**Introduction**

When the organs of the intestinal tract fail due to surgical removal, birth defect, or disease-related impairment the body is unable to digest or absorb food and fluids. Short bowel syndrome is one cause of intestinal failure. Patients with a failing intestinal tract must receive total parenteral nutrition (TPN), liquid nutrition through a vein, to stay alive. Long-term TPN use can cause complications including liver damage that can lead to liver failure.

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

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
<table>
<thead>
<tr>
<th>Procedure</th>
<th>Coverage Criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Intestinal organ transplantation:</td>
<td>Intestinal organ transplant surgery using a deceased donor (cadaveric) organ may be considered medically necessary in adult and pediatric patients when all of the following criteria are met:</td>
</tr>
<tr>
<td>• Isolated small bowel</td>
<td>- Intestinal failure is present and patient has developed complications due to long-term use of total parenteral nutrition (TPN). (Examples include loss of nutrient absorption with the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balance, many lengthy hospitalizations to treat TPN-related catheter-related sepsis, venous access failure due to infection, clots, or venous insufficiency or evidence of progressive liver failure such as a total bilirubin &gt;3 mg/dL).</td>
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<tr>
<td>• Small bowel/liver</td>
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<tr>
<td>• Multivisceral (e.g. small/bowel and or</td>
<td>AND</td>
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<tr>
<td>stomach, duodenum, jejunum, ileum, pancreas,</td>
<td>• All of the following are present:</td>
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<tr>
<td>colon)</td>
<td>o Adequate cardiovascular function</td>
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<td>o Documentation of patient compliance with medical management</td>
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<td></td>
<td>o HIV [human immunodeficiency virus] is controlled per CDC criteria (if applicable):</td>
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<tr>
<td></td>
<td>▪ CD4 count &gt;200 cells per cubic millimeter for greater than 6 months</td>
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<td></td>
<td>▪ HIV-1 RNA undetectable</td>
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<td></td>
<td>▪ On stable antiretroviral therapy &gt;3 months</td>
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<td></td>
<td>▪ No other complications from AIDS [acquired immune deficiency syndrome] are present (e.g., opportunistic infection including aspergillus, tuberculosis, coccidiosis mycosis, resistant fungal infections, Kaposi sarcoma, or other neoplasm)</td>
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<td></td>
<td>AND</td>
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<td></td>
<td>• No contraindications to transplant surgery are present, including but not limited to the following (subject to the judgment of the transplant center):</td>
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<tr>
<td></td>
<td>o Known current malignancy, including metastatic cancer</td>
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<tr>
<td></td>
<td>o Recent malignancy with high risk of recurrence</td>
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<tr>
<td></td>
<td>o History of cancer with a moderate risk of recurrence</td>
</tr>
<tr>
<td></td>
<td>o Systemic disease that could be exacerbated by immunosuppression</td>
</tr>
</tbody>
</table>
## Procedure Coverage Criteria

- Untreated systemic infection making immunosuppression unsafe, including chronic infection
- Other irreversible end stage disease not related to intestinal failure
- Psychosocial conditions or chemical dependency affecting the patient’s ability to adhere to therapy

<table>
<thead>
<tr>
<th>Use of deceased (cadaveric) or living donor organ</th>
<th>Intestinal transplantation with a living donor organ may be considered medically necessary only when a cadaveric donor organ is not available and the transplant criteria are met.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Intestinal transplantation using a cadaveric or living donor organ is considered investigational when criteria are not met, including adults and children who can tolerate TPN.</td>
</tr>
<tr>
<td>Intestinal organ retransplant</td>
<td>A retransplant surgery of a small bowel alone, small bowel/liver or multivisceral organ(s) may be considered medically necessary after a failed primary transplant.</td>
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</tbody>
</table>

### Coding

<table>
<thead>
<tr>
<th>CPT</th>
<th>Description</th>
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<tbody>
<tr>
<td>44135</td>
<td>Intestinal allotransplantation; from cadaver donor</td>
</tr>
<tr>
<td>44136</td>
<td>Intestinal allotransplantation; from living donor</td>
</tr>
<tr>
<td>44799</td>
<td>Unlisted procedure, intestine</td>
</tr>
<tr>
<td>47135</td>
<td>Liver allotransplantation, orthotopic, partial or whole, from cadaver or living donor, any age</td>
</tr>
<tr>
<td>47399</td>
<td>Unlisted procedure, liver</td>
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</tbody>
</table>

