

Notice of OPTN Policy, Guidelines, and Guidance Changes

Further Enhancements to the National Liver Review Board

Sponsoring Committee:	Liver and Intestinal Organ Transplantation
Policies Affected:	<i>Policy 9.5.G: Requirements for Portopulmonary Hypertension MELD or PELD Score Exceptions</i> <i>Policy 9.5.I.i: Initial Assessment and Requirements for HCC Exception Requests</i>
Guidelines Affected:	National Liver Review Board Operational Guidelines
Guidance Affected:	Guidance to Liver Transplant Programs and the National Liver Review Board for Adult MELD Exception Review
Public Comment:	August 4, 2020 – October 1, 2020
Board Approved:	December 7, 2020
Effective Date:	February 9, 2021: Guidance to Liver Transplant Programs and the National Liver Review Board for Adult MELD Exception Review Pending implementation and notice to OPTN members: <i>Policy 9.5.G: Requirements for Portopulmonary Hypertension MELD or PELD Score Exceptions</i> <i>Policy 9.5.I.i: Initial Assessment and Requirements for HCC Exception Requests</i> National Liver Review Board Operational Guidelines

Purpose of Policy, Guidelines, and Guidance Changes

The National Liver Review Board (NLRB) was implemented on May 14, 2019.¹ The purpose of the NLRB is to provide equitable access to transplant for liver candidates whose calculated model for end-stage liver disease (MELD) score or pediatric end-stage liver disease (PELD) score does not accurately reflect the candidate's medical urgency for transplant. Since the implementation of the NLRB, the OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) has continued to evaluate the effectiveness of the system and has identified a number of ways in which the NLRB could be improved through updates to the NLRB policy, operational guidelines, and guidance documents. The purpose of this proposal is to improve the NLRB by incorporating feedback from the transplant community. The proposed changes are anticipated to create a more efficient and equitable system for the review of exception requests.

¹ *Proposal to Establish a National Liver Review Board*, OPTN Liver and Intestinal Organ Transplantation Committee, June 2017, Available at <https://optn.transplant.hrsa.gov/>

Proposal History

Prior to the implementation of the NLRB, MELD and PELD exception requests were reviewed by regional review boards (RRBs). The implementation of the NLRB was a significant change in the process for reviewing MELD or PELD exception requests and because of the significance and complexity of the change, the Committee anticipated that there would be areas for improvement identified after implementation. This proposal represents the second proposal approved by the OPTN Board of Directors to improve the NLRB.²

Summary of Changes

The changes included in this proposal are listed below:

- **Policy:** The changes to policy include updating the criteria for a standardized MELD or PELD exception for portopulmonary hypertension (POPH) to match updated clinical guidelines and creating a more effective process for reviewing *Post-Transplant Explant Pathology* forms for candidates with hepatocellular carcinoma (HCC).
- **Operational Guidelines:** The improvements to the operational guidelines include creating a separate Appeals Review Team (ART) specifically for pediatric cases and adding an ART leader to each ART.
- **Guidance:** The proposal updates the guidance for polycystic liver disease (PLD) to clarify the MELD score recommendation, provide guidance for candidates also requiring a kidney, and add new comorbidities that should be considered for a MELD exception in conjunction with PLD.

Implementation

The changes to the standardized criteria for POPH exceptions involve new data collection. Two new fields will be added to the initial exception form for POPH, as well as new data validation and label changes. Three new fields will be added to the exception extension form for POPH and one field will be removed. Transplant programs will need to be familiar with the new data collection and develop processes to provide the necessary data. The proposed changes to the explant pathology form review process will require members to submit additional documentation or imaging studies less frequently

Transplant programs will also need to be aware of the pediatric ART and be prepared to speak to a more pediatric-focused audience when appealing cases to the pediatric ART. Similarly, transplant programs will need to be familiar with the updated guidance for PLD. Members of the NLRB serving on the Pediatric specialty board will need to serve on the Pediatric ART. All NLRB reviewers should be familiar with changes to guidance for PLD. The proposal does not impact the operations of organ procurement organizations or histocompatibility laboratories.

The OPTN will implement programming changes in UNetSM to update the POPH criteria, create the new process for reviewing explant pathology forms, and institute the pediatric ART.

Affected Policy, Guidelines, and Guidance Language

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

² *Enhancements to the National Liver Review Board*, OPTN Liver and Intestinal Organ Transplantation Committee, June 2020, Available at <https://optn.transplant.hrsa.gov/>

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 submits evidence of *all* of the following:

1. 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. Initial pulmonary vascular resistance (PVR) level~~
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. Post-treatment MPAP less than 35 mmHg within 90 days prior to submission of the initial exception~~
- ~~6. Post-treatment PVR less than 400 dynes*sec/cm⁵, or less than 5.1 Wood units (WU), on the same test date as post-treatment MPAP less than 35 mmHg~~
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 a score according to *Table 9-7* below.

