OPTN

Notice of OPTN Policy and Guidelines Changes

Calculate Median MELD at Transplant around the Donor Hospital and Update Sorting within Liver Allocation

Sponsoring Committee: Liver and Intestinal Organ Transplantation Committee **Policies Affected: Policy 1.2: Definitions** Policy 9.4.A: MELD or PELD Score Exception Requests Policy 9.4.C.ii: Other MELD or PELD Score Exception Extensions Policy 9.4.D: Calculation of Median MELD or PELD at **Transplant** Policy 9.5: Specific Standardized MELD or PELD Score **Exceptions** Policy 9.5.A: Requirements for Cholangiocarcinoma (CCA) **MELD or PELD Score Exceptions** Policy 9.5.B: Requirements for Cystic Fibrosis (CF) MELD or **PELD Score Exceptions** Policy 9.5.C: Requirements for Familial Amyloid Polyneuropathy (FAP) MELD or PELD Score Exceptions Policy 9.5.D: Requirements for Hepatic Artery Thrombosis (HAT) MELD or PELD Score Exceptions Policy 9.5.E: Requirements for Hepatopulmonary Syndrome (HPS) MELD or PELD Score Exceptions Policy 9.5.F: Requirements for Metabolic Disease MELD or **PELD Score Exceptions** Policy 9.5.G: Requirements for Portopulmonary Hypertension MELD or PELD Score Exceptions Policy 9.5.H Requirements for Primary Hyperoxaluria MELD or **PELD Score Exceptions** Policy 9.5.1: Requirements for Hepatocellular Carcinoma (HCC) **MELD or PELD Score Exceptions** Policy 9.5.I.vii Extension of HCC Exceptions Policy 9.6.A: Waiting Time for Liver Candidates Policy 9.8: Liver Allocation, Classifications and Rankings Policy 9.8.D: Sorting Within Each Classification **Guidelines Affected:** National Liver Review Board Operational Guidelines **Public Comment:** January 21, 2021 – March 23, 2021 **Board Approved:** June 14, 2021 **Effective Date:** Pending implementation and notice to OPTN members

Purpose of Policy and Guidelines Change

The purpose of this proposal is to better align the geographic units used in the calculation of median model for end-stage liver disease (MELD) at transplant (MMaT) with the geographic units used in liver allocation, as well as to improve access for pediatric candidates.

Prior to this proposal, the MMaT was calculated based on transplants performed within 250 nautical miles (NM) of each transplant program over a prior 365 day period. This proposal alters the MMaT calculation to instead be based on the donor hospital, which is also the geographic basis for the allocation of deceased donor livers. In addition, the proposal alters the way in which liver transplant candidates are sorted within allocation classifications to align with the change to MMaT and provide additional priority to pediatric candidates.

Proposal History

On February 4, 2020, the use of donation service areas (DSAs) and OPTN Regions was removed from liver allocation with the implementation of the Acuity Circles (AC) allocation policy, which is a series of concentric circles around the donor hospital.¹ When the AC policy was implemented, the geographic basis for the calculation of the MMaT was changed.

The MMaT is used to assign MELD exception scores for liver transplant candidates whose medical urgency for transplant is not appropriately represented by their calculated MELD score. Under the AC policy, the MMaT score for each transplant program was based on a subset of transplants performed within 250 NM of the transplant program.

However, the calculation of MMaT around the transplant program created a situation whereby transplant programs in close geographic proximity had different MMaT scores and therefore, exception candidates at those transplant programs had different exception scores, despite having similar urgency for transplant. This proposal will align the MMaT calculation with liver allocation by basing MMaT on the donor hospital.

