

**OPTN Liver & Intestinal Organ Transplantation
PELD/Status 1B Criteria Workgroup
Meeting Summary
August 20, 2020
Conference Call**

Evelyn Hsu, M.D., Chair

Introduction

The PELD/Status 1B Criteria Workgroup (the Workgroup) met via Citrix GoToMeeting teleconference on 08/20/2020 to discuss the following agenda items:

1. Status 1B Data Request and Discussion

The following is a summary of the Workgroup's discussions.

1. Status 1B Data Request and Discussion

The Workgroup reviewed a data report on Status 1B exceptions.

Summary of Data

The goals of the data request is to understand the utilization and impact of Status 1B by criteria and by non-standard exception to inform updates in Status 1B exception guidance and policy for standard criteria.

The report evaluated the following data:

- Counts of liver Status 1B Waitlist registrations ever waiting by year, 2015-2019
- Distribution of liver Status 1B Waitlist registrations ever waiting by year and diagnosis at listing, 2015-2019
- Distribution of liver Status 1B Waitlist registrations ever waiting by year and age at listing, 2015-2019
- Data specific to Waitlist registrations that submitted Status 1B forms from January 1, 2018-December 31, 2019
- Data specific to Pediatric liver Waitlist registrations that were removed for death or too sick to transplant from January 1, 2018-December 31, 2019

The report concluded:

- 344 waitlist registrations submitted at least one Status 1B form from January 1, 2018 – December 31, 2019
- 61 forms did not meet standard criteria; 43 (70 percent) of these forms were approved
- The most common criteria not met for Status 1B requests was “chronic liver disease but calculated MELD or PELD score is less than or equal to 25”
- Of the 344 waitlist registrations that submitted at least one Status 1B form, 33 (10 percent) were removed for death or too sick and 290 (84%) received a transplant
- Of the 33 waitlist registrations that were removed for death or too sick, 19 were Status 1B at removal

- 93 pediatric liver waitlist registrations were removed for death or too sick between 2018 and 2019
- 21 (23 percent) of these registrations were Status 1A and 17 (18 percent) were Status 1B by criteria
- Over half (53 percent) of deaths or removals for too sick were for children less than 2 years old; some are Status 1B but they can also have low MELD or PELD scores less than 15
- Over half (51 percent) of deaths or removals for too sick were for children that had a chronic liver disease diagnosis at listing

Summary of Discussion

The Workgroup discussed the results of the data report. Some members requested additional details on the data presented which will be brought back to the Workgroup. A Workgroup member commented the data shows a need to broaden the Status 1B exception criteria based on diagnosis. Another member commented the data suggests candidates with metabolic disease may be overprioritized when compared to other candidates. A member responded although waitlist mortality for metabolic disease candidates is low, there are other consequences of the disease that should be considered.

Next Steps

The Workgroup members were asked to review the data results independently to develop ideas on how to change the policy and guidance for Status 1B criteria. Additionally, the Workgroup reviewed current criteria for chronic liver disease in OPTN policy and were asked to consider whether changes should be made to policy in addition to guidance.

Upcoming Meetings

- September 17, 2020

Attendance

- **Workgroup Members**
 - Walter Andrews
 - Emily Perito
 - Evelyn Hsu
 - Douglas Mogul
 - John Magee
 - Jorge Reyes
 - Regino Gonzalez-Peralta
 - Sara Rasmussen
 - Steve Lobritto
 - Jim Pomposelli
 - James Trotter
- **HRSA Staff**
 - Jim Bowman
 - Marilyn Levi
 - Bob Walsh
- **SRTR Staff**
 - Michael Conboy
 - David Schladt
 - John Lake
- **UNOS Staff**
 - Matt Cafarella
 - Julia Foutz
 - Kiana Stewart
 - Lindsay Larkin
 - Samantha Noreen
 - Joann White