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Isolated Small Bowel Transplant

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Coverage

A small bowel transplant using cadaveric intestine **may be considered medically necessary** in adult and pediatric individuals with intestinal failure (characterized by loss of absorption and the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balance), who have

established long-term dependence on total parenteral nutrition (TPN) and are developing or have developed severe complications due to TPN.

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.

A small bowel retransplant **may be considered medically necessary** after a failed primary small bowel transplant.

A small bowel transplant using living donors **is considered not medically necessary** in all other situations.

A small bowel transplant **is considered experimental, investigational and/or unproven** for adult and pediatric individuals with intestinal failure who can tolerate TPN.

Policy Guidelines

General Criteria

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.

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 1 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.

Description

Solid Organ Transplantation
Solid organ transplantation offers a treatment option for patients with different types of end-stage organ failure that can be lifesaving or provide significant improvements to a patient's quality of life. (1) Many advances have been made in the last several decades to reduce perioperative complications. Available data support 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. Patients are prioritized for transplant by mortality risk and severity of illness criteria developed by the Organ Procurement and Transplantation Network (OPTN) 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 patient databases, its prevalence is estimated to be 30 cases per million in the U.S. (2)

<u>Treatment</u>
The small intestine, particularly the ileum, can adapt to some functions of the diseased or removed portion over a period of 1 to 2 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 patients with short bowel syndrome are unable to obtain adequate nutrition from enteral feeding and become chronically dependent on total parenteral nutrition (TPN). For patients with short bowel syndrome, the rate of parenteral nutrition dependency at 1, 2, and 5 years has been reported to be 74%, 64%, and 48%, respectively. (2) Patients with complications from TPN 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 2024, 97 intestinal transplants were performed in the U.S. (3) The number of patients on the intestinal transplant waiting list as of July 16, 2025, was 174.

Regulatory Status
Solid organ transplants are a surgical procedure 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

Medical policies assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent 1 or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Small Bowel Transplantation
Clinical Context and Therapy Purpose
The purpose of a small bowel transplant in individuals who have an intestinal failure is to provide a treatment option that is an alternative to or an improvement on existing therapies.

Parenteral nutrition has been a mainstay of therapy for individuals with intestinal failure for decades. (4) Medical advances have resulted in improved survival in individuals who are parenteral nutrition-dependent, primarily through an increased likelihood of weaning (i.e., achieving enteral autonomy) and reduced rates and progression of intestinal failure-associated liver disease and other life-threatening complications of prolonged parenteral nutrition administration.

The following PICO was used to select literature to inform this policy.

Populations
The relevant population of interest is individuals with intestinal failure.

Interventions
The therapy being considered is a small bowel transplant.

Comparators
The following practices are currently being used to make decisions about intestinal failure: medical management and parenteral nutrition.

Outcomes
The general outcomes of interest are overall survival (OS) and treatment-related adverse events (e.g., immunosuppression, graft failure, surgical complications, infections). See the Adverse Events section for a detailed discussion of potential negative outcomes. Short-term follow-up ranges from immediately postsurgery to 30 days posttransplantation; lifelong follow-up (out to 10 years or more given current survival data) is necessary due to ongoing immunosuppressive drugs and risk of graft failure.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Case Series
The majority of the published literature consists of case series, mainly reported by single centers in the United States, Japan, and Europe. Tables 1 and 2 summarize the characteristics and results of these case series, respectively. Many case series have included small bowel/liver transplantations and multivisceral transplantations (which are the focus of medical policy SUR703.009).

The main reason for transplantation across case series was short bowel syndrome. Other reasons included congenital enteropathies and motility disorders. The most commonly reported outcomes were survival rates and weaning off total parenteral nutrition (TPN). Several studies have presented survival rates by type of transplantation, while others have combined multiple types of transplants when reporting survival rates. When rates were reported by type of transplant, isolated transplantations had higher survival rates than multivisceral transplants (Table 2).

Several investigators have reported higher survival rates in transplantations conducted more recently than those conducted earlier. (5, 6) Reasons for improved survival rates in more recent years have been attributed to the development of more effective immunosuppressive drugs and the learning curve for the complex procedure.

