Pediatric Liver Status 1A Form

To assign a candidate status 1A, the candidate's transplant hospital must submit a Liver Status 1A Justification Form to the OPTN. A candidate is not registered as status 1A until this form is submitted.

Status 1A listing automatically reverts to MELD/PELD score ranking after 7 days unless relisted by an attending physician. To avoid automatic reversion, you must complete the Liver Status 1A Extension form. If an extension form is not completed by midnight on the seventh day then the candidate is assigned to the most recent MELD/PELD score. If no previous MELD/PELD score exists, the candidate is assigned a score of 6.

Pediatric Liver Status

Status: Verify the candidate's listing of Status 1A is correct.

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

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

Liver Status 1A Listing Date: Verify the candidate's liver Status 1A listing date is correct.

Initial Listing/Extension Form Effective Date: Verify the candidate's initial listing/extension form effective date is correct.

Patient Name: Verify that the candidate's name is correct.

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

Waitlist ID: Verify that the candidate's Waitlist ID number is correct.

Patient's Date of Birth: Verify that the candidate's date of birth is correct.

Transplant Center: Verify that the transplant center is correct.

Hospital Telephone Number: Enter the transplant hospital's telephone number. This is a **required** field.

<u>Height</u>: Enter the candidate's height in feet and inches or centimeters. The height must fall between 0 and 7 feet or 1 and 225 centimeters. This is a **required** field for pediatric candidates.

<u>Date</u>: Enter the date the candidate's height was measured.

Weight: Enter the weight of the candidate at the time of listing in the appropriate space, in pounds or kilograms. The weight must fall between 0 and 650 pounds or 0 and 295 kilograms. This is a **required** field for pediatric candidates.

<u>Date</u>: Enter the date the candidate was weighed.

Status 1A Criteria

Select one of the following criteria:

Fulminant liver failure: If the candidate has fulminant liver failure, select the condition(s) that apply:

A diagnosis of hepatic encephalopathy within 56 days of the first signs or symptoms of liver disease

Absence of pre-existing liver disease. For purposes of this section, any diagnoses of liver disease that occurred prior to a subsequent liver transplant do not constitute pre-existing liver disease.

Ventilator dependence

Requires dialysis

Requires continuous veno-venous hemofiltration (CVVH)

Requires continuous veno-venous hemodialysis (CVVHD)

Note: The INR value entered in the MELD/PELD Data Collection section of this form is also used to qualify for Status 1A.

Primary non-function of a transplanted liver?: If the candidate has primary non-function of a transplanted liver, complete the required questions. All laboratory results reported for any tests required for the primary non-function of a transplanted liver diagnosis must be from the same blood draw taken between 24 hours and 7 days after the transplant.

<u>Within how many days of transplantation</u>: Enter the number of days, between the transplant date and the current date, within which primary non-function occurred. This is a **required** field.

<u>Transplant Date</u>: Enter the date of the liver transplant using the format MM/DD/YYYY. This is a **required** field.

Draw Date: Enter the date the labs used to qualify for Status 1A were drawn using the format MM/DD/YYYY. If **Draw Date** is entered, enter at least one of the following values:

<u>ALT value</u>: Enter the alanine aminotransferase (ALT) value in U/L. The entry must fall between 0 and 20000.

Arterial pH value: Enter the arterial pH value. The entry must fall between 0 and 14.

Venous pH value: Enter the venous pH value. The entry must fall between 0 and 14.

Lactate value: Enter the lactate value in mmol/L. The entry must fall between 0 and 15.

Note: One of Arterial PH or Venous PH or Lactate values are used to define acidosis and together they only count as one of the two criteria necessary to qualify for pediatric Status 1A for primary non-function.

Note: The INR value entered in the MELD/PELD Data Collection section of this form is also used to qualify for Status 1A.

<u>Hepatic artery thrombosis (HAT) in a transplanted liver</u>: If the candidate had a hepatic artery thrombosis of a transplanted liver within 7 days of implantation, complete the following questions:

<u>Within how many days of transplantation</u>: Enter the number of days, between the transplant date and the current date, within which hepatic artery thrombosis occurred. This is a required field if Hepatic Artery Thrombosis is selected.

