III. Policy Proposals

At-a-Glance

- **Proposal for Improved Imaging Criteria for HCC Exceptions**

- **Affected/Proposed Policy:** 3.6.4.4 (Liver Candidates with Hepatocellular Carcinoma (HCC))

- **Liver and Intestinal Organ Transplantation Committee**

  Patients awaiting a liver transplant who are diagnosed with hepatocellular carcinoma (HCC) are eligible for additional priority through MELD/PELD exceptions. Under this proposal, HCC lesions would be classified more precisely according to newly-defined imaging criteria, with only Class 5 potentially eligible for automatic upgrades.

  Currently, HCC exceptions are based on diagnostic criteria that rely on imaging characteristics rather than liver biopsy. The attendees of a multi-disciplinary HCC Consensus Conference held November 2008 made specific recommendations regarding the appropriate imaging criteria to properly determine HCC staging. The Committee is proposing to incorporate these recommendations into Policy 3.6.4.4. A survey of all U.S. liver transplant programs in October 2010 indicated strong support for these changes.

- **Affected Groups**
  Directors of Organ Procurement, OPO Executive Directors, OPO Medical Directors, OPO Coordinators, Transplant Administrators, Transplant Data Coordinators, Transplant Physicians/Surgeons, PR/Public Education Staff, Transplant Program Directors, Transplant Social Workers, Liver Candidates, General Public

- **Number of Potential Candidates Affected**
  Based on data from 2008-2009, approximately 2500 candidates with a MELD/PELD exception for HCC are waiting for a transplant during any given year. This represents 13% of all liver candidates listed waiting during the period.

- **Compliance with OPTN Strategic Goals and Final Rule**
  One of the 2010-2011 Annual Goals for this Committee is to "Update Liver Waitlist HCC exception criteria based on recommendations from the consensus conference held in November 2008." This proposal meets the Final Rule allocation performance goals of "Standardizing the criteria for determining suitable transplant candidates" and "setting priority rankings expressed, to the extent possible, through objective and measurable medical criteria." This proposal addresses the objective for "best use of donated organs," in that it will better ensure that candidates are more appropriately given priority for HCC.

- **Specific Requests for Comment**
  Because patients with HCC receive a high priority for transplantation, this policy change is attempting to more rigorously define the criteria for the radiographic diagnosis of HCC. Do you feel this policy accomplishes this goal? If no, what changes would you recommend?

Proposal for Improved Imaging Criteria for HCC Exceptions

Affected/Proposed Policy: 3.6.4.4 (Liver Candidates with Hepatocellular Carcinoma (HCC))

Liver and Intestinal Organ Transplantation Committee

Summary and Goals of the Proposal:

Patients awaiting a liver transplant who are diagnosed with hepatocellular carcinoma (HCC) are eligible for additional priority through MELD/PELD exceptions. Under this proposal, HCC lesions would be classified more precisely according to newly-defined imaging criteria, with only Class 5 potentially eligible for automatic upgrades.

Currently, HCC exceptions are based on diagnostic criteria that rely on imaging characteristics rather than liver biopsy. The attendees of a multi-disciplinary HCC Consensus Conference held November 2008 made specific recommendations regarding the appropriate imaging criteria to properly determine HCC staging. The Committee is proposing to incorporate these recommendations into Policy 3.6.4.4. A survey of all U.S. liver transplant programs in October 2010 indicated strong support for these changes.

Background and Significance of the Proposal:

The OPTN/UNOS Liver Committee, along with the ASTS, AST, and ILTS, sponsored a consensus conference on HCC in November 2008. One of the five working groups was specifically charged with developing more specific imaging criteria for HCC exceptions. As noted in the conference report, "There is considerable concern that the limited imaging criteria in the current policy may be inadequate and lead to inappropriate organ allocation.[1]" The purpose of the imaging work group, which included radiologists, transplant surgeons, and hepatologists, was to define new imaging criteria meeting the following goals:

1. Reducing the false-positive rate resulting from the current policy;
2. Developing recommendations for minimum technical requirements for scanner hardware and scan protocols; and
3. Standardizing the reporting of imaging findings while recognizing that robust and high-quality liver imaging is dependent on careful execution of imaging examinations performed on appropriate equipment.

The details of the imaging work group's deliberations, examination of the published literature, and consensus-building efforts, which included solicitation of input from radiologists at more than 30 major academic centers, are described in the conference report by Pomfret, et al. The recommendations of this working group are summarized in the conference report as follows:

1. A new OPTN liver imaging policy is proposed that requires:
    a. Minimum technical specifications for acquisition of images.
    b. A standardized imaging protocol.
    c. Structured reporting.

