OPTN Thoracic Organ Transplantation Committee
Heart Subcommittee
Meeting Summary
April 23, 2020
Conference Call

Shelley Hall, MD, Subcommittee Chair

Introduction

The Thoracic Committee's Heart Subcommittee met via Citrix GoTo teleconference on 04/23/2020 to discuss the following agenda items:

1. Heart Project Updates
2. Review Extension Criteria Related to Statuses 3 – 6

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

1. Heart Project Updates

UNOS staff reviewed the schedule of upcoming meetings, noting that the November and December dates fall on holidays and will be rescheduled.

UNOS staff reviewed the decisions made by the Subcommittee during the previous meeting on 4/17:

- Make general revisions to the status 2 guidance document as outlined on the 4/17 call
- Address *Policy 6.1.B.iv: Percutaneous Endovascular Mechanical Circulatory Support Device* in the guidance document
- Update language for *Policy 6.1.D.ii: Inotropes without Hemodynamic Monitoring*

The Chair clarified that the guidance document should apply to all temporary and percutaneous devices. With regard to *Policy 6.1.D.ii*, the Subcommittee recommended updating the policy to indicate that the status is valid for up to 180 days from initial submission, rather than 90 days, so that the 180-day timeline is consistent throughout the policy.

2. Review Extension Criteria Related to Statuses 3 – 6

The Chair led the Subcommittee in a review of extension criteria for adult heart statuses 3 – 6.

Summary of discussion:

UNOS staff prefaced the discussion by noting that the Subcommittee previously determined that differences in extension criteria language were not acceptable; that it was necessary to review all extension criteria; and that potential solutions include policy changes and additional guidance. While reviewing policy, the Subcommittee considered the potential for requiring candidates to be removed from therapy to capture values required by policy; inconsistencies with other policies; and additional information or details that might clarify existing policies.

Policy 6.1.C.i: Dischargeable Left Ventricular Assist Device (LVAD) for Discretionary 30 Days

This policy does not have extension criteria. The Subcommittee did not have any changes.

Policy 6.1.C.ii: Multiple Inotropes or a Single High Dose Inotrope and Hemodynamic Monitoring

A member asked what left ventricular filling pressures refers to, and the Chair said it refers to a wedge. The member asked if the language should be changed accordingly. The Chair did not know why this language was chosen initially. A member suggested that the intent was to provide leeway for transplant programs to use pulmonary arterial diastolic (PAD) pressure as a proxy for wedge, but noted that some programs get nervous about blowing a balloon up on a regular basis. UNOS staff offered to review the history behind this language choice. Another member said that the policy is fine as written with less specificity because sometimes a wedge is not possible and the PAD is adequate. Another member noted that the policy language only requires either the pulmonary artery catheter or the hemodynamic monitoring. The Chair suggested that the intent was to account for future technologies that can provide this information. The Subcommittee agreed not to make changes to this section.

Policy 6.1.C.iii: Mechanical Circulatory Support Device (MCSD) with Hemolysis

The Chair noted that the policy language requires submission of the same justification form to apply for an extension, meaning that the candidate has to meet the same criteria to qualify for an extension. The Chair asked if the candidate should get an extension after 14 days when the candidate has stopped hemolyzing and their blood lactate dehydrogenase (LDH) levels have returned to normal, noting that as written, the candidate would not qualify for an extension. A member said the candidate should have to maintain the criteria to get an extension because otherwise the hemolysis is resolved. The Subcommittee agreed not to make changes to this section.

Policy 6.1.C.iv: MCSD with Pump Thrombosis

The Chair noted that under this policy, a candidate could continue to apply indefinitely for an extension every 14 days based on one incident of pump thrombosis. Members expressed concern with this policy. A member said that "transient ischemic attack" could refer to a lot of different things that could be extremely transient or minor, though the member said it is a different situation if the candidate has had a real thromboembolic event or stroke. A member suggested changing it to a "transient ischemic attack in the last 14 days." The Chair said that the Subcommittee can either create separate extension language or break up the listing language and continue to allow extensions every 14 days. The Subcommittee agreed to develop better language reflecting evolved technology defining MCSD with pump thrombosis, using the Intermacs definition as a reference, which may alleviate the need to clarify the extension criteria.

A member said he thought "visually detected thrombus in a paracorporeal ventricular assist device (VAD)" was by definition a CentriMag, which was by definition already status 2 or 3. The Chair explained that when this policy was developed, there were dischargeable paracorporeal VADs, which are no longer in use. The Subcommittee considered removing this language from policy but decided to leave the policy language as written in case a similar device comes on the market.

