3.6 ALLOCATION OF LIVERS. Unless otherwise approved according to Policy 3.4.8 (Variances), Policy 3.9.3 (Organ Allocation to Multiple Organ Transplant Candidates) and Policy 3.11.4 (Combined Intestine-Liver Organ Candidates), the allocation of livers according to the following system is mandatory. For the purpose of enabling physicians to apply their consensus medical judgement for the benefit of liver transplant candidates as a group, each candidate will be assigned a status code or probability of candidate death derived from a mortality risk score corresponding to the degree of medical urgency as described in Policy 3.6.4 below. Mortality risk scores shall be determined by the prognostic factors specified in Tables 1 and 2 and calculated in accordance with the Model for End-Stage Liver Disease (MELD) Scoring System and Pediatric End Stage Liver Disease (PELD) Scoring System described in Policy 3.6.4.1 and 3.6.4.2, respectively. Candidates will be stratified within MELD or PELD score by blood type similarity as described in Policy 3.6.2. No individual or property rights are conferred by this system of liver allocation.

Livers will be offered to candidates with an assigned Status of 1A and 1B in descending point sequence with the candidate having the highest number of points receiving the highest priority before being offered for candidates listed in other categories within distribution areas as noted below. Following Status 1, livers will be offered to candidates based upon their probability of candidate death derived from assigned MELD or PELD scores, as applicable, in descending point sequence with the candidate having the highest probability ranking receiving the highest priority before being offered to candidates having lower probability rankings. Additionally, Alternative Allocation/Distribution Systems, as described in Policy 3.1.7, shall no longer contain liver payback provisions.

At each level of distribution, adult livers (i.e., greater than or equal to 18 years old*)* will be allocated in the following sequence *(*adult donor liver allocation algorithm*)*:

Adult Donor Liver Allocation Algorithm

Combined Local and Regional

1. Status 1A candidates in descending point order
2. Status 1B candidates in descending order

Local and Regional

3. Candidates with MELD/PELD Scores >=35 in descending order of mortality risk (MELD) scores, with Local candidates ranked above Regional candidates at each level of MELD score

Local

~~3~~4. Candidates with MELD/PELD Scores ~~>=15~~ 29-34 in descending order of mortality risk scores (probability of candidate death)

National

~~4~~5. Liver-Intestine Candidates in descending order of Status and mortality risk scores (probability of candidate death)

Local

~~5~~6. Candidates with MELD/PELD Scores 15-28 in descending order of mortality risk scores (probability of candidate death)

Regional

~~4~~67. Candidates with MELD/PELD Scores ~~>=~~15-34 in descending order of mortality risk scores (probability of candidate death)

National

8. Status 1A candidates in descending point order
9. Status 1B candidates in descending point order
10. Candidates with MELD/PELD Scores >=15 in descending order of mortality risk scores (probability of candidate death)

Local

~~57~~11. Candidates with MELD/PELD Scores < 15 in descending order of mortality risk scores (probability of candidate death)

Regional

~~68~~12. Candidates with MELD/PELD Scores < 15 in descending order of mortality risk scores (probability of candidate death)

National

~~79~~ ~~Status 1A candidates in descending point order~~

~~810~~ ~~Status 1B candidates in descending point order~~

~~911~~13. ~~All other~~ ~~c~~Candidates with MELD/PELD Scores < 15 in descending order of mortality risk scores (probability of candidate death)

NOTE: The amendments to Policy 3.6 (Adult Donor Liver Allocation Algorithm) shall be effective pending programming. (Approved at the November 15, 2011 and June 25, 2012 Board of Directors Meetings.)

Within liver Status 1A and B and the organ distribution system defined in this policy for adult donor livers, a liver recovered from a pediatric organ donor shall be allocated to a pediatric liver candidate before the liver is allocated to an adult candidate (according to the pediatric donor liver allocation algorithm set forth below); provided, however, that the recipient transplant program cannot use only part of the liver in a single candidate without offering the remaining portion(s) for transplantation:

(i) in sequence, as determined by the adult donor liver allocation algorithm set forth above and defining "local" based upon the Host OPO's local area, to the highest-ranking candidate on the Waiting List of candidates; provided, however, that the Host OPO places the liver segment(s) by the time the donor organ procurement procedure has started, or

(ii) into candidates listed with the recipient program or any medically appropriate candidate on the Waiting List, if, after reasonable attempts by the Host OPO to place the remaining portion(s) of the donor liver, the liver segment(s) is not placed by the time the donor organ procurement procedure has started.

In the event that the transplant program receiving the liver offer declines to transplant the whole organ into the designated candidate or to transplant a part of the organ into the designated candidate, offering the remaining portion(s) for transplantation as described earlier in this paragraph, then the donor liver shall be allocated to the next candidate on the Waiting List, in the sequence outlined below (i.e., the pediatric donor liver allocation algorithm). For purpose of Policy 3.6, pediatric candidates and organ donors are defined as less than 18 years of age.

0-10 year-old Pediatric Donor Liver Allocation Algorithm

Combined Local and Regional

1. Pediatric Status 1A candidates (age 0-17) in descending point order

National

2. Pediatric Status 1A (age 0-11) in descending point order

Local

3. Adult Status 1A candidates in descending point order

Regional

4. Adult Status 1A candidates in descending point order

Combined Local and Regional

5. Pediatric Status 1B candidates (age 0-17) in descending point order

Regional

6. Pediatric Candidates age 0-11 in descending order of mortality risk scores (probability of candidate death)

Local

7. Pediatric candidates age 12-17 with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

8. Adult candidates with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

Regional

9. Pediatric candidates age 12-17 with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)
10. Adult candidates with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

Local

11. All other pediatric candidates age 12-17 in descending order of mortality risk scores (probability of candidate death)
12. All other adult candidates in descending order of mortality risk scores (probability of candidate death)

Regional

13. All other pediatric candidates age 12-17 in descending order of mortality risk scores (probability of candidate death)
14. All other adult candidates in descending order of mortality risk scores (probability of candidate death)

National

15. Pediatric Status 1A (age 12-17) candidates in descending point order
16. Adult Status 1A candidates in descending point order
17. Pediatric Status 1B candidates in descending point order
18. All other pediatric candidates age 0-11 in descending order of mortality risk scores (probability of candidate death)
19. All remaining pediatric candidates in descending order of mortality risk scores (probability of candidate death)
20. All remaining adult candidates in descending order of mortality risk scores (probability of candidate death)

11-17 year-old Pediatric Donor Liver Allocation Algorithm

Local

1. Pediatric Status 1A candidates (age 0-17) in descending point order

Regional

2. Pediatric Status 1A candidates (age 0-17) in descending point order

Local

3. Adult Status 1A candidates in descending point order

Regional

4. Adult Status 1A candidates in descending point order

Local

5. Pediatric Status 1B candidates (age 0-17) in descending point order

Regional

6. Pediatric Status 1B candidates (age 0-17) in descending point order
7. Pediatric Candidates age 0-11 in descending order of mortality risk scores (probability of candidate death)

Local

8. Pediatric candidates age 12-17 with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

9. Adult candidates with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

Regional

10. Pediatric candidates age 12-17 with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)
11. Adult candidates with MELD scores of 15 or greater, in descending order of mortality risk scores (probability of candidate death)

Local

12. All other pediatric candidates age 12-17 in descending order of mortality risk scores (probability of candidate death)
13. All other adult candidates in descending order of mortality risk score (probability of candidate death)

Regional

14. All other pediatric candidates age 12-17 in descending order of mortality risk scores (probability of candidate death)
15. All other adult candidates in descending order of mortality risk scores (probability of candidate death)

National

16. Pediatric Status 1A candidates in descending point order
17. Adult Status 1A candidates in descending point order
18. Pediatric Status 1B candidates in descending point order
19. All other pediatric candidates age 0-11 in descending order of mortality risk scores (probability of candidate death)
20. All remaining pediatric candidates in descending order of mortality risk scores (probability of candidate death)
21. All remaining adult candidates in descending order of mortality risk scores (probability of

The liver must be transplanted into the original designee or be released back to the Host OPO or to the Organ Center for distribution. If a liver is offered to a candidate who is unavailable to receive the transplant at his/her listing transplant center in the organ allocation unit to which the liver is being distributed, then the liver shall be released back to the Host OPO or to the Organ Center for allocation to other liver transplant candidates in accordance with Policy 3.6. The final decision whether to use the liver will remain the prerogative of the transplant surgeon and/or physician responsible for the care of that candidate. This will allow physicians and surgeons to exercise judgement about the suitability of the liver being offered for their specific candidate; to be faithful to their personal and programmatic philosophy about such controversial matters as the importance of cold ischemia and anatomic anomalies; and to give their best assessment of the prospective recipient's medical condition at the moment. If a liver is declined for a candidate, a notation of the reason for the decision not to accept the liver for that candidate must be made on the appropriate form and promptly submitted.

