

NLRB Update

October 1, 2019

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Agenda

- NLRB 101
- Case volumes and metrics NLRB so far
- Reviewer best practice tips
- Center best practice tips

National Liver Review Board (NLRB)

- Consists of:
 - auto approved path (those meeting policy approved diagnoses),
 - adult HCC specialty review board (HCC not meeting standard),
 - adult other diagnosis specialty review board,
 - pediatrics specialty review board,
 - Appeals Review Team (ART) specialty review board.

Please note: *the non-standard 1A/1B appeal process is separate.*

- Policy identifies diagnosis-specific criteria to automatically receive score defined in policy
 - Exception request forms meeting policy criteria may still opt to request a different score from the NLRB

National Liver Review Board Standard Exception Scores

Diagnosis	18 years or older at time of registration	At least 12 years old and less than 18 years old at time of registration	Less than 12 years old
Hepatic Artery Thrombosis (HAT)	MELD 40	No standard score	No standard score
Hepatocellular Carcinoma (HCC)	MMaT -3 <u>upon 2nd extension</u>	MELD 40	PELD 40
Cholangiocarcinoma (CCA)	MMaT -3	MMaT	MPaT
Cystic Fibrosis	MMaT-3	MMaT	MPaT
Familial Amyloid Polyneuropathy (FAP)	MMaT-3	MMaT	MPaT
Hepatopulmonary Syndrome (HPS)	MMaT -3	MMaT	MPaT
Metabolic Disease	No standard score	MMaT	MPaT
Portopulmonary Hypertension	MMaT -3	MMaT	MPaT
Primary Hyperoxaluria	MMaT	MMaT +3	MPaT +3

National Liver Review Board (NLRB)

- Most scores requested on exception request forms are relative to the **median MELD at transplant (MMaT)** or **median PELD at transplant (MPaT)**, and are referred to as 'median adjusted'
 - Requested scores of 40 and higher are **not** median-adjusted
 - Re-calculated MMaT scores on 9/24/19.
 - Currently based on MMaT for the DSA, or national MPaT.

National Liver Review Board (NLRB)

- **Five reviewers** are randomly assigned to review and vote on an exception request
 - Vote to **approve** or **deny** the requested score, based on the justification and lab values that are provided
 - Reviewers have 7 days to complete vote
 - Exception request is approved if there are **4 affirmative votes** (**supra-majority**)

National Liver Review Board (NLRB)

- Initial or Extension exception requests that are **denied** may be appealed, with changes to the requested score or justification for exception, to the same 5 reviewers.
- If the appealed exception request is denied, it may be appealed to the Appeals Review Team (ART) specialty board
 - Council of 9 NLRB members assigned each month
 - Meets via conference call weekly
- If the ART appealed exception request is denied, it may then go the OPTN Liver & Intestinal Transplantation Committee via the NLRB sub-committee for final review

Summary

During the time period from May 14, 2019 implementation to June 24, 2019,

- The overall approval rate was 60.6%
- By specialty board, the approval rates were
 - 73.7% for the adult HCC board,
 - 45.9% for the adult other diagnosis board, and
 - 67.4% the pediatrics board
- There were 239 instances of a reviewer being re-assigned due to inactivity
- Overall approval 60.5%. Analysis of how this compares to prior RRB system is in process.

Summary

- Since implementation (up to 9/29/19), total cases resolved:
 - Pediatric specialty board: 347
 - HCC specialty board: 2,007
 - Adult other specialty board: 1,182
- Total votes cast: 14,195
- Average time to respond: 1 day
- Average time to resolution: 4 days

Adults with standard diagnoses:

HAT, HCC, CCA, HPS, PPH, cystic fibrosis, amyloidosis, primary hyperoxaluria, metabolic

- Anticipate they will generally receive the scores determined by policy
 - (see table previous slide)
- If the patient is more urgent, centers may appeal to the NLRB and justify relative to other patients, why a higher score is needed.
 - Include relevant data which allows reviewer to understand the acuity.
 - Information that the patient is a mother of 3, or a surgical resident, or other considerations is not helpful
- New HCC appeals go to HCC board
 - Use HCC form to ensure proper routing
 - Non-HCC go to Adult other. ***Cases of existing HCC appeals which were initially filed by center under diagnosis of “other” will go to Adult Other until transplanted.***

