

Notice of OPTN Policy Change

Modify Heart Policy to Address Patient Safety Following Device Recall

Sponsoring Committee:	Heart Transplantation Committee
Policy Affected:	<i>Policy 6.4: Adult and Pediatric Status Exceptions</i>
Public Comment:	August 3, 2022-September 28, 2022
Executive Committee Approved¹:	July 11, 2022 (emergency policy)
Board Approved:	December 5, 2022 (policy made permanent)
Effective Date:	July 14, 2022

Purpose of the Emergency Policy Changes

The OPTN Heart Transplantation Committee (Committee) developed this proposal to assist adult heart candidates who have implanted mechanical circulatory support devices (MCS) that are the subject of a device recall issued by the United States Food and Drug Administration (FDA). In some circumstances, such candidates would not be eligible for an exception at a higher priority status because they are not hospitalized. The Committee identified a patient safety risk for candidates with a recalled device and intends to resolve the risk by creating an exception pathway to allow such candidates to be assigned at a higher priority status.

Proposal History

In June 2021, a recall was issued for a specific ventricular assist device (VAD) which is a type of MCS. Subsequently, more recalls were issued pertaining to the device in question, including two recall notices issued in June 2022. The Committee recognized the patient safety risk associated with the recalls and developed a policy proposal creating a pathway for impacted candidates to submit an exception request for assignment at a higher priority status, which does not require hospitalization, in order to be eligible for a donor offer sooner. In some circumstances, such candidates are not eligible for an exception at a higher priority status because they are not hospitalized. The Executive Committee considered the action pursuant to *OPTN Bylaw 11.7: Emergency Actions*, which allows the OPTN to create policy due to patient safety factors. The Executive Committee, on behalf of the OPTN Board of Directors, met and approved the policy action on July 11, 2022.

The emergency policy was submitted for retrospective comment from August 3, 2022 through September 28, 2022. Community feedback was requested as to whether the policy should be made permanent or be allowed to expire after the one-year period. During the regional meetings, no opposition was expressed to making the policy permanent. A total of four written comments addressing the permanency question were received during public comment, with three of the four recommending

¹ OPTN Bylaws, *Article IV Executive Committee*, (December 6, 2021), (“Considers any issues that require expedited action between meetings of the Board of Directors.”).

Board adoption as permanent policy. The OPTN Board of Directors approved the action as permanent policy on December 5, 2022.

Summary of Changes

The emergency action modifies *Policy 6.4: Adult and Pediatric Status Exceptions* by permitting a transplant program to request an exception for assignment at adult heart status 1, 2, or 3 for a candidate whose implanted MCSD, or an implanted component of the device, has been recalled by the FDA. The candidate is eligible for the exception pathway even if not admitted to the transplant hospital. Implemented on July 14, 2022 as an emergency action, the OPTN Board of Directors approved adoption of the policy as permanent on December 5, 2022. As a result, the policy changes will not expire at one year post-implementation.

Implementation

The policy was implemented on July 14, 2022. The policy's impact during the first three months after implementation was evaluated. The policy will be evaluated again at six months and 12 months post-implementation. The Committee will review these evaluations to monitor policy impact and whether any adjustments may need to be considered. The OPTN is notifying the community that the policy is now permanent through this policy notice, a system notice in the OPTN Computer System, and other appropriate communication channels.

Affected Policy Language

Language that is proposed for extension is in italics (*example*).

6.4 Adult and Pediatric Status Exceptions

A heart candidate can receive a status by qualifying for an exception according to *Table 6-3* below.

Table 6-3: Exception Qualification and Periods

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
Adult status 1	<ol style="list-style-type: none"> Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and Transplant physician believes, using acceptable medical criteria, that the heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status 	RRBs retrospectively review requests for status 1 exceptions	14 days	<ul style="list-style-type: none"> Require RRB approval for each successive 14 day period RRB will review and decide extension requests retrospectively
Adult status 2	<ol style="list-style-type: none"> Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and Transplant physician believes, using acceptable medical criteria, that the heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status 	RRBs retrospectively review requests for status 2 exceptions	14 days	<ul style="list-style-type: none"> Require RRB approval for each successive 14 day period RRB will review and decide extension requests retrospectively
Adult status 3	<ol style="list-style-type: none"> Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and Transplant physician believes, using acceptable medical criteria, that the heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status 	RRBs retrospectively review requests for status 3 exceptions	14 days	<ul style="list-style-type: none"> Require RRB approval for each successive 14 day period RRB will review and decide extension requests retrospectively

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
Adult status 1, 2, or 3	<p>1. Candidate's implanted mechanical circulatory support device, or an implanted component within, has a U.S. Food and Drug Administration recall that the transplant physician determines is a risk to patient safety that cannot be sufficiently mitigated without replacement of the device or the component, and</p> <p>2. Transplant physician believes, using acceptable medical criteria, that the heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status</p>	RRBs retrospectively review requests for exceptions associated with a heart device recall	14 days	<ul style="list-style-type: none"> • Require RRB approval for each successive 14 day period • RRB will review and decide extension requests retrospectively
Adult status 4	Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	RRBs retrospectively review requests for status 4 exceptions	90 days	<ul style="list-style-type: none"> • Require RRB approval for each successive 90 day period • RRB will review and decide extension requests retrospectively
Pediatric status 1A	<ul style="list-style-type: none"> • Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and • Transplant physician believes, using acceptable medical criteria, that the heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status 	The national heart review board (NHRB) retrospectively review requests for Status 1A-exceptions	14 days	<ul style="list-style-type: none"> • Require the NHRB approval for each successive 14 day period • The NHRB will review and decide extension requests retrospectively

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
				<ul style="list-style-type: none"> • If no extension request is submitted, the candidate will be assigned pediatric status 1B
Pediatric status 1B	Transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the requested status	The NHRB retrospectively review requests for Status 1B exceptions	Indefinite	<ul style="list-style-type: none"> • Not required as long as candidate's medical condition remains the same

The candidate's transplant physician must submit a justification form with the requested status and the rationale for granting the status exception.