Adult Heart and HeartLung Status 3 Initial Justification Form Medical Urgency Data

The Adult Heart Status 3 Justification form displays for completion when assigning the candidate to status 3.

All required data must be submitted in order to list a candidate at status 3, or extend their listing at status 3, in accordance with criteria that are specified in OPTN Policy.

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.

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

Status 3 Justification Form Section IV

To qualify for status 3, the candidate must meet one of the following criteria.

Dischargeable left ventricular assist device (LVAD) for discretionary 30 days
Candidate is supported by a dischargeable LVAD. The 30 days do not have to be consecutive. If the candidate undergoes a procedure to receive another replacement dischargeable LVAD, then the candidate qualifies for a new term of 30 days. When a candidate receives a replacement device, the 30 day period begins again, and the candidate cannot use any time remaining from the previous period.

Multiple inotropes or a single high dose inotrope and hemodynamic monitoring
Candidate is admitted to the transplant hospital that registered the candidate on the waiting list. Within 7 days prior to inotrope administration or while on inotropes, all of the following are true.

Select one of the following:

Candidate has an invasive pulmonary artery catheter

Candidate has daily hemodynamic monitoring to measure cardiac output and left ventricular filling pressures

Candidate is supported by either:

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

The candidate is in cardiogenic shock as evidenced by all the following values obtained within one 24 hour period

Cardiac index was:

- Less than 1.8 L/min/m^2 if the candidate was not on inotropic or mechanical support within 7 days prior to inotrope administration or
- Less than 2.2 L/min/m^2 if the candidate was on inotropic or mechanical support

Pulmonary capillary wedge pressure greater than 15 mmHg

Systolic blood pressure less than 90 mmHg

Was the candidate on inotropic or mechanical support at the time cardiac index was obtained?: If the candidate was on inotropic or mechanical support at the time of cardiac arrest, 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 L/min/m^2 if the candidate was not on inotropic or mechanical support and must be less than 2.2 L/min/m^2 if the candidate was on inotropic or mechanical support. 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.

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.

Mechanical circulatory support device (MCSD) with hemolysis

Candidate is supported by an MCSD that is not experiencing device malfunction, but is experiencing hemolysis, as evidenced by both of the following:

Two separate samples collected within 48 hours of each other confirming markers of active hemolysis as evidenced by at least two of the following:

- Blood lactate dehydrogenase (LDH) at least 2.5 times the upper limit of normal at the laboratory reference range
- Plasma free hemoglobin greater than 20 mg/dL
- Hemoglobinuria

- Documentation is available of at least one attempt to treat the condition using an intravenous anticoagulant, intravenous anti-platelet agent, or thrombolytic, with persistent or recurrent hemolysis.

Mechanical circulatory support device (MCSD) with pump thrombosis

Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by MCSD, and the transplant program has identified a suspected pump thrombosis in either an implanted LVAD or a dischargeable paracorporeal device and both of the following criteria are met:

The candidate has one of the following conditions:

Transient Ischemic Attack (TIA) lasting less than 24 hours or Reversible Ischemic Neurologic Deficit (RIND) lasting less than 72 hours (as observed by symptoms such as, but not limited to unilateral facial weakness, vision problems, and/or slurred speech), Cerebrovascular Accident (CVA), or peripheral thromboembolic event in the absence of intracardiac thrombus or significant carotid artery disease

A condition that requires inotropic support and presence of leftsided heart failure not explained by structural heart disease such as Aortic Insufficiency (AI) as demonstrated by

- Pulmonary Capillary Wedge Pressure (PCWP) greater than 15, and
- Mean Arterial Pressure (MAP) less than 90

Abnormal pump parameters, such as significant and persistent increase in pump power and low flow despite good blood pressure control

Visually detected thrombus in a paracorporeal ventricular device (VAD)

AND The candidate is supported by one of the following treatments in the hospital:

- Intravenous anticoagulation (e.g., heparin)
- Intravenous thrombolytics (e.g., tPA)
- Intravenous antiplatelet therapy (e.g., eptifibatide or tirofiban)

Mechanical circulatory support device (MCSD) with right heart failure

Candidate is supported by an MCSD and has at least moderate right ventricular malfunction in the absence of the left ventricular assist device (LVAD) malfunction and meets the following qualifying requirements:

Has been treated with at least one of the following therapies for at least 14 consecutive days and requires ongoing treatment with at least one of the following therapies:

Dobutamine: Enter the dosage of dobutamine in mcg/kg/min. The entry must fall between 5 and 999 mcg/kg/min. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

Dopamine: Enter the dosage of dopamine in mcg/kg/min. The entry must fall between 4 and 999 mcg/kg/min. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

Epinephrine: Enter the dosage of epinephrine in mcg/kg/min. The entry must fall between 0.05 and 999 mcg/kg/min. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

Milrinone: Enter the dosage of milrinone in mcg/kg/min. The entry must fall between 0.35 and 999 mcg/kg/min. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

Inhaled nitric oxide: Select checkbox, if applicable. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

Intravenous prostacyclin: Select checkbox, if applicable. Enter the **Date of Initiation**. The date must be in the following format: MM/DD/YYYY. A calendar link is available.

