OPTN

Notice of OPTN Policy and Guidance Changes

Improving Liver Allocation: MELD, PELD, Status 1A, Status 1B

Sponsoring Committee:	**OPTN Liver and Intestinal Organ Transplantation Committee**
Policies Affected:	***1.2: Definitions***
	9.1.B: Pediatric Status 1A Requirements
	9.1.C: Pediatric Status 1B Requirements
	9.1.D: MELD Score
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Guidance Affected:	**Guidance to Liver Transplant Programs and the National Liver Review Board for Pediatric MELD/PELD Exception Review**
Public Comment:	**January 27, 2022 – March 23, 2022**
Board Approved:	**June 27, 2022**
Effective Date:	**Pending implementation and notice to OPTN members**

Purpose of Policy and Guidance Changes

When being listed for a liver transplant, candidates receive a model for end-stage liver disease (MELD) or pediatric end-stage liver disease (PELD) score, which is calculated using a combination of the candidate's clinical lab values.[1] These scores are designed to reflect the probability of death on the waiting list within a 90-day period, with higher scores indicating a higher probability of mortality and increased urgency for transplant. Candidates who are less than 12 years old receive a PELD score, while candidates who are at least 12 years old receive a MELD score. Candidates that are particularly urgent are assigned status 1A or 1B.

The MELD score's ability to predict risk of waitlist mortality has decreased since the time it was developed.[2] A primary concern highlighted in recent literature is a disparity in access to transplant and

[1] The calculations for the MELD and PELD scores can be found in OPTN Policy, Available at https://optn.transplant.hrsa.gov/.
[2] Elizabeth L. Godfrey et al., "The Decreasing Predictive Power of MELD in an Era of Changing Etiology of Liver Disease," *American Journal of Transplantation* 19, no. 12 (April 2019): pp. 3299-3307, https://doi.org/10.1111/ajt.15559.

waitlist outcomes for female candidates under the current MELD score.[3,4,5] This proposal updates the MELD score to better predict risk of waitlist mortality for all candidates and provide priority to female candidates to address these issues.

Furthermore, recent research has shown that the current PELD score underpredicts the risk of pediatric waitlist mortality by as much as 17%, especially when compared to adult candidates with a MELD score.[6] Almost two-thirds of pediatric (age under 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.[7] Also, in the current PELD score, growth failure is a categorical variable and research has shown that 17% of pediatric liver transplant candidates fall into the "growth failure gap," in which candidates do not meet the current criteria in the PELD score for growth failure, despite actually having growth failure, and therefore inappropriately losing six to seven PELD points.[8] This proposal updates the PELD score to better predict mortality for pediatric candidates and addresses these additional issues.

In addition to the changes to the MELD and PELD scores, this proposal also updates the criteria candidates must meet in order to be approved for Status 1A or Status 1B and better sorts candidates within Status 1B based on mortality risk.

Together, the changes to the MELD score, PELD score, Status 1A, and Status 1B represent a necessary effort to update liver allocation policies in advance of future allocation changes.

Proposal History

The MELD score was developed in 2001 and incorporated into OPTN policy in 2002.[9] It was updated in 2016 to include serum sodium in the calculation.[10] Currently, the MELD score, typically called MELD Na, includes the following laboratory values: creatinine, bilirubin, INR, and sodium.[11] MELD scores range from six to 40, with higher scores indicating a higher risk of waitlist mortality and therefore increased urgency for transplant.

The PELD score was incorporated into OPTN policy in 2002 and has not been updated since it was first developed in 2000.[12] The PELD score is currently calculated using the following variables: age, albumin,

