

OPTN Heart Subcommittee**Meeting Minutes****August 29, 2019****Conference Call****Shelley Hall, MD, Subcommittee Chair****Introduction**

The Heart Subcommittee met via Citrix GoTo teleconference on 08/29/2019 to discuss the following agenda items:

1. Adult Heart Policy Exception Project: Request Review
2. Adult Heart Policy Language Clarification: Extension Criteria Requirements

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

1. Adult Heart Policy Exception Project: Request Review

Committee leadership are currently reviewing and categorizing the redacted adult heart status 2 exception request narratives. The plan is to potentially share the findings to date with the Subcommittee during the October 17th in-person meeting.

Summary of discussion:

So far to date, the Committee leadership has been given approximately 220 to 230 narratives that were submitted June 1, 2019 through August 20, 2019. The purpose of this review is to identify any patterns or trends in the use of exceptions to list individuals at status 2. There were no questions or concerns from any of the Subcommittee members.

Next steps:

Committee leadership will continue to review the redacted narratives, and plan to share any findings at the October 17th in-person meeting.

2. Adult Heart Policy Language Clarification: Extension Criteria Requirements

The Subcommittee continued discussions regarding inconsistent extension criteria requirements. For this discussion, the Subcommittee discussed whether each heart status needed specific extension criteria, or whether transplant hospitals have to provide any updated information to extend their candidates.

Summary of discussion:

One Committee member stated that though they had previously discussed having more specific extension criteria, this may not always be true for each candidate. For example, if a candidate is listed for a total artificial heart or a single-ventricle with a VAD, then they may not have any changes from their time of listing to their time at extension. However, a candidate with a balloon pump was not intended to have said device for a long period of time, and therefore would need a good justification in order to extend. In this way, if there are certain criteria that will not change over time, then the Subcommittee agreed to not put in the effort of changing the extension policy language to incorporate these criteria.

To begin the discussion, the Subcommittee reviewed whether OPTN Policy 6.1.A.i: *Veno –Arterial Extracorporeal Membrane Oxygenation (VA ECMO)* required transplant hospitals to submit new data in order to extend a candidate. One Committee member stated suggested including a reason why the candidate may have a contraindication to receiving a durable device. To this point, one Committee member opined that there is a lack of guidance on “acceptable or nonacceptable contraindications” in heart policy, which has shown to be a prominent theme when analyzing the status exception narratives. Subcommittee members agreed that this issue should be pursued further once there is more information gleamed from the exceptions analysis.

In terms of the clinical narrative, UNOS staff clarified that narratives are not necessarily required for extensions, only for exceptions. A Subcommittee member stated that still, they cannot see the contraindications for an exception or extension when the justification form is submitted to the RRB for review. Subcommittee members asked whether extension forms had to be reviewed by the RRB. UNOS staff clarified that some status extensions do have to be reviewed by the RRB. However, Subcommittee members stated that in their opinion most of the candidates are already transplanted by the time the RRB sees an extension request (though it was noted that even if a candidate is transplanted before the RRB reviews an extension request, the RRB is still required to review and either approve or deny the candidate at the status). For this reason, the Subcommittee was supportive of defining contraindications at a later date.

Next, the Subcommittee reviewed OPTN Policy 6.1.A.ii: *Non-dischargeable, Surgically Implanted Non-Endovascular Biventricular Support Device*. The Subcommittee agreed to keep the extension criteria as is, because it would be highly unlikely that a candidate is transplanted with this type of support device just to receive a transplant. Another Subcommittee member agreed, and stated that they should continue to monitor this status.

