OPTN

Public Comment Proposal

Ongoing Review of National Liver Review Board (NLRB) Diagnoses

OPTN Liver and Intestinal Organ Transplantation Committee

Prepared by: Matthew Cafarella
UNOS Policy and Community Relations Department

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Ongoing Review of National Liver Review Board (NLRB) Diagnoses

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Sponsoring Committee:	*Liver and Intestinal Organ Transplantation*
Public Comment Period:	*January 27, 2022 – March 27, 2022*

Executive Summary

This proposal includes four updates to OPTN policy and guidance related to the National Liver Review Board (NLRB).

The purpose of the 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 for transplant.[1] Since implementation, the OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) has regularly evaluated the NLRB to identify opportunities for improvement. This proposal is the latest in a series of enhancements made to the NLRB after implementation. This proposal seeks to make improvements to the NLRB policy and guidance documents, including the following changes:

- **Hepatocellular Carcinoma (HCC) policy**: Update policy language to align with Liver Imaging Reporting and Data System (LI-RADS) terminology and classifications. These changes will ensure the transplant community is using a consistent lexicon for HCC imaging.
- **HCC Guidance**: Simplify guidance for candidates who had HCC that was treated and subsequently recurs. The proposed changes will provide a more consistent and equitable pathway for these candidates to receive a MELD exception.

[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/

- **Ischemic Cholangiopathy (IC) Guidance**: Recommend candidates meeting criteria for an exception be provided a score equal to median model for end-stage liver disease (MELD) at transplant (MMaT). This proposed change will allow these candidates to access transplant more quickly.
- **Polycystic liver disease (PLD) guidance**: Add more objective definition for moderate to severe protein calorie malnutrition, add sarcopenia as a qualifying comorbidity, remove unnecessary language, and recommend all candidates meeting criteria be considered for MMaT. These changes will ensure that the appropriate candidates are provided an exception and increase equity for all PLD candidates.

The Committee is seeking public comment feedback on the proposed changes to NLRB policy and guidance.

Purpose

The purpose for updating NLRB policy and guidance documents is to continue to improve the NLRB by creating a more efficient and equitable system for reviewing MELD and PELD exception requests. These changes ensure that guidance and policy language remain clear and aligned with current research so that the appropriate candidates receive MELD or PELD exceptions.

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 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.

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.

The NLRB was approved by the OPTN Board of Directors (the Board) at their June 2017 meeting and was implemented on May 14, 2019.[3] The NLRB was designed to create an efficient and equitable system for reviewing exception requests for candidates across the country.[4]

Under the NLRB, candidates who meet the criteria outlined in OPTN policy for one of the nine standardized diagnoses are eligible to have their exception automatically approved.[5] In addition, each of the three specialty review boards (Pediatric, Adult - Hepatocellular Carcinoma (HCC), and Adult - Other Diagnosis) has an associated guidance document.[6] The guidance documents contain information for review board members and transplant programs on diagnoses and clinical situations not included as one of the standardized diagnoses in policy. They provide recommendations on which candidates should be considered for a MELD or PELD exception and are based on published research, clinical guidelines, medical experience, and data. The documents are intended to help ensure consistent and equitable review of exception cases and are not OPTN policy.

Because these documents are consulted by transplant programs and NLRB reviewers when applying for and reviewing exception requests, they have the ability to impact which candidates are approved for a MELD or PELD exception. Therefore, it is necessary for the Committee to systematically and proactively review the documents to ensure they continue to align with current clinical consensus and updated data. This proposal was developed using a systematic and proactive review process. Rather than waiting to consider a change once an issue was identified, the Committee is continuing to examine current guidance and policy for a specific subset of NLRB diagnoses using a set schedule and review process.

[2] The calculations 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] See OPTN Policy 9.5: Specific Standardized MELD or PELD Exceptions, Available at https://optn.transplant.hrsa.gov/
[6] NLRB Guidance Documents are available at https://optn.transplant.hrsa.gov/

As a result of this process, the Committee is proposing updates to OPTN policy related to HCC, as well as guidance for HCC, IC, and PLD. The review process included reviewing recent literature, correcting ambiguity in current guidance, reviewing cases that were appealed to the Appeals Review Team (ART), consultation with subject matter experts, and review of updated data, as needed. In addition to the changes included in this proposal, the Committee reviewed current guidance for post-transplant complications and the policy for hyperoxaluria and is not recommending any changes at this time.

Overview of Proposal

HCC Policy

The Committee is proposing a number of updates to OPTN policy to align with the terminology used by the American College of Radiology. The proposed updates do not change which candidates will be approved for an HCC exception. Rather, the new language will align OPTN terminology with the terminology used by radiologists as documented in the LI-RADS v2018 manual.[7] The proposed changes were drafted in consultation with leaders from the American College of Radiology who are subject matter experts in this area and have the expertise necessary to suggest such changes. The updated policy will allow the liver transplant community to use a consistent lexicon for the classification of HCC lesions. The changes should simplify the work of transplant coordinators, who currently must translate between the terms used by radiologists and the terms used by the liver transplant team. Aligning the terminology between these groups will reduce the chance of data entry error.

A summary of the proposed changes is included in **Table 1** below.

Table 1: Overview of Proposed Changes to HCC Policy[8]

Current Language	Proposed Language
Local regional	Locoregional
Lesions	Class 5 lesions
T2 lesions	T2 Stage
Residual Lesions	Viable Lesions
CT or MRI	Dynamic-contrast enhanced CT or MRI
Scan is inadequate or incomplete	Lesion cannot be categorized due to image degradation or omission
OPTN Class 0	NC - Not Categorizable
Increased contrast enhancement, relative to hepatic parenchyma, on late arterial phase	Nonrim arterial phase hyper-enhancement
Washout during the later contrast phases and peripheral rim enhancement on delayed phase	Nonperipheral washout
Maximum diameter increase of 50% documented on serial MRI or CT obtained 180 days or less apart	Threshold growth defined as size increase of a mass by $\geq$ 50% in $\leq$ 180 days on MRI or CT
Washout on portal venous/delayed phase	Nonperipheral washout
Peripheral rim enhancement	Enhancing capsule
Ablated	Treated by locoregional therapy

[7] See CT/MRI LI-RADS v2018 Core available at acr.org.
[8] Table 1 does not include every change to HCC policy included in this proposal. Please review the Policy and Guidance section for all proposed changes.