[3] Ibid.
[4] A. K. Mathur et al., "Sex-Based Disparities in Liver Transplant Rates in the United States," *American Journal of Transplantation* 11, no. 7 (June 30, 2011): 1435–43, https://doi.org/10.1111/j.1600-6143.2011.03498.x.
[5] J. C. Lai et al., "Height Contributes to the Gender Difference in Wait-List Mortality Under the MELD-Based Liver Allocation System," *American Journal of Transplantation* 10, no. 12 (November 18, 2010): 2658–64, https://doi.org/10.1111/j.1600-6143.2010.03326.x.
[6] 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.
[7] 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.
[8] 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.
[9] Kamath PS, Wiesner RH, Malinchoc M, et al "A Model to Predict Survival in Patients with End-Stage Liver Disease," *Hepatology* 33, no. 2 (2001): pp. 464-470, https://doi.org/10.1053/jhep.2001.22172.
[10] See OPTN/UNOS Liver and Intestinal Organ Transplant Committee Report to the Board of Directors, June 2014.
[11] See *OPTN Policy 9.1.D: MELD Score* for the full MELD calculation. Available at https://optn.transplant.hrsa.gov/.
[12] Sue V. McDiarmid, Ravinder Anand, and Anne S. Lindblad, "Development of a Pediatric End-Stage Liver Disease Score to Predict Poor Outcome in Children Awaiting Liver transplantation1," *Transplantation* 74, no. 2 (2002): pp. 173-181, https://doi.org/10.1097/00007890-200207270-00006.

bilirubin, INR, and growth failure.[13] PELD scores range from -99 to 99, although candidates generally have PELD scores between six and 40.

In addition to the MELD and PELD scores, liver transplant candidates can be listed as Status 1A or 1B, if they are particularly urgent. These statuses are reserved for those candidates most in need of a liver transplant and candidates listed as Status 1A and 1B are provided priority in the allocation schema. Both pediatric and adult candidates can be listed as Status 1A, which is the most urgent status, while only pediatric candidates can be listed as Status 1B.

Summary of Changes

This policy change was developed by the OPTN Liver and Intestinal Organ Transplantation Committee in collaboration with the OPTN Pediatric Transplantation Committee. The impact of the new MELD score, or MELD 3.0, was modeled using the Liver Simulated Allocation Model (LSAM). The new PELD score is referred to as PELD Creatinine or PELD Cr. The policy was approved by the OPTN Board of Directors in June 2022. The changes include:

- **MELD 3.0**: This policy improves 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.[14]
- **PELD Cr**: The policy improves 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. The updated PELD score, or PELD Cr, also includes 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 18-year-old candidate with an equivalent MELD score.
- **Status 1A**: This policy improves the Status 1A criteria for pediatric candidates with fulminant liver failure by updating the definition for hepatic encephalopathy so it aligns with the definition developed by the North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition.[15]
- **Status 1B**: First, the new policy removes the MELD/PELD 25 threshold for liver-intestine and liver-alone candidates with chronic liver disease as the threshold is not clinically relevant and can inappropriately preclude candidates from accessing Status 1B priority. 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 removes the Glasgow Coma Score (GCS) criteria for both liver-alone and liver-intestine candidates. Finally, the policy updates candidate sorting within Status 1B by prioritizing candidates with chronic liver disease, who are at the highest risk of waitlist mortality.[16]
- **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.

[13] See *OPTN Policy 9.1.E: PELD Score* for the full PELD calculation. Available at https://optn.transplant.hrsa.gov/.
[14] W. Ray Kim et al., "MELD 3.0: The Model for End-Stage Liver Disease Updated for the Modern Era," *Gastroenterology* 161, no. 6 (2021), https://doi.org/10.1053/j.gastro.2021.08.050.
[15] James E. Squires et al., "North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition Position Paper on the Diagnosis and Management of Pediatric Acute Liver Failure," *Journal of Pediatric Gastroenterology & Nutrition* Publish Ahead of Print (March 2021), https://doi.org/10.1097/mpg.0000000000003268.
[16] Descriptive Data Request: Status 1B Waitlist Removals, Prepared for PELD/1B Work Group meeting on August 19, 2021.

- Finally, the policy updates guidance for the pediatric National Liver Review Board (NLRB) to align with changes to PELD Cr.

Implementation

Transplant hospitals will need to educate staff and candidates about the changes to the MELD and PELD scores and Status 1A and 1B policy. MELD and PELD scores for candidates will change at the time of implementation. Transplant programs will need to inform their candidates of any potential changes in their MELD or PELD score as a result of the new policy, especially if a candidate's new score will be lower. Similarly, the laboratory update schedule for individual candidates could change based on their new MELD or PELD score at the time of implementation.

Transplant programs will need to submit albumin values for all adult MELD candidates prior to implementation. They will also have the opportunity to provide a candidate's current sex if it does not match the candidate's birth sex.

