Current Liver Allocation Policies*

Policy 3.6 Organ Distribution

3.6 Allocation of Livers. Unless otherwise approved according to Policies 3.1.7 (Local and Alternative Local Unit), 3.1.8 (Sharing Arrangement and Sharing Agreement), 3.1.9 (Alternate Point Assignments [Variances]), and Policy 3.4.6 (Application, Review, Dissolution, and Modification Processes for Alternative Organ Distribution or Allocation Systems), the allocation of livers according to the following point system is mandatory first locally, then regionally, and then nationally. Each patient will be assigned a status code corresponding to the degree of medical urgency as described in Policy 3.6.4 below. Each patient also will be assigned points for conditions as described in Policies 3.3.5, 3.6.2, 3.6.3, and 3.6.4.

Livers will be offered for patients with an assigned status of 1 in descending point sequence with the patient having the highest number of points receiving the highest priority before being offered for patients listed in other status categories. Following Status 1, livers will be offered for patients with an assigned status of 2A in descending point sequence with the patient having the highest number of points receiving the highest priority before being offered for patients listed in less urgent statuses.

Following Status 2A, livers will be offered for patients with an assigned status of 2B in descending point sequence with the patient having the highest number of points receiving the highest priority. Following Status 2B, livers will be offered for patients with an assigned status of 3 in descending point sequence with the patient having the highest number of points receiving the highest priority.

^{*}United Network for Organ Sharing (UNOS). 1999 Policies. Available at http://www.unos.org/About/policy_policies3.6.htm (accessed April 16, 1999).

Livers will not be offered to patients with a status of 7. Livers will be allocated in the following sequence:

Local

- 1. Status 1 patients in descending point order
- 2. Status 2A patients in descending point order
- 3. Status 2B patients in descending point order
- 4. Status 3 patients in descending point order

Regional

- 1. Status 1 patients in descending point order
- 2. Status 2A patients in descending point order
- 3. Status 2B patients in descending point order
- 4. Status 3 patients in descending point order

National

- 1. Status 1 patients in descending point order
- 2. Status 2A patients in descending point order
- 3. Status 2B patients in descending point order
- 4. Status 3 patients in descending point order

The liver must be transplanted into the original designee or be released back to the donor center or to the UNOS Organ Center for distribution. The final decision whether to use the organ will remain the prerogative of the transplant surgeon and/or physician responsible for the care of that patient. This will allow physicians and surgeons to exercise judgment about the suitability of the organ being offered for their specific patients; 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 an organ is declined for a patient, a notation of the reason for the decision not to accept the liver for that patient must be made on the appropriate UNOS form and promptly submitted to UNOS.

Amended UNOS Policy 3.6—Allocation of Livers (Approved by the UNOS Board of Directors on June 24, 1999 and will be implemented immediately following programming modifications to the UNOS computer system)

3.6 Allocation of Livers. Unless otherwise approved according to Policies 3.1.7 (Local and Alternative Local Unit), 3.1.8 (Sharing Arrangement and Sharing Agreement), 3.1.9 (Alternate Point Assignments [Variances]), and Policy 3.4.6 (Application, Review, Dissolution, and Modification Processes for Alternative Organ Distribution or Allocation Systems), the allocation of livers according to the following point system is mandatory first locally, then regionally, and then nationally. Each patient will be assigned a status code corresponding to the degree of medical urgency as described in Policy 3.6.4 below. Each patient also will be assigned points for conditions as described in Policies 3.3.5, 3.6.2, 3.6.3, and 3.6.4.

Livers will be offered for patients with an assigned status of 1 in descending point sequence with the patient having the highest number of points receiving the highest priority before being offered for patients listed in other status categories. Following Status 1, livers will be offered for patients with an assigned status of 2A in descending point sequence with the patient having the highest number of points receiving the highest priority before being offered for patients listed in less urgent statuses.

