Adult Heart and HeartLung Status 2 Criteria 4 Extension Justification Form Medical Urgency Data

To qualify for status 2 extension, the patient must meet one of the following criteria:

1. Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD)
2. Total artificial heart (TAH), BiVAD, right ventricular assist device (RVAD), or ventricular assist device (VAD) for single ventricle patients
3. Mechanical circulatory support device (MCSD) with malfunction
4. Percutaneous endovascular mechanical circulatory support device
5. Intra-aortic balloon pump
6. Ventricular tachycardia (VT) or ventricular fibrillation (VF)
7. Exception for status 2

Criterion selection made on the candidate's initial justification form displays. Verify that the correct criterion is selected. If you wish to select a different criterion, you must submit a new form.

Status 2 Extension Criteria 4

If status 2, criteria 4: Percutaneous endovascular mechanical circulatory support device, is selected, enter the following information:

Percutaneous endovascular mechanical circulatory support device

Candidate is admitted to the transplant center that registered the candidate on Waitlist 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 and within 24 hour period

- Cardiac index was less than 2.0 L/min/m^2
- pulmonary capillary wedge pressure was greater than 15 mmHg and
- systolic blood pressure was less than 90 mmHg

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 were 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. 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. 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. 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 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. Time must be in military format. This is a **required** field.

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. 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. 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. 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. 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. 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. Time should 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. 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. 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. 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. Time must be in military format.

Extending the candidate's status under criteria 4

The candidate qualifies for an extension if the following requirements are met:

The candidate remains supported by percutaneous device and demonstrated contraindication to being supported by a durable device.

Provide a clinical narrative for contraindication to being supported by a durable device. ***Note:*** A maximum of 5000 characters is accepted.

Select one of the following

Within 48 hours prior to the status expiring, the transplant program failed at weaning the candidate from acute percutaneous endovascular circulatory support device 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 15mmHg
- SvO_2 less than 50 percent measured by central venous catheter

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

Mean arterial pressure: Enter the candidate's mean arterial pressure in mmHg. Enter the **Test Date** of when the mean arterial 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. Time must be in military format. This is a **required** field.

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 were 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. 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. 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. Time must be in military format. This is a **required** field.

SvO_2: Enter the percent of the candidate's SvO_2. Enter the **Test Date** of when the SvO_2 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. Time must be in military format. This is a **required** field.

Note: Test dates and times must be two days prior to expiration date.

Example – if the expiration date of a form is 1/15/2018, then the acceptable window for test dates is on or after 01/13/2018 for all time zones.

Within 48 hours prior to the status expiring, the candidate 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

Public Burden Statement: The private, non-profit Organ Procurement and Transplantation Network (OPTN) collects this information in order to perform the following OPTN functions: to assess whether applicants meet OPTN Bylaw requirements for membership in the OPTN; and to monitor compliance of member organizations with OPTN Obligations. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0915-0157 and it is valid until XX/XX/202X. This information collection is required to obtain or retain a benefit per 42 CFR §121.11(b)(2). All data collected will be subject to Privacy Act protection (Privacy Act System of Records #09-15-0055). Data collected by the private non-profit OPTN also are well protected by a number of the Contractor's security features. The Contractor's security system meets or exceeds the requirements as prescribed by OMB Circular A-130, Appendix III, Security of Federal Automated Information Systems, and the Departments Automated Information Systems Security Program Handbook. The public reporting burden for this collection of information is estimated to average 0.27 hours per response, including the time for reviewing instructions, searching existing data sources, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Information Collection Clearance Officer, 5600 Fishers Lane, Room 14N39, Rockville, Maryland, 20857 or paperwork@hrsa.gov.