Liver and Intestinal Organ Transplantation Committee

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Proposal to Allow Centers to Place Liver Candidates with HCC Exceptions on 'HCC Hold' Without Loss of Accumulated MELD Exception Score

PROBLEM STATEMENT / BACKGROUND

Problem Statement - I

Currently:

- Candidates listed with an HCC exception continue to receive increases in priority every three months regardless of whether the tumors have shown progression
  - As score increases (22, 25, 28, etc.) candidates begin to receive offers
- Centers may wish to inactivate some candidates until there is demonstrated tumor progression so that they are not turning down offers:
  - Candidates initially listed with stable small tumors
  - Those with well-treated stable tumors
  - Patients who choose to “wait and see”

Problem Statement - II

- No mechanism to do this unless inactivated:
  - Automatic increases in score (if extended while inactivated with submission of data) OR
  - Loss of accumulated score (if not extended while inactive)
- If inactivated, centers must submit extensions every three months
  - Otherwise candidate loses accumulated MELD score
  - Score continues to increase even though risk of drop-out may be low
  - Significant extra “paperwork” for coordinators, multidisciplinary teams, etc

Proposal

- Allow centers to place liver candidates with HCC Exceptions on ‘HCC Hold’ without loss of accumulated MELD exception score or standard increases in the score
- In practice: Candidate is inactivated at a MELD score determined by center. Reason provided is “HCC hold”, not a “status 7” type of inactivation. Allows for observation of tumor while not losing place on list

Benefits

- Will eliminate turn down of offers for high-MELD patients that the center is not yet ready to transplant
  - Improve efficiency of the system
  - Decrease required applications for extensions, and tests required to complete applications
- Allows centers to utilize different ways of treating these patients (e.g., TACE, RFA), while providing the safety net of transplant if/when tumor recurs or demonstrates growth. Allows innovation and better patient-centered care.

Summary

Current Process in UNet℠	Proposed Change
Centers can extend an approved HCC Exception while candidate is in inactive status.	No change.
Approved HCC Exception applications must be extended every 3 months, even while the candidate is in inactive status. If the application is not extended, the candidate will lose the accumulated exception score upon re-activation.	Approved HCC Exception applications may remain on 'HCC hold' as long as a candidate is in inactive status; once re-activated, the candidate will retain the accumulated exception score (most recent tumor information must be provided).

Example A

- 1/1/2012: Candidate has approved HCC exception, one 2.1 cm tumor (MELD 22).
- Exception extended 4/1 (25) and 7/1 (28).
- Candidate begins receiving offers; tumor size still 2.1cm. Imaging demonstrates no viable tumor.
- Transplant team decides to observe tumor behavior before proceeding to transplant
- Candidate placed on “HCC hold,” periodic serial imaging continues in order to monitor the lesion.

Example A (cont'd)

- 3/10/13: MRI shows tumor has grown to 2.8 cm.
- 3/15/13: Patient reviewed at multidisciplinary tumor conference and decision made to proceed with transplant. Center submits the routine tumor information and re-activates candidate
- Candidate's score of 28 maintained until the next extension

Example B

- 1/1/2012: Candidate has approved HCC exception, one tumor treated with RFA that is 2.5 cm in size (MELD 22).
- Exception extended 4/1 (25) and 7/1 (28) and 10/1 (29).
- Candidate begins receiving offers, however the candidate has an ablation defect with no evidence of viable tumor
- Transplant team decides to observe tumor behavior before proceeding to transplant.
- Candidate placed on “HCC hold,” periodically undergoes serial imaging to monitor the lesion.

