Optum

Mechanical circulatory support devices

Clinical guidelines

Effective May 12, 2023

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Instructions for use

This Clinical Guideline aids in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this Clinical Guideline. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Clinical Guideline. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Clinical Guideline is provided for informational purposes. It does not constitute medical advice.

Benefit considerations

Where the use of a mechanical circulatory support device is deemed unproven, benefits may be available under Certificates of Coverage or Summary Plan Descriptions that describe coverage for promising but unproven treatments for life-threatening illnesses and coverage for clinical trials. The enrollee-specific benefit document must be consulted to determine coverage.

E&I

- The Guideline applies to all plans

- C&S
- The Guideline applies to those plans with Medical Necessity language and that apply United Healthcare Medical Policy when making coverage determinations.

M&R

- The guideline applies to coverage determinations concerning total artificial hearts
- The guideline does not apply to coverage determinations concerning long-term, durable mechanical circulatory devices. The National Coverage Determination 20.9.1 Ventricular Assist Devices must be followed. Available at: NCD - Ventricular Assist Devices (20.9.1) (cms.gov)

Some state mandates and benefit designs allow for out-of-network coverage of mechanical circulatory support devices that supersede the guidance in this clinical guideline. The enrollee-specific benefit document must be consulted to determine the availability of out-of-network coverage.

Enhancements to already implanted mechanical circulatory support devices that are functioning well are not medically necessary. Replacement and repair of already implanted mechanical circulatory support devices is subject to individual case review.

The enrollee specific benefit document must be consulted to determine the ability to apply facility-based criteria in making coverage determinations.

General information

This guideline applies to MCSD use in adults and adolescent children 13 to 21 years of age whether in a pediatric or adult setting and the use of total artificial hearts in adults. Approval of pediatric (pre-adolescent) MCSD whether in a pediatric or adult setting is out of scope for Optum. MCSD coverage determinations for pre-adolescent children for United Health members will be referred to United Clinical Services (UCS) and will be reviewed for potential coverage under the member's medical benefit.

Devices that **ARE** in-scope include:

- At this time, the only FDA approved artificial heart that is in-scope for this Guideline are the 70 cc SynCardia Total

Artificial Heart and the 50cc SynCardia Total Artificial Heart.

- The following MCSDs for use in adults when used in accordance with the FDA approved indications:
  - Abbott HeartMate II™ Left Ventricular Device (LVAD) in adults
  - Abbott HeartMate 3™ LVAD in adults and adolescents
  - Other durable MCSDs intended for use in adults subject to the benefit within the coverage document.

Devices that are **NOT** in-scope include:

- All non-durable cardiac assist devices including but not limited to:
  - Intra-Aortic Balloon Pump (IABP)
  - Impella® 5.5
  - Impella® CP
  - Impella® RP
  - CentriMag™ and PediMag™
  - TandemHeart®
  - Berlin Heart® EXCOR®
  - Other temporary circulatory support devices
- Pediatric MCSDs
- Automatic Intracardiac Defibrillators (AICDs), with or without synchronous pacemaker
- Pacemakers of any description

Permanently implantable aortic counter pulsation ventricular assist systems (e.g., the NuPulseCV iVAS) are considered investigational. Proposed as a bridge to recovery for patients with advanced CHF, counter pulsation devices are implanted in the aorta and inflate during diastole to reduce end diastolic ventricular pressure on a long-term basis without re-routing blood flow. Several devices are being investigated but presently none have received FDA-approval.

MCSD implantation for Medicaid and commercial plans is limited to facilities that have the necessary infrastructure and experience as documented by having been awarded Advanced Certification in Ventricular Assist Device by the Joint Commission (TJC). Facilities with TJC certification can be found listed at the following link: Search | QualityCheck.org

MCSD implantation for Medicare plans must be credentialed by an organization approved by CMS. A list of CMS credentialed facilities can be found at the following link: cms.gov/Medicare/Medicare-General-Information/MedicareApprovedFacilitie/VAD-Destination-Therapy-Facilities.html.

Transplant evaluation, when required, must be done at a Medicare-approved heart transplant program that is a Designated Facility. However, members may have out-of-network transplant benefits that can be applied.

