OPTN Heart Committee
Meeting Summary
March 19, 2024
Conference Call

Richard Daly, MD, Chair
J.D. Menteer, MD, Vice Chair

Introduction

The Heart Committee (Committee) met via WebEx teleconference on 03/19/2024 to discuss the following agenda items:

1. Welcome and agenda review
2. Results of 1-Year Monitoring Report of the policy changes associated with the Amend Status Extension Requirements implemented in October 2022
3. Review list of heart devices identified in OPTN Computer System and identify potential removals, additions, and/or modifications
4. Open Forum

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

1. Welcome and agenda review

Members were encouraged to complete the Values Prioritization Exercise (VPE) associated with the Request for Feedback (RFF) document, both of which are currently available for public comment. They were reminded that public comment was scheduled to end the day of the meeting, March 19, 2024, and that it is also the last day to complete the VPE. An overview of the agenda was provided. For the review of the list of heart devices discussion, OPTN Contractor staff added that part of the conversation will involve informing the Committee about member questions as to whether certain device configurations qualify their candidates for status 1 or status 2.

2. Results of 1-Year Monitoring Report of the policy changes associated with the Amend Status Extension Requirements implemented in October 2022

This part of the meeting discussed the results of the monitoring report for the implementation of status extension requirements, and the Committee's feedback. The Committee made the policy changes to clarify the requirements for extending certain status criteria, with a focus on reducing confusion among the transplant programs as to what information is required to qualify and ensuring candidates meet ongoing medical urgency.

Summary of discussion:

The following topics were discussed in more detail concerning changes in extension usage since the policy amendments were implemented:

- The report covers changes to adult heart status 1 and status 3 criteria, with some criteria seeing increased usage but minimal changes in waiting times under extensions.
- There has been a reduction in the number of extension forms being submitted for various criteria, including infection, recurrent debridement, and pump thrombosis.

- The extent to which the reduction in the usage of extensions indicates a better understanding of the policy criteria or removals from the waiting list for other reasons.
- More data is needed to determine the impact on mortality for specific criteria such as device infections and right heart failure.
- How the Committee might want to consider the monitoring report results in light of their work addressing medical urgency as part of developing a continuous distribution allocation system.

OPTN Contractor staff provided an overview of the year one-year monitoring report for the changes associated with the Amend Status Extension Requirements project. Members were reminded that the project's intent was to clarify the requirements to extend certain status criteria. According to transplant programs, it wasn't always clear in policy that if a program wanted to extend the status for candidate, that the candidate still needed to meet the same requirements that they met when they initially applied. In addition to making that clarification, there were a number of other changes to the duration of extensions or initial requests, in some cases changes to the requirements themselves. The goal of the policy changes then was both to reduce confusion and also to ensure that Candidates were not being extended more than they should be. The Committee made the changes where appropriate to clarify that candidates needed to continue to show a high level of urgency in order to continue receiving repeated extensions. All in all, there were 11 status criteria that were amended as part of this project. Four of the changes addressed status criteria 1and seven addressed status 3 criteria. There are also two new status 3 criteria added.

The presentation addressed the one-year year monitoring report of the changes that went into effect on October 27, 2022. Therefore, the data that was analyzed covered the period from October 27, 2021 through October 26, 2023. Members were reminded that The full report was emailed out to members, and it contains the complete details on all the different status criteria. The report also has additional information about waiting list and about transplant. The discussion focused on five of the criteria.

A summary was provided of the two changes made to the status 1 criteria. One policy change was a clarification that the candidate needed to remain hospitalized to remain qualified. The other status 1 change involved the non-dischargeable, surgically implanted, non-endovascular support device criteria. The change clarified that a candidate needs to continue meeting the initial requirements in order to extend. The status 1 criteria with the most changes was the MCSD with life threatening ventricular arrythmia. Changes to the criterion involved reducing the duration of the initial extension timeframe in half. In addition, the time frame over which the candidates must have experienced episodes of ventricular fibrillation, or ventricular tachycardia was also reduced by half. There was also a pathway created whereby candidates who are not able to extend at status 1 could transition to status 3.

