# Improving MELD, PELD and Status 1A/1B:

# **Frequently Asked Questions for patients and caregivers**

In summer 2023, a set of changes will be made to how medical urgency is decided for liver transplant candidates. These changes will improve how the liver allocation system prioritizes transplant need. They will also provide more transplant priority to adult female candidates to make their access to transplant more equal to adult male patients.

The updates address the following formulas and classifications:

- The Model for End-Stage Liver Disease (MELD) equation, used for liver candidates ages 12 and older
- The Pediatric End-Stage Liver Disease (PELD) equation, used for liver candidates younger than age 12
- The Status 1A and 1B classifications, which are assigned to especially urgent liver candidates

Below are answers to frequently asked questions that liver transplant candidates or their caregivers may have related to the policy updates.

## Questions regarding MELD (liver candidates aged 12 and older)

#### How will MELD point assignments change?

All liver transplant candidates identified as female will automatically get 1.33 MELD points added to their calculated MELD score. The current MELD formula has not been as accurate in capturing the medical need of female liver candidates.

In addition, all adolescent male and female liver transplant candidates (age 12 or older, but younger than 18) will also get 1.33 MELD points added to their calculated MELD score.

#### How will female sex be reported?

The transplant hospital, in consultation with the individual candidate, will report the candidate's sex for the purpose of MELD calculation for adult candidates. In most instances, this will be the same as the candidate's reported birth sex. In some instances, the candidate's reported sex may differ from their sex at birth.

#### What else will be added to the MELD score?

An albumin test result will now be required for all candidates and will be part of the MELD calculation. (It is already a factor used in the PELD calculation.) Medical data have shown that using an albumin value will make MELD a better predictor of a short-term risk of death without a liver transplant. Albumin is a protein, made by the liver, that regulates fluid in your blood. It is measured by a standard blood test result. Lower than normal levels can be a sign of increasingly severe liver or kidney disease.

### How will existing data values change in the calculation?

There will be changes to the MELD formula in terms of the values placed on some existing test results used in the calculation. Each of these results comes from standard blood tests. Medical data have shown that adjustments to these values will allow MELD to predict more accurately a person's short-term risk of death without a liver transplant. The factors that will have adjusted values include:

- Bilirubin, which assesses how well the liver works to digest food
- Serum sodium, which measures the sodium content in the blood
- International Normalized Ratio (INR), which measures how well the blood is able to clot
- Serum creatinine, which measures kidney function

Each test used to calculate MELD measures different things critical to your health. Because a new test is being added and changes are being made to other test values, various factors may work together to affect the new score. A sample calculator will be available to compare the current and updated score.

Your score may remain the same as before. It could also increase or decrease. The amount of any increase or decrease will likely be fairly small for most patients. By being more accurate, the changes should help the organ allocation system better identify candidates with the most urgent medical need and give them appropriate priority for available organs.

MELD values often change over weeks or months. Your liver transplant program must report data to recalculate your score at certain points in time (more frequently if you are highly urgent). Your program can also report new data at any time it believes there has been a major change in your condition. Updates made after the policy changes could also result in your MELD score being higher or lower than it was before. If you have any questions about what data your transplant program has supplied for the calculation, or when your score should be recalculated, contact your transplant team.

# Questions regarding PELD (liver candidates younger than age 12)

# Will the minimum PELD score change?

The current liver allocation policy can, in theory, create a PELD value less than zero. In the updated policy, the minimum PELD value used for organ allocation will be 6, to be consistent with the minimum MELD value of 6.

#### What will be added to the PELD score?

A value for serum creatinine will be required for all candidates and included in the PELD calculation. (It is already a part of the MELD formula). Medical data shows that adding this factor to PELD will make it better able to predict short-term risk of death without a liver transplant.

Creatinine is a waste product of creatine, a chemical the body makes to supply energy to muscles. The kidneys remove creatinine from the body. Higher levels of serum creatinine mean that the kidneys are not working effectively, allowing more of this waste product to stay in the blood. Creatinine is measured by a standard blood test.

#### How will existing data values change in the calculation?

There will be changes to the PELD formula in terms of the values placed on some existing test results used in the calculation. Each of these results comes from standard blood tests. Medical data have shown that adjustments to these values will allow PELD to predict more accurately a person's short-term risk of death without a liver transplant. The factors that will have adjusted values include:

- Bilirubin, which assesses how well the liver works to digest food
- Albumin, which helps maintain fluid balance in the blood
- International Normalized Ratio (INR), which measures how well the blood is able to clot

There will also be adjustments to the way the child's age and potential growth failure are assessed. Currently these are categories in the formula. For example, in the current formula, patients receive points based on whether their age is less than one year old., regardless of whether the patient just turned one or is one day away from becoming one year old. Similarly, for growth failure, patients receive points based on whether growth failure is present or not, regardless of the extent to which patients may differ from the average height or weight of children of similar age. In the new formula, age and growth failure will now be on a scale to reflect a continuous progression.

