

Updating National Liver Review Board (NLRB) Guidance and Policy Clarification

OPTN Liver and Intestinal Organ Transplantation Committee

Purpose of Proposal

- Continue to improve the NLRB based on feedback and experience
 - NLRB was implemented in May 2019
 - The Board previously approved two proposals to improve the NLRB
 - Proposal includes one policy clarification and updates to guidance documents
- Proposal will increase equity and efficiency in granting exception requests

Proposal: Policy Clarification

- Candidates with cholangiocarcinoma (CCA) are automatically approved for an exception if they meet specific criteria in policy
- In addition to other criteria, candidates are automatically approved if they meet the diagnostic criteria for hilar CCA with a malignant appearing stricture on cholangiography and at least one of the following:
 - Biopsy or cytology results demonstrating malignancy
 - Carbohydrate antigen 19-9 greater than 100 U/ml in absence of cholangitis
 - Aneuploidy
- Candidates can also meet diagnostic criteria for CCA with presence of a malignant appearing-stricture and an associated hilar mass that is ≤ 3 cm in radial diameter
- Proposal adds this to list of diagnostic criteria to ensure appropriate candidates are automatically approved

Proposal: Pediatric Guidance

- Complications of portal hypertension, including ascites and gastrointestinal (GI) bleeding
 - More detail on information submitted in exception requests for GI bleeding with ongoing transfusion requirement and candidates with serum sodium less than 130 g/dL on two occasions more than two weeks apart
 - Candidates with severe or complicated ascites should have at least two thoracenteses in the last 60 days not including the diagnostic thoracentesis (similar language already exists for paracentesis)
 - Candidates requiring a hospitalization of at least five days with ascites not adequately controlled by oral diuretics and requiring IV diuretic therapy should be considered for exception

Proposal: Pediatric Guidance

- **Growth failure or nutritional insufficiency**
 - PELD score does not provide additional points to all candidates with growth failure
 - Updated guidance allows candidates with growth failure to be provided a PELD exception
- **Metabolic liver disease**
 - Adds guidance for candidates with rare metabolic disorders
- **Conclusion Section**
 - Programs and reviewers should consider pertinent information even if not stated in guidance

Proposal: Neuroendocrine Tumors Guidance

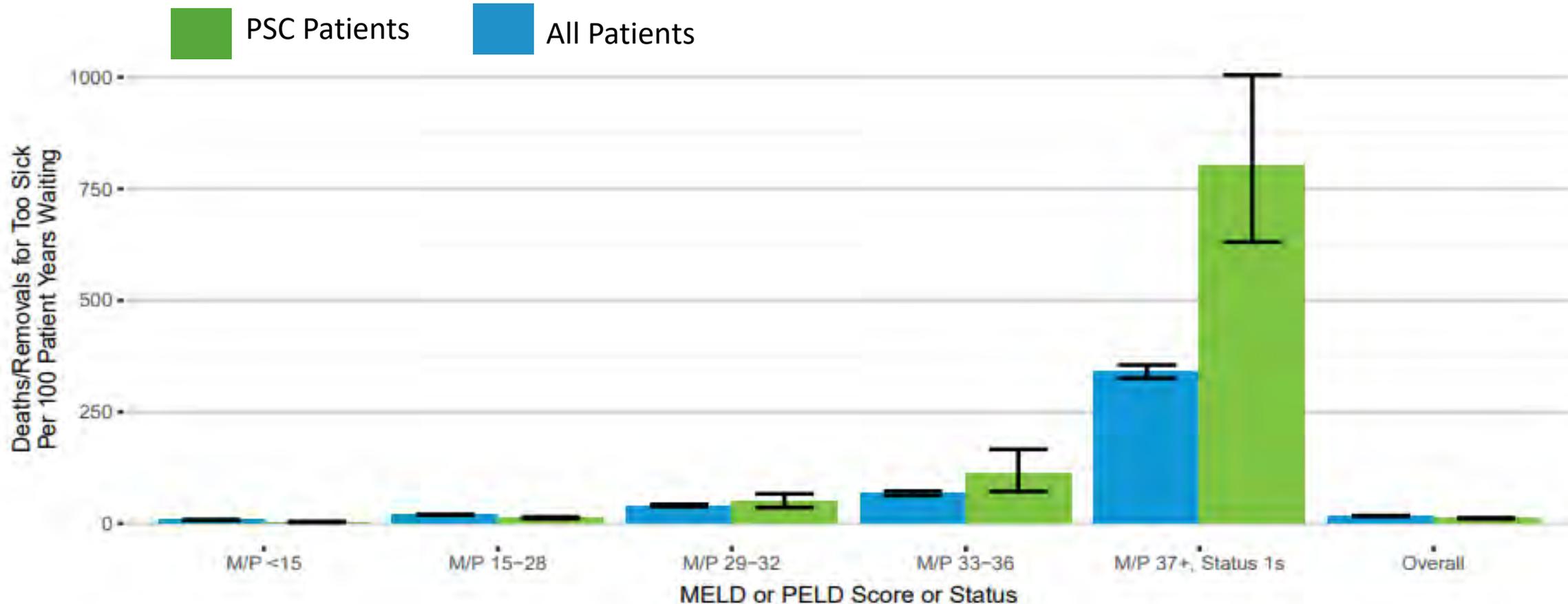
- **Current**
 - Guidance for neuroendocrine tumors (NET) recommends that candidates be under the age of 60
- **Proposal**
 - Removes age less than 60 threshold based on updated data showing acceptable post-transplant outcomes for candidates age 60 and older

Proposal: Primary Sclerosing Cholangitis and Secondary Sclerosing Cholangitis Guidance

- Feedback from patient community to update primary sclerosing cholangitis (PSC)/secondary sclerosing cholangitis (SSC)
- PSC candidates with MELD or PELD greater than 37 or Status 1A/1B had significantly higher waitlist dropout
- Current:
 - Recommends candidates should be admitted to ICU two or more times in last three months
- Proposal:
 - Recommends candidates should be admitted to hospital two or more times in previous year

Proposal: PSC and SSC

Liver Waiting List Drop-Out Rates per 100 Patient-Years Waiting
Patients Ever Waiting During 1/1/2015 - 7/31/2020, by PSC Diagnosis and Overall



Rationale

- **CCA Policy Clarification**
 - Aligns policy with established diagnostic criteria for CCA
- **Pediatric Guidance**
 - Proposed changes to pediatric guidance based on published literature, feedback from pediatric transplant community, and collaboration with OPTN Pediatric Transplantation Committee
- **Proposed changes to NET and PSC/SSC guidance based on updated data**

Member Actions

- Transplant programs and NLRB reviewers will need to be familiar with:
 - Changes to guidance
 - CCA policy criteria when applying for and reviewing exception requests

What do you think?

- Does the CCA policy clarification appropriately capture the diagnostic criteria?
- Please provide feedback on the proposed changes to pediatric guidance
 - Growth failure or nutritional insufficiency
 - Complications of portal hypertension, including ascites and gastrointestinal bleeding
 - Metabolic liver disease
- Do you support the proposed changes to NET and PSC/SSC guidance?