Analysis of the status 1 changes suggests not a lot happened. There was an increase in the usage of both criteria, but no real change in the use of the non-dischargeable criteria and a slight decline in the use of the ventricular arrhythmia criteria. When reviewing the time spent waiting under an extension, there wasn't a great deal that changed here. This finding was not surprising because these are status 1 criteria and even prior to implementation, candidates were waiting fairly briefly at these statuses. They were not extending the assignments more than maybe five times in some cases.

A member had questions about whether the status 3 policy changes involving MCSD with Device Infection. Specifically, the member asked if, in order to extend a candidate, the program has to provide evidence that the candidate has a positive culture even though they have been receiving antibiotics to treat the culture for some extended period of time? The member was concerned that this was unfair because it required an additional procedure to determine if the culture is still positive. Another member stated that when the policy changes were discussed, the Committee was attempting to ensure that the

criteria was available for candidates who had an on-going high-level of need, and that the criterion was not designed to support a candidate for an indefinite period of time once the candidate was determined to be eligible. The member who raised the initial question wanted to underscore the challenges to the candidate's health of requiring an additional surgical procedure, and added that the Committee might want to consider the impact of this change. Others indicated that perhaps the information in the report should be used to make adjustments to the Committee's continuous distribution efforts, and opposed to revisiting current policy.

A member asked whether the reduced usage of the criteria, as described in the monitoring report, should be considered improvements to the allocation policy or whether the reductions should be interpreted as meaning the criteria are now too difficult to meet? For example, is requiring additional heart catheterizations benefiting a patient? The member added that the reduction in the number of exceptions as indicated may also be a signal that policy is not working appropriately. Other members disagreed and said that a deeper dive into the monitoring report results may indicate advantages stemming from the policy changes. Moreover, the intent of the policy changes was to clarify that a candidate who met initial criteria was not then guaranteed an indefinite assignment at the criteria, and that appears to have happened as a result of the changes. The members said that the matter speaks to addressing the fact that patients on devices develop complications over time and that the Committee should continue discussing how to use the medical urgency attribute in continuous distribution to address the problem, and potentially considering whether to account for waiting time as part of continuous distribution.

The analysis suggests that for MCSD with device infection: Bacteremia, the number of extension forms submitted decreased following implementation but the distribution of time spent waiting on the extension did not change that much. The analysis suggests that the clarification to the debridement criteria and the inclusion of new policy addressing recurrent debridement resulted in a decrease in the number of extension forms being submitted.

For the changes made to the MCSD with device infection: Erythema criterion, the analysis suggests more use of the criterion and more extensions, but not much change in the amount of time candidates spend waiting.

The Committee made the most changes to the status 3 criterion MCSD with Pump Thrombosis. When considering the potential policy changes, the Committee was aware that candidates remained at this status for long periods of time and that a large number of extensions were requested and provided. The Committee chose to add qualifying criteria while extending the initial assignment from up to 14 days to up to 30 days. The Committee also increased the number of days available under an extension from up to 14 days to up to 90 days.

As a result of the changes, use of the MCSD with Pump Thrombosis criterion substantially declined. During the pre-implementation period of analysis, more than 300 extension forms were submitted, but none were submitted in the post-implementation period. The changes also reduced the number of initial forms being submitted from 39 in the pre-implementation period and three in the post-implementation period. As expected, the time waiting also decreased substantially. So, with this particular criterion, the analysis suggests that there were fewer candidates assigned to the MCSD with Pump Thrombosis criterion and also that the candidates who were assigned to the criterion were transitioned to status 4 rather than extending under this criterion.

The takeaways from the report are that when looking at the changes in the use of extensions across all the policy changes, the number of extensions decreased by nearly 50 percent in the post-implementation period. The primary driver of the decrease was the MCSD with Pump Thrombosis

criterion, where there were and no extensions submitted at all post-implementation. There was little change in the number of extensions or time spent waiting under the Status 1 criteria. The criterion "MCSD with life-threatening ventricular arrhythmia after 7 days," which was added at implementation, saw no use in the first year post-implementation. The other criterion added at implementation, "MCSD with device infection- Recurrent debridement," saw use in line with the other Status 3 device infection criteria.

