

At-a-Glance

Proposal to Cap the HCC Exception Score at 34

- **Affected/Proposed Policy:** 9.3.G.vi Extensions of HCC Exceptions

- **Liver and Intestinal Organ Transplantation Committee**

Candidates with a MELD/PELD score exception for HCC receive high priority on the liver waiting list, especially as their exception scores may increase automatically every three months. Increasingly, there are candidates with multiple HCC exception extensions who are now receiving regional offers under the “Share 35 Regional” policy implemented in June 2013. These candidates are likely to have a much lower risk of disease progression or dropout (i.e., removal from the waiting list for death or being too sick) than candidates with calculated MELD/PELD scores of 35 and higher. This proposal would cap the HCC exception score at 34, in effect giving candidates with calculated MELD/PELD scores of 35 and higher a better opportunity to receive regional offers under the new policy.

- **Affected Groups**

Transplant Administrators
Transplant Data Coordinators
Transplant Physicians/Surgeons
Transplant Program Directors
Organ Candidates

- **Number of Potential Candidates Affected**

There have been 93 candidates listed with an HCC exception extension score of 35 or higher between January 1, 2010 and October 31, 2013. This represents 1.1% of those who ever reached a score of 35, and 17.6% of all exceptions reaching 35 during this time period. However, this number has been steadily increasing and will continue to rise without a policy change.

- **Expected Impact on OPTN Strategic Plan and Final Rule**

This proposal would increase access to transplants for candidates without HCC exceptions.

Proposal to Cap the HCC Exception Score at 34

Affected/Proposed Policy: 9.3.G.vi Extensions of HCC Exceptions

Liver and Intestinal Organ Transplantation Committee

Public comment response period: March 14, 2014 – June 13, 2014

Summary and Goals of the Proposal

Candidates with a MELD/PELD score exception for HCC receive high priority on the liver waiting list, especially as their exception scores may increase automatically every three months. Increasingly, there are candidates with multiple HCC exception extensions who are now receiving regional offers under the “Share 35 Regional” policy implemented in June 2013. However, candidates with HCC exceptions are likely to have a much lower risk of disease progression or dropout (i.e., removal from the waiting list for death or being too sick) than those without HCC exceptions^{1,2}. This proposal would cap the HCC exception score at 34, in effect giving candidates with calculated MELD/PELD scores of 35 and higher a better opportunity to receive regional offers under the new policy.

Background and Significance of the Proposal

The “Share 35 Regional” policy for deceased donor liver allocation was implemented in June 2013. Under this policy, candidates with MELD/PELD score of 35 and higher are offered livers, first locally, then regionally, by descending MELD/PELD scores. (i.e., local MELD/PELD 40, Regional MELD/PELD 40, local MELD/PELD 39, Regional MELD/PELD 39, etc.) prior to local candidates with scores less than 35. This was intended to reduce waiting list mortality in this very sick group of patients, whose risk of mortality is similar to those in Status 1³. Livers have been shared on a full regional basis for Status 1s since 2010.

One unintended consequence of this policy is that livers are being offered regionally to a subset of candidates with a very low risk of waiting list death or dropout. Candidates with an approved HCC exception receive increases in their MELD/PELD exception scores every three months, even if there is no change in the size or number of tumors. Many of these candidates have received loco-regional therapy and show no residual tumor growth, and thus do not require such high priority. In recent years, these candidates have begun to accrue scores of 35 and higher, and are now competing with very sick candidates for the regional donor pool. Capping the HCC exception score at 34 will prevent candidates with a low risk of death or dropout from competing for regional liver offers with much sicker patients. For candidates with an accumulated HCC exception score of 35 or higher at the time of implementation, the exception scores will be reset to 34 for the duration of their time with an HCC exception. Candidates with scores greater than 34 at the time of implementation may be referred to the Regional Review Board (RRB) if they demonstrate the need for higher priority.

¹ Washburn K, Edwards E, Harper A, Freeman RB. Hepatocellular Carcinoma Patients Are Advantaged in the Current Liver Transplant Allocation System. *American Journal of Transplantation* 2010; 10: 1652–1657

² Massie AB, Caffo B, Gentry SE, Hall EC, Axelrod DA, Lentine KL, Schnitzler MA, Gheorghian A, Salvalaggio PR, Segev DL. MELD Exceptions and Rates of Waiting List Outcomes. *Am J Transplant*. 2011 Nov;11(11):2362-71.

³ Sharma P, Schaubel DE, Gong Qi, Guidinger MK, Merion RM. End stage liver disease (ESLD) patients with high MELD have higher wait list mortality than Status 1 patients. *Am J Transplantation*, 2009, Vol 9, Suppl2, p 347.