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

The Chair noted that getting an extension in this category requires new submission of a *Heart Status 3 Justification Form* every 14 days and asked the Subcommittee if candidates should have to come off of inotropes every 14 days to confirm that the candidate meets criteria. The Subcommittee agreed that the policy is consistent with other policies involving administration of inotropes. A member said that it does not seem reasonable for these candidates to have to get a right heart catheterization every 14 days. Another member noted that it is rare to place patients on both LVAD and inotropes because it is challenging to manage, so these candidates should not need to get measurements every 14 days to prove that they are sick. A member asked how frequently this situation arises. UNOS staff shared that

only a few candidates were added to the waitlist or transplanted in this category within a one-year period. Because this situation is rare, the Subcommittee decided not to make changes to this policy.

Policy 6.1.C.vi: MCSD with Device Infection – Erythema and Pain Along Driveline

The Chair noted that to extend in this category requires new submission of a *Heart Status 3 Justification Form* every 14 days, which means the candidate must still have persistent positive wound culture and leukocytosis. Members said that at their transplant centers, these candidates are generally downgraded after 14 days once they have responded to antibiotics and no longer meet the criteria. The Chair noted that the justification form just has a checkbox, so it would not be a clear whether the candidates met these criteria at each extension until the center was audited. A member suggested clarifying the policy language to indicate that the criteria must still apply at the time of the extension request.

Policy 6.1.C.vi: MCSD with Device Infection – Other Issues

The Chair noted that candidates get more time at this status based on the severity of their infection. A member asked why candidates maintain status for 42 days if they have evidence of bacteremia treated with antibiotics. The Chair noted that 42 days covers six weeks of antibiotics and that might have been the origin of the timeline. UNOS staff asked the Subcommittee if having the information in the table is helpful or if it is confusing. A member suggested reordering the table so that the criterion regarding material from the pump pocket should follow the criterion referring to debridement of the driveline, and the two criteria regarding bacteremia should follow. The Subcommittee agreed with these changes. Members noted that these candidates are not required to be in the hospital.

Policy 6.1.C.vii: MCSD with Mucosal Bleeding

A member said that since the frequency of gastrointestinal bleeding is so high, the strict criteria in the definition is good. The Subcommittee agreed not to make changes to this section.

Policy 6.1.C.viii: MCSD with Aortic Insufficiency

The Subcommittee noted that this is situation is not very common. UNOS staff confirmed that it applies to a small population of candidates. The Subcommittee agreed not to make changes to this section.

Policy 6.1.C.ix: VA ECMO after 7 Days

The Subcommittee did not have any changes to this section.

Policy 6.1.C.x: Non-Dischargeable Surgically Implanted, Non-Endovascular LVAD After 14 Days

The Subcommittee did not have any changes to this section.

Policy 6.1.C.xi: Percutaneous Endovascular Mechanical Support Device After 14 Days

The Subcommittee did not have any changes to this section.

Policy 6.1.C.xii: Intra-Aortic Balloon Pump (IABP) After 14 Days

The Subcommittee did not have any changes to this section.

Policy 6.1.D.i: Dischargeable LVAD without Discretionary 30 Days

The Subcommittee did not have any changes to this section.

Policy 6.1.D.iii: Congenital Heart Disease

The Chair noted that there are existing guidance documents for congenital heart disease candidates, so if the Subcommittee wants to make changes to this section, they will have to review the guidance document as well. A member suggested that these candidates should not need to update their status

every 90 days. The Chair suggested that the 90-day requirement provides an opportunity for data collection and to check if the candidates have developed qualifying criteria for status 2 or 3. The Subcommittee agreed not to make changes to this section.

Policy 6.1.D.iv: Ischemic Heart Disease with Intractable Angina

The Chair noted that as long as a candidate still has angina, the candidate can extend at this status. A member noted that the number of candidates in this category is very low. The Subcommittee did not have any changes to this section.

Policy 6.1.D.v: Amyloidosis, or Hypertrophic or Restrictive Cardiomyopathy

The Chair noted there is a guidance document for this category. The Subcommittee did not have any changes to this section.

Policy 6.1.D.vi: Re-transplant

The Subcommittee did not have any changes to this section.

Policy 6.1.E: Adult Heart Status 5 Requirements

The Subcommittee did not have any changes to this section.

Policy 6.1.F: Adult Heart Status 6 Requirements

The Subcommittee did not have any changes to this section.

Next steps:

The Chair asked the Subcommittee to work on the pump thrombosis definition via email. The Chair noted that the Subcommittee is on track to finish the adult heart exceptions project this year. The Chair noted that half of the incoming Heart Transplantation Committee will be new to the OPTN process, so the new Committee will take some time in upcoming meetings to help orient the new members.

Upcoming Meetings

- May 28, 2020
- June 25, 2020