Background

Heart failure is a complex syndrome resulting from cardiac overload and injury leading to considerable morbidity and mortality. There is no single diagnostic test for heart failure because it is largely a clinical diagnosis characterized by specific symptoms (dyspnea and fatigue) in the medical history and signs (edema and rales) on the physical exam. An individualized, patient-centered treatment approach that focuses on guideline-directed pharmacologic and device therapies is required for optimal management. Despite optimal management, heart failure often progresses with increasing symptoms over time. End-stage treatment options include ventricular assist devices (VADs), total artificial hearts, and heart transplant.

VADs, also referred to as mechanical circulatory support devices (MCSDs), are mechanical blood pumps surgically attached to one or more ventricles of a damaged or weakened heart to assist in pumping blood. Patients receiving VADs must be managed by a multidisciplinary medical team with appropriate

qualification, training and experience. Significant changes to the United Network for Organ Sharing (UNOS) allocation system for cardiac allografts were instituted in 2018. The goal of the restructuring was to minimize transplant waitlist mortality. The changes will potentially impact the number of durable LVAD implants (Teuteberg et al., 2020).

The SynCardia total artificial heart (SynCardia Systems, LLC, Tucson, AZ), is FDA-approved for transplant-eligible patients at risk of imminent death from biventricular failure. A pulsatile biventricular device implanted in the thoracic cavity, the total artificial heart is intended to temporarily replace both native cardiac ventricles and all cardiac valves.

The purpose of this guideline is to identify the characteristics of those patients most likely to benefit from the use of VADs and total artificial hearts.

VAD use in children and adolescents

While the use of VADs in the pediatric and adolescent population has increased over the past decade, the majority of centers implant fewer than 10 of these devices in children per year, due in part to a lack of durable devices that are appropriate for children, as well as a lack of outcomes data (Blume et al., 2016). In December 2020, the FDA approved updated labeling for the HeartMate 3™ LVAD for short- and long-term use in pediatric patients with advanced refractory left ventricular heart failure. The updated labeling was supported by clinical data from the Advanced Cardiac Therapies Improving Outcomes Network (ACTION). ACTION is a multicenter learning network comprised of more than 50 pediatric hospitals established with the goal of sharing and disseminating knowledge in pediatric and congenital mechanical circulatory support and heart failure (O'Connor et al., 2020).

ACTION provided clinical data on 35 patients with a median age of 15.7 (8.8–47.3) years undergoing HeartMate 3 implantation at 9 centers between December 12, 2017, and September 19, 2019. Diagnoses included dilated cardiomyopathy (63%), dilated cardiomyopathy in neuromuscular disease (20%) and congenital heart disease (CHD) (17%). Of the 6 patients with CHD, 5 (83%) had a Fontan circulation and one had a failing systemic right ventricle late following an atrial switch procedure. Bridge-to-transplant was the device strategy for 19 (54%) patients, while bridge-to-candidacy (n = 10, 29%), destination therapy (n = 4, 11%) and bridge-to-recovery (n = 2, 6%) accounted for the remainder of the cohort. Adverse events were uncommon over a follow-up period of a median of 78 days of support (range 2–646 days). There were no incidents of pump dysfunction requiring operative exchange, stroke or pump thrombosis. One patient experienced a fatal global hypoxic-ischemic encephalopathy while on support. As of September 19, 2019, 13 patients were alive on device, 20 had undergone heart transplantation, one underwent device explantation for recovery, and one died. Of the patients undergoing heart transplantation, 14 (67%) were transplanted during the same hospitalization as the device implantation; all were alive on September 19, 2019 (O'Connor et al., 2020).

Indications for pediatric VADs are described by Lorts et al. (2021) and include decompensated heart failure unresponsive to medical management, post-cardiotomy failure to wean from cardiopulmonary bypass, and uncontrollable arrythmias. End-organ dysfunction, while known to be associated with poor outcomes among VAD patients, is also common in pediatric patients prior to implantation, making it critical that these children are identified and implanted early enough to reverse dysfunction and thereby potentially improve outcomes.

