OPTN/UNOS Pancreas Transplantation Committee Meeting Minutes March 28, 2018 Conference Call

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Introduction

The Pancreas Transplantation Committee (hereafter, the Committee) met via Citrix GoToTraining teleconference on 03/28/2018 to discuss the following agenda items:

1. Changes to Kidney-Pancreas (KP) Waiting Time Criteria

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

1. Changes to Kidney-Pancreas (KP) Waiting Time Criteria

The Committee continued a discussion of the potential changes to the KP waiting time criteria proposal. The Committee reviewed feedback on public comment that was received after the inperson meeting on March 22, 2018. The Committee also reviewed the themes and concerns raised in public comment.

Summary of discussion:

The Committee discussed how the percentage of Type 2 KP recipients has changed, in part due to a decrease in a total number of Type 1 candidates. There are other reasons that may impact the ratio of Type 1 and Type 2 candidates: variety in how programs determine whether a candidate is Type 1 or Type 2, and an increase in identifying candidates as Type 2 (not necessarily an increase in Type 2 candidates, but an increase in scrutiny to identify whether a candidate is Type 2 or not). Overall, the percent of active KP candidates with C-peptide \leq 2 and BMI \leq maximum has increased from 9% to 13% since 2014. A Committee member noted that as the characteristics of KP candidates is shifting there may be other shifts in terms of age and demographics as well. Also, determining whether a candidate is Type 1 or Type 2 is not always obvious. A candidate may have a C-peptide lower than 2 but be better characterized as Type 2. Age can also impact BMI as a factor, indicating the waiting time limitation based on BMI is arbitrary.

The Committee discussed the options related to including insulin in the KP waiting time. Previously, the Committee agreed that a history of insulin use would be supported if it didn't incur modification to the data collection forms. If requiring a history of insulin use to accrue waiting time wasn't an option, then the Committee supported leaving in a requirement that the candidate currently be on insulin to accrue waiting time. The Committee agreed this addressed one of the concerns raised during public comment about insulin usage, and would also provide a compromise with the kidney community by requiring more evidence of the need for a pancreas transplant in the KP waiting time criteria. The Committee also agreed to monitor kidney alone outcomes as part of the post-implementation data.

The Committee then discussed options for modifying the maximum BMI requirement or removing it completely. The Committee expressed confusion at the table in policy (11-1) that dictates the maximum BMI through the percent of active KP candidates with C-peptide \leq 2 and BMI less than or equal to the current maximum. The Committee agreed this table would still be arbitrary and unfair even if the cap on the percent of active KP candidates that are "Type 2" (represented by having a high C-peptide) is raised. Because of the confusion and because the

table represented an arbitrary limit on certain candidates' ability to accrue waiting time, the Committee opposed this option.

Some Committee members supported removing the BMI cap and references to the maximum allowable BMI in policy. These members felt the alternative, to change the BMI to a fixed number and remove the table from policy, would still represent an arbitrary solution that doesn't address the problem as well as it could. Other Committee members supported the fixed BMI option as a compromise to send to the Board. The Committee will discuss these two options during its April 16 call to vote on language.

The Committee briefly discussed whether patients that don't currently meet waiting time criteria but will after implementation should get waiting time back dated to their listing date. Several Committee members expressed support for back dating but no decisions were made.

Next steps:

The Committee will discuss two options during its April 16 call – require insulin and no BMI/C-peptide requirement, or require insulin and make the maximum BMI a fixed number.

Upcoming Meetings

- April 16, 2018 (teleconference)
- May 14, 2018 (teleconference)