highmark Health Options may provide coverage under medical surgical benefits of the Company's Medicaid products for medically necessary small bowel, liver, and multivisceral transplantation.

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

The qualifications of the policy will meet the standards of the National Committee for Quality Assurance (NCQA) and the Delaware Department of Health and Social Services (DHSS) and all applicable state and federal regulations.

DEFINITIONS

Highmark Health Options (HHO) – Managed care organization serving vulnerable populations that have complex needs and qualify for Medicaid. Highmark Health Options members include individuals and families with low income, expecting mothers, children, and people with disabilities. Members pay nothing to very little for their health coverage. Highmark Health Options currently services Delaware Medicaid: Delaware Healthy Children Program (DHCP) and Diamond State Health Plan Plus members.

PROCEDURES

A small bowel transplant may be performed as an isolated procedure. Isolated small bowel transplant is commonly performed in individuals with short bowel syndrome.

Multivisceral transplantation/retransplantation may be performed as an intestinal allograft in combination with a liver allograft, either alone or in combination with one or more of the following organs: stomach, duodenum, jejunum, ileum, pancreas, or colon.

Small Bowel Transplant

A small bowel transplant using cadaveric intestine may be considered medically necessary in adult and pediatric individuals with ALL the following:

- Intestinal failure (characterized by loss of absorption and the inability to maintain protein-energy, fluid, electrolyte, or micro-nutrient balance); and
- Who have established long-term dependence on total parenteral nutrition; and
- Who are developing or have developed severe complications due to total parenteral nutrition.

A small bowel transplant using a living donor may be considered medically necessary only when a cadaveric intestine is not available for transplantation in an individual who meets the criteria noted above for a cadaveric intestinal transplant.

A small bowel re-transplant meeting the criteria indicated in this policy may be considered medically necessary after a failed primary small bowel transplant.

A small bowel transplant using cadaveric or living donors not meeting the criteria as indicated in this policy is considered not medically necessary.

A small bowel transplant is considered experimental/investigational for adult and pediatric individuals with intestinal failure who can tolerate total parenteral nutrition and therefore non-covered because the safety and/or effectiveness of this service cannot be established by the available published peer-reviewed literature.

In addition to the above criteria and subject to the discretion of the transplant center, a Hepatitis C Virus (HCV) positive donor organ maybe considered an acceptable organ option for an HCV negative adult recipient 18 years of age or older

Multivisceral Transplant

Transplants, such as a multi-visceral transplant and a small bowel and liver transplant, may be considered medically necessary for pediatric and adult individuals with ALL the following:

- Intestinal failure (characterized by loss of absorption and the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balance); and
- Have been managed with long-term total parenteral nutrition; and
- Have developed evidence of impending end-stage liver failure.

Multi-visceral or a small bowel and liver re-transplant may be considered medically necessary after a failed primary small bowel and liver transplant or multi-visceral transplant.

A multivisceral or small bowel and liver transplant not meeting the criteria as indicated in this policy is considered not medically necessary.

General Criteria

Potential contraindications for solid organ transplant subject to the judgment of the transplant center may include the following:

- Known current malignancy, including metastatic cancer; or
- Recent malignancy with high risk of recurrence; or

- Untreated systemic infection making immunosuppression unsafe, including chronic infection; or
- Other irreversible end-stage diseases not attributed to intestinal failure; or
- History of cancer with a moderate risk of recurrence; or
- Systemic disease that could be exacerbated by immunosuppression; or
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy.

Intestinal failure results from surgical resection, congenital defect, or disease-associated loss of absorption, and is characterized by the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balance. Short bowel syndrome is an example of intestinal failure.

Candidates should meet the following criteria:

- Adequate cardiopulmonary status
- Documentation of Individuals compliance with medical management.

Small Bowel-Specific Criteria

Individuals who are developing or have developed severe complications due to total parenteral nutrition (TPN) include, but are not limited to, the following: multiple and prolonged hospitalizations to treat TPN-related complications (especially repeated episodes of catheter-related sepsis) or the development of progressive liver failure. In the setting of progressive liver failure, small bowel transplant may be considered a technique to avoid end-stage liver failure related to chronic TPN, thus avoiding the necessity of a multivisceral transplant. In those receiving TPN, liver disease with jaundice (total bilirubin >3 mg/dL) is often associated with development of irreversible, progressive liver disease. The inability to maintain venous access is another reason to consider small bowel transplant in those who are dependent on TPN.

Small Bowel/Liver-Specific Criteria

Evidence of intolerance of total parenteral nutrition (TPN) includes, but is not limited to, multiple and prolonged hospitalizations to treat TPN-related complications or the development of progressive but reversible liver failure. In the setting of progressive liver failure, small bowel transplant may be considered a technique to avoid end-stage liver failure related to chronic TPN and would thus avoid the necessity of a multivisceral transplant.

Post-payment Audit Statement

The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark Health Options at any time pursuant to the terms of your provider agreement.

Place of Service

Experimental/Investigational (E/I) services are not covered regardless of place of service.

CODING REQUIREMENTS

CPT codes	Description
44133	Donor enterectomy, open, with preparation and maintenance of allograft; partial, from living donor.
44135	Intestinal allotransplantation; from cadaver donor.
44136	Intestinal allotransplantation; from living donor.

47135	Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any type.
47399	Unlisted procedure, liver.
44799	Unlisted procedure, intestine.

Diagnosis Codes	Description
K72.00	Acute and subacute hepatic failure without coma.
K72.01	Acute and subacute hepatic failure with coma.
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.
K76.2	Central hemorrhagic necrosis of liver.
K90.0	Celiac Disease.
K90.1	Tropical sprue.
K90.2	Blind loop syndrome, not elsewhere specified.
K90.3	Pancreatic steatorrhea.
K90.49	Malabsorption due to intolerance, not elsewhere classified.
K90.9	Intestinal malabsorption, unspecified.
K90.81	Whipple's disease.
K90.89	Other intestinal malabsorption.
K91.2	Postsurgical malabsorption, not elsewhere classified.

REIMBURSEMENT

Participating facilities will be reimbursed per their Highmark Health Options contract.

POLICY SOURCES

American Gastroenterological Association-2003

The American Gastroenterological Association (2003) produced a medical position statement on short bowel syndrome and intestinal transplantation. It recommended dietary, medical, and surgical solutions. Indications for intestinal transplantation mirrored those of the Centers for Medicare & Medicaid Services. The guidelines acknowledged the limitations of transplant for these individuals. The statement recommended the following Medicare-approved indications, pending availability of additional data:

- Impending or overt liver failure
- Thrombosis of major central venous channels
- Frequent central line-related sepsis
- Frequent severe dehydration.

American Society of Transplantation-2017

The American Society of Transplantation (2017) convened a consensus conference of experts to address issues related to the transplantation of hepatitis C virus (HCV) viremic solid organs into HCV non-viremic recipients.

- Definition of HCV positive
 - HCV viremic reflecting a positive NAT should be adopted
- Data interpretation
 - HCV antibody status alone limits interpretation of outcomes of transplantation of HCV "positive" organs
- Transmission and Treatment
 - Highest risk for unexpected HCV transmission is associated with organ donation from a person who injected drugs within the eclipse or pre-viremic period
- OPTN policy
 - No current policies prevent transplantation of HCV-viremic organs into HCV non-viremic recipients
- Ethical considerations
 - Transplantation of HCV-viremic organs into HCV non-viremic recipients should be conducted under site specific IRB approved protocols with multi-step informed consent.

References

Kubal C, Mangus R, Saxena R, et al. Prospective monitoring of donor-specific anti-HLA antibodies after intestine/multivisceral transplantation: Significance of de novo antibodies. *Transplant*. 2015; 99(8):e49-56.