In addition, transplant programs are not currently required to submit creatinine values for candidates age 10 and under. With the incorporation of creatinine in PELD Cr, transplant programs will need to submit creatinine values for all PELD candidates.

The OPTN will consider implementation procedures to ensure transplant programs have sufficient time to update any required lab values, but transplant programs will need to be proactive in submitting the required laboratory values.

At the time of implementation, no Status 1A or Status 1B candidates will lose their priority status. However, these candidates will need to meet the updated requirements in policy to continue at the respective status.

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.

M

Model for End Stage Liver Disease (MELD)
The scoring system used to measure illness severity in the allocation of livers to ~~adults~~ transplant candidates at least 12 years old.

P

Pediatric End Stage Liver Disease (PELD)
The scoring system used to measure illness severity in the allocation of livers to pediatric candidates under the age of 12.

9.1.B Pediatric Status 1A Requirements

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

The candidate's transplant program may assign the candidate pediatric status 1A if *all* the following conditions are met:

1. The candidate is less than 18 years old at the time of registration. This includes candidates less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, but does not include candidates removed from the waiting list at any time who then return to the waiting list after turning 18 years old.

2. The candidate has at least *one* of the following conditions:

    a. Fulminant liver failure~~, defined as the onset of hepatic encephalopathy within 56 days of the first signs or symptoms of liver disease. In addition~~ and the candidate:
        i. Must not have a pre-existing diagnosis of 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.
        ii. Must meet at least *one* of the following conditions:
            1. Is ventilator dependent
            2. Requires dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
            3. Has an international normalized ratio (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
            4. Has an ~~international normalized ratio (~~INR~~)~~ greater than or equal to 2.0

    b. Diagnosis of primary non-function of a transplanted liver within 7 days of transplant, evidenced by at least *two* of the following:
        i. Alanine aminotransferase (ALT) greater than or equal to 2,000 U/L
        ii. INR greater than or equal to 2.5
        iii. Total bilirubin greater than or equal to 10 mg/dL

iv. Acidosis, defined as *one* of the following:
- Arterial pH less than or equal to 7.30
- Venous pH less than or equal to 7.25
- Lactate greater than or equal to 4 mmol/L

All laboratory results reported for any tests required for the primary non-function of a transplanted liver diagnosis above must be from the same blood draw taken between 24 hours and 7 days after the transplant.

c. Diagnosis of hepatic artery thrombosis (HAT) in a transplanted liver within 14 days of transplant

d. Acute decompensated Wilson's disease

9.1.C Pediatric Status 1B Requirements

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

The candidate's transplant program may assign the candidate pediatric status 1B if *all* the following conditions are met:

1. The candidate is less than 18 years old at the time of registration. This includes candidates less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, but does not include candidates removed from the waiting list at any time who then return to the waiting list after turning 18 years old.

2. The candidate has *one* of the following conditions:

   a. The candidate has a biopsy-proven hepatoblastoma without evidence of metastatic disease.

   b. The candidate has an organic acidemia or urea cycle defect and an approved MELD or PELD exception meeting standard criteria for metabolic disease for at least 30 days.

   c. Chronic liver disease ~~with a calculated MELD or PELD greater than 25~~ and ~~has~~ meets at least *one* of the following criteria due to complications of chronic liver disease:
      i. Is on a mechanical ventilator
      ii. Has gastrointestinal bleeding requiring red blood cell replacement of at least 30 mL/kg ~~of red blood cell replacement~~ within the previous ~~24~~ 96 hours or 20 mL/kg within the previous 24 hours
      iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
      ~~iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension.~~

d. Chronic liver disease and is a combined liver-intestine candidate ~~with an adjusted MELD or PELD score greater than 25 according to *Policy 9.1.F: Liver-Intestine Candidates*~~ and ~~has~~ meets at least *one* of the following criteria due to complications of chronic liver disease:
    i. Is on a mechanical ventilator
    ii. Has gastrointestinal bleeding requiring at least 10 mL/kg of red blood cell replacement within the previous 24 hours
    iii. Has renal failure or renal insufficiency requiring dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
    ~~iv. Has a Glasgow coma score (GCS) less than 10 within 48 hours before the status 1B assignment or extension.~~

