Protocol

Small Bowel/Liver and Multivisceral Transplant

(70305)

Medical Benefit		**Effective Date**: 07/01/14	**Next Review Date**: 05/19
Preauthorization	Yes	**Review Dates**: 05/09, 05/10, 05/11, 05/12, 05/13, 07/13, 05/14, 05/15, 05/16, 05/17, 05/18	

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.

Populations	Interventions	Comparators	Outcomes
Individuals: • With intestinal failure and evidence of impending end-stage liver failure	Interventions of interest are: • Small bowel and liver transplant alone or multivisceral transplant	Comparators of interest are: • Medical management • Parenteral nutrition	Relevant outcomes include: • Overall survival • Morbid events • Treatment-related mortality • Treatment-related morbidity
Individuals: • With a failed small bowel and liver or multivisceral transplant without contraindications for retransplant	Interventions of interest are: • Small bowel and liver retransplant alone or multivisceral retransplant	Comparators of interest are: • Medical management • Parenteral nutrition	Relevant outcomes include: • Overall survival • Morbid events • Treatment-related mortality • Treatment-related morbidity

DESCRIPTION

This protocol 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.

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. Relevant outcomes are overall survival, 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 postprocedural survival rates. Given these results and bearing in mind the abysmal survival rates of patients who exhaust all other treatments, transplantation may prove not only to be the last option, but also a beneficial one. To be clear, transplantation is contraindicated for patients in whom the procedure is expected to be futile due to comorbid disease, or in whom posttransplantation 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. Relevant outcomes are overall survival, morbid events, and treatment-related mortality and morbidity. Although limited in quantity, the available post retransplantation data has 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.

POLICY

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.

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

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 to solid organ transplant (subject to the judgment of the transplant center):

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

Candidates should meet the following criteria:

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

Human immunodeficiency virus (HIV)-positive patients who meet the following criteria, as stated in the 2001 guidelines of the American Society of Transplantation (Steinman et al, 2001), could be considered candidates for small bowel and liver or multivisceral transplantation under the following conditions:

- CD4 count greater than 200 cells per cubic millimeter for greater than six months
- HIV-1 RNA undetectable
- On stable anti-retroviral therapy greater than three months
- No other complications from acquired immune deficiency syndrome (AIDS) (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections, Kaposi sarcoma, or other neoplasm), and meeting all other criteria for transplantation.

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, thus avoiding the necessity of a multivisceral transplant.

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

SHORT BOWEL SYNDROME

Small bowel transplants are typically performed in patients with short bowel syndrome, defined as an inadequate absorbing surface of the small intestine due to extensive disease or surgical removal of a large portion of small intestine. In some instances, short bowel syndrome is associated with liver failure, often due to the long-term complications of TPN.

Treatment

These patients may be candidates for a small bowel and liver transplant or a multivisceral transplant, which includes the small bowel and liver with one or more of the following organs: stomach, duodenum, jejunum, ileum, pancreas, and/or colon. The type of transplantation depends on the underlying etiology of intestinal failure, quality of native organs, presence or severity of liver disease, and history of prior abdominal surgeries.[1] A multivisceral transplant is indicated when anatomic or other medical problems preclude a small bowel and liver transplant. Complications following small bowel and liver and multivisceral transplants include acute or chronic rejection, donor-specific antibodies, infection, lymphoproliferative disorder, graft-versus-host disease, and renal dysfunction.[2]

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.

RELATED PROTOCOL

Isolated Small Bowel Transplant

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

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