POLICY AND PROCEDURE MANUAL

Policy Title: Lung Transplant	**Policy Number: F.24**
Primary Department: Medical Management **Affiliated Department(s): N/A**	**NCQA Standard: N/A** **URAC Standard: N/A**
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Applicable Lines of Business: ☐MeridianCare ☒MeridianHealth ☐MeridianComplete ☒MeridianChoice	
Applicable States: ☐All ☒MI ☒IL ☐OH ☐_____ ☐_____	
Applicable Programs: ☒All ☐Other _____	
Policy is to be published: Internally Only ☐ Internally & Externally ☒	

If the request is for a Medicare of MMP member please refer to the Medicare specific version of F.24

Policy:
Lung transplantation is indicated for carefully selected patients with progressive, disabling and irreversible chronic lung disease, who are un-responsive to maximum medical therapy. The following are guidelines to be used for determination of potential coverage.

Procedure:

Actual Lung Transplant

Criteria for Coverage:

I. General Information Required:
- a. History of Present Illness and other information required:
  - i. Clinically and physiologically severe disease for which medical therapy is ineffective or unavailable
  - ii. The risk of death from lung disease without transplantation is >50 percent within two years
  - iii. The likelihood of surviving at least 90 days after lung transplantation is >80 percent
  - iv. Absence of non-pulmonary medical comorbidity that would be expected to limit life expectancy substantially in the first five years after transplantation
  - v. Diagnosis must be noted in medical records within the last 12 months

II. Specific Diagnoses: Member must have one of the following diagnosis
- a. **Restrictive Lung Diseases**

i. Idiopathic Pulmonary Fibrosis
    1. Member must have histologic or radiographic evidence of UIP (usual interstitial pneumonia) and any of the following:
        a. A decrease in pulse oximetry below 88% during a six minute walk test (6-MWT)
        b. A 10% or greater decrement in FVC during 6 months follow up
        c. Diffusing capacity of the lung for carbon monoxide (DLCO) <39% of predicted value
        d. Honeycombing on HRCT (fibrosis score of >2)

ii. Eosinophilic Granuloma (Pulmonary Langerhans Cell Histiocystois): Member must have NYHA class III or IV and meet one of the following
    1. Severe impairment in lung function and exercise capacity (VO_2 < 50% predicted)
    2. Hypoxemia at rest

iii. Sarcoidosis: Member must have NYHA class III or IV and meet one of the following:
    1. Hypoxemia at rest
    2. Presence of cor pulmonale or pulmonary hypertension
    3. Elevated right atrial pressure exceeding 15 mm Hg

iv. Collagen vascular disease, post-chemotherapy, and Scleroderma

v. Pulmonary fibrosis is a common lung pathology in a number of systemic diseases, e.g., scleroderma, rheumatoid arthritis. Evidence that the systemic disease is not active is required. Should be considered on a case by case basis.

vi. Allergic alveolitis

vii. Asbestosis

viii. Desquamative interstitial fibrosis

ix.

b. **Primary Pulmonary Hypertension**
    i. Symptomatic, progressive disease which, despite optimal medical and/or surgical treatment, leaves the patient in NYHA III or NYHA IV.
    ii. Cardiac index of less than 2 L/min/m^2
    iii. Right atrial pressure of more than 15 mm Hg
    iv. Low (< 350 meter or <1,148 feet) or declining 6 MWT
    v. Failing therapy with iv epoprostenol or equivalent

c. **Advanced Cystic Fibrosis:** FEV1 <30% of predicted, or rapidly declining lung function if FEV1 >30% (females and patients <18 years of age have a poorer prognosis; consider earlier listing) and any 2 of the following:
    i. Oxygen dependent respiratory failure
    ii. Pulmonary hypertension
    iii. Hypercapnia $Pa_{CO2} \geqslant 55$ mm Hg
    iv. Other Lung Diseases
    v. Complications due to Chronic Infections
    vi. Recurrent massive hemoptysis
    vii. Recurrent pneumothorax
    viii. Non-invasive nocturnal mechanical ventilation
    ix.