Next, the Subcommittee reviewed OPTN Policy 6.1.A.iii: *Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia*. Subcommittee members agreed that candidates should be extended if they are hospitalized and still being maintained on IV antiarrhythmic medications. The reasoning is that it would pose a patient safety issue if a candidate’s medications were stopped in order to prove they had an arrhythmia. However, there were concerns that there is a lack of time limit on when a candidate had to have experienced an arrhythmia. One Subcommittee member stated that previously they had decided to not implement a time limit, and suggested to continue monitoring this status to determine if there needs to be changes. Another member stated that though a candidate should not have to be an IV antiarrhythmic medications for 6 months, it might be a failure of the system that they must wait that long. However, other Subcommittee members stated that a status 1 candidate would likely not wait 6 months for a transplant, and agreed to keep the policy language as is.

Next, the Subcommittee reviewed OPTN Policy 6.1.B.i: *Non- Dischargeable Surgically Implanted Non-Endovascular Left Ventricular Assist Device (LVAD)*. Subcommittee members agreed to wait on determining whether the extension criteria are correct until after viewing the results from the Adult Heart Exception project. Staff explained that standard extension requests are not in the exception request data being analyzed by leadership.

Next, the Subcommittee reviewed OPTN Policy 6.1.B.ii: *Total Artificial Heart (TAH), BiVAD, Right Ventricular Assist Device (RVAD) or Ventricular Assist Device (VAD) for Single Ventricle Patients*. Based on earlier discussion in the meeting, members agreed to leave the extension criteria as is for this status.

Next, the Subcommittee reviewed OPTN Policy 6.1.B.iii: *Mechanical Circulatory Support Device (MCSD) with Malfunction*. Subcommittee members agreed that this policy needs further clarification, and the creation of new policy language. To note, members stated that some complete device replacements are

not as technically difficult due to the way they are done. However, due to the ambiguity surrounding the number of candidates waiting at the end of the most recent month at each status and criteria, members requested data on the volume of extensions by status criteria. Subcommittee members stated that determining volume by status criteria would allow members to prioritize which criteria they should focus on first. Members also wanted volume by initial justification form and volume by extension form. A suggestion was to analyze the raw data showing at which status a candidate was listed or the number of days a candidate was under a criteria (initial form and extension forms combined). However, members did not want the data request to be too difficult to obtain. UNOS research staff agreed to work on writing up a data request for the Subcommittee.

Next, the Subcommittee reviewed OPTN Policy 6.1.B.iv: *Percutaneous Endovascular Mechanical Circulatory Support Device*. One Subcommittee member opined that this particular criteria makes up nearly 50% of the exceptions submitted for status 2. Another member stated that the reason there might be an increase in exceptions is because candidates are unable to meet the extension criteria. This member opined that the purpose of having specific extension criteria for this policy was so that there were fewer candidates under status 2 for a percutaneous device, and would encourage the use of durable devices. In this way, the goal was not to have candidates waiting on a percutaneous device for long periods of time. In terms of the exception narratives, there is no clear consensus yet on why the majority of candidates are being listed for an exception under this criteria.

SRTR commented that they have found certain centers not updating hemodynamic data values, and using older data values in order to extend. Furthermore, there are discrepancies between information being documented in the clinical narratives, and the hemodynamic values being entered. One Committee member believed this could be that physicians do not want to re-insert a swan catheter into the patient due to infection and safety risks. So, in order to extend a candidate, they will rely on those older data values. Another member opined that their understanding was the physicians know to provide updated hemodynamic values, but they are choosing not to do so. A suggestion was to clarify that hemodynamics need to be updated for the initial and extension (example: “including extending the status”). UNOS staff clarified that hemodynamic values are required in order to submit an extension form. On the other hand, exceptions only require clinical narratives, which are then dependent on the RRBs to approve or reject the application. A Subcommittee member suggested that RRBs need additional education.

Another data request by Subcommittee members was to analyze the number of candidates that go from having a standard form (initial or extension) to requesting an exception of the same status. For example, if a candidate had an initial status form for Policy 6.1.B.iv, then members would want to know if they applied for an exception afterwards. Members agreed to prioritize the first data request above this one.

Upcoming Meetings

- September 26th
- October 17th (in person)
- October 24th