The Committee is seeking public comment feedback on the proposed changes to HCC policy and is particularly interested in feedback from transplant coordinators responsible for entering this data in UNet[SM].

HCC Guidance

The Committee is proposing an update to HCC guidance that will simplify how candidates with a history of HCC who subsequently have an HCC recurrence should be considered by the NLRB.

In the current HCC guidance document, there are two sections related to candidates with a history of HCC that subsequently recurs. One section of the guidance document states that candidates with a history of unresected HCC more than two years ago that was completely treated, who then develop new or recurrent lesions should be considered the same as candidates with no history of HCC, as long as the transplant program is applying for the candidate's initial MELD exception.[9] In effect, this guidance recommends that these candidates wait the standard six month period before receiving their full MELD exception (MMaT-3). It is important to reiterate that this section of the guidance document is only intended to apply to candidates for whom a transplant program is submitting an initial HCC exception. It does not apply to candidates who have been listed with an HCC exception for any amount of time.[10]

In addition, there is a subsequent section which states that candidates with cirrhosis who present with T2 resectable HCC who undergo complete resection and develop T1 or T2 recurrence can be considered for a MELD exception without a six month waiting period. During the previous public comment period, the Committee added language to this section of the guidance to make it clear that candidates with a history of HCC more than two years ago that was resected and recurs do not need to wait six months to receive a full MELD exception score.[11]

However, upon further discussion, the Committee is now proposing that each of these sections be removed and replaced by a single section that will handle all candidates with a history of HCC who subsequently have an HCC recurrence, regardless of the initial treatment method.[12]

The updated guidance recommends that candidates who presented with T2 HCC which was completely treated either by locoregional therapy or resection, but who then developed T1 or T2 recurrence and the transplant program is requesting an initial exception more than six months but less than 60 months following the initial treatment or resection be provided an exception score equal to MMaT-3 without the six month delay.

Table 2 includes the relevant sections of guidance that are slated to be removed, as well as the proposed new guidance.

[9] See Guidance to Liver Transplant Programs and the National Liver Review Board for: Adult MELD Exceptions for Hepatocellular Carcinoma (HCC). Available at https://optn.transplant.hrsa.gov/
[10] Ibid.
[11] *Review of National Liver Review Board (NLRB) Diagnoses and Update to Alcohol Associated Diagnoses*, OPTN Liver and Intestinal Organ Transplantation Committee, December 2021, Available at https://optn.transplant.hrsa.gov/
[12] See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, November 5, 2021. Available at https://optn.transplant.hrsa.gov/

Table 2: Proposed Changes to HCC Guidance

Section 1 (Being Removed)	Section 5 (Being Removed)	NEW Section
Patients who have a history of prior unresected 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.	Patients with cirrhosis who presented with stage T2 resectable HCC (one lesion >2 cm and <5 cm in size, or two or three lesions >1 cm and <3 cm in size, based on resection specimen pathology) who underwent complete resection but developed T1 (biopsy proven), or T2 HCC (LI-RADS 5) following complete resection should be considered for MELD score exception, without a six month delay period. This includes candidates who initially presented with T2 resectable HCC and who underwent complete resection more than 2 years ago.	Patients who presented with stage T2 HCC (LI-RADS 5 or biopsy proven; one lesion >2 cm and <5 cm in size, or two or three lesions >1 cm and <3 cm in size) which was treated by locoregional therapy or resected but developed T1 or T2 HCC (LI-RADS 5 or biopsy proven) recurrence and the transplant program is requesting an initial HCC exception more than 6 months but less than 60 months following initial treatment or resection are eligible for a MELD score exception without a six month delay period.

As an example, under the proposed guidance, consider a patient who presented with T2 HCC 28 months ago. The HCC is completely treated via locoregional therapy and there is no evidence of recurrence. The HCC then recurs and the patient is diagnosed with another T2 lesion. Under the guidance currently in place, if the transplant program submitted an initial exception request for this candidate, he or she would need to wait six months to get MMaT-3.

Alternatively, the program could have listed this candidate for transplant upon initial HCC occurrence, and there is a strong likelihood the candidate would have been transplanted. But this would not have been the optimal outcome for the transplant system, as the program could have attempted treatment without resorting to transplant, thereby taking a liver that could have been offered to a candidate with no other treatment options besides transplantation. Under the proposed guidance, this candidate would be eligible for an exception equal to MMaT-3 without the six month delay. The updated guidance will give transplant programs the latitude to attempt to treat candidates with HCC prior to registering them for transplant without the fear that the candidate will recur and they will have lost time they would have been accruing on the waitlist.

The Committee chose the six to 60 month timeframe based on their clinical expertise.[13] Sixty months was chosen as the cutoff to ensure that the recurrence is not new lesions that are unrelated to the initial occurrence.[14] The six month timeframe was chose to align with the six month waiting period for HCC candidates and to ensure favorable tumor biology.[15] The Committee considered the example of a candidate who presented with T2 HCC that was completely treated via resection with no evidence of recurrence. The HCC then recurs four months after the initial presentation. The Committee did not think it was appropriate for this candidate to bypass the six month waiting period. However, the transplant program could monitor the candidate for two months to ensure favorable tumor biology and then submit an exception to bypass the six month waiting period and access an exception equal to MMaT-3 at the time of the initial exception.[16]

The Committee is seeking public comment feedback on the proposed change to HCC guidance. Specifically, the Committee asks transplant programs to consider the updated guidance in the context of their HCC candidates. Under the new guidance, are there candidates who would be able to bypass the six month waiting period that shouldn't be able to? Or, are there candidates who should be able to bypass the six month waiting period but are not able to?