Sudan (2010) published a review of the literature on long-term outcomes after intestinal transplantation. (7) Sudan noted that intestinal transplantation had become standard therapy for patients with life-threatening complications from parenteral nutrition therapy. Data from current single center series have indicated 1-year patient survival rates between 78% and 85% and 5-year or more survival rates between 56% and 61%. Concerning pediatric intestinal transplant patients, most achieve normal growth velocity at 2 years posttransplant. However, oral aversion is common; tube feedings are necessary for 45% of children. Sudan also reported on parental surveys of quality of life for pediatric transplant patients in which intestinal transplant patients appear to have modestly improved quality of life compared with those remaining on TPN and slightly worse than matched school-age controls without intestinal disease.

Authors of these series, as well as related reviews, have observed that while outcomes have improved over time, recurrent and chronic rejection and complications of immunosuppression continue to be obstacles to long-term survival. A separate discussion of adverse events follows the evidence tables.

Table 1. Summary of Key Case Series Characteristics for Transplantations

Study	Location	N	Median Age (Range), y	Interventions		Follow-Up (Range), mo
				Treatment	**n**	
Lacaille et al. (2017) (8)	France	110	5.3 (0.4 to 19)	• Isolated IT • Combined liver IT • Multivisceral graft	• 60 • 45 • 5	Of 55 alive: • 17 at <5 y • 17 at 5-10 y • 21 at ≥10 y
Garcia Aroz et al. (2017) (9)	U.S.	10	1.5 (0.7 to 13)	• Isolated IT • Combined liver IT	• 7 • 3	6/7 alive at follow-up ≥10 y

Dore et al. (2016) (10)	U.S.	30	0.2 (0.1 to 18)	• Isolated IT • Combined liver IT • Multivisceral graft	• 6 • 6 • 18	28 (4 to 175)
Rutter et al. (2016) (11)	U.K.	60	1.8 (0 to 8)	• Isolated IT • Multivisceral graft • Modified multivisceral	• 16 • 35 • 9	21.3 (0 to 95)
Lauro et al. (2014) (12)	Italy	46	34 (NR)	• Isolated IT • Combined liver IT • Multivisceral graft	• 34 • 6 • 6	51.3
Ueno et al. (2014) (5)	Japan	24[b]	0-2 y: 6[c] 3-6 y: 6 7-18 y: 8 ≥19 y: 4	• Isolated IT • Combined liver IT	• 23 • 1	NR
Benedetti et al. (2006) (6)[a]	U.S.	11	27 (1.5 to 50)	• Isolated IT	• 11	NR

IT: intestinal transplantation; mo: months(s); n/N: number; NR: not reported; U.K.: United Kingdom; U.S.: United States; y: year.

[a] All living donors.

[b] Twelve living donors and 12 cadaveric donors.

[c] Reported as age range and n.

Table 2. Summary of Key Case Series Results for Transplantations

Study	**Interventions**		**Survival**		**Off Total Parenteral Nutrition**	
	Treatment	**n**	**Years**	**%**	**Measure**	**%**
Lacaille et al. (2017) (8)	• Isolated IT • Combined liver IT • Multivisceral graft	• 60 • 45 • 5	OS at 10 Patient survival for liver-containing grafts at 10 and 18 Patient survival for isolated IT	• 52 • 48; 45 • 59; 56	All combined at last FU	73

			at 10 and 18			
Garcia Aroz et al. (2017) (9)[a]	• Isolated IT • Combined liver IT	• 7 • 3	All combined	70	All combined at last FU	100
Dore et al. (2016) (10)	• Isolated IT • Combined liver IT • Multivisceral graft	• 6 • 6 • 18	• 9 • 10 • 2.5	• 83 • 33 • 67	All combined: • In 31 days • At last FU	 • 71 • 62
Rutter et al. (2016) (11)	• Isolated IT • Multivisceral graft • Modified multivisceral	• 16 • 35 • 9	• 1 • 5	• 92; 71; • 85 83; • 33: 65		NR
Lauro et al. (2014) (12)	• Isolated IT • Combined liver IT • Multivisceral graft	• 34 • 6 • 6	All combined: • 1 • 3 • 5 • 10	 • 77 • 58 • 53 • 37		NR
Ueno et al. (2014) (5)[b]	• Isolated IT • Combined liver IT	• 23 • 1	All combined: • 1 • 5	 • 86 • 68		80
Benedetti et al. (2006) (6)[a]	• Isolated IT	• 11	• 1 • 3	• 82 • 82		100

FU: follow-up; IT: intestinal transplantation; n/N: number; NR: not reported; OS: overall survival.
[a] All living donors.
[b] Twelve living donors and 12 cadaveric donors.

