Policy Number	**SUR703.009**
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Small Bowel/Liver and Multivisceral Transplant

Table of Contents

Related Policies (if applicable)
SUR703.001: Organ and Tissue Transplantation (General Donor and Recipient Information)

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Coverage

A small bowel/liver transplant or multivisceral 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 (TPN) and who have developed evidence of impending end-stage liver failure.

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

A small bowel/liver transplant or multivisceral transplant **is considered experimental, investigational and/or unproven** 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.

Description

This medical policy 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.

Background

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 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. Patients 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 2024, 48,149 transplants were performed in the United States procured from 41,119 deceased donors and 7,030 living donors. (2) Intestinal transplants occur less frequently than other organ transplants, with 10 or fewer patients receiving liver-intestine transplant each year from 2008 to 2019. Small bowel and liver or multivisceral transplant is 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 1 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)

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

Medical policies assess the clinical evidence to determine whether the use of a 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 to 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 the 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.

Transplantation of Small Bowel and Liver or Multivisceral Organs

Clinical Context and Therapy Purpose

The purpose of small bowel and liver transplant alone or multivisceral transplant in individuals who have intestinal failure and evidence of impending end-stage liver failure 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 with intestinal failure and evidence of impending end-stage liver failure.

Interventions

The therapy being considered is small bowel and liver transplant alone or multivisceral transplant.

Comparators

The following practices are currently being used to make decisions about intestinal failure and evidence of impending end-stage liver failure: medical management and parenteral nutrition.

Outcomes
The general outcomes of interest are overall survival (OS), morbid events, and treatment-related mortality and morbidity, including short- and long-term graft survival and 1- and 5-year OS.

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.
- Within each category of study design, studies with larger sample sizes and longer duration were preferred.
- Studies with duplicative or overlapping populations were excluded.

Registry Studies and Case Series
The published literature consists of a registry study and case series, mainly reported by single centers in the U.S. and Europe. Tables 1 and 2 summarize the characteristics and results of these publications, respectively. Many case series have included isolated small bowel transplantations (see medical policy SUR703.014).

Reasons for transplantations were mainly short bowel syndrome. Other reasons included congenital enteropathies and motility disorders. Outcomes most commonly reported were survival rates and weaning off total parenteral nutrition (TPN). Several studies have presented survival rates by type of transplantation, while others have combined all or some types of transplants when reporting survival rates. When rates were reported by type of transplant, isolated transplantations had higher survival rates than multivisceral transplants (see Table 2).

Several investigators have reported higher survival rates in transplants conducted more recently than those conducted earlier. (6-9) 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.

Authors of these publications, 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 complications follows the evidence tables.

Table 1. Summary of Key Registry Studies and Case Series Characteristics for Transplantations

Study	Country	N	Median Age (Range), y	Interventions		Follow-Up (Range)
				Treatment	n	
Raghu et al. (2019) (9)	International	2080	2.5 (1.1-6.3)	• Isolated ITx • Combined liver ITx • Multivisceral graft (including modified [intestine and stomach without liver] and full [intestine, stomach, and liver])	• 725 • 966 • 389	5 y
Lacaille et al. (2017) (10)	France	110	5.3 (0.4-19)	• Isolated ITx • Combined liver ITx • Multivisceral graft	• 45 • 60 • 5	Of 55 alive: • 17 at <5 y • 17 at 5-10 y • 21 at ≥ 10 y
Garcia Aroz et al. (2017) (11)[a]	U.S.	10	1.5 (0.7-13)	• Isolated ITx • Combined liver ITx	• 7 • 3	6/7 alive at ≥ 10 y
Dore et al. (2016) (12)	U.S.	30	0.2 (0.1-18)	• Isolated ITx • Combined liver ITx • Multivisceral graft	• 6 • 6 • 18	28 (4-175) mo
Rutter et al. (2016) (13)	U.K.	60	1.8 (0-8)	• Isolated ITx • Combined liver ITx • Modified multivisceral	• 16 • 35 • 9	21.3 (0-95) mo
Lauro et al. (2014) (14)	Italy	46	34 (NR)	• Isolated ITx • Combined liver ITx	• 34 • 6 • 6	51.3 mo

				• Multivisceral graft		
Varkey et al. (2013) (15)	Sweden	20	• Adults: 44 (20-67) • Children: 6 (0.5-13)	• Isolated ITx • Combined liver ITx • Multivisceral graft	• 4 • 1 • 15	NR
Mangus et al. (2013) (6)	U.S.	100	• Adults: 48 (NR to 66) • Children: 1 (0.6 to NR)	• Multivisceral graft • Modified multivisceral	• 84 • 16	25 mo

ITx: intestinal transplantation; mo: month(s); NR: not reported; U.S.: United States; y: year(s).
[a] Living donors.

