OPTN/UNOS Liver & Intestinal Organ Transplant Committee
Meeting Summary
December 29, 2016
Conference Call

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Discussions of the full committee on December 29, 2016 are summarized below. All committee meeting summaries are available at https://optn.transplant.hrsa.gov.

Committee Projects

1. National Liver Review Board (NLRB) Policy: Structure, Operations, Policy Language and Exceptions Points, and Pediatric Exception Assignments

The Chair of the Liver and Intestinal Organ Transplant Committee (Committee) presented an update on the NLRB project to date. The NLRB structure was sent for public comment in January 2016. Since January 2016, the Committee has been working on the standardization of exception points through the NLRB Subcommittee. On its December 15, 2016 teleconference, the Committee voted to send three guidance documents out for public comment in January 2017 to assist the review board in making consistent decisions on exception requests for adult candidates, pediatric candidates, and candidates with HCC that do not meet criteria for a standardized exception. By the end of this teleconference the Committee reviewed the final NLRB proposed policies and voted in favor of sending for public comment in January of 2017 with 13 unanimous votes by Committee (0 opposed and 0 abstained).

NLRB Structure Policy Language for Public Comment

The Committee reviewed the use of the override button which was considered in 2006, but was not programmed until 2016. The purpose of the override button is to allow a transplant program whose exception request for a candidate has been denied by the review board to immediately register the candidate with the requested MELD or PELD points value and the Committee reviews the transplant program's use of the override retrospectively. Since its implementation in February 2016, the override button has only been used intentionally one time. Due to the lack of use, and because there is an alternative pathway for boosting a medically urgent candidate's position on the waitlist by registering them as status 1A, the Committee proposes removing the override button.

The Committee then reviewed the effective date of exceptions/extensions. The Committee agreed the start date of the exceptions/extensions should stay the same as currently programmed. UNOS staff will provide the Committee with more information on current programming on a future call. The Committee discussed that if an extension is requested but not approved until after the date the extension was supposed to start, then the effective date upon approval should be the date the extension was due to start (i.e. the next day after the 3 month exception period).

Exception Points for Candidates with Approved Standardized Exceptions

The Committee discussed the current value of the exception points assignments for the diagnoses listed below. After review of data regarding the current exception points assignments compared to the proposed exception points assignments based on the median MELD at transplant (MMaT) for liver recipients in the DSA, and discussion of the

intent of the NLRB to award exception points consistently nationally the Committee discussed the proposed exception points assignments with the following outcome for adult candidates:

Diagnosis	Current Exception Points Assignment	Recommended Proposed Exception Points Assignment
Cholangiocarcinoma	MELD 22 (w/ 10% point escalator)	MMaT – 3
Cystic Fibrosis	MELD 22 (w/ 10% point escalator)	MMaT – 3
Familial amyloid polyneuropathy	MELD 22 (w/ 10% point escalator)	MMaT – 3
Hepatic artery thrombosis	MELD 40	MELD 40
Hepatopulmonary syndrome	MELD 22 (w/ 10% point escalator if PaO_2 remains under 60 mmHg)	MMaT – 3
Portopulmonary hypertension	MELD 22 (w/ 10% point escalator if repeat heart cath shows MPAP <35)	MMaT – 3
Primary Hyperoxaluria	MELD 28 (w/ 10% point escalator)	MMaT
HCC	Delay 6 months, then 28, 30, 32, 34	MMaT-3 after delay. With no escalator and keep cap of 34.

The Committee discussed the national range for patients transplanted with no exception points compared to patients with exceptions points is -3. Adopting points assignment of MMaT -3 for most standardized exceptions would result in a marginal impact and not cause sweeping fluctuations at the regional level. According to data reviewed by the Committee transplants may occur sooner than the current rate and at a lower MMaT. The rate of transplants will be monitored every 6 months and reviewed by the Committee for trends and the exception points will be revised as necessary.

The Committee considered MMaT -5 points because modeling suggested that the percentage of candidates transplanted with HCC exceptions would decrease under each of the points scenarios at MMaT -5, and because data by region showed that -3 would not be a substantial change for candidates with HCC. However, the Committee chose to continue with the -3 because the overall national impact of -3 intends to create a larger impact nationally and the modeling predicts the MMaT would decrease over time which would also decrease outliers in regions with a higher MMaT.