Following Status 2A, livers will be offered for patients with an assigned status of 2B in descending point sequence with the patient having the highest number of points receiving the highest priority. Following Status 2B, livers will be offered for patients with an assigned status of 3 in descending point sequence with the patient having the highest number of points receiving the highest priority. Livers will not be offered to patients with a status of 7. Livers will be allocated in the following sequence:

Local

- 1. Status 1 patients in descending point order
- 2. Status 2A patients in descending point order
- 3. Status 2B patients in descending point order
- 4. Status 3 patients in descending point order

Regional

- 42. Status 1 patients in descending point order
- 2. Status 2A patients in descending point order
- 3. Status 2B patients in descending point order
- 4. Status 3 patients in descending point order

Local

- 3. Status 2A patients in descending point order
- 4. Status 2B patients in descending point order
- 5. Status 3 patients in descending point order

[Continued]

Regional

- 6. Status 2A patients in descending point order
- 7. Status 2B patients in descending point order
- 8. Status 3 patients in descending point order

National

- 4 9. Status 1 patients in descending point order
- 2 10. Status 2A patients in descending point order
- 3 11. Status 2B patients in descending point order
- 4 12. Status 3 patients in descending point order

(NO FURTHER CHANGES TO TEXT OF UNOS POLICY 3.6)

- **3.6.1 Preliminary Stratification**. For every potential liver recipient, the acceptable donor size must be determined by the responsible surgeon. The UNOS Match System will consider only potential liver recipients who are an acceptable size for that particular donor liver.
- **3.6.2 Blood Type Similarity Points**. Except as specified in Policy 3.6.2.1 and 3.6.2.2, transplant candidates 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 an A_2 blood type donor shall receive 5 points for ABO incompatible matching.
 - **3.6.2.1 Blood Type O Liver Allocation**. Blood type O livers shall not be transplanted into Statues 2B or 3 candidates who are not a blood type O.
 - **3.6.2.2** Liver Allocation to Candidates Registered Under Blood Type 'Z'. The blood type 'Z' designation may be added as a suffix to a candidate's actual blood type, (e.g., 'AZ') only for Status 1 candidates, or Status 2A candidates, who will accept a liver from a donor of any blood type. Liver candidates registered under blood type Z shall receive 0 points for ABO incompatible matching.
- **3.6.3 Time Waiting**. The 'time of waiting' begins when a patient is initially placed on the UNOS Patient Waiting List. Ten points will be accrued by the patient waiting for the longest period for a liver transplant and proportionately fewer points will be accrued by those patients 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 $(75/75 \times 10)$. A person whose rank order was 60 would accrue 2 points. $(75-60/75 \times 10 = 2)$

3.6.3.1 Statuses 1 and 2A Liver Patients. Time of waiting will be calculated for Status 1 and Status 2A liver patients from the time the patient is listed as a Status 1 or 2A and will only include time listed as a Status 1 or 2A.

3.6.3.2 Waiting Time for Liver Transplant Candidates in an Inactive Status. Patients shall be allowed to accrue an aggregate of 30 days inactive status waiting time. A patient's waiting time accrued during each occurrence of inactivation shall be calculated on a cumulative basis so that once the 30-day aggregate limit is reached no additional waiting time shall accrue on further occurrences of inactivation.

3.6.4 Degree of Medical Urgency. Each patient is assigned a status code which corresponds to how medically urgent it is that the patient receive a transplant.

3.6.4.1 Adult Patient Status. Medical urgency is assigned to an adult liver transplant patient (greater than or equal to 18 years of age) based on the criteria set forth in Table 1 and defined as follows. A patient who does not meet the criteria for a particular status may nevertheless be assigned to such status upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the patient is considered, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other patients in this status as defined below. The justification must include a rationale for incorporating the exceptional case as part of the criteria. A report of the decision of the Regional Review Board and the basis for it shall be forwarded to UNOS 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 patient status criteria.

Status	Definitions
7	A patient listed as Status 7 is temporarily inactive; however, the patient continues accruing waiting time up to a maximum of 30 days. UNOS staff will confirm the inactive status at the end of 30 days. Patients who are considered to be temporarily unsuitable transplant patients are listed as Status 7, temporarily inactive.
3	A patient listed as Status 3 requires continuous medical care and has a Child-Turcotte-Pugh (CTP) score greater than or equal to 7. Status 3 patients may be followed at home or near the transplant center. Short hospitalizations for intercurrent problems are not considered justifications for a change in status.
2B	A patient listed as Status 2B has a CTP score greater than or equal to 10, or a CTP score greater than or equal to 7 and meets at least one of the following medical criteria: [Continued]

