Adult Heart and HeartLung Status 2 Initial Justification Form Medical Urgency Data

The Adult Heart Status 2 Justification form displays for completion when assigning the candidate to status 2.

All required data must be submitted in order to list a candidate at status 2, or extend their listing at status 2, in accordance with criteria that are specified in OPTN Policy. For guidance and details on adult heart exceptions for status 2 candidates experiencing cardiogenic shock, see guidance document.

If you do not submit this form to extend the candidate's status beyond the time frame described in policy, the candidate will automatically be downgraded to status 5 (if the candidate is registered for at least one other organ at the same transplant hospital) or status 6. The heart review board will review all adult candidates registered at status 2 by exception.

Note: All fields denoted with an **R** are required and must be completed. Submitted forms cannot be edited.

Status 2 Justification Form Section IV

To qualify for status 2, the candidate must meet one of the following criteria.

Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD)

Candidate is admitted to the transplant center that registered the candidate on the waiting list, is supported by a surgically implanted, non-endovascular LVAD, and must remain hospitalized because the device is not FDA approved for out of hospital use.

Total artificial heart (TAH), BiVAD, right ventricular assist device (RVAD), or ventricular assist device (VAD) for single ventricle patients

Candidate is supported by a TAH, BiVAD, RVAD, or VAD for single ventricle patients.

Mechanical circulatory support device (MCSD) with malfunction

Candidate is admitted to the transplant center that registered the candidate on the Waitlist℠ and is supported by an MCSD that is experiencing device malfunction as evidenced by all of the following.

- Malfunction of at least one of the components of the MCSD
- The malfunction cannot be fixed without an entire device replacement
- The malfunction is currently causing inadequate circulatory support or places the candidate in imminent risk of device stoppage

Percutaneous endovascular mechanical circulatory support device

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 for cardiogenic shock.

Within 7 days prior to support (select one of the following):

- Hemodynamic measurements were obtained within one 24 hour period

- Cardiac index was less than 2.0 L/min/m^2 AND
- Pulmonary capillary wedge pressure was greater than 15 mmHg AND
- Systolic blood pressure was less than 90 mmHg

Enter a value for each of the following fields:

- **Cardiac index:** Enter the candidate's cardiac index in L/min/m^2. The entry must be less than 2.0 L/min/m^2. Enter the **Test Date** of when the cardiac index value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the Test Time. The time must be in the following 24-hour format: HH:MM. This is a **required** field.
- **Pulmonary capillary wedge pressure:** Enter the candidate's pulmonary capillary wedge pressure in mmHg. The entry must fall between 16 and 100 mmHg. Enter the **Test Date** of when the PCWP value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the Test Time. The time must be in the following 24-hour format: HH:MM. This is a **required** field.
- **Systolic blood pressure:** Enter the candidate's systolic blood pressure in mmHg. The entry must fall between 50 and 89 mmHg. Enter the **Test Date** of when the systolic blood pressure was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the Test Time. The time must be in the following 24-hour format: HH:MM. This is a **required** field.

AND the candidate (select one of the following):

- Was being supported by inotropic therapy according to either of the following qualifying doses:
  - A continuous infusion of **at least one high dose** intravenous inotrope:
    - 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 3mcg/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
- 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

- Hemodynamic measurements were not obtained. However, within 24 hours prior to percutaneous endovascular mechanical support:
  - CPR was performed on the candidate OR

- Systolic blood pressure was less than 70 mmHg **OR**
- Arterial lactate was greater than 4.0 mmol/L **OR**
- Aspartate transaminase was greater than 1,000 U/L **OR**
- Alanine transaminase was greater than 1,000 U/L

Enter a qualifying value for at least one of the following:

- **Date of administration of CPR:** Enter the date of administration of CPR. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. Enter the time that CPR was administered. The time must be in the following 24-hour format: HH:MM.
- **Systolic blood pressure:** Enter the candidate's systolic blood pressure in mmHg. The entry must fall between 50 and 69 mmHg. Enter the **Test Date** of when the systolic blood pressure was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM.
- **Arterial lactate:** Enter the candidate's arterial lactate in mmol/L. The entry must fall between greater than 4 and 50 mmol/L. Enter the **Test Date** of when the arterial lactate value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM.
- **Aspartate transaminase:** Enter the candidate's aspartate transaminase in U/L. The entry must fall between 1001 and 40000 U/L. Enter the **Test Date** of when the aspartate transaminase value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM.
- **Alanine transaminase:** Enter the candidate's alanine transaminase in U/L. The entry must fall between 1001 and 40000 U/L. Enter the **Test Date** of when the alanine transaminase value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM.