Allocation Sequence for Candidates with PELD or MELD Scores Less Than or Equal to 6 (All Donor Livers).

Adult candidates and pediatric adolescent candidates with a MELD score of 6 will be considered together with pediatric candidates <12 years with a PELD score less than or equal to 6. These candidates will be initially ranked based upon waiting time. Those waiting list positions assigned to pediatric candidates based on this initial ranking (e.g., if the 3rd and 5th on the ranked list are held by pediatric candidates) will then be re-distributed amongst the pediatric group based on PELD or MELD score, with the candidate with the highest PELD or MELD, as applicable score receiving the highest available pediatric ranking position. The next available pediatric ranking position will be assigned to the pediatric candidate with the next highest PELD or MELD score. Re-distribution of pediatric candidates continues until the pediatric candidate with the lowest

PELD or MELD score is assigned the last pediatric ranking position.

3.6.1 Preliminary Stratification. For every potential liver recipient, the acceptable donor size must be determined by the responsible surgeon. The Match System will consider only potential liver recipients who are an acceptable size for that particular donor liver.

3.6.2 Blood Type Similarity Stratification/Points. For Status 1A and 1B transplant candidates, those with the same ABO type as the liver donor shall receive 10 points. Candidates with compatible but not identical ABO types shall receive 5 points, and candidates with incompatible types shall receive 0 points. Blood type O candidates who will accept a liver from a non-A_1 (negative for A_1 subtype) blood type donor shall receive 5 points for ABO incompatible matching. Within each MELD/PELD score, donor livers shall be offered to transplant candidates who are ABO-identical with the donor first, then to candidates who are ABO-compatible, followed by candidates who are ABO-incompatible with the donor.

3.6.2.1 Allocation of Blood Type O Donors. With the Exception of Status 1A and 1B candidates, blood type O donors may only be allocated to blood type O candidates, or B candidates with a MELD or PELD score greater than or equal to 30. Any remaining blood type compatible candidates will appear on the match run list for blood type O donors after the blood type O and B candidate list has been exhausted at the regional and national level.

3.6.2.2 Liver Allocation to Candidates Willing to Accept an Incompatible Blood Type. For Status 1A or 1B candidates or candidates with a match MELD or PELD score of 30 and greater, centers may specify on the Waiting List those candidates who will accept a liver from a donor of any blood type.

3.6.3 Time Waiting. Transplant candidates on the Waiting List shall accrue waiting time within Status 1A or 1B or any assigned MELD or PELD score; however, waiting time accrued while listed at a lower MELD/PELD score will not be counted toward liver allocation if the candidate is upgraded to a higher MELD/PELD score. Stratification of candidates within a particular MELD/PELD score shall be based on total waiting time currently and previously accrued at that score on the same Waiting List registration added to waiting time accrued at any higher MELD/PELD score. For example, if there are 2 persons with a MELD score of 30 who were both of identical blood types with the donor, the candidate with the longest accrued waiting time in MELD score 30 or higher would receive the first offer. Waiting time will not be accrued by candidates awaiting a liver transplant while they are registered on the Waiting List as inactive.

Candidates in Status 1A or 1B will receive waiting time points based on their waiting time in that Status. Ten points will be accrued by the candidate waiting for the longest period for a liver transplant and proportionately fewer points will be accrued by those candidates with shorter tenure. For example, if there were 75 persons of O blood type waiting who were of a size compatible with a blood group O donor, the person waiting the longest would accrue 10 points (75/75 x 10). A person whose rank order was 60 would accrue 2 points. ((75-60)/75 x 10 = 2).

3.6.4 Degree of Medical Urgency. Each candidate is assigned a status code or mortality risk score (probability of candidate death) which corresponds to how medically urgent it is that the candidate receive a transplant.

3.6.4.1 Adult Candidate Status. Medical urgency is assigned to an adult liver transplant candidate (greater than or equal to 18 years of age) based on either the criteria defined below for Status 1A, or the candidate's

mortality risk score as determined by the prognostic factors specified in Table 1 and calculated in accordance with the MELD Scoring System. A candidate who does not have a MELD score that, in the judgment of the candidate's transplant physician, appropriately reflects the candidate's medical urgency, may nevertheless be assigned a higher MELD score upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the candidate is considered, by consensus medical judgment, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other candidates having the higher MELD score. The justification must include a rationale for incorporating the exceptional case as part of MELD calculation. A report of the decision of the Regional Review Board and the basis for it shall be forwarded to for review by the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the MELD criteria.

Status	Definition
7	A candidate listed as Status 7 is temporarily inactive. Candidates who are considered to be temporarily unsuitable transplant candidates are listed as Status 7, temporarily inactive.
1A	A candidate greater than or equal to 18 years of age listed as Status 1A has fulminant liver failure with a life expectancy without a liver transplant of less than 7 days. For the purpose of Policy 3.6, fulminant liver failure shall be defined as described in (i)-(iv). Centers that list candidates not meeting these criteria for Status 1A will be referred to the Liver and Intestinal Organ Transplantation Committee for review; this review by the Liver and Intestinal Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee for appropriate action in accordance with Appendix A of the Bylaws. Candidates meeting the criteria in (i)-(iv) will be listed in Status 1A without RRB review. (i) fulminant hepatic failure defined as the onset of hepatic encephalopathy within 8 weeks of the first symptoms of liver disease. The absence of pre-existing liver disease is critical to the diagnosis. One of three criteria below must be met to list an adult candidate, who must be in the ICU, with fulminant liver failure: (1) ventilator dependence (2) requiring dialysis or continuous veno-venous hemofiltration (CVVH) or continuous veno-venous hemodialysis (CVVD) or (3) INR > 2.0, or (ii) primary non-function of a transplanted liver within 7 days of implantation; as defined by (a) or (b): (a) AST ≥ 3,000 and one or both of the following: • an INR ≥ 2.5 • Acidosis, defined as having an arterial pH ≤ 7.30 or venous pH of 7.25 and/or Lactate ≥ 4 mMol/L (b) Anhepatic candidate, or (iii) hepatic artery thrombosis in a transplanted liver within 7 days of implantation, with evidence of severe liver injury as defined in (ii(a)) and (ii(b)) above; Candidates with HAT in a transplanted liver within 14 days of implantation not meeting the above criteria will be listed at a MELD of 40; or

(iv) acute decompensated Wilson's disease.

For (ii) and (iii), all labs must be from the same blood draw within 24 hours to 7 days following the transplant. For (ii)(a), there is no AST requirement for recipients of segmental grafts from deceased or living donors.

Candidates who are listed as a Status 1A automatically revert back to their most recent MELD Score after 7 days unless these candidates are relisted as Status 1A by an attending physician. Candidates must be listed with MELD laboratory values in accordance with Policy 3.6.4.1.1 (Adult Candidate Recertification and Reassessment Schedule) at the time of listing. A completed Liver Status 1A Justification Form must be submitted on UNet^{SM} for a candidate's original listing as a Status 1A and each relisting as a Status 1A. If a completed Liver Status 1A Justification Form is not entered into UNet^{SM} when a candidate is registered as a Status 1A, the candidate shall be reassigned to their most recent MELD score. A relisting request to continue a Status 1A listing for the same candidate waiting on that specific transplant beyond 14 days accumulated time will result in a review of all local Status 1A liver candidate listings.