Per policy, as long as transplant centers submit the required HCC extension forms, the score increases are automatic within UNetSM, i.e., without any RRB review.

In its effort to assign more appropriate priority to candidates with HCC, the Committee is also proposing another modification to the HCC exception policy, which would delay the HCC score assignment. This proposal is being circulated for public comment separately, but could be combined into one programming effort if both are approved.

Supporting Evidence and/or Modeling

The number of HCC exceptions that reach scores of 35 or higher has been increasing over time, with only 6 instances in 2010, rising to 34 cases in the first nine months of 2013. Most of these are occurring in a few regions, with 70% of cases in Region 5, 10% in Region 9, and 6% in Region 1. Several regions have not yet had an occurrence (Regions 6, 10, and 11). This number is expected to continue to increase over time unless the policy is changed.

While analysis using the Liver Simulated Analysis Model (LSAM) suggested capping the MELD/PELD exception score had little or no impact on several metrics⁴, the models examined capped the HCC exception MELD/PELD score at 29, 30, 31, and 33. At the time this modeling was performed, LSAM was using data from 2010, when the median MELD score at transplant was less than 29 for the majority of regions, and there were very few HCC exception scores that had reached 35.

Expected Impact on Living Donors or Living Donation

Not applicable.

Expected Impact on Specific Patient Populations

There is no known impact on any specific patient population.

Expected Impact on OPTN Strategic Plan and Adherence to OPTN Final Rule

The proposal should improve access to liver transplantation and reduce waiting list mortality for candidates with calculated MELD/PELD score of 35 and higher by reducing the number of candidates in this pool without adversely impacting candidates with HCC exceptions.

Plan for Evaluating the Proposal

This proposal is intended to reduce the disparity in waiting list drop-out rates (removals for death/"too sick"/other removals due to HCC) between HCC and non-HCC candidates, particularly in regions with relatively short waiting times to transplant. As such, drop-out rates for these groups will be compared at 6-months, 1 year, 2-years and, if deemed necessary by the Committee, up to 3-years post-implementation of the policy. A review of the existing data at 6 months after implementation will be performed to determine if a sufficient number of events have occurred to support the analysis. For each analysis, a comparable time period prior to implementation will serve as the baseline. Event rates (transplant rates, drop-out rates) will be

⁴ e.g., the ratio of HCC to non-HCC transplants, transplant rates by HCC status, the average number of waitlist and removal deaths, waitlist removal rates, and the average calculated MELD/PELD score at transplant

compared overall and, if possible, by region. To detect unintended consequences, event rates pre- and post-policy will also be estimated by age (pediatric vs. adult) and by ethnicity. Note: A reasonable lag time (6-8 weeks) should be expected for each report to allow time for more complete data reporting and for analyzing/collating the results. Disclaimer: Since these are observational data, it should be noted that any observed differences in the results (pre- vs. post-implementation) may be due to external factors and are not necessarily due to the impact of the policy.

In addition to the above analyses, the event rates of MELD/PELD candidates with scores of 35 and above (non-HCC) will be estimated in the pre- and post-implementation period. This will be accomplished using an intent-to-treat analysis, measuring the time from the candidate's first entry into MELD/PELD 35 and above category until removal from the waiting list.

Additional Data Collection

This proposal does not require additional data collection.

Expected Implementation Plan

If public comment is favorable, this proposal will be submitted to the OPTN Board of Directors in November, 2014. If approved by the Board, this proposal will become effective upon the required programming in UNetSM.

Communication and Education Plan

Communication Activities			
Type of Communication	Audience(s)	Deliver Method(s)	Timeframe
Policy Notice following Board Approval	Liver candidates, transplant surgeons, transplant physicians, transplant coordinators, transplant administrators	OPTN and UNOS websites	1 month after Board approval
System Notice upon implementation	All UNet SM Users	Blast e-mail, UNet SM notice	30 days before the implementation, and again upon implementation

Education/Training Activities			
Education/Training Description	Audience(s)	Deliver Method(s)	Timeframe and Frequency
Brief Training Session	All UNet SM Users	Webinar	Prior to Implementation

Compliance Monitoring

This proposal will not affect routine compliance monitoring of transplant hospitals.

Policy or Bylaw Proposal

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

9.3.G.vi *Extensions of HCC Exceptions*

A candidate will receive additional MELD or PELD points equivalent to a 10 percentage point increase in the candidate's mortality risk every three months after receiving an HCC exception until the candidate receives a transplant or is unsuitable for transplantation based on the candidate's HCC progression. The HCC exception score will be capped at 34. Upon implementation, candidates with HCC exception scores greater than 34 will receive a score of 34 for their remaining HCC exception extensions. Candidates with scores greater than 34 at the time of implementation may be referred to the RRB if they demonstrate the need for higher priority.