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Public Comment Proposal

Modification to Hepatocellular Carcinoma (HCC) Extension Criteria

OPTN/UNOS Liver and Intestinal Organ Transplantation Committee

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Modification to Hepatocellular Carcinoma (HCC) Extension Criteria

Affected Policies: *Policy 9.3.F.vii Extensions of HCC Exceptions*
Sponsoring Committee: *Liver and Intestinal Organ Transplantation Committee*
Public Comment Period: *January, 2, 2018 – January, 31, 2018*

Executive Summary

In December 2016, the Board of Directors approved the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee's *Changes to HCC Criteria for Auto Approval* proposal[1] and on December 12th 2017, UNOS implemented these changes. The recently implemented changes include policy that changed the required eligibility criteria for candidates to receive an automatic extension of their currently approved hepatocellular carcinoma (HCC) exception. The policy language, and corresponding programming, removes automatic extensions for a subset of HCC candidates with treated lesions that fall below the eligibility criteria for an initial exception request. These candidates therefore require review board approval to receive an extension of their exception score. The Committee's intent is to allow these candidates to continue to receive automatic approval of their HCC exception at time of extension, as they had prior to the policy change on December 12th, 2017.

Is the sponsoring Committee requesting specific feedback or input about the proposal?

Yes, the Committee is requesting specific feedback on the proposed policy change that provides automatic extension of a HCC exception score for candidates with HCC lesions that fall below T2 lesion criteria at time of their extension.

Members are asked to comment on both the immediate and long term budgetary impact of resources that may be required if this proposal is approved. This information assists the Board in considering the proposal and its impact on the community

[1] Board briefing paper available on the OPTN Website

What problem will this proposal address?

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 3 months 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 candidates' exceptions and manually apply to the review board for extensions every three months. 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 automated approval.

Why should you support this proposal?

Treatment of HCC while waiting for transplant and the related decline in the number and/or size of lesions is standard medical practice. The Committee does not want policy that discourages treatment of HCC candidates because of the delay and potential denial of a candidate's HCC exception extension. Therefore, the Committee does not want review boards to review extensions for HCC candidates with treated lesions below T2 criteria as long as they meet all other requirements at extension.

How was this proposal developed?

On December 12th 2017, UNOS implemented the *Changes to HCC Criteria for Auto Approval* proposal. Shortly after implementation, members of the Committee identified that a candidate who initially qualifies for an HCC exception, is treated with residual lesions below T2 criteria, then is not "auto-approved" at their next extension. Instead, review boards must approve these extension requests.

The Committee met by conference call on December 21, 2017 to discuss the recent implementation. There was unanimous agreement the policy regarding extensions for candidates with lesions below T2 criteria was an unintended consequence of the new policy. Additionally, the Committee stated that the policy and programming would result in unnecessary delay for HCC candidates, and additional burden on review board members due to the increase in the number of cases referred to the review board.

The OPTN/UNOS Executive Committee met by conference call on December 28, 2017 to discuss the policy and the sentiments of the Committee. Several Executive Committee members stated that the policy and programming is not in line with the clinical intent for HCC candidates and agreed with the sentiment of the Committee. The Executive Committee voted unanimously in support of policy language that allows candidates who initially qualified for an HCC exception, but have subsequently been treated with residual lesions below T2 criteria, to be subject to automatic approval of their HCC exception extensions and to not require review by the review boards for approval of their extension. This unanimous vote by the Executive Committee also authorized an expedited period of public comment (30 days) because this proposal is expected to be non-controversial. The process follows the principles of non-controversial changes in *Bylaw 11.8 Expedited Actions.*[2]

How well does this proposal address the problem statement?

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 1,0000 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.

Which populations are impacted by this proposal?

The goal of this proposal is for candidates who initially qualified for an HCC exception, but have subsequently been treated and therefore have residual lesions below T2 criteria, to not require review board approval of their extension as long as all other requirements are met. In the 15 days following the implementation of the changes to HCC (December 12–27, 2017), there were 158 HCC Exception Extension Forms with lesions below T2 Criteria (either 0 tumors or 1 tumor less than 2 centimeters) referred to the regional review boards. This trend of added cases for the review board will continue in the future. This proposal will reduce the burden on review boards by providing automatic extensions to HCC candidates that have lesions below T2 criteria but otherwise meet all the requirements for an automatic extension of their HCC exception score.

How does this proposal impact the OPTN Strategic Plan?

1. *Increase the number of transplants:* There is no expected impact to this goal
2. *Improve equity in access to transplants:* There is no expected impact to this goal
3. *Improve waitlisted patient, living donor, and transplant recipient outcomes:* The Committee expects the change to HCC extension criteria will improve waitlisted patient outcomes by reducing unnecessary delay resulting from review by the review board.
4. *Promote living donor and transplant recipient safety: There is no expected impact to this goal*

[2] OPTN Bylaws are available on the OPTN Website

5. *Promote the efficient management of the OPTN:* The change to HCC extension criteria will reduce the number of HCC extensions requiring approval from the review board. This will improve the efficiency of the review board by reducing the burden of cases for reviewers.

How will the OPTN implement this proposal?

This proposal will require programming in UNet^{SM}. UNOS IT provides cost estimates for each public comment proposal that will need programming to implement. The estimates can be small (108-419 hours), medium (420-749 hours), large (750-1,649 hours), very large (1,650-3,999 hours), or enterprise (4,000-8,000 hours). The IT estimate for this proposal is small.

The OPTN/UNOS will follow normal processes to inform members and educate them on any policy changes through Policy Notices. The OPTN/UNOS will deliver communications to the membership to promote knowledge, awareness, and compliance related to policy and system changes in advance of implementation. It is expected that the proposed changes would be implemented in early 2018, following public comment and pending approval.

How will members implement this proposal?

Transplant Hospitals

Liver 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/or 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 candidates' exceptions and manually apply to the review board for extensions every three months for candidates with treated lesions below T2 criteria.

Will this proposal require members to submit additional data?

No, this proposal does not require additional data collection.

How will members be evaluated for compliance with this proposal?

The proposed language will not change the current monitoring of OPTN members. Any data entered in UNet^{SM} is still subject to OPTN review, and members are still required to provide documentation as requested.

How will the sponsoring Committee evaluate whether this proposal was successful post implementation?

The OPTN will assess the impact of these policy changes along with the other implemented changes to HCC on December 12th 2017[3] using a pre vs. post analysis at 6-month intervals, up to 24 months after implementation. Analyses beyond 24 months will be performed at the request of the Committee. Several metrics will be monitored, including, but not limited to, the following:

Waiting List Metrics

- Number of approved exceptions for HCC
    - Meeting criteria
    - Outside of criteria
- Candidate characteristics
    - Demographics
    - Tumor characteristics

[3] Policy is available on the OPTN website

    - AFP value
    - Local-regional treatments
    - Other characteristics as possible
- Removal rates for death, too sick, and transplant for HCC compared to non-HCC candidates

Transplant Metrics

- Number of approved exceptions for HCC
    - Meeting criteria
    - Outside of criteria
- Recipient characteristics
    - Demographics
    - Tumor characteristics
    - AFP
    - Local-regional treatments
    - Other characteristics as possible
- Graft and patient survival
- HCC recurrence after transplant

Note that graft and patient survival rates and recurrence rates require sufficient follow-up data in order to report meaningful results. Such metrics are typically not provided prior to 1 year following implementation.

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.

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 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-implement policy.

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. 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.

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