OPTN

Briefing to the OPTN Board of Directors on

Enhancements to the National Liver Review Board

OPTN Liver and Intestinal Organ Transplantation Committee

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Enhancements to the National Liver Review Board

Affected Policies:	*Policy 9.4.A: MELD or PELD Score Exception Requests* *Policy 9.4.C: MELD or PELD Score Exception Extensions* *Policy 9.4.D: Calculation of Median MELD or PELD at Transplant* *Policy 9.5.I.vii: Extensions of HCC Exceptions*
Affected Guidelines:	*National Liver Review Board Operational Guidelines* *Guidance to Liver Transplant Programs and the National Liver Review Board for Adult MELD Exception Review* *Guidance to Liver Transplant Programs and the National Liver Review Board for Adult MELD Exceptions for Hepatocellular Carcinoma*
Sponsoring Committee:	*Liver and Intestinal Organ Transplantation*
Public Comment Period:	*January 22, 2020 – March 24, 2020*
Board of Directors Date:	*June 8, 2020*

Executive Summary

The purpose of the National Liver Review Board (NLRB), which was implemented on May 14, 2019, 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.[1] Since implementation, the transplant community and the OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) have noted numerous ways to improve the NLRB in its goal to provide more efficient and equitable access to transplant.

This proposal seeks to make the following enhancements to the NLRB policy, operational guidelines, and guidance documents in order to make the system more efficient and equitable.

- Policy: The proposed changes to policy will clarify the scope of the NLRB by instructing reviewers to base decisions on the medical urgency of the candidate, allow any candidate with hepatocellular carcinoma (HCC) meeting standardized extension criteria to be automatically approved, and clarify the update schedule for median MELD at transplant (MMaT) and median PELD at transplant (MPaT) to allow for more time to calculate, communicate, and implement the new scores.
- Operational Guidelines: The improvements to the operational guidelines include aligning the scope of the NLRB with the changes to policy, adjusting the threshold and schedule for removing inactive reviewers to reflect differences in individual reviewer caseloads and allow for more timely removal of inactive reviewers, and outlining the process for final appeals to the Committee.
- Guidance: The proposed updates to the guidance documents include the addition of guidance for secondary sclerosing cholangitis (SSC) and adults with metabolic disease, the removal of unnecessary language for portopulmonary hypertension (PH), and clarifying that candidates

[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/

who had HCC more than two years ago that was treated but then recurs should be considered the same as those with no prior HCC only when applying for an initial exception.

The proposal was well supported throughout public comment. In response to the feedback submitted, the Committee is proposing post-public comment changes to the timeframe for evaluating inactive reviewers, further clarifying the guidance for adults with metabolic disease, and aligning language related to review board scope in policy and the operational guidelines.

This proposal helps promote the efficient management of the OPTN and seeks to improve the NLRB in accordance with the OPTN Final Rule.

Background

When being listed for a liver transplant, candidates receive a calculated MELD or PELD score, which is based on a combination of the candidate's clinical lab values.[2] These scores are designed to reflect the probability of death on the waitlist within a 3-month 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 a priority 1A or 1B status.

When a transplant program believes that a candidate's calculated MELD or PELD score does not accurately reflect a candidate's medical urgency, they may request a score exception. The NLRB is responsible for reviewing exception requests and either approving or denying the requested score.

Prior to the implementation of the NLRB, exception requests were reviewed by regional review boards that evaluated all exception requests for candidates listed in that particular region. Most regions had their own criteria for exception review, contributing to differences in exception review practices between regions.[3]

To address this issue, the OPTN Board of Directors (Board) approved a proposal to establish the NLRB at their June 2017 meeting.[4] The NLRB was designed to create a more efficient and equitable system for reviewing exception requests for candidates across the country.

Under the NLRB, if an exception request or an extension of a granted exception request meets the criteria outlined in OPTN policy for one of the standardized diagnoses, then the request is automatically approved by the system. In the first six months of the NLRB, 2,257 (30.3%) of the 7,451 exception request forms were auto-approved by the system.[5] Allowing requests that meet standardized criteria to be automatically approved ensures that similar candidates are treated consistently and reduces the workload for NLRB reviewers and transplant programs.

Exception requests that are automatically approved are granted a policy-assigned exception score that is relative to the median MELD at transplant (MMaT) in the area of the transplant program where the candidate is listed or the median PELD at transplant (MPaT) for the nation. The assigning of exception points relative to the MMaT for the area around the transplant program at which the candidate is listed ensures that similar diagnoses are treated consistently across the country but also reflects local differences in the candidate pool.[6] The cohort and update schedule for the MMaT and MPaT calculations are included in NLRB policy.

[2] The calculation for the MELD and PELD scores can be found in OPTN Policy, Available at https://optn.transplant.hrsa.gov/.
[3] *Proposal to Establish a National Liver Review Board*, OPTN Liver and Intestinal Organ Transplantation Committee, June 2017, Available at https://optn.transplant.hrsa.gov/
[4] Ibid.
[5] OPTN Descriptive Data Request. "National Liver Review Board Out-of-the-Gate Report, Six Months Data Report" Prepared for Liver and Intestinal Organ Transplantation Committee Meeting, March 1, 2020, Available at https://optn.transplant.hrsa.gov/
[6] 42 C.F.R. §121.8(a)(8) requires that allocation policies "shall not be based on the candidate's place of residence or place of listing except to the extent required" by the other requirements of Section 121.8 of the Final Rule. In developing the Acuity Circles allocation policy, the Committee determined that the use of MMaT based on the transplant program where the candidate is registered is required to meet the requirements in 42 C.F.R. §121.8(a)(1)-(5).

