Intestinal and Multivisceral Transplantation

Policy Number: **20211201061**

Effective Date: **1/1/2022**

Sponsoring Department: **Health Care Services**

Impacted Department(s): **Health Care Services**

Type of Policy: ☐ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒MediSource Connect; ☒Child Health Plus; ☒Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To set forth Independent Health's medical necessity criteria for **intestinal transplantation** and **multivisceral transplantation**.

Policy:

Commercial and Self-Funded

Intestinal and/or multivisceral transplantation procedures listed below are medically necessary for pediatric and adult members to restore function in those with irreversible intestinal failure when meeting the following criteria:

1. Transplantation Procedures
    - Isolated intestinal transplantation is indicated for members who have only isolated intestinal failure and no liver disease.
    - Combined intestinal and liver transplant is indicated in those with intestinal failure and end stage liver disease.
    - Multivisceral transplant is indicated for adults and children who meet criteria for the combined small bowel/liver transplant and require one or more abdominal visceral organs to be transplanted due to concomitant organ failure or anatomical abnormalities which preclude a small bowel/liver transplant.

2. Transplantation Criteria, all apply:
    - Failure of total parenteral nutrition (TPN) in a patient with intestinal failure as indicated by one of the following:
        a. Impending or overt liver failure due to TPN, indicated by elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopenia, gastro-esophageal varices, coagulopathy, peristomal bleeding, or hepatic fibrosis/cirrhosis;
        b. Thrombosis of ≥ 2 central veins, including jugular, subclavian, and femoral veins;
        c. Two or more episodes of systemic sepsis due to line infection, per year, or one episode of septic shock, acute respiratory distress syndrome, and/or line related fungemia;
        d. Frequent episodes of dehydration despite IV fluid supplementation;
        e. Other complications leading to loss of vascular access;
    - High risk of death if transplant is not performed;
    - Severe short bowel syndrome (gastrostomy, duodenostomy, and/or residual small bowel <10 cm in infants and <20 cm in adults);
    - Frequent hospitalizations for complications directly related to intestinal failure;
    - Significant hepatic cirrhosis associated with diffuse post-mesenteric thrombosis;
    - Documentation of patient compliance with medical management.

3. Contraindications, any apply:
    - Malignancy, except for non-melanoma localized skin cancer that has been treated appropriately, low grade prostate cancer, a malignancy that has been completely resected, or a treated malignancy determined to have a small likelihood of recurrence and acceptable future risks;
    - Untreatable significant dysfunction of another major organ system, unless combined organ transplantation can be performed;
    - Presence of other gastrointestinal diseases;
    - Acute medical instability, including, but not limited to, acute sepsis or myocardial infarction;
    - Uncorrectable bleeding diathesis;
    - Chronic infection with highly virulent and/or resistant microbes that are poorly controlled pre-transplant;
    - Current non-adherence to medical therapy or a history of repeated or prolonged episodes of non-adherence to medical therapy that are perceived to increase the risk of non-adherence after transplantation;
    - Psychiatric or psychological condition associated with the inability to cooperate or comply with medical therapy;

- Absence of an adequate or reliable social support system;
- Severely limited functional status with poor rehabilitation potential;
- Substance abuse or dependence (including tobacco and alcohol) without convincing evidence of risk reduction behaviors, such as meaningful and/or long-term participation in therapy for substance abuse and/or dependence. Serial blood and urine testing may be used to verify abstinence from substances of concern.

Medicare Advantage
There is currently a National Coverage Determination (NCD) for intestinal and multivisceral transplantation. Please refer to the link listed in the Reference section for Medicare Advantage members.

MediSource, MediSource Connect, Essential Plan and Child Health Plus
MediSource, MediSource Connect, Essential Plan and Child Health Plus cover intestinal and multivisceral transplants utilizing the Commercial criteria above.

Background
Intestinal failure is the inability of the gut to absorb sufficient macronutrients, micronutrients or water, resulting in the need for intravenous supplementation to maintain health or facilitate growth. The most common cause of intestinal failure is **short bowel syndrome (SBS),** which accounts for over 70% of cases, with the remaining cases caused by functional disorders. The core of therapy for intestinal failure is **total parenteral nutrition (TPN).** TPN is considered safe and effective, and patients may be weaned from TPN if bowel function improves, but when intestinal failure is irreversible and refractory to other medical and surgical therapies, TPN may be required for the remainder of a person's life. However, TPN may be associated with severe complications such as central line infections and sepsis. Intestinal transplantation has become an option for patients with intestinal failure who become ineligible for TPN.

Intestinal transplantation can involve the isolated small bowel, a combination of the small bowel and liver, or the small bowel, liver, and one or more other visceral organs such as the stomach, pancreas, or duodenum in a procedure known as multivisceral transplantation. The goal of intestinal transplantation is to improve the life expectancy and quality of life for patients with chronic, irreversible intestinal failure by allowing them to become independent of total parenteral nutrition, to receive nutrients and fluids via absorption in the small bowel, and to begin or resume normal eating habits.