The Committee then focused on the "cap" aspect of the current HCC exception score policy. The cap lessens the current elevator by ensuring that, no matter how long an HCC candidate waits with an approved exception, their score cannot exceed a MELD score of 34. The Committee agreed the cap of 34 should remain in place for HCC candidates, and agreed it should be extended to all adult candidates with approved standardized exceptions. This follows a practice already adopted in some regions and will help achieve greater nationwide uniformity by preventing candidates in regions with particularly high MMaTs from receiving an undue advantage under the new policy. It also provides greater access for candidates registered according to their lab MELD instead of an exception.

Some Committee members expressed concern the cap may disadvantage non-HCC exception candidates but the Committee determined there are very few non-HCC exception candidates and this policy change will not have a major impact on them. Additionally, a transplant program can always request the NLRB grant a different MELD score to an exception candidate if the candidate is more urgent than others awaiting with the same diagnosis. Therefore, if the exception points calculation based on the MMaT of the DSA would result in a candidate receiving a MELD score higher than 34, the candidate will only receive a MELD score of 34.

The Committee discussed the candidates seeking nonstandard exception points would be reviewed by the NLRB on a case by case basis, and the NLRB members would be advised to follow the points assignments used for the standardized exceptions. Therefore, non-standardized exception candidates should be awarded a score equal to MMaT -1 or -2 and less urgent cases would receive -5. This guidance is also provided in the NLRB Guidance Documents being distributed for public comment in January 2017.

Pediatric Exception Points

It was determined that this policy would apply to all candidates less than 18 years old. There is a substantially smaller number of pediatric candidates seeking exception points annually as compared to adult candidates and according to recent data; only 700 to 800 cases in the past year. Of the 70% of the pediatric transplants with exception points, most are not standardized exceptions and most patients are status 1B. There is a plan to reexamine the effectiveness of the PELD system in the future. Current policy permits standardized exceptions for pediatric candidates, including qualifying criteria and a points value if the candidate qualifies for the exception. The Committee determined if there was no change to how the current policy assigns exception points to pediatric candidates, then in the proposed policy changes adult exception candidates would almost always have priority over pediatric candidates because current pediatric scores would almost always be lower than the new exception scoring system for adults. The Committee therefore determined that the system for assigning exception points to pediatric candidates must change along with the adult system.

The Committee determined that pediatric candidates should be further subdivided into candidates less than 12 (who receive a PELD) and candidates between 12 and 17 (who

receive a MELD) because they are already divided this way for allocation purposes. The Committee discussed the MMaT for pediatric liver recipients cannot be used as the cohort for the MMaT calculation because the cohort is too small and would be subject to skewed results. For candidates between 12 and 17, the Committee decided to use the MMaT for all liver recipients in the DSA of the candidate for exception criteria because the score will be more reflective of MMaT for exception scores. For candidates less than 12, the Committee decided that the cohort should be based on the MMaT for all liver candidates in the region, because candidates less than 12 compete for offers on a regional basis and should therefore be assigned the same MELD score based on the region.

Additionally, the Committee agreed that candidates with exceptions for certain diagnoses should be treated slightly differently:

- All pediatric candidates less than 18 with approved standardized exceptions for HAT and pediatric HCC will be assigned a MELD or PELD of 40
- Candidates less than 12 with approved standardized exceptions for hyperoxaluria will be assigned a score equal to the MMaT for region plus 3
- Candidates between 12 and 17 with approved standardized exceptions for hyperoxaluria will be assigned a score equal to the MMaT for the DSA plus 3

NLRB Implementation

The Committee decided that, on the date of implementation for candidates with existing exceptions, candidates will be given the highest of the 2 options: if the MMaT calculation would make the candidate's exception points value increase then the candidate's score can increase immediately; but if the candidate's score would decrease as a result of the new MMaT calculation then the candidate can keep the score under which he or she is listed until the candidate is due for an extension.

Upcoming Meeting

- January 19, 2017