- (i) Document unresponsive active variceal hemorrhage; Endoscopically confirmed variceal hemorrhage requiring at least two units of red blood cell replacement which continues or recurs after a series of endoscopic sclerotherapy/banding treatments to ablate the varices, or endoscopically confirmed portal hypertensive gastropathy requiring at least two units of red blood cell replacement which continues or recurs. For either variceal or gastropathy hemorrhage, transjugular intrahepatic portosystemic shunt placement (TIPS), or other surgical shunt, must be either contraindicated or failed to control the bleeding.
- (ii) Hepatorenal syndrome; The presence of progressive deterioration of renal function in a patient with advanced liver disease requiring hospitalization for management, with no other known etiology of renal insufficiency, and a rising serum creatinine of 1.5 mg/dl. In addition to these major criteria, the patient should meet at least one of the following: a) urine volume < 500 ml/d; b) urine sodium < 10 mEq/ml; or c) urine osmolality > plasma osmolality (U/P ratio > 1.0).
- (iii) Spontaneous bacterial peritonitis; The occurrence of a single episode of spontaneous bacterial peritonitis documented by at least one of the following: a) a positive culture of ascitic fluid for bacteria; b) a gram stain of ascitic fluid positive for the presence of bacteria; or c) any polymorphonuclear cells per milliliter, or a total of 500 white blood cells per milliliter.
- (iv) Refractory-Ascites/Hepato-Hydrothorax; Severe persistent ascites or hepato-hydrothorax unresponsive to diuretic and salt restriction therapy and requiring either large volume paracenteses of at least 4 liters, or for respiratory distress, more frequently than every 2 weeks with a contraindication or failure of a TIPS procedure to control ascites.

A completed Liver Status 2B Justification Form must be received by UNOS within one working day of a patient's listing as a Status 2B. If a completed Liver Status 2B Justification Form is not received by UNOS within one working day of a patient's listing as a Status 2B, the patient shall be re-assigned to a Status 3. The appropriateness of each Status 2B patient listing shall be re-assessed by the listing transplant center at 6 months from the date the patient is initially listed as a Status 2B and every 6 months thereafter. This reassessment must be based on clinical information (e.g., laboratory test results and diagnosis) that is obtained within the prior 30 days. A completed Liver Status 2B Justification Form must be received by UNOS 6 months from the date the patient is initially listed as a Status 2B and every 6 months thereafter for the duration of the patient's listing as a Status 2B. UNOS shall notify the listing transplant center of the need to reassess a Status 2B patient 30 days prior to the 6-month deadline. If a completed Liver Status 2B Justification Form is not received by UNOS 6 months from the date the

patient is initially listed as a Status 2B and every 6 months thereafter, the patient shall be re-assigned to a Status 3.

Status	Definitions
2A	Status 2A provides a transition for currently listed adult patients with chronic liver disease who may have qualified for Status 1, as this category was defined prior to July 4, 1997, and an opportunity to assess the usefulness of such a category when monitored by UNOS Regional Review Boards. An upgrade to Status 2A shall be reviewed by the applicable UNOS Regional Review Board and is intended for the exceptional patient with chronic liver disease who meets the criteria for Status 2B and whose clinical condition acutely deteriorates as defined by the following criteria. A patient listed as Status 2A is in the hospital's critical care unit due to chronic liver failure with a life expectancy without a liver transplant of less than 7 days, and with a long-term prognosis with a successful liver transplant equivalent to that of a patient with fulminant liver failure. The patient also has a CTP score greater than or equal to 10 and meets at least one of the following
(i)	medical criteria: Documented unresponsive active variceal hemorrhage; Endoscopically confirmed variceal hemorrhage requiring at least two units of red blood cell replacement which continues or recurs after a series of endoscopic sclerotherapy/banding treatments to ablate the varices, or endoscopically confirmed portal hypertensive gastropathy requiring at least two units of red blood cell replacement which continues or recurs. For either variceal or gastropathy hemorrhage, transjugular intrahepatic portosystemic shunt placement (TIPS), or other surgical shunt, must be either contraindicated or failed to
(ii	control the bleeding. Hepatorenal syndrome; The presence of progressive deterioration of renal function in a patient with advanced liver disease requiring hospitalization for management, with no other known etiology of renal insufficiency, and a rising serum creatinine of 1.5 mg/dl. In addition to these major criteria, the patient should meet at least one of the following: a) urine volume < 500 ml/d; b) urine sodium < 10 mEq/ml; or c) urine osmolality > plasma osmolality (U/P ratio > 1.0).
(ii	,

