Mechanical Circulatory Support Devices

Clinical Guideline

Effective April 1, 2021
# Table of Contents

**INSTRUCTIONS FOR USE** .................................................................................................................. 3

**BENEFIT CONSIDERATIONS** ............................................................................................................... 3

**GENERAL INFORMATION** .................................................................................................................. 3

**BACKGROUND** .................................................................................................................................. 4

**TOTAL ARTIFICIAL HEART INDICATIONS** ....................................................................................... 5

**MCSD INDICATIONS** .......................................................................................................................... 5

**MINIMUM PATIENT EVALUATION REQUIREMENTS** ........................................................................ 6

**CONTRAINDICATIONS** ....................................................................................................................... 8

**SPECIAL CONSIDERATIONS** ............................................................................................................... 8

**APPENDICES** ....................................................................................................................................... 10
  
  Appendix A New York Heart Association Classification of Heart Failure .................... 10
  Appendix B WHO Classification of Pulmonary Hypertension (PH) ................................. 11
  Appendix C Pre-operative optimization ................................................................................. 12
  Appendix D Intermacs clinical profiles (AHA) ................................................................. 13
  Appendix E Alcohol and Substance Abuse ............................................................................. 14

**REFERENCES** .................................................................................................................................... 16
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: National Coverage Determination (NCD) for 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 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) and total artificial hearts. 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 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 covered under the member’s medical benefit.

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

- At this time, the only FDA approved artificial hearts in-scope for this Guideline are the 70 cc SynCardia Total Artificial Heart® and the 50 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 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
- Automatic Intracardiac Defibrillators (AICD), with or without synchronous pacemaker
- Pacemakers of any description

Permanently implantable aortic counterpulsation ventricular assist systems (i.e., the NuPulseCV iVAS) are considered investigational. Proposed as a bridge to recovery for patients with advanced CHF, counterpulsation 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.

**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.

**TOTAL ARTIFICIAL HEART INDICATIONS**

The Syncardia™ Total Artificial Heart is considered medically necessary when ALL of the following criteria are met:

- There is imminent risk of death from biventricular failure with no other appropriate medical or surgical options
- Member is waiting for a donor heart or is being evaluated for a donor heart
- Member has structural abnormalities related to congenital heart disease (CHD) precluding the use of VAD (Optum MCSD Expert Panel, 2021; Thangappan et al., 2018)
- Intractable ventricular arrhythmias including, but not limited to, arrhythmias which fail to terminate after appropriate AICD therapy or catheter ablation and polymorphic arrhythmias not amenable to catheter ablation (Optum MCSD Expert Panel, 2021; Santangeli et al., 2017)
- Member has adequate space in the chest area vacated by the natural ventricles (general body surface areas > 1.7m² for the 70cc device or ≤ 1.85m² for the 50cc device) as measured by computed tomography (CT) imaging

**MCSD INDICATIONS**

Mechanical circulatory support devices/ventricular assist devices are considered medically necessary for long-term support in heart failure patients meeting the following criteria:

- 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 (eGFR < 30ml/min/1.73 m²)
  - 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 six months
  - Age > 70 years
  - BMI > 35 kg/m²
  - Social and psychiatric issues that can have significant impact on the outcomes of a transplant
  - Patient chooses not to have a heart transplant
• Have New York Heart Association (NYHA) Class III - IV heart failure (Yancy et al., 2013; Yancy et al., 2017)
• Have a left ventricular ejection fraction (LVEF) ≤ 25%
• Are inotrope dependent OR
• Have a Cardiac Index (CI) < 2.2 L/min/m², while not on inotropes, and meet one of the following:
  o Are on optimal medical management (OMM), based on current heart failure practice guidelines for at least 45 out of the last 60 days and are failing to respond
  o Have advanced heart failure for at least 14 days and are dependent on an intraaortic balloon pump (IABP) or similar temporary mechanical circulatory support for at least 7 days.

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:
  o Body habitus
  o SRTR reported time to transplant for waitlist patients
  o PRA
  o UNOS region
  o Blood group “O”

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.

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.

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)
  o Power elevation
    ▪ Sustained (> 24 hours) power elevations > 10 W OR
    ▪ Sustained (> 24 hours) power increase > 2 W from baseline
  o Isolated LDH rise
    ▪ 3x upper limit of normal for your reference lab
  o Evidence of hemolysis
    ▪ Clinical diagnosis OR
    ▪ LDH > 3x normal and pfHgb > 40
  o 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 the following is required:

• 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:
o Inability to operate the MCS device pump or respond to device alarms
o 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:
  o Treatment adherence and health behaviors
  o Substance use history
  o Cognitive status and knowledge of current illness and treatment options
  o Social support including availability, stability, and capacity of family and others to provide support
  o 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.
  o FFVC ≥ 50%
  o FFEV1 ≥ 50%
  o 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.
- 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.
  