Ischemic Cholangiopathy (IC) Guidance

Diffuse ischemic cholangiopathy is a complication associated with donation after cardiac death (DCD) liver transplant.[17] The current guidance document recommends that candidates with a prior DCD transplant who demonstrate two or more of the following criteria within 12 months of transplant should be considered for an exception:[18]

- Persistent cholestasis as defined by abnormal bilirubin (greater than 2 mg/dL)
- Two or more episodes of cholangitis with an associated bacteremia requiring hospital admission
- Evidence of non-anastomotic biliary strictures not responsive to further treatment

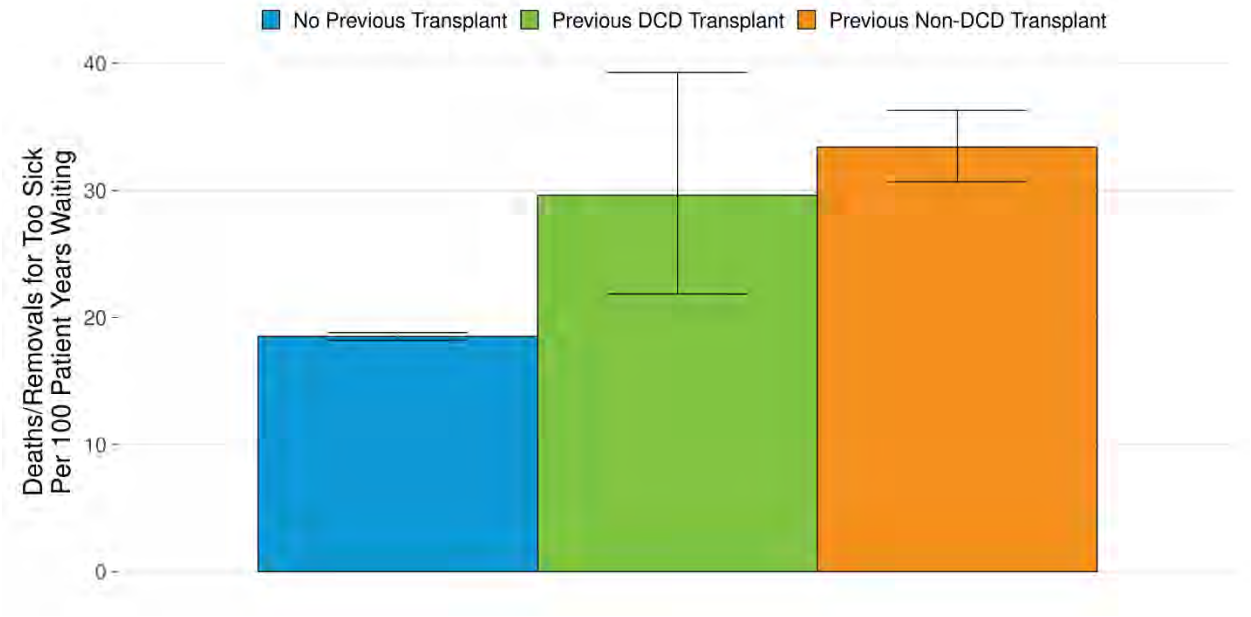
However, the current guidance does not recommend a specific exception score for these candidates.[19] The Committee is proposing that these candidates be provided a MELD exception equal to MMaT, which is higher than most other exception candidates, who receive MMaT-3. The Committee is proposing the higher score for these candidates to ensure they are able to access a high quality donor in time for re-transplant.[20]

The Committee reviewed data on candidates re-listed or re-transplanted after receiving a DCD donor liver.[21] As **Figure 1** depicts, this data showed that waitlist mortality rates for candidates re-listed for a

[13] See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 20, 2021. Available at https://optn.transplant.hrsa.gov/
[14] Ibid.
[15] Ibid.
[16] See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, November 5, 2021. Available at https://optn.transplant.hrsa.gov/
[17] See Guidance to Liver Transplant Programs and the National Liver Review Board for: Adult MELD Exception Review. Available at https://optn.transplant.hrsa.gov/
[18] Ibid.
[19] Ibid.
[20] See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 20, 2021. Available at https://optn.transplant.hrsa.gov/
[21] See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 1, 2021. Available at https://optn.transplant.hrsa.gov/

liver had higher waitlist mortality than candidates with no previous transplant, but there was no significant difference in waitlist mortality rate between candidates re-listed after receiving a DCD transplant as opposed to a non-DCD transplant.

Figure 1: Waiting List Mortality Rates for Adult Liver Transplant Candidates by Previous Transplant Group, 2015-2020



The Committee felt it was appropriate to provide candidates with IC an exception score equal to MMaT so that these candidates can access a high quality donor and be listed ahead of other, less urgent exception diagnoses.[22] In addition, the Committee felt that the higher exception score may incentivize transplant programs to use more DCD donors.[23]

The Committee is seeking public comment feedback on the proposed changes to IC guidance.

Polycystic Liver Disease Guidance

Finally, the Committee is proposing a number of updates to the guidance for candidates with PLD. The current guidance states that candidates with PLD with severe symptoms and any of the following criteria should be considered for a MELD exception:[24]

- Hepatic decompensation
- Concurrent hemodialysis
- GFR less than 20 ml/min

[22] See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 20, 2021. Available at https://optn.transplant.hrsa.gov/
[23] Ibid.
[24] See Guidance to Liver Transplant Programs and the National Liver Review Board for: Adult MELD Exception Review. Available at https://optn.transplant.hrsa.gov/

- Patient with a prior kidney transplant
- Moderate to severe protein calorie malnutrition

The current guidance then recommends that liver-alone candidates meeting these criteria be provided a score of MMaT-3 and liver-kidney candidates be provided a score equal to MMaT.[25]

The Committee is recommending a number of updates. First, the updated guidance adds language to make it clear that only candidates with PLD who are not clinically eligible for resection/fenestration or alternative therapy should be considered for an exception.[26] In addition, the updated guidance requires the presence of any of the qualifying comorbidities to be related to the candidate's PLD. This will ensure a causal relationship between the candidate's liver disease and the qualifying comorbidity, rather than a contemporaneous relationship.[27] The Committee is also recommending that "severe portal hypertensive complications" be added to the hepatic decompensation criterion.[28]

The updated guidance also includes more objective criteria to define moderate to severe protein calorie malnutrition. When the Committee last updated PLD guidance in 2020, they added "moderate to severe protein calorie malnutrition" as a qualifying comorbidity and debated if and how it should be more objectively defined to ensure only those candidates meeting the criteria are approved for an exception.[29] However, the Committee did not reach a consensus on how to further define moderate to severe protein calorie malnutrition at that time.[30] After additional review, the Committee is now proposing to further define moderate to severe protein calorie malnutrition by requiring a registered dietician to document the malnutrition using any of the following methods:

- Modified Global Leadership Initiative on Malnutrition (GLIM) Phenotypic criteria
- American Society for Enteral and Parenteral Nutrition (ASPEN) criteria
- Nutrition Focused Physical Exam (NFPE)
- Subjective Global Assessment (SGA-C score)

These tests include the standard methods by which a registered dietician would measure moderate to severe protein calorie malnutrition in a patient.[31,32,33,34,35,36] The updated guidance will ensure that only those candidates with documented malnutrition will be able to access a MELD exception. The

[25] Ibid.
[26] See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, November 5, 2021. Available at https://optn.transplant.hrsa.gov/
[27] Ibid.
[28] See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, October 20, 2021. Available at https://optn.transplant.hrsa.gov/
[29] *Further Enhancements to the National Liver Review Board*, OPTN Liver and Intestinal Organ Transplantation Committee, December 2020, Available at https://optn.transplant.hrsa.gov/
[30] Ibid.
[31] See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, November 5, 2021. Available at https://optn.transplant.hrsa.gov/
[32] T. Cederholm et al., "Glim Criteria for the Diagnosis of Malnutrition – a Consensus Report from the Global Clinical Nutrition Community," *Clinical Nutrition* 38, no. 1 (2019): pp. 1-9, https://doi.org/10.1016/j.clnu.2018.08.002.
[33] Charles Mueller, Charlene Compher, and Druyan Mary Ellen, "A.S.P.E.N. Clinical Guidelines," *Journal of Parenteral and Enteral Nutrition* 35, no. 1 (2011): pp. 16-24, https://doi.org/10.1177/0148607110389335.
[34] Beth Mordarski, "Nutrition-Focused Physical Exam Hands-on Training Workshop," *Journal of the Academy of Nutrition and Dietetics* 116, no. 5 (2016): pp. 868-869, https://doi.org/10.1016/j.jand.2016.03.004.
[35] Allan S. Detsky et al., "Predicting Nutrition-Associated Complications for Patients Undergoing Gastrointestinal Surgery," *Journal of Parenteral and Enteral Nutrition* 11, no. 5 (1987): pp. 440-446, https://doi.org/10.1177/0148607187011005440.
[36] AS Detsky et al., "What Is Subjective Global Assessment of Nutritional Status?," *Journal of Parenteral and Enteral Nutrition* 11, no. 1 (1987): pp. 8-13, https://doi.org/10.1177/014860718701100108.

Committee does not intend for the updated definition to create an undue documentation burden on transplant programs or preclude any candidates who would have previously been approved for an exception. The inclusion of the multiple documentation methods is intended to give transplant teams the ability to use whichever method is preferred by their dieticians.[37]

The Committee is also proposing the addition of sarcopenia as a qualifying comorbidity. This new criterion will allow candidates with severe sarcopenia as documented with skeletal muscle index related to their PLD to be considered for an exception. The addition of this new qualifying comorbidity reflects the fact that sarcopenia has been shown to be associated with chronic liver disease and is a prognostic factor for liver transplant candidates.[38,39]

The Committee is also proposing the removal of language that is not needed and confusing. Removing this language does not substantively change the guidance but makes it more clear and understandable for the NLRB and transplant programs.[40]

And finally, the Committee is proposing that all candidates meeting criteria for a PLD exception be considered for MMaT. The Committee agreed that the liver involvement (with or without kidney involvement) is what drives this patient population's mortality risk and therefore, all PLD candidates should be provided the same exception score.[41,42]

The Committee is seeking public comment feedback on the proposed changes to PLD guidance.

NOTA and Final Rule Analysis

The OPTN issues the *Guidance to Liver Transplant Programs and the National Liver Review Board for Adult MELD Exception Review* and *Guidance to Liver Transplant Programs and the National Liver Review Board for Adult MELD Exceptions for Hepatocellular Carcinoma (HCC)* for the operation of the OPTN.[43] This guidance will support the operation of the NLRB by assisting the reviewers with evaluating exception requests. The OPTN Final Rule requires the Board to establish performance goals for allocation policies, including "reducing inter-transplant program variance" in performance indicators.[44] The changes to these guidance documents will assist in reducing inter-transplant program variance in the types of cases reviewed and approved by the NLRB by facilitating more consistent review of exception cases.

[37] Ibid.
[38] Ching-Sheng Hsu and Jia-Horng Kao, "Sarcopenia and Chronic Liver Diseases," *Expert Review of Gastroenterology & Hepatology* 12, no. 12 (2018): pp. 1229-1244, https://doi.org/10.1080/17474124.2018.1534586.
[39] Elizabeth J. Carey et al., "A Multicenter Study to Define Sarcopenia in Patients with End-Stage Liver Disease," *Liver Transplantation* 23, no. 5 (2017): pp. 625-633, https://doi.org/10.1002/lt.24750.
[40] See OPTN Liver and Intestinal Organ Transplantation Committee meeting summary, November 5, 2021. Available at https://optn.transplant.hrsa.gov/
[41] Ibid.
[42] Ronald D. Perrone, Robin Ruthazer, and Norma C. Terrin, "Survival after End-Stage Renal Disease in Autosomal Dominant Polycystic Kidney Disease: Contribution of Extrarenal Complications to Mortality," *American Journal of Kidney Diseases* 38, no. 4 (2001): pp. 777-784, https://doi.org/10.1053/ajkd.2001.27720.
[43] 2019 OPTN Contract Task 3.2.4: Development, revision, maintenance, of OPTN Bylaws, policies, standards and guidelines for the operation of the OPTN.
[44] 42 C.F.R. §121.8(b)(4)

The Committee submits the proposed changes to policy under the authority of NOTA, which states, "The Organ Procurement and Transplantation Network shall…establish…medical criteria for allocating organs and provide to members of the public an opportunity to comment with respect to such criteria…"[45], and the OPTN Final Rule, which states "The OPTN Board of Directors shall be responsible for developing…policies for the equitable allocation for cadaveric organs."[46] 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**[47] because it is an evidenced-based change relying on the collective clinical experience of the Committee to align the terminology with LI-RADs.
- **Is designed to…promote patient access to transplantation**[48] **by** giving similarly situated candidates equitable opportunities to receive an organ offer by making the requirements for HCC exception requests clearer and thus more consistently applied.
- **Is not based on the candidate's place of residence or place of listing**[49]

