LIVER TRANSPLANT
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COVERAGE:

A liver transplant, whether cadaveric or living donor, is considered medically necessary for carefully selected patients with end stage liver disease (ESLD). Irreversibly damaged livers may have conditions that include, but are not limited to:

A. Hepatocellular diseases;
   1. Alcoholic cirrhosis;
   2. Cryptogenic cirrhosis;
   3. Viral hepatitis;
      a) Type A;
      b) Type B;
      c) Type C;
      d) Non-A; OR
      e) Non-B.
   3. Auto-Immune hepatitis.

B. Cholestatic liver diseases;
   1. Primary biliary cirrhosis;
   2. Primary sclerosing cholangitis with development of secondary biliary cirrhosis; OR

C. Vascular disease;
   1. Budd Chiari syndrome.

D. Primary hepatocellular carcinoma;

E. Inborn errors of metabolism;

F. Trauma and toxic reactions;

G. Miscellaneous
   1. Polycystic disease of the liver; AND
   2. Familial amyloid polyneuropathy.

Liver transplantation is considered experimental or investigational in the following patients:

• HIV-positive patients; OR
• Patients with an extrahepatic malignancy including cholangiocarcinoma; OR

• Patients with hepatocellular carcinoma extending beyond the liver; OR

• Patients with ongoing alcohol and/or drug abuse. (Facility abstinence criteria may vary among transplant programs, but usually, a minimum of 3 months is required.)

DESCRIPTION:

A liver transplant consists of replacing a diseased liver with healthy liver or a healthy lobe. It is used as a last resort for patients with compromising liver failure.

Recipients:

Liver transplants are now consistently performed as a treatment for patients with ESLD. Prioritization for transplant is based on length of time on the waiting list and severity of illness. The priority classification was developed by the United Network of Organ Sharing (UNOS). Since February 2002, UNOS eliminated the original liver classification system, which was based on assignment to a status of:

• 1;
• 2A;
• 2B;
• 3; or
• 7.

The new classification retains the status 1, describing patients with acute liver failure with a life expectancy of less than 7 days, and status 7, relating to patients who are temporarily inactive due to intercurrent medical problems.

Status 2A through 3, are replaced with the Model for End Stage Liver Disease (MELD) and Pediatric End Stage Liver Disease (PELD), for patients under the age of 18 years. MELD and PELD are a continuous disease severity scale based on objective laboratory values. These scales have been found to be highly predictive of the risk of dying from liver disease for patients on a transplant list. These scores incorporate bilirubin, prothrombin time (INR) and creatinine into an equation, producing a number ranging from 1 to 40.
Apart from the status 1 level, donor livers are prioritized to those with the highest MELD or PELD score. Waiting time will only be used to break ties among patients with same MELD or PELD score and blood type compatibility. With the old classification system, time was often a determining factor of liver distribution, since patients were listed early in the course of disease, while others were listed only when they became sicker. With the new MELD and PELD system, patients with higher scores will always be considered before those with lower scores, even if some patients have waited longer.

**Donors:**

Because of the scarcity of donor livers, numerous strategies have been developed to expand the donor pool. An example is the use of split graft. This refers to dividing a donor liver into two segments that can be used for 2 recipients. Living donor transplantation of the left lateral segment is commonly performed between child and parent. Another form of transplantation, called adult to adult living donor, uses the right lobe of the liver from a related or unrelated donor. While the problem of donor organ scarcity continues, living donation allows procedure scheduling electively, shortening the preservation time of the donor liver and before transplant, allows more time for optimizing the recipient’s condition.

Patients with familial amyloid polyneuropathy do not experience liver disease but develop polyneuropathy and cardiac amyloidosis because of the making of a variant transthyretin molecule by the liver. The MELD/PELD score may apply with these cases. Candidacy for liver transplant is an individual consideration based on the morbidity of polyneuropathy. Therefore, many patients may not be eligible for liver transplant due to the coexisting cardiac disease.