Adults with non-standard diagnoses: see guidance documents for adult other, peds, and HCC boards

- https://optn.transplant.hrsa.gov/media/2175/liver_boardreport_guidance_201706.pdf#nameddest=Adult
- Cases which are covered in adult other guidance include:

May be suitable for exception

Budd Chiari
Hepatic Epithelioid Hemangioendothelioma
Hepatic Hydrothorax
Hereditary Hemorrhagic Telangiectasia
Multiple Hepatic Adenomas
Neuroendocrine Tumors (NET)
Polycystic Liver Disease (PLD)
Primary Sclerosing Cholangitis (PSC)
Small for Size Syndrome
Diffuse Ischemic Cholangiopathy
Late Vascular Complications

Generally not suitable for exception

Ascites
GI Bleeding
Hepatic Encephalopathy
Pruritus
Chronic rejection

Budd-Chiari

- Failed medical management (please specify)
- Etiology of hypercoagulable state
- Any contraindications to TIPS or TIPS failure; provide specific contraindication
- Decompensated portal hypertension in the form of hepatic hydrothorax requiring thoracentesis more than 1 liter per week for at least 4 weeks (transudate, no evidence of empyema, and negative cytology or any evidence of infection)
- Documentation that extrahepatic malignancy has been ruled out

HEHE

- Need biopsy to diagnose
- Needs to be unresectable
- ***Controversy regarding the role of liver transplant in treating HEHE relates to the variable course of disease in the absence of liver transplant, with some patients demonstrating regression or stabilization of disease and prolonged survival*

Hepatic Hydrothorax

- At least 1 thoracentesis over 1 L weekly in last 4 weeks
 - report date and volume of each thoracentesis
- Pleural fluid is transudative by pleural albumin-serum albumin gradient of at least 1.1 and by cell count
- No evidence of heart failure
 - provide objective evidence excluding heart failure
- Pleural fluid culture negative on 2 separate occasions
- Pleural fluid cytology is benign on 2 separate occasions
- There is contraindications to TIPS; specify specific contraindication
- Diuretic refractory

HHT:

- Hereditary hemorrhagic telangiectasia is an uncommon, autosomal dominant genetic disorder characterized by mucocutaneous telangiectasias, as well as arteriovenous malformations in the brain, spine, lungs, gastrointestinal tract, and liver. For appeal:
 - Documentation of high output cardiac failure by echocardiography
 - Imaging supporting intra-hepatic AV malformations or severe diffuse bilobar hepatic necrosis in the setting of hepatic AV malformations

Multiple hepatic adenomas

- Should be a very rare indication for transplantation
- Reason not resectable must be provided plus:
 - Malignant transformation proven by biopsy
or
 - Presence of glycogen storage disease which increases the risk for malignant transformation

NET: general guidance

- Recipient age <60 years (guidance)
- Resection of primary malignancy and extra-hepatic disease without any evidence of recurrence at least six months prior to MELD exception request
- metastasis limited to the liver, bi-lobar, and not amenable to resection
- Low or intermediate grade
- Gastro-entero-pancreatic (GEP) origin of tumors with portal system drainage.
- Staging and surveillance to rule out extra-hepatic solid organ metastasis

PCLKD

- PCLKD disease classification Mayo C or D with severe symptoms plus one or more of the following:
 - Hepatic decompensation
 - Concurrent hemodialysis
 - GFR less than 20 ml/min
 - *In process of revision– see next public comment cycle*

PLD Classification – *Mayo Modification*

Types	A	B	C	D
Symptoms	0 - +	++/+++	++/+++	++/+++
Cyst Findings	Focal	Focal	Diffuse	Diffuse
Spared Remnant Volume	≥ 3	≥ 2	≥ 1	< 1
PV/HV Occlusion	No	No	No	Yes

PSC

- The candidate must meet both of the following two criteria:
 - The candidate has been admitted to the intensive care unit (ICU) two or more times over a three month period for hemodynamic instability requiring vasopressors

AND

- The candidate has cirrhosis

- In addition the candidate must have one of the following criteria:

- The candidate has biliary tract stricture which are not responsive to treatment by interventional radiology (PTC) or therapeutic endoscopy (ERCP)

OR

- The candidate has been diagnosed with a highly-resistant infectious organism (e.g. Vancomycin Resistant Enterococcus (VRE), Extended Spectrum Beta-Lactamase (ESBL) producing gram negative organisms, Carbapenem-Enterobacteriaceae (CRE), and Multidrug-resistant Acinetobacter.)