[1] Pomfret EA, Washburn K, Wald C, Nalesnik MA, Douglas D, Russo M, Roberts J, Reich DJ, Schwartz ME, Mieles L, Lee FT, Florman S, Yao F, Harper A, Edwards E, Freeman R, Lake J. Report of a national conference on liver allocation in patients with hepatocellular carcinoma in the United States. Liver Transpl. 2010 Mar;16(3):262-78. http://www.natap.org/2010/HCV/newliver.pdf

2. A new OPTN classification of liver nodules is proposed. The diagnosis of HCC will be based on the presence of specific, well-defined imaging findings on dynamic contrast-enhanced CT and/or MRI.

Highlights of Proposed Changes:

Using the working group's recommendations for imaging classification and minimum technical specifications for MRI and CT as guidance, the Committee has developed a proposal that incorporates the conference recommendations into OPTN policy. Key changes to the policy are as follows:

As in current policy, only patients within Milan criteria (Stage T2) are eligible for an automatic HCC exception.

- In the proposed policy, Stage T2 is defined as:
  - 1 lesion ≥ 2 cm and ≤ 5cm, OR 2-3 lesions, all ≥ 1cm and ≤ 3cm in size.
  - Lesions less than 1cm are indeterminate, and will not count towards the overall staging of HCC for automatic priority.

- Stage T1 HCC would no longer be eligible for automatic priority, regardless of the AFP level.

- A more precise classification scheme for liver nodules is also proposed (OPTN Class 0-5). Class 5 lesions meet all diagnostic criteria for HCC and are eligible to be considered for automatic HCC MELD exception.

- Smaller lesions (1-2 cm) must meet more stringent imaging criteria than larger lesions (2-5cm) in order to be diagnosed as HCC on multiphase contrast enhanced imaging (CT or MRI) and qualify for automatic priority. Candidates will still be required to have more than one (may have two or three) smaller lesions to meet T2 criteria and qualify for MELD exception points.
  - Lesions between 1-2 cm must be hypervascular on arterial phase imaging, and demonstrate portal vein/delayed phase washout **and** pseudocapsule enhancement. If both wash-out and pseudocapsule enhancement are not present, they must demonstrate growth on serial imaging.
  - Lesions between 2-5 cm must be hypervascular on arterial phase imaging and demonstrate portal vein/delayed phase washout or pseudocapsule enhancement. If no wash-out or pseudocapsule enhancement, lesion must demonstrate growth on serial imaging.
  - Lesions less than 1 cm are indeterminate (and thus, not eligible to be considered as HCC).

Liver imaging with multiphase contrast enhanced imaging (CT or MRI) must be performed or interpreted at a transplant center, and should meet minimum technical standards as described in Tables 4 and 5 of the policy.

For example, a candidate would be eligible for additional priority with:
- Two 1.5 cm (5A) lesions; or
- One 1.5 cm lesion (5A) and one 2.5 cm lesion (5B); or
- One 3.5cm lesion (5B); or
- Two 2.1cm lesions (5B).

The classification of HCC is summarized in the flow chart shown in Figure 1. While many of these terms may be unfamiliar to the non-radiologist, the criteria were developed by an expert panel of radiologists, and are considered to be minimum standards for appropriate radiologic diagnosis of HCC.