This proposal also preserves the ability of a transplant program to decline an offer or not use the organ for a potential recipient,[50] and it is specific to an organ type, in this case liver.[51]

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:

- **Seeks to achieve the best use of donated organs**[52]
- **Is designed to avoid wasting organs**[53]
- **Is designed to avoid futile transplants**[54]
- **Promotes the efficient management of organ placement**[55]

[45] 42 USC §274(b)(2)(B).
[46] 42 CFR §121.4(a).
[47] 42 CFR §121.8(a)(1).
[48] 42 CFR §121.8(a)(5).
[49] 42 CFR §121.8(a)(8).
[50] 42 CFR §121.8(a)(3).
[51] 42 CFR §121.8(a)(4).
[52] 42 CFR §121.8(a)(2).
[53] 42 CFR §121.8(a)(5).
[54] Id.
[55] Id.

Implementation Considerations

Member and OPTN Operations

The proposed changes to HCC policy will need to be updated in UNet^{SM}. This will include updating data labels and the reasons for which HCC exception requests do not meet standard criteria. These changes will be made on historic forms as well.

Relevant guidance documents and policy language will need to be updated. No changes in UNet^{SM} are required for the updated guidance documents. All changes will be communicated to the community prior to implementation. Transplant programs and NLRB reviewers will need to be aware of the changes

Operations affecting Histocompatibility Laboratories

This proposal will have no operational impact on histocompatibility laboratories.

Operations affecting Organ Procurement Organizations

This proposal will have no operational impact on organ procurement organizations.

Operations affecting Transplant Hospitals

Transplant programs will need to be familiar with the proposed changes to NLRB policy and guidance when submitting exception requests for candidates.

Operations affecting the OPTN

The proposed changes to HCC policy will need to be implemented in UNet^{SM}. Relevant guidance documents and policy language will need to be updated. The OPTN will communicate any changes prior to becoming effective and will provide educational resources as appropriate.

Potential Impact on Select Patient Populations

The proposed changes to NLRB guidance documents will impact the HCC, IC, and PLD candidate populations. The proposed changes to HCC guidance should make it easier for candidates with a history of HCC that subsequently recurs to receive an exception for MMaT-3 without the six month wait. However, for candidates who were initially treated with resection, the updated guidance, which requires the exception request to be submitted between six and 60 months after initial HCC occurrence, is a bit more limiting. In current guidance, there is no such timeframe and any candidate with a history of resected HCC that subsequently recurs can access an exception for MMaT-3 regardless of the time between the initial occurrence and the exception request. However, the timeframe included in the updated guidance is not anticipated to have a meaningful impact on access to transplant for these candidates. More generally, a higher number of HCC candidates whose HCC has recurred should be able to receive an exception without the six month delay.

In addition, the proposed change to IC guidance will increase the exception scores provided to IC candidates which should improve their access to transplant.

Finally, the proposed changes to PLD guidance should provide higher exception scores to liver alone candidates, improving their access to transplant. The addition of sarcopenia as a qualifying comorbidity should increase the number of candidates receiving a MELD exception for PLD. The more objective definition of moderate to severe protein calorie malnutrition is not intended to preclude any candidates from accessing an exception who previously would have qualified without the objective definition.

No exception candidates will lose a current exception at the time of implementation of the updated guidance. However, NLRB reviewers and transplant programs will need to consult the updated guidance for initial exceptions and extension requests submitted after implementation.

The proposed changes to HCC policy will not impact any select patient population. The Committee discussed if any population would be disadvantaged by the policy changes or if any transition procedures are needed and no such population or procedures were identified.[56]

Projected Fiscal Impact

Projected Impact on Histocompatibility Laboratories

No impact.

Projected Impact on Organ Procurement Organizations

No impact.

Projected Impact on Transplant Hospitals

Transplant hospitals will need to train staff on updated guidance documents for MELD exceptions.

Projected Impact on the OPTN

The proposed changes to HCC policy will require updates in UNet[SM]. Additional effort will be required to update the guidance documents and policy language, as well as communicate the proposed changes to the transplant community and monitor the changes after implementation.

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."[57]

This proposal will not change current routine monitoring of OPTN members. At transplant hospitals, site surveyors will continue to review a sample of medical records, and any material incorporated into the

[56] 42 C.F.R. § 121.8(d). The Final Rule requires the OPTN to "consider whether to adopt transition procedures that would treat people on the waiting list and awaiting transplantation prior to the adoption or effective date of the revised policies no less favorably than they would have been treated under the previous policies" whenever organ allocation policies are revised.
[57] 42 CFR §121.8(a)(7).

medical record by reference, to verify that data reported in UNet℠ are consistent with source documentation, including qualifying criteria for standardized MELD or PELD exceptions or exception extensions.

Policy Evaluation

The Final Rule requires that allocation policies "be reviewed periodically and revised as appropriate."[58]

Using pre- and post-policy implementation comparisons, the following metrics will be analyzed at 6 months and 12 months post implementation, as requested by the NLRB subcommittee. The following metrics, and any others subsequently requested by the NLRB subcommittee, will be evaluated:

- Count of exception forms submitted with an ischemic cholangiopathy diagnosis and distribution of MELD or PELD score requested relative to median MELD at transplant
- Count of transplants with an ischemic cholangiopathy exception diagnosis and distribution of allocation MELD or PELD score at transplant
- Count of exception forms submitted with a polycystic liver disease diagnosis and distribution of MELD or PELD score requested relative to median MELD at transplant
- Count of transplants with a polycystic liver disease exception diagnosis and distribution of allocation MELD or PELD score at transplant

Conclusion

This proposal includes changes to HCC policy, as well as the guidance documents for HCC, IC, and PLD. The updated HCC policy will align OPTN terminology with the terminology used by radiologists responsible for HCC imaging. This will create consistency in the liver transplant community. The proposed change to HCC guidance creates a more equitable pathway for candidates with a history of HCC who subsequently recur to access a MELD exception equal to MMaT-3 without the six month delay. The updated IC guidance includes a higher score for candidates meeting the criteria in guidance so these candidates can more quickly access transplant. And finally, the changes to PLD guidance include a more objective definition for moderate to severe protein calorie malnutrition, the addition of sarcopenia as a qualifying comorbidity, the removal of unnecessary language, and a recommendation that all candidates meeting the criteria be considered for and exception score equal to MMaT.