VAD therapy in children with congenital heart disease (CHD) is challenging and the risk of stroke is significant. Bryant et al. (2018) examined the effects of VADs on posttransplant outcomes in patients with CHD using the Standard Transplant Analysis and Research data set from the United Network for Organ Sharing (UNOS) database. Identifying patients with a diagnosis of CHD from all patients receiving transplant between January 1, 2006, and June 30, 2015, the authors were able to further subdivide the cohorts to evaluate post-transplant survival and compare patient baseline characteristics and outcomes. The significant finding of these comparisons was survival of CHD patients receiving a VAD as a bridge-to-transplant (BTT) was equivalent to CHD patients who received a transplant without being bridged. This equivalency occurred even though the bridged patients were more critically ill at the time of transplant,

including having worse functional status, spending more time on the waiting list, and requiring dialysis and ventilator support.

Heart transplant in children with CHD continues to increase. Colvin et al. (2021) reported the proportion of pediatric heart transplant candidates with congenital heart defects increased from 46.4% in 2008 to 55.7% in 2019 and congenital heart defects remained the most common primary cause of disease, affecting 51.3% of recipients who underwent transplant in 2017–2019. Congenital heart defect was the leading cause of heart disease (62.4%) for children waiting for a transplant on December 31, 2019. VAD use at the time of transplant increased from 15.7% of pediatric transplant recipients in 2007–2009 to 32.4% in 2017–2019.

In June 2021, Medtronic halted its sale and distribution of the HeartWare HVAD System, a durable LVAD approved for bridge to transplant in 2012 and destination therapy in 2019. The decision was based on evidence of critical device malfunction in which the HVAD experienced a delay or failure to restart after elective or accidental discontinuation of pump operation (Medtronic Device Recall Notice, 2021). The decision to cease commercial distribution of the HVAD now requires surgeons to use the HeartMate 3 as the only commercially available device for primary implantation as well as for exchanging a previously implanted HVAD (Salerno et al., 2022). Understanding how to manage patients currently supported with the HVAD pump has been the focus of recent analyses. An analysis by The Society of Thoracic Surgeons of 3 Intermacs cohorts (primary HVAD implant cohort [January 2017 to March 2021, n = 3797], HVAD to HeartMate 3 exchange cohort [December 2017 to March, 2021, n = 45], and HVAD to HVAD exchange cohort [January 2017 to March 2021, n = 234]) found HVAD to HeartMate 3 exchange was associated with significantly reduced survival compared to survival while remaining on HVAD support (6 months after exchange, 73.8% [70% confidence interval, 68.6–77.8] vs 79% [70% confidence interval, 78.3–79] for continued HVAD support). Compared with HVAD to HVAD exchange, survival was higher after replacement with HeartMate 3 (one year: 85.9% [70% confidence interval, 79.5-90.5] vs 66.6% [70% confidence interval, 63.0–70.0], p = .009). There is insufficient evidence, at this time, to support elective exchange from an HVAD to HeartMate 3. (Cogswell et al., 2022).

Total artificial heart indications

The SynCardia™ Total Artificial Heart is considered medically necessary when all the following criteria are met:

- There is imminent risk of death from biventricular failure with no other appropriate medical or surgical options
- Patient is waiting for a donor heart or is being evaluated for a donor heart
- Patient has structural abnormalities related to congenital heart disease (CHD) precluding the use of VAD. (Optum MCSD Expert Panel, 2021; Thangappan et al., 2020)
- Intractable ventricular arrythmias including, but not limited to, arrythmias which fail to terminate after appropriate AICD therapy or catheter ablation and polymorphic arrythmias not amenable to catheter ablation. (Optum MCSD Expert Panel, 2021; Santangeli et al., 2017)
- Patient is not a candidate for LVAD or BiVAD
- Patient has adequate space in the chest area vacated by the natural ventricles (general body surface areas > 1.7m2 for the 70cc device or ≤ 1.85 for the 50cc device as measured by computed tomography (CT) imaging

Adult MCSD indications

Left ventricular assist devices (LVADs) are covered if they are FDA-approved as a durable[1] mechanical circulatory support device (MCSD) support for heart failure patients who meet the following criteria:

(A) Have New York Heart Association (NYHA) Class III – IV heart failure

AND

(B) Have a left ventricular ejection fraction (LVEF) ≤ 25%;

