MEDICAL POLICY

Excellus

SUBJECT: SMALL BOWEL AND MULTIVISCERAL TRANSPLANTS IN ADULTS AND CHILDREN	**EFFECTIVE DATE: 02/16/00** **REVISED DATE: 07/19/01, 06/20/02, 04/24/03, 02/19/04, 02/17/05, 02/16/06, 03/15/07, 03/20/08, 03/19/09, 03/18/10, 03/17/11, 03/15/12, 02/21/13, 02/20/14** **ARCHIVED DATE: 02/19/15**
POLICY NUMBER: 7.02.05 **CATEGORY: Transplants**	**EDITED DATE: 03/17/16, 03/16/17, 03/15/18** **PAGE: 1 OF: 5**

- ***If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.***
- ***If a commercial product, including an Essential Plan product, covers a specific service, medical policy criteria apply to the benefit.***
- ***If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.***

POLICY STATEMENT:

I. Small Bowel Transplant

A. Based upon our criteria and the review of the peer-reviewed literature, small bowel transplantation has been medically proven to be effective and therefore, **medically appropriate** in pediatric and adult patients with short-bowel syndrome (SBS) for any of the following indications:

1. Impending or overt liver failure due to TPN-induced liver injury. Progressive thrombocytopenia and cholestasis are the most reliable indicators of developing liver dysfunction. Complications of portal hypertension such as variceal bleeding, ascites, and hepatorenal syndrome do not arise until late in the course of disease. Timely referral may allow salvage of the native liver with the more accessible intestinal allograft. Given the higher patient survival rates with this single-organ transplant, patients should be identified and considered for transplant before development of irreversible liver dysfunction.
2. Thrombosis of 2 or more central veins.
3. Development of 2 or more episodes of systemic sepsis secondary to line infection per year that requires hospitalization.
4. A single episode of line-related fungemia, septic shock, and/or acute respiratory distress syndrome.
5. Frequent episodes of severe dehydration despite intravenous fluid supplementation in addition to TPN.

B. Based upon our criteria and the lack of peer-reviewed literature, small bowel transplant in adults has not been medically proven to be effective and is considered **investigational** for adults who are able to tolerate TPN.

C. Based upon our criteria and the lack of peer-reviewed literature, living donations of small bowel for transplantation has not been medically proven to be effective and is considered **investigational.**

II. Multivisceral Transplant

Based upon our criteria and the review of the peer-reviewed literature, multivisceral transplantation has been medically proven to be effective and therefore, **medically appropriate** in pediatric and adult patients with intestinal failure and concurrent liver failure.

III. Candidates must meet all of the following criteria:

A. Adequate cardiopulmonary status;
B. Absence of active infection;
C. Absence of malignancy (other than non-melanoma skin cancers), or malignancy has been completely resected, or (upon medical review) it is determined that malignancy has been treated with small likelihood of recurrence and acceptable future risks; and
D. Documentation of patient compliance with medical management.

IV. Transplant is contraindicated in patients with HIV infection unless *ALL* of the following criteria are met:

A. CD4 count greater than 200 cells/mm^3,

B. HIV-1RNA undetectable,
C. On stable anti-retroviral therapy greater than 3 months, and
D. No other complications from AIDS (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis; resistant fungal infections, Kaposi's sarcoma, or other neoplasm).

POLICY GUIDELINES:

I. Prior authorization is contract dependent. Approvals for all transplants, including arrangements with an approved transplant center, may be required.

II. Pre-transplant evaluation documentation could include the following clinical information. If testing is unable to be performed, the rationale for not performing the testing should be included in the documentation:

A. Clinical Evaluation:
1. Confirmation of diagnosis;
2. Identification of comorbidities;
3. Treatment of co-morbidities;
4. Current assessment of co-morbidities;
5. Consult notes (if applicable).

B. Psycho-Social Evaluation:
1. Karnosfsky performance score;
2. Identification of stressors (family support, noncompliance issues, motivational issues, alcohol or substance abuse).

C. Dental Evaluation.

D. Lab Tests:
1. CBC, metabolic profile;
2. Serologies: CMV,
3. Hepatitis B and C;
4. HIV Testing.

E. Cardiac Assessment:
1. 12Lead EKG;
2. Stress echo or MUGA Scan.

F. Pulmonary Assessment:
1. Chest x-ray;
2. Pulmonary function tests (PFTs);
3. Low dose screening CT for individuals considered high-risk for lung cancer (e.g., 20-30 pack history of smoking).

G. Age Appropriate Screening Tests:
1. Age greater than or equal to 50 years:
   a. Colonoscopy (within 10 years); or
   b. Flexible sigmoidoscopy (within 5 years); or
   c. Guaiac stool testing (within 1 year); or
   d. Rationale of contraindication to testing (if applicable).
2. Women age 21-70 years:
   a. Pap smear (within 3 years).
3. Women age greater than or equal to 40 years:
   a. Mammogram (within 2 years).

