OPTN ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK

OPTN Heart Subcommittee
Meeting Minutes
July 25, 2019
Conference Call

Shelley Hall, MD, Subcommittee Chair

Introduction

The Heart Subcommittee met via Citrix GoTo teleconference on 07/25/2019 to discuss the following agenda items:

1. Modifications to Pediatric Heart Allocation Policy: Update
2. Adult Heart Policy Language Clean-Up

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

1. Modifications to Pediatric Heart Allocation Policy: Update

UNOS staff gave a brief update on the Modifications to Pediatric Heart Allocation Policy project.

Summary of discussion:

The Executive Committee approved this project on June 25, 2019. The proposed plan moving forward is to reconvene the monthly Workgroup meetings starting in September. Currently, UNOS staff are working to add another Pediatric Committee member to the Workgroup. The project is projected to be released for public comment in Fall 2020, with an anticipated Board of Directors approval date in December 2020.

The Chair of the Thoracic Committee encouraged other members to join the Workgroup if they have a vested interest in the project.

2. Adult Heart Policy Language Clean-Up

UNOS staff gave a brief overview of the process developed for reviewing the adult heart policy language .Then, UNOS staff started the discussion on this project, primarily focusing on two policy areas for this discussion: Policy 6.1.C.vi: Mechanical Circulatory Support Device (MCSD) with Aortic Insufficiency (AI) and Policy 6.1.C.vi: Mechanical Circulatory Support Device (MCSD) with Device Infection. UNOS staff also discussed the next steps regarding Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring.

Data Summary:

Table 1: Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring

Spring 2016 Public Comment (Round 1)	Fall 2016 Public Comment (Round 2)	Post-Public Comment Changes (post-Round 2)	Board-approved policy language
The candidate is supported by a continuous infusion of a positive inotropic agent, had a cardiac index of less than or equal to 2.2 L/min/m2 within seven days prior to inotrope initiation, and 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 as long as the candidate meets the above criteria.	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 <2.2 L/min/m2 for candidates without inotropic or mechanical support within 7 days prior to inotrope administration 2. Pulmonary Capillary Wedge Pressure >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 days from submission of the Heart Status 4 Justification Form. After the initial 90 days, this status can be extended by the transplant program every 90 days by submission of another Heart Status 4 Justification Form.	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 <2.2 L/min/m2 ~~for candidates without inotropic or mechanical support within 7 days prior to inotrope administration~~ within 7 days prior to submission of the Heart Status 4 Status Justification Form 2. Pulmonary Capillary Wedge Pressure >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 days from submission of the Heart Status 4 Justification Form. After the initial 90 days, this status can be extended by the transplant program every 90 days by submission of another Heart Status 4 Justification Form.	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 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 days from submission of the Heart Status 4 Justification Form. After the initial 90 days, this status can be extended by the transplant program every 90 days by submission of another Heart Status 4 Justification Form.

Table 2: Policy 6.1.C.vi: Mechanical Circulatory Support Device (MCSD) with Aortic Insufficiency (AI)

Current Policy	Policy Interpretations	Questions	Clarification Previously Suggested by Committee
A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by an MCSD and is not exhibiting evidence of device malfunction, but is experiencing AI, with all of the following: • At least moderate AI by any imaging modality in the setting of the mean arterial pressure (MAP) less than or equal to 80 mmHG • Pulmonary capillary wedge pressure greater than 20 mmHG • New York Heart Association (NYHA) Class III-IV symptoms	• Candidate must be experiencing the symptoms at time of status request	• Do the values of the criteria used to demonstrate AI need to have date validations against each other? • Do the values of the criteria used to demonstrate AI need to have date validations against the presentation of AI?	A candidate's transplant program may assign a candidate to adult status 3 if the candidate is supported by an MCSD and is not exhibiting evidence of device malfunction, but is experiencing AI, with all of the following ***within the past 30 days***: • At least moderate AI by any imaging modality in the setting of the mean arterial pressure (MAP) less than or equal to 80 mmHG • Pulmonary capillary wedge pressure greater than 20 mmHG • New York Heart Association (NYHA) Class III-IV symptoms

Table 3: Policy 6.1.C.vi: Mechanical Circulatory Support Device (MCSD)

Current Policy	Policy Interpretations	Questions	Clarification Previously Suggested by Committee
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.	• Policy does not specify a timeframe related to the timing of the infection	• Should there be a specific timeframe identifying when the candidate experienced local or systemic infection occurred? • Member asked "what the time frame is for the occurrence of the Bacteremia treated with antibiotics?"	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 ***within the past 14 days***.