AND

Either C or D1 or D2 as follows:

(C) Are inotrope dependent

OR

(D1) Have a cardiac index (CI) < 2.2 L/min/m2, while not on inotropes AND are on goal-directed medical therapy (GDMT) for at least 45/60 days and are failing to respond

OR

(D2) Have a cardiac index (CI) < 2.2 L/min/m2, while not on inotropes AND have advanced heart failure for at least 14 days and are dependent on a non-durable[2] MCSD device [intra-aortic balloon pump (IABP), Impella, etc.] for at least 7 days

AND

For those centers without a heart transplant program:

- Are permanently or temporarily ineligible for heart transplant due to at least one of the following reasons (Mehra et al., 2016):
  - Diabetes with end-organ damage or persistent poor glycemic control (glycosylated hemoglobin [HbA1c] > 7.5% or 58 mmol/mol), despite optimal management
  - Irreversible renal dysfunction (eGRF < 30ml/min/1.73 m^2)
  - Irreversible severe pulmonary disease with FEV1 < 1 L or FVC < 50%
  - Irreversible hepatic dysfunction
  - Clinically severe symptomatic cerebrovascular disease or significant peripheral vascular disease not correctable with surgery
  - Active tobacco smoking during the previous 6 months
  - Age > 70 years
  - BMI > 35 kg/m^2
  - Social and psychiatric issues that can have significant impact on the outcomes of a transplant
  - Patient chooses not to have a heart transplant
  - Lack of organ availability

Typically, durable devices are implantable systems (intracorporeal) used long term for months to years. These patients are able to be discharged from the hospital. Acute (short-term non-durable) support devices, are located outside the body (extracorporeal or paracorporeal), are used temporarily for days to weeks, and require the patient to remain in the hospital (Aaronson & Pagani, 2022; Bernhardt et al., 2023).

[1] Durable >/= 30 days.
[2] Non-durable </= 30 days.

Adolescent MCSD indications

The HeartMate 3™ LVAD is considered medically necessary in adolescent (ages 13–21 years) patients for short- and long-term support when the following criteria are met:

- Decompensated heart failure unresponsive to oral medical management
- Inability to wean off inotropic support or escalating support
- Evidence of end-organ dysfunction, evident by one or more of the following:
  - Liver dysfunction, evident by rising transaminases or bilirubin
  - Evidence of renal insufficiency, evident by creatinine 2x normal
  - Respiratory insufficiency, evident by need for positive pressure ventilation of any type
  - Poor nutritional status requiring tube feeding or TPN or combination of both

OR

- Concern for impending end-organ dysfunction deemed reversible based on multidisciplinary assessment
- As a bridge to transplant in heart failure secondary to congenital heart disease

Device exchange

Device exchange in patients presenting with pump thrombosis is medically necessary. Presenting signs/symptoms of pump thrombosis include, but may not be limited to (Goldstein et al., 2013)

- Power elevation
  - Sustained (> 24 hours) power elevations > 10 W **OR**
  - Sustained (> 24 hours) power increase > 2 W from baseline
- Isolated LDH rise
  - 3x upper limit of normal for your reference lab
- Evidence of hemolysis
  - Clinical diagnosis **OR**
  - LDH > 3x normal and pfHgb > 40
- New or worsening HF symptoms, with or without hemodynamic abnormalities including shock, with failed ramp test with no improvement after changing pump speeds
  - Failure to unload the LV on echocardiography with increased pump speeds

Device exchange from the HeartWare HVAD to Heartmate 3 may be considered medically necessary for any of the following indications:

- Pump thrombosis
- Device malfunction
- Persistent or relapsing infection
- Recurrent stroke that cannot be attributed to another cause, provided patient is an acceptable surgical risk (Optum Expert Panel, 2023)

There is insufficient evidence to support elective device exchange form HeartWare to HeartMate 3.