All other adult liver transplant candidates on the Waiting List shall be assigned a mortality risk score calculated in accordance with the MELD scoring system. For each liver candidate registration, the listing transplant center shall enter data on UNet^{SM} for the prognostic factors specified in Table 1. These data must be based on the most recent clinical information (e.g., laboratory test results and diagnosis) and include the dates of the laboratory tests.

Table 1
Model for End-Stage Liver Disease (MELD) Scoring System

Prognostic Factor	Regression Coefficient	Std. Error	*P*
Serum creatinine (Log_e value)	**0.957**	**0.142**	**<0.01**
Serum bilirubin (Log_e value)	**0.378**	**0.117**	**<0.01**
INR (Log_e value)	**1.120**	**0.331**	**<0.01**

* The maximum serum creatinine considered within the MELD score equation will be 4.0mg/dl (i.e., for candidates with a serum creatinine of greater than 4.0 mg/dl, the serum creatinine level will be set to 4.0 mg/dl). For candidates on dialysis, defined as having 2 or more dialysis treatments within the prior week, or candidates who have received 24 hours of CVVHD within the prior week, the serum creatinine level will automatically be set to 4.0 mg/dl.

Using these prognostic factors and regression coefficients, the UNet^{SM} shall assign a MELD score for each candidate based on the following calculation:

MELD Score = 0.957 x Log_e(creatinine mg/dL) + 0. 378 x Log_e(bilirubin mg/dL) + 1.120 x Log_e (INR) + 0.643

Laboratory values less than 1.0 will be set to 1.0 for the purposes of the MELD score calculation.

As an example, for a hypothetical candidate with cirrhosis caused by hepatitis C virus who has a serum

creatinine concentration of 1.9 mg/dL, a serum bilirubin concentration of 4.2 mg/dL and an INR value of 1.2, the risk score would be calculated as follows:
MELD Score= (0.957 x Log_e1.9) + (0.378 x Log_e4.2) + (1.120 x Log_e1.2) + 0.643= 2.0039

The MELD score for each liver transplant candidate derived from this calculation shall be rounded to the tenth decimal place and then multiplied by 10. The hypothetical candidate in the example described above, therefore, would be assigned a risk score of 20. The MELD score will be limited to a total of 40 points maximum.

3.6.4.1.1 Adult Candidate Reassessment and Recertification Schedule. The appropriateness of the MELD score assigned to each candidate listing shall be re-assessed and recertified by the listing transplant center to the OPTN Contractor in accordance with the following schedule:

Adult Candidate Reassessment and Recertification Schedule

Status 1A	Status recertification Every 7 days.	Laboratory values must be no older than 48 hours.
MELD Score 25 or greater	Status recertification Every 7 days.	Laboratory values must be no older than 48 hours.
Score <= 24 but > 18	Status recertification every 1 month.	Laboratory values must be no older than 7 days.
Score <= 18 but >=11	Status recertification every 3 months.	Laboratory values must be no older than 14 days.
Score <= 10 but > 0	Status recertification every 12 months.	Laboratory values must be no older than 30 days.

This reassessment and recertification must be based on the most recent clinical information (e.g., laboratory test results and diagnosis), including the dates of the laboratory tests. In order to re-certify, laboratory values must not be older than the "age of laboratory values" specified in the chart above. In order to change a MELD score voluntarily, all laboratory values must be obtained within 48 hours. The OPTN contractor shall notify the listing transplant center of the need to reassess and recertify a candidate's MELD score within 48 hours of the applicable deadline indicated in the recertification schedule. If a candidate is not recertified in accordance with the schedule, the candidate shall be re-assigned to their previous lower MELD score. The candidate may remain at that previous lower score for the period allowed based upon the recertification schedule for the previous lower score, minus the time spent in the uncertified score. If the candidate remains uncertified past the recertification due date for the previous lower score, the candidate will be assigned a MELD score of 6. If a candidate has no previous lower MELD score, and is not recertified in accordance with the schedule, the candidate shall be reassigned to a MELD score of 6.

3.6.4.2 Pediatric Candidate Status. Medical urgency is assigned to a pediatric liver transplant candidate (less than 18 years of age) based on either the criteria defined below for Status 1A or 1B, or the candidate's mortality risk score as determined by the prognostic factors specified in Table 2 and calculated in accordance with the Pediatric End-Stage Liver Disease Scoring System (PELD) for pediatric candidates <12 years or with the MELD System (defined above in Policy 3.6.4.1) for pediatric candidates 12-17 years. Based on the variables included in allocation score calculation in the MELD system, MELD scores may offer a more accurate picture of mortality risk and disease severity for adolescent candidates. Pediatric candidates 12-17 years will use a risk score calculated with the MELD system while maintaining other priorities assigned to pediatric candidates. A candidate who does not have a risk of candidate mortality expressed by the PELD or MELD score that, in the judgement of the candidate's transplant physician, appropriately reflects the candidate's medical urgency or was listed at less than 18 years of

age and remains on or has been returned to the Waiting List upon or after reaching age 18 may nevertheless be assigned to a higher or the appropriate PELD or MELD score and pediatric classification (for candidates listed at less than age 18 who turn age 18) upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the candidate is considered, by consensus medical judgement, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other candidates having the PELD or MELD score. The justification must include a rationale for incorporating the exceptional case as part of the PELD/MELD calculation. A report of the decision of the Regional Review Board and the basis for it shall be forwarded for review by the Liver and Intestinal Organ Transplantation and Membership and Professional Standards Committees to determine consistency in application among and within Regions and continued appropriateness of the PELD or MELD criteria.

Status	Definition
7	A pediatric candidate listed as Status 7 is temporarily inactive. Candidates who are considered to be temporarily unsuitable transplant candidates are listed as Status 7, temporarily inactive.
1A/1B	For purposes of Status 1A/1B definition and classification, candidates listed at less than 18 years of age who remain on or have returned to the Waiting List upon or after reaching age 18 may be considered Status 1A/1B and shall qualify for other pediatric classifications under the following criteria. There are six allowable diagnostic groups: (i) fulminant liver failure; (ii) primary non function; (iii) hepatic artery thrombosis; (iv) acute decompensated Wilson's Disease; (v) chronic liver disease; and (vi) non-metastatic hepatoblastoma. Candidates meeting criteria (i) (ii), (iii), or (iv) may be listed as a Status 1A; those meeting criteria (v) and (vi) may be listed as a Status 1B. Within each diagnostic group specific conditions must be met to allow for listing a pediatric candidate at Status 1A or 1B. Centers that list candidates not meeting these criteria for Status 1A or 1B will be referred to the Liver and Intestinal Organ Transplantation Committee for review; this review by the Liver and Intestinal Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee for appropriate action in accordance with Appendix A of the Bylaws. Candidates meeting the criteria in (i)-(vi) will be listed in Status 1A or Status 1B without RRB review. (i) Fulminant hepatic failure. Fulminant liver failure is defined as the onset of hepatic encephalopathy within 8 weeks of the first symptoms of liver disease. The absence of pre-existing liver disease is critical to the diagnosis. One of three criteria below must be met to list a pediatric candidate with fulminant liver failure: (1) ventilator dependence (2) requiring dialysis or continuous veno-venous hemofiltration (CVVH) or continuous veno-venous hemodialysis (CVVD), or (3) INR > 2.0. (ii) Primary non-function of a transplanted liver. The diagnosis is made within 7 days of implantation. Additional criteria to be met for this indication must include 2 of the following: ALT >/= 2000, INR ≥ 2.5, total bilirubin >/= 10 mg/dl, or acidosis, defined as having an arterial pH ≤ 7.30 or venous pH of 7.25 and/or lactate

≥ 4 mMol/L. All labs must be from the same blood draw within 24 hours to 7 days following the transplant.

(iii) Hepatic artery thrombosis. The diagnosis must be made in a transplanted liver within 14 days of implantation.

(iv) Acute decompensated Wilson's disease.

