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## Hepatitis Screening (for Louisiana Only)

**Policy Number:** CS053LA.~~NO~~

**Effective Date:** TBD

[➔ Instructions for Use](#)

Table of Contents	Page
<a href="#">Application</a>	1
<a href="#">Coverage Rationale</a>	1
<a href="#">Definitions</a>	2
<a href="#">Applicable Codes</a>	<del>43</del>
<a href="#">Description of Services</a>	<del>54</del>
<a href="#">Clinical Evidence</a>	<del>85</del>
<a href="#">U.S. Food and Drug Administration</a>	<del>87</del>
<a href="#">References</a>	<del>137</del>
<a href="#">Policy History/Revision Information</a>	<del>138</del>
<a href="#">Instructions for Use</a>	<del>179</del>

### Application

This Medical Policy only applies to the state of Louisiana.

### Coverage Rationale

~~Hepatitis~~Hepatitis A testing is proven and medically necessary for individuals who were born in, or have travelled to regions with high or moderate prevalence of hepatitis A virus (HAV).

Hepatitis B screening is proven and medically necessary ~~for high risk in~~ individuals with the following indications:

- Blood transfusion prior to 1992
- Birth in or travel to regions ~~or have traveled to countries with high or intermediate~~ moderate prevalence of hepatitis ~~A virus (HAV) or hepatitis B virus (HBV)~~ infection
- ~~Chronic or long-term liver disease with elevated liver enzymes (abnormal ALT/AST)~~
- Elevated ALT/AST of unknown etiology
- Clotting-factor disorders, such as hemophilia
- Exposure to blood or body fluids
- Donors of blood, plasma, organs, tissue, or semen
- Exposure Following exposure to individuals an individual with HBV infection through household, secondary contacts or needle sharing
- ~~Health-care workers~~
- Hemodialysis
- ~~Hepatitis C virus (HCV) positive~~

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- ~~High-risk sexual behavior, multiple partners, intercourse with trauma~~
- HIV-positive infection, and ~~sexually transmitted diseases (STD)~~ those who are high risk of HIV acquisition
- Immunosuppression due to immunosuppressive therapy, ~~including chemotherapy, immunosuppression related to organ transplantation, and immunosuppression for rheumatologic or gastroenterologic disorders~~, chemotherapy, and, organ transplantation
- Infants born in the U.S. whose parents were born in regions with high rates of Hepatitis B
- Infants born to HBV ~~or HCV~~ infected mothers ~~(do not test before 18 months of age)~~
- ~~Known exposure to HCV (health care workers after needle sticks involving HCV positive blood)~~
- Men who have sexual relations with men (MSM)
- Pregnancy
- Present sexual ~~partners of~~ partner is infected with HBV
- Prior to anti-TNF initiation
- Recipient of clotting factor concentrates made before 1987
- Recipients of blood or organs from a donor who later tested ~~HCBV~~ positive
- Residents and ~~I~~institutional care workers
- ~~Those who work with non-human primates~~
- ~~Use of recreational drugs, whether injected or not~~
- Hepatitis Current and past recreational use of injection drug(s), including those individuals with a history limited to a single use of injection drug and regardless of the duration since use

Hepatitis C virus (HCV) screening is proven and medically necessary for one-time screening for HCV infection for in adults born between 1945-1965, aged 18 to 79 years whether or not risk factors have been identified.

## Definitions

~~**HCV Antibody Test:** The third-generation HCV EIA test is the most frequently used antibody test to initially screen for HCV infection. This test has high sensitivity, wide availability, and low cost. However, antibody is not detected for many months after infection.~~

~~**Hepatitis A:**~~ **Hepatitis A:** A highly contagious viral condition that causes inflammation affecting the liver's ability to function. Hepatitis A virus (HAV) infection is primarily transmitted by the fecal-oral route, by either person-to-person contact or consumption of contaminated food or water. Although viremia occurs early in infection and can persist for several weeks after onset of symptoms, bloodborne transmission of HAV is uncommon. HAV, has an incubation period of approximately 28 days (range: 15-50 days). HAV replicates in the liver and is shed in high concentrations in feces from 2 weeks before to 1 week after the onset of clinical illness. HAV infection produces a self-limited disease that does not result in chronic infection or chronic liver disease. (CDC, 2020).

~~**Hepatitis A Antibody Test:** Also known as HAV IgM antibody, is the preferred test for diagnosis of acute hepatitis A infection because it rises early and persists only 3 to 12 months.~~

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**Hepatitis A Antibody Test:** Hepatitis A antibody testing, also known as hepatitis A total antibody testing, is performed to determine whether an individual is currently infected with HAV or has previously had HAV infection. Positive antibodies mean a person has HAV, has previously had HAV, or has been vaccinated against the virus. This person is immune to future HAV infection. When antibodies are undetected, the test result will indicate negative. These individuals are susceptible to HAV infection (Center for Substance Abuse Treatment, 2011).