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<tr>
<th>HCPCS</th>
<th>Description</th>
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<tbody>
<tr>
<td>S2053</td>
<td>Transplantation of small intestine and liver allografts</td>
</tr>
<tr>
<td>S2054</td>
<td>Transplantation of multivisceral organs</td>
</tr>
</tbody>
</table>

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Benefit Application

Transplant requests should be reviewed by the plan medical director or his/her designee. Only patients accepted for organ transplantation by an approved transplantation center and actively listed for transplant should be considered for precertification or prior approval. Guidelines should be followed for transplant network or consortiums, if applicable.

Typically, the following are covered under the human organ transplant (HOT) benefit:

- Hospitalization of the recipient for medically recognized transplants from a donor to a transplant recipient;
- Pre-hospital workup and hospitalization of a living donor undergoing a partial hepatectomy should be considered as part of the recipient transplant costs;
- Evaluation tests requiring hospitalization to determine the suitability of both potential and actual donors, when such tests cannot be safely and effectively performed on an outpatient basis;
- Hospital room, board, and general nursing in semi-private rooms;
- Special care units, such as coronary and intensive care;
- Hospital ancillary services;
- Physicians’ services for surgery, technical assistance, administration of anesthetics, and medical care;
- Acquisition, preparation, transportation, and storage of organ;
- Diagnostic services;
- Drugs that require a prescription by federal law.

Expenses incurred in the evaluation and procurement of organs and tissues are benefits when billed by the hospital. Included in these expenses may be specific charges for participation with registries for organ procurement, operating rooms, supplies, use of hospital equipment, and transportation of the tissue or organ to be evaluated.

Administration of products with a specific transplant benefit needs to be defined as to:
• When the benefit begins (at the time of admission for the transplant or once the patient is
determined eligible for a transplant, which may include tests or office visits prior to
transplant)

• When the benefit ends (at the time of discharge from the hospital or at the end of required
follow-up, including the immunosuppressive drugs administered on an outpatient basis)

Coverage is usually not provided for the following:

• HOT services, when the cost is covered/funded by governmental, foundational, or charitable
grants

• Organs sold rather than donated to the recipient

• An artificial organ

Description

Intestinal failure has several causes that damage the body’s ability to absorb nutrition from food
and is characterized by the inability to maintain protein-energy, fluid, electrolyte, or
micronutrient balance.¹ Short-bowel syndrome is one cause of intestinal failure that may be an
indication for transplant surgery. Small bowel, small bowel/liver and multivisceral transplantation
surgery is known collectively as intestinal organ transplantation because it involves organs in the
digestive system. Total parenteral nutrition (TPN) is used to maintain the health of a person with
short bowel syndrome or intestinal failure. TPN is liquid nutrition entering the body through a
catheter or needle inserted into a vein in the arm, groin, neck or chest. Long-term TPN use can
have complications such as infections related to the catheter, permanent damage to the vein(s)
used for infusion, metabolic bone disorders, and liver failure partly caused by omega-6 fatty
acids in parenteral nutrition formulas. Intestinal organs are usually transplanted as a treatment
of last resort when a person has complications from the long-term use of TPN.

Background

Intestinal organ transplants represent a small minority of all solid organ transplants. In 2011, 129
intestinal transplants were performed in the United States; out of that number only one was not
from a deceased donor.² In 2012, 106 intestinal transplants were performed in the United States;
all organs were from deceased donors.
Evidence Review

The policy was created with searches of the MEDLINE database. Most recently, the literature was reviewed through November 2016.