Summary of Changes

The proposal includes the following changes:

- **MMaT Calculation**: The MMaT calculation will be based on transplants performed within 150 NM of each donor hospital from a previous 365 day period. MELD exception scores will be calculated relative to the MMaT of the donor hospital at the time of the match run.
- **Calculation of Waiting Time**: Because exception scores will fluctuate based on the MMaT of the donor hospital, the waiting time calculation for exception candidates was changed from time at current score or higher score to be time since submission of earliest approved exception. Time at current score or higher is still used for candidates with a lab MELD or PELD score.
- **Sorting Liver Candidates**: The proposal also changes the order in which candidates are sorted within liver allocation classifications and includes additional pediatric priority. When MELD and PELD score and blood type compatibility are equal, pediatric candidates are sorted ahead of adult candidates. If MELD or PELD score, blood type compatibility, and age at registration

¹ Liver and Intestine Distribution Using Distance from Donor Hospital, OPTN Liver and Intestinal Organ Transplantation Committee, December 2018, Available at https://optn.transplant.hrsa.gov/

(pediatric vs. adult) are equal, candidates with a lab score are sorted ahead of candidates with an exception score. Lab candidates are then sorted based on time at score or higher and exception candidates are sorted based on time since submission of earliest approved exception.

Implementation

Liver transplant programs will need to be familiar with the proposed changes and be prepared to educate candidates on the new MMaT calculation. MELD exception candidates will no longer have a set MELD score; their scores will change with each match run based on the MMaT of the donor hospital. The proposal will not affect organ procurement organizations or histocompatibility laboratories.

Currently, the system does not distinguish between time spent at current or higher exception score or current or higher lab score. Upon implementation of this proposal, candidates with a lab score are sorted by time at current lab score or a higher lab score. Time spent at current or higher exception score is not included. However, upon implementation, there may be candidates with a lab score whose time at current score or higher includes time at current or higher exception score that was accrued prior to implementation. These candidates will be able to keep the time accrued at the current or higher exception score, but after implementation, time will be restricted to just time accrued at lab scores, including liver-intestine points.

The OPTN will implement changes in UNetSM to calculate MMaT around the donor hospital and update sorting within liver allocation.

Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (example).

1.2 Definitions

The definitions that follow are used to define terms specific to the OPTN Policies.

A

Allocation MELD or PELD Score

The highest exception or calculated MELD or PELD score, including liver-intestine points, available to the candidate <u>at the time of the match run for a liver or liver-intestine</u> according to Policy. Allocation MELD or PELD score includes liver intestine points.

Approved MELD or PELD Exception

A MELD or PELD exception or exception extension that met standardized criteria in OPTN policy or was reviewed and approved by the NLRB.

Assigned MELD or PELD Exception

<u>A MELD or PELD exception or exception extension where the NLRB failed to make a decision within 21</u> days of the date of submission of the request and the candidate was assigned the requested score.

M

Match MELD or PELD Score

The MELD or PELD score available to the candidate at the time of the match for a deceased donor liver or liver-intestine.

Policy 9: Allocation of Livers and Liver-Intestines

9.4 MELD or PELD Score Exceptions

If a candidate's transplant program believes that a candidate's current MELD or PELD score does not appropriately reflect the candidate's medical urgency for transplant, the transplant program may submit a MELD or PELD score exception request to the National Liver Review Board (NLRB).

9.4.A MELD or PELD Score Exception Requests

A MELD or PELD score exception request must include *all* the following:

- 1. A request for a specific MELD or PELD score either:
 - a. <u>An adjustment of a certain amount of points higher or lower than MMaT or</u> <u>MPaT or</u>
 - b. A specific MELD or PELD score of 40 or higher
- 2. A justification of how the medical criteria supports that the candidate has a higher MELD or PELD score
- 3. An explanation of how the candidate's current condition is comparable to that of other candidates with that MELD or PELD score

2. <u>A justification that outlines how a candidate's medical condition warrants an exception</u> and the specific score being requested.

Approved MELD or PELD exceptions scores are valid for 90 days from the date the exception is approved or assigned.