**Hepatitis B:** Hepatitis B virus (HBV) is transmitted through exposure to infective blood, semen, and other body fluids. HBV can be transmitted from infected mothers to infants at the time of birth or from family member to infant in early childhood. Transmission may also occur through transfusions of HBV-contaminated blood and blood products, contaminated injections during medical procedures, and through injection drug use. HBV also poses a risk to healthcare workers who sustain accidental needle stick injuries while caring for infected-HBV patients. Among persons with chronic HBV infection, the risk for premature death from cirrhosis or hepatocellular carcinoma is 15% to 25% (CDC, 2020).

**Hepatitis B Core Antibody Test:** Also known as HBV Core IgM Antibody (HBcAb, IgM), is detectable during At the onset of symptoms in acute but not chronic HBV hepatitis B, the total hepatitis B core antibody (anti-HBc) appears and persists for life. The presence of anti-HBc indicates previous or ongoing infection with hepatitis B virus in an undefined time frame (CDC Division of Viral Hepatitis, 2005; updated 2011).

**Hepatitis B Surface Antigen Test:** Also known as HBV Surface Antigen (HBsAg). Hepatitis B antigen is a protein on the surface of the hepatitis B virus; it. During acute or chronic HBV infection, HBsAg can be detected in high levels in serum during acute or chronic hepatitis B virus infection. The presence of HBsAg indicates that the person is infectious. The body normally produces antibodies to HBsAg as. As part of the normal immune response to infection. HBsAg is the antigen used to make hepatitis B vaccine., the body normally produces antibodies to HBsAg, however, the presence of HBsAg indicates that the person is infectious (CDC Division of Viral Hepatitis, 2005; updated 2011).

**Hepatitis C:** Hepatitis C virus (HCV) is mostly transmitted through direct percutaneous exposure to infective blood. This may happen through transfusions of HCV-contaminated blood and blood products, contaminated injections during medical procedures, and through injection drug use. Sexual transmission is also possible but is much less common. According to the Center for Disease Prevention and Control and Prevention (CDC) Hepatitis C Guideline, hepatitis C virus (HCV), is the most common chronic bloodborne pathogen in the United States; approximately 2.7-3.9 million persons are chronically infected (CDC, 2020).

**Hepatitis C Antibody Test:** The HCV antibody test, also known as an anti-HCV test, looks for antibodies to the hepatitis C virus in the blood. A negative or non-reactive test result means the patient is not currently infected. However, if there has been exposure to HCV within the last six months, repeat testing will need to be performed. A positive or reactive test means you have been infected with the hepatitis C virus at some point in time. Once infected, the patient will always have antibodies in their blood. This is true whether they have cleared the virus, have been cured, or still have the virus in their blood. A reactive antibody test does not necessarily mean the patient currently has hepatitis C, and a follow-up test will be required (CDC Division of Viral Hepatitis, 2020).

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**Hepatitis D:** Hepatitis D (HDV), also known as "delta hepatitis," is a serious liver disease caused by infection with the Hepatitis D virus. This is an RNA virus structurally unrelated to the Hepatitis A, B, or C viruses. Hepatitis D, which can be acute or chronic, is uncommon in the United States. HDV is an incomplete virus that requires the helper function of HBV to replicate and only occurs among people who are infected with the Hepatitis B virus (HBV). The dual infection of HDV and HBV can result in a more serious disease and worse outcome. (CDC, 2020).

**Hepatitis E:** ~~Hepatitis~~ The hepatitis E virus (HEV) is ~~mostly transmitted through consumption of contaminated water or food. HEV is a common cause of hepatitis outbreaks spread by the fecal-oral route, however,~~ in developing parts of the world and is increasingly recognized as an important cause of disease in developed countries. where HEV genotypes 1 and 2 are predominant, HEV infection usually results in a self-limited, acute illness. When through contaminated drinking water is the most common source. In addition, certain mammals can become infected with HEV and consumption of raw or undercooked meat or organs from infected animals can lead to foodborne HEV transmission to humans. HEV RNA (genotypes 3 and 4) has been extracted from deer, boar and pork meat. ~~HEV infection does occur, it is usually the result of travel to a developing country where Hepatitis E is endemic. should be considered in any person with symptoms of viral hepatitis who tests negative for serologic markers of hepatitis A, hepatitis B, hepatitis C, other hepatotropic viruses, and all other causes of acute liver injury~~ (CDC Division of Viral Hepatitis, 2018) ~~(Quest Diagnostics, 2017)~~ 2020).

## Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy 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 federal, state, or contractual requirements 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.

CPT Code	Description
<del>81596</del>	<del>Infectious disease, chronic hepatitis C virus (HCV) infection, six biochemical assays (ALT, A2-macroglobulin, apolipoprotein A-1, total bilirubin, GGT, and haptoglobin) utilizing serum, prognostic algorithm reported as scores for fibrosis and necroinflammatory activity in liver</del>
86704	Hepatitis B core antibody (HBcAb); total
86705	Hepatitis B core antibody (HBcAb); IgM antibody
86706	Hepatitis B surface antibody (HBsAb)
86707	Hepatitis Be antibody (HBeAb)
86708	Hepatitis A antibody (HAAb)
86709	Hepatitis A antibody (HAAb); IgM antibody
86803	Hepatitis C antibody
86804	Hepatitis C antibody; confirmatory test (e.g., immunoblot)

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CPT Code	Description
87340	Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], <u>fluorescence immunoassay [FIA]</u> , immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, <del>multiple-step method</del> ; hepatitis B surface antigen (HBsAg)
87341	Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], <u>fluorescence immunoassay [FIA]</u> , immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, <del>multiple-step method</del> ; hepatitis B surface antigen (HBsAg) neutralization
87350	Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], <u>fluorescence immunoassay [FIA]</u> , immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, <del>multiple-step method</del> ; hepatitis <del>Be</del> B antigen (HBeAg)
87902	Infectious agent genotype analysis by nucleic acid (DNA or RNA); hepatitis C virus
87912	Infectious agent genotype analysis by nucleic acid (DNA or RNA); hepatitis B virus

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HCPSC Code	Description
<u>*G0472</u>	Hepatitis C antibody screening for individual at high risk and other covered indication(s)
<u>*G0499</u>	Hepatitis B screening in non-pregnant, high-risk individual includes hepatitis B surface antigen (HBSAG), antibodies to HBSAG (anti-HBS) and antibodies to hepatitis B core antigen (anti-HBC), and is followed by a neutralizing confirmatory test, when performed, only for an initially reactive HBSAG result

Codes labeled with an asterisk (\*) are not on the state of Louisiana Fee Schedule and therefore may not be covered by the State of Louisiana Medicaid Program.

#### Diagnosis Codes

[Hepatitis Screening: Diagnosis Code List](#)

## Description of Services

The word "hepatitis" means inflammation of the liver. Viral hepatitis is caused by infection with any of at least five distinct viruses: (A, B, C, D, and E). The most common types are Hepatitis A, Hepatitis B, and Hepatitis C. ~~and also refers to a group of viral infections that affect the liver. Viral hepatitis is a relatively common disease (25 per 100,000 individuals in the United States) caused by a diverse group of hepatotropic agents that lead to liver inflammation and cell death. Viral hepatitis is the leading cause of liver cancer and the most common reason for liver transplantation. Five hepatitis viruses have been well characterized (A, B, C, D, and E). All of~~ All the major hepatotropic viruses can cause viral hepatitis but only hepatitis B with or without co-infection with hepatitis D and hepatitis C can cause liver disease. Chronic infection can lead to cirrhosis and hepatocellular carcinoma (Turner, White 2004). CDC Division of Viral Hepatitis, 2020 ~~The most common types are Hepatitis A, Hepatitis B, and Hepatitis C.~~

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~~The following statements regarding all forms of viral hepatitis were listed on the documents on the CDC website (CDC Division of Viral Hepatitis, 2017).~~

In the United States, new cases of hepatitis B virus (HBV) among adults are largely transmitted through injection drug use or sexual intercourse, but most prevalent cases of HBV infection are chronic infections from exposure occurring in infancy or childhood. Another major risk factor for HBV infection is country of origin. In the United States, adults with HBV born in high-prevalence countries were commonly infected during childhood. In children, the primary source of infection is perinatal transmission at birth.

Testing and diagnosis of hepatitis B and C infection is the gateway for access to both prevention and treatment services and is a crucial component of an effective response to the hepatitis epidemic. Early identification of persons with chronic HBV or HCV infection enables them to receive the necessary care and treatment to prevent or delay progression of liver disease. Testing also provides an opportunity to link people to interventions to reduce transmission, through counselling on risk behaviors and provision of prevention commodities (such as sterile needles and syringes) and hepatitis B vaccination. (WHO, 2017)

#### **Regions with High Rates of Hepatitis B (USPSTF 2015)**

- ~~Africa: All countries~~
- ~~Asia~~

~~Australia and South Pacific: All countries except Australia~~The USPSTF maintains a list of countries and their estimated prevalence of HCB. Complete information can be found at: <https://www.uspreventiveservicestaskforce.org/uspstf/recommendation/hepatitis-b-virus-infection-screening#bootstrap-panel--6>. (Accessed June 6, 2022).

