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MEDICAL POLICY – 7.03.05

Small Bowel, Liver and Multivisceral Transplant

BCBSA Ref. Policy:	7.03.05	
Effective Date:	Nov. 1, 2024	RELATED MEDICAL POLICIES:
Last Revised:	Oct. 7, 2024	7.03.04 Isolated Small Bowel Transplant
Replaces:	7.03.511	

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Introduction

Food is digested and nutrients are absorbed in the intestines. If the intestines are damaged because of surgery, disease, or a birth defect, the ability to absorb nutrients and fluids may be affected. If part of the intestines is damaged, it may result in a condition called "short bowel syndrome". People with short bowel syndrome have a hard time absorbing nutrients and fluids. As a result, they may become malnourished and need to get their nutrition through "total parenteral nutrition" (TPN) in order to stay alive. TPN is liquid nutrition that is given through a vein. Long-term use of TPN can cause complications including liver damage that can lead to liver failure.

An intestinal transplant is a last-resort treatment for individuals with life-threatening complications from TPN. This policy addresses transplantation of the small bowel, the small bowel/liver together, and multivisceral transplantation that may include the stomach, duodenum, jejunum, ileum, pancreas, or colon.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Transplant	Medical Necessity
Multivisceral, small bowel and liver transplants	**Transplants, such as a multivisceral transplant and a small bowel and liver transplant, may be considered medically necessary for pediatric and adult individuals with all of the following:** • Individuals with intestinal failure ○ Characterized by loss of absorption and the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balance; **AND** • Individuals who have been managed with long-term total parenteral nutrition; **AND** • Individuals who have developed evidence of impending end-stage liver failure (e.g., total bilirubin > 3 mg/dL)
Multivisceral, small bowel and liver retransplants	**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.**

Transplant	Investigational
Other situations	**A small bowel and liver transplant, or multivisceral transplant, is considered investigational in all other situations not outlined above.**

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the relevant history and physical supporting that the individual has intestinal failure, has been managed with long-term TPN, and has developed evidence of impending end-stage liver failure. Specify if the request is for small bowel and liver and/or multivisceral organs or a retransplantation.

Coding

Code	Description
CPT	
47135	Liver allotransplantation, orthotopic, partial or whole, from cadaver or living donor, any age
HCPCS	
S2053	Transplantation of small intestine and liver allografts
S2054	Transplantation of multivisceral organs
S2152	Solid organ(s), complete or segmental, single organ or combination of organs; deceased or living donor (s), procurement, transplantation, and related complications; including: drugs; supplies; hospitalization with outpatient follow-up; medical/surgical, diagnostic, emergency, and rehabilitative services, and the number of days of pre and posttransplant care in the global definition

Related Information

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.

Contraindications

Potential contraindications for solid organ transplant 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.

Benefit Application

See individual's plan contract language for organ transplant benefits and specific benefits related to transport, lodging, and donor services. Please note limitations in coverage based on the transplant benefit, if applicable.

Evidence Review

Description

This policy addresses transplantation and retransplantation of 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.

Background

Solid organ transplantation offers a treatment option for individuals with different types of end-stage organ failure that can be lifesaving or provide significant improvements to an individual's quality of life.[1] Many advances have been made in the last several decades to reduce perioperative complications. Available data supports improvement in long-term survival as well as improved quality of life particularly for liver, kidney, pancreas, heart, and lung transplants. Allograft rejection remains a key early and late complication risk for any organ transplantation. Transplant recipients require life-long immunosuppression to prevent rejection. Individuals are prioritized for transplant by mortality risk and severity of illness criteria developed by Organ Procurement and Transplantation Network and United Network of Organ Sharing.

Small Bowel/Liver and Multivisceral Transplant

In 2023, 46,629 transplants were performed in the United States (US) procured from 39,679 deceased donors and 6,950 living donors.[2] Intestinal transplants occur less frequently than other organ transplants, with 10 or fewer individuals receiving liver-intestine transplant each year from 2008 to 2019. Small bowel and liver or multivisceral transplant are usually considered in adults and children who develop serious complications related to parenteral nutrition, including inaccessibility (e.g., due to thrombosis) of access sites, catheter-related sepsis, and cholestatic liver disease.

Short Bowel Syndrome

Short bowel syndrome is defined as an inadequate absorbing surface of the small intestine due to extensive disease or surgical removal of a large portion of the small intestine.[3] In some instances, short bowel syndrome is associated with liver failure, often due to the long-term complications of total parenteral nutrition.

Treatment

A small bowel/liver transplant or a multivisceral transplant includes the small bowel and liver with one or more of the following organs: stomach, duodenum, jejunum, ileum, pancreas, and/or colon. The type of transplantation depends on the underlying etiology of intestinal failure, quality of native organs, presence or severity of liver disease, and history of prior

abdominal surgeries.[4] A multivisceral transplant is indicated when anatomic or other medical problems preclude a small bowel/liver transplant. Complications following small bowel/liver and multivisceral transplants include acute or chronic rejection, donor-specific antibodies, infection, lymphoproliferative disorder, graft-versus-host disease, and renal dysfunction.[5]

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. The relevant outcomes are overall survival, 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 individuals who exhaust all other treatments, transplantation may prove not only to be the last option but also a beneficial one. Transplantation is contraindicated for individuals 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. The relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. Although limited in quantity, the available post retransplantation data have suggested reasonably high survival rates. Given the exceedingly poor survival rates without retransplantation of individuals 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 individuals. Retransplantation is contraindicated for individuals 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.

Ongoing and Unpublished Clinical Trials

A search of **ClinicalTrials.gov** in July 2024 did not identify any ongoing or unpublished trials that would likely influence this review.

Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.

Guidelines or position statements will be considered for inclusion 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 individuals with life-threatening complications due to intestinal failure or long-term 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 individuals 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.

Medicare National Coverage

Medicare covers intestinal transplantation for the purposes of restoring intestinal function in individuals with irreversible intestinal failure only when performed for individuals 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 actuarial survival rate of 65 percent."

Regulatory Status

Small bowel/liver and multivisceral transplantation are surgical procedures and, as such, are not subject to regulation by the US 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.

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History

Date	Comments
11/01/19	New policy, approved October 4, 2019. This policy replaces policy 7.03.511 which is now deleted. Policy created with literature review through June 2019. Multivisceral, small bowel, and liver transplants may be considered medically necessary when criteria are met, considered investigational in all other situations not outlined in the medical necessity criteria. Policy statement on transplantation of HCV viremic organs is taken from BCBSA policy 7.03.14.
11/01/20	Annual Review, approved October 22, 2020. Policy updated with literature review through July, 2020; references added. Policy statements unchanged.
11/01/21	Annual Review, approved October 5, 2021. Policy updated with literature review through July 2, 2021; no references added. Policy statements unchanged.
11/01/22	Annual Review, approved October 10, 2022. Policy updated with literature review through June 10, 2022; no references added. Minor editorial refinements to policy statements; intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
11/01/23	Annual Review, approved October 9, 2023. Policy updated with literature review through June 28, 2023; reference added. Removed the policy statement regarding the

Date	Comments
	transplantation of HCV-viremic solid organs to an HCV non-viremic recipient combined with direct-acting antiviral treatment for HCV is considered investigational. Otherwise, policy statements unchanged.
11/01/24	Annual Review, approved October 7, 2024. Policy updated with literature review through July 8, 2024; no references added. Policy statements unchanged.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.