Stage III or IV encephalopathy unresponsive to medical therapy; A patient shall not be listed as Status 2A if the patient meets at lest

one of the following medical criteria:

(iv)

[Continued]

- (i) Extrahepatic sepsis unresponsive to antimicrobial therapy;
- (ii) Requirement for high-dose, or 2 or more pressors to maintain adequate blood pressure;
- (iii) Severe irreversible multi-organ system failure.

Patients who are listed as a Status 2A automatically revert back to Status 2B after 7 days unless these patients are relisted as Status 2A by an attending physician. A completed Liver Status 2A Justification Form must be received by UNOS within 24 hours of a patient's original listing as a Status 2A and each relisting as a Status 2A. If a completed Liver Status 2A Justification Form is not received by UNOS within 24 hours of the Status 2A liver candidate registration on the waiting list, the candidate shall be reassigned to a Status 2B. A relisting request to continue a Status 2A listing for the same patient waiting on that specific transplant beyond 14 days accumulated time will result in an onsite review of all local Status 2 liver patient listings.

Status		Definitions
1		A patient greater than or equal to 18 years of age listed as Status 1 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:
	(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. While no single clinical observation or laboratory test defines fulminant hepatic failure, the diagnosis is based on the finding of stage II encephalopathy (i.e., drowsiness, inappropriate behavior, incontinence with asterixis) in a patient with severe liver dysfunction. Evidence of severe liver dysfunction may be manifest by some or all of the following symptoms and signs: asterixis (flapping tremor), hyperbilirubinemia (i.e., bilirubin > 15 mg%), marked prolongation of the prothrombin time (i.e., > 20 sec or INR > 2.5), or hypoglycemia.; or
	(ii)	Primary non-function of a transplanted liver within 7 days of implantation; or
	(iii)	Hepatic artery thrombosis in a transplanted liver within 7 days of implantation; or
	(iv)	Acute decompensated Wilson's disease.

Patients who are listed as a Status 1 automatically revert back to Status 2B after 7 days unless these patients are relisted as Status 1 by an attending physician. A patient listed as Status 1 shall be reviewed by the applicable UNOS Regional Review Board. A completed Liver Status 1 Justification Form must be received by UNOS within 24 hours of a patient's original listing as a Status 1 and each relisting as a Status 1. If a

completed Liver Status 1 Justification Form is not received by UNOS within 24 hours of the Status 1 liver candidate registration on the waiting list, the candidate shall be reassigned to a Status 2B. A relisting request to continue a Status 1 listing for the same patient waiting on that specific transplant beyond 14 days accumulated time will result in an on-site review of all local Status 2 and 1 liver patient listings.

TABLE C-1 Child-Turcotte-Pugh (CTP) Scoring Systems to Assess Severity of Liver Disease

Points	1	2	
Encephalopathy	None	1–2	3–4
Ascites	Absent	Slight (or con- trolled by diu- retics)	At least moderate despite diuretic treatment
Bilirubin (mg/dl)	<2	2–3	>3
Albumin ((g/dl)	<3.5	2.8-3.5	< 2.8
Prothrombin time (secs. Prolonged)	<4	4-6	>6
Or (INR)	<1.7	1.7-2.3	>2.3
For primary biliary cirrhosis, primary sclerosing cholan- gitis, or other cho- lestatic liver dis- ease: Bilirubin (mg/dl)*	<4	4–10	>10

^{*}For cholestatic liver diseases, these values for bilirubin are to be substituted for the values above.