Within 7 days prior to initiation of any of the therapies above, all of the following are true within one 24 hour period:

Pulmonary capillary wedge pressure less than 20 mmHg

Central venous pressure greater than 18 mmHg

Pulmonary capillary wedge pressure: Enter the candidate's pulmonary capillary wedge pressure in mmHg. The entry must fall between 0 and 19 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.

Central venous pressure: Enter the candidate's central venous pressure in mmHg. The entry must fall between 19 and 50 mmHg. Enter the **Test Date** of when the CVP 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.

Mechanical circulatory support device (MCSD) with device infection

Candidate is supported by an MCSD, is experiencing a pump-related local or systemic infection and has one of the following symptoms or continues to require IV antibiotics:

- Erythema and pain along the driveline with either leukocytosis or a 50 percent increase in white blood cell count from the last recorded white blood cell count, and either:
    - Positive bacterial or fungal cultures from the driveline exit site within the last 14 days
    - A culture positive fluid collection between the exit site and the device
- Debridement of the driveline with positive cultures from sites between the exit site and the device requiring IV antibiotics
- Recurrent debridement
- Positive culture of material from the pump pocket of an implanted device
- Bacteremia treated with antibiotics
- Recurrent bacteremia that recurs from the same organism within four weeks following antibiotic treatment to which the bacteria is susceptible

Mechanical circulatory support device (MCSD) with mucosal bleeding

Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, and meets all of the following qualifying requirements:

- Is supported by an MCSD
- Has been hospitalized for mucosal bleeding at least two times within the past six months, excluding the candidate's hospitalization for implantation of the MCSD
- The candidate has received blood transfusions of at least two units of packed red blood cells per hospitalization during at least two hospitalizations for mucosal bleeding
- The candidate's international normalized ratio (INR) was less than 3.0 at the time of at least one of the bleeds
- The candidate's hematocrit upon admission is less than or equal to 0.20 or decreased by 20 percent or more relative to the last measured value at any time during the bleeding episode

  Number of hospitalizations for mucosal bleeding within the past six months: Select **2** or **3 or more**.
  Note: Hospitalizations must exclude candidate's hospitalization for implantation of the MCSD.

Mechanical circulatory support device (MCSD) with aortic insufficiency (AI)

Candidate is supported by an MCSD and is not exhibiting evidence of device malfunction, but is experiencing AI and meets all of the following requirements:

- At least moderate AI by any imaging modality in the setting of the mean arterial pressure (MAP) less than or equal to 80 mmHg
- Pulmonary capillary wedge pressure greater than 20 mmHg
- New York Heart Association (NYHA) Class III-IV symptoms
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Veno-arterial extracorporeal membrane oxygenation (VA ECMO) after 7 days

Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by VA ECMO, and the transplant hospital has already assigned the candidate to status 1 under the VA ECMO criteria for 7 days.
Note: The system will not allow this selection unless the prerequisites have been met.

Non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD) after 14 days

Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by a non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD), and the transplant hospital has already assigned the candidate to status 2 under the non-dischargeable, surgically implanted, non-endovascular left ventricular assist device (LVAD)criteria for 14 days.
Note: The system will not allow this selection unless the prerequisites have been met.

Percutaneous endovascular circulatory support device after 14 days

Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by a percutaneous endovascular circulatory support device, and the

transplant hospital has already assigned the candidate to status 2 under the percutaneous endovascular circulatory support device criteria for 14 days.
Note: The system will not allow this selection unless the prerequisites have been met.

Intra-aortic balloon pump after 14 days
Candidate is admitted to the transplant hospital that registered the candidate on the waiting list, is supported by an intra-aortic balloon pump, and has already assigned the candidate to status 2 under the intra-aortic balloon pump criteria for 14 days.
Note: The system will not allow this selection unless the prerequisites have been met.

Mechanical Circulatory Support Device (MCSD) with life threatening ventricular arrhythmia after 7 days
Candidate is admitted to the transplant hospital that registered the candidate on the waitlist, has already been assigned to status 1 under Mechanical Circulatory Support Device (MCSD) with Life Threatening Ventricular Arrhythmia for 7 days criteria for 7 days, and is supported by:

Select at least one of the following:

- **Placement of a biventricular mechanical circulatory support device for the treatment of sustained ventricular arrhythmias.**
- **Receiving continuous intravenous antiarrhythmic therapy.**

Exception for status 3
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 3 criteria to status 3 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 3 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.

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.

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.