Subject: Small Bowel, Small Bowel/Liver and Multivisceral Transplantation
Document #: CG-UM-009
Status: Revised

Publish Date: 12/31/2024
Last Review Date: 12/16/2024

Description/Scope

This document addresses small bowel, small bowel/liver and multivisceral transplantation. A small bowel transplant, also known as intestinal transplant, is typically performed on individuals with short bowel syndrome or intestinal failure. In some instances, short bowel syndrome is associated with liver failure, often due to the long-term complications of total parenteral nutrition (TPN). These individuals may be candidates for a small bowel/liver transplant, or a multivisceral transplant.

Position Statement

Medically Necessary:

A small bowel transplant using cadaveric intestine is considered **medically necessary** for adults and children with short bowel syndrome or irreversible intestinal failure who have failed total parenteral nutrition (TPN) **and** meet the general individual selection criteria listed below.

TPN failure is defined when any **one** of the following is met:

1. Impending or overt liver failure due to TPN induced liver injury. (Clinical indicators include: increased serum bilirubin or liver enzyme levels, splenomegaly, thrombocytopenia, gastroesophageal varices, coagulopathy, stomal bleeding, hepatic fibrosis, or cirrhosis); **or**
2. Thrombosis of two or more major central venous channels (subclavian, jugular, or femoral veins). Thrombosis of two or more of these vessels is considered a life-threatening complication and TPN failure; **or**
3. Frequent central line-related sepsis. Two or more episodes of line-induced systemic sepsis per year that require hospitalization are considered TPN failure. A single episode of line-related fungemia, septic shock, or acute respiratory distress syndrome is considered TPN failure; **or**
4. Frequent episodes of severe dehydration despite TPN and intravenous fluid supplement. Under certain medical conditions such as secretory diarrhea and non-constructable gastrointestinal tract, the loss of combined gastrointestinal and pancreatobiliary secretions exceed the maximum intravenous infusion rates that can be tolerated by the cardiopulmonary system.

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.

Combined small bowel/liver transplants from deceased donors are considered **medically necessary** for adults and children who meet criteria for intestinal transplant **and** have overt or imminent liver failure or anatomical abnormalities which preclude an isolated

small bowel transplant.

Multivisceral transplants from deceased donors are considered **medically necessary** for adults and children who meet criteria for the combined small bowel/liver transplant **and** require one or more abdominal visceral organs to be transplanted due to concomitant organ failure or anatomical abnormalities which preclude a small bowel/liver transplant.

Retransplantation in individuals with graft failure of an initial small bowel, small bowel/liver, or multivisceral transplant, due to either technical reasons or hyperacute rejection is considered **medically necessary.**

Retransplantation in individuals with chronic rejection or recurrent disease is considered **medically necessary** when the individual meets general selection criteria as defined below.

Not Medically Necessary:

A small bowel transplant in adults or children is considered **not medically necessary** for those who can tolerate TPN.

A small bowel transplant using a living donor in adults or children is considered **not medically necessary** when a cadaveric intestine is available for transplantation.

Investigational and Not Medically Necessary:

All other indications for small bowel or multivisceral transplants in adults or children, including but not limited to treatment of pseudotumor peritonei, are considered **investigational and not medically necessary.**

Living donor multivisceral transplants in adults or children are considered **investigational and not medically necessary.**

General Individual Selection Criteria

In addition to having one of the clinical indications above, the individual must not have a contraindication as defined by the American Society of Transplantation in Guidelines for the Referral and Management of Patients Eligible for Solid Organ Transplantation (2001) listed below.

Absolute Contraindications for Transplant *Recipients* include, but are not limited to, the following:

A. Metastatic cancer
B. Ongoing or recurring infections that are not effectively treated
C. Serious cardiac or other ongoing insufficiencies that create an inability to tolerate transplant surgery
D. Serious conditions that are unlikely to be improved by transplantation as life expectancy can be finitely measured
E. Demonstrated patient noncompliance, which places the organ at risk by not adhering to medical recommendations
F. Potential complications from immunosuppressive medications are unacceptable to the patient
G. Acquired immune deficiency syndrome (AIDS) (diagnosis based on Centers for Disease Control and Prevention (CDC) definition of CD4 count, 200cells/mm^3) unless the following are noted:
    1. CD4 count greater than 200cells/mm^3 for greater than 6 months
    2. HIV-1 RNA undetectable
    3. On stable anti-retroviral therapy greater than 3 months
    4. No other complications from AIDS (for example, opportunistic infection, including aspergillus, tuberculosis, coccidioide-mycosis, resistant fungal infections, Kaposi's sarcoma or other neoplasm)
    5. Meeting all other criteria for small bowel or multivisceral transplantation

Steinman, Theodore, et al. Guidelines for the Referral and Management of Patients Eligible for Solid Organ Transplantation. Transplantation. Vol. 71, 1189-1204, No. 9, May 15, 2001.