3.6.4.2 Pediatric Patient Status. Medical urgency is assigned to a pediatric liver transplant patient (less than 18 years of age) based on the criteria defined as follows, including criteria set forth in Appendix 3B. A patient who does not meet the criteria for a particular status may nevertheless be assigned to such status upon application by his/her transplant physician(s) and justification to the applicable Regional Review Board that the patient is considered, using accepted medical criteria, to have an urgency and potential for benefit comparable to that of other patients in this status as defined below. The justification must include a rationale for incorporating the exceptional case as part of the criteria. A report of the decision of the Regional Review Board and the basis for it shall be forwarded to UNOS 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 patient status criteria.

Status	Definitions		
7		A pediatric patient listed as Status 7 is temporarily inactive; however, the patient continues accruing waiting time up to a maximum of 30 days. UNOS staff will confirm the inactive status at the end of 30 days. Patients who are considered to be temporarily unsuitable transplant patients are listed as Status 7, temporarily inactive.	
3		A pediatric patient listed as Status 3 has met the inclusion criteria to be listed for pediatric liver transplantation as set forth in Appendix 3B, and requires continuous medical care. Status 3 patients may be followed at home or near the transplant center. Short hospitalizations for intercurrent problems are not considered justification for a change in status.	
2B		cation for a change in status. A pediatric patient listed as Status 2B meets at least one of the following medical criteria:	
	(i)	Documented, unresponsive upper gastrointestinal bleeding requiring transfusion of at least 10 cc/kg of red blood cells.	
	(ii)	Hepatorenal syndrome; The presence of progressive deterioration of renal function in a patient with advanced liver disease requiring hospitalization for management, with no other known etiology of renal insufficiency, and a rising serum creatinine 3 times baseline. In addition to these major criteria, the patient should meet at least one of the following: a) urine volume < 10 ml/kg/d; b) urine sodium < 10 mEq/l; or c) urine osmolality > plasma osmolality (U/P ratio > 1.0).	
	(iii)	Spontaneous bacterial peritonitis; The occurrence of a single episode of spontaneous bacterial peritonitis documented by at least one of the following: a) a positive culture of ascitic fluid for bacteria; b) a gram stain of ascitic fluid positive for the presence of bacteria; or c) an ascitic fluid white blood cell count with greater than 300 polymorphonuclear cells per milliliter, or a total of 500 white blood cells per milliliter.	
	(iv)	Refractory Ascites/Hepato-Hydrothorax; Severe persistent ascites or hepatohydrothorax defined as any one of the following: unresponsive to diuretic and salt restriction therapy leading to respiratory distress, or requiring supplemental tube feeding, or requiring parenteral nutrition, or requiring paracenteses.	
	(v)	Recurrent cholangitis defined as 2 or more episodes in 6 months requiring hospitalization and intravenous antibiotics.	
	(vi)	Growth failure, that is < 5th percentile for weight and/or height, or loss of 1.5 standard deviations score of expected growth (height or weight) based on the National Institute of Health Statistics for pediatric growth curves and requiring initiation of parenteral nutritional support, or nasogastric feedings to supply a minimum of 30 percent of caloric needs.	
	(vii)	A patient who meets at least 3 of the 5 following criteria: 1) ascites requiring diuretic therapy 2) bilirubin > 4 mg/dl 3) albumin < 3 g/dl (4) INR > 1.7 (5) malnutrition defined as loss of 1 standard deviation score of expected growth.	

A completed Liver Status 2B Justification Form must be received by UNOS within one working day of a pediatric patient's listing as a Status 2B. If a completed Liver Status 2B Justification Form is not received by UNOS within one working day of a patient's listing as a Status 2B, the patient shall be re-assigned to a Status 3. The appropriateness of each Status 2B patient listing shall be re-assessed by the listing transplant center at 6 months from the date the patient is initially listed as a Status 2B and every 6 months thereafter. This reassessment must be based on clinical information (e.g., laboratory test results and diagnosis) that is obtained within the prior 30 days. A completed Liver Status 2B Justification Form must be received by UNOS 6 months from the date the patient is initially listed as a Status 2B and every 6 months thereafter for the duration of the patient's listing as a Status 2B. UNOS shall notify the listing transplant center of the need to reassess a Status 2B patient 30 days prior to the 6-month deadline. If a completed Liver Status 2B Justification Form is not received by UNOS 6 months from the date the patient is initially listed as a Status 2B and every 6 months thereafter, the patient shall be re-assigned to a Status 3.

