Amend Status Extension Requirements in Adult Heart Allocation Policy

OPTN Heart Transplantation Committee

Purpose of Proposal

- Clarify status extension eligibility criteria to improve consistency of adult heart allocation policies
  - Do initial qualifying criteria need to be re-met?
  - What information or data needs to be submitted?
- Amend adult heart policy to appropriately account for candidates transitioning from Status 1 under *Policy 6.1.A.iii: MCSD with Life Threatening Arrhythmia*
- *Policy 6.1.C.iv: MCSD with Pump Thrombosis* vaguely describes symptoms and treatments needed for assignment

Proposal

- Clarifies eligibility requirements for extending adult heart candidates' status assignment to improve consistency across adult heart statuses
  - Adds language stating candidate must still be hospitalized to extend status
  - Identifies specific extension criteria
  - Modifies certain adult heart status eligibility timeframes
- Creates new Status 3 criterion for MCSD with Life Threatening Arrhythmia candidates who no longer qualify for Status 1
- Revises *MCSD with Pump Thrombosis* policy to clarify which treatments and therapies should be associated with status

Proposal: Improving Consistency

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

A candidate's transplant program may assign a candidate to adult status 1 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by a surgically implanted, non-endovascular biventricular support device and must remain hospitalized because the device is not FDA-approved for out of hospital use.

This status is valid for up to 7 days from submission of *the Heart Status 1 Justification Form*. This status can be extended by the transplant program every 7 days by submission of another *Heart Status 1 Justification Form* if the candidate remains hospitalized.

Proposal: Changes to Timeframes of Statuses

Status	Policy	Number of Days Assignment Is Valid Under Initial Request		Number of Days Assignment Is Valid Under Extension Request	
		Current	Proposal	Current	Proposal
1	*6.1.A.iii: MCSD with Life Threatening Ventricular Arrhythmia*	14	7	14	7
3	*6.1.C.iv: MCSD with Pump Thrombosis*	14	30	14	90
3	*6.1.C.v: MCSD with Right Heart Failure*	14	14	14	90

Rationale

- Analysis suggests large extension form usage associated with certain adult heart statuses, particularly statuses addressing MCSD complications
- Candidates assigned to Status 3, MCSD with Pump Thrombosis as of January 2021 had used an average of 13 extensions
- Consecutive extension use suggests some candidates' medical conditions are not improving as a result of therapy/treatment or candidates are remaining "parked"
- Clarifying that a transplant program should provide appropriate evidence demonstrating a candidate's medical circumstances require remaining at the current status assignment
- Status extension use should be supported by appropriate evidence demonstrating a candidate's current medical circumstances warrant remaining at the status
- Improving alignment of certain extension timeframes with current usage patterns should better reflect medical priority of candidates and reduce extension usage

What do you think?

- Are medical conditions and treatments identified in proposed MCSD with Pump Thrombosis changes clear and understandable?
- Should MCSD with Pump Thrombosis changes include a temporal relationship associating timing of medical conditions with treatments?
- Is Status 3 appropriate for transitioning patients no longer eligible for MCSD with Life Threatening Ventricular Arrhythmia?
- Should all adult heart policies require submission of objective evidence demonstrating candidate's ongoing need for treatment?
- Should changes to extension requirements and criteria in other adult heart policies be considered, and if so, which policies and why?