Patients with polycystic disease of the liver do not develop liver failure but due to the anatomic complications of an enlarged liver, may require transplantation. The MELD/PELD score may not be applicable in these cases. One of the following symptoms should be present:

- Enlargement of the liver impinging on respiratory function; or
- Extremely painful enlargement of the liver; or
- Enlargement of the liver compressing and interfering with the function of other abdominal organs.

Those patients with hepatocellular carcinoma are suitable candidates for liver transplant if the disease remains confined to the liver.
Therefore, periodic monitoring is indicated while on the waiting list. If metastatic disease develops, patients are removed from the waiting list. At the time of transplant, if extensive or metastatic cancer is discovered during exploration, the transplant should be discontinued and a back up candidate should be utilized.

RATIONALE:

Liver transplantation is an established form of treatment for ESLD, which can be caused by numerous etiologies.

As experience with liver transplantation matures, criteria for patient selection have broadened to include a wide variety of etiologies. The most controversial etiologies include viral hepatitis and primary hepatocellular cancer. The presence of hepatitis B virus (HBV) has been a controversial indication for liver transplantation because of the high potential for recurrence of the virus and subsequent recurrence of liver disease. Nonetheless, liver transplantation represents the only curative method for many of these patients who present with unresectable organ-confined disease. However, liver transplantation cannot be considered curative in patients with locally extensive or metastatic liver cancer, or in patients with isolated liver metastases with extrahepatic primaries or in cholangiocarcinoma due to the degree of growth and mutation associated with these types of cancer.

With the shortage of donor organs and the success of living donation between parent and child, adult to adult living liver transplantations (AALLT) have been examined and are being performed at several transplants centers. AALLT involves the living donor having a right lobe liver hepatectomy, which is transplanted into the recipient. Right lobe liver hepatectomy involves resecting 60% to 70% of the total quantity of the donor liver; major concerns regarding safety of the donor have been noted. Recent review of data, reported by Columbia University in 2003, related information from a multicenter retrospective questionnaire of 449 AALLT performed. Complications with the donor were more frequent in the center performing the fewest transplants from adult living donors. These included biliary complications requiring intervention (6%), reoperation (4.5%) and the death of one donor (0.2%). Among the recipients, 1.6% did not meet criteria for cadaveric transplant; with cancer, retransplant and acute liver failure being uncommon indications for transplant from a living donor. The researchers concluded mortality among donors is low but complications with the donor remains common. In 2000, the National Institutes of Health arranged a workshop concentrating on living donor liver transplantation. A summary of the workshop was published in 2002. The results reported donor morbidity as common; 7% requiring re-exploration, 10% re-hospitalization, and biliary tract complications
at 7%. Donor mortality approximately 0.2% to 0.5% and the mean complication rate, by responding centers, was 21%.

With the probable morbidity and mortality experienced by the donor, the seminar noted donor consent for hepatectomy must be voluntary and free of coercion and preferably the donor have a significant, long term relationship with the recipient. The workshop summary reads, “As a result, approximately one third of persons originally interested in becoming a living liver donor, actually completes the evaluation process and are accepted as candidates for the procedure.”

Criteria for recipients of a living related liver are also open to discussion. Some groups support living related livers be used in the most critically ill, while others state the risk to the donor is intolerable because of the increased risk of post operative mortality with critically ill recipients. Based on this idea, living related livers are best used in stable recipients who have a higher chance of long term survival. Overall, the greatest concern must be for the health and safety of the donor and should remain paramount in living organ donation.

PRICING:
None

REFERENCES:

• Azoulay, E., et al. “Split-liver transplantation. The Paul Brousse


- Pitkin, Z. and C. Mullon. "Evidence of absence of porcine endogenous retrovirus (PERV) infection in patients treated with a bioartificial liver support system." Artificial Organs (1999 May) 23(9); 829-33.


DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically. HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.