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

Effective: October 10, 2018

Prior Authorization Required
IF REQUIRED, submit supporting clinical documentation pertinent to service request.

<table>
<thead>
<tr>
<th>Applies to:</th>
<th>Yes ☒ No ☐</th>
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<tbody>
<tr>
<td><strong>COMMERCIAL Products</strong></td>
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<tr>
<td>☒ Tufts Health Plan Commercial products; Fax: 617.972.9409</td>
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<tr>
<td>☒ Tufts Health Freedom Plan products; Fax: 617.972.9409</td>
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<tr>
<td>☒ CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</td>
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<tr>
<td><strong>TUFTS HEALTH PUBLIC PLANS Products</strong></td>
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<tr>
<td>☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 888.415.9055</td>
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<tr>
<td>☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax: 888.415.9055</td>
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<tr>
<td>☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax: 857.304.6404</td>
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<tr>
<td>☒ Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax: 781.393.2607</td>
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<td>*The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists</td>
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<td><strong>SENIOR Products</strong></td>
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<tr>
<td>• Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product) – Refer to the Tufts Health Plan SCO Prior Authorization List</td>
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<tr>
<td>• Tufts Medicare Preferred HMO, (a Medicare Advantage product) – Refer to the Tufts Medicare Preferred HMO Prior Authorization and Inpatient Notification List</td>
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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/mm³
  - 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:

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

REFERENCES

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
- December 10, 2014: Reviewed by IMPAC, renewed without changes
- 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

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.