Medical Policy
Isolated Small Bowel Transplant

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Policy Number: 631
BCBSA Reference Number: 7.03.04
NCD/LCD: National Coverage Determination (NCD) for Intestinal and Multi-Visceral Transplantation (260.5)

Related Policies
- Small Bowel-Liver and Multivisceral Transplant, #632

Policy
Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity

A small bowel transplant using a cadaveric intestine may be **MEDICALLY NECESSARY** in adult and pediatric patients to treat the following conditions:

- Intestinal failure (characterized by loss of absorption and the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balance), **AND**
- Established long-term dependency on total parenteral nutrition (TPN), **AND**
- Developing or have developed severe complications due to (TPN).

A small bowel transplant using a living donor may be **MEDICALLY NECESSARY** only when a cadaveric intestine is **NOT** available for transplantation in a patient who meets the criteria noted above for cadaveric intestinal transplant.

A small bowel retransplant may be **MEDICALLY NECESSARY** after a failed primary small bowel transplant.

A small bowel transplant using living donors is **NOT MEDICALLY NECESSARY** in all other situations.

A small bowel transplant in adult patients with intestinal failure who are able to tolerate TPN is **INVESTIGATIONAL**.
In addition to the above information, we do not cover small bowel transplant transplantation when any of the following conditions are present:

- Known current malignancy, including metastatic cancer
- Recent malignancy with high risk of recurrence
  - Note: the assessment of risk of recurrence for a previously treated malignancy is made by the transplant team; providers must submit a statement with an explanation of why the patient with a recently treated malignancy is an appropriate candidate for a transplant.
- Untreated systemic infection making immunosuppression unsafe, including chronic infection
- Other irreversible end-stage disease not attributed to intestinal failure
- History of cancer with a moderate risk of recurrence
- Systemic disease that could be exacerbated by immunosuppression
- Psychosocial conditions or chemical dependency affecting ability to adhere to therapy.

**Medicare HMO BlueSM and Medicare PPO BlueSM Members**

**Indications and Limitations of Coverage**

**Nationally Covered Indications**

Effective for services performed on or after April 1, 2001, this procedure is covered only when performed for patients who have failed total parenteral nutrition (TPN) and only when performed in centers that meet approval criteria.

1. Failed TPN
   - The TPN delivers nutrients intravenously, avoiding the need for absorption through the small bowel. TPN failure includes the following:
     - Impending or overt liver failure due to TPN induced liver injury. 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. A single episode 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 non-constructable 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.

2. Approved Transplant Facilities
   - Intestinal transplantation is covered by Medicare if performed in an approved facility. The criteria for approval of centers will be based on a volume of 10 intestinal transplants per year with a 1-year actuarial survival of 65 percent using the Kaplan-Meier technique.

**Nationally Non-covered Indications**

All other indications remain non-covered.

**National Coverage Determination (NCD) for Intestinal and Multi-Visceral Transplantation (260.5)**

Prior Authorization Information
Pre-service approval is required for all inpatient services for all products. See below for situations where prior authorization may be required or may not be required for outpatient services. Yes indicates that prior authorization is required. No indicates that prior authorization is not required. N/A indicates that this service is primarily performed in an inpatient setting.

<table>
<thead>
<tr>
<th>Outpatient</th>
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<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
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<tr>
<td>Commercial PPO and Indemnity</td>
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<tr>
<td>Medicare HMO BlueSM</td>
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<td>Medicare PPO BlueSM</td>
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CPT Codes / HCPCS Codes / ICD Codes
Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes

<table>
<thead>
<tr>
<th>CPT diagnosis codes:</th>
<th>Code 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>
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ICD-10 Procedure Coding

<table>
<thead>
<tr>
<th>ICD-10-PCS Procedure codes:</th>
<th>Code Description</th>
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<tbody>
<tr>
<td>0DY80Z0</td>
<td>Transplantation of Small Intestine, Allogeneic, Open Approach</td>
</tr>
<tr>
<td>0DY80Z1</td>
<td>Transplantation of Small Intestine, Syngeneic, Open Approach</td>
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Description

SMALL BOWEL SYNDROME
Short bowel syndrome is a condition in which the absorbing surface of the small intestine is inadequate due to extensive disease or surgical removal of a large portion of small intestine. In adults, etiologies of short bowel syndrome include ischemia, trauma, volvulus, and tumors. In children, gastroschisis, volvulus, necrotizing enterocolitis, and congenital atresia are predominant causes.

Treatment
The small intestine, particularly the ileum, can adapt to some functions of the diseased or removed portion over a period of 1 to 2 years. Prognosis for recovery depends on the degree and location of small intestine damage. Therapy focuses on achieving adequate macro- and micronutrient uptake in the remaining small bowel. Pharmacologic agents have been studied to increase villous proliferation and slow transit times, and surgical techniques have been advocated to optimize remaining small bowel.

However, some patients with short bowel syndrome are unable to obtain adequate nutrition from enteral feeding and become chronically dependent on total parenteral nutrition. Patients with complications from total parenteral nutrition may be considered candidates for a small bowel transplant. Complications include catheter-related mechanical problems, infections, hepatobiliary disease, and metabolic bone disease. While cadaveric intestinal transplant is the most commonly performed transplant, there has been a recent interest in using living donors.
Intestinal transplants (including multivisceral and bowel/liver) represent a small minority of all solid organ transplants. In 2016, 147 intestinal transplants were performed in the United States; all were from cadaver donors.

**Summary**

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 worsen comorbid conditions significantly. Guidelines and U.S. federal policy no longer view HIV infection as an absolute contraindication for solid organ transplantation. The evidence is sufficient to determine that the technology results in 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 a small number of patients undergoing retransplantation are available. Although limited in quantity, the available data have suggested a reasonably high survival rate after small bowel retransplantation in patients who continue to meet criteria for transplantation. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**Policy History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>9/2017</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>7/2015</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>6/2014</td>
<td>Updated Coding section with ICD10 procedure and diagnosis codes, effective 10/2015.</td>
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<tr>
<td>1/2014</td>
<td>New references added from BCBSA National medical policy.</td>
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<tr>
<td>12/2013</td>
<td>Removed ICD-9 diagnosis code as the policy requires prior authorization.</td>
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<tr>
<td>5/2012</td>
<td>BCBSA National medical policy review. Changes to policy statements.</td>
</tr>
<tr>
<td>10/2010</td>
<td>BCBSA National medical policy review. No changes to policy statements.</td>
</tr>
<tr>
<td>5/2009</td>
<td>BCBSA National medical policy review. No changes to policy statements.</td>
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Information Pertaining to All Blue Cross Blue Shield Medical Policies
Click on any of the following terms to access the relevant information:

- Medical Policy Terms of Use
- Managed Care Guidelines
- Indemnity/PPO Guidelines
- Clinical Exception Process
- Medical Technology Assessment Guidelines

References