9.1.D MELD Score

~~Candidates who are at least 12 years old receive an initial $MELD_{(i)}$ score equal to: *0.957 x Loge(creatinine mg/dL) + 0. 378 x Log_e(bilirubin mg/dL) + 1.120 x Loge (INR) + 0.643*~~

~~Laboratory values less than 1.0 will be set to 1.0 when calculating a candidate's MELD score.~~

~~The following candidates will receive a creatinine value of 4.0 mg/dL:~~

- ~~Candidates with a creatinine value greater than 4.0 mg/dL~~
- ~~Candidates who received two or more dialysis treatments within the prior 7 days~~
- ~~Candidates who received 24 hours of continuous veno-venous hemodialysis (CVVHD) within the prior 7 days~~

~~The maximum MELD score is 40. The MELD score derived from this calculation will be rounded to the tenth decimal place and then multiplied by 10.~~

~~For candidates with an initial MELD score greater than 11, the MELD score is then re-calculated as follows:~~

~~$MELD = MELD_{(i)} + 1.32*(137-Na) - [0.033*MELD_{(i)}*(137-Na)]$~~

~~Sodium values less than 125 mmol/L will be set to 125, and values greater than 137 mmol/L will be set to 137.~~

Candidates who are at least 18 years old at the time of registration receive a MELD score equal to:

$$MELD = 1.33 \text{ (if female)} + [4.56 \times \log_e(\text{bilirubin})] + [0.82 \times (137-\text{sodium})] - [0.24 \times (137-\text{sodium}) \times \log_e(\text{bilirubin})] + [9.09 \times \log_e(\text{INR})] + [11.14 \times \log_e(\text{creatinine})] + [1.85 \times (3.5-\text{albumin})] - [1.83 \times (3.5-\text{albumin}) \times \log_e(\text{creatinine})] + 6$$

Candidates who are currently at least 12 years old and were less than 18 years old at the time of registration receive a MELD score equal to:

MELD = [4.56 x $\log_e$(bilirubin)] + [0.82 x (137-sodium)] – [0.24 x (137-sodium) x $\log_e$(bilirubin)] + [9.09 x $\log_e$(INR)] + [11.14 x $\log_e$(creatinine)] + [1.85 x (3.5-albumin)] – [1.83 x (3.5 – albumin) x $\log_e$(creatinine)] + 7.33

Bilirubin, INR, and creatinine values less than 1.0 will be set to 1.0 when calculating a candidate's MELD score.

The following candidates will receive a creatinine value of 3.0 mg/dL when calculating a candidate's MELD score:

- Candidates with a creatinine value greater than 3.0 mg/dL
- Candidates who received two or more dialysis treatments within the 7 days prior to the serum creatinine test
- Candidates who received 24 hours of continuous veno-venous hemodialysis (CVVHD) within the 7 days prior to the serum creatinine test

Sodium values less than 125 mmol/L will be set to 125 mmol/L, and values greater than 137 mmol/L will be set to 137 mmol/L.

Albumin values less than 1.5 g/dL will be set to 1.5 g/dL, and values greater than 3.5 g/dL will be set to 3.5 g/dL.

The minimum MELD score is 6. The maximum MELD score is 40. The MELD score derived from this calculation will be rounded to the nearest whole number.

9.1.E PELD Score

Candidates who are under the age of 12 ~~less than 12 years old~~ receive a PELD score equal to:

~~*0.436 (Age (<1 YR.)) – 0.687 x Log$_e$(albumin g/dL) + 0.480 x Log$_e$(total bilirubin mg/dL) + 1.857 x Log$_e$(INR) +0.667 (Growth failure (< -2 Std. Deviations present))*~~

~~The PELD score derived from this calculation will be rounded to the tenth decimal place and then multiplied by 10.~~

~~Scores for candidates registered for liver transplantation before the candidate's first birthday continue to include the value of 0.436 until the candidate is 24 months old.~~

~~Laboratory values less than 1.0 will be set to 1.0 when calculating a candidate's PELD score.~~

~~A candidate has growth failure if the candidate is more than two standard deviations below the candidate's expected growth based on age and gender using the most recent Centers for Disease Control and Prevention's (CDC) National Center for Health Statistics pediatric clinical growth chart.~~

