I. POLICY

It is the policy of MedStar Health, Inc. to cover pediatric heart transplant when it is medically necessary (refer to CRM.015.MH – Medical Necessity policy) and covered under the member’s specific benefit plan.

MedStar Health, Inc. recognizes heart transplantation as appropriate and consistent with good medical practice and will be considered after review on an individual basis for the specific indications detailed in this policy.

All denials that are based on medical necessity and appropriateness are made by a physician or health care practitioner with expertise comparable to that of the prescriber.

II. DEFINITIONS

N/A

III. PURPOSE

The purpose of this policy is to define the criteria for pediatric heart transplantation.
IV. **SCOPE**

This policy applies to various MedStar Health, Inc. Departments as indicated by the Benefit and Reimbursement Committee. These include but are not limited to Medical Management, Benefit Configuration and Claims Departments.

V. **PROCEDURE**

A. **Medical Description**

A heart transplant refers to the surgical procedure by which the diseased heart of the end-stage heart failure member is removed and replaced with a healthy donor heart. Members who receive cardiac transplants have an in-hospital mortality rate of less than 5%, a 1-year survival rate of about 85%, and a 5-year survival rate of 75 to 80%.

Heart transplantation is an accepted treatment option for selected pediatric members with end-stage heart disease characterized by intractable symptoms and heart failure that cannot be treated with conventional medical or surgical methods. In children, the most common indications for cardiac transplantation are congenital heart disease, dilated cardiomyopathy, and retransplantation.

Evaluation of the potential transplant recipient should be undertaken by a multidisciplinary team with experience in management of refractory heart failure, high-risk cardiac surgery, and transplantation. The decision of whether or not to transplant is based on selection of recipient candidates most likely to obtain long-term benefits in quality of life and survival.

B. **Specific Indications**

Members under the age of 18 years old requesting heart transplants must meet the specific criteria for recipient characteristics and the specific criteria for the transplant. (For members 18 years of age or older refer to MP.029.MH-Transplant: Adult Heart)

**Recipient Characteristics**

The member's caregiver or established social support network which may include the mother and/or father, other family members, foster care parents, professional health providers, or some combination must meet both of the following:

1. Be capable of long-term intensive care of the child; and
2. Be able to support the exceptional needs of the child.

**Specific Criteria for Pediatric Heart Transplant**

Clinical indications for heart transplantation include the following:

1. Low cardiac output, and
2. Estimated life expectancy of less than one year without a transplant, and
3. Symptoms refractory or intolerable despite maximal medical therapy with digitalis, diuretics, and vasodilators at maximally-tolerated doses, and
4. Any one of the following underlying conditions:
   a. Hypoplastic left heart syndrome and variants
   b. Multiple obstructive cardiac neoplasms
   c. Severe cardiomyopathy
   d. Severe Ebstein’s anomaly in early infancy
   e. Complex single ventricle with systemic outflow obstruction
   f. Single ventricle of right ventricular type with arterio-venous (AV) valve regurgitation
   g. Pulmonary atresia and intact ventricular septum and sinusoids
   h. Severe intra-uterine AV valve insufficiency and ventricular dysfunction
   i. Severe endocardial fibroelastosis
   j. Complex heart disease associated with the Asplenia Syndrome

**C. Limitations**

1. Non-surgical treatment of the member’s medical condition must first be attempted and shown to be unsuccessful before consideration of transplant
2. Members must first undergo stringent physical and age appropriate psychological evaluation to determine eligibility for transplant

**General Contraindications**

1. Infant less than one (1) month of age
2. Unstable metabolic or hemodynamic status while receiving PGE-1 and other supportive measures (e.g., cardiac inotrope, mechanical ventilation, parenteral nutrition)
3. Active infection (members developing infections while on a waiting list may become temporarily inactive and may return to active status if the infection resolves)
4. Any significant systemic illness that would severely limit life expectancy or compromise recovery
5. Abnormal renal evaluation: if BUN > 30 and creatinine < 1.5, pediatric nephrology consultation is necessary to exclude gross renal abnormalities
6. Contraindication to immunosuppressive drugs
7. Abdominal ultrasonography study showing significant renal malformations
8. HIV positive or chronic active hepatitis B or C
9. Absent of appropriate familial or social support group
10. Not up to date with all applicable preventive services recommended by the American Academy of Pediatrics (i.e., immunizations)
11. Females of childbearing potential with either positive pregnancy test or inability/unwillingness to use contraception

**Cardiac Contraindications**
1. Severe pulmonary hypertension
2. Pulmonary vascular resistance (PVR) > 6 Wood Units, (i.e., Wood Unit = mean pulmonary artery pressure – mean pulmonary capillary wedge pressure/cardiac output.) At higher levels of PVR, heart transplant may be required

**D. Information Required for Review**

In order to assess medical necessity for heart transplant, adequate information must be furnished by the transplant center. Necessary documentation includes **but is not limited** to the following:
1. Member’s age, clinical history, physical and functional status
2. Documentation of diagnosis, staging, and treatment history
3. Social work and nutritional assessment consultations
4. Results of pre-transplant tests including:
   - Cardiac catheterization
   - Echocardiogram
   - Complete pulmonary function studies
5. Results of laboratory studies and serologic testing including:
   - Blood typing
   - CBC, chemistry profile (including blood urea nitrogen (BUN), creatinine, electrolytes, glucose, calcium (Ca), phosphorus, uric acid, magnesium (Mg), total protein, albumin, amylase)
   - Prothrombin Time /Partial Thromboplastin Time (PT/PTT)
   - Glycosylated hemoglobin (diabetes member.)
   - Histocompatibility Antigens (HLA) typing
   - Human immunodeficiency virus (HIV) antibody
   - Hepatitis panel
   - Lyme disease
   - Legionella
E. Review Process

1. The Medical Management Ancillary Service staff reviews the request. If the case does not meet the established criteria, it is referred to a MedStar Health, Inc. Medical Director (Medical Director).
2. If referred, the Medical Director determines if the requested service is medically necessary and appropriate.
3. The Medical Management Ancillary Service staff completes the review process and communicates the review decision according to the Timeliness of UM Decisions policy for the member's benefit plan.

F. Variations

N/A

G. Records Retention

Records Retention for documents, regardless of medium are provided within the MedStar Health, Inc. Policy and Procedure CORP.028.MH Records Retention.

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