

Notice of OPTN Policy and Guidance Changes

Guidance and Policy Clarifications Addressing Adult Heart Allocation Policy

Sponsoring Committee:	Heart Transplantation
Policies Affected:	<i>6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device</i> <i>6.1.C.vi: Mechanical Circulatory Support Device (MCSD) with Device Infection</i> <i>6.1.D.ii: Inotropes without Hemodynamic Monitoring</i>
Guidance Affected:	<i>Guidance for Adult Heart Exceptions for Status 2 Candidates Experiencing Cardiogenic Shock</i>
Public Comment:	August 4, 2020 – October 1, 2020
Board Approved:	December 7, 2020
Effective Date:	February 9, 2020: <i>Guidance for Adult Heart Exceptions for Status 2 Candidates Experiencing Cardiogenic Shock</i> Pending implementation and notice to OPTN members: <i>Policies 6.1.A.ii: Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device, 6.1.C.vi: Mechanical Circulatory Support Device (MCSD) with Device Infection, and 6.1.D.ii: Inotropes without Hemodynamic Monitoring</i>

Purpose of Policy and Guidance Changes

These policy changes amend adult heart allocation requirements to align criteria for similar medical urgencies in status 1 and status 4 by changing the initial qualifying and extension timeframes. In addition, policy changes will reduce the potential for unnecessary invasive procedures for certain adult heart status 4 patients. The changes also reorder the list of device infections associated with Mechanical Circulatory Support Devices (MCSD).

The guidance is a resource for transplant programs and Regional Review Boards (RRB) regarding the information needed in the clinical narrative portion of an initial exception request or extension request for adult heart status 2 candidates. The guidance aims to establish the baseline of information that would reasonably be expected to describe a candidate's clinical status. Such a baseline, consistently applied, should minimize the differences found in the narratives across such requests. This should assist the RRBs to consistently apply policy across the requests.

Proposal History

Substantial changes to the adult heart allocation system were implemented in October, 2018. The modifications included increasing the number of clinical statuses to better capture transplant

candidates' medical acuity. It was believed that more closely aligning patients with their medical acuity would reduce the need for transplant programs to use exception requests to obtain the appropriate status. However, subsequent data monitoring found that the number of exception requests had not decreased. Moreover, the volume of Status 2 exception requests raised concerns that certain temporary therapies implemented in the 2018 modifications were being used for longer periods of time than the policy intended. The Heart Committee saw an opportunity to clarify the types of clinical information that would assist the Regional Review Boards (RRBs) with their decision-making involving exception requests. The Committee also identified policy changes that would more closely align with clinical practice. This proposal provides a guidance resource to educate the heart transplant community about the use of adult heart Status 2 exception requests. It also clarifies components of existing adult heart allocation policy.

Summary of Changes

The changes are listed below:

- Reduce time at adult heart status 1 from 14 to seven days for patients with non-dischargeable, surgically implanted, non-endovascular bi-ventricular support devices
- Align timing of cardiac index measurement with initiation of inotrope administration for adult heart status 4 patients receiving inotropes without hemodynamic monitoring
- Increase time at adult heart status 4 from 90 to 180 days for patients receiving inotropes without hemodynamic monitoring
- Reorder the listing of device infections associated with MCSDs for adult heart status 3
- Create a guidance document clarifying the clinical information that should be included in exception and extension requests for listing at adult heart status 2.

Implementation

Adult heart transplant programs will need to educate their personnel on the details associated with the policy modifications and the availability of the guidance document. Transplant programs may need to update their training protocols related to the completion of adult heart status justification forms related to initial, extension, and exception applications. Program staff should provide more substantive information detailing the reasons a candidate meets the clinical criteria associated with the adult status criteria than has been provided previously. Programs with adult status 1 patients who meet the criteria of non-dischargeable, surgically implanted, non-endovascular biventricular support device will need to update their adult heart status 1 justification forms more quickly in order to extend their candidates at the status. Transplant programs assisting adult heart status 4 candidates who are meeting the criteria for inotropes without hemodynamic monitoring will need to provide the date a candidate's inotrope administration started in order to validate that the cardiac index value was collected within seven days of the start of inotrope administration. A transplant program will provide the date when inotrope administration was started on the adult heart status 4 justification form.

