

Liver Transplant SRG-010

Iowa Medicaid Program:	Pre-Procedure	Effective Date:	9/11/2009
Revision Number:	14	Last Rev Date:	1/19/2024
Reviewed By:	Liver Transplant Consultant, MMD	Next Rev Date:	1/17/2025
Approved By:	Medicaid Clinical Advisory Committee	Approved Date:	3/21/2018

Criteria

Pre-procedure review is required.

Liver transplants are considered medically necessary for members with any form of end-stage liver disease, except that coverage is not provided for persons with a malignancy extending beyond the margins of the liver. Otherwise, **ALL** the following must be met:

1. Must have clearance from psycho/social necessity consult. Evaluation should include an assessment of the member's ability to give informed consent and comply with pre- and post-transplant instruction, including drug therapy, as well as assessment of the support systems in place at home or in the community (Level of Evidence: C); **AND**
2. Dental exam and clearance must be provided; **AND**
3. Must be abstinent of all street drugs and alcohol. Physician documentation must specifically address abstinence. Need for laboratory testing to confirm sobriety may be at the discretion of the attending physician (there is increasing evidence that many centers are considering and transplanting patients with acute alcoholic hepatitis); **AND**
4. Documentation of underlying co-morbidity must be provided; **AND**
5. Pertinent lab values must be provided; **AND**
6. Model for End-Stage Liver Disease Scores, based on INR, bilirubin, sodium, and creatinine with or without dialysis. Scores that range from 15-40 are given priority, the higher the score the more critical the condition. It also predicts short-term mortality for members with chronic liver disease, with an exception score given for hepatocellular carcinoma within Milan criteria; **AND**
7. If history of past/current drug or alcohol abuse, transplant program must require that potential candidates be substance free at least 6 months prior to listing, must have documentation of completion of a substance abuse program, and must remain substance free throughout waiting period:
 - a. If member unable to maintain sobriety, approval will be revoked; **AND**
 - b. Members must demonstrate a period of abstinence outside of an acute hospital setting.

Contraindications

Transplantation cannot be approved in the presence of the following:

1. Active smoking is not necessarily considered an absolute contraindication. Smoking cessation for a minimum of 3 months is recommended.
2. Malignancy in the last 2 years, with the exception of cutaneous squamous and basal cell tumors and hepatocellular carcinoma within Milan criteria. In general, a 5-year disease-free interval is prudent.
3. Untreatable advanced dysfunction of another major organ system (exception for dual-organ transplants).
4. Non-curable chronic infection including actively replicating chronic active viral hepatitis B and uncontrolled human immunodeficiency virus (HIV).
 - a. Adequately controlled HIV infection is defined by **ALL** the following:
 - 1) D4 count greater than 200 cells/mm³; **AND**
 - 2) HIV-1 ribonucleic acid (RNA) undetectable; **AND**
 - 3) Stable combination anti-retroviral therapy for more than 3 months; **AND**
 - 4) Absence of serious complications associated with or secondary to HIV disease, such as progressive multifocal leukoencephalopathy, opportunistic infections within the past 12 months, including aspergillosis, tuberculosis, or other mycobacterial infection, coccidioimycosis, resistant fungal infections, chronic intestinal cryptosporidiosis greater than 1 month, Kaposi's sarcoma, or other neoplasm.
5. Documented non-adherence or inability to follow through with pre- and post-transplant medical therapy or office follow-up, or both.
6. Untreatable psychiatric or psychological condition associated with the inability to cooperate or comply with pre- and post-transplant medical therapy.
7. Absence of a consistent or reliable social support system.
8. Substance addiction (e.g., alcohol, tobacco, narcotics) that is either active or within the last 6 months (there is increasing evidence that many centers are considering and transplanting patients with acute alcoholic hepatitis).

Other coverage issues

- Liver transplants require pre-procedure review and approval.
- Covered liver transplants are only payable when performed in a facility that meets the requirements under Iowa Administrative Code (IAC) 441-78.3(10).
- Donor expenses incurred directly in connection with a covered transplant are payable.
- Expenses incurred for complications that arise with respect to the donor are covered only if they are directly and immediately attributed to surgery.
- Expenses of searching for a donor are not covered.
- Expenses associated with organ preparation (e.g., "backbench prep") are not separately payable and are considered paid as part of the transplant procedure.

Milan Criteria

In 1996, the results of a landmark study were published in the New England Journal of Medicine. The Milan Criteria continue to be used by the UNOS allocation “special points”.

The study helped to determine which patients were likely to have a good outcome after liver transplantation in the treatment of patients with cirrhosis and hepatocellular carcinoma.

Forty-eight patients were studied with cirrhosis who had small, unresectable hepatocellular carcinomas and who underwent liver transplantation. In 94 percent of the patients, the cirrhosis was related to infection with hepatitis B virus, hepatitis C virus, or both. The presence of tumor was confirmed by biopsy or serum alpha-fetoprotein assay.

The criteria for eligibility for transplantation were the presence of a tumor 5 cm or less in diameter in patients with single hepatocellular carcinomas and no more than three tumor nodules, each 3 cm or less in diameter, in patients with multiple tumors. Twenty-eight patients with sufficient hepatic function underwent treatment for the tumor, mainly chemoembolization, before transplantation. After liver transplantation, the patients were followed prospectively for a median of 26 months (range, 9 to 54). No anticancer treatment was given after transplantation. The study concluded that liver transplantation is an effective treatment for small, unresectable hepatocellular carcinomas in patients with cirrhosis.

Coding

The following list of codes is provided for reference purposes only and may not be all inclusive. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment, nor does the exclusion of a code imply that its association to the HCPCS/CPT code is inappropriate.