- Transmission and New Zealand
- ~~Middle East: All countries except Cyprus and Israel~~
- ~~Eastern Europe: All countries except Hungary~~
- ~~Western Europe: Malta, Spain and indigenous populations of Greenland~~
- ~~North America: Alaska natives and indigenous populations of northern Canada~~
- ~~Mexico and Central America: Guatemala and Honduras~~
- ~~South America: Ecuador, Guyana, Suriname, Venezuela, and Amazonian areas of Bolivia, Brazil, Colombia and Peru~~
- ~~Caribbean: Antigua and Barbuda, Dominica, Grenada, Haiti, Jamaica, St. Kitts and Nevis, St. Lucia, Turks and Caicos~~

## Clinical Spectrum Course of Viral Hepatitis (Nichols, Updated 2017 CDC, 2020)

Hepatitis Virus	Transmission Route	Incubation Period	Mortality	Likelihood of Carrier StateChronic Disease	Likelihood of Chronic Disease	Associated Hepatic Complications
HAV	<ul style="list-style-type: none"> <li>• <u>Fecal-oral</u></li> <li>• <u>Close person-to-person contact with an infected person</u></li> <li>• <u>Sexual contact</u></li> <li>• <u>Ingestion of contaminated food or water</u></li> </ul>	<u>15-50 days (average: 28 days)</u> <del>2-6 wk</del>	<u>1%</u>	None	None	<ul style="list-style-type: none"> <li>• <u>No chronic disease</u></li> <li>• <u>Besides transient symptoms</u></li> </ul>
HBV	<ul style="list-style-type: none"> <li>• <u>Percutaneous, mucosal, or nonintact skin exposure to infectious blood, semen, and other body fluids. HBV is concentrated most highly in blood, and percutaneous exposure is an efficient mode of transfer.</u> <del>Parenteral, perinatal, sexual</del></li> </ul>	<u>60-150 days (average: 90 days)</u> <del>4-26 wk</del>	<u>1%-2%</u>	<u>Chronic infection develops in:</u> <ul style="list-style-type: none"> <li>• <u>90% of infants after acute infection at birth</u></li> <li>• <u>25%-50% of children newly infected at ages 1-5 years</u></li> <li>• <u>5% of people newly infected as adults</u> <del>10% (adults) 90% (infants)</del></li> </ul>	<u>5%</u>	<ul style="list-style-type: none"> <li>• <u>Yes, medical surveillance and treatment are recommended for chronic hepatitis B.</u></li> <li>• <u>Chronic hepatitis B can lead to liver disease, liver failure, and liver cancer.</u></li> </ul>



Hepatitis Virus	Transmission Route	Incubation Period	Mortality	Likelihood of Carrier StateChronic Disease	Likelihood of Chronic Disease	Assee Hepa Carcin
HCV	<ul style="list-style-type: none"> <li>Direct percutaneous exposure to infectious blood. Mucous membrane exposures to blood can also result in transmission, although this route is less efficient. Parenteral, perinatal, sexual</li> </ul>	14-182 days (average range: 14-84 days) 2-23 wk	1%-5%	Chronic infection develops in over 50% of newly infected people 50%-80%	50%-85%	<ul style="list-style-type: none"> <li>Accu AAS rec tre acu wit wai</li> <li>Chr 90% wit cur req HCV wit of the</li> </ul>
HDV	Parenteral, perinatal, sexual	6-26 wk	2%-20%	Variable	90% in superinfection <sup>a</sup>	<ul style="list-style-type: none"> <li>Yes</li> </ul>
HEV	Fecal-oral	2-9 wk	1% <sup>e</sup>	Rare	Rare <sup>e</sup>	<ul style="list-style-type: none"> <li>No</li> </ul>

HCC, ~~h~~Hepatocellular ~~e~~Carcinoma.

