



# Mechanical Circulatory Support Devices

Clinical Guideline

Effective April 1, 2020

## Table of Contents

<b>Instructions for Use .....</b>	<b><u>3</u></b>
<b>Benefit Considerations.....</b>	<b><u>3</u></b>
<b>General Information.....</b>	<b><u>3</u></b>
<b>Glossary of Terms.....</b>	<b><u>4</u></b>
<b>Background .....</b>	<b><u>5</u></b>
<b>Indications .....</b>	<b><u>6</u></b>
<b>Minimum Patient Evaluation Requirements.....</b>	<b><u>8</u></b>
<b>Contraindications.....</b>	<b><u>9</u></b>
<b>Special Considerations .....</b>	<b><u>10</u></b>
<b>Appendices.....</b>	<b><u>13</u></b>
Appendix A New York Heart Association Classification of Heart Failure .....	<u>13</u>
Appendix B World Health Organization Classification of Pulmonary Hypertension .....	<u>14</u>
Appendix C AIDS-defining Conditions .....	<u>15</u>
Appendix D Minimal Pre-operative Optimization Goals.....	<u>16</u>
Appendix E INTERMACS Clinical Profiles.....	<u>17</u>
Appendix F Alcohol and Substance Abuse.....	<u>18</u>
<b>References.....</b>	<b><u>20</u></b>

## **INSTRUCTIONS FOR USE**

*This Clinical Guideline provides assistance 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 does not apply. The National Coverage Determination must be followed. (CMS) Publication 100-03 National Coverage Determination (NCD) for ARTIFICIAL HEARTs and Related Devices (20.9), Published December 8, 2010. Available at: <http://www.cms.gov/medicare-coverage-database/>

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 covered. 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 describes the indications, minimum evaluation requirements, contraindications, and special considerations for the use of long-term, durable mechanical circulatory support devices (MCSD). In addition, there are appendices with important supplemental information useful when applying the directions contained within this guideline and the references used in constructing the guideline.

This guideline applies to MCSD use in adults and adolescent children whether in a pediatric or adult setting. 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 covered 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 is the 70 cc SynCardia Total Artificial Heart®
- The following MCSDs for use in adults when used in accordance with the FDA approved indications: Thoratec HeartMate II®, Thoratec HeartMate 3™ Left Ventricular Assist Device, Thoratec PVAD™, Thoratec® IVAD™ and HeartWare® Ventricular Assist system.
- Other permanently implantable MCSDs intended for use in adults subject to the benefit within the coverage document.
- Devices including but not limited to the HeartWare HVAD® Pump for destination therapy and the Total Artificial Heart (70 cc and 50 cc) when implanted under a qualifying clinical trial in accordance with the provisions of the member's benefit plan and/or the Affordable Care Act.

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

- All non-permanent cardiac assist devices including but not limited to:
  - Intra-Aortic Balloon Pump (IABP)
  - Impella 2.5
  - Impella 5.0
  - Impella CP
  - CentriMag
  - Tandem Heart
  - Circulite
  - Other temporary circulatory support devices
- Pediatric MCSDs
- The AbioCor Implantable Replacement Heart, although approved by the FDA in 2006, is no longer being manufactured. (United Healthcare Medical Policy Number: 2018T0384R, TOTAL ARTIFICIAL HEART, Effective Date: November 1, 2018)
- Automatic Intracardiac Defibrillators (AICD), with or without synchronous pacemaker
- Pacemakers of any description

## **GLOSSARY OF TERMS**

**BTT:** BTT refers to Bridge to Transplant. Patients so designated have been fully evaluated for transplant, have been found to be suitable candidates for transplant, have met all of the Indications for MCSD contained within the Guideline and have been placed on the UNOS list as active candidates. See UNOS Listing.

**DT:** DT refers to Destination Therapy. Patients so designated have been fully evaluated for transplant and are not transplant candidates for whatever reason but meet all of the other Indications for MCSD contained within this Guideline

**BTD:** BTD refers to Bridge to Decision and Bridge to Candidacy (BTC). Patients so designated have been fully evaluated for transplant. These patients may not be transplant candidates for any reason but could be a transplant candidate in the future following remediation of a disqualifying condition. Patients in this category meet all of the other Indications for MCSD contained within this Guideline. These patients will be

categorized as DT in the future if the underlying condition that prevents listing for heart transplant cannot be remediated. These patients will be listed with UNOS by the programs as Status 7. Medicare does not recognize this category.