Minimum patient evaluation requirements

Documentation of all the following is required within the last 12 months:

- Patients with a history of significant psychiatric illness should undergo a psychiatric evaluation to identify potential risk factors or significant psychiatric barriers. A MCSD is not recommended in patients with active psychiatric illness that requires long-term institutionalization or who have the inability to care for or maintain their device. Psychiatric consultation and clearance are required with expectation that the patient has a favorable prognosis and can take care of themselves upon discharge. Examples of significant psychiatric barriers include, but are not limited to:
  - Inability to operate the MCS device pump or respond to device alarms
  - Inability to recognize and report signs and symptoms of physical compromise, device malfunction or other health care issues
- Optum expects programs will conduct a thorough psychosocial assessment and monitor receipt of and response to interventions for any problems identified. Psychosocial evaluation is an important component of the multidisciplinary assessment process to determine candidacy for long term MCSD implantation. While there is no consensus-based set of recommendations for the full range of domains to be evaluated or the process to be used to conduct the evaluation, a synthesis of expert opinion and a comprehensive literature review (ISHLT, APM, AST, ICCAC, and STSW, 2018) resulted in recommendations designed to promote consistency across programs. An assessment for poor post-implantation outcomes may include:
  - Treatment adherence and health behaviors
  - Substance use history
  - Cognitive status and knowledge of current illness and treatment options
  - Social support including availability, stability, and capacity of family and others to provide support
  - Social history including financial status and living arrangements
- NYHA functional class (See Appendix A)
- Chest radiograph with no active disease demonstrated
- Pulmonary function testing (PFT): If abnormal, pulmonary consultation and clearance is required.
  - FFVC ≥ 50%
  - FFEV1 ≥ 50%
  - DLCO (corrected) 40% for adults (≥ 50% for children). If abnormal, pulmonary consultation and clearance is required.
- Liver function tests (LFT): Evaluation in the setting of complex heart failure may make this complicated, however if there is concern for an underlying hepatic condition it should be evaluated by a specialist.
- Renal function: Accurate interpretations of changes in markers of kidney function is challenging in the setting of heart failure.
  - eGFR < 30 ml/min/1.73 m^2 requires nephrology clearance (Optum Expert Panel, 2023)
  - The following resource may aid on understanding the prognosis of chronic kidney disease (CKD) by GFR and albuminuria categories: MDRD GFR Equation — MDCalc
- All patients with congenital heart disease should have recent imaging to fully document cardiac morphology, assess for the presence of shunts or collateral vessels, and the location and course of their great vessels.
- All patients with known atherosclerotic vascular disease or significant risk factors for its development should be screened for peripheral vascular disease prior to mechanical circulatory support. If present, intervention and/or clearance are required.

- All patients being considered for mechanical circulatory support should have a carotid and vertebral Doppler examination as a screen for occult vascular disease.
- Patients with a history of coronary artery bypass grafting should have a chest computed tomography (CT) scan to provide the location and course of the bypass grafts to guide the surgical approach and to evaluate the degree of aortic calcification.
- Echocardiography or CT, with contrast when necessary, should be used pre-operatively to screen for intracardiac thrombus, intracardiac shunts and valvular heart disease.
- All patients being considered for mechanical circulatory support should have an invasive hemodynamic assessment of pulmonary vascular resistance, cardiac filling pressures and cardiac output.
- All patients with ischemic heart disease should have had a left heart catheterization.
- All patients should be screened for diabetes with a fasting glucose and hemoglobin A1C prior to mechanical circulatory support.
  - All patients with an abnormal fasting glucose or hemoglobin A1C should be assessed for the degree of end organ damage (retinopathy, neuropathy, nephropathy and vascular disease).

Contraindications

These are absolute contraindications for the implantation of a long-term or durable MCSD. These are based on the 2020 AATS/ISHLT Guidelines on Selected Topics in Mechanical Circulatory Support (Kirklin et al., 2020), unless otherwise noted.

