Improving Liver Allocation: Pediatric FAQ

This document provides background information and answers to frequently asked questions **specific to the pediatric population** related to the implementation of the updated model for end stage liver disease (MELD) score, or MELD 3.0, and the updated pediatric end-stage liver disease score (PELD) score, or PELD creatinine (Cr), along with other liver allocation policy changes slated for implementation in July 2023.

This document is intended to help transplant programs providing care to pediatric liver transplant candidates prepare for the implementation of the updated MELD and PELD scores and associated policy changes. Additional resources will be available on the OPTN website, including the following FAQ documents:

- MELD 3.0: more detailed information about MELD 3.0
- General Implementation: more detail on the implementation of the new policies
- Patient-focused: information on the policy changes for patients

If you have any additional questions, please contact member.questions@unos.org for assistance.

Background

In June 2022, the OPTN Board of Directors approved a proposal from the OPTN Liver and Intestinal Organ Transplantation Committee that included changes to the current MELD and PELD scores, as well as the policy for pediatric Status 1A and Status 1B candidates. Details about the proposal are here.

In summary, the following changes, relevant to the pediatric population, are slated to be implemented in July 2023:

- **MELD 3.0**: This policy improves the accuracy of the MELD score by incorporating additional variables (albumin and sex), updating coefficients for existing variables, introducing interaction terms, and lowering the maximum creatinine value from 4.0 to 3.0 mg/dL.
- **PELD Cr**: This policy improves the accuracy of the PELD score by incorporating a creatinine variable to capture renal function, updating parameters for existing coefficients, and converting age and growth failure from categorical to continuous variables. PELD Cr also includes a factor for age-adjusted mortality, which aligns the risk of waitlist mortality at a given PELD Cr with the risk of mortality at the same MELD 3.0 score.
- **Status 1A**: This policy improves the Status 1A criteria for pediatric candidates with fulminant liver failure by updating the definition for hepatic encephalopathy. The new definition aligns with the definition developed by the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition.
- **Status 1B:** This policy removes the MELD/PELD 25 threshold for liver-intestine and liver-alone candidates with chronic liver disease. The policy also changes the gastro-intestinal (GI) bleeding threshold for liver-alone candidates to match the definition of persistent mild shock or moderate shock, and it removes the Glasgow Coma Score (GCS) criteria for both liver-alone and liver-intestine candidates. Finally, the policy updates sorting within Status 1B by prioritizing candidates with chronic liver disease, who are at the highest risk of waitlist mortality.
- **Other changes**:

- The policy updates how liver-intestine points are assigned such that they are based on candidate age at the time of registration, rather than current age.
- The policy updates guidance for the pediatric National Liver Review Board (NLRB) to align with changes to PELD Cr and Status 1B criteria.

New Data Collection

As part of these updates to liver allocation policy, there are changes to data collection that pediatric liver transplant programs will need to know.

For all MELD candidates (ages 12 and older), transplant programs will be required to submit an albumin value when editing a candidate record, as albumin is included in the MELD 3.0 calculation. Albumin is already required when adding an adult or adolescent liver candidate to the OPTN Waiting List.

For all PELD candidates (ages 11 and younger), transplant programs will be required to submit creatinine values in OPTN Waiting List when adding or editing a candidate record, as creatinine is included in the PELD Cr score. Creatinine is already required when adding or editing a candidate who is age 10 or older.

Implementation Overview

To give transplant programs time to submit the required data for their candidates, the implementation of MELD 3.0 and PELD Cr will occur in two phases.

Phase 1 :

- Planned to be implemented on June 15, 2023
- Will provide transplant programs time to enter required data prior to implementation of changes for MELD 3.0 and PELD Cr scores (Phase 2)
- Upon Phase 1 release:
  - The label on the current “Gender” field will be updated to “Birth sex” for all organs.
  - A new field, “Sex for Purposes of Adult MELD Calculation” will be deployed for all adult liver candidates (age 18 or older at the time of registration). This field will be required for all adult candidates registered after implementation of Phase 1. The field will be optional for adult candidates already on the OPTN Waiting List.

