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 ≤ 3cm in radial diameter.

- Proposal adds this to list of diagnostic criteria to ensure appropriate candidates are automatically approved.
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

- PSC Patients
- All Patients
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
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?