Except as noted, authorization for the implantation of a MCSD will not be given if any of the following are present:

- Heart failure that can be reasonably expected to recover without MSCD (Khazanie and Rogers, 2011)
- Major comorbid illness that is anticipated to limit survival to < 2 years (Peura/AHA, 2012) such as:
  - An advanced malignancy
  - Severe and irreversible hepatic disease; i.e., cirrhosis not expected to improve with long-term MCSD support
  - Severe lung disease (including pulmonary arterial hypertension that is not related to chronic heart failure, not World Health Organization group II) [See Appendix B]
  - Severe neurological or neuromuscular disorder
- Acute valvular infective endocarditis with bacteremia
- Patients with cognitive impairment such that he or she is unable to comprehend and manage the VAD
- History of non-adherence with demonstrated inability to comply with medical recommendations on multiple occasions that has not been successfully remediated
- Active and uncontrolled alcohol and substance abuse-See Appendix E
- Neuromuscular disease that severely compromises the ability to use and care for external system components or to ambulate and exercise
- Current pregnancy

Special considerations

These may or may not represent contraindications to implantation of a MCSD and depend upon individual patient circumstance, the totality of the clinical presentation and results of a comprehensive evaluation. Unless otherwise noted, these are based on the 2020 AATS/ISHLT Guidelines on Selected Topics in Mechanical Circulatory Support (Kirklin et al., 2020).

- Previous history of heparin-induced thrombocytopenia (HIT). If this is present in the patient's history, confirmatory testing is required with hematology clearance.
- Patients with a history of malignancy require an oncology evaluation to determine status of disease.
- Past history (> 6 months in the past) of alcohol, crystal meth, heroin, cocaine, methadone, narcotics, etc., requires a recent evaluation documenting status of their condition and any ongoing treatment requirements.
- Malnutrition and debilitation. If evidence of malnutrition is present, a nutritional consultation is indicated and will be required prior to approval. Markers of severe malnutrition include:
  - BMI < 20 kg/m2
  - albumin < 3.2 mg/dl
  - pre-albumin < 15 mg/dl
  - total cholesterol < 130 mg/dl
  - lymphocyte count < 100
- Mechanical circulatory support may be contraindicated in the setting of diabetes-related proliferative retinopathy, very poor glycemic control, or severe nephropathy, vasculopathy or peripheral neuropathy.
- Coagulopathies (Peura, 2012):
  - INR ≥ 2.5 (in the absence of concurrent anticoagulation therapy)
  - Platelet count ≤ 50,000
  - Diagnosed coagulopathy including but not limited to Factor V Leiden
  - A history of intolerance to anticoagulation
- Carotid artery disease that could result in an adverse neurological event if left untreated (Khazanie and Rogers, 2011).
- Patients with active systemic and/or localized infection should not be considered until the infection is adequately treated.
- History of gastrointestinal (GI) bleeding or other known GI problem that would limit the ability to tolerate anticoagulation. Active peptic ulcer disease, active diverticulitis and known arteriovenous malformations (AVM) are examples.
- Candidates for short-term support are generally those considered appropriate for heart transplant but unlikely to survive the wait time to obtain an acceptable donor organ. In those patients, the following circumstances can be taken into consideration:
  - Body habitus
  - SRTR reported time to transplant for waitlist patients
  - PRA
  - UNOS region
  - Blood group "O"

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Appendixes

Appendix A: New York Heart Association Classification of Heart Failure

NYHA class	Symptoms
I	Patients with cardiac disease but resulting in no limitation of physical activity. Ordinary physical activity does not cause undue fatigue, palpitation, dyspnea or anginal pain.
II	Patients with cardiac disease resulting in slight limitation of physical activity. They are comfortable at rest. Ordinary physical activity results in fatigue, palpitation, dyspnea or anginal pain.
III	Patients with cardiac disease resulting in marked limitation of physical activity. They are comfortable at rest. Less than ordinary activity causes fatigue, palpitation, dyspnea or anginal pain.
IV	Patients with cardiac disease resulting in inability to carry on any physical activity without discomfort. Symptoms of heart failure or the anginal syndrome may be present even at rest. If any physical activity is undertaken, discomfort increases.

Classes of Heart Failure | American Heart Association

Appendix B: World Health Organization (WHO) Classification of Pulmonary Hypertension (PH)

WHO group	Group descriptor
I	Pulmonary arterial hypertension
II	PH from left-sided heart disease
III	PH from chronic hypoxic lung disease including obstructive lung disease (COPD, emphysema), restrictive lung disease (interstitial lung disease or pulmonary fibrosis), sleep apnea, or living in an area of high altitude for a long period of time
IV	PH from chronic thromboembolic pulmonary hypertension (CTEPH)
V	PH due to unknown causes

Types of Pulmonary Hypertension: The WHO Groups — Pulmonary Hypertension Association (phassociation.org)

Appendix C: Minimal pre-operative optimization goals

Pre-operative optimization is directed toward minimizing the frequency and severity of adverse events following implantation of mechanical circulatory support devices. Results of a complete systematic assessment should be considered during the review process. These parameter values should be used as a guide during the review process.

