

OPTN/UNOS Policy Notice

Modification to Hepatocellular Carcinoma (HCC) Extension Criteria

Sponsoring Committee:	Liver and Intestinal Organ Transplantation Committee
Policy/Bylaws Affected:	Policies 9.3.F (Candidates with Hepatocellular Carcinoma (HCC)), 9.3.F.vii (Extensions of HCC Exceptions), 9.5.I (Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions), and 9.5.I.vii (Extensions of HCC Exceptions)
Public Comment:	January 2, 2018 – January 31, 2018
Effective Date:	February 5, 2018

Problem Statement

HCC candidates must meet specific eligibility criteria for a standardized HCC exception request. This eligibility criteria includes, but is not limited to, criteria based on the size and number of HCC lesions (known as “T2 criteria”) and their alpha-fetoprotein (AFP) level. The current policy about T2 criteria is below:

9.3.F.ii Eligible Candidates Definition of T2 Lesions

Candidates 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 9.3.F.iv: Candidates with Alpha-fetoprotein (AFP) Levels Greater than 1000.

Following their initial approved exception score, policy requires candidates to continue to apply for an extension every 90 days in order to maintain their approved HCC exception. During this time it is common for HCC candidates to receive treatment that reduces the size and number of their HCC lesions. These treated lesions often fall below T2 criteria. Subsequently, HCC candidates often have lesions that fall below the criteria that is required for an initial HCC exception.

The recently implemented policy requires that a “candidate will receive the additional priority as long as they continue to *meet initial eligibility criteria*”. The policy included this new phrase which was intended to capture those exceeding initial eligibility criteria, progressing beyond T2 criteria prior to extension. However, candidates who initially qualified for an HCC exception, but later are treated with residual lesions below T2 criteria, are no longer “automatically-approved” at their next extension. Instead, a review board must review the extension request. The Committee has identified this specific change to policy as being an unintended outcome of the previous proposal. The current policy creates a heavy burden for liver transplant program staff, who must track each HCC candidate’s exceptions and manually apply to the review board for extensions every 90 days. This policy also increases the burden of cases for the review boards. Additionally, the review board oversight results in unnecessary delay for the HCC

candidates that, before policy implementation, have previously been identified as receiving automatic approval.

Summary of Changes

This proposal changes policy to allow candidates who at first qualified for an HCC exception, but later were treated and therefore have residual lesions below T2 criteria, not to need review board approval of an HCC exception extension. This proposal also keeps the current policy on HCC progression, indicated by an increase in the size of HCC lesions above T2 criteria and increases in alpha-fetoprotein (AFP) above the recently established criteria.

Candidates whose HCC lesions exceed T2 criteria, but not those whose lesions fall below T2 criteria, will require review board approval for an extension of their HCC exception. Candidates with an AFP level that was less than or equal to 1,000 ng/mL on the initial exception request, but later rises above 1,000 ng/mL will need review board approval for an extension of their HCC exception. Finally, candidates with an AFP level that was greater than 1,000 ng/mL, but fell below 500 ng/mL after treatment but before the initial exception request, then later rises to greater than or equal to 500 ng/mL will require review board approval for an extension of their HCC exception. This policy about AFP at extension is currently implemented.

What Members Need to Do

Liver transplant programs will need to prepare for implementation of the new policy. Hospitals will need to ensure that their staff understand the proposed criteria for HCC extension requests. This may involve training for staff and changes to current hospital processes regarding HCC exception requests. This proposal will reduce the burden for liver transplant program staff, who must track each HCC candidate's exceptions and manually apply to the review board for extensions every 90 days for candidates with treated lesions below T2 criteria.

Affected Policy Language

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

Policy or Bylaws Language

Proposed new language is underlined (example) and language that is proposed for removal is struck through (~~example~~).

The Board approved changes to this policy section in June 2017 with the approval of the National Liver Review Board (NLRB). These changes are pending programming. For clarity, the proposed changes with this proposal are shown below in the currently approved and implemented policy, without the NLRB changes awaiting implementation.

RESOLVED, that changes to Policies 9.3.F (Candidates with Hepatocellular Carcinoma (HCC)) and 9.3.F.vii (Extensions of HCC Exceptions), as set forth below, are hereby approved, effective February 5, 2018.