Most standardized diagnoses are granted a score of MMaT-3. Adolescent candidates who meet the criteria for a standardized diagnosis are typically given a score of MMaT and pediatric candidates are given a score of MPaT. Some diagnoses are given additional priority due to their increased urgency.

If an exception request or extension does not meet the criteria for a standardized diagnosis, the candidate has a diagnosis not included in the list of standardized diagnoses, or the transplant program is requesting a score different than the policy-assigned score, then the request is reviewed by one of three specialty review boards that make up the NLRB. The three specialty boards are: Adult HCC, Adult Other Diagnosis, and Pediatric. The Adult HCC specialty board reviews exception cases for all adult candidates with hepatocellular carcinoma (HCC). The Adult Other Diagnosis specialty board reviews all exception cases for adult candidates with any diagnosis besides HCC. The Pediatric specialty board reviews all exception cases for pediatric candidates.

All active liver transplant programs can appoint a representative and alternate to the Adult HCC and Adult Other Diagnosis specialty boards. Liver programs with an active pediatric component may appoint a representative and alternate to the pediatric specialty review board.

Each request that is reviewed by a specialty board is assigned five random reviewers from across the country. The request is approved if four of the five reviewers submit their approval. If the case is denied, the submitting program has the opportunity to appeal the decision, first to the same group of reviewers, then to the Appeals Review Team (ART), and finally to the Committee.

When reviewing requests, NLRB members are provided with clinical guidance documents that were approved by the Board and are posted to the OPTN website.[7] Each specialty board has its own guidance document summarizing the available evidence to guide reviewers in approving exception requests.

During the time that the NLRB has been in place, the Committee has continuously assessed the system for ways in which it can be improved. Much of the work described herein was led by the NLRB Subcommittee, a subgroup of the Committee specifically focused on the NLRB. Committee members drew upon their own experiences with the NLRB and solicited feedback from members of the transplant community, including NLRB reviewers and transplant programs submitting exception requests, to identify ways in which the NLRB can be improved. The identified enhancements involve changes to OPTN policy language, the operational guidelines, and the guidance documents.

Purpose

Since the implementation of the NLRB, the Committee has carefully evaluated the effectiveness of the system. The Committee 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.

[7] The guidance documents for each of the NLRB specialty boards are available at https://optn.transplant.hrsa.gov/

The Committee submits the following proposal for the Board consideration under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[8]

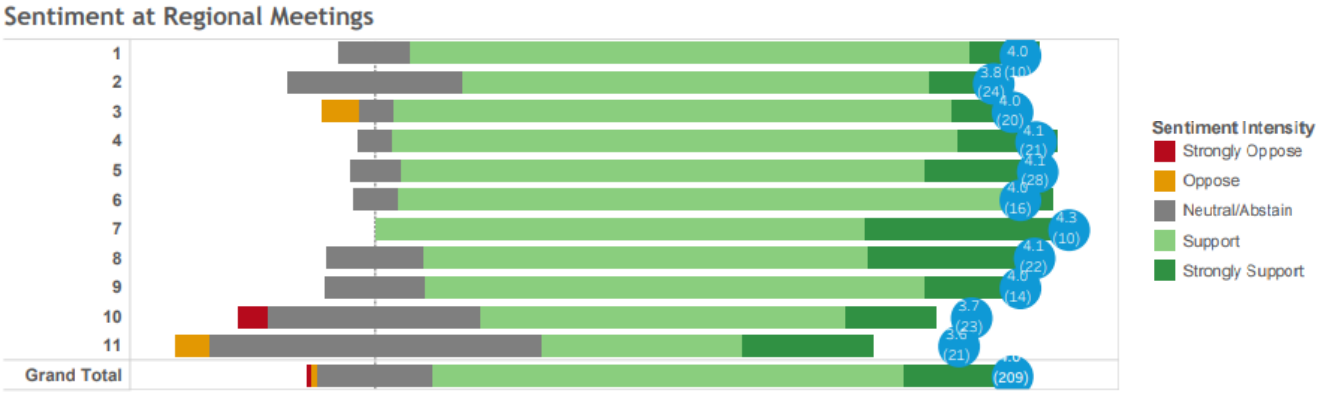
Overall Sentiment from Public Comment

The proposal was out for public comment from January 22, 2020 to March 24, 2020. It was presented at 11 OPTN regional meetings and received a total of 20 comments on the OPTN website. The OPTN regional meetings in regions 9, 10, and 11 were held virtually due to the COVID-19 crisis.

The proposal was well supported throughout public comment. It was supported by all 11 OPTN regions, as well as the American Society of Transplant Surgeons (ASTS), the American Society of Transplant (AST), NATCO, the Society for Pediatric Liver Transplant (SPLIT), and the Starzl Network for Excellence in Pediatric Transplantation.

The voting results from the 11 OPTN regions are included below in Figure 1.

