

Prevea360 Health Plan Medical Policy

This policy was developed with input from specialists in cardiology, cardiovascular surgery, pulmonology, thoracic surgery and transplant surgery, 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

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).

Prevea360 Health Plan Medical Policy

- 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/Lung Transplantation **Evaluation**
 - Heart/Lung **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. The Health Plan 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.

Prevea360 Health Plan Medical Policy

7. If the Medical Necessity Criteria and Benefit Considerations are met, Prevea360 Health Plan will authorize benefits within the limits in the member's plan document.
8. If it appears that the Medical Necessity Criteria and Benefit Considerations 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 Heart/Lung **Evaluation**

(NOTE: For multiorgan transplant, in addition to heart/lung transplantation, the individual must meet criteria for each additional organ. Please refer to applicable Medica UM policy.)

A. Documentation in the medical records indicates that the individual has a diagnosis of end-stage pulmonary vascular disease with end-stage non-reversible cardiac disease due to **one of the following** conditions:

1. Diagnosis of Eisenmenger's syndrome with a cardiac defect not amenable to surgical repair
2. Primary pulmonary hypertension
3. Irreversible disease of one or both lungs with severe cardiac disease not otherwise treatable.

II. Indications for Heart/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. All of the criteria in section I are met.

III. Indications for Heart/Lung **Retransplantation**

Documentation in the medical records indicates that **all of the following** criteria are met:

- A. Failed previous heart/lung 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.

Prevea360 Health Plan Medical Policy

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

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|-------------------------|------------------------|
| Original Effective Date | Created 12/01/2022 |
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| Administrative Updates | 04/17/2024 |

Prevea360 Health Plan Medical Policy

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Prevea360 Health Plan Medical Policy

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