Table 2. Summary of Key Registry Studies and Case Series Results for Transplantations

Study	Interventions		Survival	Off TPN
	Treatment	**n**		
Raghu et al. (2019) (9)	• Isolated ITx • Combined liver ITx • Multivisceral graft (including modified [intestine and stomach without liver] and full [intestine, stomach, and liver])	• 725 • 966 • 389	All transplantations combined: • Patient survival: 72.7% at 1 y; 57.2% at 5 y • Graft survival: 66.1% at 1 y; 47.8% at 5 y	NR
Lacaille et al. (2017) (10)	• Isolated ITx • Combined liver ITx • Multivisceral graft	• 60 • 45 • 5	• 59% at 10 y: 54% at 18 y • 48% at 10 y • NR	All treatments combined: • 73% at last follow-up
Garcia Aroz et al. (2017) (11)[a]	• Isolated ITx • Combined liver ITx	• 7 • 3	All transplantations combined: • 70%	All treatments combined: • 100% at last follow-up

Dore et al. (2016) (12)	• Isolated ITx • Combined liver ITx • Multivisceral graft	• 6 • 6 • 18	• 83% at 9 y • 33% at 10 y • 67% at 2.5 y	All treatments combined: • 71% in 31 d • 62% at last follow-up
Rutter et al. (2016) (13)	• Isolated ITx • Combined liver ITx • Modified multivisceral	• 16 • 35 • 9	• 92% at 1 y; 37% at 5 y • 71% at 1 y; 33% at 5 y • 85% at 1 y; 65% at 5 y	NR
Lauro et al. (2014) (14)	• Isolated ITx • Combined liver ITx • Multivisceral graft	• 34 • 6 • 6	All transplantations combined: • 77% at 1 y • 58% at 3 y • 53% at 5 y • 37% at 10 y	NR
Varkey et al. (2013) (15)	• Isolated ITx • Combined liver ITx • Multivisceral graft	• 4 • 1 • 15	All transplantations combined: • 78% at 1 y • 50% at 5 y	NR
Mangus et al. (2013) (6)	• Multivisceral graft • Modified multivisceral	• 84 • 16	All transplantations combined: • 72% at 1 y • 57% at 5 y	NR

d: day(s); ITx: intestinal transplantation; NR: not reported; TPN: total parenteral nutrition; y: year(s).
[a] Living donors.

Complications

Several case series have focused on complications after small bowel and multivisceral transplantation. For example, Spence et al. (2020) performed a retrospective chart review of intra-abdominal and bloodstream infections in adults undergoing intestinal or multivisceral transplant at a single center in the U.S. (16) A total of 103 adult patients (median age, 44 years) were included who received 106 intestinal or multivisceral transplants between 2003 and 2015. Intra-abdominal infection occurred in 46 (43%) patients, and concurrent bloodstream infection occurred in 6 (13%) patients. The median time to first intra-abdominal infection was 23 days (interquartile range, 10 to 48). All-cause mortality was not significantly different between patients with versus without intra-abdominal infections (p=.654).

Nagai et al. (2016) reported on cytomegalovirus (CMV) infection after intestinal or multivisceral transplantation at a single center in the U.S. (17) A total of 210 patients had either an intestinal transplant, multivisceral transplant, or modified multivisceral transplant between 2003 and 2014. The median length of follow-up was 2.1 years. Thirty-four (16%) patients developed CMV

infection at a median of 347 days after transplantation. Nineteen patients had tissue-invasive CMV disease. Cytomegalovirus infection was significantly associated with rejection (odds ratio, 2.6; p<.01) and adversely affected patient survival (hazard ratio, 2.7; p<.001). In a 2016 report from another U.S. center, Timpone et al. (2016) reported that 16 (19%) of 85 patients undergoing intestinal or multivisceral transplantation developed CMV infection a mean of 139 days (range, 14 to 243) postoperatively. (18)

Wu et al. (2016) investigated the incidence and risk factors of acute antibody-mediated rejection (ABMR) among patients undergoing intestinal transplantation (N=175). (19) All patients were 25 years of age. 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 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 and small bowel transplantations, 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.

In a series by Cromvik et al. (2016), 5 (19%) of 26 patients were diagnosed with graft-versus-host disease after intestinal or multivisceral transplantation. (20) Risk factors for graft-versus-host disease were: malignancy as a cause of transplantation; neoadjuvant chemotherapy; or brachytherapy before transplantation.

