

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 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](#).

Clinical Guideline Coverage Criteria

Indications for lung transplant include pulmonary disease such as, but not limited to the following: alpha-1-antitrypsin deficiency, advanced obstructive lung disease, pulmonary hypertension, Bronchopulmonary dysplasia, cystic fibrosis, interstitial lung disease (ILD), Lymphangioleiomyomatosis, sarcoidosis, Eisenmenger’s syndrome, and severe bronchiectasis. In general, transplant recipients over the age of 70 years have an increased likelihood for poor outcome and worse long-term survival compared to younger recipients.

The Plan may authorize a lung transplant for Members with chronic end stage pulmonary disease when **ALL** of the following are met:

1. The Member has clinically and physiologically irreversible disease unresponsive to maximum medical or surgical treatment resulting in progressive symptoms; **and**

2. High functioning status (i.e., ambulatory) with good rehabilitation potential; **and**
3. Life expectancy less than 3 years; **and**
4. Nutrition status with BMI greater than 16 kg/m² or less than 35 kg/m²; **and**
5. Satisfactory psychosocial profile and support system is present

Special Considerations:

The 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 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)

Limitations

The Plan will not authorize the coverage of a lung transplant for Member meeting **ONE** of the following:

1. Active inhaled substance use (e.g., smoking cigarettes, smoking marijuana, inhaling e-cigarettes, vaping)
2. Active or uncontrolled alcohol use disorder or substance use disorder
3. Acute illness or clinically unstable
4. Active Hepatitis C disease
5. Any unresolved psychosocial concerns or history of noncompliance with and/or medical management
6. Acute coronary syndrome or myocardial infarction within 30 days (excluding demand ischemia)
7. Hepatitis B sAg+
8. Human immunodeficiency virus (HIV) infection unless **ALL** of the following are met:
 - a. CD4 count greater than 200 cells/mm³ for > 3 months prior to transplantation; **and**
 - b. Undetectable HIV-1 ribonucleic acid (RNA); **and**
 - c. Stable anti-retroviral therapy for > 3 months; **and**
 - d. 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)
9. Malignancy with high risk of recurrence or death
10. Significant Coronary Artery Disease or Right or Left Ventricular Dysfunction Significant dysfunction of the liver, kidney, or central nervous system
11. Stroke within 30 days or progressive cognitive impairment
12. Uncontrolled or untreatable infection, any source
13. Ventilator dependent and actively treated for acute respiratory failure (Chronic ventilator dependency is not a contraindication)
14. Other severe uncontrolled medical condition expected to limit survival after transplant

Codes

The following code(s) require prior authorization:

Table 1: CPT/HCPCS Codes

*Codes are applicable only to THP Products

Code	Description
32850	Donor pneumonectomy(s) (including cold preservation), from cadaver donor
32851	Lung transplant, single; without cardiopulmonary bypass
32852	Lung transplant, single; with cardiopulmonary bypass
32853	Lung transplant, double (bilateral sequential or en bloc); without cardiopulmonary bypass
32854	Lung transplant, double (bilateral sequential or en bloc); with cardiopulmonary bypass
32855	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
32856	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
33930	Donor cardiectomy-pneumonectomy (including cold preservation)
33933	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
33935	Heart-lung transplant with recipient cardiectomy-pneumonectomy
S2060*	Lobar lung transplantation
S2061*	Donor lobectomy (lung) for transplantation, living donor

References:

1. 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.
2. Crespo MM, Lease ED, Sole A, et al. ISHLT consensus document on lung transplantation in patients with connective tissue disease: Part I: Epidemiology, assessment of extrapulmonary conditions, candidate evaluation, selection criteria, and pathology statements. *J Heart Lung Transplant*. 2021;40(11):1251-1266. doi:10.1016/j.healun.2021.07.014
3. Crespo MM, Claridge T, Domsic RT, et al. ISHLT consensus document on lung transplantation in patients with connective tissue disease: Part III: Pharmacology, medical and surgical management of post-transplant extrapulmonary conditions statements. *J Heart Lung Transplant*. 2021;40(11):1279-1300. doi:10.1016/j.healun.2021.07.013.
4. Laporta Hernandez R, Aguilar Perez M, Lázaro Carrasco MT, Ussetti Gil P. Lung Transplantation in Idiopathic Pulmonary Fibrosis. *Med Sci (Basel)*. 2018;6(3):68. Published 2018 Aug 23. doi:10.3390/medsci6030068.
5. Leard LE, Holm AM, Valapour M, et al. Consensus document for the selection of lung transplant candidates: An update from the International Society for Heart and Lung Transplantation. *J Heart Lung Transplant*. 2021;40(11):1349-1379. doi:10.1016/j.healun.2021.07.005.
6. Lung transplantation: An overview: UpToDate.com/login [via subscription only]. Published May 13, 2020. Updated July 2021. Accessed August 17, 2021.
7. Lung transplantation: General guidelines for recipient selection UpToDate.com/login [via subscription only]. Published September 8, 2022. Accessed November 15, 2022.

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 MPAC, renewed without changes
- March 15, 2023: Reviewed by MPAC, removed age requirement from criteria and nutrition status criteria for BMI changed from BMI greater than 17 kg/m² to 16 kg/m² or less than 30 kg/m² changed to 35 kg/m². Multiple changes made to the limitations section, including updated language for active tobacco use to “Active inhaled substance use

(e.g., smoking cigarettes, smoking marijuana, inhaling e-cigarettes, vaping”; changed “Active drug, substance abuse, or alcohol abuse within the last 6 months” to “Active or uncontrolled alcohol use disorder or substance use disorder”; Added the following limitations: Acute Coronary syndrome or myocardial infraction within 30 days, Stroke within 30 days or progressive cognitive impairment, and other severe uncontrolled medical condition expected to limit survival after transplant. 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.