(v) Chronic liver disease. Pediatric candidates with chronic liver disease can be listed at Status 1B if the candidate has a calculated PELD score of >25 or calculated MELD score of >25 for adolescent candidates (12-17 years) and one of the following criteria is met (candidates listed for a combined liver-intestine transplant may meet these criteria with their adjusted match score as described in Policy 3.6.4.7 (Combined Liver-Intestine Candidates):

a. On a mechanical ventilator; or
b. Gastrointestinal bleeding requiring at least 30 cc/kg of red blood cell replacement within the previous 24 hours; or
candidates also on the intestine list, at least 10 cc/kg of red blood cell replacement within the previous 24 hours; or
c. Renal failure or renal insufficiency defined as requiring dialysis or continuous CVVH or continuous CVVD; or
d. Glasgow coma score <10 within 48 hours of the listing/extension.

(vi) Non-metastatic hepatoblastoma. A pediatric candidate with a biopsy proven hepatoblastoma without evidence of metastatic disease at the time of listing may be listed as Status 1B.

Candidates who are listed as a Status 1A or 1B automatically revert back to their most recent PELD or MELD score after 7 days unless these candidate~~s~~ are relisted as Status1A or 1B 1 by an attending physician. Extensions for Status 1B candidates indicating a gastrointestinal bleed as the initial Status 1B upgrade criteria must have had another bleed in the past 7 days prior to upgrade in order to remain in Status 1B. Status 1B candidates listed with a metabolic disease (in accordance with Policy 3.6.4.3) or a hepatoblastoma will require recertification every three months with lab values no older than 14 days. Candidates must be listed with PELD/MELD laboratory values in accordance with Policy 3.6.4.2.1 (Pediatric Candidate Recertification and Reassessment Schedule) at the time of listing. A completed Liver Status 1_A or 1B Justification Form must be received on UNet^{SM} for a candidate's original listing as a Status 1 A or 1B and each relisting as a Status 1 A or 1B. If a completed Liver Status 1 A or 1B Justification Form is not entered into UNet^{SM} when a candidate is registered as a Status 1 A or 1B, the candidate shall be reassigned to their most recent PELD or MELD score. A relisting request to continue a Status 1 A or 1B listing for the same candidate waiting on that specific transplant beyond 14 days accumulated time (excluding hepatoblastoma candidates that meet criteria (vi), and candidates listed with a metabolic disease as described in Policy 3.6.4.3) will result in a review of all local Status 1 A or 1B liver candidate listings.

All other pediatric liver transplant candidates on the Waiting List shall be assigned a mortality risk score calculated in accordance with the PELD (0-11 years) or MELD (12-17 years) scoring system. For each liver candidate registration, the listing transplant center shall enter data on the UNet^{SM} for the prognostic factors specified in Table 2 for pediatric

candidates <12 years or Table 1 for pediatric candidates 12-17 years. These data must be based on the most recent clinical information (e.g., laboratory test results and diagnosis) and include the dates of the laboratory tests.

Table 2
Pediatric End-Stage Liver Disease (PELD) Scoring System

Prognostic Factor	Regression Coefficient	*P Value*
Albumin (Log_e value)	**-0.687**	**0.0111**
Total Bilirubin (Log_e value)	**0.480**	**0.0004**
INR (Log_e value)	**1.857**	**<0.0001**
Growth Failure (<- 2SD)	**0.667**	**0.009**
Age (<1 Yr.)*	**0.436**	**0.11**

* Scores for candidates listed for liver transplantation before the candidate's first birthday continue to include the value assigned for age (<1 Year) until the candidate reaches the age of 24 months.

Using these prognostic factors and regression coefficients, UNet[SM] shall assign a PELD score for each candidate based on the following calculation:

PELD Score= 0.436 (Age (<1 YR.)) – 0.687 x Log_e (albumin g/dL) + 0. 480 x Log_e (total bilirubin mg/dL) + 1.857 x Log_e (INR) +0.667 (Growth failure (<- 2 Std. Deviations present))

Laboratory values less than 1.0 will be set to 1.0 for the purposes of the PELD score calculation. Growth failure will be calculated based on age and gender using the current CDC growth chart.
As an example, for a hypothetical candidate 6 months of age with growth failure (<- 2 standard deviations) who has a serum albumin concentration of 1.9 g/dL, a serum bilirubin concentration of 4.2 mg/dL and an INR value of 1.2, the risk score would be calculated as follows:
PELD Score = 0.436 – (0.687 x Log_e1.9) + (0.480 x Log_e 4.2) + (1.857 x Log_e 1.2) + 0.667 = 1.689

The PELD score for each liver transplant candidate derived from this calculation shall be rounded to the tenth decimal place and then multiplied by 10. The hypothetical candidate in the example described above, therefore, would be assigned a risk score of 17.

3.6.4.2.1 Pediatric Candidate Reassessment and Recertification Schedule. The appropriateness of the PELD or MELD score assigned to each candidate listing shall be re-assessed and recertified by the listing transplant center to the OPTN contractor in accordance with the following schedule:

Pediatric Candidate Reassessment and Recertification Schedule

Status 1A or 1B	Status recertification every 7 days.	Laboratory values must be no older than 48 hours.
PELD/MELD Score 25 or greater	Status recertification every 14 days.	Laboratory values must be no older than 72 hours.
Score < =24 but > 18	Status recertification every 1 month.	Laboratory values must be no older than 7 days.
Score <= 18 but >=11	Status recertification every 3 months.	Laboratory values must be no older than 14 days.

Score <= 10	Status recertification every 12 months.	Laboratory values must be no older than 30 days.

This reassessment and recertification must be based on the most recent clinical information (e.g., laboratory test results and diagnosis) including the dates of the laboratory tests. In order to recertify, laboratory values must not be older than the "age of laboratory values" specified in the chart above. In order to change a PELD/MELD score voluntarily, all laboratory values must be obtained within 48 hours. The OPTN contractor shall notify the listing transplant center of the need to reassess and recertify a candidate's PELD/MELD score within 48 hours of the applicable deadline indicated in the recertification schedule. If a candidate is not recertified in accordance with the schedule, the candidate shall be re-assigned to their previous lower PELD/MELD score. The candidate may remain at that previous lower score for the period allowed based upon the recertification schedule for the previous lower score, minus the time spent in the uncertified score. If the candidate remains uncertified past the recertification due date for the previous lower score, the candidate will be assigned a PELD score of 6. If a candidate has no previous lower PELD/MELD score, and is not recertified in accordance with the schedule, the candidate shall be reassigned to a PELD/MELD score of 6 or will remain at the uncertified PELD score if it is less than 6.

3.6.4.3 Pediatric Liver Transplant Candidates with Metabolic Diseases. A pediatric liver transplant candidate with a urea cycle disorder or organic acidema shall be assigned a PELD (less than 12 years old) or MELD (12-17 years old) score of 30. If the candidate does not receive a transplant within 30 days of being listed with a MELD/PELD of 30, then the candidate may be listed as a Status 1B. Candidates meeting these criteria will be listed in as a MELD/PELD of 30 and subsequent Status 1B without RRB review. Hospitalization is not a requirement for listing in Status 1B for these candidates. Candidates with other metabolic diseases may apply to the Regional Review Board for an appropriate PELD (less than 12 years old) or MELD (12-17 years old) score. Decisions by the Regional Review Boards in these cases shall be guided by standards developed jointly by the Liver/Intestinal Organ Transplantation and Pediatric Transplantation Committees. In such cases the requested score must receive prospective approval by the applicable RRB within twenty-one days after application; if approval is not given and the physician wishes to pursue the listing, then the physician and the RRB must meet by conference to review the case. If approval is not given within twenty-one days, the candidate's transplant physician may list the candidate at the higher PELD or MELD score, subject to automatic referral to the Liver and Intestinal Organ Transplantation Committee for review; this review by the Liver and Intestinal Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee for appropriate action in accordance with Appendix A of the Bylaws.