~~a - Higher in immunocompromised patients.~~

~~b - Requires coinfection with HBV. Simultaneous infection with HBV is associated with severe acute disease and low likelihood of chronic infection (<5%); superinfection with HBV carries high likelihood of fulminant disease (2%-20%), chronic HDV infection (up to 80%), and cirrhosis (60%-70%), and may progress to hepatocellular carcinoma (HCC).~~

~~c - 10%-30% in pregnant women.~~

## Clinical Evidence

The CDC, in collaboration with the New York City (NYC) Department of Health and Mental Hygiene (DOHMH), conducted a chronic HBV surveillance, selecting a random sample of newly reported cases and collecting more detailed information from the patients' clinicians. Analysis was presented on 180 randomly selected HBV cases reported during June 2008 to November 2009. Approximately two-thirds (67%) of the patients were Asian, and the most commonly reported reason for HBV testing was the patient's birth country or race/ethnicity (27%). In 70% of cases, the clinician did not know of any patient risk factors and 62% did not know their patient's hepatitis A vaccination status despite recommendations. Sixty-nine percent of clinicians stated that they counseled their patients about notifying close contacts about their infection, and 75% counseled about transmission and prevention. This surveillance effort provided quantitative data on health disparities, illustrating that not all patients received recommended prevention and treatment services. In response to these findings, DOHMH now routinely distributes HBV patient education materials to populations in need (CDC, 2014).



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Pauly et al. (2018) conducted a retrospective analysis of 8887 adult patients. They each began treatment with TNF antagonists for autoimmune diseases (dermatologic, rheumatologic, or gastrointestinal) from 2001 through 2010, followed through December 2012. The authors obtained data on HBV infection (52% of patients were screened for HBV before treatment), demographic features, comorbidities, and use of immunosuppressive agents. Of the 4267 patients with unknown HBV status at baseline, 2 had HBV reactivation. Those treated with TNF antagonists for autoimmune diseases, had 39% HBV reactivation rate in those who were HBsAg+ before therapy, but not patients who were HBsAg-negative and anti-HBc+ before therapy. The authors concluded that patients should be screened for HBV infection before anti-TNF therapy; HBsAg+ patients should receive prophylactic antiviral therapy, but not HBsAg-negative, anti-HBc+ patients.

~~Evidence regarding the frequency of testing in persons at risk for ongoing exposures to HCV is lacking. Therefore, clinicians should determine the periodicity of testing based on the risk of infection or reinfection. Because of the high incidence of HCV infection among persons who inject drugs and HIV infected men who have unprotected sex with men, HCV testing at least annually is recommended for these populations (Aberg, 2014); (Linac, 2012); (Wandeler, 2012); (Witt, 2013); (Williams, 2011).~~

~~Wiersma et al (2011) reported that most of the estimated 350 million people with chronic hepatitis B virus (HBV) live in resource constrained settings and that up to 25% of those persons will die prematurely of hepatocellular carcinoma or cirrhosis. They further state that an informal World Health Organization consultation of experts concluded that chronic HBV is a major public health problem in emerging nations, all HIV-infected persons should be screened for HBV infection, HIV/HBV co infected persons should be treated with therapies active against both viruses and that reduce the risk of resistance, and that standards for the management of chronic HBV infection should be adapted to resource-constrained settings.~~

~~Smith et al (2012) reported that many of the 2.7 to 3.9 million persons living with HCV infection, an increasing cause of morbidity and mortality in the United States, are unaware they are infected and do not receive care (e.g., education, counseling, and medical monitoring) and treatment. The CDC estimates that although persons born between 1945 and 1965 comprise an estimated 27% of the population, they account for approximately three-fourths of all HCV infections in the United States, 73% of HCV-associated mortality, and are at greatest risk for hepatocellular carcinoma and other HCV-related liver disease. The CDC is augmenting previous recommendations for HCV testing to recommend one-time testing without prior ascertainment of HCV risk for persons born during 1945 to 1965. These recommendations do not replace previous guidelines for HCV testing that are based on known risk factors and clinical indications, but rather define an additional target population for testing: persons born during 1945 to 1965. The CDC developed these recommendations with the assistance of a work group representing diverse expertise and perspectives. The recommendations are informed by the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework, an approach that provides guidance and tools to define the research questions, conduct the systematic review, assess the overall quality of the evidence, and determine the strength of the recommendations.~~

~~Denniston et al (2012) the authors analyzed data from persons who tested positive for past or current HCV infection during participation in the National Health and Nutrition Examination Survey (NHANES) during the years 2001 through 2008. They conducted a follow-up survey 6 months after examination to determine how many participants testing positive for HCV infection were aware of their HCV status, what actions participants took after~~

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~~becoming aware of their first positive test, and participants' knowledge about hepatitis C. Of the 30, 140 participants tested, 393 had evidence of past or current HCV infection and 170 could be contacted during the follow-up survey and interviewed. Only 49.7% were aware of their positive HCV infection status before being notified by NHANES and only 3.7% of these respondents reported that they had first been tested for HCV because they or their doctor thought they were at risk for infection. The investigators concluded that this data indicated that fewer than 50% of those infected with HCV may be aware of their infection. The findings suggest that more intensive efforts are needed to identify and test persons at risk for HCV infection.~~

### **In 2014, Clinical Practice Guidelines**

#### **American College of Obstetricians and Gynecologists (ACOG)**

In May 2021, reaffirmed January 2022, the American College of Obstetricians and Gynecologists (ACOG) Practice Advisory recommended hepatitis C screening for all pregnant individuals during each pregnancy. Screening during the first prenatal blood assessment obtained in every pregnancy is recommended to identify pregnant individuals with HCV infection and infants who should receive testing at a pediatric visit.