Intra-aortic balloon pump (IABP)

Candidate is admitted to the transplant hospital that registered the candidate on the waiting list and is supported by IABP for cardiogenic shock**.**

Within 7 days prior to support (select one of the following):

- Hemodynamic measurements were obtained and within one 24 hour period:
  - Cardiac index was:
    - Less than 1.8 L/min/m^2 if the candidate was not supported by inotropes or
    - Less than 2.0 L/min/m^2 if the candidate was supported by inotropes
  - Pulmonary capillary wedge pressure was greater than 15 mmHg and
  - Systolic blood pressure was less than 90 mmHg

  Enter a value for each of the following fields:

  - **Cardiac index:** Enter the candidate's cardiac index in L/min/m^2. The entry must be less than 2.0 L/min/m^2. Enter the **Test Date** of when the

cardiac index value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the Test Time. The time must be in the following 24-hour format: HH:MM. This is a **required** field.

- **Pulmonary capillary wedge pressure:** Enter the candidate's pulmonary capillary wedge pressure in mmHg. The entry must fall between 16 and 100 mmHg. Enter the **Test Date** of when the PCWP value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the Test Time. The time must be in the following 24-hour format: HH:MM. This is a **required** field.
- **Systolic blood pressure:** Enter the candidate's systolic blood pressure in mmHg. The entry must fall between 50 and 89 mmHg. Enter the **Test Date** of when the systolic blood pressure was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the Test Time. The time must be in the following 24-hour format: HH:MM. This is a **required** field.

AND the candidate (select one of the following):

- Was being supported by inotropic therapy according to either of the following qualifying doses:
  - A continuous infusion of at least one high dose intravenous inotrope:
    - 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 3mcg/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
- 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

- Hemodynamic measurements were not obtained. However, within 24 hours prior to IABP support:
  - CPR was performed on the candidate OR
  - Systolic blood pressure was less than 70 mmHg OR
  - Arterial lactate was greater than 4.0 mmol/L OR
  - Aspartate transaminase was greater than 1,000 IJ/L OR
  - Alanine transaminase was greater than 1,000 IJ/L

  Enter a qualifying value for at least one of the following:

- **Date of administration of CPR:** Enter the date of administration of CPR. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. Enter the time that CPR was administered. The time must be in the following 24-hour format: HH:MM.
- **Systolic blood pressure:** Enter the candidate's systolic blood pressure in mmHg. The entry must fall between 50 and 69 mmHg. Enter the **Test Date** of when the systolic blood pressure was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM.
- **Arterial lactate:** Enter the candidate's arterial lactate in mmol/L. The entry must fall between greater than 4 and 50 mmol/L. Enter the **Test Date** of when the arterial lactate value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM.
- **Aspartate transaminase:** Enter the candidate's aspartate transaminase in U/L. The entry must fall between 1001 and 40000 U/L. Enter the **Test Date** of when the aspartate transaminase value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM.
- **Alanine transaminase:** Enter the candidate's alanine transaminase in U/L. The entry must fall between 1001 and 40000 U/L. Enter the **Test Date** of when the alanine transaminase value was obtained. The date must be in the following format: MM/DD/YYYY. A calendar link is available. Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM.

Ventricular tachycardia (VT) or ventricular fibrillation (VF)

Candidate is admitted to the transplant center that registered the candidate on Waitlist℠ and is not considered a candidate for other treatment alternatives, such as ablation, by an electrophysiologist, and is experiencing recurrent or sustained VT or VF with at least three episodes separated by at least one hour within a period of 14 days. The VT or VF must have occurred in the setting of normal serum magnesium and potassium levels and required electrical cardioversion despite receiving antiarrhythmic therapies. ***Note:*** Anti-tachycardia pacing (ATP) qualifies as electrical cardioversion, in a hospitalized candidate experiencing VT on anti-arrhythmic medication.

Exception for status 2

Candidate does not meet any of the criteria above but is admitted to the transplant hospital that registered the candidate on the waiting list and has an urgency and potential for benefit comparable to that of other candidates at this status. A clinical narrative must be provided to support the candidate's eligibility at this status.

A transplant program may assign a candidate who does not meet any of the above status 2 criteria to status 2 by requesting an exception. The candidate must be admitted to the transplant hospital that registered the candidate on the waiting list, and the program must explain why it considers the candidate to have an urgency and potential for benefit comparable to other status 2 candidates using acceptable medical criteria. The review board will retrospectively review exception requests. If the review board denies an exception request, then within one day of receiving notification of the denial, the candidate's transplant program must either appeal to the review board or assign the candidate to the status for which the candidate qualifies.

This exception request is specifically related to a device recall: Select the checkbox if applicable.

Clinical Narrative: Enter a clinical narrative which supports the eligibility of the candidate for an exceptional case. ***Note:*** A maximum of 5000 characters is accepted.