**MCS D:** MCS D as specifically used in this Guideline refers to a mechanical circulatory support device that is intended for non-temporary use. Examples of such devices are listed in the section labeled Devices in Scope. Terms frequently used to describe a MCS D include VAD, LVAD, TAH, RVAD, IVAD and PVAD (when used to describe the Thoratec PVAD, not a peripheral, non-permanent assist device such as those listed above).

**Indication:** All criteria that must be met to document that the implantation of a MCS D is medically necessary.

**Contraindication:** A contraindication is a circumstance or condition that, when present, is sufficient reason to conclude that the use of a MCS D is not medically indicated because it is not safe and effective. Alternative therapy must be considered.

**Designated Facility:** A designated facility has entered into an agreement with us, 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 the member's geographic area. The fact that a Hospital is a network hospital does not mean that it is a designated facility.

**Special Consideration:** A special consideration is a circumstance or condition that by itself is not necessarily a Contraindication to the implantation of a MCS D. Special considerations are frequently referred to as relative contraindications. When a special consideration is found, additional information must be provided that, when taken into account, may indicate that it is both safe and advisable to proceed with MCS D implantation. Frequently, when a special consideration exists, a subspecialty consultation will be required to assess the safety and medical appropriateness of MCS D implantation.

**Minimum Patient Evaluation Requirements:** These tests are required prior to approval of MCS D implantation. Certain outcome parameters or "flags" are included in the descriptions of Minimum Patient Evaluation Requirements. If these "flags" are uncovered, additional information must be provided in the form of an explanation by the requesting physician. We may require that this explanation include a consultation by the appropriate sub-specialty consultant with clearance by the consultant.

**United Network for Organ Sharing (UNOS) Listing:** A patient will be considered to be actively listed when listed with UNOS as Status 1, 2, 3, 4, 5, or 6. Active listing is not a requirement for the application of this Guideline. As transplant candidacy frequently is not known until after a period of months following implantation, Optum will allow Bridge to Decision.

## **BACKGROUND**

Heart failure (HF) is a complex clinical condition in which the heart fails to adequately pump blood. According to the American College of Cardiology (ACC) and the American Heart Association (AHA), "heart failure is a complex clinical syndrome that can result from any structural or functional cardiac disorder that impairs the ability of the ventricle to fill with or eject blood. It is defined as a clinical syndrome that is characterized by specific symptoms (dyspnea and fatigue) in the medical history and signs (edema, rales) on the physical examination. There is no single diagnostic test for HF because it is largely a clinical diagnosis. Heart failure can be a progressive disease with increasing symptoms over time despite optimal medical management (OMM), though the time course is difficult to predict (Schiller et al). Eventually, the heart fails completely and can no longer pump enough blood to sustain life. At this end-stage, eligible patients can undergo heart transplant; however, only around 2,000 heart transplants are performed annually in the United States (HRSA, 2012). In addition, older patients are often not eligible for heart transplant due to comorbid conditions which greatly increase the risk of poor outcomes.

Mechanical circulatory support devices (MCSD), also referred to as ventricular assist devices (VAD), are mechanical blood pumps that are surgically attached to one or both intact ventricles of a damaged or weakened native heart to assist in pumping blood. For durable long-term devices, the pump is implanted in the abdomen or chest allowing patient mobility and hospital discharge. All devices require a driveline that goes from the pump to an external power source and control unit. Patients with heart failure who may be candidates for MCSD implantation undergo extensive clinical evaluation to ensure an adequate severity of heart failure but acceptable severity of comorbidities. The evaluation seeks to balance the benefits that might be achieved by MCSD implantation with the significant risks of the surgery itself as well as prolonged device support. Durable, long-term devices were initially used in patients on the heart transplant waitlist as a "bridge to transplant (BTT)" since the duration of support was intended to be finite. With donor hearts for transplant in limited supply and additional clinical experience in managing HF, devices were subsequently implanted as "destination therapy (DT)" in patients ineligible for heart transplant who required permanent support. Patients who are neither BTT nor DT are referred to as bridge to decision (BTD). This indication provides opportunity for remediation of reversible conditions which may be hindering transplant eligibility. The use of MCSDs has continued to evolve. The purpose of this guideline is to identify the characteristics of those patients most likely to benefit from the use of mechanical circulatory support.

## **INDICATIONS**

Indications addressed in this guideline include bridge-to-decision (BTD), bridge-to-transplant (BTT) and destination therapy (DT).