~~**3.6.4.4 Liver Transplant Candidates with Hepatocellular Carcinoma (HCC).** Candidates with Stage II HCC in accordance with the modified Tumor-Node-Metastasis (TNM) Staging Classification set forth in Table 3 that meet all of the medical criteria specified in (i) and (ii) may receive extra priority on the Waiting List as specified below. A candidate with an HCC tumor that is greater than or equal to 2 cm and less than or equal to 5cm or no more than 3 lesions, the largest being less than 3 cm in size (Stage T2 tumors as described in Table 3) may be registered at a MELD/PELD score equivalent to a 15% probability of candidate death within 3 months. The largest dimension of each tumor must be reported (i.e., 3.2cm x 5.1cm must be reported as 5.1cm).~~

(i) The candidate has undergone a thorough assessment to evaluate the number and size of tumors and to rule out any extrahepatic spread and/or macrovascular involvement (i.e., portal or hepatic veins). A pre-listing biopsy is not mandatory but the lesion must meet the following imaging criteria. The assessment of the candidate should include ultrasound of the candidate's liver, a computerized tomography (CT) or magnetic resonance imaging (MRI) scan of the abdomen that documents the tumors and a CT of the chest that rules out metastatic disease. In addition, the candidate must have at least one of the following: a vascular blush corresponding to the area of suspicion seen on the above imaging studies, an alpha-fetoprotein level of >200 ng/ml, an arteriogram confirming a tumor, a biopsy confirming HCC, chemoembolization of lesion, radio frequency, cryo, or chemical ablation of the lesion. The alpha-fetoprotein level is required for all HCC exception applications. Candidates with chronic liver disease who have a rising alpha-fetoprotein level ≥500 nanograms may be listed with a MELD/PELD score equivalent to an 8% mortality risk without RRB review even though there is no evidence of a tumor based on imaging studies.

(ii) The candidate is not a resection candidate.

Candidates will receive additional MELD/PELD points equivalent to a 10% 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% 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. Candidates meeting criteria based on an alpha-fetoprotein level of ≥ 500 nanograms, as specified in (i), must continue to demonstrate an ongoing rise in the alpha-fetoprotein level in order to extend the application.

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, will continue to receive additional MELD/PELD points (equivalent to a 10% 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.

A candidate not meeting the above criteria may continue to be considered a liver transplant candidate in accordance with each center's own specific policy or philosophy, but the candidate must be listed at the calculated MELD/PELD score with no additional priority given because of the HCC diagnosis. Candidates meeting all of the criteria in (i) and (ii) will receive a MELD/PELD score based on the tumor stage as described above without RRB review. All other candidates with HCC including

those with downsized tumors whose original/presenting tumor was greater than a Stage T2), must be referred to the applicable RRB for prospective review.

If the initial request is denied by the RRB, the center may appeal via a conference call with the RRB but the candidate will not receive the additional MELD/PELD priority until the case is approved by the RRB. Cases where the appropriate RRB has found the listing center to be out of compliance with Policy 3.6.4.4 will be referred to the Liver and Intestinal Organ Transplantation Committee for review and possible action. Cases not resolved within 21 days will be referred to the Liver and Intestinal Organ Transplantation Committee for review; this review by the Liver and Intestinal Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee for appropriate action in accordance with Appendix A of the Bylaws.

For those candidates who receive a liver transplant while receiving additional priority under the HCC criteria, the recipient's explant pathology report must be sent to the OPTN contractor. If the pathology report does not show evidence of HCC, the transplant center must also submit documentation and/or imaging studies confirming HCC at the time of listing. Additionally, if more than 10% of the HCC cases on an annual basis are not supported by pathologic confirmation or subsequent submission of clinical information, the center will be referred to the Liver and Intestinal Organ Transplantation Committee.

Table 3
American Liver Tumor Study Group Modified Tumor-Node-Metastasis (TNM) Staging Classification
(1)

Classification	Definition
TX, NX, MX	Not assessed
TO, NO, MO	Not found
T1	1 nodule <=1.9 cm
T2	One nodule 2.0-5.0 cm; two or three nodules, all <3.0 cm
T3	One nodule >5.0 cm; two or three nodules, at least one >3.0 cm
T4a	Four or more nodules, any size
T4b	T2, T3, or T4a plus gross intrahepatic portal or hepatic vein involvement as indicated by CT, MRI, or ultrasound
N1	Regional (portal hepatis) nodes, involved
	M1 Metastatic disease, including extrahepatic portal or hepatic vein involvement
Stage 1	T1
Stage II	T2
Stage III	T3
Stage IVA1	T4a
Stage IVA2	T4b
Stage IVB	Any N1, any M1

Reference

1. American Liver Tumor Study Group – A Randomized Prospective Multi-Institutional Trial of Orthotopic Liver Transplantation or Partial Hepatic Resection with or without Adjuvant Chemotherapy for Hepatocellular Carcinoma. Investigators Booklet and Protocol. 1998.

NOTE: Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)) is repealed and reenacted and shall be effective pending programming. (Approved at the November 14-15, 2011 Board of Directors Meeting.)

3.6.4.4 Liver Transplant Candidates with Hepatocellular Carcinoma (HCC). Candidates with stage T2 HCC that meet the staging and imaging criteria specified in sections A-E may receive extra priority on the Waiting List as specified below.

A. **Eligible Candidates**. A candidate with an HCC tumor that is stage T2 may be registered at a MELD/PELD score equivalent to a 15% probability of candidate death within 3 months if the criteria listed in sections B-D are also met. For the purposes of this policy, stage T2 lesions are defined as

- 1 lesion >= 2 cm and <= 5cm; OR
- 2 or 3 lesions, >= 1cm and <= 3cm in size.

The largest dimension of each tumor must be reported (i.e., 1.5cm x 2.5cm must be reported as 2.5cm). Nodules <1cm are indeterminate and cannot be considered for additional priority.

B. **Initial Assessment for Listing**. The candidate must have undergone a thorough assessment to evaluate the number and size of tumors and to rule out any extrahepatic spread (i.e. lymph node involvement) and/or macrovascular involvement (i.e., tumor thrombus in portal or hepatic vein) with dynamic contrast enhanced computed tomography (CT) or magnetic resonance imaging (MRI). The assessment of the candidate prior to transplant listing must include a CT of the chest that rules out metastatic disease. The candidate must not be eligible for resection. The alpha-fetoprotein level is required for all HCC exception applications.

C. **Requirements for Imaging**. Any imaging examination performed for the purpose of obtaining or updating priority points on the transplant waitlist should meet minimum recommended technical and imaging protocol requirements for CT and MRI listed in Table 4 and Table 5. These must be interpreted by a radiologist at an OPTN approved transplant center. Technically inadequate or incomplete imaging examinations must be classified as OPTN Class 0 and must be repeated or completed in order to be considered for priority point allocation.

D. **Definitions of OPTN Class 5 Nodules.** Nodules found on imaging of cirrhotic livers must be classified according to the OPTN classification shown in Table 6. OPTN class 5 nodules correspond to an imaging diagnosis of HCC and are as follows:

OPTN Class 5B nodules: The combination of the following imaging findings constitutes an OPTN class 5B nodule and qualifies for automatic MELD priority score (all 3 criteria must be met):

1. Single nodule diameter greater than or equal to 2cm and less than or equal to 5cm. Maximum diameter of lesion(s) should be measured on late arterial or portal phase images.

2. Increased contrast enhancement on late hepatic arterial images (relative to hepatic

parenchyma)

3. One of the following:

- **Washout** on portal venous/delayed phase
- **Late capsule or pseudocapsule enhancement** OR
- **Growth** (maximum diameter increase in the absence of ablative therapy) by 50% or more documented on serial MRI or CT obtained < 6 month apart. Serial imaging and measurements should be performed on corresponding contrast phases with the same modality preferred. ; OR
- **Biopsy**.

Growth criteria do not apply to previously ablated lesions. A pre-listing biopsy is not mandatory.

OPTN Class 5A nodules are defined as follows:

1. Single nodule, maximum diameter of >1 cm and <2cm. Maximum diameter of lesion(s) should be measured on late arterial or portal phase images.
2. Increased contrast enhancement on late arterial phase (relative to hepatic parenchyma)
3. Both of the following:
   - **Washout** during the later contrast phases **AND**
   - **Peripheral rim enhancement** (capsule/pseudocapsule) on delayed phase;

   OR

   - Biopsy

OPTN Class 5A-g (growth) are defined as follows (all criteria must be met):

- Single nodule, maximum diameter of >1 cm and <2cm. Maximum diameter of lesion(s) should be measured on late arterial or portal phase images.
- Increased contrast enhancement on late arterial phase (relative to hepatic parenchyma)
- Growth (maximum diameter increase) by 50% or more documented on serial MRI or CT obtained < 6 months apart. Growth criteria do not apply to ablated lesions.

