

CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-04 Medicare Claims Processing	Centers for Medicare & Medicaid Services (CMS)
Transmittal 2513	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	3/90.4/Liver Transplants

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. 100-04	Transmittal: 2513	Date: August 3, 2012	Change Request: 7908
-------------	-------------------	----------------------	----------------------

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 the Centers for Medicare & Medicaid Services (CMS) reviewed liver transplantation for malignancies other than HCC; therefore, we opened this national coverage determination (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 nationally non-covered 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 M A C	F I I E C	C A R I E R	R H H I I E R	Shared-System Maintainers				OTHER
7908-04.1	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	Responsibility (place an "X" in each applicable column)									
		A / B M A C	D M M A C	F I I E C	C A R I E R	R H H I I E R	Shared-System Maintainers				OTHER
7908.04.2	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	X		X	X						

Number	Requirement	Responsibility (place an "X" in each applicable column)									
		A / B	D M E	F I	C A R R I E R	R H I	Shared-System Maintainers				OTHER
		M A C	M A C				F I S S	M C S	V M S	C W F	
	community in billing and administering the Medicare program correctly.										

IV. SUPPORTING INFORMATION

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

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: For all other recommendations and supporting information, use this space: N/A

V. CONTACTS

Pre-Implementation Contact(s): Coverage and Policy Related Issues: Roya Lotfi at (410) 786-4072 or roya.lotfi@cms.hhs.gov, Wanda Belle at (410) 786-7491 or wanda.belle@cms.hhs.gov. or Patti Brocato-simons, 410-786-0261, patricia.brocato-simons@cms.hhs.gov; Professional Claims Issues (MAC/Carriers): Yvette Cousar at (410) 786-2160 or Yvette.cousar@cms.hhs.gov; 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.

90.4 - Liver Transplants

(Rev.2513, Issued: 08-03-12, Effective: 06-21- 12, Implementation: 09-04- 12)

A. Background

For Medicare coverage purposes, liver transplants are considered medically reasonable and necessary for specified conditions when performed in facilities that meet specific criteria. *Coverage guidelines may be found in Publication 100-03, Section 260.1.*

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 (below). All other nationally non-covered malignancies continue to remain nationally non-covered.

To review the current list of approved Liver Transplant Centers, see http://www.cms.hhs.gov/CertificationandComplianc/20_Transplant.asp#TopOfPage