Liver Hepatocellular Carcinoma (HCC) MELD/PELD Initial Exception Score Form

Diagnosis

The following fields, from the candidate's Waitlist record, are read-only. If the information is incorrect, it may be updated on the candidate's Waitlist record.

<u>Transplant Center</u>: Verify the transplant center code is correct.

Name: Verify the candidate's name is correct.

<u>Date of birth</u>: Verify the candidate's date of birth is correct.

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

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

ABO: Verify the candidate's blood type is correct.

<u>Diagnosis</u>: Select the candidate's diagnosis from the drop-down list.

Cholangiocarcinoma (CCA)

Cystic fibrosis (CF)

Familial amyloid polyneuropathy (FAP)

Hepatic artery thrombosis (HAT)

Hepatocellular carcinoma (HCC)

Hepatopulmonary syndrome (HPS)

Metabolic disease

Portopulmonary hypertension

Primary hyperoxaluria

Other specify

<u>Candidate MELD/PELD data</u>: The fields, from the candidate's Waitlist record in the MELD/PELD Data Collection section, are read-only. Click **view details** to expand. Click **hide details** to collapse.

Details

Hepatocellular carcinoma (HCC): If hepatocellular carcinoma is selected for a candidate, complete the following fields:

Most Recent Tumor Evaluation

Number of Tumors: Enter the size of each tumor and indicate the type of imaging used to observe the tumor and the date of the imaging study on which the tumor was observed. This is a **required** field.

<u>Size</u>: Enter the size of the tumor indicated for the candidate in centimeters. Tumor size must fall between 1 and 99.99.

<u>Imaging study</u>: Indicate whether the imaging used to observe the candidate's tumor was a **CT of abdomen** and/or **MRI of abdomen**, and enter the **Date** of the imaging study.

Note: For number of tumors, include all tumors that meet the criteria. Stage T2 is defined as 1 lesion with a maximum diameter of greater than or equal to 2 cm and less than or equal to 5 cm OR 2-3 lesions all with a maximum diameter of greater than or equal to 1 cm and less than or equal to 3 cm. The largest diameter of each tumor must be reported. Tumors that are less than 1 cm are considered indeterminate and cannot be considered (or counted).

Select all that apply:

Nonrim arterial phase hyper-enhancement

Nonperipheral washout

Enhancing capsule

Threshold growth defined as size increase of a mass by $\geq 50\%$ in ≤ 180 days on MRI or CT

Corroborating Data

Indicate the assessment and/or therapy, used on the tumor. Enter the **Date** the assessment/therapy was performed. Select all that apply:

Biopsy confirming HCCA Surgical Resection

Loco-Regional Treatments

Indicate the assessment and/or therapy, used on the tumor. Enter the **Date** the assessment/therapy was performed. If **Other** is selected, we recommend including the type of treatment in the **Justification Narrative** field at the end of this form. Select all that apply:

Chemical Ablation

Chemoembolization

External beam radiation

Histotripsy

Radiation microspheres

Thermal ablation

Other

Additional assessment questions

<u>Alpha-fetoprotein (AFP)</u>: Enter the candidate's alpha-fetoprotein level in ng/mL. Alpha-fetoprotein value must fall between 0 and 20000. This is a **required** field.

<u>Is the candidate eligible for resection?</u>: If the candidate is eligible for resection, select **Yes**. If not, select **No**. If unknown, select **N/A**. This is a **required** field.

<u>Does your assessment rule out macrovascular involvement (i.e., tumor in vein -portal or hepatic veins)?</u>: If the physician's assessment rules out macrovascular involvement, select **Yes**. If not, select **No**. This is a **required** field.

<u>Does your assessment rule out an extrahepatic spread?</u>: If the physician's assessment rules out an extrahepatic spread, select **Yes**. If not, select **No**. This is a **required** field.

Please indicate the type of imaging used to assess extrahepatic spread and metastatic disease (select all that apply): Check any applicable type of imaging used to assess extrahepatic spread, and enter the Date. If one or more tumors are indicated, indicate whether the imaging used was a CT of Chest and/or MRI of Chest, and enter the Date of the imaging study.

Original/Presenting Tumor Evaluation

<u>Is the most recent tumor evaluation reported above the original/presenting tumor evaluation?</u>: If the most recent tumor evaluation reported above the original tumor evaluation, select **Yes**. If not, select **No**. This is a **required** field.

<u>Are the original tumor quantity, size, and imaging available?</u>: If the original/presenting tumor number, size and imaging information is available, select **Yes**. If not, select **No.** This is a **required** field.

<u>Date of original imaging</u>: Enter the original/presenting imaging date. This is a **required** field.

Number of original tumors: Enter the number of original/presenting tumors. This is a **required** field.

<u>Tumor</u>: Enter the original size of each tumor in centimeters. Tumor size must fall between 0 and 99.99. This is a **required** field.

Reason Unavailable: Enter an explanation of why the original/presenting tumor information is unavailable. This is a **required** field.

Results

Review results: The candidate's result details display.

Score

<u>Policy score for candidates meeting standard criteria</u>: The policy score for candidates meeting standard criteria displays.

Please request an exception score: Select an exception score for the candidate:

Equal to the policy assigned score for candidates meeting standard criteria Score adjusted from the median MELD at transplant (MMaT)

Less than MMaT (the number must fall between 1 and 20)

Equal to MMaT

More than MMaT (the number must fall between 1 and 20)

MELD 40

PELD 40 or higher (for pediatric candidates; the number must fall between 40 and 99)

<u>Justification narrative</u>: Enter text justifying the requested higher MELD or PELD score. If **Other** is selected for **Loco-Regional Treatment**, we recommend including the type of treatment here. 8000 character limit.

OMB No. 0915-0157; Expiration Date: XX/XX/20XX

Confirm

<u>Transplant physician name</u>: Enter the transplant physician's name. This is a **required** field. <u>Transplant physician NPI</u>: Enter the transplant physician's NPI number. The NPI must be 10 digits. This is a **required** field.

<u>Email decision to</u>: 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.