

## Medical Necessity Guidelines: Solid Organ Transplant: Intestinal (Small Bowel, Simultaneous Small Bowel-Liver) and Multivisceral

Effective: October 21, 2020

<b>Prior Authorization Required</b> If <u>REQUIRED</u> , submit supporting clinical documentation pertinent to service request.	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<p><b>Applies to:</b></p> <p><b>COMMERCIAL Products</b></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Tufts Health Plan Commercial products; Fax: 617.972.9409</li> <li><input checked="" type="checkbox"/> Tufts Health Freedom Plan products; Fax: 617.972.9409</li> <li>• CareLink<sup>SM</sup> – Refer to <a href="#">CareLink Procedures, Services and Items Requiring Prior Authorization</a></li> </ul> <p><b>TUFTS HEALTH PUBLIC PLANS Products</b></p> <ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 888.415.9055</li> <li><input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055</li> <li><input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404</li> <li><input checked="" type="checkbox"/> Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 857.304.6304</li> </ul> <p>*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.</p> <p><b>SENIOR Products</b></p> <ul style="list-style-type: none"> <li>• Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the <a href="#">Tufts Health Plan SCO Prior Authorization List</a></li> <li>• Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the <a href="#">Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List</a></li> </ul>	

**Note:** While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to make sure that prior authorization has been obtained.

### 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 Multivisceral Transplant Request for Coverage Form](#).

### CLINICAL COVERAGE CRITERIA

#### Small Bowel Transplant:

Tufts Health Plan may authorize a small bowel transplant for a pediatric or adult Member meeting all of the following criteria:

- Irreversible intestinal failure
- 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.
  - Severe complications of TPN, including at least one of the following:
    - Liver dysfunction
    - Repeated infection
    - Thrombosis
  - 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
- Satisfactory psychosocial and support systems in place
- Adult Members with iatrogenic, traumatic or vascular thrombosis and loss of small bowel.

**Simultaneous Small Bowel-Liver Transplant:**

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

- Irreversible intestinal failure
- TPN dependency established minimum of 2 years
- Evidence of impending liver failure, including both of the following:
  - Prolonged prothrombin time
  - Decreasing albumin level
- Severe complications of TPN including at least **one** of the following:
  - Liver dysfunction
  - Repeated infections
  - Thrombosis
  - Venous access difficulty with TPN
- Satisfactory psychosocial and support systems in place

**Multivisceral Transplants:**

Tufts Health Plan may authorize multivisceral 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**

Tufts Health Plan will not authorize the coverage of a small bowel, simultaneous small bowel and liver or multivisceral transplant for Members with any one of the following:

- Systemic disease affecting multiple body systems, including but not limited to scleroderma, amyloidosis, diffuse atheromatous disease, and/or aggressive malignancies
- Any unresolved psychosocial concerns or history of noncompliance with medical management
- 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.
- Active drug, substance, or alcohol abuse within the last 6 months
- Active tobacco use within the last 6 months such as actively smoking cigarettes, or using any nicotine delivery system products (e.g., gum, patches, electronic cigarettes)
- Uncontrolled or untreatable infection, any source
- Human immunodeficiency virus (HIV) infection unless ALL of the following are met:
  - CD4 count greater than 200 cells/mm<sup>3</sup>
  - Undetectable HIV-1 ribonucleic acid (RNA)
  - Stable anti-retroviral therapy for > than three months
  - Absence of serious complications associated with or secondary to HIV disease (e.g., opportunistic infection, including aspergillus, tuberculosis, coccidioidomycosis, resistant fungal infections; Kaposi's sarcoma; or other neoplasm)

**CODES**

The following HCPCS/CPT code(s) require prior authorization:

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

Code	Description
S2054	Transplantation of multivisceral organs
S2055	Harvesting of donor multivisceral organs, with preparation and maintenance of allografts; from cadaver donor

### REFERENCES

1. Abu-Elmagd, K, Reyes, J, Fung, J.J. "Clinical intestinal transplantation: recent advances and future consideration." Primer on Transplantation. Ed. D.J. Norman and L.A. Turka. 2<sup>nd</sup> ed. Mt. Laurel, New Jersey: American Society of Transplantation, 2001. 610-625.
2. American Gastroenterological Association. American Gastroenterological Association Medical Position Statement: short bowel syndrome and intestinal transplantation. *Gastroenterology*. 2003; 124(4):1105-10.
3. Centers for Medicare & Medicaid Services (CMS). NCD 260.5 for intestinal and multi-visceral transplantation. Updated April 2001. Updated May 2006. Accessed on March 22, 2007. Last accessed on August 12, 2015.

### APPROVAL HISTORY

January 2004: Reviewed by the Clinical Coverage Criteria Committee

Subsequent endorsement date(s) and changes made:

- April 14, 2007: Criteria placed in new format
- April 25, 2008: Reviewed and renewed without changes
- May 4, 2009: Clarification to length of TPN dependency and difficulty with access, addition of aggressive malignancies to limitations, clarification of serious health conditions of limitations.
- November 1, 2009: Reviewed by Medical Affairs Medical Policy Committee, no change.
- November 2010: Reviewed by MCMC. Coverage added for "Adult Members with iatrogenic, traumatic or vascular thrombosis and loss of small bowel"
- December 14, 2011: Reviewed by Integrated Medical Policy Advisory Committee (IMPAC), no changes
- December 12, 2012: Reviewed by IMPAC. No changes
- August 6, 2013: Tobacco use clarified
- December 11, 2013: Reviewed by IMPAC, renewed without changes
- October 15, 2014: Adopted by Tufts Health Plan – Network Health Commercial Plans and Tufts Health Plan – Network Health Medicaid Plans.
- December 10, 2014: Reviewed by IMPAC, renewed without changes
- February 23, 2015: Administrative update.
- August 12, 2015: Reviewed by IMPAC, renewed without changes
- September 2015: Branding and template change to distinguish Tufts Health Plan products in "Applies to" section. Added Tufts Health Freedom Plan products, effective January 1, 2016.
- July 20, 2016: Reviewed by IMPAC renewed without changes
- December 13, 2016: Contact information updated
- April 2017: Added RITogether Plan product to template. For MNGs applicable to RITogether, effective date is August 1, 2017
- July 20, 2017: Reviewed by IMPAC, renewed without changes
- September 18, 2017: Administrative update
- October 10, 2018: Reviewed by IMPAC, renewed without changes
- October 2018: Template and disclaimer updated
- October 16, 2019: Reviewed by IMPAC, renewed without changes
- October 21, 2020: Reviewed by IMPAC, renewed without changes
- December 8, 2020: Fax number for Unify updated

### 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.

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.

[Provider Services](#)