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>
</tr>
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<tbody>
<tr>
<td><strong>Commercial Managed Care (HMO and POS)</strong></td>
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<tr>
<td><strong>Commercial PPO and Indemnity</strong></td>
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<tr>
<td><strong>Medicare HMO BlueSM</strong></td>
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<td><strong>Medicare PPO BlueSM</strong></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>Code</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>
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ICD-9 Procedure Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>46.97</td>
<td>Transplant of intestine</td>
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</table>

ICD-10 Procedure Coding

<table>
<thead>
<tr>
<th>Code</th>
<th>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
A small bowel transplant may be performed as an isolated procedure or in conjunction with other visceral organs, including the liver, duodenum, jejunum, ileum, pancreas, or colon. Isolated small bowel transplant is commonly performed in patients with short bowel syndrome. Small bowel/liver transplants and multivisceral transplants are considered in a separate policy (see Related Policies section).
**Background**

A small bowel transplant is typically performed in patients with short bowel syndrome. This 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 atresias are predominant causes.

The small intestine, particularly the ileum, does have the capacity to 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 is focused on achieving adequate macro- and micro-nutrient 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 (TPN). Patients with complications from TPN may be considered candidates for 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 recent interest in using living donors.

Intestinal transplants (including multivisceral and bowel/liver) represent a small minority of all solid organ transplants. In 2011, 129 intestinal transplants were performed in the United States, of which all but 1 was from deceased donors. In 2012, 106 intestinal transplants were performed in the U.S.; all were from deceased donors.

**Summary**

Based on the evidence review and clinical input, small bowel transplant may be considered medically necessary in patients with intestinal failure who are developing severe total parenteral nutrition (TPN)-related complications, to obviate the subsequent need for a multivisceral transplant. Small bowel transplantation using a living donor may be considered medically necessary only when a cadaveric intestinal transplant is not available. The available published survival data suggest that small bowel re-transplant is a reasonable option after a failed primary small bowel transplant; thus, this may be considered medically necessary. Routine use of living-donor intestinal transplants is considered not medically necessary because the net health outcome associated with this procedure is reduced (compared with cadaveric transplant) because of donor-related morbidity.

**Policy History**

<table>
<thead>
<tr>
<th>Date</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>5/2014</td>
<td>BCBSA National medical policy review.</td>
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<tr>
<td></td>
<td>New medically necessary indications described. Effective 5/1/2014.</td>
</tr>
<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>11/2011-4/2012</td>
<td>Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements</td>
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<tr>
<td>5/2012</td>
<td>BCBSA National medical policy review.</td>
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<td>Changes to policy statements.</td>
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<tr>
<td>10/2010</td>
<td>BCBSA National medical policy review.</td>
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<td></td>
<td>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