9.4.C MELD or PELD Score Exception Extensions

9.4.C.ii Other MELD or PELD Score Exception Extensions

A candidate's approved <u>or assigned</u> exception will be maintained if the transplant hospital program enters a MELD or PELD Exception Score Extension Request before the due date, even if the NLRB does not act before the due date. If the extension request is denied or if no MELD or PELD Exception Score Extension Request is submitted before the due date, then the candidate will be assigned the calculated MELD or PELD score based on the most recent reported laboratory values.

Each approved <u>or assigned</u> MELD or PELD exception extension is valid for an additional 90 days beginning from the day that the previous exception or extension expired.

9.4.D Calculation of Median MELD or PELD at Transplant

Median MELD at transplant (MMaT) is calculated by using the median of the MELD scores at the time of transplant of all recipients at least 12 years old who were transplanted at hospitals within 250 nautical miles of the candidate's listing hospital in a prior 365 day period.

Median PELD at transplant (MPaT) is calculated by using the median of the PELD scores at the time of transplant of all recipients less than 12 years old in the nation.

The MMaT and MPaT calculations exclude recipients who are either of the following:

- 1.—Transplanted with livers from living donors, DCD donors, and donors from donor hospitals more than 500 nautical miles away from the transplant hospital
- 2.—Status 1A or 1B at the time of transplant.

The OPTN will recalculate the MMaT and MPaT twice a year based on an updated cohort. The updated cohort will include transplants over a prior 365 day period. If there have been fewer than 10 qualifying transplants within 250 nautical miles of a transplant hospital in the cohort, the MMaT will be calculated based on a total of a 730 day period.

For each donor hospital, the OPTN will calculate the MMaT based on a cohort of recipients transplanted at programs at or within 150 nautical miles of the donor hospital in a prior 365 day period. If there are either less than two active liver transplant programs or less than 10 qualifying transplants within 150 nautical miles of the donor hospital, the geographic area used to calculate the MMaT will increase in 50 nautical mile increments until two active liver transplant programs and 10 qualifying transplants are included in the MMaT cohort.

The MMaT is calculated by using the median of the MELD scores at the time of transplant of all recipients within the geographic area defined above that are at least 12 years old at the time of transplant. Recipients are excluded who are either of the following:

- 1. <u>Transplanted with livers from living donors, DCD donors, or donors from donor hospitals</u> more than 500 nautical miles away from the recipient's transplant program or
- 2. <u>Status 1A or 1B at the time of transplant.</u>

If a transplant program has not performed at least one transplant included in the MMaT calculation, the program is not included in the MMaT cohort.

If there are less than 10 qualifying transplants within 250 nautical miles of a donor hospital in Hawaii or Puerto Rico, the MMaT will be calculated based on a total of 730 days. There does not need to be two transplant programs within 250 nautical miles of donor hospitals in Hawaii or Puerto Rico.

<u>Median PELD at transplant (MPaT) is calculated by using the median of the PELD scores at the time of transplant of all recipients less than 12 years old at the time of transplant in the nation.</u> Recipients are excluded who are either of the following:

- 1. <u>Transplanted with livers from living donors, DCD donors, or donors from donor hospitals</u> more than 500 nautical miles away from the recipient's transplant program or
- 2. <u>Status 1A or 1B at the time of transplant.</u>

The OPTN will recalculate the MMaT and MPaT twice a year based on an updated cohort. The updated cohort will include transplants over a prior 365 day period.

9.4.E: MELD or PELD Exception Scores Relative to Median MELD or PELD at Transplant

A match run will provide MELD exception candidates on the match run a MELD exception score relative to the MMaT for the donor hospital. PELD exception candidates are provided a PELD exception score relative to the MPaT for the nation. If a candidate's exception score relative to MMaT or MPaT would be lower than 15, the candidate's exception score will be 15.