Figure 1: Sentiment at Regional Meetings[9]

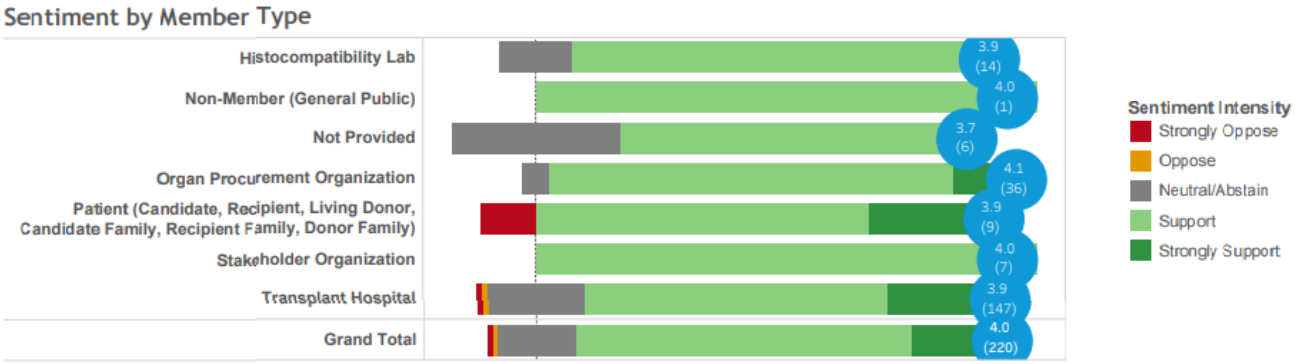


The voting results by member type are included below in Figure 2.

[8] 42 C.F.R. §121.4(a)(1)

[9] This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment for regional meetings only includes attendees at that regional meeting. Region 6 uses the average score for each institution. The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

Figure 2: Sentiment by Member Type[10]



While the proposal was well supported throughout public comment, there was specific feedback on some aspects of the proposal. Two themes that emerged through public comment were that inactive NLRB reviewers should be evaluated on a more frequent basis and that the exception score included in the proposed guidance for adults with metabolic disorders is too specific for a diverse candidate pool.

In addition, the Committee recognizes that the language used to describe the scope of the NLRB in the proposed guidelines was not consistent with the language used in OPTN Policy. More so, the discussion of review board scope within policy is not always consistent. As a result, the Committee is proposing additional changes to the language related to scope of NLRB review in both policy and the guidelines.

The Committee is proposing post-public comment changes to the timeframe for removing inactive reviewers, the guidance for adults with metabolic disorders, the scope of NLRB review in the guidelines and policy, and a few, minor clarifications. These changes are described more in the subsequent sections.

Much of the feedback submitted on the proposal throughout public comment involved operational aspects of the NLRB, including standardizing exception narratives, reviewing the NLRB reviewers, and improving the way that the system displays information to end users. While outside the scope of this proposal, the Committee appreciates this feedback and will consider it within the appropriate venues.

Proposal for Board Consideration

This proposal includes changes to OPTN Policy, the NLRB Operational Guidelines, and the NLRB Guidance Documents. The proposed changes to each of these documents is described in detail below.

OPTN Policy Language

OPTN Policies 9.4: MELD or PELD Score Exceptions and *9.5: Specific Standardized MELD or PELD Score Exceptions* outline the processes through which exception cases are reviewed, how the MMaT and MPaT calculation cohorts are defined, and the standardized diagnoses and related clinical criteria that

[10] This chart shows the sentiment for the public comment proposal. Sentiment is reported by the participant using a 5-point Likert scale (1-5 representing Strongly Oppose to Strongly Support). Sentiment by member type includes all comments regardless of source (regional meeting, committee meeting, online, fax, etc.) The circles after each bar indicate the average sentiment score and the number of participants is in the parentheses.

must be met for an exception request or extension of an exception request to be automatically approved by the system.

The Committee is proposing changes to OPTN policy related to the scope of the NLRB, automatic approval of HCC extensions, and the recalculation of MMaT and MPaT.

Scope of NLRB Review

The proposal that went out for public comment included the addition of language to the operational guidelines outlining the factors that NLRB reviewers should consider when there is no applicable policy or guidance for an exception case. Specifically, the Committee sought to add language to the guidelines instructing reviewers to consider the medical urgency, anticipated transplant efficacy, waitlist dropout rates, and waitlist mortality risk of the candidate if no guidance or policy is relevant. This language was included due to the wide diversity of factors NLRB reviewers provide in the comments explaining their decision to approve or deny an exception cases. The intent of the Committee was to put parameters on the factors NLRB reviewers should consider and provide instruction on how they should review cases when there is no applicable policy or guidance.

A number of public comments noted the need for clear and consistent language on the scope of the NLRB review and what factors should be considered when guidance and policy are not available. Therefore, the Committee reconsidered the factors included in the operational guidelines and re-evaluated how the scope of NLRB review is discussed in policy to ensure complete alignment.

As a result, the Committee is proposing post-public comment changes to *OPTN Policy 9.4: MELD or PELD Exceptions* and the operational guidelines (discussed more in the next section).

The introductory paragraph of *OPTN Policy 9.4: MELD or PELD Exceptions* states that the purpose of the NLRB is to review exceptions requests when a transplant program believes that a candidate's calculated MELD or PELD score does not appropriately reflect the candidate's medical urgency for transplant.

However, *OPTN Policy 9.4.A: MELD or PELD Score Exception Requests* states that transplant programs must include an explanation of how the candidate's potential benefit from transplant is comparable to other candidates with the requested MELD or PELD score.

The Committee agreed that the requirement for explaining the potential benefit for transplant does not align with the purpose of the NLRB, which is previously described as being based on the medical urgency of the candidate. As such, the Committee seeks to remove the policy language requiring transplant programs to submit an explanation of the exception candidate's potential benefit for transplant.

This change, in conjunction with the proposed changes to the operational guidelines, ensure that the scope of the NLRB is aligned in policy and the operational guidelines and that NLRB reviewers have clear instruction on how cases with no relevant guidance or policy should be evaluated.

