curative

TITLE:	HEART TRANSPLANT POLICY
POLICY #:	MM-PNP-032
VERSION #:	01
DEPARTMENT:	UTILIZATION REVIEW
ORIGINAL EFFECTIVE DATE:	12/01/2023
CURRENT REVISION DATE:	N/A

1. PURPOSE

To establish medical necessity criteria and requirements for Heart Transplantation..

2. SCOPE

For use by the Medical UM Department.

3. DEFINITIONS

N/A

4. RESPONSIBILITIES

N/A

5. POLICY

Provides guidelines regarding the medical necessity review of a heart transplant request.

Medical Necessity

Human Heart Transplantation

Curative considers heart transplantation medically necessary for *any* of the following conditions (not an all-inclusive list) when the member meets the transplanting institution's protocol eligibility criteria.

- In the absence of a protocol, Curative considers heart transplantation medically necessary for heart failure with irreversible underlying etiology, including the following indications when the selection criteria listed below are met and none of the absolute contraindications are present:
  - Cardiac arrhythmia
  - Cardiac re-transplantation due to graft failure
  - Cardiomyopathy due to nutritional, metabolic, hypertrophic or restrictive etiologies
  - Congenital heart disease
  - End-stage ventricular failure
  - Idiopathic dilated cardiomyopathy
  - Inability to be weaned from temporary cardiac-assist devices after myocardial infarction or non-transplant cardiac surgery
  - Intractable coronary artery disease
  - Myocarditis

- Postpartum cardiomyopathy
- Right ventricular dysplasia/cardiomyopathy
- Valvular heart disease.

Selection Criteria for Human Heart Transplantation

For members off protocol, *all* criteria listed below must be met:

- New York Heart Association (NYHA) classification of heart failure III or IV (see Note below) - *does not apply to pediatric members*; ***and***
  - Member has potential for conditioning and rehabilitation after transplant (i.e., member is not moribund); *and*
  - Life expectancy (in the absence of cardiovascular disease) is greater than 2 years; *and*
  - No malignancy (except for non-melanomatous skin cancers or low grade prostate cancer) or malignancy has been completely resected or (upon individual case review) malignancy has been adequately treated with no substantial likelihood of recurrence with acceptable future risks; *and*
  - Adequate pulmonary, liver and renal function; *and*
  - Absence of active infections that are not effectively treated; *and*
  - Absence of uncontrolled HIV infection, defined as:
  - CD4 count greater than 200 cells/mm3 for greater than 6 months; ***and***
    - HIV-1 RNA (viral load) undetectable; *and*
    - On stable antiviral therapy greater than 3 months; *and*
    - No other complications from AIDS, such as opportunistic infections (e.g., aspergillus, tuberculosis, coccidiodomycosis, resistant fungal infections) or neoplasms (e.g., Kaposi's sarcoma, non-Hodgkin's lymphoma); *and*
    - Absence of active or recurrent pancreatitis; *and*
    - Absence of diabetes with severe end-organ damage (neuropathy, nephropathy with declining renal function and proliferative retinopathy); *and*
    - No uncontrolled and/or untreated psychiatric disorders that interfere with compliance to a strict treatment regimen; *and*
    - No active alcohol or chemical dependency that interferes with compliance to a strict treatment regimen.

Note: NYHA Class III and Class IV for heart failure are defined as follows:

Table 1: NYHA Class III and Class IV for heart failure

Class	Classification
Class III:	Persons with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity (i.e., mild exertion) causes fatigue, palpitation, dyspnea, or anginal pain.
Class IV:	Persons with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of cardiac insufficiency or of the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort is increased.

Contraindications

Heart transplant is considered not medically necessary for persons with ***any*** of the following contraindications:

- Presence of irreversible end-organ diseases (e.g., renal, hepatic, pulmonary) (unless person is to undergo dual organ transplantation, e.g., heart-lung, heart-kidney, etc.); *or*
- Presence of severe pulmonary hypertension with irreversibly high pulmonary vascular resistance; *or*
- Presence of a recent intra-cranial cerebrovascular event with significant persistent deficit; *or*
- Presence of bleeding peptic ulcer; *or*
- Presence of hepatitis B antigen; *or*
- Presence of diverticulitis; *or*
- Presence of immediately life-threatening neuromuscular disorders; *or*
- Presence of HIV/AIDS with profound immunosuppression (CD4 count of less than 200 cells/mm3); *or*
- Presence of AL amyloidosis (although amyloidosis is considered a contraindication to heart transplantation, exceptions may be made in circumstances where curative therapy of amyloidosis has been performed or is planned (e.g., stem cell transplantation in primary amyloidosis, liver transplantation in familial amyloidosis)).

