MedStar Health, Inc.
POLICY AND PROCEDURE MANUAL

Policy Number: PA.004.MH
Last Review Date: 11/14/2019
Effective Date: 01/01/2020

PA.004.MH – Transplant: Small Bowel/Liver and Multivisceral

This policy applies to the following lines of business:
- ✓ MedStar Employee (Select)
- ✓ MedStar CareFirst PPO

MedStar Health considers **Small Bowel, Small Bowel/Liver, and Multivisceral Transplants** medically necessary for the following indications:

Recipient Characteristics
- The member has no medical, cognitive, or other psychiatric condition that is likely to interfere with their ability to manage the sequelae of the transplant, including complex medication regimens.

General Criteria for Transplantation
- The member meets the institution's selection criteria for small bowel, small bowel/liver, and multivisceral transplants.

Specific Criteria for Small Bowel Transplant
Indications for small bowel transplant include any of the following:

1. Impending or overt liver failure due to TPN-induced liver injury. Clinical manifestations include any of the following:
   a) Elevated serum bilirubin and/or liver enzymes
   b) Splenomegaly
   c) Thrombocytopenia
   d) Gastroesophageal varices
   e) Coagulopathy
   f) Stomal bleeding or hepatic fibrosis/cirrhosis

2. TPN Failure for any of the following reasons:
   a) Thrombosis of the major central venous channels; jugular, subclavian, and femoral veins. Thrombosis of two or more of these vessels is considered a life threatening complication and failure of TPN therapy.
   b) Frequent line infection and sepsis. The development of two or more episodes of systemic sepsis secondary to line infection per year that requires hospitalization indicates failure of TPN therapy. A single episode of line related fungemia, septic shock and/or Acute Respiratory Distress Syndrome are considered indicators of TPN failure.

c) Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN under certain medical conditions. Under certain medical conditions such as secretory diarrhea and non-constructable gastrointestinal tract, the loss of the gastrointestinal and pancreatobiliary secretions exceeds the maximum intravenous infusion rates that can be tolerated by the cardiopulmonary system. Frequent episodes of dehydration are deleterious to all body organs particularly kidneys and the central nervous system with the development of multiple kidney stones, renal failure, and permanent brain damage.

Specific Criteria for Small Bowel /Liver Transplant- Indications for small bowel/liver transplantation include short bowel syndrome and any of the following*:*

A. Irreversible intestinal failure
B. Evidence of impending end-stage liver failure
C. Established TPN dependence (two year minimum) and evidence of severe complications from TPN, such as:
    - Liver dysfunction
    - Repeated infections
    - Thrombosis of two or more major central venous channels
    - Difficult venous access for TPN administration
    - Frequent episodes of dehydration

Specific Criteria for Small Bowel/Multivisceral Transplant (MVT)- Indications for a small bowel/multivisceral transplantation include:

1. Criteria are met for a small bowel/liver transplant and
2. Anatomic or other medical problems associated with other visceral organs (e.g., liver, duodenum, jejunum, ileum, pancreas, or colon); preclude a small bowel/liver transplant. Such problems might include:
    - Extensive thrombosis of the splanchnic venous system
    - Massive gastrointestinal polyposis
    - Generalized hollow visceral myopathy or neuropathy

Specific Criteria for Small Bowel, Small Bowel/Liver, Multivisceral Transplant in HIV+ Members- Small bowel transplantation in HIV+ members is considered medically necessary when all of the following conditions are met:

1. The member has a life expectancy of at least five years,
2. CD4 count ≥200 cells/mL for at least six months or > 100 cells/mL if portal hypertension is present

3. Absence of HIV viremia*****
4. Demonstrated adherence to highly active antiretroviral therapy (HAART regiment for ≥ six months
5. Available antiretroviral treatment options post-transplant.

***** Exception to absence to viremia – A demonstrated clinical response to HAART is considered evidence of suppressible HIV disease. Patients with absence of viremia on HAART may develop low viral loads if HAART is held due to severe liver failure before transplant. If this occurs in a patient with previously suppressible HIV disease and the patient is expected to resume HAART post-transplant, it is considered an exception to the absence of viremia and is not a contraindication to transplant.

Limitations

1. All other medical and surgical therapies that might be expected to yield both short-and long-term survival comparable to that of transplantation must have been tried or considered.

Background

Small bowel transplantation is done to restore intestinal function in patients/ members with irreversible intestinal failure. Small bowel transplantation (SBT) is the transplantation of a cadaveric intestinal allograft for the purpose of restoring intestinal function in patients with irreversible intestinal failure. SBT can be performed in isolation, in combination with transplantation of liver (for patients who have liver failure, which often occurs in children on long-term total parenteral nutrition (TPN)). Intestinal failure is defined as the loss of absorptive capacity of the small bowel secondary to severe primary gastrointestinal disease or surgically induced short bowel syndrome.

It may be associated with both mortality and profound morbidity. Multi-visceral transplantation includes organs in the digestive system (stomach, duodenum, pancreas, liver and intestine). The major causes of intestinal failure are volvulus, gastroschisis, necrotizing enterocolitis, splanchnic vascular thrombosis, inflammatory bowel disease, radiation enteritis, congenital diseases and trauma. Intestinal failure prevents oral nutrition and may be associated with both mortality and profound morbidity.