Transplant evaluation is required for all members being considered for non-temporary mechanical circulatory support. The transplant evaluation 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.

MCSD implantation 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.

### **All Criteria Must Be Met:**

- Patient has symptoms consistent with New York Heart Association class IV functional limitations. Use of MSCD in patients with less advanced symptoms (NYHA functional class I-III) is not supported by the clinical evidence. (Khazanie and Rogers, 2011)
- The patient has been evaluated for heart transplant at a Medicare-approved heart transplant program (ISHLT, 2013). The following additional criteria must be met:
  - The evaluating heart transplant program must be a Designated Facility **AND**
  - There is documentation that a decision has been reached regarding the patient's candidacy for heart transplant **AND**
  - A recommendation to implant a MCSD is made by the Patient Selection Committee as part of the Committee's recommendation **AND**
  - If found to be a heart transplant candidate, the patient must be listed with UNOS at a Designated Facility.
- Patient has an anticipated survival benefit (Joint Commission 2013, Canadian Heart Failure Guideline/Arnold et al., Heart Failure Society of America)

- Left ventricular ejection fraction (LVEF) is <25% (ACCF and AHA/Yancy et al.) [See SPECIAL CONSIDERATIONS]
- Long-term MCS/D for patients who are in acute cardiogenic shock should be reserved for the following: Refer to Medical Director.
  - Patients who are deemed too ill to maintain normal hemodynamics and vital organ function with temporary MCS/Ds, or who cannot be weaned from temporary MCS/Ds or inotropic support.
  - Patients whose ventricular function is deemed unrecoverable or unlikely to recover without long-term device support.
  - Patients with the capacity for meaningful recovery of end-organ function and quality of life.
  - Patients without irreversible end-organ damage.
- Functional limitation with a peak exercise oxygen consumption of <14 ml/kg/min in those patients who can safely exercise.
- Documented failure of optimal medical management (OMM) (ISHLT/Feldman et al.). ACCF/AHA refers to OMM as guideline-directed medical therapy (GDMT). OMM/GDMT includes:
  - Beta blocker **AND** Angiotensin-converting enzyme inhibitor (ACEI) or Angiotensin-receptor blocker (ARB) or Sacubitril/Valsartan (Entresto™).
  - Loop diuretics (bumetanide, furosemide and torsemide) for volume overload; Thiazide diuretics for hypertensive HF patients.
  - Hydralazine-Nitrates for persistently symptomatic African Americans.
  - Aldosterone Receptor Antagonists for patients with ejection fraction <35%.
- For Destination Therapy (Jacques)
  - Failure of OMM as documented above, **OR**
  - Patient has been balloon pump-dependent for 7 days, **OR**
  - IV inotrope-dependent for 14 days.
- For Bridge to Transplant or Bridge to Decision for patients listed with UNOS regardless of list listing status, **ONE** of the following is required:
  - Failure of management with intravenous inotropic agents to maintain systemic perfusion and preserve end-organ performance. These agents include adrenergic agonists (dopamine and dobutamine) and/or PDE inhibitor (milrinone). Failure of management with intravenous inotropes is indicated by **ONE** of the following:
    - On continuous intravenous inotropes with an initial favorable response but now showing signs of end-stage organ damage as measured by new onset decreased renal, hepatic, neurological function, etc. **OR**

- On continuous intravenous inotropes with no hemodynamic response as demonstrated by no improvement in end-organ function and functional capacity
  - Anticipated long wait time to obtain an acceptable donor heart. Circumstances that can be taken into consideration include the following:
    - Body habitus
    - PRA
    - UNOS region
    - Blood group “O”
    - SRTR reported time to transplant for waitlist patients
- Device exchange in patients presenting with pump thrombosis is covered. 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

### **MINIMUM PATIENT EVALUATION REQUIREMENTS**

Documentation of all of the following is required:

- NYHA functional class (See Appendix A)
- Complete psychosocial evaluation with documented clearance
- Patients with a history of significant psychiatric illness should undergo a psychiatric evaluation to identify potential risk factors or significant psychiatric barriers. Clearance must be documented by the evaluating psychiatrist. 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
- Chest radiograph with no active disease demonstrated
- Pulmonary function testing (PFT): If abnormal, pulmonary consultation and clearance is required.
  - FFVC  $\geq$  50%
  - FFEV1  $\geq$  50%



