

Effective: September 1, 2023

<p>Prior Authorization Required If <u>REQUIRED</u>, submit supporting clinical documentation pertinent to service request.</p>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<p>Notification Required IF <u>REQUIRED</u>, concurrent review may apply</p>	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>

Applies to:

Commercial Products

- Harvard Pilgrim Health Care Commercial products; 800-232-0816
- Tufts Health Plan Commercial products; 617-972-9409
CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

- Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); 888-415-9055
- Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; 888-415-9055
- Tufts Health RITogether – A Rhode Island Medicaid Plan; 857-304-6404
- Tufts Health Unify* – OneCare Plan (a dual-eligible product); 857-304-6304
*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.

Senior Products

- Harvard Pilgrim Health Care Stride Medicare Advantage; 866-874-0857
- Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); 617-673-0965
- Tufts Medicare Preferred HMO, (a Medicare Advantage product); 617-673-0965
- Tufts Medicare Preferred PPO, (a Medicare Advantage product); 617-673-0965

Note: While you may not be the provider responsible for obtaining prior authorization or notifying Point32Health, as a condition of payment you will need to ensure that any necessary prior authorization has been obtained and/or Point32Health has received proper notification. If notification is required, providers may additionally be required to provide updated clinical information to qualify for continued service.

Overview

A small bowel transplant is the transplantation of an intestinal allograft to an individual with irreversible intestinal failure. The purpose of this transplant is to restore intestinal function. An allograft refers to when transplanted cells, tissues or organs are sourced from a genetically non-identical Member of the same species.

To initiate the prior authorization process, it is necessary to complete and submit the [Intestinal and Multivesicular Transplant Request for Coverage Form](#).

Clinical Guideline Coverage Criteria

Small Bowel Transplant:

The Plan may authorize a small bowel transplant for a pediatric or adult Member meeting **ALL** of the following criteria:

1. Adult Members with iatrogenic, traumatic, or vascular thrombosis and loss of small bowel; **and**
2. Irreversible intestinal failure; **and**
3. Satisfactory psychosocial and support systems in place; **and**

4. Total parenteral nutrition (TPN) dependency established for a minimum of 2 years, or implementation of this requirement puts the Member at an unacceptably increased risk for a catastrophic event.
 - a. Severe complications of TPN, including at least **ONE** of the following:
 - i. Liver dysfunction
 - ii. Repeated infection
 - iii. Thrombosis
 - iv. Venous access difficulty with TPN, defined as more than one-half of the sites typically used for TPN (e.g., jugular, subclavian and iliac veins) becoming inaccessible due to thrombosis)

Simultaneous Small Bowel-Liver Transplant:

The Plan may authorize a simultaneous small bowel/liver transplant in all Members with Short Bowel Syndrome (SBS) when **ALL** of the following criteria are met:

1. Evidence of impending liver failure, including **BOTH** of the following:
 - a. Prolonged prothrombin time; **and**
 - b. Decreasing albumin level
2. Irreversible intestinal failure; **and**
3. Satisfactory psychosocial and support systems in place; **and**
4. Severe complications of TPN including at least **ONE** of the following:
 - a. Liver dysfunction; **or**
 - b. Repeated infections; **or**
 - c. Thrombosis; **or**
 - d. Venous access difficulty with TPN
5. TPN dependency established minimum of 2 years

Multivisceral Transplants:

The Plan may authorize multivesicular transplants in all Members with SBS when long term TPN results in impending liver failure complications (e.g., pancreatic failure, thrombosis of the celiac axis and superior mesenteric artery and/or pseudo-obstruction affecting the entire GI tract).

