

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 146	Date: August 3, 2012
	Change Request 7908

SUBJECT: Liver Transplantation for Patients with Malignancies

I. SUMMARY OF CHANGES: The purpose of this Change Request (CR) is to inform contractors that effective for claims with dates of service June 21, 2012 and later, contractors may, at their discretion cover adult liver transplantation for patients with extrahepatic unresectable cholangiocarcinoma (CCA), (2) liver metastases due to a neuroendocrine tumor (NET) or (3) hemangioendothelimo (HAE) when furnished in an approved Liver Transplant Center (below). All other nationally non-covered malignancies continue to remain nationally non-covered.

EFFECTIVE DATE: June 21, 2012

IMPLEMENTATION DATE: September 4, 2012

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/ revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)

R=REVISED, N=NEW, D=DELETED-*Only One Per Row.*

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/260.1/Adult Liver Transplantation

III. FUNDING:

For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs) and/or Carriers:

No additional funding will be provided by CMS; Contractors activities are to be carried out with their operating budgets

For Medicare Administrative Contractors (MACs):

The Medicare Administrative contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Business Requirements

Manual Instruction

**Unless otherwise specified, the effective date is the date of service.*

Attachment - Business Requirements

Pub. 100-03	Transmittal: 146	Date: August 3, 2012	Change Request: 7908
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SUBJECT: Liver Transplantation for Patients with Malignancies

Effective Date: June 21, 2012

Implementation Date: September 4, 2012

I. GENERAL INFORMATION

A. Background: Liver transplantation, which is *in situ* replacement of a patient's liver with a donor liver, in certain circumstances, may be an accepted treatment for patients with end stage liver disease due to a variety of causes. The procedure is used in selected patients as a treatment for malignancies, including primary liver tumors and certain metastatic tumors, which are typically rare but lethal with very limited treatment options. It has also been used in the treatment of patients with extrahepatic perihilar malignancies. Examples of malignancies include extrahepatic unresectable cholangiocarcinoma (CCA), (2) liver metastases due to a neuroendocrine tumor (NET) and (3) hemangioendothelioma (HAE). Despite potential short and long-term complications, transplantation may offer the only chance of cure for selected patients while providing meaningful palliation for some others.

It had been approximately 10 years since CMS reviewed liver transplantation for malignancies other than HCC, therefore, we opened this NCD reconsideration on October 14, 2011 and solicited public comment. CMS decided to review the NCD for more recent evidence related to the following malignancies: CCA, liver metastases due to a neuroendocrine tumor (NET) and HAE.

B. Policy: In accordance with the current Publication 100-03, Section 260.1, NCD Manual, Medicare covers liver transplantation for one malignancy, (hepatocellular carcinoma [HCC] - a liver cancer) in certain circumstances. On June 21, 2012, CMS issued a final decision memorandum stating that liver transplantation for patients with certain malignancies offers the potential for some clinical benefit in patients carefully selected on a case-by-case basis. These malignancies are (1) extrahepatic unresectable cholangiocarcinoma (CCA), (2) liver metastases due to a neuroendocrine tumor (NET), and, (3) hemangioendothelioma (HAE). The evidence base for these malignancies is sparse and especially limited in the Medicare population. In carefully selected patients, there appears to be a survival benefit from limited case series and reviews. Thus, we believe that our local Medicare Administrative Contractors (MACs) are in a better position to consider the clinical characteristics of individual beneficiaries and the performance of transplant centers within their jurisdictions in the best interest of Medicare beneficiaries.

Therefore, MACs acting within their respective jurisdictions may determine coverage for adult liver transplantation for patients with extrahepatic unresectable cholangiocarcinoma (CCA), (2) liver metastases due to a neuroendocrine tumor (NET) or (3) hemangioendothelioma (HAE) when furnished in a facility that meets CMS institutional criteria. All other malignancies continue to remain nationally non-covered. See Pub. 100-04, Claims Processing Manual, Chapter 3, section 90.4 for claims processing information, and Pub. 100-03, NCD Manual, Chapter 1, section 260.1, for coverage criteria.

II. BUSINESS REQUIREMENTS TABLE

Use "Shall" to denote a mandatory requirement

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M E M A C	F I M A C	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
						F I S S	M C S	V M S	C W F		
7908-03.1	Effective for claims with dates of service June 21, 2012 and later, contractors may, at their discretion cover adult liver transplantation for patients with extrahepatic unresectable cholangiocarcinoma (CCA), (2) liver metastases due to a neuroendocrine tumor (NET) or (3) hemangioendothelimo (HAE) when furnished in an approved Liver Transplant Center. All other nationally non-covered malignancies continue to remain nationally non-covered.	X		X	X						

