OPTN Heart Transplantation Committee
Status Extension Review Subcommittee
Meeting Summary
February 10, 2021
Conference Call

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

Introduction

The Status Extension Review Subcommittee met via Citrix GoToMeeting teleconference on 2/10/2021 to discuss the following agenda items:

1. Consider opportunities to improve consistency of extension criteria in adult heart policy

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

1. Consider opportunities to improve consistency of extension criteria in adult heart policy

The Subcommittee discussed extension requirements for the adult heart policy status criteria of interest.

Summary of discussion:

UNOS staff presented a summary of the data request presented at the previous meeting.

- 777 candidates ever waiting at one of the criteria of interest
- Of the 777, a little over 50% submitted at least one extension
- Most forms were submitted to Adult Status 3 mechanical circulatory support device (MCSD) with pump thrombosis
- Next most forms submitted to MCSD with device infection
- MCSD with pump thrombosis, right heart failure, and device infection had the highest ratio of extensions to candidates ever waiting

UNOS staff shared the number of days permitted at each criteria under *Policy 6.1.C.vi: MCSD with Device Infection*. A member asked about the distinction between the positive culture and bacteremia criteria. The Chair clarified that positive culture refers to an infection of the pump pocket.

Policy 6.1.C.vi: MCSD with Device Infection

UNOS staff asked the members to consider what information should be provided in order to appropriately justify extending a candidate under *Policy 6.1.C.vi: MCSD with Device Infection* and to provide rationale.

The Chair commented that the Committee has proposed the addition of language that requires that a candidate must continue to meet the criteria in order to be eligible for extension.

A member suggested combining the debridement of the driveline criteria with the criteria listed in the first row of Table 6-1: Evidence of Device Infection since these criteria have the same timeframe. The Chair noted that candidates who were eligible for this status under the debridement criteria had a larger volume of extension requests and asked if these extensions could be reviewed to learn why there were

so many. The Chair noted that the candidate needs to continue meeting the criteria to extend so there may need to be more member education around this if these proposed changes are implemented.

A member asked how "ongoing infection" can be defined. The Chair commented that qualifying incidents would be if the candidate requires more debridement or continues to have positive cultures. A member asked if eligibility would be evaluated by culture negativity or biopsy of the wound, and asked if there would be a threshold for quantity of organisms to define the infection?

A member suggested considering the criteria in different levels: local infection that may be able to be controlled through debridement and recurrent bacteremia or pump pocket infection, both of which require ongoing care until transplant. The Vice Chair commented that recurrent bacteremia and pump pocket infections may not need an expiration date. The Vice Chair also commented that there is no data that would allow a quantitative measure to be applied to these criteria.

The Chair suggested increasing the timeframe for the driveline debridement criterion to 42 days in order to be consistent with the bacteremia criterion. She suggested including discrete examples to describe how the candidate continues to meet the criteria such as needing recurrent debridement or continues to have positive culture. These examples could be provided in the policy or in educational material.

UNOS staff suggested adding a radio button to the extension form to allow indication that positive cultures still exist but extra information is not required. A member commented that the presence of bacteremia is clear and it is recommended that these patients are given six weeks of antibiotics which is the timeframe of 42 days. If the infection clears, they would move to Status 4, if not, they would continue to be treated with antibiotics and remain at status. The member commented that local tissue infection is more difficult to assign a timeframe but likely requires more than 14 days as some patients require a wound vacuum and need additional time to recover.

The Chair asked what the average length of antibiotics is for debridement. Members said two weeks at a minimum but no longer than six weeks. A member suggested qualifying eligibility by requiring the use of intravenous (IV) antibiotics. The Vice Chair agreed and commented that this requirement would encourage appropriate antibiotic therapy.

The Chair suggested extending the debridement length of time and adding language to the policy that requires IV antibiotics to be eligible for extension to clarify the policy language. Members agreed but one member raised a concern about a scenario where oral antibiotics are clinically preferred for some reason but noted that these cases could be handled by exception. The Vice Chair noted that "recurrent debridement" could also be added to the extension criteria but noted that if another debridement occurs, the patient would qualify for the initial status again.

A member questioned the need for the white blood cell count criteria and suggested the phrasing "localized evidence of driveline infection with positive culture or debridement requiring IV antibiotics." The Chair noted that the white blood cell count was likely included to have an objective measure for identifying an infection. The member commented that under the previous adult heart allocation policies, infections qualified candidates for Status 1A.