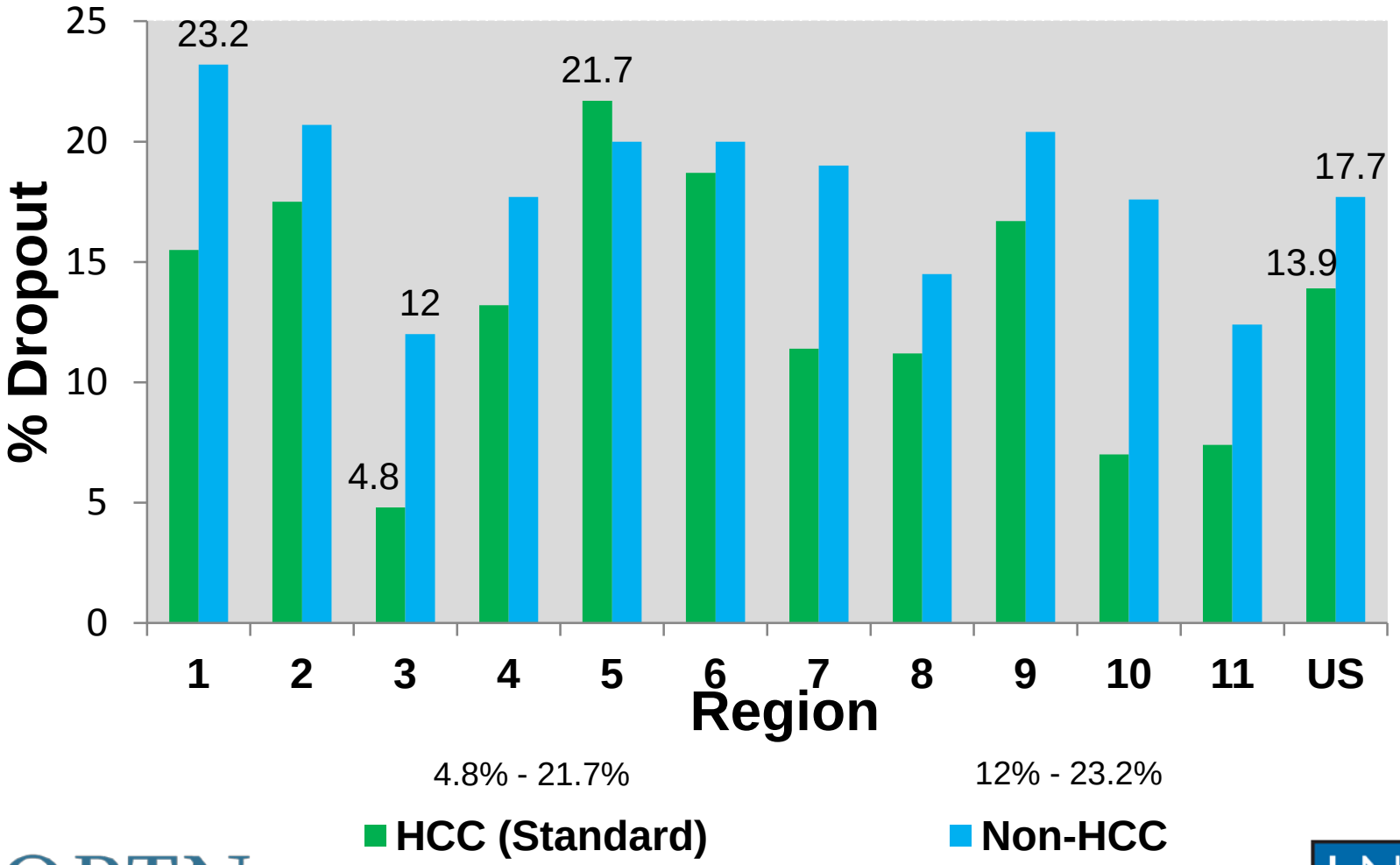
Example B (cont'd)

- 1/1/13: MRI shows no evidence of viable tumor at the ablation site. Remains inactive.
- 7/1/13: MRI shows stable ablation site but a new 1cm hypervascular lesion with wash out on delayed phase imaging.
- 7/5/13: Center submits the routine tumor information and activates candidate.
- Candidate's score of 29 is maintained until the next extension

Supporting Data

- Candidates with small HCC tumors have a low probability of waiting list dropout or growth beyond current transplant criteria within 12 months of listing
  - Washburn et al, AJT 2010
  - Massie, et al, AJT 2011
- Some candidates may have complete treatment of small tumors and eventually be withdrawn from the list completely.

