

## *Notice of OPTN Policy Change*

# Clarification of Pre-Existing Liver Disease

|                              |  |
|------------------------------|--|
| <b>Sponsoring Committee:</b> | <b>Liver and Intestinal Organ Transplantation</b>  |
| <b>Policies Affected:</b>    | <b>9.1.A: Adult Status 1A Requirements</b><br><b>9.1.B: Pediatric Status 1B Requirements</b> |
| <b>Public Comment:</b>       | <b>August 2 – October 2, 2019</b>  |
| <b>Board Approved:</b>       | <b>December 3, 2019</b>  |
| <b>Effective Date:</b>       | <b>March 1, 2020</b>   |

### **Purpose of Policy Change**

A liver candidate with a diagnosis of fulminant liver failure may qualify to be listed as Status 1A on the liver waiting list. Status 1A is the highest medical urgency category for liver candidates, and is reserved for candidates who have the highest risk of mortality within one week if they do not receive a transplant. In order to qualify for Status 1A based on this diagnosis, the candidate must not have pre-existing liver disease. There had not been a clear policy on whether a candidate who previously received a liver transplant would be disqualified because of liver disease before that transplant.

### **History**

- This proposal was developed by the Committee in 2019.
- This proposal was on the consent agenda at the fall 2019 regional meetings and at the OPTN Board of Directors' meeting in December 2019.
- It was supported in all regions and by all major stakeholders.

### **Summary of Changes**

The proposal modifies the definition of pre-existing liver disease in OPTN Policy so that it is clear that liver disease in a prior liver transplant recipient would not disqualify them as a candidate for Status 1A fulminant liver failure unless the candidate had a diagnosis of liver disease following that liver transplant. This proposal ensures that candidates for re-transplant who are experiencing fulminant hepatic failure receive the same access to organ transplant as other similar candidates with fulminant hepatic failure.

### **What Members Need to Do**

Liver transplant programs will need to ensure that their transplant teams are aware of the updated criteria for Status 1A. This proposal does not require additional data collection.

## Affected Policy Language

New language is underlined (example) and language that is deleted is struck through (~~example~~).

### 9.1 Status and Score Assignments

#### 9.1.A Adult Status 1A Requirements

To assign a candidate adult status 1A, the candidate's transplant hospital must submit a *Liver Status 1A Justification Form* to the OPTN Contractor. A candidate is not registered as status 1A until this form is submitted. When reporting laboratory values to the OPTN Contractor, transplant hospitals must submit the most recent results including the dates of the laboratory tests.

The candidate's transplant program may assign the candidate adult status 1A if *all* the following conditions are met:

1. The candidate is at least 18 years old at the time of registration
2. The candidate has a life expectancy without a liver transplant of less than 7 days and has at least *one* of the following conditions:
  - a. Fulminant liver failure, ~~without pre-existing liver disease, and currently in the intensive care unit (ICU),~~ defined as the onset of hepatic encephalopathy within 56 days of the first signs or symptoms of liver disease. ~~In addition the candidate;~~ ~~and has~~
    - i. Must not have a pre-existing diagnosis of liver disease. For purposes of this section, any diagnoses of liver disease that occurred prior to a subsequent liver transplant do not constitute pre-existing liver disease.
    - ii. Must currently be admitted in the intensive care unit
    - iii. Must meet at least *one* of the following conditions:
      1. Is ventilator dependent
      2. Requires dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
      3. Has an international normalized ratio (INR) greater than 2.0
  - b. Anhepatic
  - c. Primary non-function of a transplanted whole liver within 7 days of transplant, with aspartate aminotransferase (AST) greater than or equal to 3,000 U/L and at least *one* of the following:
    1. International normalized ratio (INR) greater than or equal to 2.5
    2. Arterial pH less than or equal to 7.30
    3. Venous pH less than or equal to 7.25
    4. Lactate greater than or equal to 4 mmol/L

All laboratory results reported for the tests required above must be from the same blood draw taken 24 hours to 7 days after the transplant.

- d. Primary non-function within 7-days of transplant of a transplanted liver segment from a deceased or living donor, evidenced by at least *one* of the following:
    - 1. INR greater than or equal to 2.5
    - 2. Arterial pH less than or equal to 7.30
    - 3. Venous pH less than or equal to 7.25
    - 4. Lactate greater than or equal to 4 mmol/L
  - e. Hepatic artery thrombosis (HAT) within 7-days of transplant, with AST greater than or equal to 3,000 U/L and at least *one* of the following:
    - 1. INR greater than or equal to 2.5
    - 2. Arterial pH less than or equal to 7.30
    - 3. Venous pH less than or equal to 7.25
    - 4. Lactate greater than or equal to 4 mmol/L
- All laboratory results reported for the tests required above must be from the same blood draw taken 24 hours to 7 days after the transplant.
- f. Acute decompensated Wilson's disease

### **9.1.B Pediatric Status 1A Requirements**

To assign a candidate pediatric status 1A, the candidate's transplant hospital must submit a *Liver Status 1A Justification Form* to the OPTN Contractor. A candidate is not assigned pediatric status 1A until this form is submitted.

The candidate's transplant program may assign the candidate pediatric status 1A if *all* the following conditions are met:

- 1. The candidate is less than 18 years old at the time of registration. This includes candidates less than 18 years old at the time of registration, who remain on the waiting list after turning 18 years old, but does not include candidates removed from the waiting list at any time who then return to the waiting list after turning 18 years old.
- 2. The candidate has at least *one* of the following conditions:
  - a. Fulminant liver failure, ~~without pre-existing liver disease, and currently in the intensive care unit (ICU),~~ defined as the onset of hepatic encephalopathy within 56 days of the first signs or symptoms of liver disease. In addition the candidate: ~~and has~~
    - i. Must not have a pre-existing diagnosis of liver disease. For purposes of this section, any diagnoses of liver disease that occurred prior to a subsequent liver transplant do not constitute pre-existing liver disease.
    - ii. Must currently be admitted in the intensive care unit
    - iii. Must meet at least *one* of the following conditions:
      - 1. Is ventilator dependent
      - 2. Requires dialysis, continuous veno-venous hemofiltration (CVVH), or continuous veno-venous hemodialysis (CVVHD)
      - 3. Has an international normalized ratio (INR) greater than 2.0
  - b. Diagnosis of primary non-function of a transplanted liver within 7 days of transplant, evidenced by at least *two* of the following:

- i. Alanine aminotransferase (ALT) greater than or equal to 2,000 U/L
- ii. INR greater than or equal to 2.5
- iii. Total bilirubin greater than or equal to 10 mg/dL
- iv. Acidosis, defined as *one* of the following:
  - 1. Arterial pH less than or equal to 7.30
  - 2. Venous pH less than or equal to 7.25
  - 3. Lactate greater than or equal to 4 mmol/L

All laboratory results reported for any tests required for the primary non-function of a transplanted liver diagnosis above must be from the same blood draw taken between 24 hours and 7 days after the transplant.

- c. Diagnosis of hepatic artery thrombosis (HAT) in a transplanted liver within 14 days of transplant
- d. Acute decompensated Wilson's disease

#