The corresponding post-public comment changes to the operational guidelines are described in the "Operational Guidelines" section below.

Automatic Approval of HCC Extensions

Candidates with HCC are eligible to have their initial exception and subsequent extension requests automatically approved, as long as they meet the criteria described in *OPTN Policy 9.5*. However, many HCC candidates do not meet the standardized criteria and must have their requests reviewed by the Adult HCC specialty board. HCC candidates that do not initially meet standardized exception criteria may eventually be within the standardized extension criteria listed in OPTN Policy. However, the current system does not allow candidates meeting the standardized extension criteria to be automatically approved if the initial exception or a previous extension was reviewed by the NLRB. This means that candidates who, at some point, did not meet standardized criteria cannot have subsequent extension requests automatically approved, even when they do meet standardized extension criteria.

The Committee is proposing updating OPTN policy so that any HCC candidate can have an extension form automatically approved as long as they meet the standardized extension criteria and are requesting a policy-assigned score. This change will reduce the workload on NLRB reviewers and transplant programs and ensure that candidates with similar clinical characteristics are treated consistently.

A large portion of the cases reviewed by the Adult HCC specialty board have been extension requests and members of the Committee have noted that many of the extension requests submitted to the HCC review board appeared to meet the standardized extension criteria for automatic approval. Allowing candidates who meet the standardized extension criteria to be automatically approved will enable reviewers to devote more attention to those cases where their discretion is needed and increase the overall efficiency of the system.

The proposed changes will also reduce the administrative burden on transplant programs. Currently, transplant programs submitting extension requests for candidates that meet standardized extension criteria but who were not previously automatically approved must explain in the candidate's narrative that they meet standardized extension criteria and should be approved. This requires unnecessary time and effort. Allowing any HCC candidate who meets standardized extension criteria to be automatically approved will reduce the need for transplant programs to write extensive narratives and reduce the time needed to manage exception extensions for HCC candidates.

Finally, the proposed enhancements will ensure that candidates with similar clinical characteristics are treated in the same manner throughout the system.

This aspect of the proposal was supported throughout public comment and no changes were made by the Committee in response to the public comments submitted.

Recalculation of MMaT and MPaT

OPTN Policy 9.4.D: Calculation of Median MELD or PELD at Transplant outlines when the OPTN will recalculate the MMaT and MPaT upon which exception scores are based. The current policy states that scores will be updated every 180 days using a cohort from the previous 365 days. However, after recalculating the scores once, it became evident that such restrictive language regarding when the scores must be updated was unreasonable. For example, when updating the scores, it is impossible to base the scores on a cohort from the immediately previous 365 days, as there needs to be time to complete programming and data validation. Additionally, the new scores are published and

communicated to the community at least two weeks in advance of their implementation. The current language also does not take into account that the 180-day update could occur on a holiday or weekend.

As a result, the proposed language allows for more discretion regarding the precise timing of the updates, giving the OPTN sufficient time to properly calculate, publish, and communicate the updated scores in advance of their implementation. The proposed language still requires that the OPTN update the MMaT and MPaT scores on a semi-annual basis.

This aspect of the proposal was supported throughout public comment. In reviewing the policy after public comment, the Committee determined that an additional, clarifying change was needed. Specifically, the first paragraph of *OPTN Policy 9.4.D* still had language requiring that the cohort used in the MMaT calculation be from the last 365 days. The Committee is proposing an additional change to policy to clarify that the cohort be from a previous 365 day period but it does not need to be the immediately previous 365 days.

Operational Guidelines

The operational guidelines outline who may participate as an NLRB reviewer, the responsibilities of NLRB reviewers, the voting procedure, and the appeal process. [11] The Committee is proposing changes to the operational guidelines related to the scope of NLRB review, the removal of inactive reviewers, and the Committee appeal process.

Scope of NLRB Review

As noted previously, the original proposal included the addition of language to the operational guidelines outlining what information should be taken into account when NLRB reviewers are assigned a case when there is no clear policy or guidance. In the original proposal, the Committee proposed instructing NLRB reviewers to consider the medical urgency, anticipated transplant efficacy, waitlist dropout rates, and waitlist mortality risk of the candidate when no guidance or policy was relevant.

The language was changed in response to Committee deliberations after the public comment period. Upon further consideration, the Committee determined that anticipated transplant efficacy, waitlist dropout rates, and waitlist mortality risk were outside the scope of the NLRB, did not align with the purpose of the NLRB as articulated in policy, and could have led to inconsistent review of exception cases. Instead, the Committee is proposing that review board members only consider the medical urgency of the candidate as compared to other candidates with the requested MELD or PELD score. This better aligns with the purpose of the NLRB as described in OPTN policy and is consistent with the Final Rule.[12]

The addition of this language is intended to constrain the scope of NLRB review and to best approximate the purpose of MELD and PELD exception scores. The goal is to eliminate the variety of factors that NLRB reviewers consider when evaluating unique exception requests and instruct them to only consider the medical urgency of the candidate. This will increase the consistency with which case reviews are conducted.

[11] Current operational guidelines are available at https://optn.transplant.hrsa.gov/

[12] As an allocation goal, the Final Rule states regarding priority ranking candidates, "These rankings shall be ordered from most to least medically urgent…There shall be a sufficient number of categories (if categories are used) to avoid grouping together patients with substantially different medical urgency."