Rationale

Intestinal failure is a malabsorptive condition characterized by the inability of the gastrointestinal tract to maintain adequate nutrition, fluid and electrolyte balance for normal growth and development of the body (Bhamidimarri, 2014; Mangus, 2013). A common cause of intestinal failure is short bowel syndrome (SBS). Intestinal failure or SBS may result from extensive surgical resection for various indications, including but not limited to: volvulus; atresias; necrotizing enterocolitis; Crohn's disease; gastroschisis; thrombosis of the superior mesenteric artery; desmoid tumors; or trauma. Other causes of intestinal failure include motility disorders (for example, Hirschsprung's disease, visceral neuropathy, and chronic pseudo-obstruction); malabsorptive disorders (for example, microvillus inclusion); as well as intestinal secretory disorders. Individuals with intestinal failure are unable to maintain adequate nutrition orally or with enteral tube feedings and as a result, intravenous total parenteral nutrition (TPN) is utilized to provide essential nutrients, vitamins, lipids, and fluids. However, long-term use of TPN may fail, resulting in life-threatening complications and a need for surgical intervention or small bowel transplant/intestinal transplant.

Intestinal transplants mainly utilize organs from deceased donors. However, there have been rare cases of using a portion of the intestine from a living-related donor for small bowel transplant. Smith and colleagues (2016) reported that in the United States, six living donor intestinal transplants occurred in 2004 and one occurred in 2014. It has been proposed that the theoretical advantages of a living donor intestinal transplant include elimination of waiting time, the ability to plan the transplantation electively, better tissue matching, and short cold ischemia time (Tzvetanov, 2010). The number of living donor small bowel transplants performed to date has been small and published literature is mostly limited to single-center individual case reports and small case series (Benedetti, 2006; Gangemi, 2009; Ji G, 2009; Li, 2008). However, small bowel transplants using a living donor may have a role in select cases where a cadaveric intestine is not available.

Combined small bowel/liver transplants may be a treatment option in individuals with intestinal failure and irreversible liver disease (Middleton 2005; Vianna, 2008). This procedure has been more commonly used in pediatric cases where TPN liver disease has been more of a problem than with adults (Middleton, 2005).

Multivisceral transplantation is a complex procedure requiring extensive hospitalization and is associated with late mortality and lengthy complications. Although the procedure is uncommon, there is continuing experience with the operation which appears to be life-saving in a substantial portion of cases. Consequently, multivisceral transplantation is an option for the specific subset of individuals who have been managed with long-term TPN and show signs of impending end-stage liver failure, as this is a potentially life-saving treatment. Mangus and colleagues (2013) performed a retrospective case review of 95 individuals who underwent 100 multivisceral transplantations with or without a liver at a single U.S. center. There were 24 pediatric and 76 adult recipients. One-year survival was 72% and 3-year survival was 57%. A learning curve was noted by the authors, with a 48% survival rate for transplants performed between 2004 and 2007 and a 70% survival rate for those performed between 2008 and 2010.

In an Intestinal Transplant Registry (ITR) report, Grant and colleagues (2005) analyzed data for intestine, small bowel/liver and multivisceral transplants performed from April 1985 to May 31, 2003, to determine the scope and success of these transplantations. All known intestinal transplant programs were included. Transplant recipient and graft survival estimates were obtained and analyzed. A total of 61 programs provided data on 989 grafts in 923 recipients. The data demonstrated 1-year graft/recipient survival rates of 65%/77% for intestinal grafts, 59%/60% for small-bowel and liver grafts, and 61%/66% for multivisceral grafts. The 1-year overall graft/recipient survival rates were 57.6%/64.7% for cadaveric grafts versus 59.3%/66.7% for living donor grafts.