Together, these changes will create a more efficient and equitable system for reviewing MELD exception requests.

[58] 42 CFR §121.8(a)(6).

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.

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

Upon submission of the first exception request, a candidate with hepatocellular carcinoma (HCC) will receive a score according to Policy *9.5.I.vii: Extensions of HCC Exceptions* if the candidate meets the criteria according to *Policies 9.5.I.i through 9.5.I.vi.*

9.5.I.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~~ <u>locoregional</u> 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~~ <u>locoregional</u> 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 *Post-Transplant Explant Pathology Form* does not show evidence of HCC or liver-directed therapy for HCC, the transplant program must also submit documentation or imaging studies confirming HCC at the time of assignment.

The Liver and Intestinal Organ Transplantation Committee will review the submitted documentation or imaging studies when more than 10 percent of the *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.

9.5.I.ii Eligible Candidates Definition of T2 ~~Lesions~~ Stage

~~Candidates with T2 HCC lesions~~ Candidates with hepatic lesions that meet T2 stage are eligible for a standardized MELD or PELD exception if they have an alpha-fetoprotein (AFP) level less than or equal to 1000 ng/mL. T2 stage is defined as candidates with ~~and~~ *either* of the following:

- One Class 5 lesion greater than or equal to 2 cm and less than or equal to 5 cm in size.
- Two or three Class 5 lesions each greater than or equal to 1 cm and less than or equal to 3 cm in size.

A candidate who has previously had an AFP level greater than 1000 ng/mL at any time must qualify for a standardized MELD or PELD exception according to *Policy 9.5.I.iv: Candidates with Alpha-fetoprotein (AFP) Levels Greater than 1000.*

9.5.I.iii Lesions Eligible for Downstaging Protocols

Candidates are eligible for a standardized MELD or PELD exception if, before completing ~~local-regional~~ locoregional therapy, they have lesions that meet *one* of the following criteria:

- One Class 5 lesion greater than 5 cm and less than or equal to 8 cm
- Two or three Class 5 lesions that meet all of the following:
    - at least one lesion greater than 3 cm
    - each lesion less than or equal to 5 cm, and
    - a total diameter of all lesions less than or equal to 8 cm
- Four or five Class 5 lesions each less than 3 cm, and a total diameter of all lesions less than or equal to 8 cm

For candidates who meet the downstaging criteria above and then complete ~~local-regional~~ locoregional therapy, ~~their residual~~ the viable lesions must subsequently meet the size requirements for T2 ~~lesions~~ stage according to *Policy 9.5.I.ii: Eligible Candidates Definition of T2 ~~Lesions~~* Stage to be eligible for a standardized MELD or PELD exception. Downstaging to meet eligibility requirements for T2 ~~lesions~~ stage must be demonstrated by dynamic-contrast enhanced CT or MRI performed after ~~local-regional~~ locoregional therapy. Candidates with lesions that do not initially meet the downstaging protocol inclusion criteria who are later downstaged and then meet eligibility for T2 ~~lesions~~ stage are not automatically eligible for a standardized MELD or PELD exception and must be referred to the NLRB for consideration of a MELD or PELD exception.

9.5.I.iv Candidates with Alpha-fetoprotein (AFP) Levels Greater than 1000

Candidates with lesions meeting T2 ~~criteria~~ stage according to *Policy 9.5.I.ii Eligible Candidates Definition of T2 ~~Lesions~~* stage but with an alpha-fetoprotein (AFP) level greater than 1000 ng/mL may be treated with ~~local-regional~~ locoregional therapy. If the candidate's AFP level falls below 500 ng/mL after treatment, the candidate is eligible for a standardized MELD or PELD exception as long as the candidate's AFP level remains below 500 ng/mL. Candidates with an AFP level greater than or equal to 500 ng/mL following ~~local-regional~~ locoregional therapy at any time must be referred to the NLRB for consideration of a MELD or PELD exception.

9.5.I.v Requirements for Dynamic Contrast-enhanced CT or MRI of the Liver

CT ~~scans and~~ or MRI~~s~~ performed for a ~~Hepatocellular Carcinoma (~~HCC~~)~~ MELD or PELD score exception request must be interpreted by a radiologist at a transplant hospital. If the ~~scan is inadequate or incomplete~~ lesion cannot be categorized due to image degradation or omission, then the lesion will be classified as ~~OPTN Class 0~~ Not categorizable (NC) and imaging must be repeated or completed to receive an HCC MELD or PELD exception.

9.5.I.vi Imaging Requirements for Class 5 Lesions

Lesions found on ~~images of cirrhotic livers~~ imaging in patients at risk for HCC are classified according to *Table 9-9*. The imaging criteria within the table apply only to observations which do not represent benign lesions or non-HCC malignancy (i.e. targetoid or LR-M) by imaging.

Table 9-9: Classification System for Lesions Seen on Imaging of Cirrhotic Livers

Class	Description
~~0~~ NC – Not Categorizable	Incomplete or technically inadequate study due to image degradation or omission
5A	1. Maximum diameter of at least 1 cm and less than 2 cm, as measured on late arterial or portal phase images. 2. ~~Increased contrast enhancement, relative to hepatic parenchyma, on late arterial phase.~~ Nonrim arterial phase hyper-enhancement 3. *Either* of the following: • ~~Washout during the later contrast phases and peripheral rim enhancement on delayed phase~~ Nonperipheral washout • Biopsy
5A-g	Must meet *all* of the following:

Class	Description
	1. Maximum diameter of at least 1 cm and less than 2 cm, as measured on late arterial or portal phase images. 2. ~~Increased contrast enhancement, relative to hepatic parenchyma, on late arterial phase.~~ Nonrim arterial phase hyper-enhancement 3. ~~Maximum diameter increase of at least 50% documented on serial MRI or CT obtained 180 days or less apart~~ Threshold growth defined as size increase of a mass by ≥ 50% in ≤ 180 days on MRI or CT
5B	Must meet *all* of the following: 1. Maximum diameter of at least 2 cm and less than or equal to 5 cm, as measured on late arterial or portal phase images. ~~2. Increased contrast enhancement, relative to hepatic parenchyma, on late hepatic arterial images.~~ Nonrim arterial phase hyper-enhancement 3. *One* of the following: ~~a. Washout on portal venous/delayed phase.~~ Nonperipheral washout b. ~~Peripheral rim enhancement~~. Enhancing capsule ~~c. Maximum diameter increase, in the absence of ablation, by 50% or more and documented on serial MRI or CT obtained 180 days or less apart. Serial imaging and measurements must be performed on corresponding contrast phases.~~ Threshold growth defined as size increase of a mass by ≥ 50% in ≤ 180 days on MRI or CT d. Biopsy.
5T	Any Class 5A, 5A-g, 5B lesion that was automatically approved upon initial request or extension and has subsequently been ~~ablated.~~ treated by locoregional therapy.

9.5.I.vii Extensions of HCC Exceptions

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

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

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

- The candidate's lesions progress beyond T2 criteria, according to *9.5.I.ii: Eligible Candidates Definition of T2 ~~Lesions~~* stage
- 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 transplant program submits either an initial exception request or the first extension request for a liver candidate at least 18 years old at the time of registration that meets the requirements for a standardized MELD score exception, the candidate will appear on the match run according to the calculated MELD score.

A candidate who meets these requirements for a MELD or PELD score exception for HCC will receive 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	Calculated MELD
At least 18 years old	At least 18 years old	Any extension after the first extension	3 points below MMaT
At least 12 years old	Less than 18 years old	Any	40
Less than 12 years old	Less than 12 years old	Any	40

Guidance

Guidance to Liver Transplant Programs and the National Liver Review Board for:

Adult MELD Exceptions for Hepatocellular Carcinoma (HCC)

Background

A liver candidate receives a MELD[59] or, if less than 12 years old, a PELD[60] score that is used for liver allocation. The score is intended to reflect the candidate's disease severity, or 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 score. A candidate that meets the criteria for one of nine diagnoses in policy is approved for a standardized MELD exception.[61] If the candidate does not meet criteria for standardized exception, the request is considered by the Review Board.

The OPTN Liver and Intestinal Organ Transplantation Committee (hereafter, "the Committee") has developed guidance for adult MELD exceptions for Hepatocellular Carcinoma (HCC). This guidance document is intended to provide recommendations for the review board considering HCC cases which are outside standard policy.

This guidance replaces any independent criteria that OPTN regions used to request and approve exceptions, commonly referred to as "regional agreements." Review board members and transplant centers should consult this resource when considering MELD exception requests for adult candidates with the following diagnoses.

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.

[59]Model for End-Stage Liver Disease
[60]Pediatric End-Stage Liver Disease
[61]Policy 9.3.C: Specific MELD/PELD Exceptions, Organ Procurement and Transplantation Network Policies.

Evidence for the use of immunotherapy as a down-staging or bridging therapy is preliminary. However, based on the published data in transplant and non-transplant setting, the use of immunotherapy does not preclude consideration for an HCC exception.[62]

- ~~Patients who have a history of prior unresected 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.~~

- Patients beyond standard criteria who have continued progression while waiting despite ~~LRT~~ locoregional are generally not acceptable candidates for HCC MELD exception.

- Patients with AFP>1000 who do not respond to treatment to achieve an AFP below 500 are not eligible for standard MELD exception, and must be reviewed by the HCC review board to be considered. In general, these patients are not suitable for HCC MELD exception but may be appropriate in some cases.

- Patients with HCC beyond standard down-staging criteria who are able to be successfully downstaged to T2 may be appropriate for MELD exception, as long as there is no evidence of metastasis outside the liver, or macrovascular invasion, or AFP >1,000. Imaging should be performed at least 4 weeks after last down-staging treatment. Patients must still wait for 6 months from the time of the first request to be eligible for an HCC exception score.

- ~~Patients with cirrhosis who presented with stage T2 resectable HCC (one lesion >2 cm and <5 cm in size, or two or three lesions >1 cm and <3 cm in size, based on resection specimen pathology) who underwent complete resection but developed T1 (biopsy proven), or T2 HCC (LI-RADS 5) following complete resection should be considered for MELD score exception, without a six month delay period. This includes candidates who initially presented with T2 resectable HCC and who underwent complete resection more than 2 years ago.~~

- Patients who presented with stage T2 HCC (LI-RADS 5 or biopsy proven; one lesion >2 cm and <5 cm in size, or two or three lesions >1 cm and <3 cm in size) which was treated by locoregional therapy or resected but developed T1 or T2 HCC (LI-RADS 5 or biopsy proven) recurrence and the transplant program is requesting an initial HCC exception more than 6 months but less than 60 months following initial treatment or resection are eligible for a MELD score exception without a six month delay period.

Patients with cirrhosis and HCC beyond T2 but within generally accepted criteria for down-staging (such as up to 5 lesions, total tumor volume <8 cm based on resection pathology) who underwent complete resection with negative margins and developed T1 (biopsy proven) or T2 recurrence (LI-RADS 5) may

[62] Parissa Tabrizian, Sander S. Florman, and Myron E. Schwartz, "PD-1 Inhibitor as Bridge Therapy to Liver Transplantation?," *American Journal of Transplantation* 21, no. 5 (February 2021): pp. 1979-1980, https://doi.org/10.1111/ajt.16448.

also be considered for MELD score exception for HCC. Because the larger tumor size, the 6 month delay is appropriate to ensure favorable tumor biology.

