CMS Manual System	Department of Health & Human Services (DHHS)
Pub 100-03 Medicare National Coverage Determinations	Centers for Medicare & Medicaid Services (CMS)
Transmittal 177	**Date: November 19, 2014**
	Change Request 8871

Transmittal 174 dated September 5, 2014, is being rescinded and replaced by Transmittal 177 to make minor editorial revisions to the 'Policy' section of the attached business requirements. All other information remains the same.

SUBJECT: Screening for Hepatitis C Virus (HCV) in Adults

I. SUMMARY OF CHANGES: Effective for services performed on or after June 2, 2014, the Centers for Medicare & Medicaid Services will cover screening for hepatitis C virus consistent with the grade B recommendations by the USPSTF for the prevention or early detection of an illness or disability and is appropriate for individuals entitled to benefits under Medicare Part A or enrolled under Part B.

This revision to the Medicare National Coverage Determinations Manual is a national coverage determination (NCD). NCDs are binding on all carriers, fiscal intermediaries, contractors with the Federal government that review and/or adjudicate claims, determinations, and/or decisions, quality improvement organizations, qualified independent contractors, the Medicare appeals council, and administrative law judges (ALJs) (see 42 CFR section 405.1060(a)(4) (2005)). An NCD that expands coverage is also binding on a Medicare advantage organization. In addition, an ALJ may not review an NCD. (See section 1869(f)(1)(A)(i) of the Social Security Act.)

EFFECTIVE DATE: June 2, 2014
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 5, 2015 - For non-shared MAC edits and CWF analysis; April 6, 2015 - For remaining shared systems edits

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

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/Table of Contents
N	1/210.13/Screening for Hepatitis C Virus (HCV) in Adults

III. FUNDING:

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

Attachment - Business Requirements

Pub. 100-03	Transmittal: 177	Date: November 19, 2014	Change Request: 8871

Transmittal 174 dated September 5, 2014, is being rescinded and replaced by Transmittal 177 to make minor editorial revisions to the 'Policy' section of the attached business requirements. All other information remains the same.

SUBJECT: Screening for Hepatitis C Virus (HCV) in Adults

EFFECTIVE DATE: June 2, 2014
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: January 5, 2015 - For non-shared MAC edits and CWF analysis; April 6, 2015 - For remaining shared systems edits

I. GENERAL INFORMATION

A. Background: Prior to June 2, 2014, The Centers for Medicare & Medicaid Services (CMS) did not cover screening for hepatitis C virus (HCV) in adults.

Pursuant to §1861(ddd) of the Social Security Act, CMS may add coverage of "additional preventive services" through the National Coverage Determination (NCD) process. The preventive services must meet all of the following criteria:

(1) Reasonable and necessary for the prevention or early detection of illness or disability.

(2) Recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF).

(3) Appropriate for individuals entitled to benefits under Part A or enrolled under Part B.

CMS reviewed the USPSTF recommendations and supporting evidence for screening for HCV in adults and determined that the criteria listed above were met. Therefore, CMS will cover screening for HCV in adults under the conditions specified below.

B. Policy: Effective for claims with dates of service on or after June 2, 2014, CMS has determined the following: The evidence is adequate to conclude that screening for HCV, consistent with the grade B recommendations by the USPSTF, is reasonable and necessary for the prevention or early detection of an illness or disability and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B, as described below.

Therefore, CMS will cover screening for HCV with the appropriate U.S. Food and Drug Administration (FDA) approved/cleared laboratory tests, used consistent with FDA-approved labeling and in compliance with the Clinical Laboratory Improvement Act regulations, when ordered by the beneficiary's primary care physician or practitioner within the context of a primary care setting, and performed by an eligible Medicare provider for these services, for beneficiaries who meet either of the following conditions:

1. A screening test is covered for adults at high risk for HCV infection. "High risk" is defined as persons with a current or past history of illicit injection drug use; and persons who have a history of receiving a blood transfusion prior to 1992. Repeat screening for high risk persons is covered annually only for persons who have had continued illicit injection drug use since the prior negative screening test.

2. A single screening test is covered for adults who do not meet the high risk as defined above, but who were born from 1945 through 1965.

The determination of "high risk for HCV" is identified by the primary care physician or practitioner who assesses the patient's history, which is part of any complete medical history, typically part of an annual wellness visit and considered in the development of a comprehensive prevention plan. The medical record should be a reflection of the service provided.

