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

<table>
<thead>
<tr>
<th>Adult Status</th>
<th>Number of Waiting List Additions With an Exception</th>
<th>Total Number of Waitlist Additions</th>
<th>Percentage of Waitlist Additions by Exception</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>32</td>
<td>168</td>
<td>19.05%</td>
</tr>
<tr>
<td>2</td>
<td>227</td>
<td>722</td>
<td>31.44%</td>
</tr>
<tr>
<td>3</td>
<td>86</td>
<td>483</td>
<td>17.81%</td>
</tr>
<tr>
<td>4</td>
<td>249</td>
<td>1,581</td>
<td>15.75%</td>
</tr>
</tbody>
</table>
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