Phase 2:

- Planned to be implemented on July 13, 2023
- Upon Phase 2 release:
  - MELD 3.0 and PELD Cr scores will be calculated and used in allocation
  - Changes to criteria for pediatric Status 1A and Status 1B, updates to sorting within Status 1B, alignment of hepatocellular carcinoma (HCC) policy language with Liver Imaging Reporting and Data System (LI-RADS) terminology will go into effect
  - Albumin will become required for all MELD candidates
  - Creatinine will become required for all PELD candidates.

Frequently Asked Questions

PELD Cr:

How and why is the PELD score changing?

The PELD score has not been updated since it was implemented in 2002 and it has been shown to underpredict the risk of pediatric waitlist mortality by as much as 17%, especially when compared to adult candidates with a MELD score.[1] Almost two-thirds of pediatric (under age 12) liver transplant candidates are listed with an exception score, which is provided when a candidate's calculated PELD score does not adequately capture their medical urgency for transplantation.[2]

While the existing PELD score provides additional points to candidates with growth failure, 17% of pediatric liver transplant candidates fall into the "growth failure gap". This happens when candidates have z-scores less than two but do not meet the current criteria in the PELD score, and therefore they may inappropriately lose six to seven PELD points.[3,4] Candidates falling into the "growth failure gap" have an increased risk of waitlist mortality and post-transplant mortality.[5]

PELD Cr improves upon the existing PELD score by:

- Incorporating a creatinine variable to capture renal function
- Updating parameters for existing coefficients based on an updated cohort
- Converting age and growth failure from categorical to continuous variables to address the "growth failure gap"
- Including a factor for age-adjusted mortality, so the risk of waitlist mortality at a given PELD Cr scores aligns with the risk of waitlist mortality for an adult MELD 3.0 candidate with the same MELD 3.0 score

You can find more detailed information about the PELD Cr information in the calculation guide, available here.

Can you explain the age-adjusted mortality aspect of PELD Cr?

PELD Cr was adjusted so that pediatric mortality risk is the same as the age-standardized mortality risk for 18-year-old adults with a MELD 3.0 score. This age-adjusted mortality factor ensures that candidates at a given MELD 3.0 or PELD Cr score have the same risk of mortality. This is not the case in the previous system where candidates with a PELD score have higher mortality rates than adults at a given MELD score. For PELD Cr, the age-adjusted mortality factor adds 2.82 points to each candidate's PELD score.

---

[1] Chung-Chou H. Chang et al., "Accuracy of the Pediatric End-Stage Liver Disease Score in Estimating Pretransplant Mortality among Pediatric Liver Transplant Candidates," JAMA Pediatrics 172, no. 11 (January 2018): p. 1070, https://doi.org/10.1001/jamapediatrics.2018.2541

[2] H. J. Braun et al., "Nonstandard Exception Requests Impact Outcomes for Pediatric Liver Transplant Candidates," American Journal of Transplantation 16, no. 11 (2016): pp. 3181-3191, https://doi.org/10.1111/ajt.13879.

[3] For more information on how growth failure is calculated and the z-scores, please review the MELD and PELD calculators guide, available on the OPTN Website.

[4] Sonja M. Swenson et al., "Impact of the Pediatric End-Stage Liver Disease (Peld) Growth Failure Thresholds on Mortality among Pediatric Liver Transplant Candidates," American Journal of Transplantation 19, no. 12 (March 2019): pp. 3308-3318, https://doi.org/10.1111/ajt.15552.

[5] Ibid.

Will the range of PELD scores remain the same?

No, the minimum PELD Cr is 6. Under the previous PELD calculation, scores could range from -99 to 99. Under PELD Cr, any calculated score below 6 will be set to 6. PELD Cr scores can still go up to 99.

Can you explain the changes to NLRB guidance for pediatric candidates?

With the implementation of the PELD Cr score and changes to criteria for pediatric Status 1A and Status 1B, there are two associated updates to the National Liver Review Board (NLRB) Guidance Document for Pediatric MELD/PELD Exceptions.

First, the current guidance recommends that candidates be considered for a Status 1B exception if they have chronic liver disease and do not have a MELD or PELD score greater than 25. With the removal of the MELD or PELD 25 threshold, this guidance is no longer necessary and is being removed.

