

Mini-Brief

Transition Plan for HCC Auto Approval Correction Implementation

OPTN Executive Committee

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Transition Plan for HCC Auto Approval Correction Implementation

Sponsoring Committee: Executive
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Executive Summary

In October 2023, an issue in the programmatic interpretation of Policy 9.5.I.vi: *Imaging Requirements for Class 5 Lesions* was discovered impacting some candidates on the OPTN Waiting List with hepatocellular carcinoma (HCC) exceptions. This mini-brief proposes to allow candidates to retain their current exception allocation priority Model for End-Stage Liver Disease (MELD) score although they received an automatic initial exception approval without meeting all the specified policy criteria. The needed correction will be implemented in the OPTN Computer System. The Executive Committee is being asked to approve a transition plan to allow the actively waiting impacted candidates to retain their existing approved exception status upon implementation.

OPTN Policy establishes criteria for liver candidates who meet specified criteria for certain T2 stage, OPTN Class 5 HCC lesions to receive automatic approval for an exception to their MELD score. When an HCC exception request does not meet automatic approval criteria, it is then adjudicated by the National Liver Review Board (NLRB). If approved, the initial exception, as well as extension requests, are in effect for 90 days.

The Executive Committee is requested to approve a transition plan where candidates who received an auto approval by meeting some, but not all, criteria will still retain their current approved exception status upon implementation of a system correction.

Purpose

The purpose of this mini-brief is to request approval of a transition plan that will retain exception approval status for a specific cohort of liver candidates. These candidates have an active Hepatocellular carcinoma (HCC) exception that was initially auto-approved by the OPTN Computer System without demonstrating that all required criteria were met. An implementation is planned to align the logic with current policy requirements; however, it is necessary for the OPTN to decide how to handle the current candidates who received these automatic approvals. The proposed transition plan would allow these candidates to keep their approved status.

Background

Per OPTN Policy, each liver transplant candidate is assigned a score that reflects the probability of death within a 3-month period as determined by the Model for End-Stage Liver Disease (MELD) scoring system or the Pediatric End Stage Liver Disease (PELD) scoring system. If a candidate's transplant program believes that a candidate's current MELD or PELD score does not appropriately reflect the candidate's medical urgency for transplant, the transplant program may submit a MELD or PELD score exception request through the OPTN Computer System. If the MELD or PELD score exception meets certain criteria outlined in policy, the request is automatically approved by the system and does not require evaluation by the National Liver Review Board (NLRB).

The NLRB was implemented in 2019 to provide fair, equitable, and prompt peer review of requests for exceptions for candidates not meeting standard criteria.¹ As part of this proposal, all standard exceptions were programmed to be automatically approved in the OPTN computer system.

HCC is one of nine diagnoses that has a standardized exception pathway per Policy 9.5.i: *Requirements for HCC MELD or PELD Score Exceptions*. To meet the criteria for a standard HCC exception, there are certain radiologic imaging criteria that must be met along with clinical criteria. If all criteria are met, then the candidate may receive an automatic approval for an exception request; otherwise, the request is sent to the NLRB for consideration per Policy 9.4: *MELD or PELD Score Exceptions*. Tumor size and number requirements are defined in Policy 9.5.i.ii: *Eligible Candidates Definition of T2 Stage*. T2 stage is defined in the policy as candidates with 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.

¹ OPTN Liver & Intestinal Organ Transplantation Committee, Proposal to Establish a National Liver Review Board. Policy notice available at <https://optn.transplant.hrsa.gov/media/2197/policy-notice-july-2017-national-liver-review-board.pdf>.

Policy further categorizes Class 5 lesions according to Policy 9.5.1.vi: *Imaging Requirements for Class 5 Lesions*, Table 9-9: *Classification System for Lesions Seen on Imaging of Livers*. While there are criteria for 5A, 5A-g, 5B, and 5T lesions, it is only in the 5A category where an implementation issue has been discovered.

The 5A requirements implemented in December 2017 used older terminology and criteria.² They were as follows:

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.
3. *Either* of the following:
 - Washout during the later contrast phases and peripheral rim enhancement on delayed phase
 - Biopsy

In 2019, as part of the implementation of the proposal to establish the NLRB, all standardized exceptions were programmed to be automatically approved in the OPTN Computer System. During that programming, there was a programmatic interpretation related to the requirements for Class 5A lesions that resulted in the automatic approval of some HCC forms that do not meet all the criteria outlined in 9.5.1.vi; instead, these exceptions should have been sent to the NLRB for review, per *Policy 9.4: MELD or PELD Score Exceptions*.

