# OPTN

# **Guidance for Adult Heart Exceptions for Status 2 Candidates Experiencing Cardiogenic Shock**

#### Recommendations

The following resource provides guidance for transplant program staff responsible for completing the clinical narrative portion of an initial exception request or an extension exception request on behalf of a candidate to be assigned at status 2. Transplant programs are expected to demonstrate that a candidate has both the medical urgency and potential for benefit comparable to that of other candidates at this status.<sup>1</sup> In addition, the guidance is intended to provide RRB members with a roadmap to certain, useful information necessary for making informed decisions.

The guidance is organized in three sections: a clinical description of the patient, factors impacting the program's attempt to wean the candidate, and applicable contraindications to a VAD. These have been identified as important components for any description of why the temporary therapies of Percutaneous Endovascular MCSD or IABP was used to treat a candidate's cardiogenic shock. The list of clinical criteria in this section should serve as evidence that the candidate remains with persistent hemodynamic instability. When completing the clinical narrative of an exception request, transplant program staff should be submitting clinical measurements and not just indicating the presence or absence of a condition.

It is understood that the guidance will not address all cases. The guidance is intended to promote consistent review of these diagnoses and summarize the Committee's recommendations to the OPTN Board of Directors. This resource is not OPTN Policy, so it does not carry the monitoring or enforcement implications of policy. It is not an official guideline for clinical practice, nor is it intended to be clinically prescriptive or to define a standard of care. This resource is intended to provide guidance to transplant programs and the Regional Review Boards.

# TEMPLATE

# Section 1: Characterization of the Patient

Candidate (Waiting list ID#) is a (age) year old (male/female) with (Dilated/Ischemic/Restrictive) Cardiomyopathy who is status post (S/P) Percutaneous Endovascular MCSD or IABP on (implant date) in this transplant program's Intensive Care Unit on Inotropes (provide agents and dose) and Pressors (provide agents and dose). Patient has been listed as a Status (1/2/3/4/5/6) since

<sup>&</sup>lt;sup>1</sup> OPTN, Adult heart status 2 exception criteria justification form. Accessed in UNet<sup>™</sup> October 29, 2019.

Current hemodynamics are as follows (If a Swan-Ganz catheter is available,):

Right Atrium (RA):	
Pulmonary Artery (PA):	
Pulmonary Capillary Wedge	
Pressure (PCWP):	
Cardiac Index (CI):	

### Section 2: Inability to Wean Candidate

In the last 48 hours, we did not attempt weaning from Percutaneous Endovascular MCSD or IABP as the candidate remains in persistent cardiogenic shock as evidenced by: (provide the values for one or more items)

Hypotension Mean Arterial Pressure (MAP):	
Reduced Cardiac Index (CI):	
Elevated PCW:	
Low SvO <sub>2 or</sub> PA sat	
Worsening End Organ Function:	
Requiring increasing doses of inotropic agents or pressors:	
Ventricular Tachycardia (VT):	
Other:	

#### Section 3: Contraindications to LVAD

The following should be considered as general information that might be expected when describing why a patient is not a candidate for durable LVAD Support (extension only).

- 1. Severe Right Heart Failure (RHF)
  - a. Echo: Severe TR; TASPE < 7.5mm; RVEF < 20%; RV/LV size > 0.75
  - b. Hemodynamic: RA:PCW > 0.54; RVSWI < 250; PAPi < 1
- 2. Surgical Contraindications
  - a. Mechanical Aortic Valves (AV)
  - b. Mechanical Mitral Valves (MV)
  - c. Small Left Ventricle (LV) Cavity
  - d. Left Ventricular Thrombus
  - e. VSD
  - f. Body size BSA < 1.1
  - g. Other: (Describe)
- 3. Need for Multi-organ Transplant
  - a. Renal
  - b. Liver
- 4. Blood Dyscrasias
  - a. Thrombocytopenic
  - b. Hypercoagulable

- c. Contraindication to Warfarin
- 5. Active Co-morbidity
  - a. Infection
    - i. Date:\_(mm/dd/yyyy)
    - ii. Site:\_\_\_
    - iii. Culture:\_\_\_\_\_
  - b. Recent CVA
    - i. Date: \_(mm/dd/yyyy)
  - c. Bleeding
    - i. Date: \_(mm/dd/yyyy)
    - ii. Site:\_\_\_
- 6. Re-current Refractory Ventricular Arrhythmias
- 7. Other:\_\_\_

Note: It is recommended that requesting programs not rely solely on patient preference when submitting an extension exception request to maintain a candidate at Status 2.

#### Conclusion

Adult heart transplant programs should consider this guidance when submitting exception requests on behalf of Status 2 candidates supported by a Percutaneous Endovascular MCSD or by an IABP. RRB members are encouraged to consult this resource when assessing exception requests on behalf of Status 2 candidates supported by a under Percutaneous Endovascular MCSD or by an IABP.

Adult heart transplant programs should consult this resource when submitting exception requests on behalf of Status 2 candidates supported by a Percutaneous Endovascular MCSD or by an IABP. The information is provided in the form of a template that transplant program staff should consider copying and pasting into the narrative section of the exception request. Review Board members should also consult this guidance when assessing exception requests of such candidates. However, the guidance is not prescriptive of clinical practice.

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