Small Bowel/Liver and Multivisceral Transplant

Description

This evidence review addresses transplantation and retransplantation of an intestinal allograft in combination with a liver allograft, either alone or in combination with one or more of the following organs: stomach, duodenum, jejunum, ileum, pancreas, or colon.

OBJECTIVE

The objective of this evidence review is to determine whether a small bowel and liver transplant or a multivisceral transplant (or retransplant) improves the net health outcome in patients with intestinal failure and impending liver failure.

POLICY STATEMENT

Transplants, such as a multivisceral transplant and a small bowel and liver transplant, may be considered medically necessary for pediatric and adult patients with intestinal failure (characterized by loss of absorption and the inability to maintain protein-energy, fluid, electrolyte, or micronutrient balance) who have been managed with long-term total parenteral nutrition and who have developed evidence of impending end-stage liver failure.

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Retransplants, such as a multivisceral retransplant and a small bowel and liver retransplant, may be considered **medically necessary** after a failed primary small bowel and liver transplant or multivisceral transplant.

A small bowel and liver transplant or multivisceral transplant is considered **investigational** in all other situations.

**POLICY GUIDELINES**

**General Criteria**

Potential contraindications for solid organ transplant are subject to the judgment of the transplant center include the following:

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

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 an example of intestinal failure.

Candidates should meet the following criteria:

- Adequate cardiopulmonary status
- Documentation of patient compliance with medical management.

**Small Bowel/Liver-Specific Criteria**

Evidence of intolerance of total parenteral nutrition (TPN) includes, but is not limited to, multiple and prolonged hospitalizations to treat TPN-related complications or the development of progressive but reversible 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 and would thus avoid the necessity of a multivisceral transplant.

**BENEFIT APPLICATION**

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

**FDA REGULATORY STATUS**

Small bowel/liver and multivisceral transplantation are surgical procedures and, as such, are not subject to regulation by the U.S. Food and Drug Administration.

The U.S. Food and Drug Administration regulates human cells and tissues intended for implantation, transplantation, or infusion through the Center for Biologics Evaluation and Research, under Code of Federal Regulation Title 21, parts 1270 and 1271. Pancreas transplants are included in these regulations.
RATIONALE

Summary of Evidence

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 a limited number of case series. The relevant outcomes are overall survival (OS), morbid events, and treatment-related mortality and morbidity. These transplant procedures are infrequently performed and few reported case series exist. However, results from the available case series have revealed fairly high post-procedural survival rates. Given these results and the exceedingly poor survival rates of patients who exhaust all other treatments, transplantation may prove not only to be the last option but also a beneficial one. Transplantation is contraindicated for patients in whom the procedure is expected to be futile due to comorbid disease, or in whom post-transplantation 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. The relevant outcomes are OS, morbid events, and treatment-related mortality and morbidity. Although limited in quantity, the available post-retransplantation data have 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 post-transplantation 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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Gastroenterological Association

The American Gastroenterological Association (2003) 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 recommended the following Medicare-approved indications, pending availability of additional data:

- Impending liver failure
- Thrombosis of major central venous channels
- Frequent central line-associated sepsis
- Frequent severe dehydration.

American Society of Transplantation

The American Society of Transplantation (2001) issued a position paper on indications for pediatric intestinal transplantation. The Society listed the following disorders in children as being 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

Medicare covers intestinal transplantation for the purposes of restoring intestinal function in patients with irreversible intestinal failure only when performed for patients who have failed total parenteral nutrition and only when performed in centers that meet approved criteria. The criteria for approval of centers are based on a "volume of 10 intestinal transplants per year with a 1-year actuarial survival rate of 65 percent."

REFERENCES


### POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

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<td>March 2012</td>
<td>New policy</td>
<td>Policy updated with literature review through April 30, 2013. References 5, 6, 8, and 10-15 added; other references renumbered or removed. Policy statement updated.</td>
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<tr>
<td>September 2013</td>
<td>Replace policy</td>
<td>Policy updated with literature review. Reference 10 added. Statement added that procedure is investigational in all other situations.</td>
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<tr>
<td>September 2014</td>
<td>Replace policy</td>
<td>Policy updated with literature review.</td>
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<tr>
<td>September 2015</td>
<td>Replace policy</td>
<td>Policy updated with literature review; no references added. Policy statements unchanged.</td>
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<td>December 2017</td>
<td>Replace policy</td>
<td>Policy updated with literature review through June 22, 2017; references 7-9 and 15 added. Policy statements unchanged.</td>
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<tr>
<td>December 2019</td>
<td>Replace policy</td>
<td>Policy updated with literature review through June 10, 2019; no references added. Policy statements unchanged.</td>
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