Exceptions scores will be updated to reflect changes in MMaT or MPaT each time the MMaT or MPaT is recalculated. The following exception scores are not awarded relative to MMaT or MPaT and will not be updated:

- 1. Exception scores of 40 or higher awarded by the NLRB according to *Policy 9.4.A: MELD or PELD Score Exception Requests*
- 2. Any exception awarded according to *Policy 9.5.D: Requirements for Hepatic Artery Thrombosis (HAT) MELD or PELD Score Exceptions*
- 3. Exceptions awarded to candidates less than 18 years old at time of registration according to *Policy 9.5.I: Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions*
- 4. Initial exceptions and first extensions awarded to candidates at least 18 at time of registration according to Policy 9.5.1: Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions

9.5 Specific Standardized MELD or PELD Score Exceptions

Candidates are eligible for MELD or PELD score exceptions or extensions that do not require evaluation by the NLRB if they meet *any* of the following requirements for a specific diagnosis of *any* of the following:

- Cholangiocarcinoma (CCA), according to Policy 9.5.A: Requirements for Cholangiocarcinoma MELD or PELD Score Exceptions
- Cystic fibrosis, according to Policy 9.5.B: Requirements for Cystic Fibrosis MELD or PELD Score Exceptions
- Familial amyloid polyneuropathy, according to *Policy 9.5.C: Requirements for Familial Amyloid Polyneuropathy (FAP) MELD or PELD Score Exceptions*
- Hepatic artery thrombosis, according to *Policy 9.5.D: Requirements for Hepatic Artery Thrombosis (HAT) MELD or PELD Score Exceptions*
- Hepatopulmonary syndrome, according to *Policy 9.5.E: Requirements for Hepatopulmonary Syndrome (HPS) MELD or PELD Score Exceptions*
- Metabolic disease, according to Policy 9.5.F: Requirements for Metabolic Disease MELD or PELD Score Exceptions
- Portopulmonary hypertension, according to Policy 9.5.G: Requirements for Portopulmonary Hypertension MELD or PELD Score Exceptions
- Primary hyperoxaluria, according to Policy 9.5.H: Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions
- Hepatocellular carcinoma, according to Policy 9.5.1: Requirements for Hepatocellular

Carcinoma (HCC) MELD or PELD Score Exceptions

If a candidate's exception score based on the score assignments relative to MMaT or MPaT in this section would be lower than 15, the candidate's exception score will be 15.

9.5.A Requirements for Cholangiocarcinoma (CCA) MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for CCA, if the candidate's transplant hospital program meets *all* the following qualifications:

- 1. Submits a written protocol for patient care to the Liver and Intestinal Organ Transplantation Committee that must include *all* of the following:
 - Candidate selection criteria
 - Administration of neoadjuvant therapy before transplantation
 - Operative staging to exclude any patient with regional hepatic lymph node metastases, intrahepatic metastases, or extrahepatic disease
 - Any data requested by the Liver and Intestinal Organ Transplantation Committee
- 2. Documents that the candidate meets the diagnostic criteria for hilar CCA with a malignant appearing stricture on cholangiography and at least *one* of the following:
 - Biopsy or cytology results demonstrating malignancy
 - Carbohydrate antigen 19-9 greater than 100 U/mL in absence of cholangitis
 - Aneuploidy

The tumor must be considered un-resectable because of technical considerations or underlying liver disease.

- 3. Submits cross-sectional imaging studies. If cross-sectional imaging studies demonstrate a mass, the mass must be single and less than three cm.
- 4. Documents the exclusion of intrahepatic and extrahepatic metastases by cross-sectional imaging studies of the chest and abdomen within 90 days prior to submission of the initial exception request.
- Assesses regional hepatic lymph node involvement and peritoneal metastases by operative staging after completion of neoadjuvant therapy and before liver transplantation.
 Endoscopic ultrasound-guided aspiration of regional hepatic lymph nodes may be advisable to exclude patients with obvious metastases before neo-adjuvant therapy is initiated.
- 6. Transperitoneal aspiration or biopsy of the primary tumor (either by endoscopic ultrasound, operative or percutaneous approaches) must be avoided because of the high risk of tumor seeding associated with these procedures.

