

## Notice of Emergency Action

# Modify Heart Policy to Address Patient Safety Following Device Recall

<b>Sponsoring Committee:</b>	Heart Transplantation Committee
<b>Policy Affected:</b>	<i>Policy 6.4: Adult and Pediatric Status Exceptions</i>
<b>Public Comment:</b>	August 3, 2022-September 28, 2022
<b>Executive Committee Approved<sup>1</sup>:</b>	July 11, 2022
<b>Effective Date:</b>	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 (MCSD) 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 MCSD. 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.

### 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.

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

## Implementation

Transplant programs will need to educate staff regarding the availability of the exception request pathway associated with a heart device recall issued by the FDA. Transplant program staff will need to be familiar with the limited circumstances under which an exception request is permissible. Specifically, program staff need to be aware that the exception pathway is limited to those circumstances involving an implanted mechanical circulatory support device, or an implanted component within, that is the subject of an FDA recall, and that the transplant physician determines the device is a risk to patient safety that cannot be sufficiently mitigated without replacement of the device or the component. A transplant program must provide the clinical information and an explanation of why the candidate meets such criteria in the exception narrative of the request. Transplant program staff will need to indicate on the OPTN Waiting List forms that the exception request is specifically associated with a heart device recall.

Exception requests related to a device recall will be reviewed by the adult heart regional review boards (RRBs). The RRBs will approve or deny the exception request. A candidate whose initial exception request is approved will be assigned to that status for up to 14 days. The candidate's transplant program will be able to submit exception requests for extensions of the status assignment, which if approved, will be valid for up to another 14 days. If a RRB denies an exception request, then the transplant program can use the existing appeal process to ask for further review. When a candidate's clinical condition changes and the candidate's condition is no longer comparable to that of other candidates assigned at the status, then the transplant program must assign the candidate to the appropriate status as required by *Policy 6.3: Status Updates*.

When using this emergency policy, transplant programs must document any materials or information associated with the device recall in the candidate's medical record. The documentation must include the circumstances that support using the emergency policy.

This emergency policy will go into effect on July 14, 2022. This emergency policy will be reviewed by the OPTN Heart Transplantation Committee at three months and six months following implementation. The emergency policy will expire on July 13, 2023 if the OPTN Executive Committee or OPTN Board of Directors has not acted before that date.

As required by OPTN *Bylaw 11.7 Emergency Actions*, this policy will be distributed for public comment before January 11, 2023 for a period of at least 30 days. The OPTN is notifying the community through this policy notice, a system notice in the OPTN Computer System, and other appropriate communication channels. This action will require implementation in the OPTN Computer System.

## Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~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"> <li>1. Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and</li> <li>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</li> </ol>	RRBs retrospectively review requests for status 1 exceptions	14 days	<ul style="list-style-type: none"> <li>• Require RRB approval for each successive 14 day period</li> <li>• RRB will review and decide extension requests retrospectively</li> </ul>
Adult status 2	<ol style="list-style-type: none"> <li>1. Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and</li> <li>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</li> </ol>	RRBs retrospectively review requests for status 2 exceptions	14 days	<ul style="list-style-type: none"> <li>• Require RRB approval for each successive 14 day period</li> <li>• RRB will review and decide extension requests retrospectively</li> </ul>
Adult status 3	<ol style="list-style-type: none"> <li>1. Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and</li> <li>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</li> </ol>	RRBs retrospectively review requests for status 3 exceptions	14 days	<ul style="list-style-type: none"> <li>• Require RRB approval for each successive 14 day period</li> <li>• RRB will review and decide extension requests retrospectively</li> </ul>

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
<u>Adult status 1, 2, or 3</u>	<ol style="list-style-type: none"> <li>1. <u>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</u></li> <li>2. <u>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</u></li> </ol>	RRBs retrospectively review requests for exceptions associated with a heart device recall	14 days	<ul style="list-style-type: none"> <li>• <u>Require RRB approval for each successive 14 day period</u></li> <li>• <u>RRB will review and decide extension requests retrospectively</u></li> </ul>
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"> <li>• Require RRB approval for each successive 90 day period</li> <li>• RRB will review and decide extension requests retrospectively</li> </ul>
Pediatric status 1A	<ul style="list-style-type: none"> <li>• Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and</li> <li>• 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</li> </ul>	The national heart review board (NHRB) retrospectively review requests for Status 1A-exceptions	14 days	<ul style="list-style-type: none"> <li>• Require the NHRB approval for each successive 14 day period</li> <li>• The NHRB will review and decide extension requests retrospectively</li> </ul>

Requested Status:	Qualification:	Initial Review	Duration:	Extensions:
				<ul style="list-style-type: none"> <li>• If no extension request is submitted, the candidate will be assigned pediatric status 1B</li> </ul>
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"> <li>• Not required as long as candidate's medical condition remains the same</li> </ul>