In 2015, Grant and colleagues published a follow-up report on ITR data. Clinical practices and outcomes were observed to be similar worldwide with only a few differences, and indications for intestinal transplant did not change over time. A total of 82 transplant programs reported 2887 transplants in 2699 recipients. Actuarial survival rates were 76% at 1 year, 56% at 5 years and 43% at 10 years. No improvement was noted for rates of graft loss beyond 1 year.

A 2019 article reported on pediatric data from the ITR (Raghu, 2019). Between 1985 and 2017, 2010 children received 2080 intestinal transplants. The primary indications for the intestinal transplants were short bowel syndrome (65%) and motility disorders (20%). Five

percent of procedures were re-transplants. Overall, 1-year individual and graft survival rates were 72.7% and 57.2%, respectively and 5-year individual and graft survival rates were 66.1% and 48.8%, respectively.

In 2021, Hind and colleagues published an overview of ITR and other data. They noted that patient and graft survival rates have improved over time and that ITR data show that long-term survival after intestinal transplantation is 41% at 10 years overall, and higher (up to 70%) at the more experienced centers. Chronic rejection remained the most common reason for late graft loss. The authors noted that there was a lower incidence of chronic rejection in transplantations that included the liver and higher survival rates according to ITR data from Europe.

According to the Organ Procurement and Transplant Network (OPTN), as of January 7, 2022, survival rates after primary intestinal transplants performed between 2008 and 2015 in the United States were 82.8% after 1 year, 68.9% after 3 years and 58.9% after 5 years.

A 2021 article by Sogawa and colleagues retrospectively reported on 55 individuals with chronic intestinal pseudo-obstruction (CIPO) who underwent intestinal (n=15) and multivisceral (n=40) transplantation at a single center. After a mean-follow-up of 61 months, 33 of the 55 (60%) recipients were alive. This included 23 of 32 (72%) adults and 10 of 23 (43%) children. A total of 16 individuals survived beyond 5 years. Cumulative patient survival was 89% at 1 year and 69% at 5 years and cumulative graft survival was 87% at 1 year and 56% at 5 years.

In 2022, Duchateau and colleagues published a systematic review of studies on combined liver-intestinal and multivisceral transplantation for individuals with neuroendocrine tumors extending beyond the liver. The authors identified 17 retrospective case reports and case series, including a total of 48 individuals. Survival was reported for 41 individuals; 21 (51.2%) of these were alive at follow-up, with a mean survival of 35 months (range, 3 to 89 months) after transplantation. Six of the individuals were alive with evidence of disease recurrence, 11 were alive without evidence of disease recurrence and 4 were alive with unknown disease status. The authors noted that each of the included studies was small, with an even smaller number of participants having multivisceral transplants. They noted that “improving disease-free survival will require more investigation regarding patient-tailored immunosuppression with a potential role for m-TOR inhibition as well as optimization of (neo-)adjuvant treatment.”

Small bowel, small bowel/liver and multivisceral transplants have been shown to be effective options for individuals meeting specific criteria including when other treatment modalities such as TPN have failed; however, there is currently a paucity of published evidence in the peer-reviewed medical literature to support the safe and effective use of these transplants for other indications including, but not limited to individuals who can tolerate TPN.

Metastatic Pseudomyxoma Peritonei (PMP)

Standard treatment for PMP is cytoreductive surgery (CRS) associated with hyperthermic intraperitoneal chemotherapy (HIPEC) (Sommariva, 2021). Small bowel/ multivisceral transplant has been proposed for treatment of PMP, but there are no published peer-reviewed studies on this topic.

A research group in the United Kingdom (UK) has presented several abstracts at national conferences. One of these abstracts (Allan, 2016) included 4 individuals with end-stage PMP and intestinal failure who underwent small bowel and multivisceral transplantation. Two of them died (day 26 and day 64). The first death was from anastomotic leak and GVHD. The other death was from anastomotic leak and GI bleed. The 2 surviving individuals were at home and independent of TPN at the time of data analysis (7-11 months). The other abstract (Reddy, 2016) included 6 individuals with PMP (including the 4 described above) who underwent small bowel and multivisceral transplantation. Of these 6 individuals, 3 underwent radical debulking. All individuals previously had surgery; further cytoreduction was infeasible due to extensive bowel involvement. Two individuals died, as described above, and 4 individuals were alive at the time of review (2, 4, 18 and 22 months). The 4 individuals had improved quality of life with marked reduction in pain. These studies have not been published in peer-reviewed journals.

