BlueCross BlueShield Federal Employee Program.

FEP Medical Policy Manual

FEP 7.03.05 Small Bowel/Liver and Multivisceral Transplant

Annual Effective Policy Date: January 1, 2024

Original Policy Date: March 2012

Related Policies:

7.03.04 - Isolated Small Bowel Transplant

Small Bowel/Liver and Multivisceral Transplant

Description

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This evidence review addresses transplantation and retransplantation of an intestinal allograft in combination with a liver allograft, either alone or in combination with 1 or more of the following organs: stomach, duodenum, jejunum, ileum, pancreas, or colon.

OBJECTIVE

The objective of this evidence review is to determine whether a small bowel and liver transplant or a multivisceral transplant (or retransplant) improves the net health outcome in individuals with intestinal failure and impending liver failure.

POLICY STATEMENT

Transplants, such as a multivisceral transplant and a small bowel and liver transplant, may be considered **medically necessary** for pediatric and adult individuals with intestinal failure (characterized by loss of absorption and the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balance) who have been managed with long-term total parenteral nutrition and who have developed evidence of impending end-stage liver failure.

Retransplants, such as a multivisceral retransplant and a small bowel and liver retransplant, may be considered **medically necessary** after a failed primary small bowel and liver transplant or multivisceral transplant.

A small bowel and liver transplant or multivisceral transplant is considered **investigational** in all other situations.

POLICY GUIDELINES

General Criteria

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

- Known current malignancy, including metastatic cancer
- Recent malignancy with high risk of recurrence
- History of cancer with a moderate risk of recurrence
- Systemic disease that could be exacerbated by immunosuppression
- Untreated systemic infection making immunosuppression unsafe, including chronic infection
- Other irreversible end-stage disease not attributed to intestinal failure
- 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 individual compliance with medical management.

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.

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

FDA REGULATORY STATUS

Small bowel/liver and multivisceral transplantation are surgical procedures and, as such, are not subject to regulation by the U.S. Food and Drug Administration (FDA).

The 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.

RATIONALE

Summary of Evidence

For individuals who have intestinal failure and evidence of impending end-stage liver failure who receive a small bowel and liver transplant alone or multivisceral transplant, the evidence includes a registry study and a limited number of case series. Relevant outcomes are overall survival (OS), morbid events, and treatment-related mortality and morbidity. These transplant procedures are infrequently performed and few reported case series exist. However, results from the available literature have revealed fairly high postprocedural survival rates. Given these results and the exceedingly poor survival rates of patients who exhaust all other treatments, transplantation may prove not only to be the last option but also a beneficial one. Transplantation is contraindicated for patients in whom the procedure is expected to be futile due to comorbid disease, or in whom posttransplantation care is expected to significantly worsen comorbid conditions. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have a failed small bowel and liver or multivisceral transplant without contraindications for retransplant who receive a small bowel and liver retransplant alone or multivisceral retransplant, the evidence includes case series. Relevant outcomes are OS, morbid events, and treatment-related mortality and morbidity. Although limited in quantity, the available post retransplantation data have suggested reasonably high survival rates. Given exceedingly poor survival rates without retransplantation of patients who have exhausted other treatments, evidence of postoperative survival from uncontrolled studies is sufficient to demonstrate that retransplantation provides a survival benefit in appropriately selected patients. Retransplantation is contraindicated for patients in whom the procedure is expected to be futile due to comorbid disease or in whom posttransplantation care is expected to significantly worsen comorbid conditions. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information" if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Gastroenterological Association

In 2003, the American Gastroenterological Association (AGA) published a position statement on short bowel syndrome and intestinal transplantation.[28,] 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 statement recommended the following Medicare-approved indications, pending availability of additional data:

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

The AGA published an expert review update in 2022.[29,] The update made the same statements as the 2003 position statement in their best practice advice for referral for intestinal transplantation.

American Society of Transplantation

In 2001, the American Society of Transplantation issued a position paper on indications for pediatric intestinal transplantation.[30,] 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.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Medicare covers intestinal transplantation for the purposes of restoring intestinal function in patients with irreversible intestinal failure only when performed for patients who have failed TPN and only when performed in centers that meet approved criteria.[31,] The criteria for approval of centers are based on a "volume of 10 intestinal transplants per year with a 1-year actutimes survival rate of 65 percent."

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
March 2012	New policy	
September 2013	Replace policy	Policy updated with literature review through April 30, 2013. References 5, 6, 8, and 10-15 added; other references renumbered or removed. Policy statement updated.
September 2014	Replace policy	Policy updated with literature review. Reference 10 added. Statement added that procedure is investigational in all other situations.
September 2015	Replace policy	Policy updated with literature review; no references added. Policy statements unchanged.
December 2017	Replace policy	Policy updated with literature review through June 22, 2017; references 7-9 and 15 added. Policy statements unchanged.
December 2018	Replace policy	Policy updated with literature review through June 7, 2018, reference 21 added; reference 19 updated. Policy statements unchanged.
December 2019	Replace policy	Policy updated with literature review through June 10, 2019; no references added. Policy statements unchanged.
December 2020	Replace policy	Policy updated with literature review through July 1, 2020; references added. Policy statements unchanged.
December 2021	Replace policy	Policy updated with literature review through July 2, 2021; no references added. Policy statements unchanged.
December 2022	Replace policy	Policy updated with literature review through June 10, 2022; no references added. Minor editorial refinements to policy statements; intent unchanged.
December 2023	Replace policy	Policy updated with literature review through June 28, 2023; reference added. Policy statements unchanged.