d. **Obstructive Lung Disease** (Bronchiectasis, Bronchiolitis Obliterans, COPD, Emphysema, Alpha 1-antitrypsin deficiency)
    i. COPD patients are considered if they have a BODE index* of 5-6 to 10 (on a scale of 0 to 10) or at least one of the following criteria:
        1. FEV_1 < 20% of predicted and either DLCO of less than 20% or homogeneous distribution of emphysema
        2. Postbronchodilator Fev1 less than 30%

ii. Hospitalizations for COPD exacerbation associated with hypercapnia defined as Pa_{CO2} > 50 mm Hg and/or the following:
    1. Declining body mass
    2. Increasing oxygen requirements
    3. Reduced serum albumin
    4. Exacerbation of pulmonary disease requiring ICU stay
    5. Increasing frequency of exacerbations requiring antibiotic therapy
    6. Refractory and/or recurrent pneumothorax
    7. Recurrent hemoptysis not controlled by embolization
iii. Enlarged pulmonary arteries on chest Xray, mean pulmonary artery pressure greater than 25 mm HG at rest, pedal edema or JVD, or RVH or Right atrial enlargement on EKG) or pulmonary hypertension despite oxygen therapy

*(BODE takes into account the following factors: BMI, degree of airflow assessed by the percent predicted FEV_1, degree of dyspnea assessed by the MMRC dyspnea scale, and the exercise capacity as assessed with the 6 MWT)

e. **Bronchopulmonary dysplasia**
f. **Congenital Heart disease (Eisenmenger's defect or complex)** Member must meet one of the following:
    i. Severe, progressive symptoms with function at NYHA III or NYHA IV level despite optimal medical management
    ii. Pulmonary hypertension with mean pulmonary artery pressure greater than 25 mm Hg
    iii. Signs of right ventricular failure—hepatomegaly, ascites
g. **Lymphangiomyomatosis (LAM)**
    i. Severe impairment in lung function and exercise capacity (VO_2 < 50% predicted)
    ii. Hypoxemia at rest
h. **Histologic evidence of NSIP (nonspecific interstitial pneumonia**) and any of the following:
    i. A DLCO of less than 35% predicted
    ii. A 10% or greater decrease in FVC or 15% decrease in DLCO during 6 months of follow up.

III. Actual Request/Evaluation Results

a. **Required Documentation:**
    i. Transplant team evaluation recommending listing for transplant/listing status
    ii. BMI (include documentation of height and weight)
    iii. Age of less than or equal to 65
    iv. Complete PMH (Past medical history)
    v. Complete Treatment History
    vi. Documentation that if ventilation is required, it is noninvasive positive pressure
    vii. BODE score (Body mass index, airflow Obstruction, Dyspnea and Exercise capacity) of 5-6
    viii. NYHA Class (if clinically indicated):
    ix. Laboratory results
    x. Complete Pulmonary function test (FEV1 and DLCO as noted in diagnosis section)
    xi. Exercise Performance Tests (e.g. 6 minute hall walk)-evidence of completion where appropriate, failure of test
    xii. Bronchoscopy- if completed, results sent to rule out cancer
    xiii. Chest X-ray- results to rule out cancer
    xiv. Cardiac Evaluation: clearance required and noted, with detailed information on any Coronary Artery Disease
        1. ECG:
        2. Stress Echo
        3. Cardiac catheterization (if clinically indicated) report required
    xv. CT, Thorax (patients with parenchymal disease, pleural disease, or previous thoracic surgical procedures):
    xvi. Bone Density Study:

xvii. Infectious disease seriologies (hepatitis panel, human immunodeficiency virus, herpes simplex virus 1 & 2, syphilis or RPR, varicella zoster, cytomegalovirus, epstein-barr virus, tuberculosis):
xviii. Nutrition Consult with clearance for transplant noted
xix. Gastrointestinal Consult (as warranted by history of ulcer, diverticulitis, or other symptoms), with clearance from provider
xx. Neuromuscular Diagnosis- documentation or information that no diagnosis exists
xxi. Cancer screens (pap smear, mammogram, colonoscopy, PSA), as appropriate for age and gender
xxii. Irreversible, severe brain damage- notes and history if exists
xxiii. Dental exam/clearance:
xxiv. Alcohol screen- abstinence for the past 6 months prior to actual transplant approval, if member history includes use of alcohol. If no history exists then 1 negative alcohol screen must be submitted for members with no history of past alcohol use
xxv. Drug screen-abstinence for the past 6 months prior to actual transplant approval if history exists of drug use. If no history exists then 1 negative drug screen must be submitted for memories with no history of positive drug screen.
xxvi. Nicotine screening- abstinence for the past 6 months prior to actual transplant approval if history of smoking. If no history exists then 1 negative cotinine level must be submitted
xxvii. Karnofsky or Lansky score
    1. Pediatric patients should have a Lansky score > 50.
    2. Adult patients should have a Karnofsky score > 70.
xxviii. Psychosocial evaluation: summarize-social support, emotional stability, substance abuse, adherence to medical treatment plan and medications, financial means, inability to give informed consent, unless there is an authorized guardian
xxix. If there is a history of substance the following documentation must be submitted:
    1. Psychiatry clearance:
    2. Completed relapse prevention has been completed
    3. Toxicology screens showing at least 6 months of abstinence
xxx. Current list of medications

IV. Network

a. Actual Transplant must be requested at an in-State facility
b. Actual Transplant must be requested at an in-Network facility
c. Request for Re-Transplantation requests require full history including:
    i. Date of Initial Transplant
    ii. Reason for Re-Transplant
    iii. Progress notes and history of member during Post-Transplant
        1. Graft Failure
        2. Compliance to medical/pharmacologic therapy
d. Must be considered the Standard of Care as published in Society Guidelines

V. Repeat Transplant:

a. Re-Transplantation may be denied where there is evidencethat the member has a history of non-compliance with medical or pharmacologic therapy that was a significant contributor to the transplant failure.
b. Usually due to non-function of the grafted organ, rejection refractory to Immunosuppressive therapy, bronchiolitis obliterans (chronic rejection) and airway complications not correctable by other measures. Outcomes following early emergent retransplantation for primary graft dysfunction are poor, and consequently, its use in this setting is discouraged. .Experience with retransplantation for refractory airway complications (dehiscence, strictures) is limited, and results have been conflicting.
c. Retransplantation of carefully selected patients with chronic graft failure due to bronchiolitis obliterans syndrome results in survival rates that approach that of initial transplantation.
    i. Patient should be ventilator-independent and ambulatory at the time of retransplantation

ii. Meets all other transplant criteria

VI. Authorization Approval Length: Actual Transplant approval is for 12 months

VII. Relative Contraindications

a. < 30 to 34.9kg per m2 is a relative contraindication, ≥ 35 is an absolute contraindication
b. Symptomatic osteoporosis should be assessed with bone densitometry
c. Severe musculoskeletal disease or neuromuscular disease affecting the thorax, e.g., kyphoscoliosis
d. Mechanical ventilation was previously thought to be a relative contraindication for transplant but is now used as a bridge to transplant for candidates who develop respiratory failure while awaiting transplant
e. Colonization with fungi or atypical mycobacteria
f. Inadequately treated M. tuberculosis
g. Extensive prior thoracic surgery with lung resection
h. HIV infection is considered a relative contraindication to lung transplantation. If the virus is undetectable HIV-RNA, no current AIDS-defining illness, and demonstrate adherence to antiretroviral therapy, the member may be a candidate.
    1. CD4 count must be >200cells/mm3 for greater than 6 months
    2. HIV-1 RNA expected to be undetectable at time of transplant:
    3. Member must be on stable anti-retroviral therapy greater than 3 months
    4. No other complications from virus are present (e.g. opportunistic infection, Kaposi's sarcoma, or other neoplasm)
i.