- DLCO (corrected) 40% for adults ( $\geq 50\%$  for children). If abnormal, pulmonary consultation and clearance is required.
- Liver function tests (LFT): If abnormal, hepatology consultation and clearance is required. An elevated MELD score may result in the patient being ineligible to be considered for a MCS.
  - Transaminases  $\geq 2$  x upper limit of normal
  - Total bilirubin  $\geq 2.5$ mg/dL
  - Calculated MELD score
- 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 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 MCS. THESE ARE BASED ON THE 2013 ISHLT GUIDELINES FOR MECHANICAL CIRCULATORY SUPPORT, UNLESS OTHERWISE NOTED.**

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

- AIDS-Defining Conditions (See APPENDIX C for a list of these conditions)
- Heart failure that can be reasonably expected to recover without MCS. (Khazanie and Rogers, 2011)
- Active malignancy and a life expectancy of  $< 2$  years

- 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 MCS 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
- Active systemic infection (Slaughter et al., 2010)
- Acute valvular infective endocarditis with bacteremia
- Impaired cognitive function or other issues that could prevent or reduce ability to function (AHA/Peura). See SPECIAL CONSIDERATIONS section for detailed information.
- History of non-adherence with demonstrated inability to comply with medical recommendations on multiple occasions that has not been successfully remediated.
- Alcohol and substance abuse-See Appendix F
- 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 MCS AND DEPEND UPON INDIVIDUAL PATIENT CIRCUMSTANCE, THE TOTALITY OF THE CLINICAL PRESENTATION AND RESULTS OF A COMPREHENSIVE EVALUATION. THESE ARE BASED ON THE 2013 ISHLT GUIDELINES FOR MECHANICAL CIRCULATORY SUPPORT, UNLESS OTHERWISE NOTED.**

- Patients with a significant history of significant psychiatric illness should undergo psychiatric or psychological evaluation of potential risk factors for chronic impairment. Examples of significant psychiatric or psychosocial barriers include patients who:
  - Are unable to physically operate their pump or respond to device alarms
  - Are hindered or unable to report signs and symptoms of device malfunction or other health care issues.
- Impaired cognitive function or other issues that could prevent or reduce ability to function (Peura/AHA, 2012).
- Challenging housing and social issues. All of these are barriers to success with a MCS. The assessment of these barriers does not require an on-site visit by a social worker. A thorough psychosocial assessment is sufficient as long as it addresses all of these areas and a reasonable effort is made to document and remediate deficiencies. Documented deficiencies in any of the areas listed below that have not been remediated are Contraindications to the implantation of a permanent MCS:

- Lack of dedicated and committed caregiver support for MCSD management. This person must accompany the patient to all visits, complete an assessment interview by trained personnel, attends all education sessions and agrees to a care contract.
- Inadequate financial resources for out-of-pocket expenses such as travel, dressing supplies, and temporary housing prior to MCSD
- Unsafe living environment
  - A safe living environment requires:
    - Patient's physical surroundings provide adequate shelter
    - Grounded electrical outlets are available
    - Access to phone
    - Clean and clutter free environment
    - Environmental accessibility to patient, support network and emergency services personnel
- MCSD implantation in patients who have been bacteremic should have documented clearance of the bacteremia for at least 5 days on appropriate anti-microbial therapy. The anti-microbial therapy should include a total duration of at least 7 total days prior to MCSD implantation. Infectious Disease clearance is required. (ISHLT, 2013).
- Previous history of Heparin-induced thrombocytopenia (HIT). If this is present in the patient's history, confirmatory testing is required with hematology clearance.
- 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 is required with expectation that the patient has a favorable prognosis and can take care of themselves upon discharge.
- History of malignancy:
  - Patients with a history of a treated cancer in long-term remission or are considered free of disease may be a candidate for BTT, with the involvement of an oncologist to determine risk of recurrence or progression. Oncology clearance is required.
  - Patients with a history of recently treated or active cancer who have a reasonable life-expectancy (> 2 years) may be candidates for DT if evaluated in conjunction with an oncologist to determine risk and prognosis. Oncology clearance is required.
  - Patients with a history of a treated cancer in long-term remission or are considered free of disease may be a candidate for BTT, with the involvement of an oncologist to determine risk of recurrence or progression. Oncology clearance is required.
  - Patients with a history of recently treated or active cancer who have a reasonable life-expectancy (> 2 years) may be candidates for DT if evaluated in conjunction with an oncologist to determine risk and prognosis. Oncology clearance is required.
- Past history (> 6 months in the past) of alcohol, crystal meth, heroin, cocaine, methadone, narcotics, etc., requires program documentation of surveillance including but not limited to drug testing, chemical dependency/substance abuse evaluation and evaluation of hepatitis exposure. The patient should be evaluated for substance abuse. Refer to the specialist evaluation for guidance.