DESCRIPTION:

Small Bowel Transplant

The purpose of a small bowel (SB) transplant is to restore bowel function and allow for adequate nutrition in patients with short bowel syndrome (SBS). It may be an alternative to total parenteral nutrition (TPN) for selected patients who are predicted to have poor survival on TPN.

Multivisceral Transplant

Candidates for multivisceral (MV) transplant have short bowel syndrome and terminal liver failure or other gastrointestinal problems such as pancreatic failure, thromboses of the celiac axis and the mesenteric artery or pseudo-obstruction affecting the entire gastrointestinal tract. Due to anatomic or other medical problems this group of patients requires a more extensive transplant procedure than a small bowel and liver. MV transplantation may include in addition to the small bowel and liver, stomach, duodenum, jejunum, ileum, pancreas and/or colon.

MV transplantation is an infrequently performed procedure, but without this procedure most patients face 100% mortality.

RATIONALE:

Total parenteral nutrition is the only established treatment that can produce long-term survival once the small intestine is dysfunctional and oral nutrition is ineffective. TPN requires placement of a permanent venous access device. There are some serious, life threatening complications that can occur as a result of TPN including hepatobiliary disease, thrombosis due to the venous catheter, or sepsis from the venous access line.

There are limited long-term data on small bowel and multivisceral transplants due to the small numbers performed. International Intestinal Transplant Registry outcomes published in 1999 include overall patient and graft survival rates of 69% for isolated intestine recipients at 1 year and 66% and 63% for liver/bowel and multivisceral grafts. It is possible that some patient with severe TPN-associated complications face a higher probability of mortality with continued medical management than the risk of transplantation. Small bowel and multivisceral transplantation is reserved for selected patients with life threatening complications of TPN.

Living donor isolated or combined liver/intestinal transplants have been studied in very small case studies. Typically living donor transplants have been reserved for children who are at high risk for premature death while on the cadaveric waiting list and have no central venous access or for children with impending TPN-related liver failure. A living donor liver transplant may be performed first followed by an intestinal transplant from the same donor later. Advantages to living donors transplants include better HLA matching, reduction of cold ischemia time, and no wait-listing for a transplant, thus the patient is less likely to die while waiting for an organ. Results from the studies show little or no complications after transplant for the donor. Most complications such as diarrhea, weight loss, and nausea are resolved within a few weeks of surgery. However these small studies are lacking long-term follow up of the donors. Patient survival and graft survival for recipients of living donor combined liver/intestinal or isolated intestinal transplants has been favorable. More large studies are needed to determine if patient survival is comparable or better than those patients receiving cadaveric organs. Most studies suggest that living donor transplanted organs are to be reserved for those circumstances where there is high risk for death and no cadaveric donors are available.

Solid organ transplantation for candidates that are HIV positive has long been controversial, due to the long-term prognosis for HIV positivity, and the impact of immunosuppression on HIV disease. Although HIV+ transplant recipients may be a research interest of some transplant centers, the minimal data regarding long-term outcome in these patients consist primarily of case reports and abstract presentations of liver and kidney recipients. Nevertheless, some transplant surgeons would argue that HIV positivity is no longer an absolute contraindication to transplant due to the advent of highly active antiretroviral therapy (HAART), which has markedly changed the natural history of the disease. Furthermore, UNOS states that asymptomatic HIV+ patients should not necessarily be excluded for candidacy for organ

transplantation, stating "A potential candidate for organ transplantation whose test for HIV is positive but who is in an asymptomatic state should not necessarily be excluded from candidacy for organ transplantation, but should be advised that he or she may be at increased risk of morbidity and mortality because of immunosuppressive therapy". In 2001, the Clinical Practice Committee of the American Society of Transplantation proposed that the presence of AIDS could be considered a contraindication to small bowel and multivisceral transplants unless the specific criteria were present. These criteria are listed in this policy regarding HIV status and small bowel and multivisceral transplants.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

Code Key: Experimental/Investigational = (E/I), Not medically necessary/ appropriate = (NMN).

CPT:	44120	Enterectomy, resection of small intestine; single resection and anastomosis
	44121	each additional resection and anastomosis (List separately in addition to code for primary procedure)
	44125	with enterostomy
	44135	Intestinal allotransplantation from a cadaver donor
	44136 **(E/I)**	Intestinal allotransplantation from a living donor
	44137	Removal of transplanted intestinal allograft, complete
	47135	Liver allotransplantation; orthotopic, partial or whole from cadaver or living donor, any age

HCPCS:	S2053	Transplantation of small intestine, and liver allografts
	S2054	Transplantation of multivisceral organs
ICD10:	K72.10	Chronic hepatic failure without coma
	K72.11	Chronic hepatic failure with coma
	K72.90	Hepatic failure, unspecified without coma
	K72.91	Hepatic failure, unspecified with coma
	K91.2	Postsurgical malabsorption, not elsewhere classified

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*key article

KEY WORDS:

Intestine, Multivisceral Small bowel, Transplant

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for Intestinal and Multi-Visceral Transplantation. Please refer to the following NCD website for Medicare Members: http://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=280&ncd ver=2&bc=BAABAAAAAAAA&.