By instructing review board members to only consider the medical urgency of candidates when no policy or guidance is applicable and removing policy language regarding anticipated benefit for transplant (as described above), the Committee is ensuring that how the scope of the NLRB is described in policy and the operational guidelines is consistent with the purpose of the NLRB as articulated in *OPTN Policy 9.4 MELD or PELD Score Exceptions*.

Removal of Inactive Reviewers

The operational guidelines include language requiring the removal of reviewers who do not vote in a timely manner on open cases on three separate instances within a 12 month period. This requirement is intended to ensure prompt review of exception cases and remove reviewers who are consistently unable to meet the requirements of their position. However, in the first six months of the NLRB, 99 reviewers were reassigned due to inactivity at least three or more times. This represents approximately 28% of unique participants that have voted on any of the specialty review boards. [13]

Based on the data from the first six months of the NLRB, the Committee is proposing that the threshold for removal due to inactivity be changed to better align with practice. The proposed language includes two changes.

First, the threshold for removal would change from three missed cases to missing 5% of all cases assigned to the reviewer within a six month period.[14] The change from a set number to a percentage of cases reviewed accounts for the fact that the different specialty review boards are assigned a different number of cases and individual reviewers are assigned a different caseload depending on their availability. In the proposal that was released for public comment, the Committee had not changed the time period for evaluating inactive reviewers. However, during public comment, changing the time period for evaluation from every 12 months to every six months was well supported. The Committee agreed with this recommendation, as it allows for more responsive removal of inactive reviewers and ensures that cases are promptly reviewed.

In addition, the proposed language gives discretion for removal of inactive reviewers to the NLRB Chair. The Committee recognizes that there may be extenuating circumstances that disallow a reviewer from responding to cases and the proposed language provides for discretion when such situations occur. For example, NLRB reviewers have cited instances where they travelled outside of the country and did not enable the out of office functionality causing them to miss three cases. These reviewers were otherwise responsive. The proposed language would allow the NLRB Chair to consider such circumstances when deciding to remove an inactive reviewer. This aspect of the proposal was not changed in response to public comment.

Committee Appeal Process

The operational guidelines state that transplant programs can submit a final appeal to the Committee if a case is denied by the ART. However, the operational guidelines do not include information on the

[13] OPTN Descriptive Data Request. "National Liver Review Board Out-of-the-Gate Report, Six Months Data Report" Prepared for Liver and Intestinal Organ Transplantation Committee Meeting, March 19, 2020, Available at https://optn.transplant.hrsa.gov/

[14] In the first six months of the NLRB, 151 unique reviewers on the Adult HCC Specialty Board were assigned 2961 total exception requests, 135 unique reviewers on the Adult Other Diagnosis Specialty Board were assigned 1525 total exception requests, and 65 unique reviewers on the Pediatric Specialty Review board were assigned 509 total exception requests. Some individuals may be participants on more than one specialty board and this includes both primary and alternate representatives.

format of the final appeal or who must participate. Historically, the Committee has delegated this responsibility to the NLRB Subcommittee, which is made up of a subset of Committee members.

The proposed changes to the operational guidelines make it clear that the Committee can delegate responsibility for the final appeal to a subcommittee and provide more detail on the format of the appeal review. Specifically, the Committee is proposing the addition of language stating that the appeal must achieve a majority of affirmative votes to be approved and that a majority is based on the size of the subcommittee. The proposed changes also make it clear that final appeals will be reviewed electronically unless one of the subcommittee members requests a conference call at which point a quorum is a majority of the subcommittee.

These proposed changes to the operational guidelines increase transparency and efficiency in the appeal process by making it clear that the Committee can delegate the final review to a subcommittee. Delegation of final appeal review to a subcommittee will increase the efficiency of the system because the subcommittee is made up of a subset of the Committee that is specifically focused on the NLRB, allowing appeals to be reviewed more quickly than if they went to the full Committee. This aspect of the proposal was not changed in response to public comment.

Additional Post Public Comment Clarification

In reviewing the operational guidelines after public comment, the Committee also determined that the sentence instructing NLRB reviewers how to access their assigned cases was unnecessary. The sentence informed reviewers to click on the case link in the notification e-mail and how to access UNet^{SM}, which the Committee decided was not necessary. The Committee is proposing that this sentence be removed from the operational guidelines.

Guidance Documents

Each of the three specialty review boards has specific, clinical guidance to assist reviewers in evaluating exception requests for the corresponding candidate pool. The guidance documents are not OPTN policy and are intended to provide guidance to review board members and transplant programs to help ensure consistent and equitable review of exception cases. The Committee is proposing changes to the guidance documents for the Adult Other Diagnosis and Adult HCC Specialty Boards.

Adult Other Diagnosis

Portopulmonary Hypertension (PH) is a standardized diagnosis in policy that is granted an automatic exception when certain clinical criteria are met. It is also included in the Adult Other Diagnosis guidance document. The guidance document for PH includes a statement noting that candidates with PH who meet the criteria in policy are eligible for an automatic exception. However, it also includes language allowing for transplant programs to submit a request for a specific score as long as they provide a written narrative supporting the score. In addition, the guidance document includes a recommendation for transplant programs to report three specific clinical elements for the purposes of policy research and a reference to outdated policy language. Because candidates with PH are eligible for an automatic exception when they meet the criteria listed in policy, the Committee recommends striking all subsequent language from the PH section of the Adult Other Diagnosis guidance document.

The proposed changes would remove all language in the guidance related to PH, except for the language stating that candidates with PH are eligible for a standardized exception as long as they meet the criteria listed in OPTN policy. The subsequent language serves no substantive purpose, the recommended clinical elements are not being used for policy research, and the reference to policy is outdated. This section of the guidance was not changed in response to public comment.