- 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 (Slaughter et al., 2010):
  - BMI < 20 kg/m<sup>2</sup>
  - albumin < 3.2 mg/dl
  - pre-albumin < 15 mg/dl
  - total cholesterol < 130 mg/dl
  - lymphocyte count < 100
- Chronic renal failure (modified from Eason). Nephrology clearance is required.
  - CKD with GFR ≤ 50 ml/min
  - Patients with acute renal insufficiency and dialysis ≥ 8 weeks
  - Evidence of CDK and kidney biopsy demonstrating > 30% glomerulosclerosis or 30% fibrosis
- Patients over age 80. Refer to Medical Director.
- Permanent dialysis for BTT candidates. Transplant center must have on-site dialysis unit or have made arrangements in advance with an outpatient dialysis unit that is capable of managing the patient while waiting for transplant.
- 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. Refer to Medical Director.
- Coagulopathies (AHA/Peura):
  - 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)
- 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.
- Permanent dialysis when the indication is DT.

## Appendix A

### New York Heart Association Classification of Heart Failure

Doctors usually classify patients' heart failure according to the severity of their symptoms. The table below describes the most commonly used classification system, the New York Heart Association (NYHA) Functional Classification. It places patients in one of four categories based on how much they are limited during physical activity.

<b>NYHA Class</b>	<b>Symptoms</b>
<b>I</b>	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.
<b>II</b>	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.
<b>III</b>	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.
<b>IV</b>	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.

[http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/Classes-of-Heart-Failure\\_UCM\\_306328\\_Article.jsp](http://www.heart.org/HEARTORG/Conditions/HeartFailure/AboutHeartFailure/Classes-of-Heart-Failure_UCM_306328_Article.jsp) Accessed October 18, 2016.

Appendix B

World Health Organization (WHO) Classification of Pulmonary Hypertension (PH) (Simonneau et al.)

<b>WHO group</b>	<b>Group Descriptor</b>
<b>I</b>	Pulmonary veno-occlusive disease (PVOD) and/or pulmonary capillary hemangiomatosis (PCH)
<b>II</b>	Pulmonary hypertension owing to left heart disease
<b>III</b>	PH owing to lung disease and/or hypoxia
<b>IV</b>	Chronic thromboembolic PH
<b>V</b>	PH with unclear or multifactorial etiologies

## Appendix C

### AIDS-Defining Conditions

Certain serious and life-threatening diseases that occur in HIV-positive people are called "AIDS-defining" conditions. When a person gets one of these illnesses, he or she is diagnosed with the advanced stage of HIV infection known as AIDS.

The Centers for Disease Control and Prevention (CDC) has developed a list of these conditions (see below). No single patient is likely to have all of these problems. Some of the conditions are rare.

- Bacterial infections, multiple or recurrent\*
- Candidiasis of bronchi, trachea, or lungs
- Candidiasis of esophagus†
- Cervical cancer, invasive§
- Coccidioidomycosis, disseminated or extra pulmonary
- Cryptococcosis, extrapulmonary
- Cryptosporidiosis, chronic intestinal (>1 month's duration)
- Cytomegalovirus disease (other than liver, spleen, or nodes), onset at age >1 month
- Cytomegalovirus retinitis (with loss of vision)†
- Encephalopathy, HIV related
- Herpes simplex: chronic ulcers (>1 month's duration) or bronchitis, pneumonitis, or esophagitis (onset at age >1 month)
- Histoplasmosis, disseminated or extra pulmonary
- Isosporiasis, chronic intestinal (>1 month's duration)
- Kaposi sarcoma†
- Lymphoid interstitial pneumonia or pulmonary lymphoid hyperplasia complex\*†
- Lymphoma, Burkitt (or equivalent term)
- Lymphoma, immunoblastic (or equivalent term)
- Lymphoma, primary, of brain
- *Mycobacterium avium* complex or *Mycobacterium kansasii*, disseminated or extrapulmonary†
- *Mycobacterium tuberculosis* of any site, pulmonary,† § disseminated,† or extrapulmonary†
- *Mycobacterium*, other species or unidentified species, disseminated† or extrapulmonary†
- *Pneumocystis jiroveci* pneumonia†
- Pneumonia, recurrent†§
- Progressive multifocal leukoencephalopathy
- *Salmonella* septicemia, recurrent
- Toxoplasmosis of brain, onset at age
- Wasting syndrome attributed to HIV

\* Only among children aged <13 years. (CDC (1994) Revised classification system for human immunodeficiency virus infection in children less than 13 years of age. MMWR (1994) Vol. 43 No. RR-12)

† Condition that might be diagnosed presumptively.