Next steps:

The *Amend Status Extension Requirements in Adult Heart Allocation Policy* briefing paper was added to the Committee's website so that members could review the issues confronting the members at the time and their reasoning for proposing the changes they did. The members will also discuss the topic more as they address medical urgency and waiting time in continuous distribution.

3. Review list of heart devices identified in OPTN Computer System and identify potential removals, additions, and/or modifications

An analysis of the heart device usage as captured through the OPTN Computer System was shared with the members prior to the meeting. The primary findings of the report were reviewed. Committee members were asked to notify OPTN Contractor staff if they are interested in reviewing the report with the intention of removing, modifying, and/or adding devices for use in the OPTN Computer system. Additionally, the members were informed of a general trend in member questions asking whether certain device configurations qualify their candidates for status 1 or status 2. The Committee discussed what might be leading to such member questions.

Summary of discussion:

Information about heart device usage was shared with the Committee members. It was pointed out that the Impella 5.5 device was only added to the OPTN Computer System in August 2023. Prior to that, transplant programs had to use the "Other, specify" option and write-in Impella 5.5. Inclusion of Impella 5.5 has dramatically reduced the number of time programs used the Other, specify option. The Committee is seeking volunteers to review and recommend changes to the list of devices used for status assignment.

OPTN Contractor staff told the Committee that there appears to be a trend in member questions asking whether certain heart device configurations qualify a candidate for assignment at adult status 1 or adult status 2. Contractor staff wanted to make members aware of the apparent trend. In addition, contractor staff wanted Committee feedback as to whether the device configurations being submitted actually would qualify the candidates for the more urgent status assignments. For example, a member question focused on whether a certain configuration of percutaneous devices with an oxygenator should be classified as status 1 or status 2. This led to Committee discussions what constitutes a qualifying device for status 1 and the definition of terms like "add related" and "without assistance."

Several Committee members agreed that the heart device environment has changed since the heart policy modifications were implemented in October 2018. For instance, some said the aforementioned configuration should be considered as meeting the status 1 criteria, while others suggested that it should still be classified as status 2 but there should also be an allowance for exception requests. As a result, there might be a need to revisit how policy addresses the use of devices. Members pointed out that the manner by which some devices was intended to reflect the urgency. For example, a member said that the use of central cannulation is associated with status 1 urgency, while the use of peripheral cannulation was intended to reflect status 2 urgency. Another member said that currently placing a transplant candidate on an ECMO device is often done using peripheral cannulation. As a result, perhaps

the Committee should revisit the policy language or consider preparing guidance to assist the transplant programs in determining the appropriate status to assign their candidate to. A member suggested that maybe the Committee should consider reserving status 1 urgency only for candidates supported by ECMO, and the other criteria currently in status should be transitioned to status 2-level urgency. Consistency and equal treatment across transplant programs was emphasized, and it was suggested that education and clarification be provided to ensure uniform interpretation of the policy.

Next steps:

Any Committee members interested in reviewing the list of devices for the purposes discussed were asked to contact the OPTN Contractor staff.

4. Open Forum

There were no speakers for the open forum discussion period.

Upcoming Meetings

- March 29, 2024 – In-Person Meeting, Houston, TX
- April 3, 2024
- April 16, 2024
- May 1, 2024
- May 21, 2024
- June 5, 2024
- June 18, 2024

Attendance

- **Committee Members**
  - Rocky Daly
  - JD Menteer
  - Tamas Alexy
  - Jennifer Carapellucci
  - Jennifer Cowger
  - Timothy Gong
  - Eman Hamad
  - Jennifer Hartman
  - Glen Kelley
  - Earl Lovell
  - Cindy Martin
  - Martha Tankersley
- **HRSA Representatives**
  - Jim Bowman
  - Marilyn Levi
- **SRTR Staff**
  - Yoon Son Ahn
  - Katie Audette
  - Grace Lyden
- **UNOS Staff**
  - Cole Fox
  - Kelsi Lindblad
  - Alina Martinez
  - Eric Messick
  - Sarah Roache
  - Holly Sobczak
  - Sara Rose Wells
- **Other Attendees**
  - David Sutcliffe