

Further Enhancements to the National Liver Review Board (NLRB)

OPTN Liver and Intestinal Organ Transplantation Committee

Purpose of Proposal

- 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 \geq 35 mmHg and PVR \geq 240
dynes*sec/cm⁵

Post-Treatment MPAP and PVR Thresholds

Current Threshold: MPAP < 35 mmHg
and PVR < 400 dynes*sec/cm⁵

Proposed Thresholds:
MPAP < 35 mmHg and PVR < 400
dynes*sec/cm⁵
OR
MPAP \geq 35 and < 45 mmHg and PVR <
240 dynes*sec/cm⁵

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