The Adult Other Diagnosis guidance document also includes a section for primary sclerosing cholangitis (PSC) but no corresponding guidance for secondary sclerosing cholangitis (SSC). SSC and PSC have similar clinical features with the primary difference being that PSC is of unknown etiology, while SSC has a known cause.[15] Literature suggests that individuals with SSC may have a shortened life expectancy as compared to individuals with PSC and that individuals with SSC could benefit from liver transplantation.[16] Given the similarity of PSC and SSC and the potential benefit from transplant, the Committee is proposing adding SSC to the section in guidance for PSC. This would allow candidates with SSC to receive the same consideration as candidates with PSC. This addition was supported throughout public comment and was not changed from the original proposal.

The Committee is also proposing the addition of guidance for adult candidates with metabolic disorders. Individuals with metabolic disease are typically transplanted during infancy or childhood. However, in rare cases, adults can develop metabolic symptoms secondary to an inherited organic acidemia or urea cycle defect.[17] Pediatric candidates with a metabolic disorder are eligible for a standardized MELD or PELD exception, and if they have an exception for more than 30 days, they are eligible to be listed as Status 1B. However, there is no corresponding consideration for adults.

In the rare case that an adult develops metabolic symptoms, the Committee agreed that guidance on how to handle such a case would be beneficial. In the original proposal, the Committee recommended a score of MMaT-3 for adults with a metabolic disorder, but allowing for consideration of a higher score if life-threatening complications are present. However, public comment noted that the patient population covered by this guidance represented a diverse candidate pool, all of whom should not be granted an exception score of MMaT-3. As a result, the Committee changed the proposed guidance by removing the specific recommendation that these candidates receive an exception score equal to MMaT-3.

Adult HCC

The Adult HCC guidance document includes ambiguous language regarding how candidates with a history of HCC more than two years prior should be treated. The guidance states that candidates who had HCC more than two years ago that was treated but then recurs should be considered the same as those with no prior HCC when applying for an exception. The intent of this guidance was to only apply to candidates on their initial MELD exception, not if they have been listed with an exception previously. The proposed language clarifies this distinction and aligns the guidance with OPTN policy for HCC exception candidates. This clarification was supported throughout public comment and was not changed from the original proposal.

[15] Gossard, Andrea A., Paul Angulo, and Keith D. Lindor. "Secondary Sclerosing Cholangitis: A Comparison to Primary Sclerosing Cholangitis." *The American Journal of Gastroenterology* 100, no. 6 (2005): 1330–33. https://doi.org/10.1111/j.1572-0241.2005.41526.x.
[16] Ibid.
[17] Saudubray, J.-M., F. Sedel, and J. H. Walter. "Clinical Approach to Treatable Inborn Metabolic Diseases: An Introduction." *Journal of Inherited Metabolic Disease* 29, no. 2-3 (2006): 261–74. https://doi.org/10.1007/s10545-006-0358-0.

OPTN Final Rule Analysis

The Committee submits the following proposal for the Board consideration under the authority of the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[18]

The Final Rule requires that when developing policies for the equitable allocation of cadaveric organs, such policies must be developed "in accordance with §121.8," which requires that allocation policies "(1) Shall be based on sound medical judgment; (2) Shall seek to achieve the best use of donated organs; (3) Shall preserve the ability of a transplant program to decline an offer of an organ or not to use the organ for the potential recipient in accordance with §121.7(b)(4)(d) and (e); (4) Shall be specific for each organ type or combination of organ types to be transplanted into a transplant candidate; (5) Shall be designed to avoid wasting organs, to avoid futile transplants, to promote patient access to transplantation, and to promote the efficient management of organ placement;…(8) Shall not be based on the candidate's place of residence or place of listing, except to the extent required by paragraphs (a)(1)-(5) of this section." This proposal:

- **Is based on sound medical judgment**[19] of the Committee members, who are transplant professionals and the published literature, when applicable.
- **Seeks to achieve the best use of donated organs**[20] **by** increasing the likelihood that similarly urgent candidates will be treated in a similar manner, and increasing the likelihood that candidates with increased medical urgency receive organ offers before those candidates that are not as urgent.[21]
- **Is designed to…promote patient access to transplantation**[22] **by** more efficiently granting HCC exception extension requests and by adding guidance for candidates with SSC and adults with metabolic disease to make sure candidates that are similarly situated are granted access to the same scores and extensions.

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,[23] and it is specific to an organ type, in this case liver. [24]

Although the proposal outlined in this briefing paper addresses certain aspects of the Final Rule listed above, the Committee does not expect impacts on the following aspects of the Final Rule:

- Shall be designed to avoid wasting organs
- Shall be designed to avoid futile transplants
- Shall be designed to promote the efficient management of organ placement

This proposal is not based on the candidate's place of residence or place of listing.

[18] 42 CFR §121.4(a).
[19] 42 CFR §121.8(a)(1).
[20] 42 CFR §121.8(a)(2).
[21] 42 CFR §121.8(b)(2)
[22] 42 CFR §121.8(a)(5).
[23] 42 CFR §121.8(a)(3).
[24] 42 CFR §121.8(a)(4).

