



Lung Transplants Clinical Coverage Criteria

Overview

Lung Transplantation involves the surgical replacement of one or both lungs in patients with end-stage lung diseases. Lung transplantation is typically preceded by medical interventions such as surgery or oxygen therapy. The type of lung transplantation (lobar, single, double) is based upon the candidate's condition and indication for transplantation in addition to the availability of viable donor organs. Donor organs are often scarce or unsuitable for transplantation.

Policy

This Policy applies to the following Fallon Health products:

- Commercial
- Medicare Advantage
- MassHealth ACO
- NaviCare
- PACE

Fallon Health follows guidance from the Centers for Medicare and Medicaid Services (CMS) for organization (coverage) determinations for Medicare Advantage plan members. National Coverage Determinations (NCDs), Local Coverage Determinations (LCDs), Local Coverage Articles (LCAs) and guidance in the Medicare manuals are the basis for coverage determinations. When there is no NCD, LCD, LCA or manual guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations.

Medicare does not have an NCD for Lung Transplants. National Government Services, Inc. does not have an LCD or LCA for Lung Transplants (MCD search 06-25-2021).

For plan members enrolled in NaviCare and PACE plans, Fallon Health follows Medicare guidance for coverage determinations. In the event that there is no Medicare guidance or if the plan member does not meet medical necessity criteria in Medicare guidance, Fallon Health will follow guidance published by MassHealth. When there is no Medicare or MassHealth guidance, Fallon Health Clinical Coverage Criteria are used for coverage determinations for NaviCare members. Each PACE plan member is assigned to an Interdisciplinary Team. When there is no Medicare or MassHealth guidance, the member's Interdisciplinary Team is responsible for coverage determinations.

Lung Transplants require prior authorization, all the below criteria must be met as supported by the treating provider(s) medical records:

1. The member must have end-stage, irreversible pulmonary disease which has failed to respond to all other medical interventions. Pulmonary disease such as, but not limited to the following:
 - Restrictive Lung Diseases such as: Idiopathic/Interstitial pulmonary fibrosis, Asbestosis, Scleroderma, Sarcoidosis
 - Chronic Lung Diseases such as: Bronchiolitis obliterans, Chronic Obstructive Pulmonary Disease, Alpha-1 antitrypsin deficiency, Recurrent pulmonary embolus

- Pulmonary Hypertensions
 - Septic Lung Disease such as: Cystic Fibrosis, Bronchiectasis
2. The member must not have an Absolute Contraindication such as, but not limited to the following:
 - Metastatic Cancer or other active malignancies, additionally malignancies with a high rate of recurrence may be a contraindication
 - Other irreversible end-stage diseases
 - Serious conditions such a cardiac disease which would create instability or the inability to tolerate a transplant
 - Potential complications from immunosuppressive medications that are unacceptable to the patient
 - Non-compliance or the inability to comply with medical treatment plans pre/post- surgery
 - Recurring or untreated infections
 3. The member must be a non-smoker, drug free, and alcohol free for the previous 6 months or greater. The member should be receiving counseling for any previous substance use issues in order to maintain abstinence.
 4. The member must show compliance to pre-transplant care and willingness to comply with extensive post-transplant care.

In regards to bi-lateral lung transplantation further consideration will be given to the member's type of end-stage lung disease, specifically if it requires a bi-lateral rather than a single transplant. Additionally the member's ability to tolerate the procedure and others conditions, such as cardiac dysfunction, will be considered in any review.

Due to the lack of suitable donor lungs for those on the waiting list new methods are being attempted in order to increase the amount of usable donor lungs. One such method is Ex Vivo Lung Perfusion (EVLV) which attempts to maintain the lung through perfusion and ventilation after it is removed from the donor until suitable for transplantation. However this technology is new and still in the clinical trial stage. Fallon Health's Clinical Trial Payment Policy details rules surrounding coverage for member's who enroll in a qualified clinical trial: **Clinical Trial Payment Policy**. Fallon Health will review any request for Commercial Plan members who enroll in a Lung Transplant Clinical Trial to ensure the member has a life-threatening disease or condition.