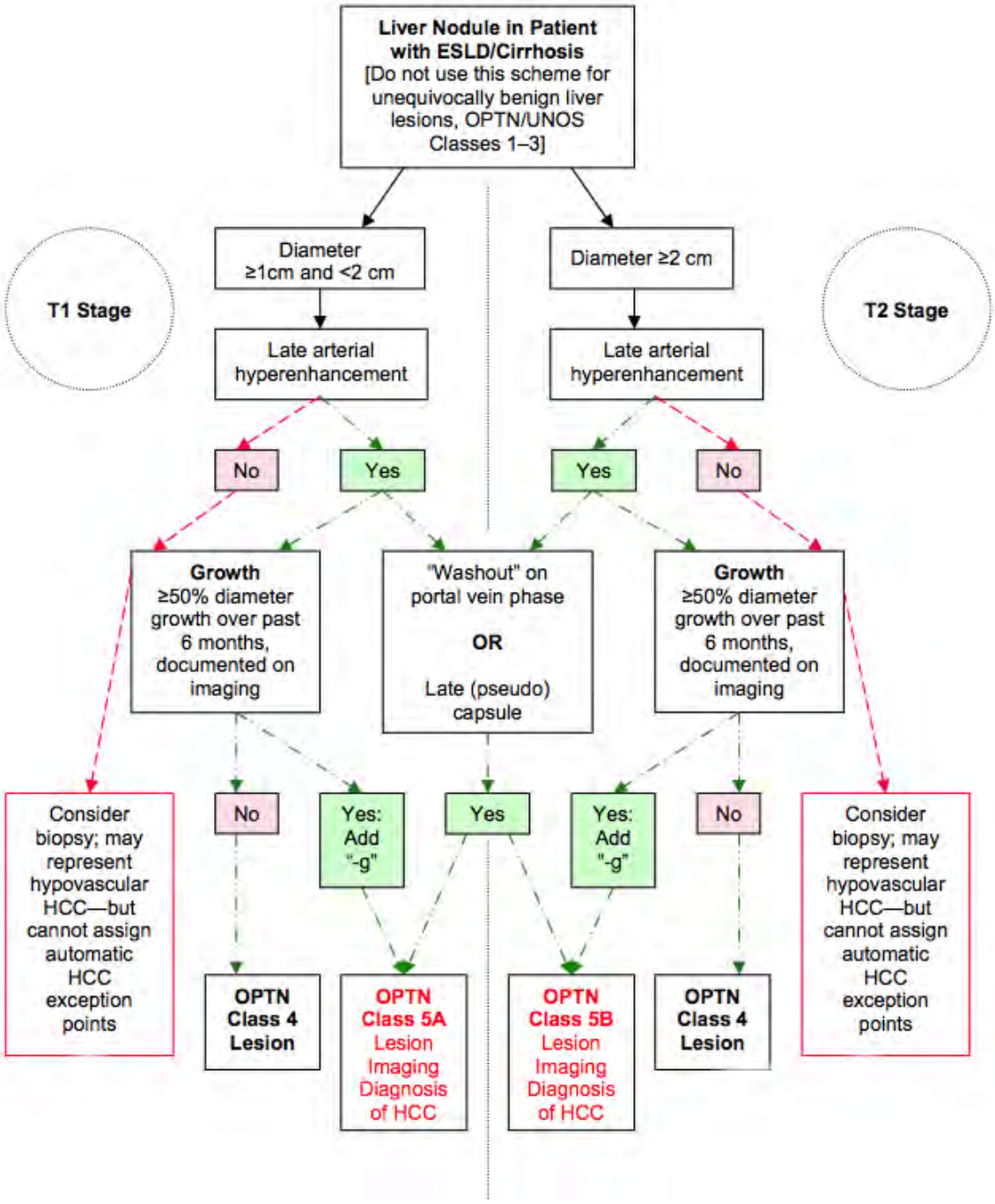
Liver Nodule in Patient with ESLD/Cirrhosis
[Do not use this scheme for unequivocally benign liver lesions, OPTN/UNOS Classes 1–3]
T1 Stage
T2 Stage
Diameter ≥1cm and <2 cm
Diameter ≥2 cm
Late arterial hyperenhancement
Late arterial hyperenhancement
No
Yes
Yes
No
Growth ≥50% diameter growth over past 6 months, documented on imaging
"Washout" on portal vein phase
OR
Late (pseudo) capsule
Growth ≥50% diameter growth over past 6 months, documented on imaging
Consider biopsy; may represent hypovascular HCC—but cannot assign automatic HCC exception points
No
Yes: Add "-g"
Yes
Yes: Add "-g"
No
Consider biopsy; may represent hypovascular HCC—but cannot assign automatic HCC exception points
OPTN Class 4 Lesion
OPTN Class 5A Lesion Imaging Diagnosis of HCC
OPTN Class 5B Lesion Imaging Diagnosis of HCC
OPTN Class 4 Lesion

Figure 1

Collaboration:

The policy recommendation was developed by a multi-disciplinary team of radiologists, hepatologists and transplant surgeons. Once the initial recommendations were developed, input from radiologists at more than 30 major academic centers was solicited for further policy refinement. The recommendations in this proposal have also been adopted for use in a large prospective multi-center trial comparing MRI to CT in patients with HCC who are awaiting liver transplantation. [see http://www.acrin.org/TabID/679/Default.aspx or http://clinicaltrials.gov/ct/show/NCT01082224]

Additional Supporting Evidence and/or Modeling:

A survey was sent to all 132 OPTN-member liver transplant programs in October 2010. The intent was to determine the impact of the proposed changes on transplant centers. The results of the survey are provided in Figures 2 and 3, and show substantial support among those who responded to the survey (n=70 centers or 53% of total).