A 2020 practice guideline from the Peritoneal Surface Oncology Group International (PSOGI) (Govaerts, 2020) contains a number of consensus statements on diagnosis and treatment of PMP. The document does not address small bowel/multivisceral transplantation.

CRS with HIPEC is recommended as initial treatment for eligible individuals. A total of 58.9% of the expert voting panel considered extensive small bowel serosal involvement to be an absolute contraindication to CRS with HIPEC. There were no clearly recommended treatments for individuals in this situation.

The NCCN Colon Cancer guideline (V.1.2022) does not included a recommendation on small bowel/multivisceral transplantation on PMP. In their discussion section, they state: "…Thus, for patients with pseudomyxoma peritonei, optimal treatment is still unclear."

Background/Overview

Possible types of transplants which include the small bowel are: isolated small bowel, combined small bowel/liver, and multivisceral transplant. The choice of transplant graft is made on a case-by-case basis depending on anatomy and disease process (Kubal, 2015). The most common of these procedures is the isolated small bowel (intestinal) transplantation (Beyer-Berjot, 2012). An isolated small bowel transplant usually involves the removal of the small intestine from a deceased donor, removal of the recipient's small intestine, and replacement with the donor's intestine. If a living donor is used, a segment of the donor's small intestine is transplanted. A small bowel transplant is intended to restore adequate nutrition in individuals with short bowel syndrome. This is a condition in which the absorbing surface of the small intestine is nonfunctional due to extensive disease or surgical removal of a large portion of the small intestine.

Evidence of intolerance or failure of 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 event 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.

A small bowel/liver transplant involves the transplantation of a cadaveric small intestine and liver into a recipient. Small bowel/liver transplants are typically performed for individuals with short bowel syndrome and concurrent liver failure or anatomical abnormalities.

A multivisceral transplant typically includes the small bowel/liver, in combination with one or more other abdominal visceral organ such as the stomach, pancreas or colon which may be transplanted due to concomitant organ failure or anatomical abnormalities. The most common indications for multivisceral transplantation are total occlusion of the splanchnic circulation, extensive gastrointestinal polyposis, hollow visceral myopathy or neuropathy, and some abdominal malignancies.

Definitions

Cadaver: The physical remains of a deceased person.

Short bowel syndrome: A malabsorption syndrome resulting from a significantly reduced small intestine.

Total parenteral nutrition (TPN): A method of supplying nourishment to children and adults who are unable to eat.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT	
44132	Donor enterectomy (including cold preservation), open; from cadaver donor

44133	Donor enterectomy (including cold preservation), open; partial, from living donor
44135	Intestinal allotransplantation; from cadaver donor
44136	Intestinal allotransplantation; from living donor
44715	Backbench standard preparation of cadaver or living donor intestine allograft prior to transplantation, including mobilization and fashioning of the superior mesenteric artery and vein
44720	Backbench reconstruction of cadaver or living donor intestine allograft prior to transplantation; venous anastomosis, each
44721	Backbench reconstruction of cadaver or living donor intestine allograft prior to transplantation; arterial anastomosis, each
47143	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; without trisegment or lobe split
47144	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with trisegment split of whole liver graft into two partial liver grafts (i.e., left lateral segment (segments II and III) and right trisegment (segments I and IV through VIII)
47145	Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with lobe split of whole liver graft into two partial liver grafts (i.e., left lobe (segments II, III, and IV) and right lobe (segments I and V through VIII)
47146	Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; venous anastomosis, each
47147	Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; arterial anastomosis, each
48551	Backbench standard preparation of cadaver donor pancreas allograft prior to transplantation, including dissection of allograft from surrounding soft tissues, splenectomy, duodenotomy, ligation of bile duct, ligation of mesenteric vessels, and Y-graft arterial anastomoses from iliac artery to superior mesenteric artery and to splenic artery
48552	Backbench reconstruction of cadaver donor pancreas allograft prior to transplantation, venous anastomosis, each

HCPCS

S2053	Transplantation of small intestine and liver allografts
S2054	Transplantation of multivisceral organs
S2055	Harvesting of donor multivisceral organs, with preparation and maintenance of allografts; from cadaver donor