Exclusions

- Lung transplants that do not meet the above criteria.
- Lung transplant where the member has an absolute contraindication..

Coding

The following codes are included below for informational purposes only; inclusion of a code does not constitute or imply coverage or reimbursement.

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
S2060	Lobar lung transplantation
S2061	Donor lobectomy (lung) for transplantation, living donor

References

1. Orens JB, Garrity Jr ER. General overview of lung transplantation and review of organ allocation. Proc Am Thorac Soc. 2009;6(1):13-19.
2. Thabut G, Christie JD, Kremers WK, et al. Survival differences following lung transplantation among US transplant centers. JAMA. 2010;304(1):53-60.
3. Yusef RD, Shearon TH, Qian Y, et al. Lung transplantation in the United States, 1999-2008. Am J Transplant. 2010;10(4 Pt 2):1047-1068.
4. Sherman W, Rabkin DG, Ross D, et al. Lung transplantation and coronary artery disease. Ann Thorac Surg. 2011;92(1):303-308
5. Kistler KD, Nalysnyk L, Rotella P, et al. Lung transplantation in idiopathic pulmonary fibrosis: a systematic review of the literature. BMC Pulm Med. 2014;14:139.
6. Date H, Sato M, Aoyama A, et al. Living-donor lobar lung transplantation provides similar survival to cadaveric lung transplantation even for very ill patients. Eur J Cardiothorac Surg. Sep 16 2014.
7. Lopez I, Zapata R, Sole J, et al. Early and mid-term results of lung transplantation with donors 60 years and older. Interact Cardiovasc Thorac Surg. 2015 Jan;20(1):47-53.
8. 53.
9. Weill D, Benden C, Corris PA, et al. A consensus document for the selection of lung transplant candidates: 2014--an update from the Pulmonary Transplantation Council of the International Society for Heart and Lung Transplantation. J Heart Lung Transplant. 2015 Jan;34(1):1-15.
10. Hartert M, Senbaklavacin O, Gohrbandt B, et al. Lung transplantation: a treatment option in end-stage lung disease. Dtsch Arztebl Int. 2014 Feb 14;111(7):107-16.
11. Schaffer JM, Singh SK, Reitz BA, et al. Single- vs double-lung transplantation in patients with chronic obstructive pulmonary disease and idiopathic pulmonary fibrosis since the implementation of lung allocation based on medical need. JAMA. 2015 Mar 3;313(9):936-48.
12. Hall DJ, Belli EV, Gregg JA, et al. Two Decades of Lung Retransplantation: A SingleCenter Experience. Ann Thorac Surg. 2016 Dec 22.
13. Keller CA, Gonwa TA, White LJ, et al. Utilization and Cost Analysis of Lung Transplantation and Survival After 10 years of Adopting the Lung Allocation Score (LAS). Transplantation. 2018 Apr 24.
14. Ali A, Cypel M. Ex-vivo lung perfusion and ventilation: where to from here? Curr Opin Organ Transplant. 2019 Apr 24.

Policy history

Origination date:	01/01/2016
Approval(s):	Technology Assessment Committee: 1/27/2016 (new policy), 01/25/2017 (removed codes 32855-32856 as they are not separately reimbursable, updated references), 05/24/2017 (added criteria based on substance abuse), 05/15/2018 (updated references, added language regarding non-smoking and compliance to care), 05/22/2019 (updated references)
	06/25/2021 (Added clarifying language related to Medicare Advantage, NaviCare and PACE under policy section.

Not all services mentioned in this policy are covered for all products or employer groups. Coverage is based upon the terms of a member's particular benefit plan which may contain its own specific provisions for coverage and exclusions regardless of medical necessity. Please consult the product's Evidence of Coverage for exclusions or other benefit limitations applicable to this service or supply. If there is any discrepancy between this policy and a member's benefit plan, the provisions of the benefit plan will govern. However, applicable state mandates take precedence with respect to fully-insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, federal mandates will apply to all plans.