TITLE: HEART TRANSPLANTATION (ADULT and PEDIATRIC)

EFFECTIVE DATE: April 23, 2018

This policy was developed with input from specialists in cardiology, cardiovascular surgery, 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 heart 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. **Total artificial heart (TAH)** is an implantable biventricular support device that serves as a total replacement for both ventricles of the failing heart. The ventricles and valves are surgically excised and the device is sewn to the remaining atria (top half of the heart). The TAH replaces the function of the two ventricles and four valves by pumping blood to both the pulmonary and systemic circulation. The TAH provides circulatory support while waiting for a donor heart and may also restore kidney and liver function due to improved blood flow. The TAH is connected to two lines that exit through the skin and connect to a large power generating console, which operates and monitors the device, while the patient is hospitalized. A portable power generating device (SynCardia Freedom® Driver System) is also available which allows the patient to leave the hospital. Currently there is only one FDA approved device, SynCardia temporary Total Artificial Heart (TAH-t).

B. **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.

C. **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).

D. **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.
E. A Ventricular Assist Device (VAD) describes any of a variety of mechanical blood pumps that are used singularly to replace the function of either the right, left or both ventricles. A VAD may be appropriate in, but not limited to, the following situations:
1. To support individuals who have had open heart surgery and cannot be weaned from cardiopulmonary bypass.
2. To support individuals after an acute myocardial infarction. Ventricular assistance after cardiotomy or a heart attack is usually short term (one day to two weeks).
3. To support individuals awaiting a heart transplant (bridge to transplant).
4. To support individuals in persistent/severe cardiogenic shock from any etiology.

BENEFIT CONSIDERATIONS
1. Prior authorization is required for:
   - Heart Transplantation Evaluation
   - Heart Transplantation
   Please see the prior authorization list for product specific prior authorization requirements.
2. Refer to Medica’s Utilization Management Policy, Mechanical Circulatory Support Devices, for medical necessity criteria for ventricular assist devices (VADs) and total artificial heart (TAH).
3. Coverage may vary according to the terms of the member’s plan document.
4. Medica has entered into separate contracts with designated facilities to provide transplant-related health services, as described in the member’s plan document.
5. Complex cases require medical director or external review and, as necessary, discussion with the patient’s physician.
6. Underlying co-morbidity that significantly alters risk/benefit of transplant may preclude transplant eligibility.
7. If the Medical Necessity and Coverage Criteria are met, Medica will authorize benefits within the limits in the member’s plan document.
8. If the Medical Necessity and Coverage Criteria are not met, the case will be submitted to the medical director or external review for individual consideration. Practitioners are advised of the appeal process in their Provider Administrative Manual.

MEDICAL NECESSITY CRITERIA
I. Indications for Heart Transplant Evaluation [For multiorgan transplant, the individual must meet criteria for each organ. Please refer to applicable Medica UM policy.]
   A. Documentation in the medical records indicates that the individual has a diagnosis of heart disease refractory to other appropriate medical or surgical therapy due to one of the following conditions:
      1. New York Heart Association (See Appendix 1) functional Class III-IV congestive heart failure; including but not limited to: idiopathic, ischemic, valvular, congenital, hypertrophic, familial, or other forms of cardiomyopathy
      2. Disabling heart disease, including refractory congestive heart failure or intractable angina on maximal medical therapy and not surgically correctable
      3. Complex congenital heart defects, not amenable to other medical or surgical intervention including, but not limited to:
         a. Hypoplastic left heart syndrome
         b. Transposition of the great arteries
         c. Tricuspid atresia
         d. Pulmonary atresia
         e. Single ventricle with associated defects
         f. Complex truncus arteriosus
         g. Severe atioventricular canal
         h. Severe Ebstein’s anomaly
         i. Tetralogy of Fallot
      4. Primary cardiac tumors without metastasis
      5. Recurrent life-threatening arrhythmias not otherwise correctable.
   II. Indications for Heart 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.
Heart Transplantation (Adult and Pediatric)  
Medica Policy No. III-TRA.12