Similarly, the current guidance notes the current PELD score does not adequately capture all candidates with growth failure using height or weight z-scores. The updated guidance reflects the changes to the growth failure calculation and the fact that PELD Cr better incorporates the growth failure calculation via height or weight z-scores.

MELD 3.0:

How and why is the MELD score changing?

MELD 3.0 will address the sex-based disparity that has existed in liver allocation since the original MELD score was implemented. MELD 3.0 includes 1.33 points for candidates who are female. In addition, MELD 3.0 better predicts risk of waitlist mortality for all liver candidates by updating the coefficients for each of the variables in the score, adding albumin as a factor, introducing interaction terms, and lowering the maximum creatinine value from 4.0 to 3.0 mg/dL.

How are adolescent candidates handled under the new score?

In the current liver allocation system, adolescent candidates (age at least 12 and less than 18) are assigned a MELD score. Under this new policy, adolescent candidates will continue to utilize MELD 3.0, but both male and female adolescent candidates will receive the 1.33 points that will be provided to all adult female candidates. This is based on data that shows there is no sex-based disparity in the adolescent population.

Both male and female adolescent candidates registered before turning 18 will maintain the 1.33 points if they remain on the OPTN Waiting List after turning 18.

You may have heard about new data collection for adult MELD candidates related to, “Sex for Purposes of Adult MELD Calculation.” This new data collection is for adult candidates only. Because both male and female adolescent candidates will get the 1.33 points. The only change to data collection for adolescent candidates under MELD 3.0 is that albumin will now be required when updating a candidate’s lab values.

Status 1A and Status 1B

Which criteria are changing for Status 1A candidates?

The new policy changes the criteria for pediatric candidates qualifying for Status 1A priority with fulminant liver failure and hepatic encephalopathy.

In existing OPTN policy, a pediatric candidate can qualify for Status 1A with fulminant liver failure, defined as the onset of hepatic encephalopathy within 56 days of the first signs or symptoms of liver disease, if the candidate has an INR greater than 2.0. However, encephalopathy is difficult to diagnose in young children, and such diagnoses can be unreliable.

As a result, the requirements for a pediatric candidate with fulminant liver failure to qualify for Status 1A priority are changing.

The table below summarizes the changes related to fulminant liver failure and hepatic encephalopathy:

Table 1: Status 1A Policy Change

Previous Policy	New Policy
Fulminant liver failure, defined as the onset of hepatic encephalopathy, within the 56 days of the first signs or symptoms of liver disease AND has an INR greater than 2.0.	Fulminant liver failure AND candidate either has: • INR greater than or equal to 1.5 and less than 2.0 and a diagnosis of hepatic encephalopathy within 56 days of the first signs or symptoms of liver disease • INR greater than or equal to 2.0

Which criteria are changing for Status 1B candidates?

In addition Status 1A criteria changes, there are also three changes to Status 1B criteria which only applies to pediatric candidates. These three changes are:

- **MELD/PELD Threshold:**
  - Previous OPTN policy required pediatric liver-alone and liver-intestine candidates with chronic liver disease to have a MELD or PELD score greater than 25 in order to meet the standard criteria for Status 1B. Liver-alone candidates must have had a *calculated* MELD or PELD score greater than 25, and liver-intestine candidates must have had an *adjusted* MELD or PELD score greater than 25, which includes the addition of liver-intestine points as outlined in *OPTN Policy 9.1.F: Liver-Intestine Candidates.*
  - This threshold is being removed from policy as part of this project, as it does not have clinical significance.
- **Gastro-intestinal (GI) bleeding threshold:**
  - Under previous policy, pediatric liver-alone candidates with chronic liver disease could automatically qualify for Status 1B if they had GI bleeding requiring at least 30 mL/kg of red blood cell replacement within the previous 24 hours. This

requirement will be changed upon implementation to match an updated definition of persistent mild shock or moderate shock.
    - The new policy will change the GI bleeding threshold for liver-alone candidates to be **30** mL/kg in the previous **96** hours or **20** mL/kg in the previous **24** hours.
    - There are no changes to the GI bleeding threshold for liver-intestine candidates, as this criterion remains clinically appropriate.
- **Glasgow Coma Score Criterion**
    - Under previous policy, pediatric candidates with chronic liver disease could be listed as Status 1B if they had a Glasgow Coma Score (GCS) less than 10 within 48 hours before Status 1B assignment or extension. This criterion applied to both liver-alone and liver-intestine candidates.
    - This criterion will be removed for both liver-alone and liver-intestine candidates. It is not clinically relevant and rarely used as a means to support a Status 1B listing.