VIII. Absolute Contraindications

a. BMI less than or equal to 30, > 30 to 34.9kg per m2 is a relative contraindication, ≥ 35 is an absolute contraindication
b. Nutritional issues
    i. Patients who have cachexia (BMI < 16) likely have poor nutritional status and would have a poor outcome following transplantation. Obesity (BMI >30) also may be a concern because of postoperative atelectasis and pneumonia.
c. Social and Psychiatric Issues - Refer for psychosocial evaluation and/or psychiatry consultation for guidance. *Psychosocial problems* that are unable to be resolved and that have a high likelihood of impacting negatively on the patient's outcome, e.g., poorly controlled major psychoaffective disorder, inability to comply with complex medication regimen, are a relative contraindication. A documented history of *noncompliance* with medical care or treatment plans even in the absence of documented psychiatric problem is a relative contraindication as per Member Compliance Policy I.7.
    i. Active alcoholism and substance abuse. Requires 6 months of documented abstinence
    ii. Through participation in a structured alcohol/substance abuse program with regular meeting attendance and negative random drug testing as per Member Compliance Policy I.7.
d. Emotional instability, significant depression or other psychiatric illness that cannot be controlled that would impact ability to comply with a complex evaluation process, surgical procedure and post-transplant plan of care and/or ability to give informed consent (and does not have a representative/guardian/conservator)
e. Limited cognitive ability (memory loss, dementia, etc.) that would impact ability to comply with a complex evaluation process, surgical procedure and post-transplant plan of care and/or ability to give informed consent (and does not have a representative/ guardian/conservator).
f. Lack of psychosocial support as indicated by either no identified caregiver or an uncommitted caregiver. This would include the lack of transportation to and from transplant related appointments, patient and/or caregiver is unable to adhere to the requirements of transplant related treatment plan. A care contract may be needed.
g. History of non-adherence that has not been successfully remediated

h. Inability to give informed consent. If the patient has an authorized representative/guardian/conservator or parent in the case of a minor, that individual must understand and support the ongoing health care needs of the patient.
i. Severe end stage organ damage other than the lung including but not limited to:
    i. irreversible severe renal dysfunction—*creatinine clearance of < 50 mg/ml/min,*
    ii. severe diabetes with end organ damage,
    iii. irreversible severe hepatic disease (total bilirubin level of greater than 2 mg/dL, is associated with an unfavorable outcome following transplant).
    iv. A patient with severe left ventricular systolic or diastolic dysfunction is not a candidate for lung only transplantation (but may be a candidate for a Heart/Lung transplant). The ejection fraction should be greater than 40 %
    v. There should be no angiographic evidence of significant coronary artery disease not amenable to revascularization or history of myocardial infarction in last 6 months.
j. Infections
    i. Untreated systemic infection making immunosuppression unsafe, including chronic infection
    ii. Colonization with highly resistant or highly virulent bacteria, fungi, or mycobacteria.
k. Active *malignancy* within the past two years with the exception of basal cell and squamous cell carcinoma of skin. In addition a waiting period of at least 5 years is needed for extracapsular renal cell tumors, breast cancer stage 2 or higher, colon cancer staged higher than Dukes A, and melanoma, level III or higher. Requires oncology clearance.
l. Hepatitis B antigen positivity.
m. Hepatitis C with biopsy-proven histologic evidence of liver disease.
n. Presences of GI disease (bleeding peptic ulcer, diverticulitis). GI clearance required.
o. Age limits: (requests outside of stated ages will be handled on a case-by- case basis
    i. Heart–lung transplants $\leq$ 55 years
    ii. Single lung transplants $\leq$ 65 years
    iii. Bilateral lung transplants $\leq$ 60 years
p. Irreversible, severe brain damage
q. Post-transplant lymphoproliferative disease (PTLD) unless no active disease demonstrated by
    i. Negative positron emission tomography (PET) scan and resolved adenopathy on computed tomography (CT) and/or magnetic resonance imaging.
r. Limited irreversible rehabilitative potential. Under established guidelines, active rehabilitation is considered important to the success of transplantation. Mechanically-ventilated or otherwise immobile persons are considered poor candidates for transplantation; however, short-term mechanical ventilation (less than 2 weeks) or bridge to transplant with ambulatory ECMO does not, in itself, rule out candidacy for lung transplantation
s. Significant chest wall or spinal deformity expected to cause severe restriction after transplantation
t. Member is already listed and approved an another facility