§ Only among adults and adolescents aged >13 years. (CDC (1993) Revised classification system for HIV infection and expanded surveillance case definition for AIDS among adolescents and adults. MMWR (1992) Vol. 41 No. RR-17).

Appendix D

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. The following table lists pre-operative goals for relevant metabolic markers as suggested by Slaughter (2010). These parameter values should be used as a guide during the review process and when considering referral to the Medical Director.

**Minimal Pre-operative Optimization Goals**

<b>Renal</b>	<b>Desired Value</b>
Blood urea nitrogen	< 40 mg/dl
Serum creatinine	< 2.5 mg/dl
Estimated GFR	> 50 ml/kg/min

<b>Hematology</b>	<b>Desired Value</b>
INR	< 1.2
Hemoglobin	> 10 g/dl
Platelets	> 150,000/mm

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

<b>Hepatic</b>	<b>Desired Value</b>
Total bilirubin	< 2.5 mg/dL
ALT, AST	< 2 times normal

<b>Hemodynamic</b>	<b>Desired Value</b>
Right atrial pressure	< 15 mm Hg
PCWP	< 24 mm Hg

ALT= alanine aminotransferase; AST= aspartate aminotransferase; GFR = glomerular filtration rate; INR = international normalized ratio; PCWP = pulmonary capillary wedge pressure.



Appendix E

INTERMACS Clinical profiles (AHA/Peura)

Level	Description	Hemodynamic Status	Time Frame for Intervention
1	Critical cardiogenic shock, <i>"crash and burn"</i>	Persistent hypotension despite rapidly escalating inotropic support and eventually IABP, and critical organ hypoperfusion	Within hours
2	Progressive decline on inotropic support, <i>"sliding on inotropes"</i>	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, <i>"dependent stability"</i>	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, <i>"frequent flyer"</i>	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, <i>"walking wounded"</i>	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 <i>"symptoms, placeholder"</i>	Patient without current or recent unstable fluid balance, NYHA class II or III	Not currently indicated

## Appendix F

### Alcohol and Substance Abuse

- Alcohol dependency and substance abuse
  - Active alcohol dependency and/or substance abuse requires six 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 six months prior to the request for transplant. EXCEPTIONS:
- Catastrophic decompensation/critical time limitation:
  - Objective failure of therapy for severe acute alcoholic hepatitis. (Mathurin et al.) See Appendix for Lille protocol.
  - 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 six months but less than two 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 two 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.

## REFERENCES

AbioCor. Available at this link: <http://www.abiomed.com/products/heart-replacement/#/> Accessed August 6, 2013.

Afilado J, Mottillo S, Eisenberg MJ et al. Addition of frailty and disability to cardiac surgery risk scores identifies elderly patients at high risk of mortality or major morbidity. *Circ Cardiovasc Qual Outcomes*. 2012;5:222-28.

Arnold JM, Liu P, Demers C, Dorian P, Giannetti N, Haddad H, Heckman GA, Howlett JG, Ignaszewski A, Johnstone DE, Jong P, McKelvie RS, Moe GW, Parker JD, Rao V, Ross HJ, Sequeira EJ, Svendsen AM, Teo K, Tsuyuki RT, White M; Canadian Cardiovascular Society. Canadian Cardiovascular Society consensus conference recommendations on heart failure 2006: diagnosis and management. *Can J Cardiol*. 2006 Jan;22(1):23-45. Erratum in: *Can J Cardiol*. 2006 Mar 1;22(3):271.

Centers for Medicare and Medicaid Services (CMS) Publication 100-03 Medicare National Coverage Determination. Published December 8, 2010. Available at: <http://www.cms.hhs.gov>

Culver BH. How should the lower limit of the normal range be defined? *Respir Care*. 2012;57:136-145.

Eason, JD, et al. Proceedings of consensus conference on simultaneous liver/kidney transplantation (SLK). *American Journal of Transplant Review Guidelines Solid Organ and Stem Cell Transplantation Transplantation* 2008; 8:2243-2251.