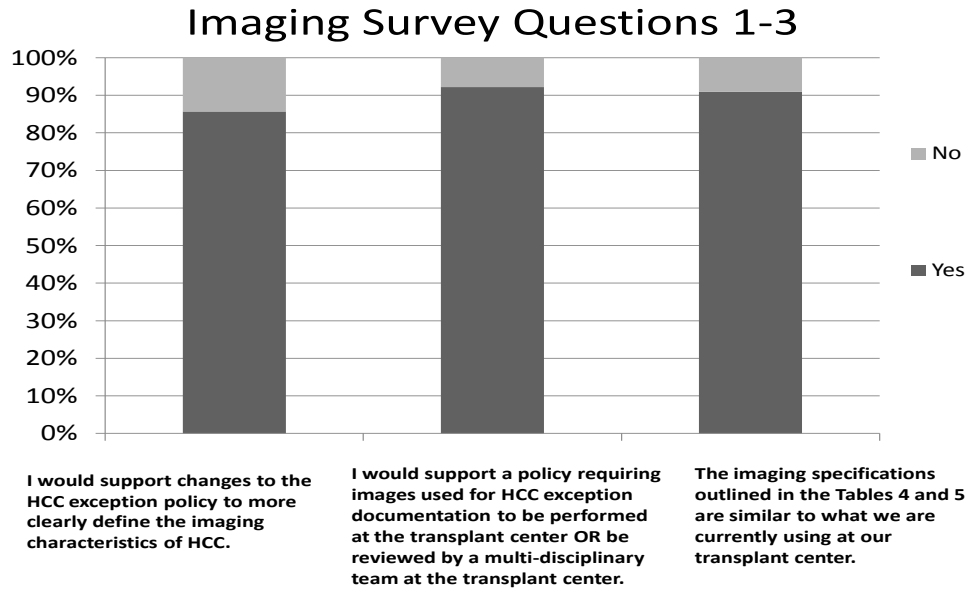

Figure 2

The Committee reviewed the comments submitted by survey respondents. Several respondents were concerned about the additional costs incurred if scans must be reordered. However, CTs and MRIs performed at outside centers would not have to be reordered, but rather reviewed by a radiologist at the center for compliance with the proposed criteria. The Committee considered an alternative method of review via a multidisciplinary tumor board; however such a board would most likely include a radiologist. The Committee felt that a transplant center radiologist is ultimately the appropriate person to read and certify these scans. Given the priority that candidates with HCC exceptions receive, it is important to ensure that these candidates meet the radiologic definition of HCC**.**

