OPTN

Notice of OPTN Policy and Data Collection Changes

Amend Adult Heart Status 2 Mechanical Device Requirements

Sponsoring Committee:	**OPTN Heart Transplantation Committee**
Policies Affected:	***6.1.B.iv: Percutaneous Endovascular Mechanical Circulatory Support Device*** ***6.1.B.v: Intra-Aortic Balloon Pump (IABP)***
Data Collection Affected:	**OPTN Waiting List**
Public Comment:	**July 27, 2023-September 19, 2023**
Board Approved:	**December 4, 2023**
Effective Date:	**Pending implementation and notice to OPTN members**

Purpose of Policy and Data Collection Changes

The policy changes are intended to better align two adult heart status 2 eligibility criteria with the appropriate medical urgency associated with status 2. The changes represent the OPTN Heart Transplantation Committee's (Committee) efforts to address community concerns that many adult heart candidates were being assigned to status 2, despite such patients having lower waitlist mortality rates than other status 2 candidates. The changes are also intended to clarify the circumstances by which a candidate would qualify for an adult heart status 2 exception.

To qualify for adult heart status 2 assignment by use of either a percutaneous endovascular mechanical circulatory support device or an intra-aortic balloon pump, a transplant program needs to demonstrate that inotropic therapies were initiated but failed to stabilize the candidate's cardiogenic shock. Similar requirements are established in order for a candidate to qualify for an extension of the assignment. Updates will be made to OPTN Waiting List data collection to capture information about attempted inotropic therapies and their failure to stabilize the cardiogenic shock being experienced.

Requiring documentation of inotrope failure prior to the use of an IABP will relieve congestion within status 2 and allow hearts to be allocated to candidates with higher mortality rates, while also not disadvantaging those patients who need an IABP. In an effort to ensure fairness within temporary support devices within status 2 and to prevent waitlist congestion from migrating to another temporary support device, percutaneous endovascular circulatory support devices will also need to provide documentation of inotrope failure prior to use.

Proposal History

Modifications to adult heart allocation policy implemented in October 2018[1] created more granular statuses based on waitlist mortality and other clinical factors.[2] Since implementation, assignments to adult heart status 2 by use of the intra-aortic balloon pump (IABP) criterion have accounted for nearly 45 percent of all status 2 waitlist additions.[3] However, data analysis indicates the waitlist mortality rates of such candidates are less aligned with those of candidates assigned to other status 2 criteria.[4] Community feedback, clinical literature, and Committee analysis of OPTN data underscored the potential benefits to waitlist mortality outcomes that could be achieved by more closely aligning the eligibility criteria with other status 2 criteria.

During public comment, the Committee received feedback that the policy changes could result in some candidates experiencing arrhythmias as a result of attempting inotropes. The Committee agreed with the commenters and created a path to eligibility for such candidates.

Summary of Changes

The changes modify the status 2 eligibility criteria by requiring programs to demonstrate a failure of inotropic therapy to stabilize the candidate's cardiogenic shock before proceeding to the placement of an IABP or percutaneous endovascular mechanical circulatory support device (MCSD). The changes also require programs to demonstrate the candidate failed weaning from the device while still receiving inotropic therapy in order to extend the candidates' status assignment. In addition, the proposal was revised following public comment permitting candidates who develop ventricular tachycardia (VT), or require cardioversion, defibrillation, or antitachycardia pacing as a result of initiating inotropic therapy to be listed at adult heart status 2, and for extending such status assignments without additional attempts to provide inotropic therapy.

Implementation

Transplant programs need to document that inotropic therapy was initiated but failed to stabilize a candidate's cardiogenic shock prior to starting IABP or percutaneous endovascular MCSD support by reporting to the OPTN the inotrope(s) attempted, the dosages, and the date(s) of administration and verifying that certain hemodynamic values were obtained. In circumstances where a candidate developed arrhythmias after attempting inotropes, a program is required to confirm the event through the OPTN data collection process. The policy changes require modifications to OPTN Waiting List data collection instruments.

Affected Policy Language

New language is underlined (<u>example</u>) and language that is deleted is struck through (~~example~~).

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[1] "Modify Adult Heart Allocation." Public Comment, Second Round. OPTN Thoracic Organ Transplantation Committee. https://optn.transplant.hrsa.gov/policies-bylaws/public-comment/modify-adult-heart-allocation-2016-2nd-round/

[2] *Proposal to Modify the Adult Heart Allocation System*.