9.3.F Candidates with Hepatocellular Carcinoma (HCC)

Upon submission of the first exception request, a candidate with hepatocellular carcinoma (HCC) that is:

- At least 18 years old ~~with Hepatocellular Carcinoma (HCC)~~ and meets the criteria according to Policies 9.3.F.i through vi will receive a MELD score according to *Table 9-4: Exception Score Assignment for Candidates at least 18 Years Old at the Time of Registration*.
- Twelve to 17 years old and the Regional Review Board (RRB) has determined that the candidate's calculated MELD score does not reflect the candidate's medical urgency, will be listed at a MELD score of ~~28~~ 40.

- Less than 12 years old, and the RRB has determined that the candidate's calculated MELD score does not reflect the candidate's medical urgency, will be listed at a PELD score of 4440.

9.3.F.vii Extensions of HCC Exceptions

In order for a candidate to maintain an approved exception for HCC, the transplant program must submit an updated MELD/PELD Exception Score Request Form every three months. The candidate will then receive the additional priority as long as they continue to meet initial eligibility criteria unless any of the following occurs:

- The candidate's lesions progress beyond T2 criteria, according to 9.3.F.ii: Eligible Candidates Definition of T2 Lesions
- 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

Exception scores for candidates that were at least 18 years old upon submission of their initial exception request at the time of registration are assigned according to *Table 9-4* below. The candidate's MELD exception score will be capped at 34.

Table 9-4: Exception Score Assignment for Candidates at least 18 Years Old at the Time of Registration

Exception Request	MELD Exception Score
Initial	Calculated MELD score
1st extension	Calculated MELD score
2nd extension	28
3rd extension	30
4th extension	32
5th extension and all subsequent extensions	34

A liver candidate less than 18 years old at the time of registration that meets the requirements for a standardized MELD or PELD score exception will be assigned a MELD or PELD score of 40.

To receive the extension, the transplant program must submit an updated MELD/PELD Exception Score Request Form that contains all of the following:

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

If a candidate's tumors have been resected since the previous request, then the transplant program must submit an updated MELD/PELD Exception Score Request Form to the RRB for prospective review.

The Board approved changes to this policy section in June 2017 with the approval of the National Liver Review Board (NLRB). These changes are pending programming. For clarity, the proposed changes with this proposal are also shown below in the currently approved but not-yet-implemented NLRB policy.

RESOLVED, that changes to Policies 9.5.I (Requirements for Hepatocellular Carcinoma (HCC) MELD or PELD Score Exceptions) and 9.5.I.vii (Extensions of HCC Exceptions), as set forth below, are hereby approved, effective pending implementation and notice to OPTN members.

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 be provided a score according to Policy 9.5.I.vii: *Extensions of HCC Exceptions* if the candidate is:

- At least 18 years old with Hepatocellular Carcinoma (HCC) and meets the criteria according to *Policies 9.5.I.i through 9.5.I.vi*.
- Twelve to 17 years old, and the National Liver Review Board (NLRB) has determined that the candidate's calculated MELD score does not reflect the candidate's medical urgency.
- Less than 12 years old, and the NLRB has determined that the candidate's calculated MELD score does not reflect the candidate's medical urgency.

9.5.I.vii Extensions of HCC Exceptions

In order for a candidate to maintain an approved exception for HCC, the transplant program must submit an updated MELD/PELD Exception Score Request Form every ~~three months~~ 90 days. The candidate will then receive the additional priority ~~as long as they continue to meet initial eligibility criteria 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*
- 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

A liver candidate at least 18 years old at the time of registration that meets the requirements for a standardized MELD score exception will be assigned the candidate's calculated MELD score upon initially requesting a MELD score exception, and upon submitting the first exception request. For each subsequent request, the candidate will receive a MELD score that is 3 points below the median MELD at transplant for liver recipients at least 18 years old in the DSA where the candidate is registered. If the candidate's exception score would be higher than 34 based on this calculation, the candidate's score will be capped at 34.

The OPTN Contractor will re-calculate the median MELD at transplant every 180 days using the previous 365-day cohort. If there have been fewer than 10 transplants in the DSA in the previous 365 days, the median MELD at transplant will be calculated for the region where the candidate is registered. At each 180 day update, candidates with existing standardized score exceptions will be assigned the score to match the re-calculated median MELD. The median MELD at transplant calculation excludes recipients transplanted with livers recovered by OPOs outside the recipient transplant hospital's region.

A liver candidate less than 18 years old at the time of registration that meets the requirements for a standardized MELD or PELD score exception will be assigned a MELD or PELD score of 40.

To receive an extension, the transplant program must submit an updated MELD/PELD Exception Score Request Form that contains all of the following:

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

If a candidate's tumors have been resected since the previous request, then the transplant program must submit an updated MELD/PELD Exception Score Request Form to the NLRB for prospective review.

#