Table 9-1: PELD Score Calculation

	If the value is:	Then the value's contribution to PELD is:
Candidate Age (fractional calendar year)	< 1	-0.1967 * 1
	1 to 5.5	-0.1967 * age at the time of most recent lab reported for use in the PELD score (fractional calendar year)
	> 5.5 and < 12	-0.1967 * 5.5
Albumin (g/dL)	1 to 1.9	-1.842 * ln(albumin)
	> 1.9	-1.842 * ln(1.9)
Total bilirubin (mg/dL)	1 to 4	0.7854 * ln(bilirubin) + 0.3434 * ln(4)
	> 4 to 40	0.7854 * ln(4) + 0.3434 * ln(bilirubin)
	> 40	0.7854 * ln(4) + 0.3434 * ln(40)
INR	1 to 2	1.981 * ln(INR) + 0.7298 * ln(2)
	> 2 to 10	1.981 * ln(2) + 0.7298 * ln(INR)
	> 10	1.981 * ln(2) + 0.7298 * ln(10)
Minimum of CDC height or weight Z-score	< -5.0	-0.1807 * (-5)
	-5.0 to -2.1	-0.1807 * (minimum z-score)
	> -2.1	-0.1807 * (-2.1)
Creatinine (mg/dL) Creatinine (mg/dL)	< 0.2	1.453 * ln(0.2)
	0.2 to 1.3	1.453 * ln(creatinine)
	> 1.3	1.453 * ln(1.3)

A candidate's PELD score will then be calculated as follows:

PELD = (sum of all terms as outlined in **Table 9-1: PELD Score Calculation** + 1.5287) x 10 + 2.82

The minimum of Center for Disease Control and Prevention's (CDC) height or weight Z-score uses the lambda-mu-alpha (LMS) method and is based on the 2000 CDC Growth Charts for the United States. The calculation uses the candidate's birth sex, most recent values submitted for height and weight, and the candidate's age in months at the time the height and weight values used in the PELD calculation were measured.

Albumin, bilirubin, and INR values less than 1.0 will be set to 1.0 when calculating a candidate's PELD score.

The following candidates will receive a creatinine value of 1.3 mg/dL when calculating a candidate's PELD score:

- Candidates with a creatinine value greater than 1.3 mg/dL
- Candidates who received two or more dialysis treatments within the 7 days prior to the serum creatinine test

- Candidates who received 24 hours of continuous veno-venous hemodialysis (CVVHD) within the 7 days prior to the serum creatinine test

The minimum PELD score is 6. The PELD score derived from this calculation will be rounded to the nearest whole number.

9.1.F Liver-Intestine Candidates

~~Adult liver candidates who are also registered and active on the waiting list for an intestine transplant at that transplant hospital~~ Liver candidates who are registered on the waiting list after turning 18 years old and are also registered and active on the waiting list for an intestine transplant at that transplant hospital will automatically receive an additional increase in their MELD or PELD score equivalent to a 10 percentage point increase in risk of 3-month mortality. Liver candidates who are registered on the waiting list before turning 18 years old and are also registered and active on the waiting list for an intestine transplant at that transplant hospital ~~Candidates less than 18 years old~~ will receive 23 additional points to their calculated MELD or PELD score ~~instead of the 10 percentage point increase~~. The transplant hospital must document in the candidate's medical record the medical justification for the combined liver-intestine transplant and that the transplant was completed.

9.2 Status and Laboratory Values Update Schedule

The OPTN will notify the transplant hospital within 2 days of the deadline for recertification when a candidate's laboratory values need to be updated. Transplant hospitals must recertify a candidate's values according to *Table 9-~~1~~2*.

When reporting laboratory values to the OPTN, transplant hospitals must submit the most recent results including the dates of the laboratory tests. In order to change a MELD or PELD score voluntarily, all laboratory values must be obtained within the same 2 day period.