Isolated Small Bowel Transplant

Two TEC Assessments conducted in the 1990s were the basis for the policy statements. A 1995 TEC Assessment concluded that in children, small bowel transplant was associated with improved survival compared with total parenteral nutrition (TPN) as the associated adverse outcomes for small bowel transplant were offset by severe TPN-related complications.³ This Assessment also concluded that, in adults, the outcomes for small bowel transplant were worse than that associated with TPN. A 1999 TEC Assessment reevaluated the data on adults and concluded that, since it is not possible to predict which patients would survive longer on TPN versus small bowel transplant, transplantation may be considered a reasonable option in selected adults.⁴

Much of the published literature consists of relatively small case series. For example, in 2014, Ueno et al. in Japan reported on 21 intestinal transplant patients; all but one received an isolated small bowel transplant for intestinal failure.⁵ The overall 1-year and 5-year survival rates were 86% and 68%, respectively. In the 15 patients who underwent transplantation after 2006, 1-year survival was 92% and 5-year survival was 83%.

These reports, as well as reviews of observational data, note that while outcomes continue to improve, obstacles to long-term survival remain. Recurrent and chronic rejections and complications of immunosuppression are significant issues in bowel transplantation.

One obstacle is the timely referral for intestinal transplantation to avoid combined liver and intestine transplantation.⁶ It has been suggested that improvements in survival may justify removing the restriction of intestinal transplantation to patients who have severe complications of TPN. However, Vianna et al. in 2008 reported on the status of intestinal transplantation, no randomized trials were identified that compare intestinal transplantation with long-term TPN, and optimal timing for earlier transplantation was not established.⁷

Another obstacle is the rate of various complications after small bowel transplant. Florescu et al. published several retrospective reviews of complications in a cohort of 98 pediatric patients. Twenty-one of these children (21.4%) had an isolated small bowel transplant; the remainder had
combined transplants. A 2012 study reported that 68 of the 98 patients (69%) developed at least 1 episode of bloodstream infection. Among the patients with an isolated small bowel transplant, the median time to infection for those who became infected was 4.5 months (95% confidence interval, 2.4 to 6.7 months). The researchers reported in 2012 that 7 of 98 patients (7%) developed cytomegalovirus disease; only 1 of these had an isolated small bowel transplant. In 2010, Florescu et al. reported that 25 of 98 cases reviewed (25.5%) developed at least 1 episode of fungal infection; Candida infection was most common. The mortality rate did not differ significantly between patients who did and did not develop a fungal infection (32.3% vs. 29.8%, respectively; p=0.46).

Several other case series have reported on renal failure after intestinal transplantation. In 2013, a research group in France reported that 7 of 12 children who had an isolated small bowel transplant had renal function complications at some point after surgery. Before treatment, all of the patients had normal renal functioning. In 2014, Calvo Pulido in Spain reported on 21 adults who underwent intestinal transplantation; 17 were isolated small bowel transplants. Thirteen patients (62%) experienced renal failure; the etiology included high ileostomy output, immunosuppression, and medical treatment.

Small Bowel/Liver and Multivisceral Transplant

A 1999 TEC Assessment focused on multivisceral transplantation and offered the following conclusions:

Multivisceral transplantation in patients with small bowel syndrome, liver failure, and/or other gastrointestinal problems such as pancreatic failure, thromboses of the celiac axis and the superior mesenteric artery, or pseudo-obstruction affecting the entire gastrointestinal tract is associated with poor patient and graft survival. Pediatric and adult patients have a similar 2-year and 5-year survival of 33% to 50%. However, without this procedure, it is expected that these patients would face 100% mortality.

The published literature consists of case series, mainly reported by single centers. Authors of these reports, as well as reviews, observe that while outcomes have improved over time, recurrent and chronic rejection and complications of immunosuppression continue to be obstacles to long-term survival.

Recent publications include a 2016 report by Rutter et al from the United Kingdom. Between January 2007, and June 2015, 60 transplant procedures were performed in 54 patients. Of these, 35 were multivisceral transplants, 9 were modified multivisceral transplants and 16 were small bowel transplants. Recipients’ median age was 47 years (range, 18-61 years). Median length of
follow-up was 21.3 months (range, 0-95 months). One- and 5-year patient survival rates were 77% and 62%, respectively. One-year survival by type of procedure was 71% for multivisceral transplant, 85% for modified multivisceral transplant and 92% for small bowel transplant. Five-year survival rates in these groups were 33%, 65% and 83%, respectively. Most deaths occurred in the first year after transplant.