A 2007 practice bulletin, reaffirmed in 2021, states that routine prenatal screening of all pregnant women by hepatitis B surface antigen (HBsAg) testing is recommended.

~~U.S. Preventive Services Task Force (USPSTF) recommended screening for HCV infection in persons at high risk for infection and recommends offering one-time screening for HCV infection to adults born between 1945 and 1965. Both are USPSTF "B" recommendations. The rationale for this recommendation is that persons born between 1945 and 1965 are more likely to be diagnosed with HCV infection, possibly because they received blood transfusions before the introduction of screening in 1992 or have other risk factors for exposure decades earlier. Many persons with chronic HCV infection are unaware of their condition. A risk-based approach may miss detection of a substantial proportion of HCV-infected persons in the birth cohort because of a lack of patient disclosure or knowledge about prior risk status. As a result, 1-time screening for HCV infection in the birth cohort may identify infected patients at earlier stages of disease that could benefit from treatment before developing complications from liver damage. The USPSTF reviewed the indirect chain of evidence that showed the benefits of screening through improvement of the intermediate outcome of SVR after triple-regimen antiviral treatments and reductions in all-cause and liver-related mortality and hepatocellular carcinoma. The USPSTF examined the evidence and accepted with moderate certainty the association between SVR after antiviral treatments and improved clinical outcomes. The USPSTF also found adequate evidence that antiviral treatment results in improved clinical outcomes (reduction in hepatocellular carcinoma). In addition, a recent modeling study with more conservative assumptions showed that birth-cohort screening provided nearly twice the benefit of risk-based screening. In reviewing the prevalence data on high-risk groups and the potential for reduced transmission, the USPSTF concluded that screening in high risk persons (prevalence  $\geq 50\%$ ) and the birth cohort (prevalence of about 3% to 4%) would result in a moderate net benefit. On the basis of the evidence, the USPSTF changed its previous recommendations to a grade "B" recommendation for screening for HCV infection in persons at high risk for infection and 1-time screening for HCV infection in the 1945-1965 birth cohort.~~

## Professional Societies

### American Association for the Study of Liver Disease (AASLD)

~~The AASLD's~~In a practice guidelines for "Treatment of Chronic Hepatitis B" (guideline published by Terrault et al, 2016) recommended that continued risk-based screening for hepatitis B is necessary to reduce morbidity. (2018) for the prevention, diagnosis, and mortality treatment of chronic hepatitis B, the American Association for the Study of Liver Disease (AASLD) recommends screening for the following persons:

- All persons born in countries with a HBsAg seroprevalence of 2%
- U.S. born persons not vaccinated as infants whose parents were born in regions with high HBV endemicity (8%)
- Pregnant women
- Persons needing immunosuppressive therapy
- Persons who have ever injected drugs
- Men who have sex with men
- Individuals with elevated ALT or AST of unknown etiology
- Donors of blood, plasma, organs, tissues, or semen
- Persons with end-stage renal disease, including pre-dialysis, hemodialysis, peritoneal dialysis, and home dialysis patients
- Infants born to HBsAg-positive mothers
- Persons with chronic liver disease
- Persons with HIV
- Household, needle-sharing, and sexual contacts of HBsAg-positive persons
- Persons who are not in a long-term, mutually monogamous relationship (e.g., >1 sex partner during the previous 6 months)
- Persons seeking evaluation or treatment for a sexually transmitted disease
- Health care and public safety workers at risk for occupational exposure to blood or blood-contaminated body fluids
- Residents and staff of facilities for developmentally disabled persons
- Travelers to countries with intermediate or high prevalence of HBV infection
- Persons who are the source of blood or body fluid exposures that might require postexposure prophylaxis
- Inmates of correctional facilities
- Unvaccinated persons with diabetes who are aged 19 through 59 years

In 2019, the AASLD and the Infectious Diseases Society of America (IDSA), revised their guidance on the identification and management of chronic hepatitis C (HCV). The guidance includes a new recommendation that all adults be screened for HCV. In addition to universal screening for hepatitis C, the guidance emphasizes universal treatment.