Wu GS, Cruz RJ, Jr, Cai JC. Acute antibody-mediated rejection after intestinal transplantation. *World J Transplant*. 2016;6(4):719-728.

Nagai S, Mangus RS, Anderson E, et al. Cytomegalovirus Infection after intestinal/multivisceral transplantation: A single-center experience with 210 cases. *Transplantation*. 2016;100(2):451-460.

Khan FA and Selvaggi G: Overview of intestinal and multivisceral transplantation. Brown R. UpToDate. Waltham, MA: UpToDate Inc.

United Network for Organ Sharing (UNOS). OPTN policies, procedures implemented to support HOPE Act. 2015. Accessed August 25, 2020.

Dore M, Junco PT, Andres AM, Sánchez-Galán A, Amesty MV, et al. Surgical rehabilitation techniques in children with poor prognosis short bowel syndrome. *Eur J Pediatr Surg*. 2016;26(1):112-116.

Rutter CS, Amin I, Russell NK, Sharkey LM, Butler AJ, et al. Adult intestinal and multivisceral transplantation: experience from a single center in the United Kingdom. *Transplant Proc*. 2016;48(2):468-472.

Lacaille F, Irtan S, Dupic L, Talbotec C, Lesage F, et al. Twenty-eight years of intestinal transplantation in Paris: Experience of the oldest European center. *Transpl Int*. 2017;30(2):178-186.

Ekser B, Kubal CA, Fridell JA, Mangus RS. Comparable outcomes in intestinal retransplantation: Single-center cohort study. *Clin Transplant*. 2018; 32(7):e13290.

Organ Procurement and Transplantation Network (OPTN). Organ Procurement and Transplantation Network Policies. 2020. Accessed August 25, 2020.

Levitsky J, Formica RN, Bloom RD, et al. The American Society of Transplantation consensus conference on the use of Hepatitis C viremic donors in solid organ transplantation. *Am J Transplant.* 2017;17:2790-2802.

Bharadwaj S, Tandon P, Gohel TD, et al. Current status of intestinal and multivisceral transplantation. *Gastroenterol Rep (Oxf).* 2017;5(1):20-28.

Loo L, Vrakas G, Reddy S, et al. Intestinal transplantation: A review. *Curr Opin Gastroenterol.* 2017;33(3):203-211.

Timponi JG, Yimen M, Cox S, et al. Resistant cytomegalovirus in intestinal and multivisceral transplant recipients. *Transpl Infect Dis.* 2016;18(2):202-209.

Cromvik J, Varkey J, Herlenius G, et al. Graft-versus-host disease after intestinal or multivisceral transplantation: A Scandinavian single-center experience. *Transplant Proc.* 2016;48(1):185-190.

Garcia Aroz S, Tzvetanov I, Hetterman EA, et al. Long-term outcomes of living-related small intestinal transplantation in children: A single-center experience. *Pediatr Transplant.* 2017;21(4).

Luckett k, Kaiser TE, Bari K, et al. Use of hepatitis C virus antibody-positive donor livers in hepatitis C nonviremic liver transplant recipients. *J AM Coll Surg* 2019;228(4):560-567.

Saberi B, Hamilton JP, Durand CM, et al. Utilization of hepatitis C virus RNA-positive donor liver for transplant to hepatitis C virus RNA-negative recipient. *Liver Transpl.* 2018;24(1):140-143.

Campos-Varela I, Agudelo EZ, Sarkar M, et al. Use of hepatitis C virus(HCV) RNA-positive donor in a treated HCV RNA-negative liver transplant recipient. *Transpl Infect Dis.* 2018;20(1).

Kwong AJ, Wall A, Melcher M, et al. Liver transplantation for hepatitis C virus (HCV) non-viremic recipients with HCV viremic donors. *Am J Transplant.* 2019;19(5): 1380-1387.

InterQual® Level of Care Criteria 2019. Acute Care Adult. Change Healthcare, LLC.

POLICY UPDATE HISTORY

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