A 2014 single-center Italian case series reported on 45 patients who received an intestinal transplant alone or a combined transplant procedure. 14 Twelve of the patients had small bowel/multivisceral transplants. Five of these had the procedure due to short-bowel syndrome, 2 had chronic intestinal pseudo-obstruction, and 5 had Gardner syndrome. Survival rates for the entire patient population were 77% at 1 year, 58% at 3 years, 53% at 5 years, and 37% at 10 years.

A 2013 single center study in Sweden included 30 patients accepted for intestinal and multivisceral transplantation. 15 One- and 3-year survival rates were 68% and 61%, respectively. Among patients awaiting transplantation after being accepted as candidates, there was a 34% survival rate.

Also in 2013, Mangus et al. reported on 95 patients who underwent multivisceral transplantation with or without liver transplantation at one site in the United States. 16 One-year patient survival was 72% and 3-year survival was 57%. The authors noted a learning curve, with a 48% survival rate for transplants performed between 2004 and 2007 and a 70% survival rate for operations between 2008 and 2010.

Complications

Several case series have focused on complications after small bowel and multivisceral transplantation. For example, in 2016, Nagai et al reported on cytomegalovirus (CMV) infection after intestinal or multivisceral transplantation at a single center in the United States. 17 A total of 210 patients had an intestinal transplant, multivisceral transplant, or modified multivisceral transplant between January 2003 and June 2014. Median length of follow-up was 2.1 years. Thirty-four (16%) patients developed CMV infection a median of 347 days after transplantation. Nineteen patients had tissue invasive CMV disease. In a report from another U.S. center, 16 (19%) of 85 patients undergoing intestinal or multivisceral transplantation developed CMV infection a mean of 139 days (range, 14-243 days) postoperatively. 18

In 2011 Wu et al. reported on 241 patients who underwent intestinal transplantation. 19 Of these, 147 (61%) had multivisceral transplants, 65 (27%) had small bowel transplants and 12% had small bowel/liver transplants. There were 151 children (63%) and 90 adults. A total of 22 patients
(9%) developed graft-versus-host disease. Children younger than 5 years-old were more likely to develop this condition; the incidence in this age group was 16 of 121 (13.2%) compared with 2 of 30 (6.7%) in children between 5 and 18 years and 9 of 90 (4.4%) in adults older than 18 years.

In a 2016 series by Cromvik et al, 5 of 26 patients (19%) were diagnosed with GVHD after intestinal or multivisceral transplantation.\textsuperscript{20} Risk factors for GVHD were malignancy as a cause of transplantation and neoadjuvant chemotherapy or brachytherapy before transplantation.

A 2012 study retrospectively reported on bloodstream infections among 98 children younger than age 18 years with small bowel/combined organ transplants.\textsuperscript{21} Seventy-seven (79%) patients underwent small bowel transplant in combination with a liver, kidney or kidney-pancreas, and 21 had an isolated small bowel transplant. After a median follow-up of 52 months, 58 (59%) patients remained alive. 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 patients (69.4%) experienced at least one 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=0.056 for difference in survival in patients with and without bloodstream infections).

**Living Donors**

Cadaveric intestines have been most commonly used, but recently there has been 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. Small case reports have been published of 1 or 2 patients with different lengths of the ileum or jejunum.\textsuperscript{22–25} While there appear to be minimal complications to the donors, of the 6 cases reported, 5 recipients remain on TPN for at least part of their nutrition. One patient remains healthy and is off TPN.

Benedetti et al. reported outcomes from 4 children and 7 adults who underwent 12 living-related small bowel transplantations between 1998 and 2004.\textsuperscript{26} All donors were reported to have had uneventful recovery following removal of up to 40% of the small intestine. The 3-year patient survival was 82%, with graft survival of 75%. Longer follow-up from the earlier cases was not reported. Gangemi and Benedetti published a literature review of living donor small bowel transplantation reports from 2003 to 2006; all of the reports listed Benedetti (et al.) as author.\textsuperscript{27} The authors comment that, “Due to the excellent result in modern series of deceased donor bowel transplantation, widespread use of the procedure [living donor] should not be
recommended, in consideration of the potential risks to donor. Furthermore, few centers have acquired the necessary experience with the procedure.”