Renal	Desired value
Blood urea nitrogen	< 40 mg/dl
Serum creatinine	< 2.5 mg/dl
Estimated GFR[3]	> 50 ml/kg/min

Hematology	Desired value
INR[4]	< 1.2
Hemoglobin	> 10 g/dl
Platelets	> 150,000/mm

Nutritional	Desired value
Pre-albumin	> 15 mg/dl
Albumin	> 3 g/dl
Transferrin	> 50 ml/kg/min

Hepatic	Desired value
Total bilirubin	< 2.5 mg/dL
ALT[5], AST[6]	< 2 times normal

Hemodynamic	Desired value
Right atrial pressure	< 15 mm Hg
PCWP[7]	< 24 mm Hg

[3] GFR = glomerular filtration rate.
[4] INR = international normalized ratio.
[5] ALT= alanine aminotransferase.
[6] AST= aspartate aminotransferase.
[7] PCWP = pulmonary capillary wedge pressure.

Appendix D: INTERMACS clinical profiles

Level	Description	Hemodynamic status	Time frame for intervention
1	Critical cardiogenic shock, "*crash and burn*"	Persistent hypotension despite rapidly escalating inotropic support and eventually IABP, and critical organ hypoperfusion	Within hours
2	Progressive decline on inotropic support, "*sliding on inotropes*"	Intravenous inotropic support with acceptable values of blood pressure and continuing deterioration in nutrition, renal function or fluid retention	Within days
3	Stable but inotrope dependent, "dependent stability"	Stability reached with mild to moderate doses of inotropes but demonstrating failure to wean from them because of hypotension, worsening symptoms, or progressive renal dysfunction	Elective over weeks to months
4	Resting symptoms, "*frequent flier*"	Possible weaning of inotropes but experiencing recurrent relapses, usually fluid retention	Elective over weeks to months
5	Exertion intolerant, housebound	Severe limited tolerance for activity, comfortable at rest with some volume overload and often with some renal dysfunction	Variable urgency, dependent on nutrition and organ function
6	Exertion limited, "*walking wounded*"	Less severe limited tolerance for activity and lack of volume overload, fatigue easily	Variable urgency, dependent on nutrition and organ function
7	Advanced NYHA III "symptoms, placeholder"	Patient without current or recent unstable fluid balance, NYHA class II or III	Not currently indicated

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Appendix E: Alcohol and substance abuse

- Alcohol dependency and substance abuse
  - Active alcohol dependency and/or substance abuse requires 6 months of documented abstinence through participation in a structured alcohol/substance abuse program with regular meeting attendance and negative random drug testing. Active alcohol and substance abuse is defined as the consumption of alcohol in someone with a prior history of active alcohol dependency or the use of any illicit substance at any time in the 6 months prior to the request for transplant. EXCEPTIONS:
- Catastrophic decompensation/critical time limitation:
  - Objective failure of therapy for severe acute alcoholic hepatitis.
  - Critical decompensation in cirrhotic patients as judged by MELD score predicting mortality prior to completion of required abstinence program.
  - Critical decompensation in heart or lung patients as judged by UNOS status or LAS score predicting mortality prior to completion of required abstinence program.
  - Special circumstances (directed donor, limited availability of a living donor, etc.) in kidney patients who have been adherent but have not yet completed the full abstinence program may be considered before completion of required abstinence program.
- Requires:
  - Appropriate patient and psychosocial support profile
    - Presence of close supportive social network
    - Absence of severe coexisting diseases or severe psychiatric disorders
    - Agreement by patient (with support of his social network) to post-transplant rehab and monitoring, and to lifelong alcohol/cigarette abstinence
  - Evaluation by addiction specialist indicating high likelihood of success of post-transplant rehab and abstinence
  - Approval by a medical review board that includes beside the regular members, a psychiatrist, addiction specialist and an ethicist
  - No special consideration for acute decompensation with illicit drug addiction and/or abuse
  - Inactive alcohol and/or substance abuse (alcohol, crystal meth, heroin, cocaine, methadone, and/or narcotics, etc.)
  - More than 6 months' but less than 2 years' abstinence
  - Requires program documentation of surveillance including but not limited to drug testing, chemical dependency/substance abuse evaluation and evaluation of hepatitis exposure
  - Evaluation by addiction specialist indicating high likelihood of abstinence
  - More than 2 years' abstinence
  - Evaluation by a substance abuse specialist (MD, PsyD, PhD or equivalent credential) may be considered

