

MEDICAL POLICY – 7.03.04

Isolated Small Bowel Transplant

BCBSA Ref. Policy: 7.03.04

Effective Date: Nov. 1, 2024

Last Revised: Oct. 7, 2024


Replaces: 7.03.511

RELATED MEDICAL POLICIES:

7.03.05 Small Bowel/Liver and Multivisceral Transplant

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Introduction

An organ transplant is the surgical process of replacing a severely diseased organ with a healthy one from a donor. The donated organ can come from a living person or a person who passed away from an accident or illness. Organ failure is the most common reason a transplant is needed. Organ failure can occur because of illness, injury, or birth defect. There are many factors that go into finding a donor organ that matches. These include blood type and the size of the organ. Other factors include how long a person has been on the waiting list, the level of illness, and the distance the donated organ must be transported. This policy describes when transplanting a small bowel may be considered medically necessary. This policy notes that a plan physician will review solid organ transplant requests together with the criteria of the transplant center.

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
<p>Small bowel transplant using cadaveric intestine</p>	<p>A small bowel transplant using cadaveric intestine may be considered medically necessary in adult and pediatric individuals with All of the following:</p> <ul style="list-style-type: none"> • Individuals with intestinal failure <ul style="list-style-type: none"> ○ Characterized by loss of absorption and the inability to maintain protein-energy, fluid, electrolyte, or micro nutrient balance; <p>AND</p> <ul style="list-style-type: none"> • Individuals who have established long-term dependence on total parenteral nutrition (TPN); <p>AND</p> <ul style="list-style-type: none"> • Individuals who are developing or have developed severe complications due to TPN
<p>Small bowel transplant using a living donor</p>	<p>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.</p> <p>A small bowel transplant using living donors is considered not medically necessary in all other situations.</p>
<p>Small bowel retransplant</p>	<p>A small bowel retransplant may be considered medically necessary after a failed primary small bowel transplant.</p>

Transplant	Investigational
<p>Small bowel transplant</p>	<p>A small bowel transplant is considered investigational for adult and pediatric individuals with intestinal failure who can tolerate TPN.</p>

Documentation Requirements
<p>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:</p> <ul style="list-style-type: none"> • Office visit notes that contain the relevant history and physical supporting that individual has intestinal failure, has had long-term dependence on TPN, and has now developed severe complications due to the TPN. Specify if the request is for cadaveric, living donor, or retransplantation



Coding

Code	Description
CPT	
44135	Intestinal allotransplantation; from cadaver donor
44136	Intestinal allotransplantation; from living donor.
HCPCS	
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

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Related Information

Small Bowel-Specific Criteria

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 one cause of intestinal failure.

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 the 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.



Contraindications

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

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

A small bowel transplant may be performed as an isolated procedure or in conjunction with other visceral organs, including the liver, duodenum, jejunum, ileum, pancreas, or colon. An isolated small bowel transplant is commonly performed in individuals with short bowel syndrome. Small bowel/liver transplants and multivisceral transplants are considered in a [Related Policy](#).



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 the Organ Procurement and Transplantation Network and United Network of Organ Sharing (UNOS).

Short Bowel Syndrome

Short bowel syndrome is a condition in which the absorbing surface of the small intestine is inadequate due to extensive disease or surgical removal of a large portion of the small intestine. The spectrum of clinical disease is widely variable from only single micronutrient malabsorption to complete intestinal failure, defined as the reduction of gut function below the minimum necessary for the absorption of macronutrients and/or water and electrolytes.² In adults, etiologies of short bowel syndrome include ischemia, trauma, volvulus, and tumors. In children, gastroschisis, volvulus, necrotizing enterocolitis, and congenital atresia are predominant causes. Although the actual prevalence of short bowel syndrome is not clear primarily due to under-reporting and a lack of reliable individual databases, its prevalence is estimated to be 30 cases per million in the United States (US).²

Treatment

The small intestine, particularly the ileum, can adapt to some functions of the diseased or removed portion over a period of one to two years. Prognosis for recovery depends on the degree and location of small intestine damage. Therapy focuses on achieving adequate macro- and micronutrient uptake in the remaining small bowel. Pharmacologic agents have been studied to increase villous proliferation and slow transit times, and surgical techniques have been advocated to optimize remaining small bowel.