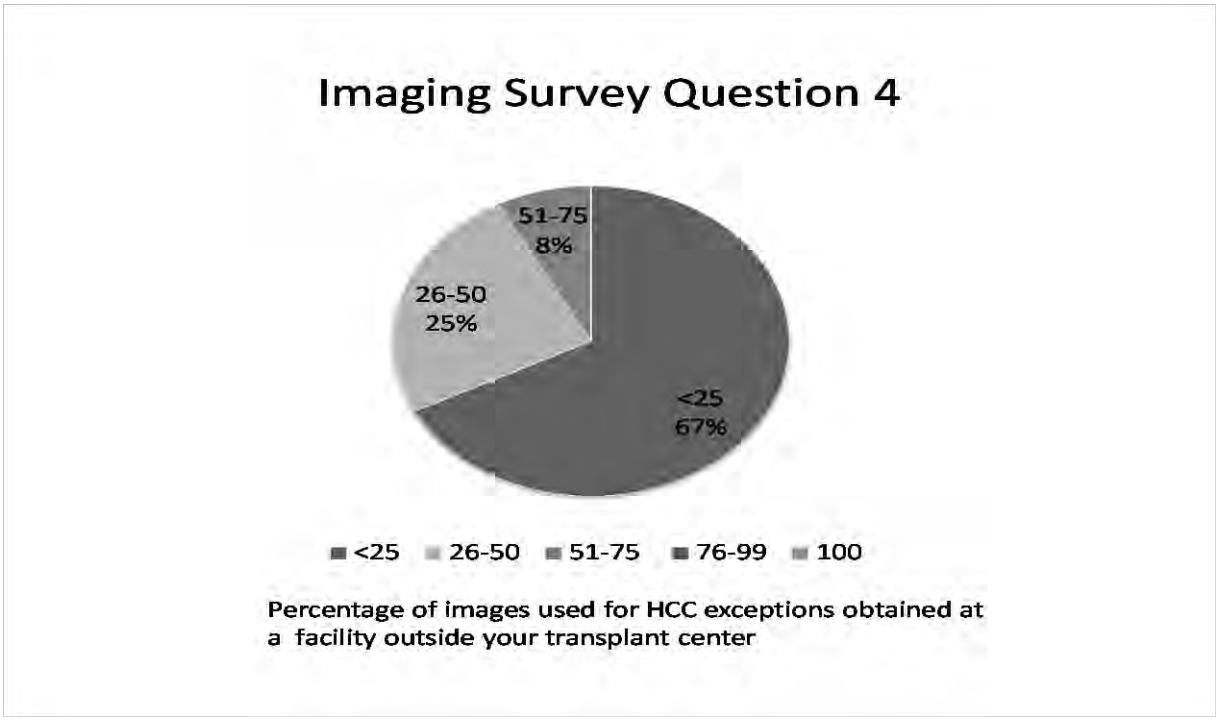

Figure 3

Several respondents were concerned that radiologists would not agree with the proposed criteria, and whether the criteria were too complicated. However, these were developed with full support of the radiologists both on the working group and those contacted by the working group. The use of these criteria in a large clinical trial is further evidence of acceptance by the radiology community. Prompt publication of these criteria in the radiology literature is anticipated if this proposal is ultimately approved by the Board**.**

Finally, some concerns were expressed regarding whether centers would be able to comply with the criteria. The survey conducted by the Committee in October 2010 indicated that most transplant centers are comfortable with these requirements. Concern was also raised by centers on how they would be able to document that exams performed on outside images met the technical standards shown in Tables 4 and 5 of the proposed policy. These minimum technical standards are intended to be the most basic requirements for adequate HCC imaging. However, ensuring that each image obtained meets all these requirements would place an undue burden on centers and auditors. Therefore, the Committee recommended that Tables 4 and 5 are recommended minimum standards and are included in the policy as a reference but are not required minimum standards.

Expected Impact on Living Donors or Living Donation:

Not applicable.

Transition Procedures at Time of Implementation:

If this proposal is approved, all new applications for HCC exceptions submitted after implementation in UNet^{SM} must meet the new policy criteria in order to receive automatic upgrades. The Committee will develop appropriate transition procedures to ensure that candidates with approved HCC exceptions at the time of implementation will not be disadvantaged.

Expected Impact on Specific Patient Populations:

Based on data from 2008-2009, approximately 2500 candidates with a MELD/PELD exception for HCC are waiting for a transplant during any given year. This represents 13% of all liver candidates listed waiting during the period.

Expected Impact on Program Goals, Strategic Plan, and Adherence to OPTN Final Rule:

One of the 2010-2011 Annual Goals for this committee is to "Update Liver Waitlist HCC exception criteria based on recommendations from the consensus conference held in November 2008." This proposal meets the Final Rule allocation performance goals of "Standardizing the criteria for determining suitable transplant candidates" and "setting priority rankings expressed, to the extent possible, through objective and measurable medical criteria." This proposal addresses the policy development objective for "best use of donated organs," in that it will better ensure that those candidates that are allocated livers based on priority given for HCC will have HCC that meets policy criteria.

Plan for Evaluating the Proposal:

- ***Policy Performance Measures:*** The Committee will monitor the number of new HCC exceptions as a percentage of the total number of new candidates listed and transplants performed for the period prior to and after adoption of the policy. The Committee will also monitor waiting list drop-out rates for patients with HCC exceptions, and the number transplanted with an HCC MELD exception found to have no evidence of HCC in the explant (and no prior local-regional therapy) for this same time period.

- ***Time Line for Evaluation:*** Analyses will be performed at 6, 12 and 24 months following implementation of this policy change.

Additional Data Collection:

This proposal does not require additional data collection.

Expected Implementation Plan:

UNOS Information Technology (IT) staff will need to reprogram UNet^{SM} to modify the MELD/PELD exception applications for candidates with HCC. The Liver and Intestinal Organ Transplantation Committee will work with UNOS IT to implement this policy modification.

Communication/Education Plan:

Communication Activities			
Type of Communication	**Audience(s)**	**Deliver Method(s)**	**Timeframe**
Policy Notice following Board Approval	Transplant surgeons, transplant physicians, transplant coordinators, transplant administrators	Blast e-mail, OPTN and UNOS websites	1 month after Board approval
System Notice upon implementation	All UNet^{SM} Users	Blast e-mail, UNet^{SM} notice	TBD

Monitoring and Evaluation:

If this change is approved, the computer match system operated by the OPTN will be updated to require transplant centers to enter the appropriate information into the HCC exception application. Transplant centers are expected to enter accurate and updated information into the all exception applications. The Department of Evaluation and Quality (DEQ) verifies the information included on MELD/PELD exception applications during on-site surveys of liver transplant programs. UNOS staff forwards potential policy violations to the OPTN/UNOS Membership and Professional Standards Committee (MPSC) for review.

Policy or Bylaw Proposal:

3.6.4.4 <u>Liver Transplant Candidates with Hepatocellular Carcinoma (HCC).</u> Candidates with stage T2 HCC that meet the staging and imaging criteria specified in sections A-E may receive extra priority on the Waiting List as specified below.