Recreational or medicinal use of marijuana is not a contraindication unless stated as an exclusion by the requesting provider.

Review and approval history

Version	Date of annual review
1.0	**09/05/2013:** New guideline. Approved by Medical Technology Assessment Committee
1.0	**09/12/2013**: Approved by National Medical Care Management Committee
1.0	**01/01/2014:** Effective date of new guideline
2.0	**12/04/2014:** Annual Review. Approved by Medical Technology Assessment Committee
2.0	**12/09/2014:** Annual Review. Approved by the National Medical Care Management Committee
3.0	**11/05/2015:** Annual Review. Approved by Medical Technology Assessment Committee
4.0	**11/03/2016:** Annual Review. Approved by Medical Technology Assessment Committee
4.0	**11/08/2016:** Annual Review. National Medical Care Management Committee requested coverage statement concerning device exchange due to pump thrombosis
4.0	**12/1/2016:** Updated content specific to device exchange approved by Medical Technology Assessment Committee.
5.0	**12/13/2016:** National Medical Care Management Committee meeting cancelled due to lack of quorum. Guideline will be presented in January 2017.
5.0	**01/10/2017:** Updated content specific to device exchange approved by National Medical Care Management Committee.
6.0	**12/6/2017:** Annual review. Optum VAD Scientific Advisory Board and Expert Panel; no recommended changes.
6.0	**12/14/2017:** Optum Policy and Guideline Committee advised guideline will be renewed without changes.
6.0	**01/04/2018:** Medical Technology Assessment Committee advised guideline will be renewed without changes.
7.0	**1/10/19:** Annual Review. Approved by Medical Technology Assessment Committee.
7.0	**2/27/19:** Annual Review. Approved by National Medical Care Management Committee.
8.0	**1/15/20:** Optum Thoracic Solid Organ Transplantation and Mechanical Circulatory Support Devices Expert Panel annual review.
8.0	**3/19/20:** Annual Review. Approved by Medical Technology Assessment Committee.

8.0	**12/17/2020:** Interim Review. Medical necessity criteria for total artificial heart added; investigational statement added for use of permanently implantable aortic counterpulsation ventricular assist systems. Approved by Medical Technology Assessment Committee.
9.0	**2/10/2021:** Annual Review. Approved by Medical Technology Assessment Committee.
9.0	**5/6/2021:** Interim revision to MCSD indications to describe characteristics of patients who may be temporarily or permanently ineligible for heart transplant. Approved by Medical Technology Assessment Committee.
10.0	**5/5/2022:** Annual Review. Adolescent MCSD criteria added. Approved by Medical Technology Assessment Committee.
10.0	**1/11/2023:** Interim update to address indications for device exchange from HeartWare to HeartMate 3. Added hyperlinks for verification of facilities with ventricular assist device advanced certification. Approved by Optum Clinical Guideline Advisory Committee.
11.0	**3/1/2023:** Optum Thoracic Solid Organ Transplantation and Mechanical Circulatory Support Devices Expert Panel annual review.
11.0	**4/12/2023:** Annual review. Updated adult implantation indications, added recurrent stroke to indications for HeartWare device exchange, and added evaluation of renal function to minimum evaluation requirements. Approved by Optum Clinical Guideline Advisory Committee. Guideline effective date: May 12, 2023.
11.0	**5/4/2023:** Annual Review. Approved by Medical Technology Assessment Committee.
11.0	**9/13/2023:** Approved by Medicare Advantage Policy and Technology Assessment Committee (total artificial heart content only).