### American Gastroenterological Association (AGA)

~~The AGA's~~American Gastroenterological Association (AGA) guideline on "The titled prevention and treatment of hepatitis B virus reactivation (HBVr) during immunosuppressive drug therapy" (Reddy et al, 2015) recommended, recommends screening for HBV (HBsAg and anti-HBc, followed by a sensitive HBV DNA test if positive) in patients at moderate or high risk who will undergo immunosuppressive drug therapy. The AGA recommended against routinely screening for HBV in patients who will undergo immunosuppressive drug therapy and are at low risk- (Reddy et al, 2014, retired - update in progress).

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### Centers for Disease Control and Prevention (CDC)

Schillie et al. (2020) presented the CDC recommendations for Hepatitis C screening for adults, from the Morbidity and Mortality Weekly Report (MMWR). The CDC recommends hepatitis C screening of all adults aged  $\geq 18$  years once in their lifetime, and screening of all pregnant women (regardless of age) during each pregnancy. The recommendations include an exception for settings where the prevalence of HCV infection is demonstrated to be  $< 0.1\%$ ; however, few settings are known to exist with a hepatitis C prevalence below this threshold. The recommendation for testing of persons with risk factors remains unchanged from 2017; those with ongoing risk factors should be tested regardless of age or setting prevalence, including continued periodic testing if risks persist.

### North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN)

The 2012 NASPGHAN's practice guidelines on "Diagnosis and management of hepatitis C infection in infants, children, and adolescents" (Mack et al, 2012) noted that children state the following individuals should be screened for HCV infection:

- Persons with recent or past use of drug injections (even those who only injected once and do not consider themselves drug users)
- Persons with conditions known to have a high incidence of Hepatitis C such as HIV infection, history of hemodialysis and unexplained abnormal aminotransferase levels.
- Recipients of blood transfusions, blood products, or organ transplants before July 1992
- Children born to HCV infected mothers
- Following needle-stick injuries
- Present sexual partners of HCV infected individuals
- Children with chronically elevated transaminases
- Children from a region with high prevalence of HCV infection

### U.S. Preventive Services Task Force (USPSTF) - as well as present sexual partners of HCV-infected

In 2020, to update its 2014 recommendation, the U.S. Preventive Services Task Force (USPSTF) commissioned a review of new randomized clinical trials and cohort studies published from 2014 to August 2019 that evaluated the benefits and harms of screening and antiviral therapy for preventing intermediate outcomes or health outcomes and the association between improvements in intermediate outcomes and health outcomes. New key questions focused on the yield of alternative HBV screening strategies and the accuracy of tools to identify persons ~~should be screened for HCV infection~~ at increased risk. This recommendation statement applies to asymptomatic, nonpregnant adolescents and adults at increased risk for HBV infection, including those who were vaccinated before being screened for HBV infection. The draft recommendation is consistent with the 2014 recommendation. It is strengthened by new evidence from trials and cohort studies reporting that antiviral therapy reduces risk of mortality and hepatocellular carcinoma and improves intermediate outcomes that are consistently associated with better health outcomes. The USPSTF concludes with moderate certainty that screening for HBV infection in adolescents and adults at increased risk for infection has moderate net benefit, and therefore recommends screening for HBV infection in adolescents and adults at increased risk for infection (B recommendation).

In 2020, the USPSTF updated its recommendation for screening for HCV infection to apply to all adults aged 18 to 79 years. In its Practice Considerations section of the updated recommendation, the USPSTF also clarifies that clinicians may want to consider screening in adolescents younger than 18 years and in adults older than 79 years who are at high risk (e.g., past or current injection drug use). It also concludes that because of the

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increasing prevalence of HCV infection in women aged 15 to 44 years and in infants born to HCV infected mothers, clinicians may want to consider screening pregnant person younger than 18 years. The USPSTF concluded that broadening the age for HCV screening beyond its previous recommendation will identify infected patients at earlier stages of disease who could greatly benefit from effective treatment before developing complications.

In 2019, the USPSTF reaffirmed it's 2009 recommendation that the benefits outweigh the harms and screening for hepatitis B virus (HBV) is recommended for women at their first prenatal visit to reduce perinatal transmission and the development of chronic HBV infection. Vaccination of all infants against HBV infection and providing postexposure prophylaxis with hepatitis B immune globulin (HBIG) at birth to infants of mothers infected with HBV substantially reduce the risk for acquisition of HBV infection in infants.

## U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Laboratories that perform hepatitis antibody screening are regulated by the FDA under the Clinical Laboratory Improvement Amendments. See the following website for more information:

<http://www.fda.gov/medicaldevices/deviceregulationandguidance/ivdregulatoryassistance/ucm124105.htm>.