In June 2010, Sudan published a review of current literature on long-term outcomes after intestinal transplantation. In this article, the author notes that intestinal transplantation has become standard therapy for patients with life-threatening complications from parenteral nutrition therapy. Data from current single-center series indicates a 1-year patient survival rate of 78% to 85% and a 5+ year survival rate of 56% to 61%. With respect to pediatric intestinal transplant patients, most achieve normal growth velocity at 2 years post-transplant. However, oral aversion is a common problem; tube feedings are necessary in 45% of children. Sudan also reports on parental surveys of quality of life in pediatric transplant patients in which intestinal transplant patients appear to have modestly improved quality of life compared with patients remaining on TPN and slightly worse than matched school-age controls without intestinal disease.

**HIV Positive Transplant Recipients**

This subgroup of recipients has long been controversial, due to the long-term prognosis for HIV positivity and the impact of immunosuppression on HIV disease. Although HIV-positive transplant recipients may be a research interest of some transplant centers, the minimal data regarding long-term outcome in these patients primarily consist of case reports and abstract presentations of liver and kidney recipients. Nevertheless, some transplant surgeons would argue that HIV positivity is no longer an absolute contraindication to transplant due to the advent of highly active antiretroviral therapy (HAART), which has markedly changed the natural history of the disease.

In 2015, the Organ Procurement and Transplant Network (OPTN) updated its policies to be consistent with the HOPE Act. OPTN and United Network for Organ Sharing policies specify that organs from HIV-positive patients be used only for HIV-positive transplant recipients.

In February 2013, the United Network for Organ Sharing (UNOS) policy on HIV-positive transplant candidates states “A potential candidate for organ transplantation whose test for HIV is positive should not be excluded from candidacy for organ transplantation unless there is a documented contraindication to transplantation based on local policy” (Policy 4, Identification of Transmissible Diseases in Organ Recipients).

The 2013 HIV Organ Policy Equity (HOPE) Act in the United States permitted scientists to research organ donations from a person with HIV to another HIV-infected person.
In 2006, the British HIV Association and the British Transplantation Society Standards Committee published guidelines for kidney transplantation in patients with HIV disease. These criteria may be extrapolated to other organs.

The guidelines recommend that any patient with end-stage organ disease with a life expectancy of at least 5 years is considered appropriate for transplantation under the following conditions:

- CD4 200 cells/micro liter for at least 6 months
- Undetectable HIV viremia (<50 HIV-1 RNA copies/mL) for at least 6 months
- Demonstrable adherence and a stable HAART regimen for at least 6 months
- Absence of AIDS-defining illness following successful immune reconstitution after HAART

In 2001, the American Society of Transplantation proposed that the presence of HIV/AIDS could be considered a contraindication to kidney transplant unless the following criteria were present. These criteria may be extrapolated to other organs:

- CD4 count greater than 200 cells/mm3 for more than 6 months
- HIV-1 RNA undetectable
- On stable antiretroviral therapy for more than 3 months
- No other complications from AIDS (e.g., opportunistic infection, including aspergillosis, tuberculosis, coccidioses mycosis, resistant fungal infections, Kaposi’s sarcoma, or other neoplasm).
- Meeting all other criteria for transplantation.

No studies were found in literature reviews that reported on outcomes in HIV-positive patients who received small bowel/liver or multivisceral transplants at the time of this review.

Retransplantation

Desai et al. reported retransplantation data from the OPTN. Between October 1987 and August 2009, there were 31 cases of small bowel/liver retransplantation in adults and 49 in children. Among adults, survival rates after retransplant were 63.1% after 1 year, 56.1% after 3 years and 46.8% after 5 years. Comparable survival rates for primary small bowel/liver transplant were 97% after 1 year, 53.3% after 3 years, and 46% after 5 years. Among children, there was a
consistent 42.1% survival rate at 1, 3, and 5 years after retransplantation. Survival rates after primary small bowel/liver transplantation were 67.6%, 56.1%, and 51.4%, respectively.

In 2013, Trevizol et al. reviewed literature on intestinal and multivisceral retransplantation. They found articles from 2 centers. Mazariegos et al. reported on 15 retransplantations in 14 pediatric patients. By the end of follow-up, 4 patients had died and 10 patients had a normal graft function. Total parenteral nutrition was weaned at a mean of 32 days after retransplantation.

