BENEFIT COVERAGE POLICY

Title: BCP-66 Cardiac Transplantation

Effective Date: 04/01/2023

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following coverage policy applies to health benefit plans administered by PHP and may not be covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Coverage determinations for individual requests require consideration of:

- The terms of the applicable benefit document are in effect on the date of service.
- Any applicable laws and regulations.
- Any relevant collateral source materials, including coverage policies.
- The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

The Health Plan covers heart transplantation for adults as medically necessary for the treatment of ANY of the following conditions, and the clinical determination guidelines below are met:

- Refractory heart failure that is not amenable or correctable by alternative medical or surgical therapies and leaves the individual in a New York Heart Association functional class III or IV; OR
- End-stage heart failure that requires continuous intravenous inotropic or mechanical circulatory support; OR
- Malignant ventricular arrhythmias unresponsive to medical and/or surgical therapy.

All transplant-related services require approval prior to the health service being provided at a Health Plan designated transplant facility. Contact the Transplant Case Manager to verify if a provider is contracted as a designated transplant facility.

Non-network transplant services are not covered.

Refer to the member's benefit coverage document for specific benefit descriptions, guidelines, coverage, and exclusions.

2.0 Background:

A. Heart transplantation has become a commonly used option for the treatment of end-stage heart disease. It has been projected that patients who receive cardiac transplants have an inpatient mortality rate of less than 5%, a one-year survival rate of about 85%, and a five-year survival rate of 75 to 80%. Moreover, 90% of cardiac transplant patients lead a relatively normal lifestyle having no limitations in their activity, and 40% return to work.

B. In adults, cardiac transplantation is most frequently performed for patients with cardiomyopathy (about 50%), coronary artery disease (about 40%), valvular disease (about 4%), re-transplantation following a failed primary transplantation (about 2%), and congenital heart disease (about 2%).

C. In children, the most common indications for cardiac transplantation are congenital heart disease (about 47%), dilated cardiomyopathy (about 45%), and re-transplantation (about 3%). Moreover, survival in children with dilated cardiomyopathy relies on accurate diagnosis and aggressive treatment. The literature indicates that patients may respond to conventional treatment for heart failure or may deteriorate, requiring mechanical support. Extracorporeal membrane oxygenation (ECMO) has been used effectively for mechanical support in children until improvement occurs or as a bridge to transplantation. For individuals who are listed to receive a heart transplant, the mortality rate while waiting for a donor organ average approximately 20%. Survival after transplantation is good, with an intermediate survival rate of about 70%.

D. Cardiac transplantation is currently the only proven curative treatment for end-stage heart disease, but the supply of donor's hearts has not kept pace with the demand. Therefore, surgical techniques such as reduction ventriculoplasty, transmyocardial laser revascularization, myoreduction operations (Batista Operation and Surgical Ventricular Restoration (Dor Procedure), or dynamic cardiomyoplasty are employed to maintain heart function or provide a bridge to heart transplantation. In addition, ventricular assist devices (VADs) and the total artificial heart (TAH) have been approved by the Food and Drug Administration (FDA) for use as a bridge to transplant in selected persons who are awaiting heart transplantation.

E. Humanitarian Use Device (HUD) is a device that has been given special approval by the FDA under the Humanitarian Device Exemption (HDE) regulations. The standard approval process for devices requires that companies demonstrate that the devices are safe and effective (better than medicine or another procedure). However, the FDA recognizes that sometimes a condition is so unusual that it would be difficult for a company to scientifically demonstrate the effectiveness of their device in the large number of patients that usually must be tested. In these special situations, they may grant an HDE provided that:

   1. The device does not pose an unreasonable or significant risk of illness or injury; and
   2. The probable benefit to health outweighs the risk of injury or illness from its use, taking into account the probable risks and benefits of currently available devices or alternative forms of treatment; and
   3. A HUD may only be used in facilities that have an Institutional Review Board (IRB) to supervise clinical testing of devices and after the IRB has approved the use of the device to treat or diagnose the specific disease.

3.0 Clinical Determination Guidelines:

See InterQual-Cardiac Transplantation for criteria.

4.0 Coding:

Prior Approval Legend: Y = All lines of business; N = None required; 1 = HMO/POS; 2 = EPO/PPO; 3 = ASO Group L0000264; 4 = ASO Group L0001269 Non-Union & Union; 5 = ASO Group L0001631; 6 = ASO Group L0002011; 7 = ASO Group L000269 Union Only; 8 = ASO group L0002184; 9 = ASO group L0002237; 10 = ASO group L0002193.