  (i.e. a 1.2 cm hyper-enhancing nodule documented on first CT scan is found to be 1.8 cm on scan obtained 3 months later would be classified as 5A-g. This individual lesion is not eligible for MELD priority score as the tumor is still at stage T1 but if found in conjunction with a second 5A or 5A-g lesion, the patient would be eligible for an automatic MELD priority score.)

OPTN Class 5T (Treated) nodules are defined as any OPTN Class 5 or biopsy-proven HCC lesion that was automatically approved upon initial application or extension and has subsequently undergone loco-regional treatment. OPTN Class 5T nodules qualify for continued priority points predicated on the pre-treatment classification of the nodule(s) and are defined as:

1. Past loco-regional treatment for HCC (OPTN class 5 lesion or biopsy proven prior to ablation).
2. Evidence of persistent/recurrent HCC such as nodular or crescentic extra-zonal or intra-zonal enhancing tissue on late arterial imaging (relative to hepatic parenchyma) may be present.

OPTN Class 5X: Lesions that meet radiologic criteria for HCC but are outside stage T2 as defined in section A will be considered Class 5X and are not eligible for automatic exception points. These cases may be considered by the Regional Review Board (RRB) as described

in section G.

E. **HCC Lesions Eligible for Automatic Upgrade.** Individual Class 5B and 5T are eligible for automatic priority. A single OPTN Class 5A nodule corresponds to T1 stage hepatocellular carcinoma and does not qualify for automatic priority MELD points but must be considered towards the overall staging of the patient according to criteria listed above. **Combinations of Class 5A nodules** that meet stage T2 criteria as described in section (A) are eligible for automatic priority.

For example, a candidate would be eligible for additional priority with:

- Two 1.5 cm (5A) lesions; or
- One 1.5 cm lesion (5A) and one 2.5 cm lesion (5B); or
- One 3.5cm lesion (5B); or
- Two 2.1cm lesions (5B).

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.

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. **Candidates Not Meeting Criteria (Class 5X)**. A candidate not meeting the above criteria may continue to be considered a liver transplant candidate in accordance with each center's own specific policy or philosophy, but the candidate must be listed at the calculated MELD/PELD score with no additional priority given because of the HCC diagnosis. All such candidates with HCC,

including those with downsized tumors whose original/presenting tumor was greater than a stage T2, must be referred to the applicable RRB for prospective review in order to receive additional priority.

H. **Appeal Procedures for Candidates not Meeting Criteria**. If the initial request is denied by the RRB, the center may appeal via a conference call with the RRB but the candidate will not receive the additional MELD/PELD priority until the case is approved by the RRB. Cases where the appropriate RRB has found the listing center to be out of compliance with Policy 3.6.4.4 will be referred to the Liver and Intestinal Organ Transplantation Committee for review and possible action. Cases not resolved within 21 days will be referred to the Liver and Intestinal Organ Transplantation Committee for review; this review by the Liver and Intestinal Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee for appropriate action in accordance with Appendix A of the Bylaws.

I. **Compliance Monitoring**. Documentation of the radiologic characteristics of each OPTN class 5 nodule (for an example, see Tables 7A-C) must be kept on file at the transplant center. If growth criteria are used to classify a nodule as HCC, prior and current dates of imaging, type of imaging and measurements of the nodule(s) must be documented in the radiology report.

For those candidates who receive a liver transplant while receiving additional priority under the HCC criteria, the Post-Transplant Explant Pathology Form must be submitted to the OPTN contractor through UNet℠ within 60 days of the transplant procedure. If the pathology report does not show evidence of HCC, the transplant center must also submit documentation and/or imaging studies confirming HCC at the time of listing. Additionally, if more than 10% of the HCC cases on an annual basis are not supported by pathologic confirmation or subsequent submission of clinical information, the center will be referred to the Liver and Intestinal Organ Transplantation Committee.

NOTE: Policy 3.6.4.4 (Liver Transplant Candidates with Hepatocellular Carcinoma (HCC)) (Section I-Compliance Monitoring shall be effective pending OMB approval of the form and programming in UNet℠. (Approved at the March 13, 2012 Executive Committe.)

Appendices:

TABLE 4: RECOMMENDED Minimum technical requirements for CT

TABLE 5: RECOMMENDED Minimum technical requirements for MRI

TABLE 6: OPTN Classification of liver lesions (Classes 0 and 5)

TABLES 7A-C: Sample templates for centers to use when recording HCC findings for auditing purposes

Table 4: Recommended minimum technical specifications for dynamic contrast-enhanced CT of the liver

Feature	**Specification**	**Comment**
Scanner Type	*Multidetector row scanner*	
Detector Type	*Minimum of 8 detector rows*	*Need to be able to image entire liver during brief late arterial phase time window*
Reconstructed slice thickness	*Minimum of 5 mm reconstructed slice thickness*	*Thinner slices are preferable, especially if multiplanar reconstructions are performed*
Injector	*Power injector, preferably dual chamber injector with saline flush*	*Bolus tracking recommended*
Contrast injection rate	*3mL/sec minimum, better 4-6 mL/sec with minimum of 300 mg I/mL or higher, for dose of 1.5mL/kg body weight*	
Mandatory dynamic phases on contrast enhanced MDCT (comments describe typical hallmark image features)	*1) late arterial phase* *2) portal venous phase* *3) delayed phase*	*1) artery fully enhanced, beginning contrast enhancement of portal vein* *2) portal vein enhanced, peak liver parenchymal enhancement, beginning contrast enhancement of hepatic veins* *3) variable appearance, >120 sec after initial injection of contrast*
Dynamic Phases (Timing)	*Bolus tracking or timing bolus recommended for accurate timing*	

Table 5:

Recommended minimum technical specifications for dynamic contrast-enhanced MRI of the liver

Feature	Specification	Comment
Scanner Type	*1.5T Tesla or greater main magnetic field strength*	*low field magnets not suitable*
Coil Type	*phased array multichannel torso coil*	*unless patient-related factors precludes use (e.g. body habitus)*
Minimum sequences	*Pre-contrast and dynamic post gadolinium T1-weighted gradient echo sequence (3D preferable), T2 (with and without FAT SAT), T1w in and out of phase imaging*	
Injector	*dual chamber power injector*	*Bolus tracking recommended*
Contrast injection rate	*2-3 mL/sec of extracellular gadolinium chelate that does not have dominant biliary excretion*	*Preferably resulting in vendor-recommended total dose*
Mandatory dynamic phases on contrast enhanced MRI (comments describe typical hallmark image features)	*0)Pre-contrast T1W* *1) late arterial phase* *2) portal venous phase* *3) delayed phase*	*0) do not change scan parameters for post contrast imaging* *1) artery fully enhanced, beginning contrast enhancement of portal vein* *2) portal vein enhanced, peak liver parenchymal enhancement, beginning contrast enhancement of hepatic veins* *3) variable appearance, >120 sec after initial injection of contrast*
Dynamic Phases (Timing)	*The use of a bolus tracking method for timing contrast arrival for late arterial phase imaging is preferable. Portal venous phase (35-55 sec after initiation of late arterial phase scan), delayed phase (120-180sec after initial contrast injection)*	
Slice thickness	*5mm or less for dynamic series, 8mm or less for other imaging*	
Breath-holding	*max length of series requiring breathhold should be about 20sec. with a minimum matrix of 128 x 256*	*Compliance with breathhold instructions very important, technologists need to understand the importance of patient instruction before and during scan*

Table 6: OPTN classification system for nodules seen on imaging of cirrhotic livers

Class	Description	Comment
0	***Incomplete or technically inadequate study***	*Repeat study required for adequate assessment; automatic priority MELD points cannot be assigned based on a OPTN 0 classified imaging study*
5	***Meets radiologic criteria for HCC***	*May qualify for automatic exception depending on stage (see 3.6.4.4 section A.)*
	5A: > or equal to 1 cm and less 2 cm measured on late arterial or portal phase images.	*Increased contrast enhancement on late hepatic arterial phase AND washout during later contrast phases AND peripheral rim enhancement (capsule/pseudocapsule).*
	5A-g: same size as 5A	*Increased contrast enhancement on late hepatic arterial phase AND growth by 50% or more documented on serial CT/MRI obtained <or equal to 6 months apart.*
	5B: maximum diameter > or equal to 2cm and less than or equal to 5 cm.	*Increased contrast enhancement on late hepatic arterial phase AND either washout during later contrast phases OR peripheral rim enhancement (capsule/pseudocapsule) OR growth by 50% or more documented on serial CT/MRI obtained <or equal to 6 months apart (5B-g).*
	5T: prior local regional treatment for HCC	*Describes any residual lesion or perfusion defect at site of prior UNOS class 5 lesion.*
	5X: maximum diameter > or equal to 5 cm.	*Increased contrast enhancement on late hepatic arterial phase AND either washout during later contrast phases OR peripheral rim enhancement (capsule/pseudocapsule)*

For descriptions of Classes 1-4, which are not applicable to OPTN policy, please see http://www.acr.org/SecondaryMainMenuCategories/quality_safety/LI-RADS.aspx.

