OPTN

Notice of OPTN Policy and Guidance Changes

Ongoing Review of National Liver Review Board (NLRB) Diagnoses

Sponsoring Committee:	**OPTN Liver and Intestinal Organ Transplantation Committee**
Policies Affected:	***9.5.I.i: Initial Assessment and Requirements for HCC Exception Requests*** ***9.5.I.ii: Eligible Candidates Definition of T2 Lesions*** ***9.5.I.iii: Lesions Eligible for Downstaging Protocols 9.5.I.iv: Candidates with Alpha-fetoprotein (AFP) Levels Greater than 1000 Policy*** ***9.5.I.v: Requirements for Dynamic Contrast-enhanced CT or MRI of the Liver*** ***9.5.I.vi: Imaging Requirements for Class 5 Lesions*** ***9.5.I.vii: Extensions of HCC Exceptions***
Guidance Affected:	***Guidance to Liver Transplant Programs and the National Liver Review Board for Adults MELD Exceptions for Hepatocellular Carcinoma (HCC)*** ***Guidance to Liver Transplant Programs and the National Liver Review Board for Adults MELD Exception Review***
Public Comment:	**January 27, 2022 – March 23, 2022**
Board Approved:	**June 27, 2022**
Effective Date:	**July 26, 2022: Guidance to Liver Transplant Programs and the National Liver Review Board for Adults MELD Exceptions for Hepatocellular Carcinoma (HCC)** **Guidance to Liver Transplant Programs and the National Liver Review Board for Adults MELD Exception Review** **Pending implementation and notice to OPTN members:** **Policies: 9.5.I.i: Initial Assessment and Requirements for HCC Exception Requests** **9.5.I.ii: Eligible Candidates Definition of T2 Lesions** **9.5.I.iii: Lesions Eligible for Downstaging Protocols** **9.5.I.iv: Candidates with Alpha-fetoprotein (AFP) Levels Greater than 1000** **9.5.I.v: Requirements for Dynamic Contrast-enhanced CT or MRI of the Liver** **9.5.I.vi: Imaging Requirements for Class 5 Lesions** **9.5.I.vii: Extensions of HCC Exceptions**

Purpose of Policy and Guidance Changes

The National Liver Review Board (NLRB) was implemented on May 14, 2019.[1] The purpose of the NLRB is to provide equitable access to transplant for liver candidates whose calculated model for end-stage liver disease (MELD) score or pediatric end-stage liver disease (PELD) score does not accurately reflect the candidate's medical urgency for transplant. Since the implementation of the NLRB, the OPTN Liver and Intestinal Organ Transplantation Committee (the Committee) has continued to evaluate the effectiveness of the system and has identified a number of ways in which the NLRB could be improved. The purpose of this guidance and policy change is to continue to improve the NLRB by creating a more efficient and equitable system for reviewing MELD and PELD exception requests. The included changes ensure that guidance and policy language remain clear and aligned with current research so that the appropriate candidates receive MELD or PELD exceptions.

Proposal History

Prior to the implementation of the NLRB, MELD and PELD exception requests were reviewed by regional review boards (RRBs). The implementation of the NLRB was a significant change in the process for reviewing MELD or PELD exception requests and because of the significance and complexity of the change, the Committee has continued to receive feedback on areas for improvement to the NLRB guidance and policy. This project is the latest in a series of improvement to the NLRB since it was implemented.

Summary of Changes

- **Hepatocellular Carcinoma (HCC) Policy:** Updates policy language to align with Liver Imaging Reporting and Data System (LI-RADS) terminology and classifications.[2] These changes will ensure the transplant community is using a consistent lexicon for HCC imaging.
- **HCC Guidance:** Simplifies guidance for candidates who had HCC that was treated and subsequently recurs. The changes will provide a more consistent and equitable pathway for these candidates to receive a MELD exception.
- **Ischemic Cholangiopathy (IC) Guidance:** Recommends candidates meeting criteria for an exception be provided a score equal to median MELD at transplant (MMaT). Because IC is a complication associated with livers from donation after cardiac death (DCD) donors, this change will allow these candidates to access retransplant more quickly.
- **Polycystic Liver Disease (PLD) Guidance:** Adds a more objective definition for moderate to severe protein calorie malnutrition, adds sarcopenia as a qualifying comorbidity, removes unnecessary language, and recommends all candidates meeting criteria be considered for MMaT. These changes will ensure that the appropriate candidates are able to access an exception and will increase equity in access to transplant for all PLD 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/ gov

[2] See CT/MRI LI-RADS v2018 Core available at https://www.acr.org/

Implementation

Liver transplant programs and NLRB reviewers will need to be familiar with the changes to NLRB policy and guidance when submitting and reviewing MELD or PELD exception requests. The updated guidance will become effective approximately one month after OPTN Board of Directors approval.

The OPTN will implement changes in the OPTN Computer System for the updated HCC policy. The changes to policy will not impact which candidates are able to receive an HCC exception. All changes will be communicated and published prior to implementation.

Affected Policy Language

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

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~~ locoregional 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. This is only required prior to applying for an initial exception. A CT of the chest is not required for exception extensions.
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~~ locoregional 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 MRIs 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.

Class	Description
	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: 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

A CT of the chest to rule out metastatic disease is not required after the initial exception request.

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 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[3] or, if less than 12 years old, a PELD[4] 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.[5] 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.

[3]Model for End-Stage Liver Disease
[4]Pediatric End-Stage Liver Disease
[5]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.[6]

- ~~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

[6] 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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Guidance to Liver Transplant Programs and the National Liver Review Board for: Adult MELD Exception Review

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 donor demonstrates that these patients have a similar or improved waitlist survival compared to donation after brain death (DBD) candidates who are re-listed with similar MELD scores.[7] 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.[8] Patients with biliary injuries and need for biliary interventions also have been demonstrated to have an increased risk of graft loss and death.[9] **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

[7]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.
[8]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.
[9]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)[10] 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~~

[10] 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.~~

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