Limitations

The plan will not authorize the coverage of a small bowel, simultaneous small bowel and liver or multivisceral transplant for Members **with ANY** of the following:

1. Active or uncontrolled alcohol use disorder or substance use disorder
2. Any unresolved psychosocial concerns or history of noncompliance with medical management
3. Human immunodeficiency virus (HIV) infection unless **ALL** of the following are met:
 - a. CD4 count greater than 200 cells/mm³ during 3 months prior to transplantation
 - b. Undetectable HIV-1 ribonucleic acid (RNA)
 - c. Stable anti-retroviral therapy for > 3 months
 - d. Absence of serious complications associated with or secondary to HIV disease
 - e. (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections; Kaposi's sarcoma; or other neoplasm)
4. Serious health condition that creates the inability to tolerate the transplant surgery or post-transplant medical regimen adherence, such as multisystem organ failure, cerebral edema, and/or severe cardiopulmonary disease
5. Systemic disease affecting multiple body systems, including but not limited to scleroderma, amyloidosis, diffuse atheromatous disease, and/or aggressive malignancies
6. Uncontrolled or untreatable infection, any source

Note: Smoking has been strongly correlated to adverse health and surgical outcomes. There is evidence to show that smoking, both by donors and by recipients, has a major impact on outcomes after organ transplantation. Smoking cessation is strongly recommended for both donors and recipients prior to transplantation.

Codes

The following code(s) require prior authorization:

Table 1: CPT/HCPCS Codes

*Codes are applicable only to THP Products

Code	Description
44132	Donor enterectomy (including cold preservation), open; from cadaver donor
44133	Donor enterectomy (including cold preservation), open; partial, from living donor
44135	Intestinal allotransplantation; from cadaver donor
44136	Intestinal allotransplantation; from living donor
44715	Backbench standard preparation of cadaver or living donor intestine allograft prior to transplantation, including mobilization and fashioning of the superior mesenteric artery and vein
44720	Backbench reconstruction of cadaver or living donor intestine allograft prior to transplantation; venous anastomosis, each
44721	Backbench reconstruction of cadaver or living donor intestine allograft prior to transplantation; arterial anastomosis, each
S2053*	Transplantation of small intestine, and liver allografts
S2054*	Transplantation of multivisceral organs
S2055*	Harvesting of donor multivisceral organs, with preparation and maintenance of allografts; from cadaver donor

References:

1. American Gastroenterological Association. American Gastroenterological Association medical position statement: short bowel syndrome and intestinal transplantation. *Gastroenterology*. 2003;124(4):1105-1110. doi:10.1053/gast.2003.50139.
2. Blumberg EA, Rogers CC; American Society of Transplantation Infectious Diseases Community of Practice. Solid organ transplantation in the HIV-infected patient: Guidelines from the American Society of Transplantation Infectious Diseases Community of Practice. *Clin Transplant*. 2019;33(9):e13499. doi:10.1111/ctr.13499.
3. Kaufman SS, Avitzur Y, Beath SV, et al. New Insights in to the Indications for Intestinal Transplantation: Consensus in the Year 2019. *Transplantation*. 2020;104(5):937-946. doi:10.1097/TP.0000000000003065.
4. Overview of intestinal and multivisceral transplantation. UpToDate.com/login [via subscription only]. Published September 16, 2020. Updated July 2021. Accessed August 22, 2021.
5. Centers for Medicare & Medicaid Services (CMS). NCD 260.5 for intestinal and multi-visceral transplantation. Published May 11, 2006. Accessed on August 22, 2021.

Approval And Revision History

October 21, 2020: Reviewed by IMPAC, renewed without changes

Subsequent endorsement date(s) and changes made:

- December 8, 2020: Fax number for Unify updated
- November 17, 2021: Reviewed by IMPAC for integration purposes between Harvard Pilgrim Health Care and Tufts Health Plan; under the “Limitations” section changed “CD4 count >200 cells/μL” to “CD4 count >200 cells/μL during 3 months prior to transplantation”
- December 1, 2022: Reviewed by Medical Policy Approval Committee, renewed without changes
- March 15, 2023: Reviewed by MPAC, limitations updated to remove smoking cessation and limitation modified from “Active drug, substance abuse, or alcohol abuse within the last 6 months” to “Active or uncontrolled alcohol use disorder or substance use disorder”. Effective September 1, 2023

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member’s health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation

organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.