3.6.4.5 Liver Candidates with Exceptional Cases. Special cases require prospective review by the Regional Review Board. The center will request a specific MELD/PELD score and shall submit a supporting narrative. The Regional Review Board will accept or reject the center's requested MELD/PELD score based on guidelines developed by each RRB. Each RRB must set an acceptable time for Reviews to be completed, within twenty-one days after application; if approval is not given and the physician wishes to pursue the listing, then the physician and the RRB must meet by conference call to review the case. If approval is not given within twenty-one days, the candidate's transplant physician may list the candidate at the higher MELD or PELD score, subject to automatic referral to the Liver and Intestinal Organ Transplantation Committee for review; this review by the Liver and Intestinal Organ Transplantation Committee may result in further referral of the matter to the Membership and Professional Standards Committee for appropriate action in accordance with Appendix A of the Bylaws.

Exceptions to the MELD/PELD score must be reapplied every three months; otherwise the candidate's score will revert back to the candidate's current calculated MELD/PELD score. If the RRB does not recertify the MELD/PELD score exception, then the candidate will be assigned a MELD/PELD score based on current laboratory values. Centers may apply for a MELD/PELD score equivalent to a 10% increase in candidate mortality every 3 months as long as the candidate meets the original criteria. Extensions shall undergo prospective review by the RRB. A candidate's approved score will be maintained if the center enters the extension application more than 3 days prior to the due date and the RRB does not act prior to that date (i.e., the candidate will not be downgraded if the RRB does not act in a timely manner). If the extension application is subsequently denied then the candidate will be assigned the laboratory MELD score. Candidates meeting the criteria listed in 3.6.4.5.1 – 3.6.4.5.6 are eligible for additional MELD/PELD exception points, provided that the criteria are included in the clinical narrative. Unless the applicable RRB has a pre-existing agreement for a higher point assignment for these diagnoses, an initial MELD score of 22/ PELD score of 28 shall be assigned. For candidates with Primary Hyperoxaluria meeting the criteria in 3.6.4.5.5, an initial MELD score of 28/ PELD score of 41 shall be assigned. These pre-existing agreements must be renewed on an annual basis.

3.6.4.5.1Liver Candidates with Hepatopulmonary Syndrome (HPS). Candidates with a clinical evidence of portal hypertension, evidence of a shunt, and a PaO_2 < 60 mmHg on room air will be listed at a MELD score of 22 without RRB review with a 10% mortality equivalent increase in points every three months if the candidate's PaO_2 stays below 60 mmHg. Candidates should have no significant clinical evidence of underlying primary pulmonary disease.

3.6.4.5.2 Liver Candidates with Cholangiocarcinoma. Candidates meeting the criteria listed in Table 8 will be eligible for a MELD/PELD exception with a 10% mortality equivalent increase every three months.

3.6.4.5.3 Liver Candidates with Cystic Fibrosis. Liver candidates with signs of reduced pulmonary function, defined as having an FEV_1 that falls below 40%,will be eligible for a MELD/PELD exception with a 10% mortality equivalent increase every three months.

3.6.4.5.4 Liver Candidates with Familial Amyloid Polyneuropathy (FAP). Candidates with a clear diagnosis, to include an echocardiogram showing the candidate has an ejection fraction > 40%, ambulatory status, and identification of TTR gene mutation (Val30Met vs. non-Val30Met) and a biopsy proven amyloid in the involved organ, will be eligible for a MELD/PELD exception with a 10% mortality equivalent increase every three months.

3.6.4.5.5 Liver Candidates with Primary Hyperoxaluria. Candidates with AGT deficiency proven by liver biopsy (sample analysis and/or genetic analysis), and listed for a combined liver-kidney transplant will be eligible for a MELD/PELD exception with a 10% mortality equivalent increase every three months. Candidates must have a GFR<= 25 ml/min for 6 weeks or more by MDRD6 or direct measurement (Iothalamate or iohexol).

3.6.4.5.6 Liver Candidates with Portopulmonary Syndrome. Candidates that meet the following criteria will be eligible for a MELD/PELD exception with a 10% mortality equivalent increase every three months if the mean pulmonary arterial pressure (MPAP) stays below 35 mmHg (confirmed by repeat heart catheterization).

- Diagnosis should include initial MPAP and pulmonary vascular resistance (PVR) levels, documentation of treatment, and post-treatment MPAP < 35 mmHg and PVR < 400 dynes/sec/cm^{-5}.

- Transpulmonary gradient should be required for initial diagnosis to correct for volume overload.

TABLE 8. Criteria for MELD Exception for Liver Transplant Candidates With Cholangiocarcinoma (CCA)

- Centers must submit a written protocol for patient care to the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee before requesting a MELD score exception for a candidate with CCA. This protocol should include selection criteria, administration of neoadjuvant therapy before transplantation, and operative staging to exclude patients with regional hepatic lymph node metastases, intrahepatic metastases, and/or extrahepatic disease. The protocol should include data collection as deemed necessary by the OPTN/UNOS Liver and Intestinal Organ Transplantation Committee.
- Candidates must satisfy diagnostic criteria for hilar CCA: malignant-appearing stricture on cholangiography and one of the following: carbohydrate antigen 19-9 100 U/mL, or and biopsy or cytology results demonstrating malignancy, or aneuploidy. The tumor should be considered unresectable on the basis of technical considerations or underlying liver disease (e.g., primary sclerosing cholangitis).
- If cross-sectional imaging studies (CT scan, ultrasound, MRI) demonstrate a mass, the mass should be 3 cm or less.
- Candidates must satisfy diagnostic criteria for hilar CCA: malignant-appearing stricture on cholangiography and biopsy or cytology results demonstrating malignancy, carbohydrate antigen 19-9 100 U/mL, or aneuploidy. The tumor should be considered unresectable on the basis of technical considerations or underlying liver disease (e.g., primary sclerosing cholangitis).
- If cross-sectional imaging studies (CT scan, ultrasound, MRI) demonstrate a mass, the mass should be 3 cm.
- Intra- and extrahepatic metastases should be excluded by cross-sectional imaging studies of the chest and abdomen at the time of initial exception and every 3 months before score increases.
- Regional hepatic lymph node involvement and peritoneal metastases should be assessed by operative staging after completion of neoadjuvant therapy and before liver transplantation. Endoscopic ultrasound-guided aspiration of regional hepatic lymph nodes may be advisable to exclude patients with obvious metastases before neoadjuvant therapy is initiated.
- Transperitoneal aspiration or biopsy of the primary tumor (either by endoscopic ultrasound, operative, or percutaneous approaches) should be avoided because of the high risk of tumor seeding associated with these procedures.

3.6.4.6 On-Site Review of Status 1A and 1B Candidate Listings. If a transplant center's listing of candidates as Status 1A and 1B has been disapproved on 3 occasions at the final review of the applicable regional review board, and the candidates receive a transplant while listed at the disapproved status, then the OPTN contractor shall conduct an on-site review of that center's Status 1A and 1B candidate listings. The listing center shall reimburse all necessary and reasonable expenses incurred by the contractor in performing this on-site review. If there are no policy violations and the disapproved listings are found to be appropriate, the center will not be responsible for the necessary and reasonable expenses incurred by the contractor while performing the on-site review.

