Adult Heart and HeartLung Status 4 Initial Justification Form Medical Urgency Data

The Adult Heart Status 4 Justification form displays for completion when assigning the candidate to status 4.

All required data must be submitted in order to list a candidate at status 4, or extend their listing at status 4, 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) or status 6. The heart review board will review all adult candidates registered at status 4 by exception.

Candidates that are downgraded to status 5 will remain in that status as long as they have one other listing at the same transplant hospital. If the other listing is removed, then they will be downgraded to status 6.

Example: A candidate is downgraded to status 5 because they have a heart listing and a kidney listing. If the kidney listing is removed, then the candidate will be downgraded to status 6.

No expected forms will be generated for candidates that are downgraded to status 5 or status 6. The candidates will be at status 5 or status 6 without a status justification form. Per policy, a status justification form must be submitted for all candidates listed at statuses 1 through 6. To obtain a list of candidates that are at status 5 and status 6 without a status justification form, use the Expected Adult Heart Justification Forms Report.

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

Status 4 Justification Form Section IV

To qualify for status 4, the candidate must meet one of the following criteria.

Dischargeable left ventricular assist device (LVAD) without discretionary 30 days

Candidate is supported by a dischargeable LVAD.

Inotropes without hemodynamic monitoring

Candidate is supported by a continuous infusion of a positive inotropic agent.

Requires treatment with at least one of the following intravenous inotropes:

Dobutamine: Enter the dosage of dobutamine in mcg/kg/min. The entry must fall between 3 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 0.25 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 0.01 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 3 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.

Meets the following qualifying requirements:

Cardiac index: Enter the candidate's cardiac index in L/min/m^2. The entry must fall between 0 and 2.19 within 7 days prior to inotropic administration or while on inotrope infusion. 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. ***Note:*** The test date for cardiac index must be within 7 days prior to, or anytime after, the date of initiation of one of the inotropes.

Pulmonary capillary wedge pressure: Enter the candidate's pulmonary capillary wedge pressure in mmHg. The entry must fall between 16 and 100. 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.

Congenital heart disease

Candidate is diagnosed with a hemodynamically significant congenital heart disease. Check all that apply.

Atrial Isomerism/Heterotaxy

Atrioventricular Septal Defect

Congenitally Corrected Transposition (L-TGA)

Double Outlet Right Ventricle

Ebstein's Anomaly

Hypoplastic Left Heart Syndrome

Other left Heart Valvar/Structural Hypoplasia

Pulmonary Atresia with Intact Ventricular Septum

Single Ventricle

Tetralogy of Fallot

Transposition of the Great Arteries

Truncus Arteriosus

Ventricular Septal Defect(s)

Other

Ischemic heart disease with intractable angina

Candidate is diagnosed with ischemic heart disease and has intractable angina with all of the following:

Coronary artery disease

Canadian cardiovascular society grade IV angina pectoris that cannot be treated by a combination of medical therapy, and percutaneous or surgical revascularization

Myocardial ischemia shown by imaging

Amyloidosis, or hypertrophic or restrictive cardiomyopathy

Candidate is diagnosed with at least one of the following:

Amyloidosis

Hypertrophic cardiomyopathy

Restrictive cardiomyopathy

Candidate meets at least one of the following requirements:

Canadian Cardiovascular Society Grade IV angina pectoris that cannot be controlled by medical therapy

New York Heart Association (NYHA) Class III-IV symptoms with either:

- **Cardiac index less than 2.2 L/min/m^2**
- **Left or right atrial pressure, left or right ventricular end-diastolic pressure, or pulmonary capillary wedge pressure greater than 20 mmHg**

Ventricular tachycardia lasting at least 30 seconds

Ventricular fibrillation

Ventricular arrhythmia requiring electrical cardioversion

Sudden cardiac death

Retransplant

Candidate has had a previous heart transplant and there is evidence of International Society of Heart and Lung Transplantation (ISHLT) coronary allograft vasculopathy (CAV) grade 2-3, or New York Heart Association (NYHA) Class III-IV heart failure symptoms. ***Note:*** Previous heart transplants include non-US transplants.

Exception for status 4

Candidate does not meet any of the criteria above, but has an urgency and potential for benefit comparable to that of other candidates at this status. Provide a clinical narrative below 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 4 criteria to status 4 by requesting an exception. The program must explain why it considers the candidate to have an urgency and potential for benefit comparable to other status 4 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.

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.