A candidate who meets the requirements for a standardized MELD or PELD score exception will be assigned receive a score according to *Table 9-2* below.

Table 9-2: CCA Exception Scores

Age	Age at registration	Score
At least 18 years old	At least 18 years old	3 points below MMaT
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

In order to be approved for an extension of this MELD or PELD score exception, transplant hospitals programs must submit an exception extension request according to *Policy 9.4.C: MELD* or *PELD Score Exception Extensions,* and provide cross-sectional imaging studies of the chest and abdomen that exclude intrahepatic and extrahepatic metastases. These required imaging studies must have been completed within 30 days prior to the submission of the extension request.

9.5.B Requirements for Cystic Fibrosis (CF) MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for cystic fibrosis if the candidate's diagnosis has been confirmed by genetic analysis, and the candidate has a forced expiratory volume at one second (FEV1) below 40 percent of predicted FEV1 within 30 days prior to submission of the initial exception request.

A candidate who meets the requirements for a standardized MELD or PELD score exception will <u>be assigned</u> receive a score according to *Table 9-3* below.

Age	Age at registration	Score
At least 18 years old	At least 18 years old	3 points below MMaT
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

Table 9-3: Cystic Fibrosis Exception Scores

In order to be approved for an extension of this MELD or PELD score exception, transplant hospitals programs must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Score Exception Extensions*.

9.5.C Requirements for Familial Amyloid Polyneuropathy (FAP) MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for FAP if the candidate's transplant hospital program submits evidence of *all* of the following:

- 1. Either that the candidate is also registered and active on the waiting list for a heart transplant at that transplant hospital, or has an echocardiogram performed within 30 days prior to submission of the initial exception request showing the candidate has an ejection fraction greater than 40 percent.
- 2. That the candidate can walk without assistance.
- 3. That a transthyretin (TTR) gene mutation has been confirmed.

4. A biopsy-proven amyloid.

A candidate who meets the requirements for a standardized MELD or PELD score exception will <u>be assigned</u> receive a score according to *Table 9-4* below.

Age	Age at registration	Score
At least 18 years old	At least 18 years old	3 points below MMaT
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

Table 9-4: FAP Exception Scores

In order to be approved for an extension of this MELD or PELD score exception, transplant hospitals programs must submit an exception extension request according to *Policy 9.4.C: MELD* or *PELD Score Exception Extensions* and meet one of the following criteria:

- 1. An echocardiogram that shows that the candidate has an ejection fraction greater than 40 percent within the last 120 days
- 2. Registered and active on the waiting list for a heart transplant at that hospital

9.5.D Requirements for Hepatic Artery Thrombosis (HAT) MELD or PELD Score Exceptions

A candidate will receive a MELD score exception for HAT if the candidate is at least 18 years old at registration and has HAT within 14 days of transplant but does not meet criteria for status 1A in *Policy 9.1.A: Adult Status 1A Requirements*.

Candidates who meet these requirements will receive a MELD score of 40.

In order to be approved for an extension of this MELD score exception, transplant hospitals <u>programs</u> must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Score Exception Extensions.*

9.5.E Requirements for Hepatopulmonary Syndrome (HPS) MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for HPS if the candidate's transplant hospital program submits evidence of *all* of the following:

- 1. Ascites, varices, splenomegaly, or thrombocytopenia.
- 2. A shunt, shown by either contrast echocardiogram or lung scan.
- 3. PaO₂ less than 60 mmHg on room air within 30 days prior to submission of the initial exception request.
- 4. No clinically significant underlying primary pulmonary disease.

A candidate who meets the requirements for a standardized MELD or PELD score exception will <u>be assigned</u> receive a score according to *Table 9-5* below.