3.6.4.7 Combined Liver-Intestine Candidates. Candidates awaiting a combined liver-intestine transplant who are registered and active on both waiting lists will automatically receive an additional increase in their MELD/PELD score equivalent to a 10% risk of 3-month mortality. Candidates age 0-17 will receive a 23 point increase in their calculated MELD/PELD score instead of the 10% increase. The center must verify that an intestinal transplant is required and took place.

3.6.4.8 Combined Liver-Intestine Allocation. For combined liver-intestine allocation, the liver must first be offered:

- according to the liver match run
- sequentially to **each** potential liver recipient (including all MELD/PELD potential recipients) through national Status 1A and 1B offers.

The liver may then be offered to combined liver-intestine potential recipients sequentially according to the intestine match run.

3.6.5 Center Contact and Acceptance. Livers shall be offered in descending computer print-out order but the offering calls may be made concurrently (e.g., 5 liver teams may be called and given donor information provided that each team is told its priority number for the liver offer). Policy 3.4.1 (Time Limit for Acceptance) assures that each team will know within one hour whether or not another center with a candidate who has higher points has accepted or rejected the offer.

3.6.5.1 Execution of the Liver Match System. The Match System for liver allocation shall be executed within 8 hours prior to the initial liver offer. This match system printout of the liver transplant candidate waiting list shall be utilized by the Host OPO for placement of the donor liver. The liver match system may be re-executed if a previously accepted liver is subsequently turned down because there is a change in specific medical information related to the liver donor. Any re-execution of the liver match system for the same donor for other reasons must be retrospectively reviewed by the Regional Review Board. This policy shall not apply to a donor liver that has been recovered and has not been placed within 2 hours of organ recovery.

3.6.6 Removal of Liver Transplant Candidates from Liver Waiting Lists When Transplanted or Deceased. If a liver transplant candidate on the Waiting List has received a transplant from a deceased or living donor, or has died while awaiting a transplant, the listing center, or centers if the candidate is multiple listed, shall immediately remove that candidate from all liver waiting lists and shall notify the contractor within 24 hours of the event. If the deceased or living donor liver recipient is again added to a liver waiting list, waiting time shall begin as of the date and time the candidate is relisted. Data necessary to calculate the candidate's current MELD or PELD score is required upon removal from the waiting list.

3.6.7 Organ Center Assistance with Liver Allocation. It is recommended that the Organ Center be notified when a liver donor is identified and provided all clinical information that is necessary to offer the liver to potential recipients on the Waiting List. Upon request by the OPO, the Organ Center shall attempt to locate a liver recipient on the Waiting List or identify backup recipients for the liver.

3.6.8 Local Conflicts. Regarding allocation of livers, locally unresolvable inequities or conflicts that arise from prevailing OPO policies may be submitted by any interested local member for review and adjudication to the Liver and Intestinal

Organ Transplantation Committee and Board of Directors.

3.6.9 Minimum Information for Liver Offers.

3.6.9.1 Essential Information Category. When the Host OPO or donor center provides the following donor information, with the exception of pending serologies, to a recipient center, the recipient center must respond to the offer within one hour pursuant to Policy 3.4.1 (Time Limit for Acceptance); however, this requirement does not preclude the Host OPO from notifying a recipient center prior to this information being available:

(i) Donor name and Donor I.D. number, age, sex, race, height and weight;
(ii) ABO type;
(iii) ABO subtype when used for allocation;
(iv) Cause of brain death/diagnosis;
(v) History of treatment in hospital including current medications, vasopressors and hydration;
(vi) Current history of hypotensive episodes, urine output and oliguria;
(vii) Indications of sepsis;
(viii) Social and drug activity histories;
(ix) Vital signs including blood pressure, heart rate and temperature;
(x) Other laboratory tests within the past 12 hours including:
  (1) Total Bilirubin
  (2) ALT
  (3) INR (PT if INR not available)
  (4) Alkaline phosphatase
  (5) WBC
  (6) HH
  (7) Creatinine;
(xi) Arterial blood gas results;
(xii) Serologies as indicated in 2.2.4.1 (qualified specimens preferred as noted in Policy 2.2.3.1).

3.6.9.2 Listing Accuracy and Appropriateness. Any instance in which an organ is allocated to a recipient center for a transplant candidate and the Host OPO or any Member questions the accuracy or appropriateness of the candidate's status may be reported retrospectively to the Host OPO's Regional Review Board with reasons for the concern. Upon receipt of two such reports regarding cases from the same institution within a one-year period, the Review Board shall refer the matter to the Membership and Professional Standards Committee with a request for an on-site audit of the institution.

3.6.10 Allocation of Livers for Other Methods of Hepatic Support. A liver shall not be utilized for other methods of hepatic support prior to being offered first for transplantation. Prior to being utilized for other methods of hepatic support, the liver shall be offered by the Organ Center in descending point order to all Status 1 A and 1B candidates, followed by all candidates in order of their MELD/PELD scores (probability of candidate death) in the Host OPO's region followed by Status 1 A and 1B candidates, and then by all candidates in order of the MELD PELD scores (probability of candidate death) in all other regions. If the liver is not accepted for transplantation within 6 hours of attempted placement by the Organ Center, the Organ Center shall offer the liver to Status 1 A and 1B, followed by all candidates in order of their MELD/PELD scores (probability of candidate death) for whom the liver will be considered for other methods of hepatic support. Livers allocated for other methods of hepatic support shall be offered first locally, then regionally, and then nationally in descending point order

to transplant candidates designated for other methods of hepatic support.

3.6.11 Allocation of Livers for Segmental Transplantation. A transplant center that accepts a liver for segmental transplantation shall offer the remaining segment:

(i) in sequence, as determined by the deceased donor liver allocation algorithm set forth in Policy 3.6 (Allocation of Livers) and defining "local" based upon the Host OPO's local area, to the highest-ranking candidate on the waiting list of candidates; provided, however, that the Host OPO places the liver segment(s) by the time the donor organ procurement procedure has started, or

(ii) into candidates listed with the recipient program or any medically appropriate candidate on the Waiting List, if, after reasonable attempts by the Host OPO to place the remaining portion(s) of the donor liver, the liver segment(s) is not placed by the time the donor organ procurement procedure has started.

Donors less than 40 years of age, on a single vasopressor or less, transaminases no greater than 3 times normal, BMI of 28 or less, would be identified on every OPO match run as potential splittable donors, concurrently the match run will identify regional recipients willing to accept a segmental graft. The center getting the primary whole graft organ offer will determine the method of splitting and use of the vessels.

3.6.12 Committee-sponsored Alternative Allocation System (CAS) for Segmental Liver Transplantation. Under this CAS, livers must be offered in sequence, as determined by the deceased donor liver allocation algorithm set forth in Policy 3.6 (Allocation of Livers). If a liver is accepted for a potential recipient who is medically suitable for segmental liver transplantation, the center may choose to transplant the right lobe/right trisegment into that individual. The transplant center may then transplant the left lobe/left-lateral segment into a medically suitable potential recipient listed at their center or an affiliated pediatric institution (if applicable). The potential recipient of the left lobe/left-lateral segment must be determined by following the same match run used to allocate the liver (right lobe/trisegment), documenting all refusals.

This CAS will only apply when the potential recipient receives the right lobe/right trisegment of the liver. If the potential recipient receives the left lobe/left lateral segment of the liver, then the right lobe/right trisegment of the liver must be allocated as per policy 3.6.11 (Allocation of Livers for Segmental Transplantation).

Each participating Region or DSA will meet to review the results of the first 10 segmental liver transplants performed as a result of this CAS, and each 10 thereafter. If the re-transplant rate for segmental liver transplant recipients at any liver transplant program participating in the CAS exceeds 3 of 20 grafts, an automatic hold will be placed on the procedure at that program until the results and surgical practices can be reviewed by the transplant program.

3.6.13 Histocompatibility Testing for Liver Transplantation. The transplant program and its histocompatibility laboratory must have a joint written policy on HLA typing, antibody screening, and crossmatching. Guidelines for policy development, including assigning risk and timing of crossmatch testing, are set out in Appendix D of Policy 3.