However, some individuals with short bowel syndrome are unable to obtain adequate nutrition from enteral feeding and become chronically dependent on total parenteral nutrition (TPN). For individuals with short bowel syndrome, the rate of parenteral nutrition dependency at one, two,



and five years has been reported to be 74%, 64%, and 48%, respectively.² Individuals with complications from total parenteral nutrition may be considered candidates for a small bowel transplant. Complications include catheter-related mechanical problems, infections, hepatobiliary disease, and metabolic bone disease. While cadaveric intestinal transplant is the most commonly performed transplant, there has been a recent interest in using living donors.

Intestinal transplants (including multivisceral and bowel/liver) represent a small minority of all solid organ transplants. In 2023, 95 intestinal transplants were performed in the US.³ The number of new patients added to the intestinal transplant waiting list as of June 27, 2024 was 192.

Summary of Evidence

For individuals who have intestinal failure who receive a small bowel transplant, the evidence includes case series. The relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. Small bowel transplants are infrequently performed, and only relatively small case series, generally single-center, are available. Risks after small bowel transplant are high, particularly related to infection, but may be balanced against the need to avoid the long-term complications of TPN dependence. In addition, early small bowel transplant may obviate the need for a later combined liver/small bowel transplant. Transplantation is contraindicated in individuals in whom the procedure is expected to be futile due to comorbid disease or in whom posttransplantation care is expected to worsen comorbid conditions significantly. Guidelines and US federal policy no longer view human immunodeficiency virus infection as an absolute contraindication for solid organ transplantation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have failed small bowel transplant without contraindication(s) for retransplant who receive a small bowel retransplant, the evidence includes case series. The relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. Data from a small number of individuals undergoing retransplantation are available. Although limited in quantity, the available data have suggested a reasonably high survival rate after small bowel retransplantation in individuals who continue to meet the criteria for transplantation. 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](https://clinicaltrials.gov) in June 2024 did not identify any ongoing or unpublished trials that would likely influence this policy.

Clinical Input Received from Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

In response to requests, input was received from two physician specialty societies and two academic medical centers while this policy was under review in 2009. The consensus of those providing input was that small bowel transplant should be performed in individuals who are developing severe TPN-related complications and that small bowel transplant from living donors may be considered when cadaveric intestinal transplants are not available.

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. 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) produced a medical position statement on short bowel syndrome and intestinal transplantation.³¹ 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 a transplant for these individuals. The statement recommended the following Medicare-approved indications, pending availability of additional data:

1. "Impending or overt liver failure...
2. Thrombosis of major central venous channels...
3. Frequent central line-related sepsis...
4. Frequent severe dehydration."

The AGA published an expert review on management of short bowel syndrome in 2022.³² Their best practice statements mirror the CMS recommendations, stating that individuals with short bowel syndrome and intestinal failure experiencing TPN complications should be referred early for intestinal transplantation consideration. They state that individuals with short bowel syndrome and intestinal failure with high morbidity or low acceptance of TPN should also be considered for early listing for intestinal transplantation on a case-by-case basis.

American Society of Transplantation

In 2001, the American Society of Transplantation issued a position paper on indications for pediatric intestinal transplantation.³³ The Society listed the following disorders in children as 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

The Centers for Medicare & Medicaid have a national coverage determination on intestinal and multivisceral transplantation. The determination covers these types of transplants only when performed for individuals who have failed TPN and only when performed in centers that meet approval criteria.

1. Failed TPN



The TPN delivers nutrients intravenously, avoiding the need for absorption through the small bowel. TPN failure includes the following:

- Impending or overt liver failure due to TPN induced liver injury.
- Thrombosis of the major central venous channels; jugular, subclavian, and femoral veins.
- Frequent line infection and sepsis.
- Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN.

2. Approved Transplant Facilities

The criteria for approval of centers will be based on a volume of 10 intestinal transplants per year with a one year actuarial survival of 65 percent using the Kaplan-Meier technique."³⁴

Regulatory Status

Solid organ transplants are a surgical procedure 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. A cadaveric or living donor small bowel transplant may be considered medically necessary when criteria are met. 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 June 2020; references added. Policy statements unchanged.
11/01/21	Annual Review, approved October 5, 2021. Policy updated with literature review through June 14, 2021; no references added. Policy statements unchanged.
11/01/22	Annual Review, approved October 10, 2022. Policy updated with literature review through June 9, 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 14, 2023; references added. Minor editorial refinements to policy statements; intent unchanged. 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.
11/01/24	Annual Review, approved October 7, 2024. Policy updated with literature review through June 27, 2024; no references added. Policy statements unchanged.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2024 Premera All Rights Reserved.

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.