Table 9-5: HPS Exception Scores

Age	Age at registration	on Score	
At least 18 years old	At least 18 years old	3 points below MMaT	
At least 12 years old	Less than 18 years old	Equal to MMaT	
Less than 12 years old	Less than 12 years old	Equal to MPaT	

In order to be approved for an extension of this MELD or PELD score exception, transplant hospitals programs must submit an exception extension request according to *Policy 9.4.C: MELD or PELD Score Exception Extensions*, with evidence that the candidate's PaO₂ remained at less than 60 mmHg on room air within the 30 days prior to submission of the extension request.

9.5.F Requirements for Metabolic Disease MELD or PELD Score Exceptions

A liver candidate less than 18 years old at the time of registration will receive a MELD or PELD score exception for metabolic disease if the candidate's transplant hospital program submits evidence of urea cycle disorder or organic acidemia.

A candidate who meets the requirements for a standardized MELD or PELD score exception will <u>be assigned</u> receive a score according to *Table 9-6* below.

Age	Age at registration	Score
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

 Table 9-6: Metabolic Disease Exception Scores

If the candidate does not receive a transplant within 30 days of being registered with the exception score, then the candidate's transplant physician may register the candidate as a status 1B.

In order to be approved for an extension of this MELD or PELD score exception, transplant hospitals programs must submit an exception extension request according to *Policy 9.4.C: MELD* or *PELD Score Exception Extensions*.

9.5.G Requirements for Portopulmonary Hypertension MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for portopulmonary hypertension if the transplant hospital program submits evidence of *all* of the following:

- Document via heart catheterization initial mean pulmonary arterial pressure (MPAP) level greater than or equal to 35 mmHg and initial pulmonary vascular resistance (PVR) level greater than or equal to 240 dynes*sec/cm⁵ (or greater than or equal to 3 Wood units (WU)). These values must be from the same test date.
- 2. Other causes of pulmonary hypertension have been assessed and determined to not be a significant contributing factor

- 3. Initial transpulmonary gradient to correct for volume overload
- 4. Documentation of treatment
- 5. Document via heart catheterization within 90 days prior to submission of the initial exception either of the following:
 - Post-treatment MPAP less than 35 mmHg and post-treatment PVR less than 400 dynes*sec/cm⁵ (or less than 5 Wood units (WU)). These values must be from the same test date.
 - Post-treatment MPAP greater than or equal to 35 mmHg and less than 45 mmHg and post-treatment PVR less than 240 dynes*sec/cm⁵ (or less than 3 Wood units (WU)). These values must be from the same test date.
- 6. Documentation of portal hypertension at the time of initial exception

A candidate who meets the requirements for a standardized MELD or PELD score exception will be assigned receive a score according to *Table 9-7* below.

Age	Age at registration	Score
At least 18 years old	At least 18 years old	3 points below MMaT
At least 12 years old	Less than 18 years old	Equal to MMaT
Less than 12 years old	Less than 12 years old	Equal to MPaT

Table 9-7: Portopulmonary Hypertension Exception Scores

In order to be approved for an extension of this MELD or PELD score exception, transplant hospitals programs must submit an exception extension request according to *Policy 9.4.C: MELD* or *PELD Score Exception Extensions* with evidence of a heart catheterization since the last exception or extension request that confirms either of the following:

- MPAP less than 35 mmHg and PVR less than 400 dynes*sec/cm⁵ (or less than 5 Wood units (WU)). These values must be from the same test date.
- MPAP greater than or equal to 35 mmHg and less than 45 mmHg and PVR less than 240 dynes*sec/cm⁵ (or less than 3 Wood units (WU)). These values must be from the same test date.

9.5.H Requirements for Primary Hyperoxaluria MELD or PELD Score Exceptions

A candidate will receive a MELD or PELD score exception for primary hyperoxaluria if the candidate's transplant hospital program submits evidence of all of the following:

- 1. The liver candidate is registered on the waiting list for a kidney transplant at that transplant hospital
- 2. Alanine glyoxylate aminotransferase (AGT) deficiency proven by liver biopsy using sample analysis or genetic analysis
- 3. Estimated glomerular filtration rate (eGFR) by six variable Modification of Diet in Renal Disease formula (MDRD6), or glomerular filtration rate (GFR) measured by iothalamate or iohexol, is less than or equal to 25 mL/min on 2 occasions at least 42 days apart

A candidate who meets the requirements for a standardized MELD or PELD score exception will <u>be assigned</u> receive an exception score according to *Table 9-8* below.