A. **Eligible Candidates**. A candidate with an HCC tumor that is stage T2 may be registered at a MELD/PELD score equivalent to a 15% probability of candidate death within 3 months if the criteria listed in sections B-D are also met. For the purposes of this policy, stage T2 lesions are defined as
   - 1 lesion >= 2 cm and <= 5cm; OR
   - 2 or 3 lesions, >= 1cm and <= 3cm in size.

   The largest dimension of each tumor must be reported (i.e., 3.2cm x 5.1cm must be reported as 5.1cm). Nodules <1cm are indeterminate and cannot be considered for additional priority.

B. **Initial Assessment for Listing**. The candidate must have undergone a thorough assessment to evaluate the number and size of tumors and to rule out any extrahepatic spread (i.e. lymph node involvement) and/or macrovascular involvement (i.e., tumor thrombus in portal or hepatic vein) with dynamic contrast enhanced computed tomography (CT) or magnetic resonance imaging (MRI). The assessment of the candidate prior to transplant listing must include a CT of the chest that rules out metastatic disease. The candidate must not be eligible for resection. The alpha-fetoprotein level is required for all HCC exception applications.

C. **Requirements for Imaging**. Any imaging examination performed for the purpose of obtaining or updating priority points on the transplant waitlist should meet minimum technical and imaging protocol requirements for CT and MRI listed in Table 4 and Table 5. These must be interpreted by a radiologist at an OPTN approved transplant center. Technically inadequate or incomplete imaging examinations must be classified as OPTN Class 0 and must be repeated or completed in order to be considered for priority point allocation.

D. **Definitions of OPTN Class 5 Nodules.** Nodules found on imaging of cirrhotic livers must be classified according to the OPTN classification shown in Table 6. OPTN class 5 nodules correspond to an imaging diagnosis of HCC and are as follows:

OPTN Class 5B nodules: The combination of the following imaging findings constitutes an OPTN class 5B nodule and qualifies for automatic MELD priority score (all 3 criteria must be met):

1. Single nodule diameter ≥ 2cm and ≤ 5cm. Maximum diameter of lesion(s) should be measured on late arterial or portal phase images.
2. Increased contrast enhancement on late hepatic arterial images (relative to hepatic parenchyma)
3. One of the following:
   - **Washout** on portal venous/delayed phase
   - **Late capsule or pseudocapsule enhancement** OR
   - **Growth** (maximum diameter increase in the absence of ablative therapy) by 50% or more documented on serial MRI or CT obtained ≤ 6 month apart. Serial imaging and measurements should be performed on corresponding contrast phases with the same modality preferred. ; OR
   - **Biopsy**.

Growth criteria do not apply to previously ablated lesions. A pre-listing biopsy is not mandatory.

OPTN Class 5A nodules are defined as follows:

1. Single nodule, maximum diameter of ≥1 cm and <2cm. Maximum diameter of lesion(s) should be measured on late arterial or portal phase images.
2. Increased contrast enhancement on late arterial phase (relative to hepatic parenchyma)
3. Both of the following:
   - **Washout** during the later contrast phases **AND**
   - **Peripheral rim enhancement** (capsule/pseudocapsule) on delayed phase;

   OR
   - Biopsy

OPTN Class 5A-g (growth) are defined as follows (all criteria must be met):

- Single nodule, maximum diameter of ≥1 cm and <2cm. Maximum diameter of lesion(s) should be measured on late arterial or portal phase images.
- Increased contrast enhancement on late arterial phase (relative to hepatic parenchyma)
- Growth (maximum diameter increase) by 50% or more documented on serial MRI or CT obtained < 6 months apart. Growth criteria do not apply to ablated lesions

  .

  (i.e. a 1.2 cm hyper-enhancing nodule documented on first CT scan is found to be 1.8 cm on scan obtained 3 months later would be classified as 5A-g. This individual lesion is not eligible for MELD priority score as the tumor is still at stage T1 but if found in conjunction with a second 5A or 5A-g lesion, the patient would be eligible for an automatic MELD priority score.)

OPTN Class 5T (Treated) nodules are defined as any OPTN Class 5 or biopsy-proven HCC lesion that was automatically approved upon initial application or extension and has subsequently undergone loco-regional treatment. OPTN Class 5T nodules qualify for continued priority points predicated on the pre-treatment classification of the nodule(s) and are defined as:

1. Past loco-regional treatment for HCC (OPTN class 5 lesion or biopsy proven prior to ablation).
2. Evidence of persistent/recurrent HCC such as nodular or crescentic extra-zonal or intra-zonal enhancing tissue on late arterial imaging (relative to hepatic parenchyma) may be present.

