SCREENING FOR HEPATITIS C VIRUS (HCV) IN ADULTS
(NCD 210.13)

Guideline Number: MPG275.02

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INSTRUCTIONS FOR USE

This Policy Guideline is applicable to UnitedHealthcare Medicare Advantage Plans offered by UnitedHealthcare and its affiliates for health care services submitted on CMS 1500 forms and, when specified, to those billed on UB04 forms (CMS 1450), or their electronic comparative. The information presented in this Policy Guideline is believed to be accurate and current as of the date of publication.

This Policy Guideline provides assistance in administering health benefits. All reviewers must first identify member eligibility, any federal or state regulatory requirements, Centers for Medicare and Medicaid Services (CMS) policy, the member specific benefit plan coverage, and individual provider contracts prior to use of this Policy Guideline. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document may differ greatly from the standard benefit plan upon which this Policy Guideline is based. In the event of a conflict, the member specific benefit plan document supersedes this Policy Guideline. Other Policies and Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

UnitedHealthcare follows Medicare coverage guidelines and regularly updates its Medicare Advantage Policy Guidelines to comply with changes in CMS policy. UnitedHealthcare encourages physicians and other healthcare professionals to keep current with any CMS policy changes and/or billing requirements by referring to the CMS or your local carrier website regularly. Physicians and other healthcare professionals can sign up for regular distributions for policy or regulatory changes directly from CMS and/or your local carrier.

This Policy Guideline is provided for informational purposes. It does not constitute medical advice.

POLICY SUMMARY

Overview
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:

• Medicare Part B pays for additional preventive services not described in paragraph (1) or (3) of the definition of “preventive services” under §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:
  o Reasonable and necessary for the prevention or early detection of illness or disability,
  o Recommended with a grade of a or b by the united states preventive services task force,
  o Appropriate for individuals entitled to benefits under Part A or enrolled under Part 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 the existing evidence and determined if the body of evidence was sufficient for Medicare coverage for screening for HCV in adults at high risk for HCV infection and 1-time screening for HCV infection for adults born between 1945 and 1965, which is recommended with a grade B by the United States Preventive Services Task Force (USPSTF).

**Guidelines**

**Nationally Covered Indications**

Effective for services performed on or after June 02, 2014, CMS has determined the evidence is adequate to conclude that screening for Hepatitis C Virus (HCV), consistent with the grade B recommendations by the U.S. Preventive Services Task Force (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 (CLIA) regulations, when ordered by the member'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:

- A screening test is covered for adults at high risk for Hepatitis C Virus 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.
- 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.

For services provided to members born between the years 1945 and 1965, who are not considered high risk, HCV screening is limited to once per lifetime.

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))

**Nationally Non-Covered Indications**

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

**APPLICABLE CODES**

The following list(s) of codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this guideline does not imply that the service described by the code is a covered or non-covered health service.
Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>G0472</td>
<td>Hepatitis C antibody screening for individual at high risk and other covered indication(s)</td>
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<table>
<thead>
<tr>
<th>Place of Service Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>11</td>
<td>Physician’s office</td>
</tr>
<tr>
<td>19</td>
<td>Off campus-outpatient hospital</td>
</tr>
<tr>
<td>22</td>
<td>On campus-outpatient hospital</td>
</tr>
<tr>
<td>49</td>
<td>Independent clinic</td>
</tr>
<tr>
<td>71</td>
<td>State or local public health clinic</td>
</tr>
<tr>
<td>81</td>
<td>Independent laboratory</td>
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**Coding Clarification:** For those members determined to be high-risk initially, ICD-10 Z72.89 is required in addition to G0472. Coverage may occur on an annual basis if appropriate, as defined in the policy, denoted by the presence of G0472, ICD-10 Z72.89 and ICD-10 F19.20.

<table>
<thead>
<tr>
<th>ICD-10 Diagnosis Code</th>
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<tr>
<td>F19.20</td>
<td>Other psychoactive substance dependence, uncomplicated</td>
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<tr>
<td>Z72.89</td>
<td>Other problems related to lifestyle</td>
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**REFERENCES**

**CMS National Coverage Determinations (NCDs)**
- **NCD 210.13 Screening for Hepatitis C Virus (HCV) in Adults**

**CMS Claims Processing Manual**
- **Chapter 18, §1 Medicare Preventive and Screening Services**

**CMS Transmittals**
- **Transmittal 174, Change Request 8871, Dated 09/05/2014 (Screening for Hepatitis C Virus (HCV) in Adults)**
- **Transmittal 177, Change Request 8871, Dated 11/19/2014 (Screening for Hepatitis C Virus (HCV) in Adults)**
- **Transmittal 3063, Change Request 8871, Dated 09/05/2014 (Screening for Hepatitis C Virus (HCV) in Adults)**
- **Transmittal 3215, Change Request 8871, Dated 03/11/2015 (Screening for Hepatitis C Virus (HCV) in Adults)**

**MLN Matters**
- **Article MM8871, Screening for Hepatitis C Virus (HCV) in Adults**
- **Article MM9360, Reporting of Type of Bill (TOB) 014x for Billing Screening of Hepatitis C Virus (HCV) in Adults**

**UnitedHealthcare Commercial Policies**
- **Hepatitis Screening**

**Others**
- **U.S. Preventive Services Task Force Recommendations for HCV**

**GUIDELINE HISTORY/REVISION INFORMATION**

<table>
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<tr>
<th>Date</th>
<th>Action/Description</th>
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<tbody>
<tr>
<td>11/09/2016</td>
<td>• Annual Review</td>
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