

 <p><b>SOUTHWESTERN MEDICAL CENTER</b></p> <hr/> <p>UNIVERSITY HOSPITALS &amp; CLINICS</p>	<p><b>UNIVERSITY HOSPITAL – ST PAUL</b></p> <p>Guideline No: UTSW-03.OLT  Created: July 2007  Revised: July 3, 2008</p>
<p><b>Liver Transplant Program</b></p>	

## PATIENT CANDIDACY

**I. Purpose** – To identify appropriate potential recipients for liver transplantation.

**II. Policy**

The following medical, psychosocial, and financial criteria will be used for identifying potential recipients for liver transplantation. All patients will be treated with compassion, dignity, and respect. In accordance with University of Texas Southwestern (UTSW) Hospital policy, we shall provide all patients with impartial access to treatment regardless of race, religion, sex, ethnicity, or handicap. These criteria assure that all potential recipients have fair, non-discriminatory access to the distribution of organs.

UT Southwestern – St. Paul (UTSWSP) is committed to providing health care services to those in need. To accomplish this goal, the institution must be a steward of the resources available to supply this care. Transplantation involves a long-term personal and financial commitment to medical care. To carry out its mission, UTSWSP must assure that transplant candidates cared for at UTSWSP possess adequate resources to fulfill the financial obligations attendant to transplantation. In doing so, the institution may preserve its assets for the greatest service to the entire patient community and to satisfy itself that the scarce organs are responsibly utilized by individuals able to obtain needed care and therefore achieve long-term benefit from the procedure.

Before being transplanted, each potential transplant candidate must demonstrate the ability to meet the expense of medical care related to transplantation. Confirmation of adequate insurance benefits or a cash deposit in accordance with the policy, accompanied by evidence of reasonable ability to provide for post-transplant needs, will satisfy this requirement.

Potential recipients should not be moribund or have such significant multi-organ failure so as to compromise the operation or their survival. Patients with chronic liver disease must be physically and mentally able to withstand the arduous surgical procedure and be highly motivated to adhere to the regimented medical program both pre- and post-transplantation.

**A. Indications.**

Liver transplantation is indicated for patients with either severe acute (“fulminant”) liver failure or chronic liver failure for which no other therapy is available.

## 1. Acute Liver Failure

Acute liver failure (ALF) is a dramatic syndrome in which previously healthy individuals rapidly lose hepatic function due to a variety of causes, develop hepatic encephalopathy, and become critically ill within days to weeks of the onset of symptoms. The mortality can be as high as 100% depending upon etiology, and many patients will die, either due to complications of this devastating disease or because donor organs are not available. Liver transplantation is the most effective treatment for patients with ALF who have evidence of profound synthetic liver failure and hepatic encephalopathy (coma). These patients require aggressive management in the intensive care unit and should be transplanted as early as possible for optimum outcome. Acute liver failure may result from a variety of causes including:

- a. *Drug-induced Hepatitis* (the most common cause of ALF in the United States)
  - 1) Acetaminophen (40% of all cases)
  - 2) other medications (make up the remainder)
- b. *Viral Hepatitis*
  - 1) Hepatitis A, B, D, and E
  - 2) hepatitis C rarely, if ever, causes ALF
  - 3) hepatitis E is rarely seen in the United States
- c. *Toxic Hepatitis* – i.e., mushroom poisoning
- d. *Other Causes*
  - 1) Genetic (i.e., Wilson’s Disease) – NOTE hemochromatosis doesn’t cause ALF
  - 2) Autoimmune (i.e., autoimmune hepatitis)
  - 3) Idiopathic (represents about 17% of cases of ALF)

## 2. Chronic Liver Failure.

Chronic liver failure leading to cirrhosis can result from a variety of causes. Patients with the following disorders have been shown to have excellent results following liver transplantation:

- a. *Chronic hepatitis/cirrhosis* due to
  - 1) autoimmune hepatitis
  - 2) chronic hepatitis B virus infection
  - 3) chronic hepatitis C virus infection
- b. *Alcoholic Liver Disease* (with demonstrated abstinence)

Transplant evaluation of patients with alcoholic liver disease is based upon four basic concepts: confirmed patient sobriety (abstinence of 6 months or greater), patient insight into substance abuse, patient completion of a formalized treatment program, and patient commitment to a relapse prevention plan. Abstinence is important for two reasons. First, many patients with alcoholic hepatitis and cirrhosis recover significant synthetic function of the liver with abstinence, and will not require transplantation. Furthermore, commitment to abstinence and a treatment program is essential for any candidate for an expensive life-saving operation such as transplantation. Only patients with a minimal risk of recidivism

(returning to drinking) should be considered for transplantation. Factors which have been shown associated with a low risk of recidivism include abstinence, completion of an alcohol rehabilitation program, good family support, and activities which can replace their previous behavior.

c. *Metabolic Diseases*

- 1) alpha-1 antitrypsin deficiency
- 2) hemochromatosis
- 3) Wilson's disease
- 4) nonalcoholic steatohepatitis (NASH)
- 5) primary oxaluria
- 6) familial amyloidosis
- 7) urea cycle defects
- 8) inborn errors of metabolism

d. *Cholestatic Liver Disorders*

- 1) primary biliary cirrhosis
- 2) secondary biliary cirrhosis (i.e., bile duct injury or cystic fibrosis)
- 3) primary sclerosing cholangitis
- 4) secondary sclerosing cholangitis
- 5) biliary atresia

e. *Miscellaneous Disorders*

- 1) Budd-Chiari syndrome
- 2) polycystic liver disease
- 3) cryptogenic cirrhosis

**3. Hepatocellular Malignancy (Liver Cancer)**

Selected patients with hepatocellular malignancy are candidates for transplantation (See Section 6. Liver Tumor Evaluation). These malignancies include hepatocellular carcinoma (HCC), fibrolamellar hepatocellular carcinoma (FLHCC), epithelioid hemangioendothelioma, or metastatic (to the liver) carcinoid tumors leading to severe symptoms which are not medically treatable. Patients with cholangiocarcinoma are potential candidates for liver transplantation. These patients must have disease confined to their liver and be able to undergo adjunctive therapy as outlined by the Mayo Protocol for Cholangiocarcinoma (See Section 6. Liver Tumor Evaluation). Patients with metastatic malignancy from other sources are not good candidates for transplantation because of a high rate of recurrent disease.