OPTN Class 5X: Lesions that meet radiologic criteria for HCC but are outside stage T2 as defined in section A will be considered Class 5X and are not eligible for automatic exception points. These cases may be considered by the Regional Review Board (RRB) as described in section G.

E. **HCC Lesions Eligible for Automatic Upgrade.** Individual Class 5B and 5T are eligible for automatic priority. A single OPTN Class 5A nodule corresponds to T1 stage hepatocellular carcinoma and does not qualify for automatic priority MELD points but must be considered towards the overall staging of the patient according to criteria listed above. **Combinations of Class 5A nodules** that meet stage T2 criteria as described in section (A) are eligible for automatic priority.

For example, a candidate would be eligible for additional priority with:

- Two 1.5 cm (5A) lesions; or
- One 1.5 cm lesion (5A) and one 2.5 cm lesion (5B); or
- One 3.5cm lesion (5B); or
- Two 2.1cm lesions (5B).

F. **Extensions of HCC Exception Applications**. Candidates will receive additional MELD/PELD points equivalent to a 10 percentage point increase in candidate mortality to be assigned every 3 months until these candidates receive a transplant or are determined to be unsuitable for transplantation based on progression of their HCC. To receive the additional points at 3-month intervals, the transplant program must re-submit an HCC MELD/PELD score exception application with an updated narrative every three months. Continued documentation of the tumor via repeat CT or MRI is required every three months for the candidate to receive the additional 10 percentage point increase in mortality points while waiting. Invasive studies such as biopsies or ablative procedures and repeated chest CTs are not required after the initial upgrade request is approved to maintain the candidate's HCC priority scores.

If the number of tumors that can be documented at the time of extension is less than upon initial application or prior extension, the type of ablative therapy must be specified on the extension application. Candidates whose tumors have been ablated after previously meeting the criteria for additional MELD/PELD points (OPTN Class 5T) will continue to receive additional MELD/PELD points (equivalent to a 10 percentage point increase in

candidate mortality) every 3 months without RRB review, even if the estimated size of residual viable tumor falls below stage T2 criteria.

For candidates whose tumors have been resected since the initial HCC application or prior extension, the extension application must receive prospective review by the applicable RRB.

G. **Candidates Not Meeting Criteria (Class 5X)**. A candidate not meeting the above criteria may continue to be considered a liver transplant candidate in accordance with each center's own specific policy or philosophy, but the candidate must be listed at the calculated MELD/PELD score with no additional priority given because of the HCC diagnosis. All such candidates with HCC, including those with downsized whose original/presenting tumor was greater than a stage T2, must be referred to the applicable RRB for prospective review in order to receive additional priority.

H. **Appeal Procedures for Candidates not Meeting Criteria**. If the initial request is denied by the RRB, the center may appeal via a conference call with the RRB but the candidate will not receive the additional MELD/PELD priority until the case is approved by the RRB. Cases where the appropriate RRB has found the listing center to be out of compliance with Policy 3.6.4.4 will be referred to the Liver and Intestinal Organ Transplantation Committee for review and possible action. Cases not resolved within 21 days will be referred to the Liver and Intestinal Organ Transplantation Committee for review; this review by the Liver and Intestinal Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee for appropriate action in accordance with Appendix A of the Bylaws.

I. **Compliance Monitoring**. Documentation of the radiologic characteristics of each OPTN class 5 nodule (for an example, see Tables 7A-C) must be kept on file at the transplant center. If growth criteria are used to classify a nodule as HCC, prior and current dates of imaging, type of imaging and measurements of the nodule(s) must be documented in the radiology report.

For those candidates who receive a liver transplant while receiving additional priority under the HCC criteria, the recipient's explant pathology report must be sent to the OPTN contractor within 60 days of the transplant procedure. If the pathology report does not show evidence of HCC, the transplant center must also submit documentation and/or imaging studies confirming HCC at the time of listing. Additionally, if more than 10% of the HCC cases on an annual basis are not supported by pathologic confirmation or subsequent submission of clinical information, the center will be referred to the Liver and Intestinal Organ Transplantation Committee.

