

Adult Heart and HeartLung Status 2 Criteria 1 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 1

If status 2, criteria 1: Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD), is selected, enter the following information:

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.

Extending the candidate's status under criteria 1

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

The candidate remains supported by LVAD 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.

Within 48 hours prior to the status expiring, the transplant program failed at weaning the candidate from the LVAD 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/m²
- Pulmonary capillary wedge pressure greater than 15mmHg
- SVO₂ 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/m². The entry must fall between 0 and 1.79 L/min/m² if the candidate was not supported by inotropes and must be less than 2.0 L/min/m² if the candidate was supported by inotropes. 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. 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.

SvO₂: Enter the percent of the candidate's SvO₂. The entry must fall between 50 and 89 mmHg. Enter the **Test Date** of when the SvO₂ 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: The candidate's status expires at midnight Eastern Time. Test dates and times must be within 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.

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.