Recommendations for Dynamic Contrast-enhanced CT or MRI of the Liver

Table 1: Recommendations for Dynamic Contrast-enhanced CT of the Liver

Feature:	CT scans should meet the below specifications:
Scanner type	Multidetector row scanner
Detector type	Minimum of 8 detector rows and must be able to image the entire liver during brief late arterial phase time window
Slice thickness	Minimum of 5 mm reconstructed slice thickness; thinner slices are preferable especially if multiplanar reconstructions are performed
Injector	Power injector, preferably dual chamber injector with saline flush and bolus tracking recommended
Contrast injection rate	3 mL/sec minimum, better 4-6 mL/sec with minimum of 300 mg I/mL or higher, for dose of 1.5 mL/kg body weight
Mandatory dynamic phases on contrast-enhanced MDCT	1. Late arterial phase: artery fully enhanced, beginning contrast enhancement of portal vein 2. Portal venous phase: portal vein enhanced, peak liver parenchymal enhancement, beginning contrast enhancement of hepatic veins 3. Delayed phase: variable appearance, greater than 120 seconds after initial injection of contrast
Dynamic phases (Timing)	Use the bolus tracking or timing bolus

Table 2: Recommendations for Dynamic Contrast-enhanced MRI of the Liver

Feature	MRIs should meet the below specifications:
Scanner type	1.5T Tesla or greater main magnetic field strength. Low field magnets are not suitable.
Coil type	Phased array multichannel torso coil, unless patient-related factors precludes its use.
Minimum sequences	Pre-contrast and dynamic post gadolinium T1-weighted gradient echo sequence (3D preferable), T2 (with and without fat saturation), T1-weighted in and out of phase imaging.
Injector	Dual chamber power injector with bolus tracking recommended.
Contrast injection rate	2-3 mL/sec of extracellular gadolinium chelate that does not have dominant biliary excretion, preferably resulting in vendor-recommended total dose.

Feature	MRIs should meet the below specifications:
Mandatory dynamic phases on contrast-enhanced MRI	1. Pre-contrast T1W: do not change scan parameters for post contrast imaging. 2. Late arterial phase: artery fully enhanced, beginning contrast enhancement of portal vein. 3. Portal venous phase: portal vein enhanced, peak liver parenchymal enhancement, beginning contrast enhancement of hepatic veins. 4. Delayed phase: variable appearance, greater than 120 seconds after initial injection of contrast.
Dynamic phases (Timing)	The use of the bolus tracking method for timing contrast arrival for late arterial phase imaging is preferable. Portal vein phase images should be acquired 35 to 55 seconds after initiation of late arterial phase. Delayed phase images should be acquired 120 to 180 seconds after the initial contrast injection.
Slice thickness	5 mm or less for dynamic series, 8 mm or less for other imaging.
Breath-holding	Maximum length of series requiring breath-holding should be about 20-seconds with a minimum matrix of 128 x 256. Technologists must understand the importance of patient instruction about breath-holding before and during scan.

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Diffuse Ischemic Cholangiopathy

Diffuse ischemic cholangiopathy is a complication associated with donation after circulatory ~~cardiac~~ death (DCD) donors. Analysis of waitlist outcomes for patients re-listed after undergoing liver transplant from a DCD d to donation after brain death (DBD) candidates who are re-listed with similar MELD scores.[63] However, patients with ischemic cholangiopathy may have significant morbidity and require multiple repeat biliary interventions and repeat hospitalizations for cholangitis. Despite similar waitlist outcomes as DBD donor liver recipients who are listed for retransplant, the Committee supports increased priority for prior DCD donor liver recipients to encourage use of DCD livers when appropriate.

In addition, analyses has shown that patients with a prior DCD transplant and an approved MELD score exception had an improved survival compared to those who never had an exception approved.[64] Patients with biliary injuries and need for biliary interventions also have been demonstrated to have an increased risk of graft loss and death.[65] **Therefore, patients with a prior DCD transplant ~~that~~ who demonstrate~~d~~ two or more of the following criteria within 12 months of transplant ~~should be considered~~ are eligible for MELD exception equivalent to MMaT:**

- Persistent cholestasis as defined by abnormal bilirubin (greater than 2 mg/dl)
- Two or more episodes of cholangitis with an associated bacteremia requiring hospital admission
- Evidence of non-anastomotic biliary strictures not responsive to further treatment

[63]Allen, A.M., W.R. Kim, H. Xiong, et al "Survival of recipients of livers from donation after circulatory death who are relisted and undergo retransplant for graft failure." Am J Transplant 15 (2014): 1120-8.
[64]Makuda, R.C., P.L. Abt, D.S. Goldberg. "Use of Model for End-Stage Liver Disease exceptions for donation after cardiac death graft recipients relisted for liver transplantation." Liver Transpl 21 (2015):554-60.
[65]Axelrod, D.A., K.L. Lentine, H. Xiao, et al. "National assessment of early biliary complications following liver transplantation: incidence and outcomes." Liver Transpl. 20 (2014): 446-56.

Polycystic Liver Disease (PLD)

~~Certain~~ ~~p~~Patients with PLD who are not clinically eligible for resection/fenestration or alternative therapy may benefit from MELD exception points. Indication for an exception include those with ~~PCLKD~~ PLD~~(Mayo type D or C)~~ with severe symptoms related to PLD plus *any* of the following:

- Hepatic decompensation or severe portal hypertensive complications
- Concurrent hemodialysis
- GFR less than 20 ml/min
- Patient with a prior kidney transplant
- Moderate to severe protein calorie malnutrition as documented by a registered dietician using any of the following:
    - Modified Global Leadership Initiative on Malnutrition (GLIM) Phenotypic criteria
    - American Society for Enteral and Parenteral Nutrition (ASPEN) criteria
    - Nutrition Focused Physical Exam (NFPE)
    - Subjective Global Assessment (SGA-C score)
- Severe sarcopenia as documented with skeletal muscle index (SMI < 39 cm^2/m^2 in women and < 50 cm^2/m^2 in men)[66] or equivalent

~~**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~~

[66] Carey, Elizabeth J., Jennifer C. Lai, Connie W. Wang, Srinivasan Dasarathy, Iryna Lobach, Aldo J. Montano-Loza, and Michael A. Dunn. "A Multicenter Study to Define Sarcopenia in Patients with End-Stage Liver Disease." *Liver Transplantation* 23, no. 5 (2017): 625–33. https://doi.org/10.1002/lt.24750.

~~**Note:** Prior resection/fenestration, alternative therapy precluded.~~

Patients who meet the criteria above ~~should be considered~~ are eligible for a MELD exception ~~similar to other policy-assigned exception scores.~~ equivalent to MMaT.

~~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.~~