A 2009 study by Abu-Elmagd et al., reported 47 retransplants after 500 intestinal and multivisceral transplantations in adults and children. Included were 31 intestinal retransplants, 9 multivisceral retransplants, and 7 intestinal/liver retransplants. For all types of retransplants combined, there is a 5-year survival rate of 47% for all retransplants.

**Summary of Evidence**

**Small Bowel Organ Transplant**

For individuals who have intestinal failure who receive a small bowel transplant, the evidence includes case series. Relevant outcomes are overall survival, 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 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 significantly worsen comorbid conditions. 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 a meaningful 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 overall survival, morbid events, and treatment-related mortality and morbidity. Data from only a small number of patients undergoing retransplantation are available. Although limited in quantity, the available data after retransplantation have suggested a reasonably high survival rate after small bowel in patients who continue to meet criteria for transplantation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.
Multivisceral Organ Transplant

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 case series. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. These procedures are infrequently performed and only relatively small case series, generally single-center, are available. These series have shown reasonably high postprocedural survival rates. Given exceedingly poor survival rates without transplantation of patients who have exhausted other treatments, evidence of postoperative survival from uncontrolled studies is sufficient to demonstrate that small bowel/liver and multivisceral transplantation provides a survival benefit in appropriately selected patients. 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 a meaningful 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 overall survival, morbid events, and treatment-related mortality and morbidity. Although limited in quantity, the available post retransplantation data has 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 a meaningful improvement in the net health outcome.

Practice Guidelines and Position Statements

American Gastroenterological Association

In 2003, the American Gastroenterological Association published a position statement on short bowel syndrome and intestinal transplantation. The statement noted that only patients with life-threatening complications due to intestinal failure or long-term total parenteral nutrition
have undergone intestinal transplantation. The statement recommends following Medicare-approved indications, pending availability of additional data. (See Medicare National Coverage)

**Medicare National Coverage**

Medicare will cover intestinal transplantation for the purpose of restoring intestinal function in patients with irreversible intestinal failure only when performed for patients who have failed total parenteral nutrition (TPN) and only when performed in centers that meet approval criteria below.39

**Failed Total Parenteral Nutrition (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. The clinical manifestations include elevated serum bilirubin and/or liver enzymes, splenomegaly, thrombocytopenia, gastroesophageal varices, coagulopathy, stomal bleeding or hepatic fibrosis/cirrhosis.

- Thrombosis of the major central venous channels; jugular, subclavian, and femoral veins. Thrombosis of two or more of these vessels is considered a life-threatening complication and failure of TPN therapy. The sequelae of central venous thrombosis are lack of access for TPN infusion, fatal sepsis due to infected thrombi, pulmonary embolism, Superior Vena Cava syndrome, or chronic venous insufficiency.

- Frequent line infection and sepsis. The development of two or more episodes of systemic sepsis secondary to line infection per year that requires hospitalization indicates failure of TPN therapy. Single episodes of line-related fungemia, septic shock and/or acute respiratory distress syndrome are considered indicators of TPN failure.

- Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN. Under certain medical conditions such as secretory diarrhea and nonconstructable gastrointestinal tract, the loss of the gastrointestinal and pancreatobiliary secretions exceeds the maximum intravenous infusion rates that can be tolerated by the cardiopulmonary system. Frequent episodes of dehydration are deleterious to all body organs particularly kidneys and the central nervous system with the development of multiple kidney stones, renal failure, and permanent brain damage.
Approved Transplant Facilities

Intestinal transplantation is covered by Medicare if performed in an approved facility. The criteria for approval of transplant centers are based on a volume of 10 intestinal transplants per year with a 1-year actuarial survival of 65% using the Kaplan-Meier technique. 36

Regulatory Status

Intestinal transplantation is a surgical procedure and, as such is not subject to regulation by the U.S. Food and Drug Administration.