[3] "OPTN Descriptive Data Request, "Three-Year Monitoring of Heart Allocation Proposal to Modify the Heart Allocation System," Prepared for OPTN Heart Transplantation Committee Meeting, October 11, 2022, https://optn.transplant.hrsa.gov/media/hx1pr13a/data_report_heart_committee_3yr_rpt1_508_compliant.pdf (accessed June 22, 2023)," p. 15.

[4] "Three-Year Monitoring of Heart Allocation Proposal," p. 31.

6.1.B.iv: Percutaneous Endovascular Mechanical Circulatory Support Device

A candidate's transplant program may assign a candidate to adult status 2 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and is supported by a percutaneous endovascular mechanical circulatory support device without an oxygenator for cardiogenic shock as evidenced by *either* of the following:

- Within 7 days prior to percutaneous endovascular mechanical circulatory support, ~~*all* of the following are true within one 24 hour period~~ *both* of the following are true:
    1. *All* of the following hemodynamic measurements were obtained for the candidate within one 24-hour period, and:
        a. Systolic blood pressure of less than 90 mmHg
        b. Cardiac index of ~~less than 1.8 L/min/m² if the candidate is not supported by inotropes or~~ less than 2.0 L/min/m^2 ~~if the candidate is supported by inotropes~~
        c. Pulmonary capillary wedge pressure of greater than 15 mmHg
    2. The candidate *either*:
        a. Was being supported by inotropic therapy according to either of the following qualifying doses, or
            - A continuous infusion of at least one high-dose intravenous inotrope, or:
                - Dobutamine greater than or equal to 7.5 mcg/kg/min
                - Milrinone greater than or equal to 0.50 mcg/kg/min
                - Epinephrine greater than or equal to 0.02 mcg/kg/min
            - A continuous infusion of at least two intravenous inotropes:
                - Dobutamine greater than or equal to 3 mcg/kg/min
                - Milrinone greater than or equal to 0.25 mcg/kg/min
                - Epinephrine greater than or equal to 0.01 mcg/kg/min
                - Dopamine greater than or equal to 3 mcg/kg/min
        b. Developed ventricular tachycardia lasting at least 30 seconds or required cardioversion, defibrillation, or antitachycardia pacing after inotropic therapy was initiated in an attempt to reach the qualifying doses
- If hemodynamic measurements could not be obtained within 7 days prior to percutaneous endovascular mechanical circulatory support, at least *one* of the following ~~is~~ was true within 24 hours prior to percutaneous endovascular mechanical circulatory support:
    - CPR was performed on the candidate
    - Systolic blood pressure less than 70 mmHg
    - Arterial lactate greater than 4 mmol/L
    - Aspartate transaminase (AST) or alanine transaminase (ALT) greater than 1,000 U/L

Candidates that meet the criteria above will remain in this status for up to 14 days from submission of the *Heart Status 2 Justification Form*. Every 14 days, the transplant program may apply to the RRB to extend the candidate's status if the candidate remains supported by the percutaneous endovascular mechanical circulatory support device. The transplant program must provide to the RRB objective evidence of *both* of the following:

1. The candidate demonstrated a contraindication to being supported by a durable device, and
2. Either

a. Within 48 hours prior to the status expiring, the transplant program ~~failed at weaning~~ <u>demonstrated a failure to wean</u> the candidate from the percutaneous endovascular mechanical circulatory support device evidenced by ~~at least *one* of the following~~:

- ~~Mean arterial pressure (MAP) less than 60 mmHg~~
- ~~Cardiac index less than 2.0 L/min/m^2~~
- ~~Pulmonary capillary wedge pressure greater than 15 mmHg~~
- ~~SvO_2 less than 50 percent measured by central venous catheter~~

<u>*at least one* of the following while being supported by inotropic therapy at a qualifying dose, or:</u>

- <u>Mean arterial pressure (MAP) less than 60 mmHg</u>
- <u>Cardiac index less than 2.0 L/min/m^2</u>
- <u>Pulmonary capillary wedge pressure greater than 15 mmHg</u>
- <u>SvO_2 less than 50 percent measured by central venous catheter</u>

b. <u>The candidate had qualified for status 2 after requiring a percutaneous endovascular mechanical circulatory support device due to failure to be supported on inotropes related to ventricular tachycardia lasting at least 30 seconds, or requiring cardioversion, defibrillation, or antitachycardia pacing.</u>

The RRB will retrospectively review extension requests. If the candidate is still supported by the percutaneous endovascular mechanical circulatory support device after 14 days and either the extension request is not granted or the transplant program does not request an extension, then the transplant program may assign the candidate to status 3.