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## Policy History/Revision Information

Date	Summary of Changes
<u>TBD</u>	<p data-bbox="337 436 654 457"><u>Coverage Rationale</u></p> <ul style="list-style-type: none"> <li data-bbox="337 472 1019 493">• <u>Revised coverage guidelines to indicate:</u> <ul style="list-style-type: none"> <li data-bbox="386 499 1437 583">○ <u>Hepatitis A testing is proven and medically necessary for individuals who were born in, or have travelled to regions with high or moderate prevalence of hepatitis A virus (HAV)</u></li> <li data-bbox="386 590 1469 642">○ <u>Hepatitis B screening is proven and medically necessary in individuals with the following indications:</u> <ul style="list-style-type: none"> <li data-bbox="435 653 976 674">▪ <u>Blood transfusion prior to 1992</u></li> <li data-bbox="435 680 1469 743">▪ <u>Birth in or travel to regions with high or moderate prevalence of hepatitis B virus (HBV) infection</u></li> <li data-bbox="435 749 1052 770">▪ <u>Elevated ALT/AST of unknown etiology</u></li> <li data-bbox="435 777 1198 798">▪ <u>Clotting-factor disorders, such as hemophilia</u></li> <li data-bbox="435 804 992 825">▪ <u>Exposure to blood or body fluids</u></li> <li data-bbox="435 831 1263 852">▪ <u>Donors of blood, plasma, organs, tissue, or semen</u></li> <li data-bbox="435 858 1469 921">▪ <u>Following exposure to an individual with HBV infection through household, secondary contacts or needle sharing</u></li> <li data-bbox="435 928 672 949">▪ <u>Hemodialysis</u></li> <li data-bbox="435 955 878 976">▪ <u>High-risk sexual behavior</u></li> <li data-bbox="435 982 1404 1045">▪ <u>HIV-positive infection, and those who are high risk of HIV acquisition</u></li> <li data-bbox="435 1052 1485 1136">▪ <u>Immunosuppression due to immunosuppressive therapy for rheumatologic or gastroenterologic disorders, chemotherapy, and organ transplantation</u></li> <li data-bbox="435 1142 1502 1205">▪ <u>Infants born in the U.S. whose parents were born in regions with high rates of Hepatitis B</u></li> <li data-bbox="435 1211 1052 1232">▪ <u>Infants born to HBV infected mothers</u></li> <li data-bbox="435 1239 1177 1260">▪ <u>Men who have sexual relations with men (MSM)</u></li> <li data-bbox="435 1266 625 1287">▪ <u>Pregnancy</u></li> <li data-bbox="435 1293 1166 1314">▪ <u>Present sexual partner is infected with HBV</u></li> <li data-bbox="435 1320 927 1341">▪ <u>Prior to anti-TNF initiation</u></li> <li data-bbox="435 1348 1404 1369">▪ <u>Recipient of clotting factor concentrates made before 1987</u></li> <li data-bbox="435 1375 1485 1438">▪ <u>Recipients of blood or organs from a donor who later tested HBV positive</u></li> <li data-bbox="435 1444 1117 1465">▪ <u>Residents and institutional care workers</u></li> <li data-bbox="435 1472 1469 1556">▪ <u>Current and past recreational use of injection drug(s), including those individuals with a history limited to a single use of injection drug and regardless of the duration since use</u></li> </ul> </li> <li data-bbox="386 1562 1502 1646">○ <u>Hepatitis C virus (HCV) screening is proven and medically necessary in adults aged 18 to 79 years whether or not risk factors have been identified</u></li> </ul> </li> </ul> <p data-bbox="337 1661 532 1682"><u>Definitions</u></p> <ul style="list-style-type: none"> <li data-bbox="337 1688 732 1709">• <u>Updated definition of:</u> <ul style="list-style-type: none"> <li data-bbox="386 1715 829 1736">○ <u>Hepatitis A Antibody Test</u></li> <li data-bbox="386 1743 911 1764">○ <u>Hepatitis B Core Antibody Test</u></li> <li data-bbox="386 1770 943 1791">○ <u>Hepatitis B Surface Antigen Test</u></li> <li data-bbox="386 1797 609 1818">○ <u>Hepatitis C</u></li> <li data-bbox="386 1824 829 1845">○ <u>Hepatitis C Antibody Test</u></li> <li data-bbox="386 1852 609 1873">○ <u>Hepatitis E</u></li> </ul> </li> </ul>

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#### Applicable Codes

- Removed CPT code 81596
- Revised description for CPT codes 87340, 87341, and 87350
- Added notation to indicate HCPCS codes G0472 and G0499 are not on the State of Louisiana Fee Schedule and therefore may not be covered by the State of Louisiana Medicaid Program

#### Supporting Information

- Updated Description of Services, Clinical Evidence, and References sections to reflect the most current information
- Archived previous policy version CS053LA.N

## Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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