Adverse Events

Systematic Reviews

One issue discussed in intestinal transplantation literature is an earlier referral to avoid combined liver and intestine transplantation. (13) It has been suggested that removing the restriction on intestinal transplantation to patients who have severe complications from TPN and recommending earlier transplantation may improve survival. However, in a review of the status of intestinal transplantation, Vianna et al. (2008) identified no randomized trials that compared intestinal transplantation with long-term TPN; therefore, optimal timing for earlier transplantation has not been established. (14)

Case Series

Wu et al. (2016) investigated the incidence and risk factors of acute antibody-mediated rejection (ABMR) among patients undergoing intestinal transplantation (N=175). (15) The mean age of enrolled patients was 25 years. Acute ABMR was diagnosed by clinical evidence; histologic evidence of tissue damage; focal or diffuse linear C4d deposition; and circulating anti-human leukocyte antigen antibodies. Of the 175 intestinal transplants, 58% were liver-free small intestine grafts, 36% included a liver graft, and 6.3% were retransplantations. Eighteen cases of acute ABMR were identified, 14 (14%) among the patients undergoing first liver-free transplantation, 2 (3%) among patients undergoing liver/small bowel transplantation, and 2 (18%) among the patients undergoing retransplantation. Graft failure occurred in 67% of patients with acute ABMR. The presence of a donor-specific antibody and a liver-free graft were associated with the development of acute ABMR.

Florescu et al. (2012) have published several retrospective reviews of complications in a cohort of 98 pediatric patients. Twenty-one (21.4%) of these children had an isolated small bowel transplant; the remainder had combined transplants. Their 2012 study reported that 68 (69%) of the 98 patients developed at least 1 episode of bloodstream infection. (16) Among patients with an isolated small bowel transplant, the median time to infection for those who developed one was 4.5 months (95% confidence interval [CI], 2.4 to 6.7 months). Also in 2012, these researchers reported that 7 (7%) of 98 patients developed cytomegalovirus disease; only 1 had an isolated small bowel transplant. (17) Florescu et al. (2010) previously reported that, in 25 (25.5%) of 98 cases reviewed who developed at least 1 episode of fungal infection, *Candida* infection was most common. (18) Mortality rates did not differ significantly between patients who did (32.3%) and did not develop a fungal infection (29.8%; p=.46).

Other series have reported on renal failure after intestinal transplantation. For example, Calvo Pulido et al. (2014) reported on 21 adults who underwent intestinal transplantation; 17 were isolated small bowel transplants. (19) Thirteen (62%) patients experienced renal failure; the etiology included high ileostomy output, immunosuppression, and medical treatment. Boyer et al. (2013) reported that 7 of 12 children who had an isolated small bowel transplant developed renal function complications at some point after surgery. (20) Before treatment, all patients had normal renal functioning.

Living Donor Transplants

Cadaveric intestines are most commonly used, but recently there has been an interest in using a portion of intestine harvested from a living, related donor. Potential advantages of a living donor include the ability to plan the transplantation electively and better antigen matching, leading to improved management of rejection. Case reports from the 1990s have reported on 1 or 2 patients with different lengths of the ileum or jejunum. (21-24) While there appear to be few complications to the donors, of the 6 cases reported, 5 recipients remain on TPN for at least part of their caloric intake. One patient was weaned off TPN.

Tables 1 and 2 provide details on case series that used living donors (Garcia Aroz et al. [2017], [9] Ueno et al. [2014], [5] and Benedetti et al. [2006] [6]). In general, survival rates of recipients with living donors are comparable to rates for recipients of cadaveric donations. Living related

donors were reported to have an uneventful recovery. Weight loss and diarrhea were reported among donors, but recovery was without complications.

