Further Enhancements to the National Liver Review Board (NLRB)

OPTN Liver and Intestinal Organ Transplantation Committee
Incorporate improvements to the NLRB based on initial experience
  - NLRB was implemented in May 2019
  - First round of enhancements approved by the Board in June 2020
  - Liver Committee has continued to consider feedback from the transplant community
  - Proposal includes improvements to policy, operational guidelines, and guidance

Improvements will increase equity and efficiency in granting exception requests
Proposal: NLRB Policy Language

- Updated Criteria for Portopulmonary Hypertension (POPH) Exceptions:
  - Proposed changes:
    - Pre-treatment MPAP and PVR must show moderate to severe POPH
    - Allow candidates with post-treatment MPAP greater than or equal to 35 mmHg to also be eligible
    - Documentation that other causes of pulmonary hypertension have been assessed and not determined to be a contributing factor and documentation of portal hypertension
    - Update extension criteria to match post-treatment criteria on initial exception

- Create a more effective process for reviewing *Post-Transplant Explant Pathology* forms for candidates with hepatocellular carcinoma (HCC)
Proposal: POPH Criteria

Pre-Treatment MPAP and PVR Thresholds

Current Threshold: None

Proposed Threshold:
MPAP ≥ 35 mmHg and PVR ≥ 240 dynes*sec/cm^5

Post-Treatment MPAP and PVR Thresholds

Current Threshold: MPAP < 35 mmHg and PVR < 400 dynes*sec/cm^5

Proposed Thresholds:
MPAP < 35 mmHg and PVR < 400 dynes*sec/cm^5
OR
MPAP ≥ 35 and < 45 mmHg and PVR < 240 dynes*sec/cm^5
Proposal: Operational Guidelines

- Create a separate Appeals Review Team (ART) specifically for pediatric cases
  - Reviewers from Pediatric Specialty Board
  - Other operational aspects would be the same as current ART
- Add member of the Liver Committee to each ART as “ART Leader”
  - Guide conversation
  - Provide feedback to Liver Committee on opportunities for improvement
Proposal: Guidance Documents

- Guidance for Polycystic Liver Disease (PLD)
  - Clarify the MELD score recommendation
  - Provide guidance for candidates also requiring a kidney
  - Add new comorbidities that should be considered for a MELD exception
    - Prior kidney transplant
    - Moderate to severe protein calorie malnutrition
Rationale

- Proposed changes are based on:
  - Experience with the NLRB
  - Medical literature
  - Input of clinicians with expertise in POPH
  - OPTN data
Member Actions

- Updated POPH Criteria:
  - Initial exception form:
    - Two new fields and updated data validation
  - Exception extension form:
    - Three new fields and one field removed
    - No new tests/procedures required – new data collection available in candidate’s medical record

- HCC Explant Form Review:
  - Additional documentation or imaging studies will not need to be submitted as often
Feedback Requested

- Do updated criteria for standardized POPH exceptions appropriately capture candidates needing a standardized exception?
  - Is new data collection sufficiently clear?

- What should responsibilities of ART leader be?

- Is updated guidance and score recommendation for PLD/PCLKD clear?

Please introduce yourself when you speak
Further Enhancements to the NLRB

- NLRB Policy language
  - Update criteria for portopulmonary hypertension (POPH) exception and extensions
  - More effective process for reviewing Post-Transplant Explant Pathology forms for candidates with hepatocellular carcinoma (HCC)

- Operational Guidelines
  - Create a separate ART for pediatric cases and add ART leader

- Guidance for Polycystic Liver Disease (PLD)
  - Clarify the MELD score recommendation, provides guidance for candidates also requiring a kidney, and add new comorbidities that should be considered for a MELD exception

Feedback is summarized and shared as public comment