The policy changes require programming by UNOS IT, and will go into effect following completion of the programming and notice to the community. Modifications are needed to the adult heart status 4 justification form to capture the dates of inotrope administration. In addition, changes are needed to the heart justification forms and to the timing associated with the extension forms. Changes to the layouts and programming of the adult heart status 1 and status 4 justification and associated extension forms, are required. The changes also necessitate special circumstances for ensuring the justification

forms submitted prior to implementation of the policy changes are extended under the new timeframes as appropriate.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

6.1 Adult Status Assignments and Update Requirements

6.1.A Adult Heart Status 1 Requirements

6.1.A.ii Non-dischargeable, Surgically Implanted, Non-Endovascular Biventricular Support Device

A candidate's transplant program may assign a candidate to adult status 1 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by a surgically implanted, non-endovascular biventricular support device and must remain hospitalized because the device is not FDA-approved for out of hospital use.

This status is valid for up to ~~147~~ days from submission of *the Heart Status 1 Justification Form*. This status can be extended by the transplant program every ~~147~~ days by submission of another *Heart Status 1 Justification Form*.

6.1.C Adult Heart Status 3 Requirements

6.1.C.vi Mechanical Circulatory Support Device (MCSD) with Device Infection

A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by an MCSD and is experiencing a pump-related local or systemic infection, with *at least one* of the symptoms according to *Table 6-1: Evidence of Device Infection* below.

Table 6-1: Evidence of Device Infection

If the candidate has evidence of:	Then this status is valid for up to:
Erythema and pain along the driveline, with either leukocytosis or a 50 percent increase in white blood cell count from the last recorded white blood cell count, and <i>either</i> : <ul style="list-style-type: none"> • Positive bacterial or fungal cultures from the driveline exit site within the last 14 days • A culture-positive fluid collection between the driveline exit site and the device 	14 days from submission of <i>the Heart Status 3 Justification Form</i> .
Debridement of the driveline with positive cultures from sites between the driveline exit site and the device	14 days from submission of <i>the Heart Status 3 Justification Form</i> .
<u>Positive culture of material from the pump pocket of an implanted device</u>	<u>90 days from submission of <i>the Heart Status 3 Justification Form</i>.</u>
Bacteremia treated with antibiotics	42 days from submission of <i>the Heart Status 3 Justification Form</i> .
Recurrent bacteremia that recurs from the same organism within four weeks of completing antibiotic treatment to which the bacteria is susceptible	90 days from submission of <i>the Heart Status 3 Justification Form</i> .
<u>Positive culture of material from the pump pocket of an implanted device</u>	90 days from submission of <i>the Heart Status 3 Justification Form</i>.

After the initial qualifying time period, this status can be extended by the transplant program by submission of another *Heart Status 3 Justification Form*.

6.1.D Adult Heart Status 4 Requirements

6.1.D.ii Inotropes without Hemodynamic Monitoring

A candidate's transplant program may assign a candidate to adult status 4 if the candidate is supported by a continuous infusion of a positive inotropic agent, and meets *all* of the following:

1. Cardiac index of less than 2.2 L/min/m² within 7 days prior to ~~submission of the *Heart Status 4 Status Justification Form*~~ inotropic administration or while on inotrope infusion as specified below
2. Pulmonary Capillary Wedge Pressure greater than 15 mmHg
3. Requires at least *one* of the following intravenous inotropes:
 - Dobutamine greater than or equal to 3 mcg/kg/min
 - Milrinone greater than or equal to 0.25 mcg/kg/min

- Epinephrine greater than or equal to 0.01 mcg/kg/min
- Dopamine greater than or equal to 3 mcg/kg/min

This status is valid for up to ~~90~~180 days from submission of *the Heart Status 4 Justification Form*. After the initial ~~90~~180 days, this status can be extended by the transplant program every ~~90~~180 days by submission of another *Heart Status 4 Justification Form*.

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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.¹ 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 MCS 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 MCS 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

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

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

¹ OPTN, Adult heart status 2 exception criteria justification form. Accessed in UNetSM October 29, 2019.

We are requesting this exception for _____ (specify data item)
because _____

Section 2: Inability to Wean Candidate

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

<u>Hypotension Mean Arterial Pressure (MAP):</u>	
<u>Reduced Cardiac Index (CI):</u>	
<u>Elevated PCW:</u>	
<u>Low SvO₂ or PA sat</u>	
<u>Worsening End Organ Function:</u>	
<u>Requiring increasing doses of inotropic agents or pressors:</u>	
<u>Ventricular Tachycardia (VT):</u>	
<u>Other:</u>	

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:
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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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