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☐ No ☒

Pre-authorization is not required at the present time. Criteria above will be utilized upon retro-review.

Definitions

Intestinal transplantation is utilized in the management of patients with irreversible intestinal failure such as short bowel syndrome. Primary indications for intestinal transplant include depletion of central venous access sites, multiple episodes of catheter-related sepsis, electrolyte disturbance, dehydration, and progressive cholestatic liver failure.

Multivisceral transplantation includes the stomach, duodenum, pancreas, small intestine, and liver. A modified multivisceral transplant excludes the liver if the recipient liver is normal. Multivisceral transplantation reserved for those patients who develop end-stage liver disease as a result of intestinal failure-associated liver disease.

Short bowel syndrome (SBS) is a malabsorptive condition most often caused by massive resection of the small intestine and is the most common cause of chronic intestinal failure (approximately 60 percent of the cases in adults).

Total parenteral nutrition (TPN) is the intravenous administration of fluids and nutrients with or without enteral feeding supplementation.

References

Related Policies, Processes and Other Documents
Transplantation of Solid Organs and Stem Cells, Policy Number M050101551.

Non-Regulatory references
Abu-Elmagd K, Bond G. Gut failure and abdominal visceral transplantation. Proc Nutr Soc. 2003 Aug;62(3):727-37.

Allan P, Lal S. Intestinal failure: a review. F1000Res. 2018 Jan 18;7:85.

Bharadwaj S, Tandon P, Gohel TD, Brown J, Steiger E, Kirby DF, Khanna A, Abu-Elmagd K. Current status of intestinal and multivisceral transplantation. Gastroenterol Rep (Oxf). 2017 Feb;5(1):20-28.

Buchman AL, Iyer K, Fryer J. Parenteral nutrition-associated liver disease and the role for isolated intestine and intestine/liver transplantation. Hepatology. 2006 Jan;43(1):9-19.

Buchman AL, Scolapio J, Fryer J. AGA technical review on short bowel syndrome and intestinal transplantation. Gastroenterology. 2003 Apr;124(4):1111-34.

DiBiase JK. Pathophysiology of short bowel syndrome. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on October 1, 2024.)

Hayes, Inc. Evidence Analysis Brief Small Bowel, Small Bowel-Liver, or Multivisceral Transplantation for Treatment of Malignancy. Lansdale, PA; February 2023.

Hayes, Inc. Health Technology Assessment Small Bowel, Small Bowel-Liver, and Multivisceral Transplantation. Lansdale, PA; February 2005.

Khan FA, Selavaggi G. Overview of intestinal and multivisceral transplantation In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on October 1, 2024.)

Kubal CA, Mangus RS, Tector AJ. Intestine and multivisceral transplantation: current status and future directions. Curr Gastroenterol Rep. 2015 Jan;17(1):427.

Madariaga JR, Reyes J, Mazariegos G, Fung JJ, Starzl TE, Abu-Elmagd K. The long-term efficacy of multivisceral transplantation. Transplant Proc. 2000 Sep;32(6):1219-20.

Mangus RS, Tector AJ, Kubal CA, et al. Multivisceral transplantation: expanding indications and improving outcomes. J Gastrointest Surg. 2013 Jan;17(1):179-86; discussion p.186-7.

Nightingale J, Woodward JM; Small Bowel and Nutrition Committee of the British Society of Gastroenterology. Guidelines for management of patients with a short bowel. Gut. 2006 Aug;55 Suppl 4(Suppl 4):iv1-12.

Pironi L, Forbes A, Joly F, et al; Home Artificial Nutrition Working Group of the European Society for Clinical Nutrition and Metabolism (ESPEN). Survival of patients identified as candidates for intestinal transplantation: a 3-year prospective follow-up. Gastroenterology. 2008 Jul;135(1):61-71.

Regulatory References

Centers for Medicare and Medicaid Services (CMS) [web site]. National Coverage Determination (NCD) 260.5 Intestinal and Multi-Visceral Transplantation. Available at: https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?ncdid=280&ncdver=2&bc=0 Accessed October 1, 2024.

New York State Department of Health [web site]. New York State Medicaid Program Physician Procedure Codes. Section 5 – Surgery. Version July 2024. Available at: https://www.emedny.org/ProviderManuals/Physician/PDFS/Physician%20Procedure%20Codes%20Sect5.pdf Accessed October 1, 2024.

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No☐

Revision Date	Owner	Notes
12/1/2025	Health Care Services	Reviewed
12/1/2024	Health Care Services	Revised
12/1/2023	Health Care Services	Revised
12/1/2022	Health Care Services	Reviewed