Medical Necessity Guidelines: Solid Organ Transplant: Liver

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>
<tr>
<td>☒ Tufts Health Plan Commercial products; Fax: 617.972.9409</td>
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</tr>
<tr>
<td>☒ Tufts Health Freedom Plan products; Fax: 617.972.9409</td>
<td></td>
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<tr>
<td>- CareLink™ – 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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<table>
<thead>
<tr>
<th>SENIOR Products</th>
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<tbody>
<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
Liver transplantation or hepatic transplantation is the replacement of a diseased liver with a healthy liver or split organ from a living or cadaveric donor.

To initiate the prior authorization process, it is necessary to complete and submit the Liver Transplant Request for Coverage Form.

CLINICAL COVERAGE CRITERIA
Tufts Health Plan may authorize coverage of a liver transplantation for Members with one of the following:
- Acute liver failure from any cause
- Decompensated chronic liver disease leading to liver failure due to portal hypertension as manifested by one of the following:
  - Variceal hemorrhage
  - Recurrent ascites
  - Recurrent encephalopathy
  - Hepatorenal syndrome
- Hepatocellular carcinoma when no lesion > 5 cm OR no more than 3 lesions the largest < 3 cm or when exceeding these parameters, and the transplant center believes the benefit of transplant outweighs the risk of post-transplant recurrence.
- Satisfactory psychosocial and support systems in place.

LIMITATIONS
Tufts Health Plan will not authorize the coverage of a liver transplant for Members with one of the following:
- Untreated/unstable cardiopulmonary disease
- Extrahepatic malignancy within the past 5 years (excluding superficial skin cancers) or those not meeting oncologic criteria for cure
• Hepatic malignancy not meeting indication criteria above
• Any unresolved psychosocial concerns or history of noncompliance with medical management
• Active drug, substance or alcohol abuse or dependency within the past 6 months, or unlikely to remain sober post-transplant
• 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)
• Members with human immunodeficiency virus (HIV) disease unless ALL of the following are met:
  - Pre-transplant evaluation by an infectious disease specialist with expertise in HIV and transplantation as well as confirmation of plans for continued follow-up after transplantation with an infectious disease specialist of same expertise
  - 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, and/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>47135</td>
<td>Liver allotransplantation; orthotopic, partial or whole, from cadaver or living donor, any age</td>
</tr>
<tr>
<td>47140</td>
<td>Donor hepatectomy (including cold preservation), from living donor; left lateral segment only (segments II and III)</td>
</tr>
<tr>
<td>47141</td>
<td>Donor hepatectomy (including cold preservation), from living donor; total left lobectomy (segments II, III and IV)</td>
</tr>
<tr>
<td>47142</td>
<td>Donor hepatectomy (including cold preservation), from living donor; total right lobectomy (segments V, VI, VII and VIII)</td>
</tr>
<tr>
<td>47143</td>
<td>Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; without trisegment or lobe split</td>
</tr>
<tr>
<td>47144</td>
<td>Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with trisegment split of whole liver graft into 2 partial liver grafts (i.e., left lateral segment [segments II and III] and right trisegment (segments I and IV through VIII)</td>
</tr>
<tr>
<td>47145</td>
<td>Backbench standard preparation of cadaver donor whole liver graft prior to allotransplantation, including cholecystectomy, if necessary, and dissection and removal of surrounding soft tissues to prepare the vena cava, portal vein, hepatic artery, and common bile duct for implantation; with lobe split of whole liver graft into two partial liver grafts (i.e., left lobe (segments II, III, and IV) and right lobe (segments 1 and V through VIII)</td>
</tr>
<tr>
<td>47146</td>
<td>Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; venous anastomosis, each</td>
</tr>
<tr>
<td>47147</td>
<td>Backbench reconstruction of cadaver or living donor liver graft prior to allotransplantation; arterial anastomosis, each</td>
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**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: Coverage guidelines clarified, recurrent cholangitis in Members with primary sclerosing cholangitis and intractable pruritis in Members with primary biliary cirrhosis were removed from the guideline; guidelines for the coverage of a liver transplant in Members with hepatocellular carcinoma were changed. Requirement was added for coverage for members with HIV: Pre-transplant evaluation by an infectious disease specialist with expertise in HIV and transplantation and confirmation of plans for continued follow-up after transplantation with an infectious disease specialist with that expertise.
- November 1, 2009: Reviewed by Medical Affairs Medical Policy Committee, no changes.
- November 2010: Reviewed by MCMC, no changes
- December 14, 2011: Reviewed by Integrated Medical Policy Advisory Committee (IMPAC), no changes
- December 12, 2012: Reviewed by IMPAC, no changes
- August 6, 2012: 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.
- December 31, 2015: Coding updated. Per AMA CPT®, effective January 1, 2016 the following code(s) deleted: 47136
- 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.