Table 9-7: Portopulmonary Hypertension 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 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 ~~the mean pulmonary arterial pressure (MPAP) remains less than 35 mmHg.~~ 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.

9.5.1.i Initial Assessment and Requirements for HCC Exception Requests

Prior to applying for a standardized MELD or PELD exception, the candidate must undergo a thorough assessment that includes *all* of the following:

1. An evaluation of the number and size of lesions before local-regional therapy that meet Class 5 criteria using a dynamic contrast enhanced computed tomography (CT) or magnetic resonance imaging (MRI)
2. A CT of the chest to rule out metastatic disease
3. A CT or MRI to rule out any other sites of extrahepatic spread or macrovascular involvement
4. An indication that the candidate is not eligible for resection
5. An indication whether the candidate has undergone local-regional therapy
6. The candidate's alpha-fetoprotein (AFP) level

The transplant hospital must maintain documentation of the radiologic images and assessments of all OPTN Class 5 lesions in the candidate's medical record. If growth criteria are used to classify a lesion as HCC, the radiology report must contain the prior and current dates of imaging, type of imaging, and measurements of the lesion.

For those candidates who receive a liver transplant while receiving additional priority under the HCC exception criteria, the transplant hospital must submit the *Post-Transplant Explant Pathology Form* to the OPTN within 60 days of transplant. If the ~~pathology report~~ *Post-Transplant Explant Pathology Form* does not show evidence of HCC or liver-directed therapy for HCC, the transplant ~~hospital~~ program must also submit documentation or imaging studies confirming HCC at the time of assignment.

The Liver and Intestinal Organ Transplantation Committee will review ~~a transplant hospital~~ the submitted documentation or imaging studies when more than 10 percent of the HCC cases in a one-year period are not supported by the required ~~pathologic confirmation or submission of clinical information.~~ *Post-Transplant Explant Pathology Forms* submitted by a transplant program in a one year period do not show evidence of HCC or liver-directed therapy for HCC.

National Liver Review Board Operational Guidelines

1. Overview

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/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 same MELD or PELD score.

The NLRB is comprised of specialty boards, including:

- Adult Hepatocellular Carcinoma (HCC)
- 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

The immediate past-Chair of the Liver and Intestinal Organ Transplantation Committee serves as the Chair of the NLRB for a two year term.

2. Representation

Every active liver transplant program may appoint a representative and alternate to each of the adult specialty boards. A liver transplant program with an active pediatric component may appoint a representative and alternate to the pediatric specialty board. Individuals may serve on more than one specialty board at the same time. Transplant programs are encouraged to appoint representatives from both hepatology and surgery who have active transplant experience. Liver transplant programs are not required to provide a representative to the NLRB.

Representatives and alternates serve a one year term. A liver transplant program may appoint the same representative or alternate to serve consecutive terms.

If a transplant hospital withdraws or inactivates its liver program, it may not participate in the NLRB. However, the transplant hospital's participation may resume once it has reactivated its liver program.

3. Representative and Alternate Responsibilities

Prior to each term of service, representatives and alternates are required to sign the *UNOS Confidentiality and Conflict of Interest Statement* and complete orientation training.

Representatives must vote within 7 days on all exception requests, exception extension requests, and appeals. A representative will receive an e-mail reminder after day 3 and day 5 if the representative has an outstanding vote that must be completed. On the eighth day, if the vote has not been completed, then the request will be randomly reassigned to another representative. The original reviewer will receive a notification that the request has been reassigned.

The representative must notify UNOS in UNetSM of an absence, during which the alternateSM will fulfill the responsibilities of the representative.

If a representative or alternate does not vote on an open request within 7 days on more than 5% of the cases assigned to that reviewer within a 6 month period, the Chair may remove the individual from the NLRB. If a representative or alternate does not vote because a case is approved and closed before the 7 day timeframe expires, it is not considered a failure to vote. A representative or alternate who has been removed for failure to perform the duties required is not eligible to serve again for 3 years.

If a transplant program exhibits a pattern of non-responsiveness, as evidenced by the removal of two members from the NLRB, the Chair may suspend the program's participation for a period of three months after notifying the program director. Further non-compliance with the review board process may result in cessation of the program's representation on the NLRB until such a time as the transplant hospital can satisfactorily assure the Chair that it has addressed the causes of non-compliance.

4. Voting Procedure

An exception request is randomly assigned to five representatives of the appropriate specialty board. A representative may vote to approve or deny the request, or ask that the request be reassigned. The request must achieve four out of five affirmative votes in order to be approved. If the request does not achieve the necessary four affirmative votes, it is denied.

As part of the MELD/PELD Exception program in UNetSM, NLRB members are notified of new cases by email.

Voting on an exception request is closed either at the end of the appeal period or when no additional votes will change the outcome of the vote, whichever occurs earlier. Members no longer have the ability to vote once a request is closed.

5. Appeal Process

A liver program may appeal the NLRB's decision to deny an exception request. Patients are not eligible to appeal exception requests. All reviewer comments are available in UNetSM. The NLRB advises programs to respond to the comments of dissenting reviewers in the appeal.