The OPTN Final Rule also requires the OPTN to "consider whether to adopt transition procedures" whenever organ allocation policies are revised.[25] The Committee did not identify any populations that may be treated "less favorably than they would have been treated under the previous policies" if these proposed policies are approved by the Board of Directors, and as such does not recommend the adoption of any transition procedures.[26]

Alignment with OPTN Strategic Plan[27]

Promote the efficient management of the OPTN: This proposal promotes the efficient management of the OPTN as it seeks to make the NLRB more efficient and equitable through changes to OPTN Policy, operational guidelines, and guidance documents.

Implementation Considerations

Member and OPTN Operations

Operations affecting Transplant Hospitals

Liver transplant programs will need to ensure that staff responsible for submitting exception requests are familiar with the updated operational guidelines and guidance documents. They will also need to be aware that any HCC candidate meeting standardized extension criteria is eligible for automatic approval, even if they were not previously automatically approved.

Operations affecting the OPTN

The OPTN will need to implement programming changes in UNet^{SM} to allow all HCC extension requests that meet standardized extension criteria to be automatically approved. No additional programming will be required for the proposed changes to the MMaT/MPaT update schedule, the operational guidelines, or the guidance documents.

The OPTN will need to communicate the proposed changes to all liver transplant programs and NLRB reviewers. Updates to existing education for NLRB reviewers and transplant programs will be made to reflect the changes in policy, operational guidelines, and guidance documents.

Operations affecting Histocompatibility Laboratories

This proposal is not anticipated to affect the operations of histocompatibility laboratories.

Operations affecting Organ Procurement Organizations

This proposal is not anticipated to affect the operations of organ procurement organizations.

[25] 42 C.F.R. § 121.8(d).
[26] See OPTN Liver and Intestinal Organ Transplant Committee Meeting from May 1, 2020 available at ttps://optn.transplant.hrsa.gov/
[27] For more information on the goals of the OPTN Strategic Plan, visit https://optn.transplant.hrsa.gov/governance/strategic-plan/.

Projected Fiscal Impact

Projected Impact on Histocompatibility Laboratories

This proposal is not anticipated to have any fiscal impact on histocompatibility labs.

Projected Impact on Organ Procurement Organizations

This proposal is not anticipated to have any fiscal impact on organ procurement organizations.

Projected Impact on Transplant Hospitals

This proposal is not anticipated to have any fiscal impact on transplant hospitals.

Projected Impact on the OPTN

Policy and Community Relations managed a subcommittee and coordinated internal departments for project work and cross-departmental coordination. Since the proposal called for many detailed changes, significant effort was required to coordinate Subcommittee and Committee discussion to review each aspect of the proposal.

A Small IT Implementation effort, estimated at 250 hours, involves system changes for submission of hepatocellular carcinoma (HCC) extension requests and regression testing.

Approximately 60 hours annually of ongoing monitoring from Research is anticipated in order to create evaluation reports. This monitoring is in addition to current monitoring of the National Liver Review Board.

Post-implementation Monitoring

Member Compliance

The Final Rule requires that allocation policies "include appropriate procedures to promote and review compliance including, to the extent appropriate, prospective and retrospective reviews of each transplant program's application of the policies to patients listed or proposed to be listed at the program."[28]

The proposed language will not change the current routine monitoring of OPTN members. Any data entered in UNet℠ may be reviewed by the OPTN, and members are required to provide documentation as requested.

Policy Evaluation

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate."[29]

[28] 42 CFR §121.8(a)(7).
[29] 42 CFR §121.8(a)(6).

The changes to NLRB policy, operational guidelines, and guidance documents will continue to be analyzed and reviewed during the 6-month intervals up to 36 months post-implementation (or longer if requested by the Committee) of the initial NLRB policy. Results will be provided nationally, by region, and specialty board type as appropriate. To monitor specific changes to HCC extension automatic approval, the metrics below, in addition to those identified for evaluation of the NLRB, will be considered:

- Number and percent of initial and extension HCC exception requests, overall and by HCC specialty board vs automatic approval
- Number and percent of extension HCC exception requests automatically approved after an NLRB-reviewed request
- Other measures as deemed appropriate by the Committee

Conclusion

The NLRB has been in place since May 14, 2019. As with any major implementation, the users of the system have noted many ways to improve the NLRB. The proposed changes to policy will ensure alignment of NLRB scope, will allow any HCC candidate meeting standardized extension criteria to be automatically approved, and increases transparency in the update schedule for MMaT and MPaT. The improvements to the operational guidelines include adding language on the scope of NLRB review, adjusting the threshold for removing inactive reviewers, and clarifying the process for final appeals to the Committee. The proposed updates to the guidance documents include the addition of recommendations for secondary sclerosing cholangitis (SSC) and adults with metabolic disease, the removal of unnecessary language for portopulmonary hypertension (PH), and clarification for how to handle cases where the candidate has a prior history of hepatocellular carcinoma (HCC).

These changes will increase equity, transparency, and efficiency in the NLRB system.

Policy Language

Proposed new language is underlined (<u>example</u>) and language that is proposed for removal is struck through (~~example~~). Heading numbers, table and figure captions, and cross-references affected by the numbering of these policies will be updated as necessary.

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
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 ~~and potential for benefit from transplant would be~~ <u>is</u> comparable to that of other candidates with that MELD or PELD score

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

9.4.C MELD or PELD Score Exception Extensions

<u>9.4.C.i Hepatocellular Carcinoma (HCC) MELD or PELD Score Exception Extensions</u>

<u>A candidate with an approved exception for HCC is eligible for automatic approval of an extension according to *Policy 9.5.I.vii Extensions of HCC Exceptions*, even if the initial exception was not a standardized MELD or PELD score exception.</u>

<u>9.4.C.ii Other MELD or PELD Score Exception Extensions</u>

A candidate's approved exception will be maintained if the transplant hospital 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 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 ~~the last 365 days.~~ 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 Contractor will recalculate the MMaT and MPaT every 180 days using the previous 365-day cohort. If there have been fewer than 10 qualifying transplants within 250 nautical miles of a transplant hospital in the previous 365 days, the MMaT will be calculated based on the previous 730 days.~~ 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.

