FEP 7.03.04 Isolated Small Bowel Transplant

**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 evidence review 7.03.05.

**FDA REGULATORY STATUS**
Small bowel transplantation is a surgical procedure and, as such, is not subject to regulation by the U.S. Food and Drug Administration.

**POLICY STATEMENT**
A small bowel transplant using cadaveric intestine may be considered *medically necessary* in adult and pediatric patients with intestinal failure (characterized by loss of absorption and the inability to maintain protein-energy, fluid, electrolyte, or micro nutrient balance), who have established long-term dependence on total parenteral nutrition and are developing or have developed severe complications due to total parenteral nutrition.

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

A small bowel retransplant may be considered *medically necessary* after a failed primary small bowel transplant.

A small bowel transplant using living donors is considered *not medically necessary* in all other situations.

A small bowel transplant is considered *investigational* for adults and pediatric patients with intestinal failure who can tolerate total parenteral nutrition.

**POLICY GUIDELINES**

**General Criteria**
Potential contraindications subject to the judgment of the transplant center include the following:

1. Known current malignancy, including metastatic cancer
2. Recent malignancy with high risk of recurrence
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3. Untreated systemic infection making immunosuppression unsafe, including chronic infection
4. Other irreversible end-stage disease not attributed to intestinal failure
5. History of cancer with a moderate risk of recurrence
6. Systemic disease that could be exacerbated by immunosuppression
7. Psychosocial conditions or chemical dependency affecting ability to adhere to therapy.

Small Bowel–Specific Criteria
Intestinal failure results from surgical resection, congenital defect, or disease-associated loss of absorption and is characterized by the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balance. Short bowel syndrome is 1 case of intestinal failure.

Patients who are developing or have developed severe complications due to total parenteral nutrition (TPN) include, but are not limited to, the following: multiple and prolonged hospitalizations to treat TPN-related complications (especially repeated episodes of catheter-related sepsis) or the development of progressive liver failure. In the setting 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. In those receiving TPN, liver disease with jaundice (total bilirubin >3 mg/dL) is often associated with development of irreversible, progressive liver disease. The inability to maintain venous access is another reason to consider small bowel transplant in those who are dependent on TPN.

BENEFIT APPLICATION
Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

RATIONALE

Summary of Evidence
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.
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SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Gastroenterological Association
In 2003, the American Gastroenterological Association produced a medical position statement on short bowel syndrome and intestinal transplantation. It recommended dietary, medical, and surgical solutions. Indications for intestinal transplantation mirrored those of the Centers for Medicare & Medicaid Services. The guidelines acknowledged the limitations of transplant for these patients. The statement recommended the following Medicare-approved indications, pending availability of additional data:

1. "Impending or overt liver failure….
2. Thrombosis of major central venous channels….
3. Frequent central line-related sepsis….
4. Frequent severe dehydration."

American Society of Transplantation
In 2001, the American Society of Transplantation issued a position paper on indications for pediatric intestinal transplantation. The Society listed the following disorders in children as potentially treatable by intestinal transplantation: short bowel syndrome, defective intestinal motility, and impaired enterocyte absorptive capacity. Contraindications for intestinal transplant to treat pediatric patients with intestinal failure are similar to those of other solid organ transplants: profound neurologic disabilities, life-threatening comorbidities, severe immunologic deficiencies, nonresectable malignancies, autoimmune diseases, and insufficient vascular patency.

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
The Centers for Medicare & Medicaid have a national coverage determination on intestinal and multivisceral transplantation. The determination covers these types of transplants 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….
 Thrombosis of the major central venous channels; jugular, subclavian, and femoral veins.
 Frequent line infection and sepsis.
 Frequent episodes of severe dehydration despite intravenous fluid supplement in addition to TPN.
2. Approved Transplant Facilities
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."

REFERENCES

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advise, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
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POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
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<tbody>
<tr>
<td>March 2012</td>
<td>New Policy</td>
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<tr>
<td>March 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review. Added references 7 and 8; other references renumbered. No change in policy statements.</td>
</tr>
<tr>
<td>March 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature review. Added reference number 10; other references renumbered. Medically necessary policy statement added following a failed primary transplants.</td>
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<tr>
<td>September 2015</td>
<td>Update Policy</td>
<td>Policy updated with literature review; references 5 and 12 added. Policy statements unchanged.</td>
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<tr>
<td>December 2017</td>
<td>Update Policy</td>
<td>Policy updated with literature review through June 22, 2017; references 7-11, 14, and 28 added. Policy statements unchanged.</td>
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