Summary of discussion:

In regards to Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring, UNOS staff have discussed with policy leadership whether the Executive Committee can approve this section of policy without having it be released for public comment. If approved by the Executive Committee, then UNOS staff will develop a mini-brief to describe the issue.

Next, UNOS staff discussed Policy 6.1.C.vi: Mechanical Circulatory Support Device (MCSD) with Aortic Insufficiency (AI). Specifically, this section of policy does not have a specific time requirement for when criteria must have occurred or been met. This differs from other areas of policy that do have specific timeframes for criteria and subcriteria. The Subcommittee had discussed possibly including more specific verbiage back in 2017, and determined that there needed to be timeframes around the policies' criteria. At that time, the Subcommittee had proposed adding in the statement "within the past 30 days". In response, a few Subcommittee members stated that they have received feedback from the community that there are places within policy whereby the timeframes for criteria are not practical. The Subcommittee members thought it was impractical and not reasonable for a patient to be listed under this policy if they had experienced AI greater longer than 30 days ago. Furthermore, members felt that 30 days would be an appropriate amount of time for relevant lab values and tests (such as results from an echocardiogram). Along those lines, members opined that 30 days would be enough time for physicians to try and "tune-up" a patient, and if that fails, then to upgrade them to status 3. Another point the Subcommittee brought up, was that there will always be outliers to the 30 day timeframe. However, these outliers should be limited, and if need be, the exception pathway is always available. The Subcommittee members thereby supported including the statement "within the past 30 days" (at form submission) under this policy.

Next, Subcommittee members discussed Policy 6.1.C.vi: Mechanical Circulatory Support Device (MCSD) with Device Infection. For this policy, there are no specific timeframes identified for when the candidate must have experienced local or systemic infection. This was an area of policy that had not been discussed previously by Subcommittee members, but had arisen from member questions. Therefore, based on the other criteria timeframe requirements in this policy, UNOS staff proposed including the phrase "within the past 14 days". One Subcommittee members stated that there are two schools of thought to this policy: one is that a VAD patient is treated with the hope that they get an infection to be upgraded to status 3, or the second is that a VAD patient is upgraded only if the device fails. Both of these thoughts would have to be encompassed under one timeframe, despite both taking place at different times. Based on the discussion and in looking at the subcriteria further, one Subcommittee member voiced support for including the phrase "within the past 30 days". For example, the member opined that most physicians would deem a transplant as necessary for a candidate with bacteremia. However, another Subcommittee member stated that the phrase should be "within the past 14 days" because the physician should know by then if the candidate has an infection. Another member supported this idea, stating that 30 days was too long because it could allow a candidate to be listed or "uplisted" incorrectly if they were treated for 14 days, and then no longer have an infection. Though this "uplisting" can occur at any timeframe, for consistencies purposes, Subcommittee members agreed to the statement "within the past 14 days".

Another Subcommittee member stated that the prior intent of the Committee was that if a candidate had a local infection, then this infection needed to be recent and proven with cultures. Then, the candidates' status would only be valid for 14 days, after which in order to extend their status a new set of positive cultures would be required. Another Subcommittee member stated that "recurrent bacteremia" could be confusing, and suggested including the phrase "within the past 14 days" under

each criteria category. Theoretically, the recurrent bacteremia that recurs within 4 weeks of antibiotic treatment would need to be defined more, so that the "14 days" pertains to the development of a second bacteremia (e.g. "within 14 days of the second culture coming back positive with the same organism"). Members noted that candidates may meet these criteria multiple times, because the candidate may have numerous infections over time. Members suggested that "within the past 14 days" either be included in the top paragraph or in the title of the left had column ("if the candidate has evidence of").

Near the end of the discussion, UNOS staff mentioned that this project would need to be released for public comment prior to the policy changes being implemented. At this point, Subcommittee members opined that they would rather work on the Adult Heart Exception Project than on this project because there is a more urgent need to address the high number of exceptions. One Subcommittee member stated that they have been pushing to work on the Exception project for the past 4 months, and have been told numerous times that it would be best if they didn't work on it (e.g lack of resources, time etc.). A Subcommittee member stated that they do not want to work on the Clarification project anymore and are frustrated by a lack of progress on the Exception project. Overall, Subcommittee members felt that their voice was not being heard, that they were not working on projects that they felt were necessary for the heart transplant community, that they have not made progress on most of their projects and that the Exception project should be prioritized.

Next Steps:

UNOS staff will reconvene to discuss next steps moving forward with the Clarifications project and the Exception project. UNOS staff will also contact the sub-committee leadership to discuss the best approach for moving forward.

Upcoming Meetings

- August 29th