In a retrospective study, Florescu et al. (2012) reported on bloodstream infections among 98 children (>18 years) with small bowel and combined organ transplants. (21) Seventy-seven (79%) underwent small bowel transplant in combination with a liver, kidney, or kidney and pancreas, and 21 had an isolated small bowel transplant. After a median follow-up of 52 months, 58 (59%) patients had survived. The 1-year survival rate was similar in patients with combined small bowel transplant (75%) and those with isolated small bowel transplant (81%). In the first year after transplantation, 68 (69.4%) patients experienced at least 1 episode of bloodstream infection. The 1-year survival rate for patients with bloodstream infections was 72% compared with 87% in patients without bloodstream infections (p=.056 for the difference in survival in patients with and without bloodstream infections).

Wu et al. (2011) reported on 241 patients who underwent intestinal transplantation. (22) Of these, 147 (61%) had multivisceral transplants, 65 (27%) had small bowel transplants, and 29 (12%) had small bowel/liver transplants. Recipients included 151 (63%) children and 90 (37%) adults. Twenty-two (9%) patients developed graft-versus-host disease. Children younger than 5 years old were more likely to develop this condition (13.2% [16/121]) than children between 5 and 18 years (6.7% [2/30]) and adults older than 18 years (4.4% [9/90]).

Human Immunodeficiency Virus-Positive Transplant Recipients

Solid-organ transplant for patients who are human immunodeficiency virus (HIV)-positive was historically controversial, due to the long-term prognosis for HIV positivity and the impact of immunosuppression on HIV disease. No studies reporting on outcomes in HIV-positive patients who received small bowel and liver or multivisceral transplants were identified in literature reviews.

Current Organ Procurement Transplantation Network policy permits HIV-positive transplant candidates. (23)

The British HIV Association and the British Transplantation Society (2017) updated their guidelines on kidney transplantation in patients with HIV disease. (24) These criteria may be extrapolated to other organs:

- Adherent with treatment, particularly antiretroviral therapy;
- CD4 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: Transplantation of Small Bowel/Liver or Multivisceral Organs

Intestinal transplantation procedures are infrequently performed and only 1 registry study and relatively small case series, generally single-center, are available. For patients experiencing significant complications from TPN, which can lead to liver failure and repeated infections, this literature has shown reasonably high posttransplant survival rates in patients who have a high probability of death without treatment. Guidelines and U.S. federal policy no longer view HIV infection as an absolute contraindication for solid organ transplantation.

Retransplantation of Small Bowel and Liver or Multivisceral Organs

Clinical Context and Therapy Purpose

The purpose of small bowel and liver retransplant alone or multivisceral retransplant in individuals who have a failed small bowel and liver or multivisceral transplant without contraindications 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 with a failed small bowel and liver or multivisceral transplant without contraindications for retransplant.

Interventions

The therapy being considered is small bowel and liver retransplant alone or multivisceral retransplant.

Comparators
The following practices are currently being used to make decisions about failed small bowel and liver or multivisceral transplant when there are no contraindications for retransplant: medical management and parenteral nutrition.

Outcomes
The general outcomes of interest are OS, morbid events, treatment-related mortality, and treatment-related morbidity, including short- and long-term graft survival and 1- and 5-year OS.

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.
- Within each category of study design, studies with larger sample sizes and longer duration were preferred.
- Studies with duplicative or overlapping populations were excluded.

Case Series
Evidence for the use of retransplantation to treat individuals who have failed intestinal transplantations includes several case series, mostly from single institutions. The case series by Desai et al. (2012) analyzed records from the United Network for Organ Sharing (UNOS) database. (8) Among the case series described in Table 3, reasons for retransplantations included: acute rejection, chronic rejection, CMV, liver failure, lymphoproliferative disorder, and graft dysfunction. Survival rates for retransplantations are listed in Table 4.

Table 3. Summary of Key Case Series Characteristics for Retransplantations

Study	Country	N	Median Age (Range), y	Interventions		Follow-Up (Range), mo
				Treatment	n	
Ekser et al. (2018) (25)	U.S.	18[b]	27.0 (17.4)[a] (0.9 to 57)	• Isolated ITx • Modified MVT • Multivisceral graft	• 1 • 1 • 16	NR
Lacaille et al. (2017) (10)	France	10	13 (5-16)	• Isolated ITx • Combined liver ITx	• 3 • 7	4

Desai et al. (2012) (8)	U.S.	• 72 (adults) • 77 (children)	NR	Adults: • Isolated ITx • Combined liver ITx Children: • Isolated ITx • Combined liver ITx	• 41 • 31 • 28 • 49	NR
Abu-Elmagd et al. (2009) (7)	U.S.	47	NR	• Isolated ITx • Combined liver ITx • Multivisceral graft	• 31 • 7 • 9	NR
Mazariegos et al. (2008) (26)	U.S.	14	94 (3.2-22.7)	• Isolated ITx • Combined liver ITx • Multivisceral graft	• 1 • 3 • 10	55.9

ITx: intestinal transplantation; mo: month(s); MVT: multivisceral transplantation; NR: not reported; U.S.: United States; y: year(s).