Total Artificial Heart

Curative considers the use of a total artificial heart (e.g., ABIOCOR Total Artificial Heart, SynCardia™ temporary Total Artificial Heart (formerly known as CardioWest Total Artificial Heart)) as permanent treatment (destination therapy) (i.e., as an alternative to heart transplantation) experimental and investigational because its safety and effectiveness for this indication has not been established.

Curative considers a U.S. Food and Drug Administration-approved total artificial heart (e.g., CardioWest Total Artificial Heart, SynCardia Systems) medically necessary when used as a bridge to transplant for transplant-eligible members who are at imminent risk of death (NYHA Class IV) due to biventricular failure who are awaiting heart transplantation.

AlloMap™ Molecular-Expression Blood Test

Curative considers the AlloMap gene expression profile medically necessary for monitoring rejection in heart transplant recipients more than 6 months post-heart transplant.

Curative considers the AlloMap gene expression profile experimental and investigational for all other indications because its clinical value has not been established.

Experimental and Investigational

Curative considers the following procedures experimental and investigational because the clinical value, safety, and/or effectiveness has not been established:

- **Xenotransplantation of the Heart** - Cardiac xenotransplantation (e.g., porcine xenografts);
- **Breath Test for Heart Transplant Rejection** - Heartsbreath Test (Menassana Research, Inc) for diagnosing heart transplant rejection and for all other indications;
- **Cytokine Gene Polymorphism Testing -** Cytokine gene polymorphism testing for evaluating graft rejection following heart transplantation;
- **Immune Repertoire Sequencing Assay -** Immune repertoire sequencing assay for measurement of the isotype and clonal composition of the circulating B cell repertoire to detect acute allograft rejection in heart transplant recipients;
- **myTAIHEART Testing** - myTAIHEART test (TAI Diagnostics, Inc., Milwaukee, WI) for evaluating graft rejection following heart transplant and all other indications;
- **Measurement of Cardiac Troponins -** Measurement of cardiac troponins for diagnosis of acute cellular rejection following heart transplantation, and for assessing prognosis of primary graft failure in heart transplant recipients;
- **Measurement of Donor-Derived Cell-Free DNA (Allosure)** - Measurement of donor-derived cell-free DNA (Allosure, Prospera Test) of transplant recipients for monitoring of rejection;
- **Heart Molecular Microscope Diagnostic System (MMDx-Heart)** - Heart Molecular Microscope Diagnostic System (MMDx-Heart) for evaluation of cardiac transplant rejection;
- **TransMedics Organ Care System** - TransMedics Organ Care System for preservation and transport of donor heart;
- **Machine Learning and Artificial Intelligence** - The use of machine learning and artificial intelligence in cardiac transplantation.

Related Policies

Ventricular Assist Devices - for left ventricular assist devices as destination therapy for persons with severe heart failure.

6. PROCEDURE

N/A

7. TRAINING REQUIREMENT

- All Medical UM associates are responsible for reading and comprehending this procedure. Employees are also responsible for contacting management or Privacy and Compliance with any questions or concerns regarding the information contained within this procedure.

8. ENFORCEMENT

Violations of this controlled document will cause the imposition of sanctions in accordance with the Curative sanctions-controlled document. This may include verbal/written warning, suspension, up to termination of employment or volunteer, intern, contractor status with Curative. Additional civil, criminal, and equitable remedies may apply.

9. DOCUMENTATION

N/A

10. REFERENCE DOCUMENTS AND MATERIALS

N/A

11. COLLABORATING DEPARTMENTS

- Medical and Pharmacy UM Departments

12. DOCUMENT CONTROL

APPROVED BY:	
(Printed Name) (Date)	**(Signature)**

REVISION HISTORY			
Date	**Author**	**Version**	**Comments**
			Initial Version

APPENDICES

Any applicable attachments, resources or other materials should be included as appendices in this section. Label each appendix as follows:

Appendix A: