

# OPTN/UNOS Policy Notice

## Clarification to Alpha-Fetoprotein (AFP) Levels for Liver Candidate Eligibility for Standardized HCC Exceptions

<b>Sponsoring Committee:</b>	<b>Liver and Intestinal Organ Transplantation Committee</b>
<b>Policy/Bylaws Affected:</b>	<b>Policies 9.5.I.ii (Eligible Candidates Definition of T2 Lesions), 9.5.I.iii (T2 Lesions Eligible for Downstaging Protocols), and 9.5.I.iv (Candidates with Alpha-fetoprotein (AFP) Levels Greater than 1000)</b>
<b>Public Comment:</b>	<b>N/A</b>
<b>Effective Date:</b>	<b>December 12, 2017</b>

### Problem Statement

In December 2016, the OPTN/UNOS Board of Directors approved the *Changes to HCC Criteria for Auto Approval* proposal. During the implementation of the proposal, UNOS staff discovered that candidates who initially present with T2 HCC lesions with an alpha-fetoprotein (AFP) equal to 1000 were inadvertently excluded from a standardized MELD exception. The Committee's intent was that candidates with AFP equal to 1000 would also receive a standardized MELD exception. Additionally, the new downstaging protocol in policy inadvertently includes some tumors that meet T2 criteria that should not fall within the downstaging protocol.

### Summary of Changes

Since the Committee's intent was that candidates with AFP equal to 1000 ng/mL would also receive a standardized MELD exception, this proposal changes the policy language to include these candidates. Additionally, since there was no intention that the description of lesions that meet downstaging criteria should include lesions that fall at or below T2 criteria, this clarification changes the criteria regarding two or three lesions in the downstaging protocol to exclude candidates that would fall within T2 criteria. Additional policy language has been provided to increase the clarity regarding eligibility for a standardized MELD exception.

### What Members Need to Do

Members will need to familiarize themselves with all of the impending changes to policy as a result of the *Changes to HCC Criteria for Auto Approval* proposal, including these clarifications.

### Affected Policy Language

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

### 9.5.I.ii Eligible Candidates Definition of T2 Lesions

Candidates ~~who initially present~~ with T2 HCC lesions are eligible for a standardized MELD exception if they have an alpha-fetoprotein (AFP) level less than or equal to 1000 ng/mL and *either* of the following:

- One lesion greater than or equal to 2 cm and less than or equal to 5 cm in size.
- Two or three 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 exception according to *Policy 9.5.I.iv: Candidates with Alpha-fetoprotein (AFP) Levels Greater than 1000.*

### 9.5.I.iii T2 Lesions Eligible for Downstaging Protocols

Candidates are eligible for ~~inclusion in a downstaging protocol~~ a standardized MELD exception if, before completing local-regional therapy, they initially present with have lesions that meet *one* of the following criteria:

- One lesion greater than 5 cm and less than or equal to 8 cm
- Two or three lesions, each greater than 3 cm and less than or equal to 5 cm, and a total diameter of all lesions less than or equal to 8 cm
- Four or five 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 therapy, their residual lesions must subsequently meet the requirements for T2 lesions according to *Policy 9.5.I.ii: Eligible Candidates Definition of T2 Lesions* to be eligible for a standardized MELD exception. Downstaging to meet eligibility requirements for T2 lesions must be demonstrated by CT or MRI performed after local-regional ~~treatment~~ 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 are not automatically eligible for a standardized MELD exception and must be referred to the RRB for consideration of a MELD exception.

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

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

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