The same five members that reviewed the original request will review the appeal. The appeal must achieve four out of five affirmative votes in order to be approved. If the appeal does not achieve the necessary four affirmative votes, it is denied. If the appeal is denied, the liver program may request a conference call with the Appeals Review Team (ART).

If the ART denies the request, the liver program may initiate a final appeal to the Liver and Intestinal Organ Transplantation Committee (Liver Committee). Referral of cases to the Liver Committee will include information about the number of previous referrals from that program and the outcome of those referrals.

6. Appeals Review Team (ART)

At the beginning of each new service term, nine NLRB members from the Adult Other Diagnosis and Adult HCC specialty boards are ~~randomly~~ assigned to serve each month of the year on the Adult ART and nine NLRB members from the Pediatric specialty board are assigned to serve each month of the year on the Pediatric ART. There may be multiple ARTs, depending on the volume of cases. ~~An NLRB member will be~~

~~selected to serve for no more than one month each year on the ART. The ART meets via conference call at the same day and time each week; however calls may be rescheduled in advance to accommodate federal holidays. Each ART will be scheduled to meet via conference call according to a predetermined schedule.~~

ART appeals from the Adult Other Diagnosis and Adult HCC specialty boards will be reviewed by the Adult ART. ART appeals from the Pediatric specialty board will be reviewed by the Pediatric ART.

In the event of a planned absence, the ART member may designate their alternate to serve. The representative must notify UNOS of this in UNetSM.

Five members of the ART must participate in the call. If at least five members do not attend the call, the appeal will be rescheduled for the following regularly scheduled conference call. If at least five members do not attend the second attempt to review the appeal, the candidate's exception request is automatically approved.

The appeal must achieve a majority plus one affirmative votes in order to be approved.

A representative at the petitioning program may serve as the candidate's advocate. If a representative is unable to attend the conference call, the program may ask for the appeal to be scheduled for the following regularly scheduled conference call. If after two attempts a representative is unable to attend the call, the ART will review the appeal without the program's participation. In the absence of a representative on the conference call, the program may submit written information for the ART's consideration.

A current member of the Liver Committee serving on either the Adult Other Diagnosis specialty board or Adult HCC specialty board will be appointed to serve as the ART leader for the Adult ART prior to each service term. A current member of the Liver Committee or current member of the OPTN Pediatric Transplantation Committee (Pediatric Committee) serving on the Pediatric specialty board will be appointed to serve as the ART leader for the Pediatric ART prior to each service term. If no current member of either the Liver Committee or the Pediatric Committee is available to serve as the ART leader, prior members of each Committee or other members of the NLRB may be appointed to serve as ART leader. The ART leader will be prepared to lead ART discussion and provide feedback to the Liver Committee.

The ART will work with UNOS staff to document the content of the discussion and final decision in UNetSM.

7. Liver Committee Review

The Liver Committee may delegate review to a subcommittee. If the review is delegated, majority is based on the size of the subcommittee.

Appeals to the Liver Committee will be considered electronically unless at least one member of the Liver Committee requests a conference call. If the case is discussed on a conference call, quorum is a majority of the Liver Committee (or the subcommittee, if delegated).

The appeal must achieve a majority affirmative votes in order to be approved.

Guidance to Liver Transplant Programs and the National Liver Review Board for Adult MELD Exception Review

Polycystic Liver Disease (PLD)

Certain patients with PLD may benefit from MELD exception points. Indication for an exception include those with PCLKD (Mayo type D or C) with severe symptoms plus *any* of the following:

- Hepatic decompensation
- Concurrent hemodialysis
- GFR less than 20 ml/min
- Patient with a prior kidney transplant
- Moderate to severe protein calorie malnutrition

Transplant programs should provide the following criteria when submitting exceptions for PLD. The Review Board should consider the following criteria when reviewing exception applications for candidates with PLD.

1. Management of PLD

PLD Classification – Mayo Modification

Types	A	B	C	D
Symptoms	0 - +	++/+++	++/+++	++/+++
Cyst Findings	Focal	Focal	Diffuse	Diffuse
Spared Remnant Volume	≥3	≥2	≥1	<1
PV/HV Occlusion	No	No	No	Yes

2. Surgical Management of PLD

- Indications:
 - a. Types C* and D **and** at least 2 of the following:
 - Hepatic decompensation
 - Concurrent renal failure (dialysis)
 - b. Compensated comorbidities

Note: Prior resection/fenestration, alternative therapy precluded.

Patients who meet the criteria above should be considered for a MELD exception similar to other policy-assigned exception scores. ~~for MELD exception points such that transplantation may be expected within the year.~~

When a candidate also meets the medical eligibility criteria for liver-kidney allocation as described in OPTN Policy 9.9: Liver-Kidney Allocation and is registered on the kidney waitlist, the candidate should be

considered for a MELD exception score similar to the score assigned to candidates with primary hyperoxaluria in OPTN Policy.