



An Independent Licensee of the
Blue Cross and Blue Shield Association

MEDICAL COVERAGE GUIDELINES
SECTION: SURGERY

ORIGINAL EFFECTIVE DATE: 04/16/13
LAST REVIEW DATE: 02/04/14
LAST CRITERIA REVISION DATE: 02/04/14
ARCHIVE DATE:

LIVER TRANSPLANT

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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Description:

Liver transplantation is performed as a treatment of last resort for individuals with end-stage liver disease. Liver transplantation may be performed with liver donation after brain or cardiac death or with a liver segment donation from a living donor.



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LIVER TRANSPLANT (cont.)

Criteria:

Liver transplants will be reviewed by the medical director(s) and/or clinical advisor(s).

Pre-Transplantation Evaluation:

- Pre-transplantation evaluation criterion is met with documentation of psychosocial screen and **ALL** of the following:
 1. Drug/alcohol screen with documentation of **ONE** of the following:
 - No drug/alcohol abuse by history
 - Drug and alcohol free for a period greater than or equal to 6 months
 2. Behavioral health disorder screening with documentation of **ONE** of the following:
 - No behavioral health disorder by history
 - Behavioral health disorder by history with documentation of **BOTH** of the following:
 - No severe psychosis/personality disorder
 - Mood/anxiety disorder excluded/treated
 3. Individual understands surgical risk and post procedure compliance and follow-up
 4. Adequate social/family support



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LIVER TRANSPLANT (cont.)

Criteria: (cont.)

Liver transplants will be reviewed by the medical director(s) and/or clinical advisor(s).

➤ Liver transplant using a cadaver or living donor for an individual with end-stage liver failure due to irreversibly damaged liver is considered ***medically necessary*** with documentation of **ALL** of the following:

1. Pretransplantation evaluation criteria above is met
2. Individual has **ANY** of the following conditions to include, *but not limited to*:

- Hepatocellular disease
 - Alcoholic liver disease
 - Viral hepatitis (either A, B, C, or non-A, non-B)
 - Autoimmune hepatitis
 - Alpha-1 antitrypsin deficiency
 - Hemochromatosis
 - Non-alcoholic steatohepatitis
 - Protoporphyria
 - Wilson's disease
- Cholestatic liver disease
 - Primary biliary cirrhosis
 - Primary sclerosing cholangitis with development of secondary biliary cirrhosis
 - Biliary atresia
- Vascular disease
 - Budd-Chiari syndrome
- Hepatocellular carcinoma, primary
- Inborn errors of metabolism
- Trauma and toxic reactions
- Miscellaneous
 - Familial amyloid polyneuropathy



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LIVER TRANSPLANT (cont.)

Criteria: (cont.)

Liver transplants will be reviewed by the medical director(s) and/or clinical advisor(s).

- Liver transplantation is considered ***medically necessary*** in individuals with polycystic disease of the liver who have massive hepatomegaly causing obstruction or functional impairment.
- Liver transplant for individuals with unresectable hilar cholangiocarcinoma, is considered ***medically necessary***.
- Liver transplantation is considered ***medically necessary*** in pediatric individuals with non-metastatic hepatoblastoma.
- Liver retransplantation is considered ***medically necessary*** with documentation of **ANY** of the following:
 1. Primary graft non-function
 2. Hepatic artery thrombosis
 3. Chronic rejection
 4. Ischemic type biliary lesions after donation after cardiac death
 5. Recurrent non-neoplastic disease causing graft failure
- Liver transplant for an individual with **ANY** of the following conditions is considered ***experimental or investigational*** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome.

Individual has **ANY** of the following conditions:

- Intrahepatic cholangiocarcinoma
- Neuroendocrine tumors metastatic to the liver



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LIVER TRANSPLANT (cont.)

Criteria: (cont.)

Liver transplants will be reviewed by the medical director(s) and/or clinical advisor(s).

- Liver transplantation is considered ***not medically necessary*** for the following:
 1. Individuals with hepatocellular carcinoma that has extended beyond the liver
 2. Individuals with ongoing alcohol and/or drug abuse
- Liver transplantation for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** based upon:
 1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
 2. Insufficient evidence to support improvement of the net health outcome, and
 3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
 4. Insufficient evidence to support improvement outside the investigational setting.

Resources:

1. 7.03.06 BCBS Association Medical Policy Reference Manual. Liver Transplant. Re-issue date 01/09/2014, issue date 12/01/1995.
2. InterQual® Care Planning, Procedures Adult. Transplantation, Liver.