COVERED CODES			
Code	**Description**	**Prior Approval**	**Benefit Plan Cost Share Reference**
33933	Backbench standard preparation of cadaver donor heart/lung allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, and trachea for implantation	N	Transplantation Services
33940	Donor cardiectomy (including cold	Y	Transplantation Services

COVERED CODES			
Code	**Description**	**Prior Approval**	**Benefit Plan Cost Share Reference**
	preservation)		
33944	Backbench standard preparation of cadaver donor heart allograft prior to transplantation, including dissection of allograft from surrounding soft tissues to prepare aorta, superior vena cava, inferior vena cava, pulmonary artery, and left atrium for implantation	N	Transplantation Services
33945	Heart transplant, with or without recipient cardiectomy	Y	Transplantation Services

NON-COVERED CODES		
Code	**Description**	**Benefit Plan Reference**
C1824	Generator, cardiac contractility modulation (implantable)	General Exclusions and Limitations: Experimental/investigational/unproven
0087U	Cardiology (heart transplant), mRNA gene expression profiling by microarray of 1283 genes, transplant biopsy tissue, allograft rejection, and injury algorithm reported as a probability score	General Exclusions and Limitations: Experimental/investigational/unproven
0018M	Transplantation medicine, quantification of donor-derived cell-free DNA using whole-genome next-generation sequencing, plasma, reported as percentage of donor-derived cell-free DNA in the total cell-free DNA	Experimental/ investigational

4.0 Unique Configuration/Prior Approval/Coverage Details:

ASO group L0001631 and L0002237 plans have a Travel and Lodging Benefit included in the Transplant Benefit (see SPDs for details).

5.0 Terms & Definitions:

ACE (angiotensin-converting enzyme) inhibitor – Drugs that reduce peripheral vascular resistance by blocking the angiotensin-converting enzyme. This action reduces the myocardial oxygen consumption, thereby improving cardiac output and moderating left ventricular and vascular hypertrophy. ACE inhibitors are used for controlling blood pressure, treating heart failure, and preventing kidney damage in people with hypertension or diabetes. e.g., Capoten (captopril), Prinivil or Zestril (lisinopril), Accupril (quinipril), Altace (ramipril), Vasotec (enalapril).

Active candidate – A candidate on the waiting list who is currently suitable for transplantation and eligible to receive organ offers.

Beta-blocker – Drugs that block beta-adrenergic substances such as adrenaline (epinephrine), a key agent in the "sympathetic" portion of the autonomic (involuntary) nervous system and activation of heart muscle. They slow the heartbeat, lessen the force with which the heart muscle contracts, and reduce blood vessel contraction in the heart, brain, and throughout the body. Beta-blockers can serve to treat cardiac arrhythmias. They are used specifically to prevent abnormal tachycardias or irregular

heart rhythms such as premature ventricular beats. e.g., Coreg (carvedilol), Toprol XL (metoprolol succinate), Lopressor (metoprolol tartrate), Inderal (propranolol), Corgard (nadolol) Tenormin (atenolol), Normadyne (labetalol).

Brain Natriuretic Peptide (BNP) test – A hormone in the blood made by the heart, which indicates how well the heart is working. Normally, only a low amount of BNP is found in the blood. If the heart has to work harder over a long period of time, such as from heart failure, the heart releases more BNP, and the blood level will get higher. The BNP level will drop when treatment for heart failure is working. Normal range = 0-100 pg/ml.

Bridge to Transplant – Mechanical devices (artificial heart or ventricular assist device/VAD) that are implanted to help support a failing heart while the patient awaits a donor's heart. The ventricular assist devices help to restore circulation of oxygenated blood to organs and tissues. Patients with a history of aborted cardiac arrest are at the highest risk for recurrent malignant arrhythmias. The implantable cardioverter-defibrillator (ICD) is the most effective therapy for preventing sudden cardiac death from ventricular tachyarrhythmias.

Cardiac Allograft Vasculopathy (CAV) – A chronic disease in which the walls of the coronary arteries in the new heart become thick, hard, and less stretchy. CAV can destroy blood circulation in the new heart and cause serious damage. CAV is a leading cause of donor heart failure and death in the years following transplant surgery.

Cardiomyopathy – A serious disease in which the heart muscle becomes inflamed and doesn't work as well as it should. There may be multiple causes, including viral infections. Cardiomyopathy can be classified as primary or secondary.

- Primary cardiomyopathy can't be attributed to a specific cause, such as high blood pressure, heart valve disease, artery diseases, or congenital heart defects.
- Secondary cardiomyopathy is due to specific causes. It's often associated with diseases involving other organs as well as the heart

Designated facility – A facility that has entered into an agreement on behalf of the facility and its affiliated staff with the Health Plan or with an organization contracting on our behalf to render covered health services for the treatment of specified diseases or conditions. A designated facility may or may not be located within a member's geographical area. The fact that a hospital Is a network hospital does not mean that it is a designated facility.