Table 9~~-1~~2: Liver Status Update Schedule

If the candidate is:	The new laboratory values must be reported every:	And when reported, the new laboratory values must be no older than :
Status 1A or 1B	7 days	2 days
MELD 25 or greater (ages 18 or older)	7 days	2 days
MELD/PELD 25 or greater (less than 18 years old)	14 days	3 days
MELD/PELD 19 to 24	30 days	7 days
MELD/PELD 11 to 18	90 days	14 days
MELD/PELD 10 or less	365 days	30 days

Status 1B candidates have these further requirements for certification:

- Candidates with a gastrointestinal bleed as the reason for the initial status 1B upgrade criteria must have had another bleed in the past 7 days immediately before the upgrade in order to recertify as status 1B.
- Candidates indicating a metabolic disease or a hepatoblastoma require recertification every 90 days with lab values no older than 14 days.

If a candidate is not recertified by the deadline according to *Table 9~~-1~~2*, the candidate will be re-assigned to their previous lower MELD or PELD score. The candidate may remain at that previous lower score for the period allowed based on the recertification schedule for the previous lower score, minus the time spent in the uncertified score.

If the candidate remains uncertified past the recertification due date for the previous lower score, the candidate will be assigned a MELD or PELD score of 6. If a candidate has no previous lower MELD or PELD score, and is not recertified according to the schedule, the candidate will be reassigned to a MELD or PELD score of 6~~, or will remain at the uncertified PELD score if it is less than 6~~.

9.7 Liver Allocation Points

Points are used for sorting liver candidates according to *Policy 9.8.D: Sorting Within Each Classification*.

9.7.A Points for Waiting Time

Points are assigned so that the status 1A or 1B candidate with the longest waiting time receives the most points as follows:

- 10 points for the candidate with the greatest total status 1A or status 1B waiting time within each classification
- A fraction of 10 points divided up among the remaining status 1A or status 1B candidates within each classification, based on the potential recipient's total waiting time

9.7.B Points Assigned by Blood Type

For status 1A and 1B transplant candidates, those with the same blood type as the deceased liver donor will receive 10 points. Candidates with compatible but not identical blood types will receive 5 points, and candidates with incompatible types will receive 0 points. Blood type O candidates who will accept a liver from a blood type A, non-A1 blood type donor will receive 5 points for blood type incompatible matching.

9.7.C Points Assigned by Diagnosis

Status 1B candidates will be assigned points based on diagnosis as follows:

- If the candidate's diagnosis is chronic liver disease, the candidate will receive 15 points.
- If the candidate's diagnosis is hepatoblastoma, the candidate will receive 5 points.
- If the candidate's diagnosis is an organic acidemia or urea cycle defect, the candidate will receive 0 points.
- If the candidate has any other diagnosis, the candidate will receive 0 points.

9.8.D Sorting Within Each Classification

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

1. ~~Total~~ The sum of waiting time and blood type compatibility points ~~(highest to lowest)~~, according to *Policy 9.7: Liver Allocation Points* (highest to lowest)
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~~ The sum of waiting time, ~~and~~ blood type compatibility ~~points~~, and diagnosis points ~~(highest to lowest),~~ according to *Policy 9.7: Liver Allocation Points* (highest to lowest)
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. Allocation MELD or PELD score (highest to lowest)
2. Blood type compatibility (identical, compatible, then incompatible)
3. Age at time of registration on the liver waitlist (less than 18 years old followed by 18 years or older)

4. Allocation MELD or PELD score type (calculated, including liver-intestine points, then exception)
5. Allocation MELD or PELD score waiting time (highest to lowest)
6. Total waiting time (highest to lowest)

Guidance to Liver Transplant Programs and the National Liver Review Board for: Pediatric MELD/PELD Exception Review

Background

For allocation purposes, a liver candidate is either registered in a status or receives a MELD or, if less than 12 years old, a PELD score. Candidates are registered in either status 1A or 1B if the candidate meets certain clinical criteria defined by policy, and transplant programs may request to register a candidate in a status if the candidate does not meet the policy requirements. The Committee retrospectively reviews candidates registered in a status by exception.

The MELD and PELD scores are intended to reflect the candidate's disease severity, based on the risk of 3-month mortality without access to liver transplant. When the calculated score does not reflect the candidate's medical urgency, a liver transplant program may request an exception for a higher score. A candidate that meets the criteria for one of the diagnoses in policy is approved for a standardized MELD or PELD exception.[17] If the candidate does not meet criteria for standardized exception, the Review Board considers the request. Pediatric candidates with approved exceptions who turn 18 while still waiting with an approved exception continue to be eligible to receive pediatric exceptions unless or until the candidate is removed from the waiting list.[18]

The Committee has developed guidance for pediatric status and MELD or PELD exception candidates. To support a recommendation for approving an exceptional status registration or additional MELD or PELD exception points, there must have been adequate evidence of increased risk of mortality associated with the complication of liver disease.

