

Guidance and Policy Clarifications Addressing Adult Heart Allocation Policy

OPTN Heart Transplantation Committee

Purpose of Proposal and Guidance

- Reduce need for invasive procedure by changing timing of cardiac index measurement
- Clarify acceptable medical conditions associated with use of adult Status 2 exception requests for candidates being treated with temporary therapies for cardiogenic shock

Proposal

- Amend policies
 - Measure cardiac index at start of inotrope administration rather than submission of justification form, and increase qualifying timeframe at status from 90 to 180 days
 - Improve consistency of Status 1 criteria by changing initial qualifying and extension timeframes from 14 to 7 days
- Create guidance
 - Clarify type of information and level of detail that should be included in Status 2 exception requests

Rationale for Policy Modifications

- Reduce patient impact associated with measuring cardiac index (CI)
 - Measuring CI requires right heart catheter procedure, which includes possible patient risks
- Aligning initial qualifying and extension timeframes for Status 1 candidates
 - Shortening timeframes to up to 7 days better reflects high medical urgency of such candidates
 - Median days to transplant for Status 1 candidates was 4 days following 2018 policy implementation

Rationale for Guidance

Adult Heart Waiting List Additions With an Exception for Statuses 1 – 4 at Listing Post-implementation

October 18, 2018 – October 17, 2019

Adult Status	Number of Waiting List Additions With an Exception	Total Number of Waitlist Additions	Percentage of Waitlist Additions by Exception
1	32	168	19.05%
2	227	722	31.44%
3	86	483	17.81%
4	249	1,581	15.75%

Member Actions

- Heart Transplant Programs
 - More frequent updates for some Status 1 candidates' justification forms
 - Status 4 patients hemodynamic monitoring will require collection and reporting of the date of the candidates' inotrope administration on justification form
- No projected impact on OPOs or Histocompatibility Labs

Feedback Requested

- Policy actions
 - Are there circumstances where measuring cardiac index prior to inotrope initiation instead of prior to form submission would be disadvantageous to the patient?
 - Is it medically appropriate to extend the initial qualifying and extension timeframes from “up to 90 days” to “up to 180 days” for patients on inotropes without hemodynamic monitoring?
 - Is it medically appropriate to reduce the initial qualifying and extension timeframes from “up to 14 days” to “up to 7 days” for certain Status 1 criteria?
 - Should the Status 1 criterion have the same initial qualifying and extension timeframes?
- Guidance action
 - Can transplant programs consistently access types of information and details suggested in guidance?
 - What factors might prevent transplant programs from providing such information?

Please introduce yourself when you speak

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- Reduce need for invasive procedure by changing timing of cardiac index collection and increasing initial and extension timeframes up to 180 days
- Reduce initial qualifying and extension timeframes to up to 7 days for certain Status 1 criterion
- Create guidance clarifying type of information and level of detail needed in Status 2 exception requests

Feedback is summarized and shared as public comment