In addition to intestinal failure, candidates for multivisceral transplantation (MVT) have developed evidence of impending liver failure and other gastrointestinal problems such as pancreatic failure, thromboses of the celiac axis and the superior mesenteric artery, or pseudo-obstruction affecting the entire gastrointestinal tract.

Codes:

Small Bowel Transplantation	
Code	Description
CPT codes covered if selection criteria are met (If Appropriate):	
44135	Intestinal allotransplantation; from cadaver donor
44136	Intestinal allotransplantation; from living donor
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

Small Bowel/Liver and Multivisceral Transplantation	
Code	Description
HCPCS codes covered if selection criteria are met (If Appropriate):	
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

References

1. Bhagani S, Sweny P, [British HIV Association]. Guidelines for kidney transplantation in patients with HIV disease. HIV Med. 2006 Apr; 7(3):133-139. http://www.bhiva.org/documents/Guidelines/Renal%20transplantation/HIV-Renal-Transplant-guidel.pdf
2. Centers for Medicare and Medicaid Services (CMS). National Coverage Decision (NCD) No. No. 260.5 - Intestinal and Multi-Visceral Transplantation. Effective Date of this Version: 05/11/2006. http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=280&ncdver=2&bc=AgAAgAAAAAAAAA%3d%3d&
3. Centers for Medicare and Medicaid Services (CMS). Decision Memo CAG-00036N for Intestinal and Multivisceral Transplantation. https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=42&ver=5&viewAMA=Y&bc=AAAAAAAAEAAA&

4. Centers for Disease Control and Prevention (CDC). What is HIV? Last updated: August 14, 2019. http://www.cdc.gov/hiv/basics/whatishiv.html#panel0
5. Gotthardt DN, Gauss A, Zech U, et al. Indications for intestinal transplantation: recognizing the scope and limits of total parenteral nutrition. Clin Transplant. 2013 Jul-Aug; 27 Suppl 25:49-55. doi: 10.1111/ctr.12161. http://www.ncbi.nlm.nih.gov/pubmed/23909502
6. Halpern SD, Ubel PA, Caplan AL. Solid organ transplantation in HIV infected patients. N Engl J Med. 2002 Jul; 347(4):284-287. http://www.nejm.org/doi/pdf/10.1056/NEJMsb020632
7. Hayes. Small Bowel, Small Bowel-Liver and Multi-visceral Transplantation. February 28, 2005. Archived March 28, 2010.
8. Henry J. Kaiser Family Foundation. AIDS 2010: The Double-Edged Sword: Long-Term Complications of ART and HIV. July 19, 2010. [Video of AIDS2010 Conference Session]. http://kff.org/global-health-policy/event/aids-2010-the-double-edged-sword-long-term-complications-of-art-and-hiv/
9. Khan FA, Selvaggi G. Overview of intestinal and multivisceral transplantation. UpToDate® – Last updated June 4, 2015. Topic 4595 Version 11.0. http://www.uptodate.com/contents/overview-of-intestinal-and-multivisceral-transplantation?topicKey=GAST%2F4595&elapsedTimeMs=4&source=search_result&searchTerm=intestinal+transplantation&selectedTitle=1%7E23&view=print&displayedView=full
10. Medline Plus: Medical Encyclopedia. Short Bowel Syndrome. Last reviewed: 05/15/2014. http://www.nlm.nih.gov/medlineplus/ency/article/000237.htm.
11. O'Grady J, Taylor Advanced Liver Disease in People with HIV. December 2017. Reviewed and endorsed by British Transplantation Society Standards Committee, Department of HIV Medicine, and the Renal Unit Royal Free Hospital, London, Central Middlesex Hospital, London. https://www.aidsmap.com/about-hiv/advanced-liver-disease-people-hiv
12. PubMed Health: A.D.A.M. Medical Encyclopedia- Short Bowel Syndrome, Last Reviewed May15, 2014. https://medlineplus.gov/ency/article/000237.htmRoland ME, Stock PG: Solid organ transplantation is a reality for patients with HIV infection. Curr HIV/AIDS Report. 2006 Sep; 3(3):132-138. http://www.ncbi.nlm.nih.gov/pubmed/16970840
13. Steinman TI, Becker BN, Frost AE, et al.: Guidelines for the referral and management of patients eligible for solid organ transplantation. Transplantation 2001 May; 71(9):1189-1204. http://www.ncbi.nlm.nih.gov/pubmed/11397947
14. Stock PG, Roland ME.: Evolving clinical strategies for transplantation in the HIV-positive recipient. Transplantation 2007 Sep; 84(5): 563-571. http://www.hemophilia.ca/files/Stock%20and%20Roland%20September%202007.pdf

15. U.S. Preventive Services Task Force: Recommendations for adults. Accessed October 2019. http://www.uspreventiveservicestaskforce.org/

Disclaimer:
MedStar Health medical payment and prior authorization policies do not constitute medical advice and are not intended to govern or otherwise influence the practice of medicine. The policies constitute only the reimbursement and coverage guidelines of MedStar Health and its affiliated managed care entities. Coverage for services varies for individual members in accordance with the terms and conditions of applicable Certificates of Coverage, Summary Plan Descriptions, or contracts with governing regulatory agencies.

MedStar Health reserves the right to review and update the medical payment and prior authorization guidelines in its sole discretion. Notice of such changes, if necessary, shall be provided in accordance with the terms and conditions of provider agreements and any applicable laws or regulations.