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

9.5.I.vii Extensions of HCC Exceptions

~~In order for a candidate to maintain an approved exception for HCC, the transplant program must submit an updated MELD or PELD Exception Score Request Form that contains the following:~~ 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 will then receive the additional priority.~~ 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.I.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 liver candidate at least 18 years old at the time of 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 according to that exception score or the calculated MELD score, whichever is higher.

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

Table 9-10: HCC Exception Scores

Age	Age at registration	Exception Request	Score
At least 18 years old	At least 18 years old	Initial and first extension	6
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

#

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 UNet[SM] of an absence, during which the alternate will fulfill the responsibilities of the representative.

If a representative or alternate does not vote on an open request within 7 days on ~~three separate instances~~ more than 5% of the cases assigned to that reviewer within a ~~12~~ 6 month period, the Chair may ~~will~~ 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 UNet[SM], NLRB members are notified of new cases by email. ~~To access the exception request, click on the emailed link or go to https://www.unet.unos.org/. Log-in using your UNet[SM] username and password and click on "Waitlist," then "NLRB."~~

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 UNet[SM]. 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 ~~and Intestinal Organ Transplantation~~ 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 are randomly assigned to serve each month of the year on the 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.

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

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.

The ART will work with UNOS staff to document the content of the discussion and final decision in UNet[SM].

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

Portopulmonary Hypertension

Candidates meeting the criteria in *Policy 9.5: Specific Standardized MELD or PELD Score Exceptions* are eligible for MELD or PELD score exceptions that do not require evaluation by the full Review Board. ~~The transplant program must submit a request for a specific MELD or PELD score exception with a written narrative that supports the requested score. Templates were developed for these exceptions to aid the transplant programs in the process of submitting the required information to justify the exception. The Committee recommends that the following three elements be considered in reviewing the exception application in addition to the requirements listed in policy for the purposes of policy research:~~

~~1. Although policy only requires reporting of the MPAP and PVR, complete Hemodynamics should be reported, including MPAP, PVR, PWAP and CO.~~

~~2. To be considered abnormal, the initial mean pulmonary artery pressure (MPAP) should be >35 mmHg and pulmonary vascular resistance (PVR) levels should be > 240 dynes.s.cm-5.~~

~~3. The initial transpulmonary gradient (MPAP-PVR) to correct for volume overload should be > 12 mmHg~~

~~As noted in policy, these candidates will receive a MELD score of 22/ PELD score of 28. In order to qualify for MELD/PELD extensions and a 10% mortality equivalent increase in points, the required documentation must be resubmit every three months and the mean pulmonary arterial pressure (MPAP) must remain below 35 mmHg, confirmed by repeat heart catheterization.~~

Primary Sclerosing Cholangitis or Secondary Sclerosing Cholangitis

Candidates with Primary Sclerosing Cholangitis (PSC) or Secondary Sclerosing Cholangitis (SSC) historically have low mortality rates, and therefore do not need exception scores. Based on clinical experience and a review of the available literature, the Committee recommends that four specific elements be considered.

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

The candidate must meet both of the following two criteria:

1. The candidate has been admitted to the intensive care unit (ICU) two or more times over a three month period for hemodynamic instability requiring vasopressors
2. The candidate has cirrhosis

In addition the candidate must have one of the following criteria:

- The candidate has biliary tract stricture which are not responsive to treatment by interventional radiology (PTC) or therapeutic endoscopy (ERCP) or

- The candidate has been diagnosed with a highly-resistant infectious organism (e.g. Vancomycin Resistant Enterococcus (VRE), Extended Spectrum Beta-Lactamase (ESBL) producing gram negative organisms, Carbapenem-resistant Enterobacteriaceae (CRE), and Multidrug-resistant Acinetobacter.)

Metabolic Disease

Adults who develop metabolic symptoms secondary to an inherited organic acidemia or urea cycle defect which are typically transplanted during infancy or childhood may be suitable for MELD exception. Given later onset, anticipate a reduced urgency compared to early-onset disease, thus priority for transplant may be similar to other exceptions, though if a patient has more urgent medical condition, as reflected by life-threatening complications, a higher priority score can be considered.

Guidance to Liver Transplant Programs and the National Liver Review Board for Adult MELD Exceptions for Hepatocellular Carcinoma (HCC)

Recommendation

1. Patients with the following are contraindications for HCC exception score:

   - Macro-vascular invasion of main portal vein or hepatic vein
   - Extra-hepatic metastatic disease
   - Ruptured HCC
   - T1 stage HCC

   While in most cases, ruptured HCC and primary portal vein branch invasion of HCC would be contraindications, some patients who remain stable for a prolonged (minimum of 12 months) interval after treatment for primary portal vein branch invasion or after ruptured HCC may be suitable for consideration.

2. Patients who have a history of prior HCC more than ~~→~~2 years ago which was completely treated with no evidence of recurrence, who develop new or recurrent lesions after 2 years should generally be considered the same as those with no prior HCC, in order to determine the current stage suitability for an initial MELD exception, and initial MELD exception score assignment.