Human Immunodeficiency Virus-Positive Transplant Recipients

The 2013 HIV Organ Policy Equity Act in the U.S. permitted scientists to carry out research into organ donations from a person with HIV to another HIV-infected person. (25) In 2015, the Organ Procurement and Transplant Network (OPTN) updated its policies to be consistent with the HIV Organ Policy Equity Act. (26) The OPTN and United Network for Organ Sharing (UNOS) policies specify that organs from HIV-positive patients be used only for HIV-positive transplant recipients.

Current OPTN policy permits HIV-positive transplant candidates. (27)

The British HIV Association and the British Transplantation Society (2017) updated their guidelines on kidney and pancreas transplantation in patients with HIV disease. (28) These criteria may be extrapolated to other organs:

- Adherent with treatment, particularly antiretroviral therapy;
- Cluster of differentiation 4 count greater than 100 cells/mL (ideally >200 cells/mL) for at least 3 months;
- Undetectable HIV viremia (<50 HIV-1 RNA copies/mL) for at least 6 months;
- No opportunistic infections for at least 6 months;
- No history of progressive multifocal leukoencephalopathy, chronic intestinal cryptosporidiosis, or lymphoma.

Section Summary: Small Bowel Transplantation

Small bowel transplant is 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. Guidelines and U.S. federal policy no longer view HIV infection as an absolute contraindication for solid organ transplantation.

Small Bowel Retransplantation

Clinical Context and Therapy Purpose

The purpose of small bowel retransplants in individuals who have failed a small bowel transplant and do not have contraindication(s) for retransplant is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this policy.

Populations

The relevant population of interest is individuals who have failed a small bowel transplant and do not have contraindication(s) for retransplant.

Interventions
The therapy being considered is a small bowel retransplant.

Comparators
The following practices are currently being used to make decisions about the intestinal failure of an initial small bowel transplant: medical management and parenteral nutrition.

Outcomes
The general outcomes of interest are OS and treatment-related adverse events (e.g., immunosuppression, graft failure, surgical complications, infections). See the Adverse Events section for initial transplants for a detailed discussion of potential negative outcomes. Short-term follow-up ranges from immediately postsurgery to 30 days posttransplantation; lifelong follow-up (out to 10 years or more given current survival data) is necessary due to ongoing immunosuppressive drugs and risk of graft failure.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs.
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Case Series
A few case series from single institutions and a single analysis of data from the UNOS database have provided evidence on the use of retransplantation in patients who failed primary small bowel transplant. Case series characteristics and results are detailed in Tables 3 and 4, respectively.

Desai et al. (2012) have published the most comprehensive reporting of outcomes after a repeat small bowel transplant in the U.S. (29) The authors evaluated data for patients in the UNOS database who underwent small bowel transplants in the U.S. between 1987 and 2009.

Table 3. Summary of Key Case Series Characteristics for Retransplantations

Study	Location	N	Median Age (Range), y	Interventions		Follow-Up (Range), mo
				Treatment	n	
Lacaille et al. (2017) (8)	France	10	13 (5 to 16)	• Isolated IT • Combined liver IT	• 3 • 7	4

Desai et al. (2012) (29)	U.S.	72 adults 77 children	NR	Adults: • Isolated IT • Combined liver IT Children • Isolated IT • Combined liver IT	 • 41 • 31 • 28 • 49	NR
Abu-Elmagd et al. (2009) (30)	U.S.	47	NR	• Isolated IT • Combined liver IT • Multivisceral graft	• 31 • 7 • 9	NR

IT: intestinal transplantation; mo: month(s); n/N: number; NR: not reported; U.S.: United States; y: year(s).

Table 4. Summary of Key Case Series Results for Retransplantations

Study	**Interventions**		**Survival**		**Off TPN**
	Treatment	**n**	**Years**	**%**	
Lacaille et al. (2017) (8)	• Isolated IT • Combined liver IT	• 3 • 7	All combined at last follow-up:	30	NR
Desai et al. (2012) (29)	Adults: • Isolated IT • Combined liver IT Children • Isolated IT • Combined liver IT	 • 41 • 31 • 28 • 49	Adults: • 1/3/5 • 1/3/5 Children: • 1/3/5 • 1/3/5	 • 80/47/29 • 63/56/47 • 81/74/57 • 42/42/42	NR
Abu-Elmagd et al. (2009) (30)	• Isolated IT • Combined liver IT • Multivisceral graft	• 31 • 7 • 9	All combined: • 1 • 5	 • 69 • 47	NR

IT: intestinal transplantation; n: number; NR: not reported; TPN: total parenteral nutrition.