The members agreed that use of IV antibiotic or recurrent debridement should establish eligibility for Status 3 under these criteria. The following revision was suggested:

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,~~ requiring IV antibiotics and *either*: • 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 *the Heart Status 3 Justification Form*.
Debridement of the driveline with positive cultures from sites between the driveline exit site and the device requiring IV antibiotics	14 days from submission of *the Heart Status 3 Justification Form*.
Recurrent debridement or persistently positive culture	90 days from submission of the *Heart Status 3 Justification Form.*
Positive culture of material from the pump pocket of an implanted device	90 days from submission of *the Heart Status 3 Justification Form*.
Bacteremia treated with antibiotics	42 days from submission of *the Heart Status 3 Justification Form*.
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 *the Heart Status 3 Justification Form*.

After the initial qualifying time period, this status can be extended by the transplant program by submission of another *Heart Status 3 Justification Form* if the candidate continues to meet the criteria identified in Table 6-1: Evidence of Device Infection including requiring IV antibiotics.

The Chair confirmed that hospital admission is not required to be eligible for this status.

UNOS staff asked if candidates can have IV antibiotics as an outpatient. The members confirmed that patients can get peripherally inserted central catheter (PICC) lines in or go to the hospital for IV infusions depending on the patient's insurance requirements.

UNOS staff will share the revised version of the policy with the members for additional comments. After reviewing, any new data collection will be discussed.

Policy 6.1.C.v: MCSD with Right Heart Failure

This policy was not previously reviewed by the Committee but was identified by UNOS Research staff as a criteria of interest due to the amount of extension requests.

The Chair recommended extending the days for this status. Once a patient with right ventricular failure is put on inotropes, recovery is unlikely. A member agreed that it would be appropriate to extend the timeframe for this status.

The Vice Chair questioned the need to repeat the hemodynamic measurements if the patient is still on IV therapy. Members commented that hemodynamics are only required for initial status qualification. The Vice Chair agrees with extending the timeframe and not requiring repeat catheterization. A member commented that it needs to be specified whether or not hemodynamics are required when extending or submitting another justification form. UNOS staff shared that the extension form for this status requires inotropes dosage and dates of initiation and does not require central venous pressure (CVP) or wedge pressure.

Candidates spend an average of 63 days at this status. The members agreed that a 90-day timeframe is appropriate and consistent with other Status 3 conditions that are terminal. The Vice Chair supported reducing barriers for LVAD patients. At the end of the 90 day extension, the patients will be required to submit another justification form rather than continue extending.

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

The members reviewed previously drafted extension criteria for *Policy 6.1.A.ii*. The Chair commented that these suggested revisions were intended to create more consistency with what is required for extensions for patients on extracorporeal membrane oxygenation (ECMO).

A member asked if this criterion includes total artificial hearts (TAH). The Chair commented that this does not include TAH.

The members reviewed *Policy 6.1.A.i: Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)*. The Chair asked UNOS staff to share this policy and ask the members to consider if patients with bilateral CentriMag devices should have the same qualifying and extension criteria as patients with ECMO.

The Chair and Vice Chair commented that the CentriMag devices are placed centrally while ECMO can be peripheral. Members discussed concerns around gaming. The Chair commented that placing these devices indicates medical urgency but there may need to be more criteria around extensions. The Chair asked for the number of patients at this status. Since the policy was implemented, there have been 100 patients at this status. Extensions are uncommon. UNOS staff noted that the low number of extensions may be due to the number of days these patients are typically transplanted.

The Vice Chair commented that some extensions may be used to cover time in which the patient is not transplantable and needs to stabilize. The Chair commented that programs should know to wait until the patient is transplantable to list them at Status 1 since the median days to transplant is so low.

The Chair commented that the policy may not need revisions beyond changing the eligibility timeframe to 7 days. The members will review all of Status 1 policies to see how to make the criteria more consistent and have the same duration.

Next steps:

UNOS staff will send the *6.1.C.iv Mechanical Circulatory Support Device (MCSD) with Pump Thrombosis* revisions drafted by the Subcommittee members for review and comment. UNOS staff will send the members all Status 1 policies for their review and consideration.

Upcoming Meeting

- March 9, 2021

Attendance

- **Subcommittee Members**
  - Greg Ewald
  - Jonah Odim
  - Rocky Daly
  - Shelley Hall
- **HRSA Representatives**
  - Adriana Martinez
  - Vanessa Arriola
- **SRTR Staff**
  - Katie Audette
  - Yoon Son Ahn
- **UNOS Staff**
  - Eric Messick
  - Janis Rosenberg
  - Julia Chipko
  - Keighly Bradbrook
  - Sara Rose Wells
  - Sarah Konigsburg