In addition, the risk of mortality based on age has been adjusted for PELD patients, to be more in line with the mortality risk of adult patients.

Each of the factors used to calculate PELD measures different things critical to a child's health. Because a new test is being added and changes are being made to other test values, various factors may work together to affect the new score. A sample calculator will be available to compare the current and updated score.

Your child's score may remain the same as before. It could also increase or decrease. The amount of any increase or decrease will likely be fairly small for most patients. But by being more accurate, the changes should help the organ allocation system be better at identifying the candidates in the most urgent medical need, and in giving them appropriate priority for available organs.

PELD values often change for patients who are listed for a liver transplant over weeks or months. Your liver transplant program must report data to recalculate your child's score at certain points in time (more frequently if they are highly urgent). They can report new data at any time they believe there has been a major change in his or her condition. Updates made after the policy change could also result in your child's PELD score being higher or lower than it was before. If you have any questions about what

data your transplant program has supplied for the calculation, or when your child's score should be recalculated, contact your transplant team.

#### **Questions regarding Status 1A and Status 1B**

#### What are these designations? How commonly are they used?

Both Status 1A and 1B are reserved for liver transplant candidates who are highly medically urgent based on rare and specific medical conditions. These are the first two groups of candidates to be considered for liver offers in the allocation system.

While these candidates will have a calculated MELD or PELD score, the status designation will be used for matching instead of the calculated score. Candidates will qualify for one of these statuses based on having a specific diagnosis listed in OPTN liver allocation policy.

By design, these are very rare statuses. Status 1A can include either adult or pediatric candidates. Status 1B only contains pediatric candidates (younger than age 18 when first listed for a transplant). At any time there may be a handful of Status 1A candidates and a few dozen Status 1B candidates nationwide.

#### What are the changes?

The updated criteria are very technical and are generally meant to make sure the definitions are as relevant as they can be to medical need. The Status 1A criteria are being updated specifically for pediatric transplant candidates who have sudden-onset liver failure with related disease affecting the brain. There are no changes to Status 1A criteria for adult candidates.

For Status 1B, the order of candidates within this status will be re-sorted to prioritize those with chronic liver disease, since they have the highest risk of death on the waiting list. In addition, certain medical thresholds previously used to qualify candidates for the designation are being removed, to allow some candidates to qualify more easily. Your transplant team would best be able to advise you on whether you or your loved one may be affected by any of the changes in criteria, again in the understanding that very few liver candidates are in either of these two statuses.

#### **General questions**

#### Will these changes affect exception scores?

Transplant candidates may qualify for an exception score if the existing MELD or PELD calculation does not address their medical need well. If your transplant team believes an exception score would be a better measure of your need, the team would send a request to a national review board to seek an exception. If the exception is granted, either it or the calculated MELD or PELD score (whichever is higher) will be used for liver allocation. That process is addressed in more detail in this <u>patient FAQ</u> <u>document</u>.

It is possible that in some cases, the changes to MELD, PELD, and Status 1A and 1B may make it less likely for you or your loved one to need an exception score. But it will not eliminate all needs for an exception, and this policy does not affect the process of applying for or receiving an exception score.

#### Do I need to do anything to prepare for the policy changes?

Your transplant program should have all of the information necessary at the time of the policy change to support the new calculation and/or status criteria. However, please check with your transplant team if you have any questions or wish to understand more detail.

## Will there be a sample calculator available to see the MELD and PELD changes?

Yes. Currently there are sample calculators for <u>MELD</u> and <u>PELD</u> on the OPTN website. If you have recent lab test results and other information for you or your loved one, you may enter the data into the calculator and see what their score would be. (Please note that this is only a sample calculator; entering data and seeing a result will not affect your actual score, which is based on data your transplant program sends to the OPTN.)

Prior to the new policy taking effect, there will be two separate sample calculators (temporarily) – one showing the current scoring system and the other showing results under the new policies. This will allow you to see how the new policies are likely to affect your score results. Once the new policy is in effect, only the calculator with updated values will be shown.

# What if I have more questions?

Your transplant team will have the most detailed information about your current medical condition and treatment. Do not be afraid to ask them questions about your treatment and how the updates may affect you or your loved one.

You also may learn more about organ donation and transplantation at <u>https://www.organdonor.gov/</u>, or contact the OPTN's Patient Services Department by email (<u>patientservices@unos.org</u>) or phone (<u>888-894-6361</u>).