  o 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, 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:
  
  o An advanced malignancy
  o Severe and irreversible hepatic disease, i.e., cirrhosis not expected to improve with long-term MCSD support.
  o Severe lung disease (including pulmonary arterial hypertension that is not related to chronic heart failure, not World Health Organization group II) [See Appendix B]
  o Severe neurological or neuromuscular disorder

• Acute valvular infective endocarditis with bacteremia

• Detailed neurocognitive evaluation is advised in patients with cognitive impairment to ascertain ability 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 remediate

• 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. THESE ARE BASED ON THE 2020 AATS/ISHLT GUIDELINES ON SELECTED TOPICS IN MECHANICAL CIRCULATORY SUPPORT.
SUPPORT UNLESS OTHERWISE NOTED.

- 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 the 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 (AATS/ISHLT, 2020):
  - BMI < 20 kg/m²
  - 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

- 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).

- 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.

- Patients with active systemic and/or localized infection should not be considered until the infection is adequately treated.
APPENDICES

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.

<table>
<thead>
<tr>
<th>NYHA Class</th>
<th>Symptoms</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>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.</td>
</tr>
<tr>
<td>II</td>
<td>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.</td>
</tr>
<tr>
<td>III</td>
<td>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.</td>
</tr>
<tr>
<td>IV</td>
<td>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.</td>
</tr>
</tbody>
</table>

Accessed January 21, 2021
Appendix B

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

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

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

<table>
<thead>
<tr>
<th>Renal</th>
<th>Desired Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood urea nitrogen</td>
<td>&lt; 40 mg/dl</td>
</tr>
<tr>
<td>Serum creatinine</td>
<td>&lt; 2.5 mg/dl</td>
</tr>
<tr>
<td>Estimated GFR</td>
<td>&gt; 50 ml/kg/min</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hematology</th>
<th>Desired Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>INR</td>
<td>&lt; 1.2</td>
</tr>
<tr>
<td>Hemoglobin</td>
<td>&gt; 10 g/dl</td>
</tr>
<tr>
<td>Platelets</td>
<td>&gt; 150,000/mm</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Nutritional</th>
<th>Desired Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-albumin</td>
<td>&gt; 15 mg/dl</td>
</tr>
<tr>
<td>Albumin</td>
<td>&gt; 3 g/dl</td>
</tr>
<tr>
<td>Transferrin</td>
<td>&gt; 50 ml/kg/min</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hepatic</th>
<th>Desired Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total bilirubin</td>
<td>&lt; 2.5 mg/dL</td>
</tr>
<tr>
<td>ALT, AST</td>
<td>&lt; 2 times normal</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Hemodynamic</th>
<th>Desired Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Right atrial pressure</td>
<td>&lt; 15 mm Hg</td>
</tr>
<tr>
<td>PCWP</td>
<td>&lt; 24 mm Hg</td>
</tr>
</tbody>
</table>

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

Intermacs clinical profiles (AHA)

<table>
<thead>
<tr>
<th>Level</th>
<th>Description</th>
<th>Hemodynamic Status</th>
<th>Time Frame for Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Critical cardiogenic shock, “crash and burn”</td>
<td>Persistent hypotension despite rapidly escalating inotropic support and eventually IABP, and critical organ hypoperfusion</td>
<td>Within hours</td>
</tr>
<tr>
<td>2</td>
<td>Progressive decline on inotropic support, “sliding on inotropes”</td>
<td>Intravenous inotropic support with acceptable values of blood pressure and continuing deterioration in nutrition, renal function or fluid retention</td>
<td>Within days</td>
</tr>
<tr>
<td>3</td>
<td>Stable but inotrope dependent, “dependent stability”</td>
<td>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</td>
<td>Elective over weeks to months</td>
</tr>
<tr>
<td>4</td>
<td>Resting symptoms, “frequent flyer”</td>
<td>Possible weaning of inotropes but experiencing recurrent relapses, usually fluid retention</td>
<td>Elective over weeks to months</td>
</tr>
<tr>
<td>5</td>
<td>Exertion intolerant, housebound</td>
<td>Severe limited tolerance for activity, comfortable at rest with some volume overload and often with some renal dysfunction</td>
<td>Variable urgency, dependent on nutrition and organ function</td>
</tr>
<tr>
<td>6</td>
<td>Exertion limited, “walking wounded”</td>
<td>Less severe limited tolerance for activity and lack of volume overload, fatigue easily</td>
<td>Variable urgency, dependent on nutrition and organ function</td>
</tr>
<tr>
<td>7</td>
<td>Advanced NYHA III “symptoms, placeholder”</td>
<td>Patient without current or recent unstable fluid balance, NYHA class II or III</td>
<td>Not currently indicated</td>
</tr>
</tbody>
</table>
Appendix E

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.
    - 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 addition 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


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


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


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

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