The 2013 International Society for Heart and Lung Transplantation Guidelines for mechanical circulatory support: executive summary. Feldman D, Pamboukian SV, Teuteberg JJ, Birks E, Lietz K, Moore SA, Morgan JA, Arabia F, Bauman ME, Buchholz HW, Deng M, Dickstein ML, El-Banayosy A, Elliot T, Goldstein DJ, Grady KL, Jones K, Hryniewicz K, John R, Kaan A, Kusne S, Loebe M, Massicotte MP, Moazami N, Mohacsi P, Mooney M, Nelson T, Pagani F, Perry W, Potapov EV, Eduardo Rame J, Russell SD, Sorensen EN, Sun B, Strueber M, Mangi AA, Petty MG, Rogers J. *J Heart Lung Transplant*. 2013 Feb;32(2):157-87.

Freedom Driver. Available at this link: <http://www.syncardia.com/medical-professionals/freedom-portable-driver.html> Accessed August 6, 2013.

Gelow JM, Desai AS, Hochberg CP et al. Clinical predictors of hepatic fibrosis in chronic advanced heart failure. *Circ Heart Fail*. 2010;3:59-64.

Goldstein DJ, John R, Salerno C et al. Algorithm for the diagnosis and management of suspected pump thrombosis. *J Heart Lung Transplant*. 2013; 32:667-70.

Heart Failure Society of America, Lindenfeld J, Albert NM, Boehmer JP, Collins SP, Ezekowitz JA, Givertz MM, Katz SD, Klapholz M, Moser DK, Rogers JG, Starling RC, Stevenson WG, Tang WH, Teerlink JR, Walsh MN. HFSA 2010 Comprehensive Heart Failure Practice Guideline. *J Card Fail*. 2010 Jun;16(6):e1-194.

HeartWare. Available at this link: <http://www.heartware.com/clinicians> Accessed August 6, 2013.

Jacobs J, Cohen A, Ein-Mor E, Maaravi Y, Stessman J. Frailty, cognitive impairment and mortality among the oldest old. *The Journal of Nutrition, Health and Aging*. 2011 Oct;15(8):678-682.

Jacques LB, Syrek Jensen T, Schafer JH, Baldwin J, Ulrich JM. Decision memo for ventricular assist devices as destination therapy (CAG-00119R2). [Internet]. Center for Medicare and Medical Services. 2010 Nov 9 Accessed at: [http://www.cms.gov/mcd/view\\_decisionmemo.asp?id=243](http://www.cms.gov/mcd/view_decisionmemo.asp?id=243).

Joint Commission Requirements for Advance Certification in Ventricular Assist Device Destination Therapy. 2013 Joint Commission. Released May 13, 2013.

Khazanie P and Rogers JG. Patient selection for left ventricular assist devices. *Congestive Heart Failure* 2011;17(5):227-34.

Kirklin JK, Naftel DC, Pagani FD, Kormos RL, Stevenson L, Miller M, Young JB. Long-term mechanical circulatory support (destination therapy): on track to compete with heart transplantation? *J Thorac Cardiovasc Surg*. 2012 Sep; 144(3):584-603; discussion 597-8.

Makary et al. Frailty and Surgical Outcomes. *J Am Coll Surg*. 2010.01.028:902-08.

Peura JL, Colvin-Adams M, Francis GS, Grady KL, Hoffman TM, Jessup M, John R, Kiernan MS, Mitchell JE, O'Connell JB, Pagani FD, Petty M, Ravichandran P, Rogers JG, Semigran MJ, Toole JM; American Heart Association Heart Failure and Transplantation Committee of the Council on Clinical Cardiology; Council on Cardiopulmonary, Critical Care, Perioperative and Resuscitation; Council on Cardiovascular Disease in the Young; Council on Cardiovascular Nursing; Council on Cardiovascular Radiology and Intervention, and Council on Cardiovascular Surgery and Anesthesia. Recommendations for the use of mechanical circulatory support: device strategies and patient selection: a scientific statement from the American Heart Association. *Circulation*. 2012 Nov 27;126(22):2648-67.

Revised Surveillance Case Definitions for HIV Infection Among Adults, Adolescents, and Children Aged ,18 Months and for HIV Infection and AIDS Among children Aged 18 Months to <13 Years—United States, 2008. *Morbidity and Mortality Weekly Report*, December 5, 2008/57 (RR-10).