6.1.B.v: Intra-Aortic Balloon Pump (IABP)

A candidate's transplant program may assign a candidate to adult status 2 if the candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and is supported by an IABP for cardiogenic shock as evidenced by *either* of the following:

- Within 7 days prior to IABP support, ~~*all* of the following are true within one 24 hour period~~ <u>*both* of the following are true</u>:
    1. <u>*All* of the following hemodynamic measurements were obtained for the candidate within one 24-hour period, and:</u>
        a. Systolic blood pressure <u>of</u> less than 90 mmHg
        b. Cardiac index <u>of</u> ~~less than 1.8 L/min/m^2 if the candidate is not supported by inotropes or~~ less than 2.0 L/min/m^2 ~~if the candidate is supported by inotropes~~
        c. Pulmonary capillary wedge pressure <u>of</u> greater than 15 mmHg
    2. <u>The candidate *either*:</u>
        a. <u>Was being supported by inotropic therapy according to either of the following qualifying doses, or</u>
            - <u>A continuous infusion of at least one high-dose intravenous inotrope, or:</u>
                - <u>Dobutamine greater than or equal to 7.5 mcg/kg/min</u>
                - <u>Milrinone greater than or equal to 0.50 mcg/kg/min</u>
                - <u>Epinephrine greater than or equal to 0.02 mcg/kg/min</u>
            - <u>A continuous infusion of at least two intravenous inotropes:</u>
                - <u>Dobutamine greater than or equal to 3 mcg/kg/min</u>
                - <u>Milrinone greater than or equal to 0.25 mcg/kg/min</u>

        - Epinephrine greater than or equal to 0.01 mcg/kg/min
        - Dopamine greater than or equal to 3 mcg/kg/min
    b. Developed ventricular tachycardia lasting at least 30 seconds or required cardioversion, defibrillation, or antitachycardia pacing after inotropic therapy was initiated in an attempt to reach the qualifying doses

- If hemodynamic measurements could not be obtained within 7 days prior to IABP support, at least *one* of the following ~~is~~ was true within 24 hours prior to IABP support:
    - CPR was performed on the candidate
    - Systolic blood pressure less than 70 mmHg
    - Arterial lactate greater than 4 mmol/L
    - Aspartate transaminase (AST) or alanine transaminase (ALT) greater than 1,000 U/L

Candidates that meet the criteria above will remain in this status for up to 14 days from submission of the *Heart Status 2 Justification Form*. Every 14 days, the transplant program may apply to the RRB to extend the candidate's status if the candidate remains supported by the IABP. The transplant program must provide to the RRB objective evidence of *both* of the following:

1. The candidate demonstrated a contraindication to being supported by a durable device, and
2. Either
    a. Within 48 hours prior to the status expiring, the transplant program ~~failed to wean~~ demonstrated a failure to wean the candidate from the IABP ~~as~~ evidenced by ~~at least *one* of the following~~:
    - ~~Mean arterial pressure (MAP) less than 60 mmHg~~
    - ~~Cardiac index less than 2.0 L/min/m^2~~
    - ~~Pulmonary capillary wedge pressure greater than 15 mmHg~~
    - ~~SvO_2 less than 50 percent measured by central venous catheter~~

    at least one of the following, while being supported by inotropic therapy at a qualifying dose, or:
        - Mean arterial pressure (MAP) less than 60 mmHg
        - Cardiac index less than 2.0 L/min/m^2
        - Pulmonary capillary wedge pressure greater than 15 mmHg
        - SvO_2 less than 50 percent measured by central venous catheter

    b. The candidate had qualified for status 2 after requiring the IABP due to failure to be supported on inotropes related to ventricular tachycardia lasting at least 30 seconds, or requiring cardioversion, defibrillation, or antitachycardia pacing.

The RRB will retrospectively review extension requests. If the candidate is still supported by the IABP after 14 days and either the extension request is not granted or the transplant program does not request an extension, then the transplant program may assign the candidate to status 3.