HCPCS	Description
47135	Liver allotransplantation; orthotopic; partial or whole, from cadaver or living donor, any age.

Compliance

1. Should conflict exist between this policy and applicable statute, the applicable statute shall supersede.
2. Federal and State law, as well as contract language, including definitions and specific contract provisions or exclusions, take precedence over medical policy and must be considered first in determining eligibility for coverage.
3. Medical technology is constantly evolving, and Iowa Medicaid reserves the right to review and update medical policy on an annual and as-needed basis.

Medical necessity guidelines have been developed for determining coverage for member benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They include concise clinical coverage criteria based on current literature

review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Criteria are revised and updated annually, or more frequently if new evidence becomes available that suggests needed revisions.

References

441 IAC 78.1(20)"a"(4).

Shiple LC, Singal AK. Liver transplantation for alcoholic hepatitis. *Transl Gastroenterol Hepatol.* 2020 Apr 5;5:26. doi: 10.21037/tgh.2019.11.17. PMID: 32258530; PMCID: PMC7063489.

Ohler, L. & Cupples, S., (2008). *Core Curriculum for Transplant Nurses*. Mosby Elsevier, Philadelphia, PA.

United Network for Organ Sharing (UNOS) at <http://www.unos.org>. Viewed on June 23, 2010.

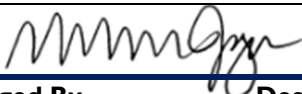
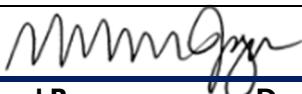

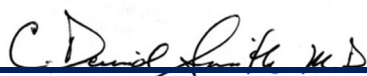
Listing Criteria for Heart Transplantation (Guidelines) (*J Heart Lung Transplant* 2006;25(9): 1024-1042).

International Guidelines for the Selection of Lung Transplant Candidates: 2006 Update - A Consensus Report from the ISHLT Pulmonary Scientific Council (Consensus Document) (*J Heart Lung Transplant* 2006;25(7) 745-755).

Mazzafreoo V, Regalia E, Doci R et al. Liver Transplantation for the Treatment of Small Hepatocellular Carcinomas in Patients with Cirrhosis. *NEJM.* Vol 334. No. 11 March 14, 1996.

Development of utilization management criteria may also involve research into other state Medicaid programs, other payer policies, consultation with experts and review by the Medicaid Clinical Advisory Committee (CAC). These sources may not be referenced individually unless they are specifically published and are otherwise applicable to the criteria at issue.

Criteria Change History

Change Date	Changed By	Description of Change	Version
Signature			
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Signature			
Change Date	Changed By	Description of Change	Version
1/19/2024	CAC	Annual specialist review.	14
Signature William (Bill) Jagiello, DO 			
Change Date	Changed By	Description of Change	Version
1/20/2023	CAC	Annual specialist review. Added criterion related to Milan criteria.	13
Signature William (Bill) Jagiello, DO 			
Change Date	Changed By	Description of Change	Version
1/21/2022	CAC	Annual specialist review. Revised criterion #2 and Contraindication #8. Added new Reference. Formatting changes.	12
Signature William (Bill) Jagiello, DO 			
Change Date	Changed By	Description of Change	Version
1/9/2018	Liver transplant consultant	Under Contraindications #1 changed smoking cessation for a minimum of three months is "required and validated by urine nicotine tests two to three weeks prior to surgery" to "recommended" and removed the validation. Under Contraindications #4 added "actively replicating" chronic active viral hepatitis B.	11
Signature C. David Smith, MD 			
Change Date	Changed By	Description of Change	Version
4/11/2017	Policy	Criterion #7 added "past/current drug or alcohol abuse". Removed Criterion #8 and added it under Criterion #7(b). Added bullet under Other Coverage Issues regarding associated expenses.	10
Signature			
Change Date	Changed By	Description of Change	Version
12/28/2016	Liver transplant consultant	Re-numbered criteria #7 and #8. Contraindications #4 iv added "progressive multifocal leukoencephalopathy" "within the past twelve months" "other mycobacterial infection" "chronic intestinal cryptosporidiosis".	9
Signature			

Criteria Change History (continued)

Change Date	Changed By	Description of Change	Version
1/21/2016	Liver transplant consultant	Added criterion #7b.	8
Signature			
Change Date	Changed By	Description of Change	Version
4/30/2015	Policy	Added “pre- and post-transplant” to criterion #1 and contraindications #5 and #6.	7
Signature			
Change Date	Changed By	Description of Change	Version
1/16/2015	Medical Director	Added last paragraph in References.	6
Signature			
Change Date	Changed By	Description of Change	Version
12/17/2014	Liver transplant consultant	Under Criteria remove “transplants are covered for extrahepatic biliary artesia or any other form of end-stage liver disease” and replace with “covered for any form of end-stage liver disease”.	5
Signature			
Change Date	Changed By	Description of Change	Version
7/24/2014	Medical Director	Contraindication #4 - removed Hepatitis C and added definitions i-iv of adequately controlled HIV infection.	4
Signature			
Change Date	Changed By	Description of Change	Version
11/15/2013	Liver transplant consultant	Remove contraindication #4 regarding incurable viral disease.	3
Signature			
Change Date	Changed By	Description of Change	Version
3/22/2013	Policy	Additions to criteria to reflect details contained in IAC.	2
Signature			
Change Date	Changed By	Description of Change	Version
1/18/2013	CAC	Re-ordering and new information added to criteria #1-#7. Contraindications added. References added.	1
Signature			