Pediatric Heart and Heart/Lung Status 1A Initial Justification Form

The Heart or Heart/Lung Status 1A justification form displays for completion when upgrading a pediatric candidate to 1A or extending a status 1A candidate.

You must complete and submit all required data on this form in UNet in order to list a patient as status 1A, or extend their listing as status 1A, in accordance with the criteria that are specified in policy. If you do not submit this form to extend the patient's status beyond the time frame described below and in policy, the patient will automatically be downgraded to status 1B. You may apply for an exception for a candidate who does not meet the status 1A criteria if the transplant program believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other 1A candidates. The heart review board will review all pediatric candidates registered as status 1A by exception.

Candidates who meet criteria will be automatically approved for the requested status.

You must recertify pediatric patients listed under status 1A criteria every 14 days to continue the status 1A listing. To manage exceptions or extensions for your candidate please use the Pediatric Heart Exception – Extension Management Report.

If a pediatric candidate is temporarily unsuitable for transplant, then the candidate's transplant program may assign the candidate inactive status and the candidate will not receive any heart offers.

See OPTN Policies for additional information. Use the search feature to locate specific policy information on Pediatric Candidate Status.

Note: Completed forms cannot be edited by a member. To report a data discrepancy, or for help resolving data discrepancies, please contact the UNet^{SM} Help Desk by calling (800) 978-4334, or e-mailing unethelpdesk@unos.org.

Status

Form title: The title indicates the age group, organ group, and the type of form.

Case number: This is the group of forms associated with an initial 1A form. This Includes extensions and any appeals.

Submitted date: The timestamp of when the form was submitted displays.

Resolved date: The timestamp of when the form was resolved (Approved or Denied) displays. For forms that are auto-approved because they meet criteria, the date Resolved is the same as the date Submitted.

Status: The status of the form displays. This will vary based on the form's disposition.

Effective: The dates that the form will be active display. For instance, the last date the form can be used is 6/4/21. If an extension is not submitted by 6/4, the system will automatically downgrade the candidate at 12 AM EST on 6/5.

Information

Transplant Center: Verify that the transplant center is correct.

Name: Verify that the patient's name is displayed correctly.

Date of birth: Verify that the patient's date of birth is correct.

WaitList ID: Verify that the patient's waitlist ID number is correct.

SSN: Verify that the patient's social security number is correct.

ABO: The patient's ABO displays.

Diagnosis

Diagnosis: The candidate's diagnosis displays.

Criteria

To qualify for status 1A, the patient must either meet at least one of the criteria below (select all that apply) or an exception request must be submitted to the NHRB for review. For more information, review the NHRB guidance document.

By criteria: Is admitted to the transplant hospital that registered the candidate on the waiting list and:

Requires continuous mechanical ventilation

Requires assistance of an intra-aortic balloon pump

Has ductal dependent pulmonary or system circulation, with ductal patency maintain by stent or prostaglandin infusion

Has a hemodynamically significant congenital heart disease diagnosis, and requires infusion of multiple intravenous inotropes or a high dose of single intravenous inotrope

Congenital Heart Disease Diagnosis (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

IV Inotropic Support

Requires infusion of a single high-dose intravenous inotrope (i.e., dobutamine greater than or equal to 7.5 mcg/kg/min, milrinone greater than or equal to 0.50 mcg/kg/min, dopamine greater than or equal to 7.5 mcg/kg/min, or epinephrine greater than or equal to 0.02 mcg/kg/min) or multiple intravenous inotropes.

Enter a dosage value for at least one of the inotropes below:

Dobutamine: Enter the value in mcg/kg/min. The normal therapeutic range falls between 1 to 30.

Dopamine: Enter the value in mcg/kg/min. The normal therapeutic range falls between 1 to 30.

Milrinone: Enter the value in mcg/kg/min. The normal therapeutic range falls between 0.1 to 3.

Epinephrine: Enter the value in mcg/kg/min. The normal therapeutic range falls between 0.01 to 10.

Norepinephrine (**Levophed**): Ener the value in mcg/kg/min. The normal therapeutic range falls between 0.1 to 10. ***Note:*** Acceptable as a justification for this criterion only if administered with one or more of the inotropes listed above.

Vasoactive Support

The following medicines are not eligible for meeting the single high-dose criteria, but are necessary for evaluating patient suitability.

IV Nitroglycerin: Enter the value in mcg/kg/min. The normal therapeutic range falls between 1 to 30.

Nesiritide (**Natrecor**): Enter the value in mcg/kg/min. The normal therapeutic range falls between 0.0005 to 0.05.

Nitroprusside (**Nipride**, **Nitropress**): Enter the value in mcg/kg/min. The normal therapeutic range falls between 0.05 to 10.

Phenylephrine (**Neo-Synephrine**): Enter the value in mcg/kg/min. The normal therapeutic range falls between 0.1 to 10.

Vasopressin (**Pitressin**): Enter the value in units/min. The normal therapeutic range falls between 0.1 to 10.

May or may not be admitted to the transplant hospital that registered the candidate on the waiting list and

Requires assistance of a mechanical circulatory support device

By exception

If the candidate is admitted to the transplant hospital that registered the candidate on the waiting list and the transplant physician believes, using acceptable medical criteria, that a heart candidate has an urgency and potential for benefit comparable to that of other candidates at the registered status.

Justification Narrative

Justification narrative: Enter a clinical narrative which supports the eligibility of the candidate for an exceptional case. Maximum of 5000 characters.

Authorization

Transplant physician name: Enter the name of the candidate's surgeon/physician. This is a **required** field.

Transplant physician NPI: Enter the NPI of the candidate's surgeon/physician. This is a **required** field.

Email decision to: Enter at least one and up to three email addresses to receive notification of the outcome of the vote. Including up to three email addresses may be important to account for time off or out-of-office. This is a **required** field.

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.