This recently discovered issue allowed automatic approval of standard HCC exceptions that met only the first two of the three imaging criteria for a class 5A lesion. This persisted during the July 2023 implementation that only had planned label changes in the OPTN Computer System.³ During exploratory work on a potential, future project, an issue was identified. See **Table 1** for a timeline of events.

² OPTN Liver and Intestinal Organ Transplantation Committee, “Changes to HCC Auto Approval Criteria.” Policy notice available at <https://optn.transplant.hrsa.gov/policies-bylaws/notices-of-implemented-actions>.

³ Current policy requires a 5A HCC lesion to 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. Nonrim arterial phase hyper-enhancement
3. *Either* of the following:
 - Non-peripheral washout
 - Biopsy

These current 5A requirements and terminology were adopted by the OPTN Board of Directors in June 2022 and implemented earlier this year on July 13, 2023. Changes were made to align with the Liver Imaging and Reporting Data System (LI-RADS) v2018 maintained by the American College of Radiology.

Table 1: Selected History of Liver Policy Implementations associated with HCC Class 5A

Date of Board Approval	Proposal	Implementation
Nov 2011	Modifications to Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)) that more clearly define the imaging characteristics of HCC	Oct 31, 2013
Dec 2016	Changes to HCC Criteria for Auto-Approval	Dec 12, 2017
June 2017	Proposal to Establish a National Liver Review Board	May 14, 2019 **
June 2022	Ongoing Review of National Liver Review Board (NLRB) Diagnoses	July 13, 2023

** NLRB implementation introduced a logic issue in some HCC auto-approvals. Some candidates start receiving automatic approval when only meeting the first two 5A criteria instead of all three requirements.

The issue was identified and declared on October 16, 2023, and reported to Health Resources and Services Administration (HRSA) as required by the OPTN contract. The situation was shared with the OPTN Liver and Intestine Organ Transplantation Committee (Committee) leadership during a call on October 17. Committee leadership reviewed Policy 9.5.I.vi: *Imaging Requirements for Class 5 Lesions* and agreed that the OPTN Computer System required updates to align with current policy language.

It is the recommendation of Committee leadership that any candidates who have current approved standard HCC exceptions due to this issue should not lose the exception. These candidates may have already received additional priority MELD points according to policy. These candidates would have been routed through the NLRB, which would have considered whether to grant the exception request in each individual case. That decision would not be possible to predict. Committee leadership suggests it would be more appropriate to continue to apply the benefit versus taking the benefit away and requiring the candidate to start over from the beginning of the exception process.

Following the recommendation of Committee leadership, this proposal would adopt a transition procedure and allow candidates currently on the OPTN Waiting List to keep their auto-approved HCC exception although these candidates were initially approved using logic that did not enforce the third criteria required by policy for 5A HCC lesions.

The alternative would be to remove the auto-approvals and request that transplant programs submit new exception requests according to the current policy in effect. This could result in the loss of MELD priority exception points for patients if they had been approved for at least 180 days. It could also have the negative impact of the candidate having to start at day 0 and waiting an additional 180 days before possibly regaining MELD priority points which are equivalent to Median MELD at Transplant (MMaT) -3.

Because MMaT is now based around the donor hospital, a candidate's MELD score may change with each match they appear on based on the location of the donor hospital. Therefore, the potential impact on the actual score cannot be more precisely predicted. By choosing a transition plan that retains the status quo, candidates will maintain their approved exception including any additional MELD priority score they have at the time of implementation.

Impact Analysis

Currently, there are 34 active candidates⁴ that have an active exception (either initial or extension) that was automatically approved without meeting all of the required policy HCC class 5A imaging criteria. This number is subject to change as candidates may be removed for transplant or other reasons and new candidates may be added until the implementation date.

Implementation

The OPTN will make changes to the OPTN Computer System to align HCC auto approval logic to the current approved policy. The transplant community will be notified through a system notice. Transplant programs will not need to take any action for their current candidates. Transplant programs will continue to enter required data for HCC exception requests. The system implementation will ensure that all exception request forms are processed according to OPTN policy. The compliance and evaluation plan will not change as a result of this system implementation.

⁴ OPTN Data as of October 13, 2023.

Resolution

RESOLVED, that candidates at risk for HCC with Class 5A lesions with an active exception pursuant to OPTN Policy 9.5.I.vi: Imaging Requirements for Class 5 Lesions that was automatically approved prior to October 25, 2023 shall maintain their current exception score until it would otherwise expire pursuant to OPTN policy.

APPROVED