Status Definitions

- A pediatric patient listed as Status 1 is located in the hospital's Intensive Care Unit (ICU) due to acute or chronic liver failure, has a life expectancy without a liver transplant of less than 7 days and meets at least 1 of the following criteria:
 - (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. While no single clinical observation or laboratory test defines fulminant hepatic failure, the diagnosis is based on the finding of stage II encephalopathy (i.e., drowsiness, inappropriate behavior, incontinence with asterixis) in a patient with severe liver dysfunction. Evidence of severe liver dysfunction may be manifest by some or all of the following symptoms and signs: asterixis (flapping tremor), hyperbilirubinemia (i.e., bilirubin > 15 mg%), marked prolongation of the prothrombin time (i.e., > 20 sec or INR > 2.5), or hypoglycemia.
 - (ii) Primary non-function of a transplanted liver within 7 days of implantation.
 - (iii) Hepatic artery thrombosis in a transplanted liver within 7 days of implantation.
 - (iv) Acute decompensated Wilson's disease.
 - (v) On mechanical ventilator.
 - (vi) Upper gastrointestinal bleeding requiring at least 10 cc/kg of red blood cell replacement which continues or recurs despite treatment.

[Continued]

- (vii) Hepatorenal syndrome; The presence of progressive deterioration of renal function in a patient with advanced liver disease requiring hospitalization for management, with no other known etiology of renal insufficiency, and a rising serum creatinine 3 times baseline. In addition to these major criteria, the patient should meet at least one of the following: a) urine volume < 10 ml/kg/d; b) urine sodium < 10 mEq/l; or c) urine osmolality > plasma osmolality (U/P ratio > 1.0).
- (viii) Stage III or IV encephalopathy unresponsive to medical therapy.
- (ix) Refractory Ascites/Hepato-Hydrothorax; Severe persistent ascites or hepatohydrothorax, defined as any one of the following: unresponsive to diuretic and salt restriction therapy leading to respiratory distress, or requiring supplemental tube feeding, or requiring parenteral nutrition, or requiring supplemental oxygen, or requiring paracentesis.
- Biliary sepsis requiring pressor support of 5 mcg/kg/min of dopamine or greater.

With the exception of hospitalized pediatric liver transplant candidates with Ornithinine Transcarbamylase Deficiency (OTC) or Crigler-Najjar Disease Type I, patients who are listed as a Status 1 automatically revert back to Status 2B after 7 days unless these patients are relisted as Status 1 by an attending physician. A patient listed as Status 1 shall be reviewed by the applicable UNOS Regional Review Board. A completed Liver Status 1 Justification Form must be received by UNOS within 24 hours of a patient's original listing as a Status 1 and each relisting as a Status 1. If a completed Liver Status 1 Justification Form is not received by UNOS within 24 hours of the Status 1 liver candidate registration on the waiting list, the candidate shall be reassigned to a Status 2B. A relisting request to continue a Status 1 listing for the same patient waiting on that specific transplant beyond 14 days accumulated time will result in an on-site review of all local Status 2 and 1 liver patient listings.

3.6.4.3 Pediatric Liver Transplant Candidates with OTC or Crigler-Najjar Disease Type I. A pediatric liver transplant candidate with Ornithine Transcarbamylase Deficiency (OTC) or Crigler-Najjar Disease Type I shall be registered as a Status 2B and may be upgraded to a Status 1 if the patient is hospitalized for an acute exacerbation of his or her disease. The patient shall remain a Status 1 as long as he or she remains hospitalized.

3.6.4.4 Liver Transplant Candidates with Hepatocellular Carcinoma (HCC). A patient with HCC may be registered as a Status 2B if the patient meets all of the following medical criteria:

(i) The patient has known HCC and 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 established imaging criteria. Histological grade, the presence of encapsulation or histological classification (fibrolamellar versus non-fibrolamellar) are not considered in determining the patient's listing as a Status 2B since a pre-listing biopsy is not required. The assessment of the patient should include ultrasound of the patient's liver, a computerized tomography (CT) or magnetic resonance imaging (MRI) scan of the abdomen and chest, and a bone scan. A re-assessment of the patient must be performed at every 3-month interval that the patient is on the UNOS waiting list.