Ejection fraction – The percentage of blood that is pumped from the left ventricle with each heartbeat. Normal ejection fraction is 50% or greater.

Graft failure – A significant complication following an allogeneic transplant in which a transplanted organ or tissue loses function. Graft failure statistics are recorded at one month, one year, and three years post-transplant.

Graft rejection – A process in which the immune system of the transplant recipient attacks the transplanted organ or tissue. Graft rejection is the major cause of graft failure and is one of the leading causes of death in the first year after transplant. During the first year, heart transplant patients have an average of one to three episodes of rejection. Rejection is most likely to occur within 6 months of the transplant surgery.

Heart Status – Scoring system, which indicates the medical urgency for which a heart transplant is needed.

Status 1A	These patients are at the top of the waiting list. They include patients in the intensive care unit on life support and/or high-dose intravenous (IV) medications to support their heart function. Or they have had a ventricular assist device (VAD) implanted or on extracorporeal membrane oxygenation (ECMO) to support their heart function.
Status 1B	These patients have end-stage heart failure and are at home on a

	VAD or continuous IV inotrope (heart) medication.
Status 2	These patients do not meet the criteria for Status 1A or 1B. Most often, these patients are waiting at home for a donor's heart and are taking oral medication for heart failure.
Status 7	These patients are temporarily inactive on the heart transplant waiting list due to an infection, have left the area, and cannot get to the transplant facility within the two-hour time limit, or their insurance has changed and needs a new authorization or had a loss of insurance coverage.

Implantable Cardioverter Defibrillator (ICD) – An implantable cardioverter-defibrillator is used in patients at risk for recurrent, sustained ventricular tachycardia or fibrillation. The device is connected to leads positioned inside the heart or on its surface. These leads are used to deliver electrical shocks, sense the cardiac rhythm and sometimes pace the heart as needed. The various leads are tunneled to a pulse generator, which is planted in a pouch beneath the skin of the chest or abdomen.

Inactive candidate – A transplant candidate who is temporarily unavailable or unsuitable for transplantation and appears inactive on the waiting list.

Inotropic drugs – Agents used in the treatment of congestive heart failure aimed to slow the heart to increase ventricular filling and augment cardiac contraction (e.g., digoxin (Lanoxin), Dobutrex (dobutamine), dopamine, isoproterenol, epinephrine, Amrinone, Inocor IV (inamrinone), Primacor (milrinone).

Myocarditis – An inflammatory disease of the heart muscle (myocardium) that can result from a variety of causes. While most cases are produced by a viral infection, an inflammation of the heart muscle may also be instigated by toxins, drugs, and hypersensitive immune reactions. Myocarditis is a rare but serious condition that affects both males and females of any age.

New York Heart Association (NYHA) classification – One of the many parameters used for selecting heart recipients. It is a 4-tier system that categorizes patients based on the subjective impression of the degree of functional compromise.

Class 1	Patients with cardiac disease but without resulting limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea, or anginal pain. Symptoms only occur on severe exertion.
Class II	Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity (e.g., moderate physical exertion such as carrying shopping bags up several flights of stairs) results in fatigue, palpitation, dyspnea, or anginal pain.
Class III	Patients 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	Patients with cardiac disease resulting in an 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.

National Organ Transplant Act (NOTA) – Act passed by the Congress of the U.S. in 1984 that called for a national network to coordinate the allocation of organs and collect clinical data about the organ donors, transplant candidates, and transplant recipients.

Organ Procurement and Transplantation Network (OPTN**)** – A unique public-private partnership that links all professionals involved in the U.S. donation and transplantation system. Efforts are focused on patients with the goals to:

- Increase the number of and access to transplants.
- Improve survival rates after transplantation.
- Promote patient safety and efficient management of the system by maintaining transplant policies and bylaws.