% Dropout within 12 Months: HCC and Non-HCC Candidates by Region Candidates Added 7/1/08 – 6/30/11



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Public Comment

- Regions 1, 2, 3, 4, 6, 7, 8, 9, 11 support; 5 and 10 supported if amended
- 62 individual responses: 29 support (46.8%), 10 opposed (16.1%) 23 no opinion (37.1%). Of the 39 with an opinion 29 supported (74.4%), 10 opposed (25.64%)
- AST opposed, ASTS supported
- Committees: PAC and TAC support

Public Comment Concerns

- Candidates would come out of inactive status with high MELD scores and appear on the top of the waiting list
  - This can happen currently; the proposed policy could prevent it
- This would become mandatory policy
  - Would require separate policy proposal
- The option would not be used by many centers
  - Many centers have expressed interest

Plan for Evaluating

The Committee will review annually:

- How often this option is used
- Mean MELD/PELD scores at transplant, number and % of candidates removed from the waiting list for reasons other than transplant for candidates with HCC exceptions versus those without, by Region
- Outcomes for candidates whose exception is placed on hold

Additional Information

Additional Data Collection:

These proposals do not require additional data collection (forms) in Tiedi[SM]

Expected Implementation Plan:

UNOS Information Technology (IT) staff will need to reprogram UNet[SM] to implement these algorithms

- Large Programming Effort

RESOLUTION

*** RESOLVED, that Policy 3.6.4.4 (F) (Extensions of HCC Exception Applications) shall be amended as set forth below, effective pending notification and programming in UNet℠.

3.6.4.4 Liver Transplant Candidates with Hepatocellular Carcinoma (HCC).

A– E. (no change)

F. **Extensions of HCC Exception Applications**. Candidates will receive additional MELD/PELD points equivalent to a 10 percentage point increase in candidate mortality to be assigned every 3 months until these candidates receive a transplant or are determined to be unsuitable for transplantation based on progression of their HCC. To receive the additional points at 3-month intervals, the transplant program must re-submit an HCC MELD/PELD score exception application with an updated narrative every three months. Continued documentation of the tumor via repeat CT or MRI is required every three months for the candidate to receive the additional 10 percentage point increase in mortality points while waiting. Invasive studies such as biopsies or ablative procedures and repeated chest CTs are not required after the initial upgrade request is approved to maintain the candidate's HCC priority scores.

<u>The following options are available while a candidate with an approved HCC Exception application is in inactive status:</u>

<u>The center may choose to submit an extension application every 3 months, as described above; the candidate will receive a MELD/PELD score equivalent to a 10 percentage point increase in candidate mortality following each approved extension.</u>

The center may keep the candidate in inactive status for any length of time, without submission of an extension application every 3 months. However, prior to reactivation, an extension application must be submitted. Once the extension application is approved, the candidate will be listed with the candidate's previously approved exception score prior to inactivation (i.e., without loss of the accumulated MELD/PELD exception score) upon re-activation.

If the number of tumors that can be documented at the time of extension is less than upon initial application or prior extension, the type of ablative therapy must be specified on the extension application. Candidates whose tumors have been ablated after previously meeting the criteria for additional MELD/PELD points (OPTN Class 5T) will continue to receive additional MELD/PELD points (equivalent to a 10 percentage point increase in candidate mortality) every 3 months without RRB review, even if the estimated size of residual viable tumor falls below stage T2 criteria.

For candidates whose tumors have been resected since the initial HCC application or prior extension, the extension application must receive prospective review by the applicable RRB.

G. – I. (no change)

Questions?

Committee Update

Ongoing Committee Initiatives

- Reducing discards /Facilitated Placement
- HCC Allocation Issues - SRTR modeling
  - Online Survey of Community
- MELD-Na
  - Proposal for next cycle
- IN Surgeon/Physician Bylaws
- Review of MELD/PELD exceptions and RRB practices
  - Establishing more uniform guidelines and education of RRB members and chairs

New Committee Initiatives

- Standard MELD Exception for recipients of DCDs
- Revisiting the PELD allocation score
- Exploring alternative options for liver distribution with regard to geographic disparity