Post transplant complications: see guidance

- Small for size: usually will be able to use MELD. If higher score is needed, document clinical status (ICU, hospital, home), risks for small-for-size, and interventions tried so far
- Diffuse ischemic cholangiopathy: Persistent cholestasis as defined by abnormal bilirubin (greater than 2 mg/dl), plus two or more episodes of cholangitis with an associated bacteremia requiring hospital admission, plus evidence of non-anastomotic biliary strictures not responsive to further treatment
- Late vascular complications : see guidance
- Biliary complications: *watch for revision to PSC guidance in future public comment*

Generally not suitable:

- Ascites
- Encephalopathy
- GI bleeding requiring chronic transfusions (may consider documented multiple episodes of hospitalizations with severe, life-threatening hemorrhage with hemodynamic instability requiring ICU care, **and** TIPS/embolization/ligation/surgical shunt/etc. cannot be done)
- Pruritus
- Chronic rejection

HCC guidance

- Non-standard HCC patients must still wait for 6 months from the time of the first request to be eligible for an HCC exception score. This requires a request for MELD=6 for initial appeal and first extension. Second extension is MMaT-3.
 - Exception to this— patients with resected HCC within T2 (Milan) who undergo resection and then recur within T1 or T2 criteria should be approved without 6 month delay.

Peds guidance

**survey ongoing through SPLIT*

- Status 1B exceptions (including neoplasms)
- Neoplasms
- Complications of Liver Disease
- Growth failure or nutritional insufficiency
- Infections
- Complications of portal hypertension
- Post-transplant complications

Improvements based on reviewer feedback

- Screen now shows a list of prior appeals and outcomes
- A link to the guidance document is provided right on the screen where you are doing the review
- Individual reviewer performance is also available here.
 - We are working to make this more granular if possible.

Review board: challenges

- Many requests for patients with ascites or pruritus or other indications which are **not** supported by guidance or any unique clinical condition.
 - Generally NOT Approve these. Follow the guidance whenever possible
- Reviewers need to provide justification for their denial which is based on guidance, or a request for more detail, or other specific objective criteria.
 - This reviewer response is used by center to appeal.
- HCC requests which initially met standard criteria and have not ever exceeded criteria.
 - Generally APPROVE these
 - Revision to guidance regarding those with completely treated lesions and long interval since last intervention is in progress

Review board

- The guidance is there to help you. If you do not agree with guidance, please work to change guidance by contacting liver committee leadership
- It is a reviewer responsibility to vote within 7 days. If you are traveling or on a very busy call week, switch to your alternate ahead of time
 - On the review board tab, click on Manage settings
 - Set your out of office time by setting begin and end date.

Center challenges

- Requests for cases where there is no guidance.
 - If this is a rare clinical condition, provide evidence how this is similar to other standard diagnoses where exception is approved, and why transplant is expected to provide benefit.
- Requests for cases based on encephalopathy, ascites, or others not supported by guidance
 - generally should not be approved
- Details on the specific medical condition including number of hospitalizations, pressor, ICU stay, and other life-threatening problems is essential.
 - Current status and a summary of prior events is key.
 - Details on patient demographics not helpful.
- HCC
 - Try to provide a treatment summary, including if they were in or out of Milan, and why it is being appealed through the manual system.
 - It is very hard for reviewers to page through large numbers of prior appeals for the case details. **HCC board has reviewed 2,007 cases since the implementation.**

Center: appeal process

- If the case is denied, best practice is to read the reasons for denial and re-appeal to the same group.
- If denied again, read responses and appeal to the ART.
- If you opt to file for a new exception, be aware that the prior exception requests are visible to the new reviewers.

Summary

- NLRB has been busy
- Cases are being reviewed in a timely way
- Actively working on **consistency**

- Questions?

Questions – click hand button

