MEDICAL POLICY – 7.03.04
Intestinal and Multivisceral Organ Transplant Surgery

BCBSA Ref Policy: 7.03.04 & 7.03.05

Effective Date: Oct. 1, 2017
Last Revised: Sept. 5, 2017
Replaces: 7.03.510 & 7.03.05

RELATED MEDICAL POLICIES:
7.03.509 Solid Organ Transplant
8.02.02 Plasma Exchange

Select a hyperlink below to be directed to that section.

POLICY CRITERIA | CODING | RELATED INFORMATION
EVIDENCE REVIEW | REFERENCES | HISTORY

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Food is digested and nutrients are absorbed in the intestines. If the intestines are damaged because of surgery, disease, or a birth defect, the ability to absorb nutrients and fluids may be affected. If part of the intestines is damaged, it may result in a condition called “short bowel syndrome”. People with short bowel syndrome have a hard time absorbing nutrients and fluids. As a result, they may become malnourished and need to get their nutrition through “total parenteral nutrition” (TPN) in order to stay alive. TPN is liquid nutrition that is given through a vein. Long-term use of TPN 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 transplantation of the small bowel, the small bowel/liver together, and multivisceral transplantation that may include the 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.
### Policy Coverage Criteria

<table>
<thead>
<tr>
<th>Procedure</th>
<th>Medical Necessity</th>
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| Gastrointestinal organ transplantation:  
  - Isolated small bowel  
  - Small bowel/liver  
  - Multivisceral (e.g., small bowel and/or stomach, pancreas, colon) | Gastrointestinal organ transplant surgery using a deceased donor’s (cadaveric) organ may be considered medically necessary in adult and pediatric patients when all of the following criteria are met:  
  - Intestinal failure is present and the patient has developed complications due to long-term use of total parenteral nutrition (TPN). (Examples of complications include the 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 >3 mg/dL).  
  **AND**  
  - All of the following are present:  
    - Adequate cardiovascular function  
    - Documentation of patient compliance with medical management  
    - HIV [human immunodeficiency virus] is controlled per CDC criteria (if applicable):  
      - CD4 count >200 cells per cubic millimeter for greater than 6 months  
      - HIV-1 RNA is undetectable  
      - On stable antiretroviral therapy >3 months  
      - 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)  
  **AND**  
  - No contraindications to transplant surgery are present, including but not limited to the following (subject to the
**Procedure** | **Medical Necessity**
--- | ---
 | judgment of the transplant center):  
  o Known current malignancy, including metastatic cancer  
  o Recent malignancy with high risk of recurrence  
  o History of cancer with a moderate risk of recurrence  
  o Systemic disease that could be exacerbated by immunosuppression  
  o Untreated systemic infection making immunosuppression unsafe, including chronic infection  
  o Other irreversible end stage disease not related to intestinal failure  
  o Psychosocial conditions or chemical dependency affecting the patient’s ability to adhere to therapy

**Use of living donor organ**

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.

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.

**Intestinal organ retransplant**

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.

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**Coding**

<table>
<thead>
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<th>Code</th>
<th>Description</th>
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<tr>
<td>CPT</td>
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<td>44135</td>
<td>Intestinal allotransplantation; from cadaver donor</td>
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<tr>
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<td>Intestinal allotransplantation; from living donor</td>
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<td>44799</td>
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<tr>
<td>S2053</td>
<td>Transplantation of small intestine and liver allografts</td>
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<tr>
<td>S2054</td>
<td>Transplantation of multivisceral organs</td>
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</tbody>
</table>

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### Related Information

**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

Evidence Review

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. In 2012, 106 intestinal transplants were performed in the United States; all organs were from deceased donors.

**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.\(^3\) 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 below.)

**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.\(^3\)\(^9\)

**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>
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<tr>
<th>Date</th>
<th>Comments</th>
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<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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<td>Annual Review, approved October 11, 2016. 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</td>
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<td>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>
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<td>Annual review, approved February 14, 2017. Policy updated with literature review through November 2016; references added. Policy statements unchanged.</td>
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<td>04/11/17</td>
<td>Coding update; removed CPT code 47136. Minor formatting update.</td>
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