Section Summary: Small Bowel Retransplantation

Data from a small number of patients undergoing retransplantation are available. Although limited in quantity, the available data have suggested reasonably high survival rates after small bowel retransplantation in patients who continue to meet the criteria for transplantation.

Summary of Evidence

For individuals who have intestinal failure who receive a small bowel transplant, the evidence includes case series. Relevant outcomes are overall survival (OS), morbid events, and treatment-related mortality and morbidity. Small bowel transplant is 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 total parenteral nutrition (TPN) dependence. In addition, early small bowel transplant may obviate the need for a later combined liver/small bowel transplant. Transplantation is contraindicated in patients 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 U.S. federal policy no longer view HIV 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. Relevant outcomes are OS, morbid events, and treatment-related mortality and morbidity. Data from a small number of patients undergoing retransplantation are available. Although limited in quantity, the available data have suggested a reasonably high survival rate after small bowel retransplantation in patients 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.

Practice Guidelines and Position Statements

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 (CMS). The guidelines acknowledged the limitations of a transplant for these patients. The statement recommended the following Medicare-approved indications, pending availability of additional data:

- "Impending or overt liver failure...
- Thrombosis of major central venous channels...
- Frequent central line-related sepsis...
- 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 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.

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 patients 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 1-year actuarial survival of 65 percent using the Kaplan-Meier technique." (34)

Ongoing and Unpublished Clinical Trials

A search of ClinicalTrials.gov in July 2025 did not identify any ongoing or unpublished trials that would likely influence this policy.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	44132, 44133, 44135, 44136, 44137, 44715, 44720, 44721
HCPCS Codes	S2152

*Current Procedural Terminology (CPT®) ©2024 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been changed since this medical policy document was written. See Medicare's National Coverage at <https://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
12/15/2025	Document updated. Coverage unchanged. No new references added; some updated.
10/15/2024	Reviewed. No changes.
04/15/2024	Document updated with literature review. The following change was made to Coverage: “A small bowel transplant using a living donor is considered not medically necessary when a cadaveric intestine is available for transplantation” to “A small bowel transplant using living donors is considered not medically necessary in all other situations”. Added reference 32; other(s) updated.
10/15/2022	Reviewed. No changes.
01/01/2022	Document updated with literature review. Coverage unchanged. The following references were added/updated: 1-4, 29 and 36.
10/15/2020	Reviewed. No changes.
01/15/2020	Document updated with literature review. Coverage unchanged. The following references were added/updated: 1, 7-11, 14, 24-27, 29, and 31.
10/15/2018	Reviewed. No changes.
06/01/2017	Document updated with literature review. Coverage unchanged.
11/01/2016	Reviewed. No changes.

08/01/2015	Document updated with literature review. The following was added to the coverage section: 1) A small bowel retransplant may be considered medically necessary after a failed primary small bowel transplant; and, 2) A small bowel transplant is considered experimental, investigational and/or unproven for pediatric patients with intestinal failure who are able to tolerate total parenteral nutrition.
10/01/2013	Document updated with literature review. The following changes were made to coverage: 1) “short bowel syndrome” changed to “intestinal failure”. 2) Intestinal failure defined. 3) A small bowel transplant using a living donor may be considered medically necessary only when a cadaveric intestine is not available for transplantation in a patient who meets the criteria noted above for a cadaveric intestinal transplant. 4) A small bowel transplant using a living donor is considered not medically necessary when a cadaveric intestine is available for transplantation. 5) Note added referencing policy on small bowel/liver transplants and multivisceral transplants. Title changed from: Small Bowel Transplant. CPT/HCPCS codes updated.
07/01/2004	Document updated
02/01/2002	CPT/HCPCS codes updated
06/01/2001	CPT/HCPCS codes updated
03/01/2000	Document updated
09/01/1998	Document updated
05/01/1996	Document updated
04/01/1996	Document updated
07/01/1992	New policy