Schiller JS, Lucas JW, Peregoy JA. Summary health statistics for U.S. adults: National Health Interview Survey, 2011. *National Center for Health Statistics. Vital Health Stat* 10(256). 2012. Available at: [http://www.cdc.gov/nchs/data/series/sr\\_10/sr10\\_256.pdf](http://www.cdc.gov/nchs/data/series/sr_10/sr10_256.pdf). Accessed August 23, 2013.

Simonneau G, Robbins IM, Beghetti M, et al. Updated Clinical Classification of Pulmonary Hypertension. *J Am Coll Cardiol* 2009; 54: S43-54.

Slaughter MS, Pagani FD, Rogers JG et al. Clinical Management of Continuous-flow Left Ventricular Assist Devices in Advanced heart Failure. *J Heart Lung Transplant* 2010; 29:S1-S39.

Syncardia. Available at this link: <http://www.syncardia.com/medical-professionals/small-to-large-patients.html> . Accessed August 6, 2013.

Yancy CW, Bozkurt MJ, Butler J et al. 2013 ACCF/AHA Guideline for the Management of Heart Failure: A Report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines. *Circulation*. June 5, 2013. Reviewed June 28, 2013 at: <http://circ.ahajournals.org/content/early/2013/06/03/CIR.0b013e31829e8807.full.pdf+html>

Yang JA, Kato TS, Shulman BP, Takayama H, Farr M, Jorde UP, Mancini DM, NakaY, Schulze PC. Liver dysfunction as a predictor of outcomes in patients with advanced heart failure requiring ventricular assist device support: Use of the Model of End-stage Liver Disease (MELD) and MELD eXcluding INR (MELD-XI) scoring system. *J Heart Lung Transplant*. 2012 Jun;31(6):601-10. Doi:10.1016/j.healun.2012.02.027. Epub 2012 Mar 28.

**The following are approved changes incorporated into the revision numbers indicated below.**

<b>Revision</b>	<b>Date, Description of Change, and Name</b>
1.0	<b>09/05/2013:</b> New. Approved by Medical Technology Assessment Committee
1.0	<b>09/12/2013:</b> Approved by National Medical Care Management Committee
1.0	<b>01/01/2014:</b> Effective date of new guideline
2.0	<b>12/04/2014:</b> Annual Review. Approved by Medical Technology Assessment Committee
2.0	<b>12/09/2014:</b> Annual Review. Approved by the National Medical Care Management Committee
3.0	<b>11/05/2015:</b> Annual Review. Approved by Medical Technology Assessment Committee
3.0	<b>11/10/2015:</b> Annual Review. Approved by National Medical Care Management Committee
4.0	<b>11/03/2016:</b> Annual review. Approved by Medical Technology Assessment Committee
4.0	<b>11/08/2016:</b> Annual review. National Medical Care Management Committee requested coverage statement concerning device exchange due to pump thrombosis.
5.0	<b>12/1/2016:</b> Updated content specific to device exchange approved by Medical Technology Assessment Committee.
5.0	<b>12/13/2016:</b> National Medical Care Management Committee meeting cancelled due to lack of quorum. Guideline will be presented in January 2017.
5.0	<b>01/10/2017:</b> Updated content specific to device exchange approved by National Medical Care Management Committee.
6.0	<b>12/6/2017:</b> Annual review. Optum VAD Scientific Advisory Board and Expert Panel; no recommended changes.
6.0	<b>12/14/2017:</b> Optum Policy and Guideline Committee advised guideline will be renewed without changes.
6.0	<b>1/4/2018:</b> Medical Technology Assessment Committee advised guideline will be renewed without changes.
6.0	<b>1/9/2018:</b> National Medical Care Management Committee advised

	guideline will be renewed without changes.
6.0	<b>1/18/2018:</b> Optum Policy and Guideline Committee advised guideline will be renewed without changes.
7.0	<b>1/10/19:</b> Annual review. Approved by Medical Technology Assessment Committee.
7.0	<b>2/27/19:</b> Annual review. Approved by National Medical Care Management Committee.
8.0	<b>3/19/20:</b> Annual review by Medical Technology Assessment Committee.



[www.optum.com](http://www.optum.com)

11000 Optum Circle, Eden Prairie, MN 55344

Optum and the Optum logo are registered trademarks of Optum. All other brand or product names are trademarks or registered marks of their respective owner. Because we are continuously improving our products and services, Optum reserves the right to change specifications without prior notice. Optum is an equal opportunity employer.