This guidance replaces any independent criteria that OPTN regions use to request and approve exceptions, commonly referred to as "regional agreements." Review Board members, transplant ~~centers~~ programs, and the Committee should consult this resource when considering status or MELD/PELD exception requests for pediatric candidates registered before turning 18 years old ~~less than 18 years old~~. Any guidance contained within this document that differs from the guidance offered for adult MELD exceptions is intentional, and is based on peer-review literature and/or clinical practice.

Status 1B

Status 1B - Chronic liver disease

Generally candidates that do not meet criteria in *Policy 9.1.C: Pediatric Status 1B Requirements* should not receive a status 1B exception~~. Candidates that meet criteria in *Policy 9.1.C.2.c* or *9.1.C.2.d* but without a PELD score of at least 25 may be considered for status 1B exception if the candidate is critically ill and admitted in the Intensive Care Unit (ICU).~~ Candidates without renal replacement therapy may be considered for a status 1B exception if they meet all other criteria in policy and require a liver

[17] Policy 9.3.C: Specific MELD/PELD Exceptions, Organ Procurement and Transplantation Network Policies.
[18] Policy 9.1: Status and Score Exceptions, Organ Procurement and Transplantation Network Policies.

support device (such as Molecular Adsorbent Recirculating System (MARS), albumin dialysis, plasmapheresis).

Chronic Liver Disease[19,20,21,22,23,24,25]

Growth Failure or Nutritional Insufficiency

~~It is now known that the PELD score, as currently calculated, does not accurately capture growth failure for all children.~~ The PELD-Cr score improves accuracy of capturing growth failure, but still may not entirely capture growth failure as it accounts only for height and weight z-scores, and does not correct the weight for ascites or organomegaly. Exceptions should be considered for candidates who meet any of the following criteria:

- Growth parameters[26]
  - <5th percentile for: height, weight (may adjust to estimated dry weight if ascites)[27,28]
  - Z-score (~~weight, height, or~~ BMI/weight-for-length) less than 2 standard deviations below the mean for age and ~~gender~~ sex
- Anthropometrics
  - Triceps skin fold thickness or mid-arm muscle circumference < 5th percentile for age and ~~gender~~ sex [29]
- Failure of nasoenteric tube feedings as evidenced by failure to demonstrate improvement in growth failure in the previous month based on either weight or anthropometrics[30]
- Requirement for TPN nutrition to allow for growth or to maintain euglycemia

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[19] Tamir M et al pediatric liver Transplantation for Primary Sclerosing Cholangitis Liver Transplantation 17:925-933 2011
[20] Elgendy H et al The outcome of critically ill children afterliving donor liver transplant Exp Clin Transplant Suppl 1 : 100-7 2015
[21] Malatack etal Choosing a pediatric recipient for orthotopic liver transplantation J Pediatr 111: 479-489 1987
[22] Sarin SK etal Young adult cirrhotics: a prospective comparative analysis of the clinical profile, natural course and survival Gut 29: 101-107 1988
[23] Matloff RG The Kidney in Pediatric Liver Disease Curr Gastroenterol Rep 17: 36
[24] Dara N et al Liver function, paraclinical tests, and mortality risk factors in pediatric liver transplant candidates Comparative clinical Pathology 25 (1) : 189-195 2015
[25] Keating et al Clinical course of cirrhosis in young adults and therapeutic potential of liver transplantation Gut 26: 1359-1363 1985
[26] Sokol RJ etal Anthropometric evaluation of children with chronic liver diseases Am J Nutrition 52:203-208 1980
[27] World Health Organization global Database on Child Growth and Malnutrition
[28] Yang etal Living donor liver transplantation with body weight more or less than 10 kilograms world J Gastroenterol 21 (23) 7248-53 2015
[29] UptoDate 2016. Table for skin fold thickness percentiles.
[30] Chin SE the nature of malnutrition in children with end-stage liver disease awaiting orthotopic liver transplantation Am J Clin Nutr 56:164-168 1992