Preauthorization is required and must be obtained through Case Management.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient’s contract at the time the services are rendered.

RELATED PROTOCOL

Small Bowel/Liver and Multivisceral Transplant

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals:</td>
<td>Interventions of interest</td>
<td>Comparators of interest</td>
<td>Relevant outcomes include:</td>
</tr>
<tr>
<td>• With intestinal failure</td>
<td>are:</td>
<td>are:</td>
<td>• Overall survival</td>
</tr>
<tr>
<td></td>
<td>• Small bowel transplant</td>
<td>• Medical management</td>
<td>• Morbid events</td>
</tr>
<tr>
<td>Individuals:</td>
<td>Interventions of interest</td>
<td>Comparators of interest</td>
<td>• Treatment-related mortality</td>
</tr>
<tr>
<td>• With failed small bowel</td>
<td>are:</td>
<td>are:</td>
<td>• Treatment-related morbidity</td>
</tr>
<tr>
<td>transplant without contrain-</td>
<td>• Small bowel retransplant</td>
<td>• Medical management</td>
<td></td>
</tr>
<tr>
<td>dication(s) for retransplant</td>
<td></td>
<td>• Parenteral nutrition</td>
<td></td>
</tr>
</tbody>
</table>

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 the Small Bowel/Liver and Multivisceral Transplant Protocol.

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 (OS), 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, ear-
isolate Small Bowel Transplant

Isolated 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 an 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 OS, 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 the criteria for transplantation. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome.

POLICY

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 micronutrient balance), who have established long-term dependence on total parenteral nutrition (TPN) and are developing or have developed severe complications due to TPN.

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 adult and pediatric patients with intestinal failure who can tolerate TPN.

POLICY GUIDELINES

GENERAL CRITERIA

Individual transplant facilities may have their own additional requirements or protocols that must be met in order for the patient to be eligible for a transplant at their facility.

Potential contraindications for solid organ transplant are 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
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 one case of intestinal failure.

Patients who are developing or have developed severe complications due to 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 greater than three 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.

MEDICARE ADVANTAGE

If a transplant is needed, we arrange to have the Medicare-approved transplant center review and decide whether the patient is an appropriate candidate for the transplant.

BACKGROUND

Solid organ transplantation offers a treatment option for patients with different types of end-stage organ failure that can be lifesaving or provide significant improvements to a patient’s quality of life. Many advances have been made in the last several decades to reduce perioperative complications. Available data supports improvement in long-term survival as well as improved quality of life, particularly for liver, kidney, pancreas, heart, and lung transplants. Allograft rejection remains a key early and late complication risk for any organ transplantation. Transplant recipients require life-long immunosuppression to prevent rejection. Patients are prioritized for transplant by mortality risk and severity of illness criteria developed by the Organ Procurement and Transplantation Network (OPTN) and United Network of Organ Sharing (UNOS).

SHORT 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 the small intestine. The spectrum of clinical disease is widely variable from only single micronutrient malabsorption to complete intestinal failure, defined as the reduction of gut function below the minimum necessary for the absorption of macronutrients and/or water and electrolytes. 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. Although the actual prevalence of short bowel syndrome is not clear primarily due to under-reporting and a lack of reliable patient databases, its prevalence is estimated to be 30 cases per million in the U.S.

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 (TPN). For patients with short bowel syn-
drome, the rate of parenteral nutrition dependency at 1, 2, and 5 years has been reported to be 74%, 64%, and 48%, respectively. Patients with complications from TPN 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 2019, 81 intestinal transplants were performed in the U.S. (approximately 50% of which were intestine-liver transplants). Overall, both the number of new patients added to the intestinal transplant waiting list (n=103) and the number of intestinal transplants performed declined to their lowest levels in 2019.

REGULATORY STATUS

Solid organ transplants are a surgical procedure and, as such, are not subject to regulation by the U.S. Food and Drug Administration (FDA).

The FDA 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. Solid organs used for transplantation are subject to these regulations.

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.