IX. Member Assessment of Compliance with Plan of Care (applicable for ages 10 and above)

a. Member must show commitment during Evaluation Process
b. Member must be willing to be in Meridian Health Plan Care Coordination
c. Member must be willing and able to adhere to post-transplant lifestyle
d. Alcohol screen- abstinence for the past 6 months prior to actual transplant approval, if member history includes use of alcohol. If no history exists then 1 negative alcohol screen must be submitted for members with no history of past alcohol use
e. Drug screen-abstinence for the past 6 months prior to actual transplant approval if history exists of drug use. If no history exists then 1 negative drug screen must be submitted for members with no history of positive drug screen.
f. Nicotine screening- abstinence for the past 6 months prior to actual transplant approval if history of smoking. If no history exists then 1 negative cotinine level must be submitted

Refusal or failure to undergo monthly testing for those members with a history of alcohol, tobacco, and/or drug use will be interpreted as a positive test result.

Six month abstinence period may be shortened in cases where patient's condition is sufficiently advanced that mortality is reasonably expected before the full abstinence period can be completed. Patients granted a waiver of the six month abstinence period require documentation of participation in a formal outpatient treatment program, when practical, as well as serial blood or urine testing no less frequently than monthly. A positive test result at any time prior to the procurement phase will result in denial.

g.

X. Pediatric Lung Transplantation

a. Cardiopulmonary Vascular Disease (Qualifying Conditions):
   i. Primary pulmonary hypertension,
   ii. Pulmonary hypertension associated with structural heart disease
   iii. Pulmonary vein stenosis
   iv. Pulmonary hypertension associated with parenchymal lung disease
   v. Congenital abnormalities of lung development or of lung adaptation to extrauterine life.

b. Pediatric members must meet the following criteria:
   i. Disease no longer responding to maximum medical and surgical treatment
   ii. Moderately severe or severe functional impairment (NYHA Class III or IV)
   iii. Right ventricular failure, severe cyanosis, and low cardiac output

Line of Business Applicability:
This policy applies to Michigan Medicaid, Illinois Medicaid, and Individual plans.

For **Medicaid/Medicaid Expansion Plan** members, this policy will apply. Coverage is based on medical necessity criteria being met and the codes being submitted and considered for review being included on either the Michigan Medicaid Fee Schedule (located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html), or the Illinois Medicaid Fee Schedule (located at: http://www.illinois.gov/hfs/MedicalProviders/MedicaidReimbursement/Pages/default.aspx. If there is a discrepancy between this policy and either the Michigan Medicaid Provider Manual (located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html), or the Illinois Medicaid Provider Manual (located at: http://www.illinois.gov/hfs/MedicalProviders/Handbooks/Pages/default.aspx) the applicable Medicaid Provider Manual will govern.

For **Individual** members, consult the individual insurance policy. If there is a discrepancy between this policy and the individual insurance policy document, the guidelines in the individual insurance policy will govern.

State specific special instructions:

None: ☐

ALL:

- Pre-transplant care, including the transplant evaluation. One evaluation per transplant.
- A second opinion consult only to determine transplant candidacy would be approved at a contracted or in network transplant facility if a second transplant evaluation is requested and the member has been previously turned down for transplant.
- The Chief Medical Officer and/or Senior Medical Director must receive notification for all possible approved requests by the UM team

MI:
IL:
OH:

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State Letters/Bulletins					
CMS National/Local Coverage Determination (NCD/LCD)					
Medicare Managed Care Manual:					
Medicaid CFR:					
State Administrative Codes:					
Contract Requirements:					
Related Policies:					