HEPATITIS SCREENING

Policy Number: 2018T0548Q **Effective Date**: June 1, 2018

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INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the member specific benefit plan document must be referenced. The terms of the member specific benefit plan document [e.g., Certificate of Coverage (COC), Schedule of Benefits (SOB), and/or Summary Plan Description (SPD)] may differ greatly from the standard benefit plan upon which this Medical Policy is based. In the event of a conflict, the member specific benefit plan document supersedes this Medical Policy. All reviewers must first identify member eligibility, any federal or state regulatory requirements, and the member specific benefit plan coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Before using this policy, please check the member specific benefit plan document and any federal or state mandates, if applicable.

Essential Health Benefits for Individual and Small Group

For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage for benefits which are deemed EHBs, the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this policy, it is important to refer to the member specific benefit plan document to determine benefit coverage.

COVERAGE RATIONALE

Hepatitis screening for "at-risk" persons for acute and chronic infections (see table below) is proven and/or medically necessary for the following indications:
- Individuals with a history of sexually transmitted infections (STI)
- Men who have sexual relations with men
- Individuals with multiple sexual partners
- Individuals who have experienced Intercourse with trauma
- Human immunodeficiency virus (HIV) infected persons

- Individuals who have history of using injection and non-injection illicit drugs
- Individuals born in regions or who have traveled to countries with high or intermediate prevalence of hepatitis A virus (HAV) or hepatitis B virus (HBV) infection
- All pregnant women including those with a sexually transmitted infection (STI)
- Individuals who have received blood transfusion or organ transplantation before July 1992
- Recipient of clotting factor concentrates made before 1987
- Individuals receiving hemodialysis
- Individuals prior to initiating TNF blocker immunosuppressive therapy
- Individuals needing immunosuppressive or cytotoxic therapy
- Individuals with signs and symptoms of liver disease/elevated liver enzymes (abnormal ALT/AST)
- Individuals with positive test for anti-hepatitis C virus (HCV)
- Individuals with clotting factor disorders
- Individuals with history of working with non-human primates susceptible to HAV infection
- Infants born to HBV or HCV positive mothers (do not test before 18 months of age)
- US born infants whose parents were born in regions with high rates of Hepatitis B
- Sexual partners of infected persons
- Household, needle sharing or secondary contacts of HbsAg positive persons
- 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
- Individuals with known exposure to HCV (health care workers after needle sticks involving HCV positive blood or recipients of blood or organs from a donor who later tested HCV positive)
- Donors of blood, plasma, organs, tissue or semen

Hepatitis screening is proven and/or medically necessary for one-time screening for HCV infection for adults born between 1945-1965, whether or not risk factors have been identified.

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 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 Coverage Determination Guidelines may apply.

CPT Code	Description
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)
87340	Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; hepatitis B surface antigen (HBsAg)
87341	Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; hepatitis B surface antigen (HBsAg) neutralization
87350	Infectious agent antigen detection by immunoassay technique, (e.g., enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative, multiple-step method; hepatitis Be 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

HCPCS Code	Description
G0472	Hepatitis C antibody screening for individual at high risk and other covered indication(s)
G0499	Hepatitis B screening in non-pregnant, high risk individual includes hepatitis B surface antigen (HBSAG) followed by a neutralizing confirmatory test for initially reactive results, and antibodies to HBSAG (anti-HBS) and hepatitis B core antigen (anti-HBC)

ICD-10 Diagnosis Codes
Hepatitis Screening ICD10 Codes.xls

DESCRIPTION OF SERVICES

The word "hepatitis" means inflammation of the liver 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 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). The most common types are Hepatitis A, Hepatitis B, and Hepatitis C. The following statements regarding all forms of viral hepatitis were listed on the documents on the CDC website. (CDC Division of Viral Hepatitis, 2017)

Hepatitis A, caused by infection with the Hepatitis A virus (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.

However, 10%–15% of patients might experience a relapse of symptoms during the 6 months after acute illness. Acute liver failure from Hepatitis A is rare (overall case-fatality rate: 0.5%). The risk for symptomatic infection is directly related to age, with > 80% of adults having symptoms compatible with acute viral hepatitis and the majority of children having either asymptomatic or unrecognized infection. Antibody produced in response to HAV infection persists for life and confers protection against reinfection.

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 occasionally might be detected in saliva in experimentally infected animals, but transmission by saliva has not been demonstrated.

