PREVEA360 health plan
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Prevea360 Health Plan Medical Policy

Policy Name: **Heart Transplantation (Adult and Pediatric) MP9613**

Effective Date: **May 1, 2024**

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 Prevea360 Health Plan. Coverage is subject to requirements in applicable federal or state laws. Please refer to the member's plan document for other 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, Medicaid, and other government programs, this policy will apply unless these programs require different coverage. Members may contact Prevea360 Health Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions may call the Provider Service Center. Please use the Quick Reference Guide on the Provider Communications page for the appropriate phone number.
https://www.prevea360.com/Providers/Provider-communications-library

Prevea360 Health Plan medical 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 utilization management reviewers by providing the criteria that determines the medical necessity.

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. 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.

D. 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 The Health Plan's Coverage Policies:
   - *Mechanical Circulatory Support Devices*, for ventricular assist devices (VADs) and total artificial heart (TAH) devices
   - *Gene Expression Profiling for Detection of Heart Transplantation Rejection*.
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 Criteria and Benefit Considerations are met, The Health Plan will authorize benefits within the limits in the member's plan document.
8. If the Medical Necessity Criteria and Benefit Considerations 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**

(NOTE: 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 or American Heart Association Stage D 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. Congenital heart defects, that have failed previous surgical correction or that are 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 atrioventricular canal
   h. Severe Ebstein's anomaly
   i. Tetralogy of Fallot
4. Primary cardiac tumors without metastasis
5. Recurrent life-threatening arrhythmias not otherwise correctable
6. Cardiac amyloidosis, light chain (AL) or transthyretin (ATTR) type

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

B. All of the criteria in section I are met.

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: https://www.cms.gov/medicare-coverage-database/new-search/search.aspx

DOCUMENT HISTORY

Original Effective Date	Created 12/21/2022
MPC Endorsement Date(s)	03/15/2023, 04/17/2024
Administrative Updates	04/17/2024

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APPENDIX 1 – Heart Failure Classification

New York Heart Association (NYHA) Functional Classification

Class	Patient Symptoms
I	No limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, or shortness of breath.
II	Slight limitation of physical activity. Comfortable at rest. Ordinary physical activity results in fatigue, palpitation, shortness of breath or chest pain.
III	Marked limitation of physical activity. Comfortable at rest. Less than ordinary activity causes fatigue, palpitation, shortness of breath or chest pain.
IV	Symptoms of heart failure at rest. Any physical activity causes further discomfort.
Stage	**Stages of Heart Failure Description**
A At risk for heart failure	People who are at risk for heart failure but do not yet have symptoms or structural or functional heart disease. Risk factors for people in this stage include hypertension, coronary vascular disease, diabetes, obesity, exposure to cardiotoxic agents, genetic variants for cardiomyopathy and family history of cardiomyopathy.
B Pre-heart failure	People without current or previous symptoms of heart failure but with either structural heart disease, increased filling pressures in the heart or other risk factors.
C Symptomatic heart failure	People with current or previous symptoms of heart failure.
D Advanced heart failure	People with heart failure symptoms that interfere with daily life functions or lead to repeated hospitalizations.

Source: American Heart Association (AHA). Conditions: Classes of Heart Failure. Last Reviewed: June 7, 2023. https://www.heart.org/en/health-topics/heart-failure/what-is-heart-failure/classes-of-heart-failure