MEDICA UTILIZATION MANAGEMENT POLICY

TITLE: LUNG TRANSPLANTATION

EFFECTIVE DATE: April 23, 2018

This policy was developed with input from specialists in pulmonology, thoracic surgery and transplants, and endorsed by the Medical Policy Committee.

IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY

These services may or may not be covered by all Medica plans. Please refer to the member’s plan document for specific coverage information. If there is a difference between this general information and the member’s plan document, the member’s plan document will be used to determine coverage. With respect to Medicare and Minnesota Health Care Programs, this policy will apply unless those programs require different coverage. Members may contact Medica Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Medica utilization management policy may call the Medica Provider Service Center toll-free at 1-800-458-5512.

Medica utilization management policies are not medical advice. Members should consult with appropriate health care providers to obtain needed medical advice, care and treatment.

PURPOSE

To promote consistency between reviewers in utilization management decision-making by providing the criteria that determine the medical necessity of single or double lung transplantation. The Coverage Issues box below outlines the process for addressing the needs of individuals who do not meet these criteria.

BACKGROUND

I. Definitions

A. Transplant or graft is a portion of the body or a complete organ removed from its natural site and transferred to a separate site in the same or different individual.

B. Living donor lung transplant is the transplantation of lung tissue, typically one lower lobe from each of two donors, from living donors to the recipient.

C. The Lung Allocation Score (LAS) is now used to place individuals on the lung waiting list. The LAS takes into account the severity of the illness pre-transplant including the likelihood of death on the waiting list and the likelihood of survival one year post-transplant. The LAS is a dynamic measurement that is updated on a regular basis according to a follow-up schedule determined by UNOS. Waiting time on the list is no longer an important criterion. For additional information go to: https://optn.transplant.hrsa.gov/resources/allocation-calculators/las-calculator/. Accessed December 21, 2017.

D. Substance use disorder, as defined by the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders (DSM-5), is a problematic pattern of use of an intoxicating substance leading to clinically significant impairment or distress. The symptoms associated with a substance use disorder fall into four major groupings: impaired control, social impairment, risky use, and pharmacological criteria (i.e., tolerance and withdrawal).

E. Transplant evaluation is a physical and psychosocial exam to determine if an individual is an acceptable candidate for transplantation. The specific exams and tests depend on the individual’s diagnosis and health history and vary from hospital to hospital. Tests may include the following: cardiac evaluation; lung function tests; lab tests, including blood typing, chemistry panels, and serology testing for hepatitis, HIV and other common viruses; appropriate cancer surveillance, as indicated (e.g., colonoscopy, pap smear, mammogram, prostate cancer screening); dental evaluation with treatment of existing problems; psychosocial evaluation. Additional testing or clearance may be required to address other significant coexisting medical conditions.
BENEFIT CONSIDERATIONS

1. Prior authorization is required for:
   - Lung Transplant Evaluation
   - Lung Transplantation
   - Please see the prior authorization list for product specific prior authorization requirements.

2. Coverage may vary according to the terms of the member’s plan document.

3. Medica has entered into separate contracts with designated facilities to provide transplant-related health services, as described in the member’s plan document.

4. Complex cases require medical director or external review and, as necessary, discussion with the individual’s physician.

5. Underlying co-morbidity that significantly alters risk/benefit of transplant may preclude transplant eligibility.

6. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member's plan document.

7. If it appears that the Medical Necessity and Coverage Criteria are not met, the individual's case will be reviewed by the medical director or an external reviewer. Practitioners are advised of the appeal process in their Provider Administrative Manual.

MEDICAL NECESSITY CRITERIA

I. Indications for Lung Transplant Evaluation [For multiorgan transplant, the individual must meet criteria for each organ. Please refer to applicable Medica UM policy.]
   Documentation in the medical records indicates that the individual has a diagnosis of end-stage pulmonary disease, defined as a high (greater than 50%) risk of death from lung disease within two years if lung transplantation is not performed.