ICD-10 Procedure

0DT80ZZ	Resection of small intestine, open approach
0FT00ZZ	Resection of liver, open approach
0FTG0ZZ	Resection of pancreas, open approach
0DY60Z0	Transplantation of stomach, allogeneic, open approach
0DY60Z1	Transplantation of stomach, syngeneic, open approach
0DY80Z0	Transplantation of small intestine, allogeneic, open approach
0DY80Z1	Transplantation of small intestine, syngeneic, open approach

0DYE0Z0	Transplantation of large intestine, allogeneic, open approach
0DYE0Z1	Transplantation of large intestine, syngeneic, open approach
0FY00Z0	Transplantation of liver, allogeneic, open approach
0FY00Z1	Transplantation of liver, syngeneic, open approach
0FYG0Z0	Transplantation of pancreas, allogeneic, open approach
0FYG0Z1	Transplantation of pancreas, syngeneic, open approach

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above, when criteria are not met; or when the code describes a procedure indicated in the Position Statement section as not medically necessary.

When services are Investigational and Not Medically Necessary:
For the procedure codes listed above for all other indications including but not limited to the following diagnosis code; or when the code describes a procedure indicated in the Position Statement section as investigational and not medically necessary.

ICD-10 Diagnosis

C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum [specified as pseudomyxoma peritonei]

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Peer Reviewed Publications:

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Government Agency, Medical Society, and Other Authoritative Publications:

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Document History

Status	Date	Action
Revised	11/10/2022	Medical Policy & Technology Assessment Committee (MPTAC) review. Added the term “multivisceral” and the phrase, “including but not limited to treatment of pseudotumor peritonei” to the first INV/NMN statement. Deleted the third INV/NMN on “all other multivisceral transplants”. Rationale, Coding, References and Websites sections updated.
Reviewed	02/17/2022	MPTAC review. Rationale, References and Websites sections updated.
Reviewed	02/11/2021	MPTAC review. Rationale, References and Websites sections updated.
Reviewed	02/20/2020	MPTAC review. Rationale, References and Websites sections updated.
Reviewed	03/21/2019	MPTAC review. Rationale, References and Websites sections updated.
Reviewed	03/22/2018	MPTAC review. Rationale and References sections updated.
Reviewed	11/02/2017	MPTAC review. The document header wording updated form “Current Effective Date” to “Publish Date”. References section updated.
Revised	11/03/2016	MPTAC review. Abbreviation defined in position statement. Formatting updated in position statement in “absolute contraindications for transplant recipients” section. Description, Rationale, Background and Reference sections updated.
Reviewed	11/05/2015	MPTAC review. Rationale and Reference sections updated. Removed ICD-9 codes from Coding section.
Reviewed	11/13/2014	MPTAC review. Description, Rationale and Reference sections updated.
Reviewed	11/14/2013	MPTAC review. Description, Background and Reference sections updated.
Reviewed	11/08/2012	MPTAC review. Background and Reference sections updated.
Reviewed	11/17/2011	MPTAC review. Description, Rationale and References updated.
Reviewed	11/18/2010	MPTAC review. Title, Rationale, Background, Definitions, References, and Index updated.
Revised	11/19/2009	MPTAC review. Initial medically necessary statement for small bowel transplant revised from addressing deceased or living donors to the use of a cadaveric intestine. A medically necessary statement for a small bowel transplant using a living donor and a not medically necessary for living donor small bowel transplantation was

		added. Rationale, background, references, and web sites for additional information updated.
Reviewed	05/21/2009	MPTAC review. Rationale, references and background updated.
Revised	05/15/2008	MPTAC review. Medically necessary statement revised. Description, rationale, background, definitions, coding, and references updated.
Revised	02/21/2008	MPTAC review. References and background updated. The phrase “investigational/not medically necessary” was clarified to read “investigational and not medically necessary.” This change was approved at the November 29, 2007 MPTAC meeting. Added a separate header for the “Not Medically Necessary” statement. Revisions made to the “Medically Necessary”, “Not Medically Necessary” and the “Investigational and Not Medically Necessary” statements.
Revised	03/08/2007	MPTAC review. Medical necessity statement revised. Updated rationale, references and coding.
Reviewed	03/23/2006	MPTAC review. References updated.
	11/18/2005	Added reference for Centers for Medicare & Medicaid Services (CMS) -National Coverage Determination (NCD).
Revised	04/28/2005	