Hepatitis B, which is caused by infection with the Hepatitis B virus (HBV), is found in highest concentrations in blood and in lower concentrations in other body fluids (e.g., semen, vaginal secretions, and wound exudates). HBV is efficiently transmitted by percutaneous or mucous membrane exposure to infectious blood or body fluids that contain blood. In adults, approximately half of newly acquired HBV infections are symptomatic, and approximately 1% of reported cases result in acute liver failure and death. Among persons with chronic HBV infection, the risk for premature death from cirrhosis or hepatocellular carcinoma is 15% to 25%. The primary risk factors that have been associated with infection are unprotected sex with an infected partner, birth to an infected mother, unprotected sex with more than one partner, men who have sex with other men, history of other sexually transmitted diseases, and illegal injection drug use.

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. HCV is most efficiently transmitted through large or repeated percutaneous exposure to infected blood (e.g., through transfusion of blood from unscreened donors or through use of injecting drugs). Although much less frequent, occupational, perinatal, and sexual exposures also can result in transmission of HCV.

Hepatitis D, also known as "delta hepatitis," is a serious liver disease caused by infection with the Hepatitis D virus (HDV). 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).

Hepatitis E is a liver disease caused by the Hepatitis E virus (HEV). HEV infection usually results in a self-limited, acute illness. It is widespread in the developing world. Usually, hepatitis E is spread by contaminated water; however, in developed countries eating uncooked or undercooked animal products can also cause hepatitis E. Hepatitis E is believed to be uncommon in the United States. When HEV infection does occur, it is usually the result of travel to a developing country where Hepatitis E is endemic. However, rare cases have been reported among persons with no history of travel to HEV-hyperendemic countries. (CDC Division of Viral Hepatitis, 2017)

Clinical Spectrum of Viral Hepatitis (Nichols, Updated 2017)

Hepatitis Virus	Transmission Route	Incubation Period	Mortality	Likelihood of Carrier State	Likelihood of Chronic Disease	Association with Hepatocellular Carcinoma
HAV	Fecal-oral	2-6 wk	1%	None	None	No
HBV	Parenteral, perinatal, sexual	4-26 wk	1%-2%	10% (adults) 90% (infants)	5%	Yes
HCV	Parenteral, perinatal, sexual	2-23 wk	1%-5%	50%-80%	50%-85%	Yes
HDV	Parenteral, perinatal, sexual	6-26 wk	2%-20%	Variable	90% in superinfection[a]	Yes[b]
HEV	Fecal-oral	2-9 wk	1%[c]	Rare	Rare[c]	No

HCC, hepatocellular 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).

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, HIBV/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 to1965 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 to1965. 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 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, 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 who 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 ≥ 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 American Association for the Study of Liver Disease (AASLD)'s practice guidelines for "Treatment of Chronic Hepatitis B" (Terrault et al, 2016) recommended that continued risk based screening for Hepatitis B is necessary to reduce morbidity and mortality of chronic hepatitis B.

American Gastroenterological Association (AGA)

The American Gastroenterological Association (AGA)'s guideline on "The prevention and treatment of hepatitis B virus reactivation during immunosuppressive drug therapy" (Reddy et al, 2015) recommended 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.

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

The North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition (NASPGHAN)'s practice guidelines on "Diagnosis and management of hepatitis C infection in infants, children, and adolescents" (Mack et al, 2012) noted that children from a region with high prevalence of HCV infection as well as present sexual partners of HCV-infected persons should be screened for HCV infection.

Screening Recommendations for At-Risk Populations for Acute and Chronic Infections

The risk factors for hepatitis vary by type. Below is a table of the at risk populations by hepatitis virus type.

