

**OPTN Heart Transplantation Committee
Status Extension Review Subcommittee
Meeting Summary
June 8, 2021
Conference Call**

**Shelley Hall, MD, Chair
Richard Daly, MD, Vice Chair**

Introduction

The Status Extension Review Subcommittee met via Citrix GoToMeeting teleconference on 6/8/2021 to discuss the following agenda items:

1. Policy 6.1.A.iii: MCSD with Life Threatening Ventricular Arrhythmia (VA)
2. Policy 6.1.C.iv: Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis
3. Policy 6.1.C.v: Mechanical Circulatory Support Device (MCSD) with Right Heart Failure
4. Policy 6.1.C.vi: Mechanical Circulatory Support Device (MCSD) with Device Infection

The following is a summary of the Subcommittee's discussions.

1. Policy 6.1.A.iii: MCSD with Life Threatening Ventricular Arrhythmia (VA)

UNOS staff confirmed all proposed policy modifications with the members. Members agreed with adding a new Status 3 criterion to allow candidates who are no longer eligible for this status to downgrade to Status 3, rather than default to Status 5 or 6 after 7 days.

Summary of discussion:

The Chair asked if the members agreed with changing the timeframe for initial eligibility and extension from 14 to 7 days in order to be consistent with all other Status 1 criteria. No opposition was voiced.

The Chair asked if bolding and underlining "is admitted" in the first sentence of this criteria as a way to emphasize this requirement. UNOS staff commented that published policy cannot have this stylistic change.

The Chair asked the member to confirm requiring that candidates meet one of the two initial eligibility criteria and require hospitalization to extend. The Chair commented that it needs to be clear that the candidate needs to still meet the eligibility criteria in order for the person to be eligible to extend. If the candidate no longer meets the criteria, they should be listed at a corresponding Status 3. The listing program will select radio buttons to confirm that candidate is meeting the eligibility criteria.

The Chair noted that the only way it would be known if a candidate is receiving electrical cardioversion in the last 7 days is through an audit. A member asked if a date field should be added to the form in order to identify whether or not the electrical cardioversion has occurred within 7 days as required by the eligibility criteria. UNOS staff commented that this would require a new extension form to be created. The members agreed that this is unnecessary.

The members discussed whether intravenous (IV) antiarrhythmic therapy should be required eligibility criteria. The Chair commented that patients who have been admitted because they needed multiple electrical cardioversions and have been placed on IV antiarrhythmic therapy should not be taken off of

the therapy in order to prove it is still needed. The Chair commented that patients in this scenario should be eligible to extend at Status 1.

A member commented that a patient who has been stabilized and may be on oral, rather than IV, therapies may not have a medical urgency high enough to requalify for Status 1 by extension. The member continued that a patient who remains on IV therapy needs to be transplanted.

The members considered whether including language about requiring hospitalization to extend made the criteria clearer or was duplicative and may cause confusion. A SRTR representative supported leaving the hospitalization requirement to extend as proposed. The members agreed to keep the language as proposed.

A member commented that patients who qualify for this criteria because they are on biventricular (BiVAD) support are already beyond other, standard therapies. UNOS staff confirmed that patients who qualify for this criteria by placement of a BiVAD are not also treated with IV antiarrhythmic therapy. The Chair commented that the BiVAD eliminates the cardiac function to try to decrease the toxicity and are only used when the IV antiarrhythmic therapies are not working or are becoming toxic.

The members discussed the addition of a new Status 3 criterion that would allow a program to list a patient that is no longer meeting the criteria established in *Policy 6.1.A.iii: MCS D with Life Threatening Ventricular Arrhythmia (VA)* and is unable to extend. This would create consistency with other Status 1 criteria that have corresponding Status 3 criteria which allows the patient to be downgraded to a more appropriate status for their medical urgency, rather than Status 5 or 6. The Chair noted that these patients could apply for the new Status 3 criterion if hospitalized and on IV antiarrhythmic. The members agreed to add this new Status 3 criterion for patients who are unable to extend at Status 1 through *Policy 6.1.A.iii* but remain hospitalized on IV antiarrhythmic therapy.

Next steps:

UNOS staff will draft the new Status 3 criterion based on similar Status 3 policies and send to the Subcommittee members to review prior to the Heart Committee vote to approve the proposed policy language on June 15, 2021.

2. Policy 6.1.C.iv: Mechanical Circulatory Support Device (MCS D) with Pump Thrombosis

UNOS staff confirmed all proposed policy modifications with the members.

Summary of discussion:

UNOS staff asked if the policy language should be modified to read “must have one of the following medical conditions” rather than “must of have of the following” in order to be clearer. The members agreed to “must have one of the following conditions.”

UNOS staff asked if converting the treatments into a numbered list would make the policy easier to understand. The members agreed to modify the policy to include the treatments as a numbered list.

UNOS staff asked if “LVAD” should be used to describe a paracorporeal ventricular device. The Chair commented that the language used should be consistent with other policy and that the main intention is to differentiate this device from extracorporeal membrane oxygenation (ECMO). A member suggested using “VAD.” UNOS Research staff confirmed that using “VAD” would be consistent with Policy 6.1.C.iv. The members agreed to use “VAD.”

The members confirmed they are in agreement with all other proposed changes, including extending the initial justification timeframe from 14 to 30 days and the extension timeframe from 14 to 90 days.

3. Policy 6.1.C.v: Mechanical Circulatory Support Device (MCSD) with Right Heart Failure

UNOS staff confirmed all proposed policy modifications with the members.

Summary of discussion:

The members confirmed they agreed with the proposed modifications to extend the timeframe of the extension from 14 to 90 days. The members also agreed to not require the dates of the initiation of inotropes to extend. The Chair confirmed that committing these patients to an indwelling line increases the risk of infection so this is only done when necessary.

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

UNOS staff confirmed all proposed policy modifications with the members.

Summary of discussion:

The members agreed to all proposed modifications drafted in previous meetings. The Chair asked if the table would be reordered based on duration (i.e. 42 days listed before 90 days). UNOS staff commented the order was recently changed in the previous round of policy modifications.

UNOS staff confirmed with the members that IV antibiotics should be required to extend at this status even though some criteria in the policy's table only require debridement or other treatment other than IV antibiotics.

Next steps:

UNOS staff will send the proposed policy modifications to the Subcommittee members for one more review. The Heart Committee will vote on the proposed policy language for public comment on June 15, 2021. If approved, this proposal will go through public comment August 3-September 30, 2021. The Subcommittee will meet again to review public comment feedback and make any modifications.

Upcoming Meeting

- TBD

Attendance

- **Subcommittee Members**
 - Cindy Martin
 - Greg Ewald
 - Jonah Odum
 - Jose Garcia
 - Rachel White
 - Rocky Daly
 - Shelley Hall
- **SRTR Staff**
 - Katie Audette
 - Monica Colvin
 - Yoon Son Ahn
- **UNOS Staff**
 - Eric Messick
 - Janis Rosenberg
 - Keighly Bradbrook
 - Leah Slife
 - Sara Rose Wells
 - Sarah Konigsburg