



Subject: *Liver Transplant*

Number: *200306-0004*

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Important Note

Even though this policy may indicate that a particular service or supply is considered covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare and Medicaid members, this policy will apply unless Medicare and Medicaid policies extend coverage beyond this Medical Policy & Criteria Statement. Medicare and Medicaid policies will only apply to benefits paid for under Medicare or Medicaid rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the following website:

<http://cms.hhs.gov/manuals/pub06pdf/pub06pdf.asp>

Overview

A **liver transplant** may be medically necessary for patients with irreversible, end-stage liver failure. Liver transplants are performed using a cadaver donor or a living donor, where only a portion (or lobe) of the donor liver is used for the transplant recipient.

Policy and criteria

NOTE: These services require prior authorization by the Plan Medical Director.

When services are covered:

We cover liver transplant for end-stage liver disease when the member has a life expectancy of less than 12 months and when there are no contraindications, as per the exclusion list below. Liver transplants can be covered for the following conditions (this list is not all-inclusive):

- Alpha-1 antitrypsin (anti-proteinase inhibitor) deficiency
- Biliary atresia
- Budd-Chiari Syndrome
- Primary sclerosing cholangitis
- Cirrhosis, including
 - Alcoholic cirrhosis
 - Cryptogenic cirrhosis
 - Post-necrotic cirrhosis
 - Primary biliary cirrhosis
- End-stage liver disease in children (see exclusions below)
- Epithelial hemangioendotheliomas (EHE) in the absence of metastases
- Familial amyloid polyneuropathy
- Familial cholestatic syndromes
- Large, unresectable fibrolamellar hepatocellular carcinomas
- Primary hemochromatosis
- Hepatitis, including
 - Autoimmune hepatitis
 - Viral hepatitis (either A, B, C, or non-A, non-B)

- Primary hepatocellular carcinoma confined to the liver when ALL of the following criteria are met:
 1. Member is not a candidate for subtotal liver resection; and
 2. The tumor is 5 cm or less in diameter or member has no more than 3 tumors, each less than 3 cm in diameter (live donor transplants can use the expanded criteria of a single tumor of up to 6.5 cm or no more than 3 tumors with the sum of the diameters being 8 cm or less); and
 3. There is no macrovascular involvement; and
 4. There is no identifiable extrahepatic spread of tumor to surrounding lymph nodes, lungs, abdominal organs or bone.
- Inborn errors of metabolism
- Intrahepatic cholangiocarcinomas (confined to the liver)
- Metastatic neuroendocrine tumors (i.e., carcinoid tumors, apudomas, gastrinomas, glucagonomas) in members with severe symptoms and when metastases are restricted to the liver and members who are unresponsive to adjuvant therapy after aggressive surgical resection (including excision of the primary lesion and reduction of hepatic metastases)
- Polycystic liver disease
- Protoporphyrin
- Trauma and toxic reactions
- Venous-occlusive disease
- Wilson's disease
- Retransplantation following a failed liver transplant is covered if the initial transplant was performed for a covered indication

We cover **living-related** liver transplantation when all the following conditions are met:

- **Member is an infant or young child** – other categories of patients have not been reported in the medical literature in sufficient numbers
- **The donor is a parent or sibling** – other categories of donors have not been reported in the medical literature in sufficient numbers
- **All the above inclusions are met**, and none of the exclusions are present

To be eligible for benefits, the following documentation, including medical records, must be submitted before the procedure:

- HBV serologies, including HbsAg, Anti-HBc, Anti-HBs
- IgM anti HDV, if HBsAg positive
- HIV antibody screen
- In the presence of a past history of alcohol or drug abuse, an explicit statement from the transplant team psychiatrist attesting to a period of abstinence of 6 months or more from alcohol or drugs, and good expectation that the patient will comply with a disciplined medical regimen including counseling if this is part of the program.
- There must be an explicit statement from consultants as to the appropriateness of a liver transplantation in view of any problems in their respective specialties.

In addition, the member must have completed an evaluation and been accepted by the decision making entity at the liver transplant center.

Please refer to the **Transplant Policy** for additional information regarding covered and non-covered services.

When services are not covered:

We **do not cover** liver transplantation for end-stage liver disease if any of the following **exclusions** exist:

- Active drug or alcohol abuse
- A behavior pattern or psychiatric disorder considered likely to interfere significantly with a disciplined medical regimen

- Children with either of the following:
 - malignancy extending beyond liver margins
 - persistent viremia
- Multiple uncorrectable congenital anomalies
- Liver damage caused by chemicals, drugs, toxins or external agents with irreversible systemic effect
- Acute, severe hemodynamic compromise at time of transplant, accompanied by compromise of one or more vital organs
- Combination of extensive prior hepatobiliary surgery, associated with uncorrectable severe coagulopathy (prothrombin time consistently greater than 22 seconds)
- Active infection or sepsis
 - Systemic bacterial or fungal infection, unless eliminated before transplantation
- Malignancies: intrahepatic, extrahepatic or metastatic, hepatocellular carcinoma that has extended beyond the liver.
- Persistent uremia
- Portal vein thrombosis, when radiographic studies do not support the possibility of simple reconstruction above the level of the pancreas, or by vein graft to the base of the superior mesenteric vein.
- Significant or advanced cardiac, pulmonary, renal, nervous system or other systemic disease or failure
- Viremia – known or unknown (diagnosis of viremia questioned and being ruled out):
 - Cytomegalovirus hepatitis* with concurrent illness
 - Epstein-Barr virus hepatitis* with concurrent illness
 - HIV infection with or without AIDS

*Primary viral disease is unlikely to be the reason for transplant. Patients requiring transplantation may harbor EBV as a complicating factor that should not exclude patient from undergoing transplantation.

- Need for prior, subsequent, or simultaneous transplantation of a second organ (lung, heart, pancreas or hematopoietic progenitor cell) *except* for the combined kidney and hepatic transplantation
- When other effective medical or surgical options are available
- Any of the following services or procedures;
 - Bioartificial liver transplantation
 - Hepatocellular transplantation
 - Heterotopic (ectopic or auxiliary) liver transplantation
 - Xenotransplantation (transplant of animal tissues or organs into humans)

Products to which this policy applies:

- ⊕ Commercial Plan (Direct, Select & PPO Plans)
- ⊕ The Independent Plan
- ⊕ Fallon Flex
- ⊕ Major Medical
- ∅ Medicare Plan – refer to CMS for policy and criteria.

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Approved by:	<i>Signature on file</i>	6/30/2003
	Dennis A. Batey, M.D., Vice President and Chief Medical Officer	Date