**4. Specific Indications for Consideration for Transplantation**

There are occasions when patients with liver disease may require transplantation in the absence of cirrhosis or in the setting of severe complications of cirrhosis but low MELD (model for end-stage liver disease) score. The Region 4 Review Board (Texas/Oklahoma) has granted standardized exceptions for the following situations and these patients may be considered for listing and liver transplantation:

- a. Primary Oxaluria
- b. Familial Amyloidosis (FAP)

- c. Polycystic Liver Disease
- d. Hepatopulmonary Syndrome (HPS)
- e. Portopulmonary Hypertension (ppHTN)
- f. Refractory Pleural Effusion (fluid in lungs) or Ascites (fluid in abdomen)
- g. Refractory Variceal Bleeding Requiring Blakemore Tube
- h. Recurrent Bleeding
- i. Biliary Stricture (narrowing or blockage of the bile ducts)
- k. Urea Cycle Defect
- l. Hepatocellular Carcinoma
- m. Cholangiocarcinoma

The Region 4 Review Board may be petitioned for listing for other conditions; however, there is no guarantee that listing will be permitted.

## **B. Contraindications.**

### **1. Absolute contraindications**

- a. HIV / Acquired immunodeficiency syndrome (AIDS) – patients will be referred to a program with a protocol for transplanting HIV/AIDS patients.
- b. Extrahepatic/Systemic malignancy – non-liver cancers
- c. Active intravenous drug abuse, illicit drug abuse, or alcohol abuse.
- d. Invasive hepatocellular carcinoma – liver cancer spread outside the liver
- e. Cholangiocarcinoma – except those meeting Mayo Clinic Protocol criteria
- f. Complete mesenteric and portal vein thrombosis
- g. Extreme obesity (BMI >38)
- h. Advanced cardiovascular disease
- i. Advanced pulmonary disease

### **2. Relative contraindications**

There are conditions which may contribute to a poor outcome following liver transplantation. These conditions may be reversible with appropriate medical or psychosocial support, and are therefore considered “relative” contraindications.

- a. Poor cardiopulmonary function
- b. Chronic renal insufficiency
- c. Prior portocaval shunt (or extensive prior right upper quadrant surgery)
- d. Active systemic infection
- e. History of alcoholism or drug use with a high risk of recidivism
- f. Lack of psychologic and social stability
- g. Inability to understand the complexity of the operation and postoperative course
- h. Inability to comply with a complex post-operative regimen
- i. Morbid obesity (BMI 35-38) or severe malnutrition (BMI <20)

## **C. Alcohol and/or Substance Addiction or Dependence.**

Potential candidates with documented alcohol addiction or dependency must have documented abstinence for a minimum of 6 months and, with few exceptions, must complete an Alcohol Treatment Rehabilitation Program, and must develop a personal relapse prevention plan. Candidates who have stopped alcohol consumption immediately

upon learning of their cirrhosis, have documented abstinence of several years, and who demonstrate insight, may be exempt from these requirements. Random alcohol and drug screening may be done at the time of initial Liver Transplant Evaluation. Additional random alcohol and drug screening may be done prior to and after listing. Social Work will facilitate a Treatment Contract with the patient / family and monitor for compliance (*See* Section 8. Social Work Evaluation).

#### **D. Financial.**

Patients will be evaluated for the ability to pay for the transplant, including pre-, transplant, and post-care phases. The financial evaluation will include insurance coverage, fund raising, eligibility for assistance programs, and self-pay (*See* Section 7. Financial Evaluation)

#### **E. Requirements Prior to Transplantation.**

1. Successful completion of pre-transplant evaluation
2. Successful completion of the psychosocial evaluation (must be completed prior to being listed). (*See* Social Work Policy #3.0)
3. Documentation of ABO blood type on two separate occasions
4. Recommendation for transplantation by the Liver Transplant Committee
5. Financial Clearance (resources in place to provide for the cost of hospitalization, post-transplant follow-up and long-term medications and management)
6. Completion of periodic update testing while on the transplant waiting list.

#### **F. Delisting Criteria**

1. No longer meets listing criteria (i.e., too sick or tumors too large)
2. Lost to follow-up: unable to contact patient for >1 month
3. Patient requesting removal
4. Return to substance abuse (alcohol and/or drugs)
5. A listing patient who has been transplanted

#### **G. Appeals.**

If a referring physician believes that a patient, who is determined not to be a candidate for transplant, should be reconsidered for transplantation, an appeal may be presented to the UTSW Liver Transplant Committee for potential endorsement. The patient may also appeal the decision of the Committee by discussing the matter with the Medical Director.

### **III.Procedure/Intervention(s) – N/A**

### **IV.Documentation (Documents & Forms) – N/A**

### **V. Other Related Policies/Procedures**

- A. Section 6. Liver Tumor Evaluation
- B. Section 7. Financial Evaluation
- C. Section 8. Social Work Evaluation
- D. Social Work Policy #3

## **VI. References – N/A**