Age	Age at registration	Score
At least 18 years old	At least 18 years old	Equal to MMaT
At least 12 years old	Less than 18 years old	3 points above MMaT
Less than 12 years old	Less than 12 years old	3 points above MPaT

Table 9-8: Primary Hyperoxaluria Scores

In order to be approved for an extension of this MELD or PELD score exception, transplant hospitals programs must submit an exception extension request according to Policy 9.4.C: MELD or PELD Score Exception Extensions with evidence that the candidate is registered on the waiting list for a kidney transplant at that hospital.

9.5.I Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions

Upon submission of the first exception request, a candidate with hepatocellular carcinoma (HCC) will <u>be provided</u> <u>receive</u> a score according to Policy *9.5.1.vii: Extensions of HCC Exceptions* if the candidate meets the criteria according to *Policies 9.5.1.i through 9.5.1.vi*.

9.5.I.vii Extensions of HCC Exceptions

A candidate with an approved exception for HCC is eligible for automatic approval of an extension if the transplant program enters a MELD or PELD Exception Score Extension Request that contains the following:

- 1. Documentation of the tumor using a CT or MRI
- 2. The type of treatment if the number of tumors decreased since the last request
- 3. The candidate's alpha-fetoprotein (AFP) level

The candidate's exception extension will then be automatically approved unless *any* of the following occurs:

- The candidate's lesions progress beyond T2 criteria, according to 9.5.1.ii: Eligible Candidates Definition of T2 Lesions
- The candidate's alpha-fetoprotein (AFP) level was less than or equal to 1,000 ng/mL on the initial request but subsequently rises above 1,000 ng/mL
- The candidate's AFP level was greater than 1,000 ng/mL, the AFP level falls below 500 ng/mL after treatment but before the initial request, then the AFP level subsequently rises to greater than or equal to 500 ng/mL
- The candidate's tumors have been resected since the previous request
- The program requests a score different from the scores assigned in Table 9-10.

When a <u>transplant program submits either an initial exception request or the first</u> <u>extension request for a liver candidate at least 18 years old at the time of</u> registration submits an initial request or the first extension request that meets the requirements for a standardized MELD score exception, the candidate will-receive a MELD score of 6, and appear on the match <u>run</u> according to that exception score or the calculated MELD score., whichever is higher.

A candidate who meets these requirements for a MELD or PELD score exception for HCC will be assigned receive a score according to *Table 9-10* below.

Age	Age at registration	Exception Request	Score
At least 18 years old	At least 18 years old	Initial and first extension	6-<u>Calculated</u> MELD
At least 18 years old	At least 18 years old	Any extension after the first extension	3 points below MMaT
At least 12 years old	Less than 18 years old	Any	40
Less than 12 years old	Less than 12 years old	Any	40

Table 9-10: HCC Exception Scores

9.6 Waiting Time

9.6.A Waiting Time for Liver Candidates

Liver transplant candidates on the waiting list accrue waiting time within status 1A or 1B or any assigned MELD or PELD score.

A candidate's waiting time at a MELD or PELD score equals the sum of *all* the following:

- 1. Waiting time at current MELD or PELD score
- 2. Previous waiting time accrued during an earlier period at current MELD or PELD score
- 3. Previous total waiting time accrued at any MELD or PELD score higher than the current MELD or PELD score
- 4. Previous total waiting time accrued at status 1A and status 1B

Status 1A or 1B candidates will receive waiting time points based on their waiting time in that status, according to *Policy 9.7.A: Points for Waiting Time*. <u>Status 1A candidates begin accruing</u> waiting time at status 1A upon submission of the earliest *Liver Status 1A or 1B Justification Form* for status 1A. Status 1B candidates begin accruing waiting time at status 1B upon submission of the earliest *Liver Status 1B* upon submission of the earliest *Liver Status 1B* upon submission of the earliest *Liver Status 1B* upon submission of

<u>Candidates with a MELD or PELD score begin accruing waiting time when the candidate is first</u> registered as an active liver candidate on the waiting list.