Appendices:

TABLE 4: Minimum technical requirements for CT
TABLE 5: Minimum technical requirements for MRI
TABLE 6: OPTN Classification of liver lesions (Class 0-5)

Table 4: Recommended minimum technical specifications for dynamic contrast-enhanced CT of the liver

Feature	**Specification**	**Comment**
Scanner Type	*Multidetector row scanner*	
Detector Type	*Minimum of 8 detector rows*	*Need to be able to image entire liver during brief late arterial phase time window*
Reconstructed 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*	*Bolus tracking recommended*
Contrast injection rate	*3mL/sec minimum, better 4-6 mL/sec with minimum of 300 mg I/mL or higher, for dose of 1.5mL/kg body weight*	
Mandatory dynamic phases on contrast enhanced MDCT (comments describe typical hallmark image features)	*1) late arterial phase* *2) portal venous phase* *3) delayed phase*	*1) artery fully enhanced, beginning contrast enhancement of portal vein* *2) portal vein enhanced, peak liver parenchymal enhancement, beginning contrast enhancement of hepatic veins* *3) variable appearance, >120 sec after initial injection of contrast*
Dynamic Phases (Timing)	*Bolus tracking or timing bolus recommended for accurate timing*	

Table 5: recommended minimum technical specifications for dynamic contrast-enhanced MRI of the liver

Feature	Specification	Comment
Scanner Type	*1.5T Tesla or greater main magnetic field strength*	*low field magnets not suitable*
Coil Type	*phased array multichannel torso coil*	*unless patient-related factors precludes use (e.g. body habitus)*
Minimum sequences	*Pre-contrast and dynamic post gadolinium T1-weighted gradient echo sequence (3D preferable), T2 (with and without FAT SAT), T1w in and out of phase imaging*	
Injector	*dual chamber power injector*	*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*
Mandatory dynamic phases on contrast enhanced MRI (comments describe typical hallmark image features)	*0)Pre-contrast T1W* *1) late arterial phase* *2) portal venous phase* *3) delayed phase*	*0) do not change scan parameters for post contrast imaging* *1) artery fully enhanced, beginning contrast enhancement of portal vein* *2) portal vein enhanced, peak liver parenchymal enhancement, beginning contrast enhancement of hepatic veins* *3) variable appearance, >120 sec after initial injection of contrast*
Dynamic Phases (Timing)	*The use of a bolus tracking method for timing contrast arrival for late arterial phase imaging is preferable. Portal venous phase (35-55 sec after initiation of late arterial phase scan), delayed phase (120-180sec after initial contrast injection)*	
Slice thickness	*5mm or less for dynamic series, 8mm or less for other imaging*	
Breath-holding	*max length of series requiring breathhold should be about 20sec. with a minimum matrix of 128 x 256*	*Compliance with breathhold instructions very important, technologists need to understand the importance of patient instruction before and during scan*

Table 6: OPTN classification system for nodules seen on imaging of cirrhotic livers

Class	Description	Comment
0	***Incomplete or technically inadequate study***	*Repeat study required for adequate assessment; automatic priority MELD points cannot be assigned based on a OPTN 0 classified imaging study*
1	***No evidence of HCC on good quality, appropriate surveillance exam***	*Typically, surveillance would continue according to routine practice at the respective transplant center*
2	***Benign lesion(s) or diffuse parenchymal abnormality with no dominant focal lesion***	*Typically, need for any further imaging would be determined on a clinical basis according to routine practice at the respective transplant center*
3	***Abnormal scan, indeterminate focal lesion(s), not currently meeting radiologic criteria for HCC***	*Typically, follow-up imaging would be performed in 6-12 months*
4	***Abnormal scan, intermediate suspicion for HCC (Meets some radiologic criteria for HCC - could represent HCC)***	*Consider short term F/U in 3 months (lesions ≥2cm maximum diameter) to 6 months (lesions <2cm maximum diameter). Imaging follow-up should be considered if biopsy is negative or not possible.*
5	***Meets radiologic criteria for HCC***	*May qualify for automatic exception depending on stage (see 3.6.4.4 section A.)*
	5A: > or equal to 1 cm and less 2 cm measured on late arterial or portal phase images.	*Increased contrast enhancement on late hepatic arterial phase AND washout during later contrast phases AND peripheral rim enhancement (capsule/pseudocapsule).*
	5A-g: same size as 5A	*Increased contrast enhancement on late hepatic arterial phase AND growth by 50% or more documented on serial CT/MRI obtained <or equal to 6 months apart.*
	5B: maximum diameter > or equal to 2cm and less than or equal to 5 cm.	*Increased contrast enhancement on late hepatic arterial phase AND either washout during later contrast phases OR peripheral rim enhancement (capsule/pseudocapsule) OR growth by 50% or more documented on serial CT/MRI obtained <or equal to 6 months apart (5B-g).*
	5T: prior local regional treatment for HCC	*Describes any residual lesion or perfusion defect at site of prior UNOS class 5 lesion.*
	5X: maximum diameter > or equal to 5 cm.	*Increased contrast enhancement on late hepatic arterial phase AND either washout during later contrast phases OR peripheral rim enhancement (capsule/pseudocapsule) OR growth by 50% or more documented on serial CT/MRI obtained <or equal to 6 months apart (5X-g).*