Characteristics	A *	B	C
History of sexually transmitted infections (STI)	x	x	x
Men who have sexual relations with men	x	x	x
Multiple sexual partners		x	x
Intercourse with trauma			x
Human Immunodeficiency Virus (HIV) infected persons		x	x
Persons who have a history of using injection and non-injection illicit drugs	x	x	x
Persons born in regions or who have traveled to countries with high or intermediate prevalence of hepatitis A virus (HAV) or hepatitis B virus (HBV) infection	x	x	
All pregnant women including those with a sexually transmitted infection (STI)		x	
Blood transfusion or organ transplantation before July 1992			x
Recipient of clotting factor concentrates made before 1987			x
Hemodialysis patients		x	x
Patients needing immunosuppressive or cytotoxic therapy		x	
Patients prior to initiating immunosuppressive therapy			x
Patients with signs and symptoms of liver disease/ elevated liver enzymes (ALT/AST)		x	x
Positive test for anti HCV			x
Clotting factor disorders	x		
History of working with non-human primates susceptible to HAV infection	x		
Infants born to in HBV or HCV positive mothers (do not test before 18 months of age)		x	x
US born infants whose parents were born in regions with high rates of Hepatitis B		x	
Sexual partners of infected persons		x	
Health care and public safety workers at risk for occupational exposure to blood or blood contaminated body fluids		x	
Household, needle sharing or secondary contacts of HbsAg positive persons		x	
Residents and staff of facilities for developmentally disabled persons		x	
Persons with known exposure to HCV (health care workers after needle sticks involving HCV positive blood or recipients of blood or organs from a donor who later tested HCV positive)			x
Donors of blood, plasma, organs, tissue or semen		x	x
Adults born between 1945-1965, with or without risk factors identified			x

* In the United States, nearly half of all reported hepatitis A cases have no specific risk factor identified.
* Hepatitis A is not associated with a chronic infection.

The Centers for Disease Control and Prevention (CDC) uses a prevalence threshold of 2% or greater to define countries with high risk for HBV infection.

Regions with High Rates of Hepatitis B (USPSTF 2015)

- Africa: All countries
- Asia
- Australia and South Pacific: All countries except Australia 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

Laboratory Testing

The hepatitis virus panel is a series of blood tests used to detect current or past infection. It can screen blood samples for more than one kind of hepatitis virus at the same time.

Four initial tests are generally recommended to diagnose acute hepatitis:

- **HAV Immunoglobulin M (IgM) Antibody**: 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.
- **HBV Core IgM Antibody (HBcAb, IgM)**: HBcAb IgM is detectable during acute but not chronic HBV infection.
- **HBV Surface Antigen (HBsAg)**: HBsAg, however, is detectable in both stages. Simultaneous use of these 2 tests therefore not only detects both acute and chronic HBV infection but also helps to differentiate between them.
- **HCV Antibody by EIA**: The EIA (antibody test) is used as the initial assay for diagnosing HCV infection because of its high sensitivity, wide availability, and low cost. However, antibody is not detected for many months after infection. RNA tests can detect virus prior to seroconversion and serve to differentiate between active and resolved infection. RIBA may be used in patients with positive EIA results and negative HCV RNA results, although a repeat HCV RNA assay may also be used in this setting. A negative RIBA result is required for re-entry into the blood donor pool. In cases of fulminant hepatitis, the possibility of coinfection or superinfection (HBV with HCV or HDV) should be explored. (Quest Diagnostics, 2017)

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

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. (Accessed February19, 2018)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does cover some hepatitis screenings when criteria are met. Refer to the National Coverage Determination (NCD) for Screening for Hepatitis C Virus (HCV) in Adults (210.13), Screening for Hepatitis B Virus (HBV) Infection (210.6), Hepatitis Panel/Acute Hepatitis Panel (190.33) and Screening for Sexually Transmitted Infections (STIs) and High-Intensity Behavioral Counseling (HIBC) to Prevent STIs (210.10). Local Coverage Determinations (LCDs) exist; see the LCDs for Hepatitis B Surface Antibody and Surface Antigen.
(Accessed February 16, 2018)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description

06/01/2018	• Updated coverage rationale:
	  ○ Replaced language indicating "[the listed services] are proven *and* medically necessary" with "[the listed services] are proven *and/or* medically necessary"
	  ○ Replaced reference(s)to:
	  ▪ "Patients" with "individuals"
	  ▪ "Persons" with "individuals"
	  ▪ "Hemodialysis *patients*" with "*individuals receiving* hemodialysis"
	• Updated and reformatted list of applicable ICD-10 diagnosis codes:
	  ○ Transfer content to embedded Excel file format
	  ○ Added 177 codes (detailed on list attached below)
	  ○ Revised description for 298 codes (detailed on list attached below)
	 
	Hepatitis Screening
	ICD-10 Code Changes
	• Updated supporting information to reflect the most current description of services, clinical evidence, CMS information, and references
	• Archived previous policy version 2017T0548P