- (ii) The patient has Stage I or Stage II HCC in accordance with the modified Tumor-Node-Metastasis (TNM) classification set forth in the following Table 2, or the patient has an alpha fetoprotein level that is rising on 3 consecutive occasions with an absolute value ≥ 500 nanograms even though there is no evidence of a tumor based on imaging studies.
- (iii) The patient is not a resection candidate.

A patient with HCC at Stage III or higher may continue to be considered a liver transplant candidate in accordance with each center's own specific policy or philosophy, but the patient must be listed as a Status 3, unless the candidate meets the other criteria specified for Status 2B or 2A in Policy 3.6.4. In addition, a patient with HCC must be reviewed by the applicable UNOS liver regional review board prior to being upgraded to a Status 2B.

TABLE C-2 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
Т3	One nodule > 5.0 cm; two or three nodules, all > 3.0
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 hepatic) nodes, involved
M1	Metastatic disease, including extrahepatic portal or hepatic vein involvement
Stage I	T1
Stage II	T2
Stage III	T3
Stage IV	A1 T4a
Stage IV	A2 T4b
Stage IV	B 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.

3.6.4.4.1 Pediatric Liver Transplant Candidates with Hepatoblastoma. A pediatric patient with non-metastatic hepatoblastoma who is otherwise a suitable candidate for liver transplantation may be registered as a Status 2B on the UNOS Patient Waiting List.

3.6.4.5 Status Verification for Potential Liver Recipients. As a condition for liver acceptance, it is the responsibility of the accepting surgeon to verify the status of the candidate for whom the liver is offered. If it is determined that the actual status of the candidate is lower than the UNOS waiting list status by which the offer was made, then the procuring OPO shall be notified and the points for the candidate in question shall be re-calculated after the candidate's waiting list status has been appropriately downgraded.

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 patient who has higher points has accepted or rejected the offer.

- **3.6.6 Removal of Liver Transplant Candidates from Liver Waiting Lists When Transplanted or Deceased.** If a liver transplant candidate on the UNOS Patient Waiting List has received a transplant from a cadaveric or living donor, or has died while awaiting a transplant, the listing center, or centers if the patient is multiple-listed, shall immediately remove that patient from all liver waiting lists and shall notify UNOS within 24 hours of the event. If the liver recipient is again added to a liver waiting list, waiting time shall begin as of the date and time the patient is relisted.
- **3.6.7 UNOS Organ Center Assistance with Liver Allocation**. It is recommended that the UNOS 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 UNOS Patient Waiting List. Upon request by the OPO, the Organ Center shall attempt to locate a liver recipient on the UNOS Patient 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 UNOS Liver and Intestinal Organ Transplantation Committee and Board of Directors.

3.6.9 Minimum Information for Liver Offers.

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 UNOS 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 UNOS I.D. number, age, sex, race, height, and weight;
- (ii) ABO type;
- (iii) Cause of brain death/diagnosis;
- (iv) History of treatment in hospital including current medications, vasopressors, and hydration;
- (v) Current history of hypotensive episodes, urine output, and oliguria;
- (vi) Indications of sepsis;

- (vii) Social and drug activity histories;
- (viii) Vital signs including blood pressure, heart rate, and temperature;
- (ix) Other laboratory tests within the past 12 hours including:
- (1) Bilirubin
- (2) SGOT/AST
- (3) PT
- (4) BUN
- (5) Electrolytes
- (6) WBC
- (7) HH
- (8) Creatinine;
- (9) Arterial blood gas results;
- (10) Pre- or post-transfusion serologies for HIV, hepatitis, CMV, HTLV, and VDRL/RPR.
- **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 UNOS Organ Center in descending point order to all Status 1 candidates, Status 2A candidates, and ABO-compatible Status 2B candidates in the Host OPO's region followed by Status 1 candidates, Status 2A candidates, and ABO-compatible Status 2B candidates 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 and Status 2A candidates for whom the liver will be considered 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 may allocate the remaining segment to any medically appropriate candidate on the UNOS Patient Waiting List. If the segment is not allocated for transplantation, it should be offered for other methods of hepatic support as stated in Policy 3.6.10.