NOTE: (1) For services provided to beneficiaries born between the years 1945 and 1965, who are not considered high risk, HCV screening is limited to once per lifetime. New HCPCS code G0472, short descriptor - Hep C screen high risk/other, and long descriptor- Hepatitis C antibody screening for individual at high risk and other covered indication(s), will be used. (2) For those beneficiaries determined to be high-risk initially, ICD-9 diagnosis code V69.8, other problems related to life style/ICD-10 diagnosis code Z72.89, other problems related to lifestyle (once ICD-10 is implemented) is required in addition to HCPCS code G0472. (3) Coverage may occur on an annual basis if appropriate, as defined in the policy, denoted by the presence of HCPCS code G0472, ICD diagnosis code V69.8/Z72.89, and ICD-9 diagnosis code 304.91, unspecified drug dependence, continuous/ICD-10 diagnosis F19.20, other psychoactive substance abuse, uncomplicated (once ICD-10 is implemented). Annual is defined as 11 full months must pass following the month of the last negative HCV screening.

II. BUSINESS REQUIREMENTS TABLE

"Shall" denotes a mandatory requirement, and "should" denotes an optional requirement.

Number	Requirement	Responsibility								
		A/B MAC			DME MAC	Shared-System Maintainers				Other
		A	B	HHH		FISS	MCS	VMS	CWF	
8871 - 03.1	Effective for claims with dates of service on and after June 2, 2014, contractors shall recognize new HCPCS, G0472, HCV screening, as a covered service. **NOTE:** HCPCS, G0472, HCV screening, will be in the January 2015 MPFSDB and IOCE updates, with an effective date of June 2, 2014. NOTE: Refer to Pub. 100-03, Medicare National Coverage Determinations Manual, section 210.13 for coverage policy, and Pub. 100-04, Medicare Claims Processing Manual, chapter 18, section 210, for claims processing instructions.	X	X			X				IOCE, MPFSDB 1/1/15

III. PROVIDER EDUCATION TABLE

Number	Requirement	Responsibility				
		A/B MAC			DME MAC	CEDI
		A	B	HHH		
8871 - 03.2	MLN Article: A provider education article related to this instruction will be available at http://www.cms.gov/Outreach-and-Education/Medicare-Learning-Network-MLN/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 sites 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 the contractor's 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			

IV. SUPPORTING INFORMATION

Section A: Recommendations and supporting information associated with listed requirements: N/A

"Should" denotes a recommendation.

X-Ref Requirement Number	Recommendations or other supporting information:

Section B: All other recommendations and supporting information: N/A

V. CONTACTS

Pre-Implementation Contact(s): Michelle Issa, 410-786-6656 or michelle.issa@cms.hhs.gov (Coverage), Pat Brocato-Simons, 410-786-0261 or patricia.brocatosimons@cms.hhs.gov (Coverage), Wanda Belle, 410-786-7491 or wanda.belle@cms.hhs.gov (Coverage), Bill Ruiz, 410-786-9283 or william.ruiz@cms.hhs.gov (Institutional Claims Processing), Bridgitte Davis-Hawkins, 410-786-4573 or bridgitte.davis-hawkins@cms.hhs.gov (Practitioner Claims Processing)

Post-Implementation Contact(s): Contact your Contracting Officer Representative (COR)

VI. FUNDING

Section A: 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.

ATTACHMENTS: 0

Medicare National Coverage Determinations Manual

Chapter 1, Part 4 (Sections 200 – 310.1)

Coverage Determinations

Table of Contents

(Rev. 177, Issued: 11-19-14)

210.13 – Screening for Hepatitis C Virus (HCV) in Adults

(Rev. 177, Issued: 11-19-14, Effective: 06-02-14, Implementation: 01-05-15 - For non-shared MAC edits and CWF analysis; 04-06-15 - For remaining shared systems edits)

A. General

Hepatitis C Virus (HCV) is an infection that attacks the liver and leads to inflammation. The infection is often asymptomatic and can go undiagnosed for decades. It is difficult for the human immune system to eliminate the HCV and it is a major cause of chronic liver disease. The presence of HCV in the liver initiates a response from the immune system which in turn causes inflammation. Inflammation over long periods of time (usually decades) can cause scarring, called cirrhosis. A cirrhotic liver fails to perform the normal functions of the liver which leads to liver failure. Cirrhotic livers are more prone to become cancerous and liver failure leads to serious complications, even death. HCV is reported to be the leading cause of chronic hepatitis, cirrhosis and liver cancer and a primary indication for liver transplant in the Western World.