B. 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.

C. 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.

D. Documented abstinence from tobacco for at least six months.

E. All of the criteria in section I are met

F. No documented contraindications present as indicated by all of the following:
   1. No non-cardiac uncorrectable medical condition that would itself significantly shorten life expectancy or make transplant success unlikely
   2. No pulmonary hypertension with pulmonary artery systemic pressure greater than 60 mmHg, mean transpulmonary gradient less than 15 mmHg, and/or pulmonary vascular resistance (PVR) greater than 5 Wood units on maximal vasodilator therapy
   3. No significant peripheral vascular disease not correctable with surgery
   4. No active systemic or localized infection or those associated with a left ventricular assist device
   5. No irreversible multisystem organ failure
   6. No active untreated or untreatable malignancy (NOTE: Patients with underlying malignancy may require oncology consult to assess prognosis and risk of recurrence).
   7. No HIV infection with detectable viral load and CD4 counts less than 200/mm³, acquired immunodeficiency syndrome (AIDS) or history of AIDS-defining condition that is progressive or recurrent (See Appendix 3)
   8. No active substance use disorder
   9. No irreversible severe brain damage
   10. No post-transplant lymphoproliferative disease (PTLD) unless no active disease demonstrated by negative PET scan and resolved adenopathy on CT/MRI
   11. No limited irreversible rehabilitative potential
   12. No ongoing pattern of noncompliance, psychiatric illness, psychological condition or limited cognitive ability that would make compliance with a disciplined medical regimen impossible
   13. No lack of psychosocial support as indicated by either no identified caregiver or an uncommitted caregiver
   14. No inability to obtain informed consent from patient or guardian.

III. Indications for Heart Retransplantation
Documentation in the medical records indicates that all of the following criteria are met:
A. Failed previous heart transplantation
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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</table>

References:
Pre-06/2016 MPC:


2/2017 MPC:
APPENDIX 1 – Heart Failure Classification
New York Heart Association (NYHA) Functional Classification

<table>
<thead>
<tr>
<th>Class</th>
<th>Patient Symptoms</th>
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<tbody>
<tr>
<td>I</td>
<td>No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea (shortness of breath).</td>
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<tr>
<td>II</td>
<td>Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea (shortness of breath).</td>
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<tr>
<td>III</td>
<td>Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, or dyspnea.</td>
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<tr>
<td>IV</td>
<td>Unable to carry on any physical activity without discomfort. Symptoms of heart failure at rest. If any physical activity is undertaken, discomfort increases.</td>
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<thead>
<tr>
<th>Class</th>
<th>Objective Assessment</th>
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<tbody>
<tr>
<td>A</td>
<td>No objective evidence of cardiovascular disease. No symptoms and no limitation in ordinary physical activity.</td>
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<tr>
<td>C</td>
<td>Objective evidence of moderately severe cardiovascular disease. Marked limitation in activity due to symptoms, even during less-than-ordinary activity. Comfortable only at rest.</td>
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<tr>
<td>D</td>
<td>Objective evidence of severe cardiovascular disease. Severe limitations. Experiences symptoms even while at rest.</td>
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APPENDIX 2– Pulmonary Hypertension Measures
Pulmonary vascular resistance (PVR) can be measured using international Woods units, transpulmonary gradient, or dynes. The following calculations are used:

1. **Woods units** = mean pulmonary artery pressure (MPAP) – pulmonary capillary wedge pressure (PCWP)/cardiac output (CO).
2. **Dynes** = mean pulmonary artery pressure (PAP) – pulmonary capillary wedge pressure (PCWP)/cardiac output (CO) X 80.
3. **Transpulmonary pressure gradient** = mean pulmonary artery pressure (PAP) – pulmonary capillary wedge pressure (PCWP).

APPENDIX 3 – 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, pneumonitis, 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

Effective Date: April 23, 2018
• Mycobacterium avium complex or Mycobacterium kansasii, disseminated or extrapulmonary
• Mycobacterium tuberculosis of any site, pulmonary†, disseminated, or extrapulmonary
• Mycobacterium, other species or unidentified species, disseminated or extrapulmonary
• 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).