III. PROVIDER EDUCATION TABLE

Number	Requirement	Requirement									
		A / B M A C	D M E M A C	F I M A C	C A R R I E R	R H H I	Shared-System Maintainers				OTHER
						F I S S	M C S	V M S	C W F		
7908-03.2	A provider education article related to this instruction will be available at http://www.cms.hhs.gov/MLNMattersArticles/ shortly after the CR is released. You will receive notification of the article release via the established "MLN Matters" listserv. Contractors shall post this article, or a direct link to this article, on their Web site and include information about it in a listserv message within one week of the availability of the provider education article. In addition, the provider education article shall be included in your next regularly scheduled bulletin. Contractors are free to supplement MLN Matters articles with localized information that would benefit their provider community in billing and administering the Medicare program correctly.	X		X	X						

Number	Requirement									
	A / B M A C	D M E M A C	F I I E R	C A R I E R	R H H I	Shared-System Maintainers				OTHER
						F I S S	M C S	V M S	C W F	

IV. SUPPORTING INFORMATION

Section A: For any recommendations and supporting information associated with listed requirements, use the box below: NA

Use "Should" to denote a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space: NA

V. CONTACTS

Pre-Implementation Contact(s): For Coverage and Policy Related Issues: Roya Lotfi at (410) 786-4072 or roya.lotfi@cms.hhs.gov or Wanda Belle at (410) 786-7491 or wanda.belle@cms.hhs.gov, Patti Brocato-Simons at 410-786-0261 or patricia.brocato-simons@cms.hhs.gov

For Professional Claims Issues (MAC/Carriers): Yvette Cousar at (410) 786-2160 or Yvette.cousar@cms.hhs.gov;

For Institutional Claims Issues (MAC/FIs): Fred Rooke at (404) 562-7205 or fred.rooke@cms.hhs.gov

Post-Implementation Contact(s): Contact your Contracting Officer’s Representative (COR) or Contractor Manager, as applicable.

VI. FUNDING

Section A: For Fiscal Intermediaries (FIs), Regional Home Health Intermediaries (RHHIs), and/or Carriers:

No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

Section B: For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC Statement of Work. The contractor is not obligated to incur costs in excess of the amounts allotted in your contract unless and until specifically

authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

260.1 - Adult Liver Transplantation

(Rev.146, Issued: 08-03-12, Effective: 06-21-12, Implementation; 09-04-12)

A. General

Liver transplantation, which is in situ replacement of a patient's liver with a donor liver, in certain circumstances, may be an accepted treatment for patients with end-stage liver disease due to a variety of causes. The procedure is used in selected patients as a treatment for malignancies, including primary liver tumors and certain metastatic tumors, which are typically rare but lethal with very limited treatment options. It has also been used in the treatment of patients with extrahepatic perihilar malignancies. Examples of malignancies include extrahepatic unresectable cholangiocarcinoma (CCA), liver metastases due to a neuroendocrine tumor (NET), and, hemangioendothelioma (HAE). Despite potential short- and long-term complications, transplantation may offer the only chance of cure for selected patients while providing meaningful palliation for some others.

B. Nationally Covered Indications

Effective July 15, 1996, adult liver transplantation when performed on beneficiaries with end-stage liver disease other than hepatitis B or malignancies is covered under Medicare when performed in a facility which is approved by the *Centers for Medicare & Medicaid Services (CMS)* as meeting institutional coverage criteria.

Effective December 10, 1999, adult liver transplantation when performed on beneficiaries with end-stage liver disease other than malignancies is covered under Medicare when performed in a facility which is approved by CMS as meeting institutional coverage criteria.

Effective September 1, 2001, Medicare covers adult liver transplantation for hepatocellular carcinoma when the following conditions are met:

- The patient is not a candidate for subtotal liver resection;
- The patient's tumor(s) is less than or equal to 5 cm in diameter;
- There is no macrovascular involvement;
- There is no identifiable extrahepatic spread of tumor to surrounding lymph nodes, lungs, abdominal organs or bone; and,
- The transplant is furnished in a facility that is approved by CMS as meeting institutional coverage criteria for liver transplants (see 65 FR 15006).

Effective June 21, 2012, Medicare Administrative Contractors acting within their respective jurisdictions may determine coverage of adult liver transplantation for the following malignancies: (1) extrahepatic unresectable cholangiocarcinoma (CCA); (2) liver metastases due to a neuroendocrine tumor (NET); and, (3) hemangioendothelioma (HAE).

1. Follow-Up Care

Follow-up care or re-transplantation required as a result of a covered liver transplant is covered, provided such services are otherwise reasonable and necessary. Follow-up care is also covered for patients who have been discharged from a hospital after receiving non-covered liver transplant. Coverage for follow-up care is for items and services that are reasonable and necessary as determined by Medicare guidelines.

2. Immunosuppressive Drugs

See the Medicare Benefit Policy Manual, Chapter 15, “Covered Medical and Other Health Services,” §50.5.1 and the Medicare Claims Processing Manual, Chapter 17, “Drugs and Biologicals,” §80.3.

C. Nationally Non-Covered Indications

Adult liver transplantation for other malignancies remains excluded from coverage.

D. Other

Coverage of adult liver transplantation is effective as of the date of the facility’s approval, but for applications received before July 13, 1991, can be effective as early as March 8, 1990. (See 56 FR 15006 dated April 12, 1991.)

(This NCD last reviewed June 2012.)