Medical Necessity Guidelines: Solid Organ Transplant: Lung

Effective: July 20, 2017

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<tr>
<td>Applies to:</td>
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<tr>
<td>☒ Tufts Health Plan Commercial Plans products; Fax: 617.972.9409</td>
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<tr>
<td>☒ Tufts Health Public Plans products</td>
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<tr>
<td>☒ Tufts Health Direct — Health Connector; Fax: 888.415.9055</td>
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<tr>
<td>☒ Tufts Health Together — A MassHealth Plan; Fax: 888.415.9055</td>
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<tr>
<td>☐ Tufts Health Unify — OneCare Plan; Fax: 781.393.2607</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 Freedom Plan products; Fax: 617.972.9409</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 lung transplant is surgery to replace one or both diseased lungs with healthy ones from a human donor.

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

COVERAGE GUIDELINES
Tufts Health Plan may authorize a lung transplant for ambulatory Members less than 65 years of age with end stage pulmonary disease when all of the following are met:

- Clinically and physiologically severe disease
- Ineffective medical therapy
- Life expectancy less than 3 years
- Ambulatory with rehabilitation potential
- Nutrition status with BMI greater than 17 kg/m² or less than 30 kg/m²
- Satisfactory psychosocial profile and support system is present
- Age criteria
  - <65 years of age for a single lung
  - <60 years of age for a bilateral lung transplant
  - <55 years of age for a heart-lung transplant

LIMITATIONS
Tufts Health Plan will not authorize the coverage of a lung transplant for Member meeting the following:

- Acute illness or clinically unstable
- Uncontrolled or untreatable infection, any source
- Uncured neoplasm, adenocarcinoma or epithelial origin carcinoma within the past five years.
- Significant dysfunction of the liver, kidney or central nervous system
- Significant coronary artery disease or right or left ventricular dysfunction
- Any unresolved psychosocial concerns or history of noncompliance with medical management.
- 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)
- Hepatitis B sAg+
- Active Hepatitis C 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)
- Ventilator dependent and actively treated for acute respiratory failure (chronic ventilator dependency is not a contraindication)

**SPECIAL CONSIDERATIONS**
Tufts Health Plan will consider the following types of transplants for the circumstances and/or diagnoses listed below:

**Single Lung Transplantation:**
- Appropriate for all indications except as specified in bilateral transplantation and heart-lung transplant

**Bilateral Lung Transplantation:**
- Mandatory for generalized bronchiectasis
- Mandatory for end stage Cystic Fibrosis disease
- Suitable for other forms of respiratory failure not complicated by severe left ventricular cardiac dysfunction (see Heart-Lung indications)

**Heart-Lung Transplantation:**
- Eisenmenger syndrome with a surgically uncorrectable anomaly and irreversible pulmonary hypertension
- Pulmonary disease with severe left ventricular failure (*Note:* A pulmonary diagnosis with severe right heart failure is not an indication for a heart-lung transplant unless accompanied by severe left ventricular failure)

**Living Lobar Lung Transplant:**
- May be authorized in children or small adults only and generally only for cystic fibrosis.
- May be authorized in cases where it is clear that a Member will not live long enough to receive a cadaveric transplant
- Will not be authorized in cases where the patient is in extremis (emergency situations)

**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>32850</td>
<td>Donor pneumonectomy(s) (including cold preservation), from cadaver donor</td>
</tr>
<tr>
<td>32851</td>
<td>Lung transplant, single; without cardiopulmonary bypass</td>
</tr>
<tr>
<td>32852</td>
<td>Lung transplant, single; with cardiopulmonary bypass</td>
</tr>
<tr>
<td>32853</td>
<td>Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass</td>
</tr>
<tr>
<td>32854</td>
<td>Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass</td>
</tr>
<tr>
<td>32855</td>
<td>Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; unilateral</td>
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<tr>
<td>32856</td>
<td>Backbench standard preparation of cadaver donor lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare pulmonary venous/atrial cuff, pulmonary artery, and bronchus; bilateral</td>
</tr>
<tr>
<td>33930</td>
<td>Donor cardiectomy-pneumonectomy (including cold preservation)</td>
</tr>
<tr>
<td>33933</td>
<td>Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissue to prepare aorta, superior vena cava, inferior vena cava, and trachea for implantation</td>
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<tr>
<td>33935</td>
<td>Heart-lung transplant with recipient cardiectomy-pneumonectomy</td>
</tr>
<tr>
<td>S2060</td>
<td>Lobar lung transplantation</td>
</tr>
<tr>
<td>S2061</td>
<td>Donor lobectomy (lung) for transplantation, living donor</td>
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</tbody>
</table>

**REFERENCES**
5. Trulock,E. Indications; selection of recipients; and choice of procedures for lung transplantation. UpToDate®. December 2006.

APPROVAL HISTORY
January 2004: Reviewed by the Medical Affairs Medical Policy 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: Reviewed and renewed without changes
- November 1, 2009: Reviewed by Medical Affairs Medical Policy Committee, no changes.
- November 2010: Reviewed by MCMC. Under limitations, uncured neoplasm clarified to include: “adenocarcinoma or epithelial origin carcinoma within the past five years”
- December 14, 2011: Reviewed by Integrated Medical Policy Advisory Committee (IMPAC), no changes
- December 12, 2012: Reviewed by IMPAC; no changes
- August 6, 2013: Active tobacco use clarified
- December 11, 2013: Reviewed by IMPAC, renewed without changes
- December 10, 2014: Reviewed by IMPAC, renewed without changes
- August 12, 2015: Review 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

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 the 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.

Medical Necessity Guidelines apply to the fully insured Commercial and Medicaid products when Tufts Health Plan conducts utilization review unless otherwise noted in this guideline or in the Member’s benefit document, and may apply to Tufts Health Unify to the same extent as Tufts Health Together. This guideline does not apply to Tufts Medicare Preferred HMO, Tufts Health Plan Senior Care Options or to certain delegated service arrangements. 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. Applicable state or federal mandates or other requirements will take precedence. For CareLink℠ Members, Cigna conducts utilization review so Cigna’s medical necessity guidelines, rather than these guidelines, will apply.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of these guidelines 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.