Under §1861(ddd) of the Social Security Act (the Act), the Centers for Medicare & Medicaid Services (CMS) has the authority to add coverage of additional preventive services if certain statutory requirements are met. The regulations provide:

42 CFR §410.64 Additional preventive services

> *(a) Medicare Part B pays for additional preventive services not described in paragraph (1) or (3) of the definition of "preventive services" under 42 CFR §410.2, that identify medical conditions or risk factors for individuals if the Secretary determines through the national coverage determination process (as defined in section 1869(f)(1)(B) of the Act) that these services are all of the following: (1) reasonable and necessary for the prevention or early detection of illness or disability,(2) recommended with a grade of A or B by the United States Preventive Services Task Force (USPSTF), (3) appropriate for individuals entitled to benefits under Part A or enrolled under Part B.*
>
> *(b) In making determinations under paragraph (a) of this section regarding the coverage of a new preventive service, the Secretary may conduct an assessment of the relation between predicted outcomes and the expenditures for such services and may take into account the results of such an assessment in making such national coverage determinations.*

The scope of the review for this national coverage determination (NCD) evaluated and determined if the existing body of evidence was sufficient for Medicare coverage for screening for HCV in adults at high risk for HCV infection and one-time screening for HCV infection for adults born between 1945 and 1965, which is recommended with a grade B by the USPSTF.

B. Nationally Covered Indications

Effective for services performed on or after June 2, 2014, CMS has determined the following:

The evidence is adequate to conclude that screening for HCV, consistent with the grade B recommendations by the USPSTF, is reasonable and necessary for the prevention or early detection of an illness or disability and is appropriate for individuals entitled to benefits under Part A or enrolled under Part B, as described below.

Therefore, CMS will cover screening for HCV with the appropriate U.S. Food and Drug Administration (FDA)-approved/cleared laboratory tests, used consistent with FDA-approved labeling and in compliance with the Clinical Laboratory Improvement Act regulations, when ordered by the beneficiary's primary care physician or practitioner within the context of a primary care setting, and performed by an eligible Medicare provider for these services, for beneficiaries who meet either of the following conditions:

1. A screening test is covered for adults at high risk for HCV infection. "High risk" is defined as persons with a current or past history of illicit injection drug use; and persons who have a history of receiving a blood transfusion prior to 1992. Repeat screening for high risk persons is covered annually only for persons who have had continued illicit injection drug use since the prior negative screening test.

2. A single screening test is covered for adults who do not meet the high risk definition above, but who were born from 1945 through 1965.

The determination of "high risk for HCV" is identified by the primary care physician or practitioner who assesses the patient's history, which is part of any complete medical history, typically part of an annual wellness visit and considered in the development of a comprehensive prevention plan. The medical record should be a reflection of the service provided.

A primary care setting is defined by the provision of integrated, accessible health care services by clinicians who are accountable for addressing a large majority of personal health care needs, developing a sustained partnership with patients, and practicing in the context of family and community. Emergency departments, inpatient hospital settings, ambulatory surgical centers, independent diagnostic testing facilities, skilled nursing facilities, inpatient rehabilitation facilities, clinics providing a limited focus of health care services, and hospice are examples of settings not considered primary care settings under this definition.

A "primary care physician" and "primary care practitioner" will be defined consistent with existing sections of the Act (§1833(u)(6), §1833(x)(2)(A)(i)(I) and §1833(x)(2)(A)(i)(II)).

§1833(u)

(6) Physician Defined.—For purposes of this paragraph, the term "physician" means a physician described in section 1861(r)(1) and the term "primary care physician" means a physician who is identified in the available data as a general practitioner, family practice practitioner, general internist, or obstetrician or gynecologist.

§1833(x)(2)(A)(i)

(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or

(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5)).

C. Nationally Non-Covered Indications

Unless specifically covered in this NCD, any other NCD, or in statute, preventive services are non-covered by Medicare.

D. Other

N/A

(This NCD last reviewed June 2014.)