Regions (Transplant) – For the administration of organ allocation and appropriate geographic representation within the OPTN policy structure, the membership is divided into 11 geographic regions. Members belong to the Region in which they are located. The Regions are as follows:

- Region 1: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, and Eastern Vermont
- Region 2: Delaware, District of Columbia, Maryland, New Jersey, Pennsylvania, West Virginia, and the part of Northern Virginia in the Donation Service Area served by the Washington Regional Transplant Community (DCTC) OPO.
- Region 3: Alabama, Arkansas, Florida, Georgia, Louisiana, Mississippi, Puerto Rico
- Region 4: Oklahoma and Texas
- Region 5: Arizona, California, Nevada, New Mexico, and Utah
- Region 6: Alaska, Hawaii, Idaho, Montana, Oregon, and Washington
- Region 7: Illinois, Minnesota, North Dakota, South Dakota, and Wisconsin
- Region 8: Colorado, Iowa, Kansas, Missouri, Nebraska, and Wyoming
- Region 9: New York and Western Vermont
- Region 10: Indiana, Michigan, and Ohio
- Region 11: Kentucky, North Carolina, South Carolina, Tennessee, and Virginia

Scientific Registry of Transplant Recipients (SRTR) – Provides reports and data on solid organ transplantation.

United Network for Organ Sharing (UNOS) – A Nonprofit organization that established a computerized database in 1977 that coordinates U.S. organ transplant activities. Their website contains information and statistics about organ transplantation by Region, state, and transplant center. UNOS was awarded the contract to develop the requirements for the operation of the OPTN since 1986.

Ventricular Assist Device (VAD) – Describes any variety of mechanical blood pumps that are used to replace the function of either the right (RVAD) or left (LVAD) or both (Bi-VAD) ventricles. A VAD may be used in the following situations:

- To support patients who have had open-heart surgery and cannot be weaned from cardiopulmonary bypass.
- To support patients after acute myocardial infarction. Ventricular assistance after cardiotomy or a heart attack is usually short-term (1 day to two weeks).
- To support patients who are awaiting a heart transplant (bridge to transplant).

6.0 References, Citations & Resources:

1. InterQual® 2022, Apr. 2022 Release, CP:Procedures
2. Organ Procurement and Transplantation Network (OPTN), Policies Administrative Rules and Definitions, https://optn.transplant.hrsa.gov/.

3. Scientific Registry of Transplant Recipients. Available at URL address: http://www.srtr.org/default.aspx.

7.0 Associated Documents [For internal use only]:

Benefit Coverage Policies - BCP-17 Retransplantation and Pediatric Transplantation; BCP-33 Pre-Transplant Services.

Policies and Procedures (P&Ps) - MMP-02 Transition and Continuity of care; MMP-06 Peer-to-Peer Conversations; MMP-09 Benefit determinations.

Standard Operating Procedures (SOPs) – MMS-03 Algorithm for Use of Criteria for Benefit Determinations; MMS-05 Completing a High-Cost Notification Form; MMS-09 Case Management Referrals; MMS- 10 Pre-Transplant Process, MMS-11 Transplant Event, and Listing, MMS-12 Post-Transplant Process.

Sample Letter – TCS Approval Letter; Clinically Reviewed Exclusion Letter; Specific Exclusion Denial Letter.

Form – Request Form: Out of Network/ Prior Authorization; High-Cost Notification Form; Transplant Travel and Lodging Reimbursement Form.

Other – Transplant Network contracts with Cigna LifeSource and Emerging Therapy Solutions (ETS).

8.0 Revision History:

Original Effective Date: 04/11/2007

Next Revision Date:

Revision Date	Reason for Revision
4/15	Annual review; updates and standardized format. Clinical criteria more clearly defined from General Background. Added criteria regarding member meeting a facility defined eligibility of "cancer free" period. Drug screening criteria to meet eligibility added.
3/16	Annual review with title changes, removed references to Medical Resource Management (MRM) and changed to "Medical Policy" with the responsible Dept. assigned to Case Management. Removed references to Sparrow PHP, Healthy Michigan and MI Child. Added ICD-10 codes. References and Resources: updated.
2/17	Annual review – changed from MRM Medical Policy 014 to Benefit Coverage Policy format
4/17	Annual renewal approved by QI/MRM.
118	Annual review by BCC, annual review by QI/MRM 2/14/18. New codes effective 1/1/18 added.
4/18	Annual renewal approved by QI/MRM.
1/19	1/1/2019 new code added; L8698, references updated.
4/19	Annual renewal approved by QI/MRM.
2/20	Annual review; updated HIV info, new code added
4/21	Annual review; removed medical criteria, InterQual criteria referenced, MCG removed from references; removed ICD-10 code table, new InterQual code added (33933), updated codes; updated associated documents; aligned codes with InterQual criteria; changed policy title from "Heart" to "Cardiac" Transplantation to align with InterQual.
01/22	Annual review. Removed Interlink references. Added non-covered code 0118M.
1/23	Annual review, updated InterQual references, removed pediatric language, added group L0002237 and L0002193. Updated Lifetrac's name to Emerging Therapy Solutions (ETS). Added L0002237 to section 4.0 coverage details re: travel and lodging benefit.