Adult Heart and HeartLung Status 1 Initial Justification Form Medical Urgency Data

You will be informed of any downgrades that are pending in the Critical Data section of Secure Enterprise. The “Extend” button will be available 2 days prior to expiration of the status.

All required data must be submitted in order to list a candidate at status 1, or extend their listing at status 1, in accordance with criteria that are specified in OPTN Policy. Use the search feature to locate specific policy information concerning adult heart status requirements.

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, including VCA registrations) or status 6. Heart-Lung candidates will downgrade to status 5 since they are in need of two organs; a heart and a lung.

Status 1 Extension Criteria 1

To qualify for status 1, the patient must meet one of the following criteria.

Veno-Arterial Extracorporeal Membrane Oxygenation (VA ECMO)

Candidate is admitted to the transplant center that registered the candidate on the waitlist and is supported by VA ECMO for cardiogenic shock. Within 7 days prior to support.

Select one of the following:

Hemodynamic measurements were obtained and within 24-hour period

- Cardiac index was:
  - Less than 1.8 L/min/m^2 if the candidate was not supported by an inotrope or
  - Less than 2.0 L/min/m^2 if the candidate was supported by at least one inotrope
- Pulmonary capillary wedge pressure was greater than 15 mmHg and
- Systolic blood pressure was less than 90 mmHg

Was the candidate on inotropes at the time cardiac index was obtained?: If the candidate was on inotropes at the time cardiac index was obtained, select **Yes**. If not, select **No**. This is a **required** field.

Cardiac index: Enter the candidate’s cardiac index in L/min/m^2. The entry must fall between 0 and 1.79 if the candidate was not supported by inotropes and must be less than 2.0 L/min/m^2 if the candidate was supported by inotropes.

Cardiac index - Test Date 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.

Cardiac index - Test Time Enter the Test Time. The time must be in the following 24-hour format: HH:MM. Time must be in military format. 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.

Pulmonary capillary wedge pressure - Test Date 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**.

Pulmonary capillary wedge pressure - Test Time The time must be in the following 24-hour format: HH:MM. Time must be in military format. 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 Time**.

Systolic blood pressure - Test Date 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.

Systolic blood pressure - Test Time The time must be in the following 24-hour format: HH:MM. Time must be in military format. This is a **required** field.

Hemodynamic measurements were not obtained. However, within 24 hours prior to ECMO support:

- CPR was performed on the candidate or
- systolic blood pressure was less than 70 mmHg or
- arterial lactate was greater than 4 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.

Date of administration of CPR - Test Time: Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Systolic blood pressure: Enter the candidate's systolic blood pressure in mmHg. The entry must fall between 50 and 69 mmHg.

Systolic blood pressure - Test Date: 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.

Systolic blood pressure - Test Time: Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Arterial lactate: Enter the candidate's arterial lactate in mmol/L. The entry must fall between greater than 4 and 50 mmol/L.

Arterial lactate - Test Date: 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. E

Arterial lactate - Test Time: Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Aspartate transaminase: Enter the candidate's aspartate transaminase in U/L. The entry must fall between 1001 and 40000 U/L.

Aspartate transaminase - Test Date: 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.

Aspartate transaminase - Test Time: Enter the **Test Time**. The time must be in the following 24-hour format: HH:MM. Time must be in military format.

Alanine transaminase: Enter the candidate's alanine transaminase in U/L. The entry must fall between 1001 and 40000 U/L.

Alanine transaminase - Test Date: 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.

Non-dischargeable, surgically implanted, non-endovascular biventricular support device: Candidate is admitted to the transplant center that registered the candidate on the waitlist, is supported by a surgically implanted, non-endovascular biventricular support device, and must remain hospitalized because the device is not FDA-approved for out of hospital use.

Mechanical circulatory support device (MCSD) with life threatening ventricular arrhythmia: Candidate is admitted to the transplant center that registered the candidate on the waitlist, is supported by an MCSD, and is experiencing recurrent or sustained ventricular tachycardia or ventricular fibrillation. Select at least one of the following:

Placement of a biventricular MCSD: Placement of a biventricular mechanical circulatory support device for the treatment of sustained ventricular arrhythmias.

Patient not considered for other treatments: The patient was not considered a candidate for other treatment alternatives, such as ablation, by an electrophysiologist, and has experienced 3 or more episodes of ventricular fibrillation or ventricular tachycardia separated by at least an hour, over the previous 7 days that both:

- Occurred in the setting of normal serum magnesium and potassium levels
- Required electrical cardioversion despite receiving continuous intravenous antiarrhythmic therapies

Exception for status 1: 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 1 criteria to status 1 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 1 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

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.