Enhancements to the National Liver Review Board

OPTN Liver and Intestinal Organ Transplantation Committee
Purpose of the Proposal

- Incorporate improvements to NLRB based on first six months of experience
  - Improvements include:
    - Clearer policy language to improve efficiency of the system
    - Changes to guidelines to match practice
    - Updated guidance documents based on clinical experience
  - Will increase efficiency and provide more equitable access to transplant
National Liver Review Board

- Three specialty boards
  - Adult HCC
  - Adult other diagnosis
  - Pediatric

- Appeals
  - 1\textsuperscript{st} to same review group
  - 2\textsuperscript{nd} to Appeals Review Team (ART)
  - 3\textsuperscript{rd} to Liver Committee
The proposal includes changes to:

- **NLRB policy language**: increase and standardize HCC automatic approvals and clarify MMaT/MPaT update schedule
- **Operational Guidelines**: clarify NLRB reviewer scope, update threshold for inactive reviewer removal, and clarify process for final appeals
- **Guidance Documents**: add guidance for secondary sclerosing cholangitis (SSC) and adults with metabolic disease, clarify guidance for portopulmonary hypertension and candidates with prior history of HCC
Policy Language – HCC Extensions

- Currently, HCC extension requests are automatically approved only if:
  - Meets standard extension criteria
  - Requesting policy-assigned score
  - Was automatically approved previously

- Proposal:
  - Remove requirement that candidate must be automatically approved previously
Policy Language – Recalculation of MMaT and MPaT

- **Current Policy:**
  - MMaT and MPaT scores must be updated every 180 days based on past 365 days
  - No time for calculation, communication, and programming

- **Proposal:**
  - Maintain semi-annual recalculation but give discretion for when the new scores are implemented
Operational Guidelines – Review Board Scope

- Currently, no guidance for how reviewers should make decisions if lack of applicable guidance or policy

- Proposal: Add language outlining that in such cases, these factors should be considered:
  - medical urgency of the candidate
  - anticipated transplant efficacy
  - waitlist dropout rates
  - waitlist mortality risk
Operational Guidelines – Removal of Inactive Reviewers

- Currently, reviewers not voting on three separate occasions within 12 months are to be removed from NLRB

- First four months: 25% of NLRB reviewers were reassigned at least three times

- Proposal:
  - Change threshold for removal to 5% of all cases assigned within a 12 month period
  - Give discretion for removal to NLRB Chair
Operational Guidelines – Committee Appeal Process

- Final appeal is to Liver Committee
- Currently, no information on format or participants in final appeal
- Proposal:
  - Liver Committee can delegate final appeal to a subcommittee
  - Appeal must achieve majority of affirmative votes
  - Majority is based on size of subcommittee
  - Final appeal will be reviewed electronically unless subcommittee member requests conference call
Guidance Documents – Adult Other Diagnosis

- Portopulmonary Hypertension (PH):
  - Currently, candidates with PH are eligible for automatic approval
  - Remove unnecessary and outdated language in guidance

- Secondary Sclerosing Cholangitis (SSC):
  - Current guidance includes primary sclerosing cholangitis (PSC) but not SSC
  - Add SSC to section for PSC so candidates receive similar consideration

- Adults with Metabolic Disorders
  - Currently, no guidance for adults with metabolic disorders
  - Add guidance that adults should be considered for MMaT-3, but allow for higher score if life threatening complications
Guidance Documents – Adult HCC

- Unclear if guidance on adults with history of HCC at least two years prior includes candidates with existing HCC exception
- Should only apply to candidates on initial MELD exception
Feedback Requested

• **Review Board Scope:** are these the appropriate factors for reviewers to consider for cases where there is no policy or guidance?

• **Removal of Inactive Reviewers:** is the proposed threshold (5% of cases within 12 months) the right threshold for removal?

• **SSC Guidance:** should SSC be treated in the same way as PSC?

• **Adults with Metabolic Disorders:** is MMaT-3 an appropriate score for this population?

• Are other changes helpful and clear?

• Any other suggestions for improvements to the NLRB?
Discussion:

- The proposal includes changes to:
  - **NLRB policy language**: increase and standardize HCC automatic approvals and clarify MMaT/MPaT update schedule
  - **Operational Guidelines**: clarify NLRB reviewer scope, update threshold for inactive reviewer removal, and clarify process for final appeals
  - **Guidance Documents**: add guidance for secondary sclerosing cholangitis (SSC) and adults with metabolic disease, clarify portopulmonary hypertension and candidates with prior history of HCC