Allocation MELD or PELD score waiting time is accrued as follows:

 If the candidate's allocation MELD or PELD score is based on a calculated MELD or PELD score, then allocation MELD or PELD score waiting time includes all waiting time at current or higher calculated MELD or PELD score, including liver-intestine points. Waiting time at current or higher calculated MELD or PELD score includes all of the following:

- 1. <u>Waiting time at current calculated MELD or PELD score, including liver-intestine</u> points
- 2. <u>Previous waiting time accrued during an earlier period at current calculated</u> <u>MELD or PELD score, including liver-intestine points</u>
- 3. <u>Previous total waiting time accrued at any calculated MELD or PELD score higher</u> <u>than the current calculated MELD or PELD score, including liver intestine points</u>
- 4. Previous total waiting time accrued at status 1A and status 1B
- If the candidate's allocation MELD or PELD score is an exception MELD or PELD score, then allocation MELD or PELD score waiting time equals time since submission of earliest approved or assigned MELD or PELD exception request, including time at an inactive status.

9.8 Liver Allocation, Classifications, and Rankings

Unless otherwise stated, all mentions of MELD or PELD in this section reference a candidate's match allocation MELD or PELD score.

9.8.D Sorting Within Each Classification

Within each status 1A allocation classification, candidates are sorted in the following order:

- 1. Total waiting time and blood type compatibility points (highest to lowest), according to *Policy 9.7: Liver Allocation Points*
- 2. Total waiting time at status 1A (highest to lowest)

Within each status 1B allocation classification, candidates are sorted in the following order:

- 1. Total waiting time and blood type compatibility points (highest to lowest), according to *Policy 9.7: Liver Allocation Points*
- 2. Total waiting time at status 1B (highest to lowest)

Within each MELD or PELD score allocation classification, all candidates are sorted in the following order:

- 1. <u>Allocation MELD or PELD score (highest to lowest)</u>
- 2. Identical blood types, compatible blood types, then incompatible blood types
- 3. Waiting time at the current or higher MELD or PELD score (highest to lowest)
- 4. Time since submission of initial approved MELD or PELD exception request (highest to lowest)
- 2. <u>Blood type compatibility (identical, compatible, then incompatible)</u>
- 3. <u>Age at time of registration on the liver waitlist (less than 18 years old followed by 18 years or older)</u>
- 4. <u>Allocation MELD or PELD score type (calculated, including liver-intestine points, then</u> <u>exception)</u>
- 5. <u>Allocation MELD or PELD score waiting time (highest to lowest)</u>
- 6. Total waiting time (highest to lowest)

OPTN

1 National Liver Review Board Operational Guidelines

2 1. Overview

3

The purpose of the National Liver Review Board (NLRB) is to provide fair, equitable, and prompt peer review of exceptional candidates whose medical urgency is not accurately reflected by the calculated MELD or PELD score. The NLRB will base decisions on policy, the guidance documents, and in cases which lack specific guidance, the medical urgency of the candidate as compared to other candidates with the

8 same MELD or PELD score adjustment or specific MELD or PELD score.

- 9 The NLRB is comprised of specialty boards, including:
- 10 Adult Hepatocellular Carcinoma (HCC)
- 11 Adult Other Diagnosis
- Pediatrics, which reviews requests made on behalf of any candidate registered prior to turning 18
 years old and adults with certain pediatric diagnoses
- 14
- 15 The immediate past-Chair of the Liver and Intestinal Organ Transplantation Committee serves as the
- 16 Chair of the NLRB for a two year term.
- 17

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