How will candidates be sorted within Status 1B?

This policy will also change how candidates are sorted within Status 1B. Under previous policy, Status 1B candidates were sorted based on blood type compatibility with the donor and waiting time at Status 1B using a points-based framework. With this policy, Status 1B candidates will also be sorted based on their diagnosis. The new policy provides the most priority to Status 1B candidates with chronic liver disease, followed by candidates with hepatoblastoma, and provides no additional priority within Status 1B for candidates with metabolic disease or any other diagnosis.

To be clear, this update to sorting is **within Status 1B only.** Prioritization of candidates based on diagnosis will not occur for candidates with a MELD or PELD score or listed as Status 1A.

Will any candidates lose their Status 1A or Status 1B priority upon implementation?

No candidates who have Status 1A or 1B priority will lose that priority upon implementation. However, to remain at Status 1A or Status 1B, candidates will be required to continue to meet the new criteria.

General Questions about implementation

How are liver-intestine points changing?

When a candidate is registered for a liver and an intestine, they are provided with additional MELD and PELD points to account for their increased mortality risk and need to access higher-quality donors. With this proposal, there is a small but important change to how these points are assigned based on the age of the candidate.

In *OPTN Policy 9.1.F: Liver-Intestine Candidates*, adult liver-intestine transplant candidates automatically receive an additional increase in their MELD score equivalent to a 10 percentage point increase in risk of 3-month mortality. Candidates less than 18 years old receive 23 additional points to their calculated MELD or PELD score instead of the 10 percentage point increase. Currently, these points are assigned based on the current age of the candidate. This

means that a candidate will switch from the 23 points to the 10 percent increase on the day he or she turns 18 on the OPTN Waiting List.

After Phase 2 implementation, the points will be based on the candidate's age at the time they are registered on the waitlist. As a result, if a liver-intestine candidate is registered before turning 18, they will continue to receive the 23 points for the duration of the time they remain on both the liver and intestine waitlist, even after turning 18. This change will be applied to candidates already on the OPTN Waiting List at the time of implementation.

What happens if I do not provide a required lab value for my candidate during Phase 1?

If you do not provide a required laboratory value used in MELD 3.0 or PELD Cr before Phase 2 is implemented, the candidate's calculated MELD 3.0 or PELD Cr score will be set to null upon implementation of Phase 2 and their medical urgency status will be set to MELD or PELD 6. Users will see the reason why the MELD or PELD score is set to null in the OPTN Computer System.

Will I be able to see which candidates are missing lab values before implementation of Phase 2?

Yes, the OPTN Contractor will provide candidate-level reports in the OPTN Computer System that will include detailed information about the candidates at your transplant program. This report will be available approximately one week after Phase 1 is implemented. You can access the report within the OPTN Computer System by navigating to the Data Services portal, then selecting OPTN Data Files on the left-hand side of the screen, and then filtering the "Organ" field to "Liver".

The report will include the following information for each candidate (in addition to general demographic information):

- Pediatric at time of listing (Yes/No)
- Birth Sex
- Sex for purposes of adult MELD calculation
- Liver-intestine candidate (Yes/No)
- Missing Lab Data

The report will also include the following information using **both the previous MELD and PELD and MELD 3.0 and PELD Cr,** based on the information that is available for the candidate:

- Calculated score
- Lab recertification due date
- Medical Urgency Status

These reports will help transplant programs see which candidates are missing required lab values, how candidate scores will likely change based on current information, and the new lab recertification dates based on the new scores at the time of implementation. The reports will be updated weekly.