<u>Transplant Date</u>: Enter the date of the liver transplant using the format MM/DD/YYYY. This is a required field if Hepatic Artery Thrombosis is selected.

<u>Acute decompensated Wilson's disease</u>: If the candidate has acute decompensated Wilson's disease, complete the following field:

Enter Clinical Narrative: Enter a clinical narrative for this candidate (maximum of 5000 characters). This is a required field if Wilson's disease is selected.

Diagnosis: Enter the candidate's diagnosis. This is a **required** field.

Special Case

A candidate who **does not** meet the standard Status 1A/1B criteria may be assigned a Status 1A/1B upon application for a Special Case. Check the Special Case box and enter a clinical narrative. Centers that list candidates not meeting the standard criteria for Status 1A/1B will be referred to the OPTN/UNOS Liver and Intestine Transplantation Committee and the Membership and Professional Standards Committee for review.

Special Case: Click on the check box to indicate a special case request.

<u>To qualify for Status 1A/1B, provide a current/updated clinical narrative below to</u> <u>support the candidate's eligibility at this status</u>: Enter a narrative explaining your request for a special case Status 1A or 1B.

MELD/PELD Data Collection

Serum Creatinine: Enter the serum creatinine value. The value must fall between 0.10 to 20.00 mg/dl. This field is required for candidates who are 10 and older. If a serum creatinine value is entered, then enter the **Test Date** using the format MM/DD/YYYY. Also, if a serum creatinine value is entered, then select **Yes** or **No** for **Had dialysis twice within a week prior to the test**.

Had dialysis twice, or 24 hours of CVVHD, within a week prior to the serum creatinine test?: If candidate had dialysis twice, or 24 hours of CVVHD, within a week prior to the serum creatinine test, select Yes. If not, select No. If the candidate did not have serum creatinine test, select N/A. If the candidate is 10 or older, select Yes or No.

Serum Sodium: Enter the serum sodium value. The value must fall between 100.00 and 200.00 mg/dl. Next, enter the **Test Date** using the format MM/DD/YYYY.

Child-Turcotte Pugh (CTP) Scoring System to Assess Severity of Liver Disease

Encephalopathy: Enter the date of the encephalopathy test. Next, indicate whether the value was **None**, **1–2**, or **3–4**. The severity is judged according to the candidate's symptoms. The most commonly used staging scale of hepatic encephalopathy is called the West Haven Grading System. The date is required for all values, except for **N/A**. Value cannot be **N/A** for adult candidates. This field is only required when adding or removing candidates 12 years and older. This does not affect the MELD/PELD score but is used for calculating CTP score.

Note: If lab values (excluding **Encephalopathy** and **Ascites**) are updated and the **Encephalopathy** and/or **Ascites** dates are not within 48 hours of the other values, then the data for **Encephalopathy** and/or **Ascites** will be removed. This is to eliminate the confusion of having a mix of updated and old lab values for MELD/PELD and CTP data.

<u>Ascites</u>: Enter the date of the ascites test. Next indicate whether the value was **Absent**, **Slight** (or controlled by diuretics) or **At least moderate despite diuretic treatment**. The date is required for all values, except for **N/A**. Value cannot be **N/A** for adult candidates. This field is only required when adding or removing candidates 12 years and older. This does not affect the MELD/PELD score but is used for calculating CTP score.

Note: If lab values (excluding **Encephalopathy** and **Ascites**) are updated and the **Encephalopathy** and/or **Ascites** dates are not within 48 hours of the other values, then the data for **Encephalopathy** and/or **Ascites** will be removed. This is to eliminate the confusion of having a mix of updated and old lab values for MELD/PELD and CTP data.

<u>Bilirubin (mg/dL)</u>: Enter the bilirubin value in the space provided. The entry must fall between 0 and 99 mg/dl. This is a **required** field.

<u>Albumin (g/dL)</u>: Enter the albumin value in the space provided. The value must fall between 0.50–9.90 g/dL. This field is required for candidates aged 12 and older when adding, changing the status of, or removing a candidate from the Waitlist.

INR: Enter the International Normalized Ratio (INR) value in the space provided. The value must fall between 0.50–99. 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.