II. Indications for Lung Transplantation
   Documentation in the medical records indicates that all of the following are met:
   A. The individual meets the institution’s suitability criteria for transplant.
   B. For single or bilateral sequential lung transplant, documentation in the medical records indicates that there is a diagnosis of end-stage pulmonary disease (e.g., caused by cystic fibrosis, bronchiectasis, chronic obstructive pulmonary disease, emphysema, alpha 1 antitrypsin deficiency, primary pulmonary hypertension, alveolar proteinosis, idiopathic pulmonary fibrosis).
   C. Individual or guardian is able to give informed consent. Individual/guardian and family/social support system are able to comply with the treatment regimen and the necessary follow-up. Inadequate funding to pay for immunosuppressive medications post-transplant are addressed and resolved.
   D. For individuals with a recent history (24 months) of substance use disorder, successful completion of a chemical dependency program and 6 months of documented ongoing abstinence.
   E. Documented abstinence from tobacco for at least six months.
   F. For living donor lung transplant, documentation in the medical records indicates that the individual is unlikely to survive the wait for a deceased donor allograft or may become ineligible for lung transplantation due to clinical deterioration.
   G. No documented contraindications present as indicated by all of the following:
      1. No non-pulmonary uncorrectable medical condition that would itself significantly shorten life expectancy or make transplant success unlikely.
      2. No active systemic or localized infection
      3. No significant chest wall/spinal deformity
      4. No irreversible multisystem organ failure
      5. No active untreated or untreatable malignancy (NOTE: Individuals with underlying malignancy may require oncology consult to assess prognosis and risk of recurrence)
      6. No HIV infection with detectable viral load and CD4 counts less than 200mm³, acquired immunodeficiency syndrome (AIDS) or history of AIDS-defining condition that is progressive or recurrent (See Appendix 1)
      7. No active substance use disorder
      8. No irreversible severe brain damage
      9. No post-transplant lymphoproliferative disease (PTLD) unless no active disease demonstrated by negative PET scan and resolved adenopathy on CT/MRI
      10. No ongoing pattern of noncompliance, psychiatric illness, psychological condition or limited cognitive ability that would make compliance with a disciplined medical regimen impossible

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11. No limited irreversible rehabilitative potential
12. No lack of psychosocial support as indicated by either no identified caregiver or an uncommitted caregiver
13. No inability to obtain informed consent from individual or guardian.

III. Indications for Lung Retransplantation

Documentation in the medical records indicates that all of the following criteria are met:
A. Failed previous lung transplant
B. All of the criteria in section II are met
C. No history of behaviors since the previous transplant that would jeopardize a subsequent transplant.

CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS)
- For Medicare members, refer to the following, as applicable at: http://www.cms.hhs.gov/mcd/search.asp

DOCUMENT HISTORY

<table>
<thead>
<tr>
<th>Original Effective Date</th>
<th>January 1, 1991</th>
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<tbody>
<tr>
<td>Administrative Updates</td>
<td>05/01/2017</td>
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References:

Pre-06/2016 MPC:


06/2016 MPC:

02/2017 MPC:

02/2018 MPC:
APPENDIX 1 - AIDS-Defining Conditions

• Bacterial infections, multiple or recurrent*
• Candidiasis of bronchi, trachea, or lungs
• Candidiasis of esophagus
• Cervical cancer, invasive†
• Coccidioidomycosis, disseminated or extrapulmonary
• Cryptococcosis, extrapulmonary
• Cryptosporidiosis, chronic intestinal (>1 month’s duration)
• Cytomegalovirus disease (other than liver, spleen, or nodes), onset at age >1 month
• Cytomegalovirus retinitis (with loss of vision)
• Encephalopathy attributed to HIV§
• Herpes simplex: chronic ulcers (>1 month’s duration) or bronchitis, pneumonia, or esophagitis (onset at age >1 month)
• Histoplasmosis, disseminated or extrapulmonary
• Isosporiasis, chronic intestinal (>1 month’s duration)
• Kaposi sarcoma
• Lymphoma, Burkitt (or equivalent term)
• Lymphoma, immunoblastic (or equivalent term)
• Lymphoma, primary, of brain
• Mycobacterium avium complex or Mycobacterium kansasii, disseminated or extrapulmonary
• Mycobacterium tuberculosis of any site, pulmonary†, disseminated, or extrapolmonary
• Mycobacterium, other species or unidentified species, disseminated or extrapolmonary
• Pneumocystis jirovecii (previously known as “Pneumocystis carinii”) pneumonia
• Pneumonia, recurrent†
• Progressive multifocal leukoencephalopathy
• Salmonella septicemia, recurrent
• Toxoplasmosis of brain, onset at age >1 month
• Wasting syndrome attributed to HIV§

* Only among children aged <6 years.
† Only among adults, adolescents, and children aged ≥6 years.
§ Suggested diagnostic criteria for these illnesses, which might be particularly important for HIV encephalopathy and HIV wasting syndrome, are described in the following references:

CDC. 1994 Revised classification system for human immunodeficiency virus infection in children less than 13 years of age. MMWR 1994;43(No. RR-12).

CDC. 1993 Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMWR 1992;41(No. RR-17).