References


**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
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<tbody>
<tr>
<td>07/14/15</td>
<td>New Policy. Policy renumbered from 7.03.510. Policy updated with literature review through April 28, 2015; references 5 and 12 added. Policy statements unchanged in intent from 7.03.510. However, policy statements reformatted/reordered for clarity as a local plan difference. In addition, “using a cadaveric or living donor” added for clarity to the investigational statement.</td>
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<tr>
<td>10/11/16</td>
<td>Annual Review. Policy title changed to include new content. Policy statements added from policy 7.03.05, intent unchanged. Intestinal and multivisceral organ transplant surgery for adults and pediatric patients may be considered medically necessary when criteria are met. Policy reviewed with literature review through August 2016, references added. Policy moved into new format. Coding update. Removed CPT codes 44132, 44133, 44715, 44720, and 44721. Added CPT codes 47135 and 47136. Added HCPCS codes S2053 and S2054.</td>
</tr>
<tr>
<td>02/14/17</td>
<td>Annual review. Policy updated with literature review through November 2016; references added. Policy statements unchanged.</td>
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  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
• Provides free language services to people whose primary language is not English, such as:
  - Qualified interpreters
  - Information written in other languages

If you need these services, contact the Civil Rights Coordinator.

If you believe that Premera has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, you can file a grievance with:
Civil Rights Coordinator - Complaints and Appeals
PO Box 91102, Seattle, WA 98111
Toll free 855-332-4535, Fax 425-918-5992, TTY 800-842-5357
Email AppealsDepartmentInquiries@Premera.com

You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at: https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:
U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
Complaint forms are available at:

Getting Help in Other Languages

This Notice has Important Information. This notice may have important information about your application or coverage through Premera Blue Cross. There may be key dates in this notice. You may need to take action by certain deadlines to keep your health coverage or help with costs. You have the right to get this information and help in your language at no cost. Call 800-722-1471 (TTY: 800-842-5357).

Arabic (Arabic):
لا يوجد هذا الإشعار معلومات هامة. قد يوجد هذا الإشعار معلومات هامة يخصصها لمبادئ أو
الملفات التي تحتوي على معلومات أخرى مختلفة. Premera Blue Cross. يحوي هذا الإشعار معلومات هامة. قد يوجد هذا الإشعار معلومات هامة
تتضمن تلك المكتبات. يحوي هذا الإشعار معلومات هامة. قد يوجد هذا الإشعار معلومات هامة
800-722-1471 (TTY: 800-842-5357).

Chinese (Chinese):
本通知有重要的訊息。本通知可能有關於您透過 Premera Blue Cross 提交的
申請或保險的重要訊息。本通知可能有重要的日期。您可能需要在截止日期
之前採取行動，以保留您的健康保險或費用補貼。您有權利免費以您的母
語得到本訊息和幫助。撥打電話 800-722-1471 (TTY: 800-842-5357).

Oromoo (Cushite):
Oo muujii caawinaa dhamaan baahee kaa. Beekistii kun sagantaa
yoockan karaa Premera Blue Cross tiin tajajila keessaa italchisee
barbarachisaa qabaachuu danda’a. Guyyawaanan muurrteessa
ta’an beekisii kana keessatti ilaala. Tarii kaafituulka deegagarmuu
yoockan tajajila fayyaa keessanif guyyaa dhumaa iratti wanti raawwatu
jiraachuu danda’a. Kaafitti irraa biilaas haala ta’een faa’an keessanii
odeefannoo aragulka fii deegarsaa argachuu niga qabaatuu.
Lakkoofsa bibliiwa 800-722-1471 (TTY: 800-842-5357) ti bibliiwa.

Italiano (Italian):
Questo avviso contiene informazioni importanti. Questo avviso può contenere
informazioni importanti sulla tua domanda o copertura attraverso Premera Blue Cross.
Potrebbero esserci date chiave in questo avviso. Potrebbe
essere necessario un tuo intervento entro una scadenza determinata per
consentirti di mantenere la tua copertura o sovvenzione. Hai il diritto
di ottenere queste informazioni e assistenza nella tua lingua gratuitamente.
Chiamala 800-722-1471 (TTY: 800-842-5357).
ثبت اطلاعات مربوط به پوشش در این اخبار می‌تواند به شما کمک کند. این اطلاعات مربوط به پوشش در این اخبار می‌تواند به شما کمک کند.