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
 - 1st to same review group
 - 2nd to Appeals Review Team (ART)
 - 3rd to Liver Committee

Proposal

- 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 <u>only</u> 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 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:

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