[a] Mean (standard deviation).

[b] Of a cohort of 218 transplants or retransplant procedures.

Table 4. Summary of Key Case Series Results for Retransplantations

Study	Interventions		Survival	Off TPN
	Treatment	**n**		
Ekser et al. (2018) (25)	• Isolated ITx • Modified MVT • Multivisceral graft	• 1 • 1 • 16	Graft survival: • 71% at 1 y; 56% at 3 y; 44% at 5 y Patient survival: • 71% at 1 y; 47% at 3 y; 37% at 5 y	NR
Lacaille et al. (2017) (10)	• Isolated ITx • Combined liver ITx	• 3 • 7	All transplantations combined: 30% at last follow-up	NR
Desai et al. (2012) (8)	Adults: • Isolated ITx • Combined liver ITx Children: • Isolated ITx	Adults: • 41 • 31 Children: • 28	Adults: • 80% at 1 y; 47% at 3 y; 29% at 5 y • 63% at 1 y; 56% at 3 y; 47% at 5 y Children:	NR

	• Combined liver ITx	• 49	• 81% at 1 y; 74% at 3 y; 57% at 5 y • 42% at 1 y; 42% at 3 y; 42% at 5 y	
Abu-Elmagd et al. (2009) (7)	• Isolated ITx • Combined liver ITx • Multivisceral graft	• 31 • 7 • 9	All transplantations combined: • 69% at 1 y • 47% at 5 y	NR
Mazariegos et al. (2008) (26)	• Isolated ITx • Combined liver ITx • Multivisceral graft	• 1 • 3 • 10	All transplantations combined: 71% at last follow-up	100%

ITx: intestinal transplantation; MVT: multivisceral transplant; NR: not reported; TPN: total parenteral nutrition; y: year(s).

Section Summary: Retransplantation of Small Bowel and Liver or Multivisceral Organs

Evidence for retransplantations derives mostly from single-center case series, though 1 series used records from the UNOS database. Although limited in quantity, the available follow-up data after retransplantation have suggested reasonably high survival rates after small bowel and liver transplants and multivisceral retransplantation in patients who continue to meet criteria for transplantation.

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.

Practice Guidelines and Position Statements

American Gastroenterological Association

In 2003, the American Gastroenterological Association (AGA) published a position statement on short bowel syndrome and intestinal transplantation. (27) 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. (28) 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. (29) 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.

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 total parenteral nutrition and only when performed in centers that meet approved criteria. (30) The criteria for approval of centers are based on a "volume of 10 intestinal transplants per year with a 1-year actuarial survival of 65 percent."

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	44120, 44121, 44132, 44133, 44135, 44136, 44137, 44715, 44720, 44721, 44799, 47133, 47135, 47140, 47141, 47142, 47143, 47144, 47145, 47146, 47147, 47399
HCPCS Codes	S2053, S2054, S2055, S2152

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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
11/15/2025	Document updated. Coverage unchanged. No new references added.
10/15/2024	Reviewed. No changes.
02/01/2024	Document updated with literature review. Coverage unchanged. Added reference 28; others updated.
10/15/2022	Reviewed. No changes.
07/15/2021	Document updated with literature review. Coverage unchanged. The following references were added/updated: 1-3, 10 and 17.
01/15/2021	Reviewed. No changes.
02/20/2020	Document updated with literature review. Coverage unchanged. The following references were added/updated: 1-2, 7-9, 15, 20-21, and 24.
10/15/2018	Reviewed. No changes.
06/01/2017	Document updated with literature review. Coverage unchanged.
11/01/2016	Reviewed. No changes.

02/01/2016	Document updated with literature review. The following was added: A small bowel/liver transplant or multivisceral transplant is considered experimental, investigational and/or unproven in all other situations.
02/01/2014	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/liver retransplant or multivisceral retransplant may be considered medically necessary after a failed primary small bowel/liver transplant or multivisceral transplant. Title changed from: Liver, Small Bowel, and Multivisceral Transplants. CPT/HCPCS codes updated.
07/01/2004	Document updated
03/01/2000	Document updated
05/01/1996	Document updated
04/01/1996	New medical document