ASTS Responses to OPTN Proposals Open for Public Comment

September 28, 2022

Modify Heart Policy to Address Patient Safety Following Device Recall

The American Society of Transplant Surgeons (ASTS) is pleased to provide the following feedback on modifying heart policies to address patient safety following a device recall.

Should the approved emergency policy changes be considered for permanent policy by the OPTN Board of Directors?

No, the policy should not be permanent. The recall should not automatically enable an MCS recipient with functioning pumps, without any issues, circumvent the current policies that would facilitate a status 3 or status 2 listing that are currently in place.

What, if any, data analyses, peer-reviewed literature, or evidence-based medical judgments, provide evidence demonstrating that a patient with FDA-recalled heart device should be assigned to adult heart status 2 or adult heart status 3 by policy criteria, rather than a candidate's transplant physician determining whether assignment to status 1, 2, or 3 by exception is appropriate?

To our knowledge, there is no evidence that a patient with an FDA-recalled heart device should be assigned to adult heart status 2 or heart status 3; it appears to be a fear of patient risk. It is difficult to justify a status 1 exemption with a pump that has demonstrated no errors/malfunctions. This "risk" of pump stoppage is there with all MCS in principle.

Is 14 days the appropriate amount of time for a candidate impacted by an FDA-recalled device to be initially assigned to status 1, 2, or 3 under the approved policy? Why or why not?
Is 14 days the appropriate amount of time for an extension of the assignment by exception? Why or why not?

The counterargument is that the morbidity of an exchange would outweigh the risk of transplant. A better use of extending an exception time should be reserved to those candidates who have had pump alarms or malfunctions.

In addition to the Member Compliance and Policy Evaluation actions identified in the proposal, what other actions can be taken to ensure the new exception pathway is only used for appropriate purposes as intended by the Heart Committee?

This appears to be a small number of the overall heart cohort and regional review or MPSC review would seem appropriate on all cases.

Are there any types of implanted devices that could be subject to an FDA device recall that should not qualify under the policy modifications? Describe why.

This question depends on the specific recall, the scope of the remedy (if any) and the risk of a poor outcome if an adverse event occurs.

Are there any types of devices that are not implanted that should be permitted to qualify under the policy modifications? Describe why.

No, temporary non-durable support should not be included as they are intended to be short-term and disposable. If a center is using a short-term device off label for longer than the prescribed policy, then they should proceed to durable MCS or other medical measures. Those policies are in place and appropriate.

Are the proposed data element and the associated data definition clear and understandable?

Yes.

Are the acceptable forms of documentation regarding the recall of the device identified in the proposal widely available?

Yes.

ASTS Position: Oppose