



Subject: *Small Bowel, Small Bowel/Liver, and Multi-visceral Transplant*

Number: *200308-0004*

Effective date: 08/25/2003

Revision date(s): 08/08/2003

Important note

Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the *Evidence of Coverage* to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this Medical Policy and Criteria Statement. Medicare and Medicaid policies will only apply to benefits paid for under Medicare or Medicaid rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the following Web site: <http://www.cms.hhs.gov/manuals/pub06pdf/pub06pdf.asp>

Overview

A small bowel transplant is typically performed in patients with Short Bowel Syndrome (SBS). SBS is a condition in which there is not enough nutrition absorbing surface of the small bowel due to extensive disease or surgical removal of a large portion.

For nourishment, these patients must be fed by an intravenous (IV) solution called total parenteral nutrition (TPN). Patients with complications from or failure of TPN may be considered candidates for small bowel transplant.

Cadaveric small bowel transplant is far more common than live-donor transplant. Simultaneous small bowel and liver transplants (referred to as small bowel/liver) are reserved for patients with end-stage liver disease, usually related to long-term TPN use, along with severe bowel dysfunction. Multi-visceral transplant is when three or more organs, such as small bowel, liver, and another organ such as stomach, pancreas, or colon, are transplanted at the same time.

Policy and criteria

NOTE: These services require prior authorization by the plan medical director.

When services are covered:

We cover **small bowel transplants in pediatric patients** with SBS when ALL of the following criteria are met:

- The patient is 16 years of age or less
- There is irreversible intestinal failure
- There is established TPN dependence for a minimum of two years
- There is evidence of severe complications from TPN, such as:
 - Liver dysfunction
 - Repeated infections
 - Thrombosis

- Difficult venous access for TPN administration

We cover **simultaneous small bowel/liver transplants in pediatric and adult** patients with SBS when ALL of the following criteria are met:

- There is irreversible intestinal failure
- There is established TPN dependence for a minimum of two years
- There is evidence of impending end-stage liver failure such as:
 - Prolonged prothrombin time (PT)
 - Decreasing albumin
- There is evidence of severe complications from TPN such as:
 - Liver dysfunction
 - Repeated infections
 - Thrombosis
 - Difficult venous access for TPN or fluids

We cover **multi-visceral transplants in pediatric and adult patients** with SBS who have been managed with long-term TPN and who have developed evidence of impending liver failure such as pancreatic failure, thromboses of the celiac axis and the superior mesenteric artery, or pseudo-obstruction affecting the entire gastrointestinal tract.

In addition, the member must have completed an evaluation and been accepted as a transplant candidate by the FCHP-designated transplant center.

Please refer to the *Transplant policy* for additional information regarding covered and noncovered services.

When services are not covered:

We **do not cover** small bowel, simultaneous small bowel/liver or multi-visceral transplantation when any of the following **contraindications** exist:

- Active infection or sepsis
- Multi-organ failure
- Systemic diseases affecting multiple body systems, such as scleroderma, amyloidosis or diffuse atheromatous disease
- Congenital immunodeficiency or other contraindications to immunosuppressive drugs required for transplant
- Advanced neurological disorders, such as neuroaxonal dystrophy, Tay-Sachs disease, Niemann-Pick disease and its variants, neuronal ceroid lipofuscinosis, and Huntington disease
- When other gastrointestinal diseases are present, such as bleeding peptic ulcer, diverticulitis, or chronic hepatitis
- History of malignancy, other than non-melanomatous skin cancer, where there is a substantial risk of recurrence
- Congestive heart failure with refractory symptoms and ejection fraction < 40%
- Hepatitis B surface antigen positive (HBSAg+) or Hepatitis C positive
- HIV positive, with or without AIDS
- Active alcohol, drug or tobacco use. Persons with a history of alcohol or drug abuse must be abstinent for at least 6 months before being considered for a transplant.
- Behavioral or psychiatric disorders likely to compromise adherence to strict medical regimens and post transplant follow-up

Note: Small bowel and related types of transplant are considered experimental and investigational for persons with the above contraindications.

FCHP products to which this policy applies:

- ⊕ FCHP Direct and FCHP Select Care (HMO)

- ⊕ FCHP Flex Care Direct and Select (POS)
- ⊕ Fallon Preferred Care (PPO)
- ⊕ FCHP MassHealth
- ⊕ Non-Group: FCHP Independent Care, Direct enrollment and Bill-at-home
- ⊘ Medicare plan – *reminder* to refer to CMS for policy and criteria

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Committee review dates:

Technology Assessment Committee: 11/2003

Approved by:	<i>Signature on file</i>	<i>08/19/2003</i>
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