

# Modify Heart Policy to Address Patient Safety Following Device Recall

*OPTN Heart Transplantation Committee*

# Purpose of Approved Emergency Action

- Respond to patient safety risk
  - Current policy does not specifically account for change in a patient's medical urgency when their support device is recalled and may cause serious injury or death
  - Current and future patients with recalled devices are in immediate danger
- Establish that patient safety risk is connected to recall
  - As of Dec. 2021, 41 failure to restart events identified, including 10 deaths, while supported by recalled device
- Support transplant program's ability to protect patient safety
  - This proposal allows transplant programs to use their clinical judgement to determine how to care for their patient and ability to apply for a status 1, 2, or 3 exception pathway

# Approved Emergency Policy Action

- Created exception pathway to address adult heart device recalls

<b>Eligible statuses</b>	1, 2, or 3
<b>Qualifications</b>	<ol style="list-style-type: none"><li>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</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>

# Approved Emergency Policy Action (Cont.)

<b>Initial Review</b>	RRBs retrospectively review requests for exceptions associated with a heart device
<b>Duration of Initial Assignment</b>	14 days
<b>Extensions</b>	<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>

# Approved Emergency Policy Action (Cont.)

- Created new data element for addition to Waitlist

<b>Data Element</b>	Is exception request related to a device recall
<b>Value</b>	Checkbox for a transplant program to indicate “yes” it is related to a device recall
<b>Description</b>	Candidate does not meet any of the criteria above but has an urgency and potential for benefit comparable to that of other candidates at the status and is either admitted to the transplant hospital that registered the candidate on the waiting list, or 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

# Rationale

- FDA issued 2 recalls for Medtronic's HeartWare™ Ventricular Assist Device (VAD) in June 2022
  - The Heart community has seen a pattern of FDA Class 1 recalls for this device
- Identified problems could lead to serious injury or death for device recipients
  - Malfunction where device may experience a delayed restart or fail to restart
  - Increased risk of mortality and neurological adverse events in patients using device
- As of June 17, 2022, 168 candidates on waitlist with potentially recalled VAD
  - 143 of 168 candidates with potentially recalled VAD were listed in statuses 4 through 7
  - Prior to policy change, in-patient admission was required for submitting a status 1, 2, or 3 exception request
  - Heart community indicated status 4 candidates with VADs had a limited chance for transplant

# Rationale: Recall History

Pump implant kits recalled due to failure to restart

March 1, 2021



April 15, 2021



Battery, data, and adapter cables recalled due to risk of damage to controlled ports

Manufacturer stops distribution & sale of recalled VAD system due to risk of neurological adverse events, mortality, & potential failure to restart

August 12, 2021



June 8, 2022

Pump implant kit recalled due to pump weld defect

System batteries recalled due to failure to start

June 23, 2022



# Member Actions

- **Transplant Hospitals**
  - Check new box under exception criterion for Status 1, 2 or 3 to document that request is associated with device recall
  - Complete clinical narrative including details concerning recalled device and risk to candidate's medical condition
  - Device recall information must be documented in patient records for monitoring and compliance
- **OPTN**
  - OPTN Computer System was updated to accommodate new data element



# What do you think?

- Should the approved emergency policy changes be considered for permanent policy by the OPTN Board of Directors?
- What, if any, evidence demonstrates that heart candidates impacted by a FDA-issued device recall have greater waitlist mortality or post-transplant outcomes and should; therefore, be assigned to adult heart status 2 or 3?
- Are there any types of implanted devices that could be subject to a FDA recall that should not qualify under the policy modifications?
- Are there any types of devices that are not implanted that should be permitted to qualify under the policy modifications?

# Extra slides

- If needed, add some data slides for anticipated questions