

National Liver Review Board (NLRB) Updates related to Transplant Oncology

*OPTN Liver & Intestinal Organ Transplantation Committee
Shimul Shah, Vice Chair*

Purpose of Proposal

- Broaden the scope of the Adult Hepatocellular (HCC) Review Board to become an Adult Transplant Oncology Review Board
- Create NLRB guidance for the following diagnoses:
 - Colorectal liver metastases
 - Intrahepatic cholangiocarcinoma
- Update Policy 9.5.A: *Requirements for Cholangiocarcinoma (CCA) MELD or PELD Score Exceptions* for clarity on:
 - Diagnosis type
 - Submission and approval of protocols for patient care

Background

- The National Liver Review Board (NLRB) reviews model for end-stage liver disease (MELD) and pediatric end-stage liver disease (PELD) exception score requests
- The NLRB uses OPTN policy and guidance to review exception cases

Background: Specialty Boards

Pediatrics

- Reviews requests made on behalf of:
 - Candidates registered prior to turning 18 years old
 - Adult candidates with certain pediatric diagnoses

Adult Other Diagnosis

- Reviews requests made on behalf of:
 - Adult candidates whose calculated scores do not reflect the medical urgency
 - Adult candidates that do not meet the standard criteria for one of the nine diagnoses in Policy 9.5 (excluding HCC cases)

Adult Hepatocellular Carcinoma (HCC)

- Reviews requests made on behalf of:
 - Adult candidates that do not meet the standard criteria in Policy 9.5.1: *Requirements for HCC MELD or PELD Score Exception*

Proposal: Adult Transplant Oncology Review Board

- Broaden the scope of the current Adult HCC Review Board to review all non-standard exception requests related to liver cancers or tumors

Proposal: Adult Transplant Oncology Review Board

Scope

- Reviews requests made on behalf of:
 - Adult candidates that do not meet the standard criteria for HCC in policy or request a different score
 - Adult candidates that do not meet the standard criteria for hilar CCA in policy or request a different score
 - Adult candidates with certain liver cancer or tumor diagnoses, including, but not limited to:
 - Intrahepatic Cholangiocarcinoma (*new*)
 - Neuroendocrine Tumors
 - Colorectal Liver Metastases (*new*)
 - Hepatic Epithelioid Hemangioendothelioma
 - Hepatic Adenomas

Proposal: Colorectal Liver Metastases

- Colorectal liver metastases are malignant growths in the liver that develop from colorectal cancer
- Emerging literature supports liver transplantation in for certain candidates and has demonstrated a survival benefit
 - However, candidates listed for transplant with colorectal liver metastases have low MELD scores and access to transplant remains low

Proposal: Colorectal Liver Metastases

- Proposed criteria in NLRB guidance:
 - Unresectable
 - 12 months between time of diagnosis to initial exception request
 - Treatment of primary colorectal cancer
 - No evidence of recurrence within 12 months prior to initial exception request
 - No signs of extrahepatic disease
 - Evaluation of hepatic disease and prior treatments with stability for at least six months

Proposal: Colorectal Liver Metastases

- Score recommendation: MMaT minus 20
 - Improves access to medically complex liver offers that may otherwise not be utilized
 - Select candidates/Small population size
- **If MMaT minus 20 results in an exception score below 15, the candidate's exception score will automatically be set to a MELD score of 15**
 - Per OPTN Policy 9.4.E: MELD or PELD Exception Scores Relative to Median MELD or PELD at Transplant.
- Currently, the highest MMaT around a donor hospital is 35
 - Most, if not all, candidates with this non-standard exception should appear on match runs with allocation MELD scores of 15.

Proposal: Intrahepatic Cholangiocarcinoma

- Intrahepatic cholangiocarcinoma is a type of cancer that forms in the bile ducts
- Emerging literature has observed that transplant outcomes for early intrahepatic cholangiocarcinoma have high recurrence-free survival, as well as overall survival
 - However, candidates listed for transplant with intrahepatic cholangiocarcinoma have low MELD scores and access to transplant remains low

Proposal: Intrahepatic Cholangiocarcinoma

- Proposed criteria in NLRB guidance:
 - Unresectable
 - Size is three centimeters or smaller
 - Biopsy proven
 - Six months of therapy with tumor stability before initial exception request
- Score recommendation: MMaT minus 3
 - Rationale:
 - Outcomes are similar to HCC outcomes
 - Select candidates/Small population size

Proposal: Policy 9.5.A Clarification

- Clarifies that the Committee must review *and approve* the patient care protocols developed by transplant programs
- Clarifies that the standard criteria are specific to hilar cholangiocarcinoma

Rationale

- **Adult Transplant Oncology Review Board:**
 - Ensure the individuals with the appropriate expertise are reviewing non-standard exception requests related to liver cancers and tumors
- **Guidance for Colorectal Liver Metastases and Intrahepatic Cholangiocarcinoma:**
 - Create a pathway for select candidates to receive non-standard exceptions to improve access to transplant
- **Policy 9.5.A Clarifications:**
 - Ensure policy is consistent with current practice and clear that the standard criteria is specific to hilar cholangiocarcinoma

Member Actions

- Transplant programs and NLRB reviewers will need to be familiar with updated policy language and guidance
- NLRB reviewers currently on the Adult HCC specialty board will need to be familiar with the expanded scope of reviewing non-standard exception requests related to liver cancers and tumors

FAQs

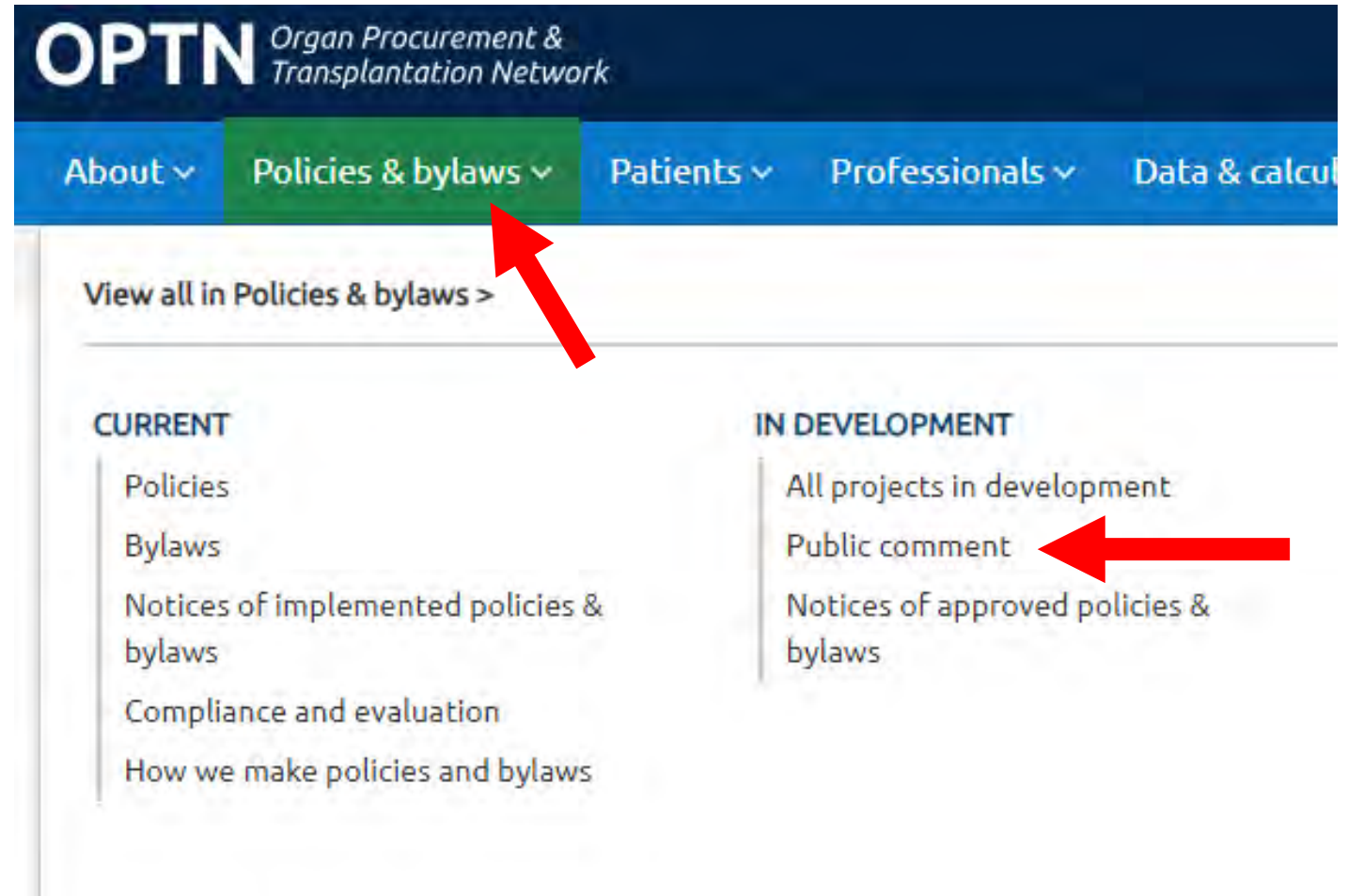
- Will any candidates lose an exception or will scores change as a result of these changes?
- Are pediatric candidates impacted by this proposal?
- Who will serve on the Adult Transplant Oncology Review Board?
- Will review processes change for the Adult Transplant Oncology Review Board?

Additional Questions?

- Please direct all questions on the OPTN Liver & Intestinal Organ Transplantation Committee's proposal *NLRB Updates related to Transplant Oncology* to Meghan McDermott at meghan.mcdermott@unos.org

Provide Feedback

- Submit public comments on the OPTN website
- January 23 – March 19, 2024
- **optn.transplant.hrsa.gov**



Regional Meeting Information

- Visit <https://optn.transplant.hrsa.gov/about/regions/regional-meetings/> for the latest regional meeting information and meeting materials

OPTN Organ Procurement & Transplantation Network

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Regional meetings

Regional meetings

Regional meetings are held twice each year during the winter and summer public comment periods. Regional meetings are an opportunity to influence policy proposals, prepare for upcoming changes, and hear perspectives from the transplant community about improvements to organ allocation.

Thank You For Listening!