

Reimbursement Policy

Hepatitis Testing

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I. Policy Description

Infectious hepatitis is an inflammation of the liver caused by the hepatitis viruses. Hepatitis C is a blood-borne virus that can be spread via sharing needles or other equipment to inject drugs as well as in inadequate infection control in healthcare settings (CDC, 2018). Hepatitis C causes liver disease and inflammation. A chronic HCV infection can lead to hepatic damage, including cirrhosis and hepatocellular carcinoma, and is the most common cause of liver transplantation in the United States (AASLD-IDSA, 2015).

Hepatitis B is spread by the “Percutaneous, mucosal, or nonintact skin exposure to infectious blood, semen, and other body fluids.” As the hepatitis B virus is concentrated most highly in blood, “percutaneous exposure is an efficient mode of transmission”, though HBV can also be transmitted through birth to an infected mother and sexual contact with an infected person and less commonly through needle-sticks or other sharp instrument injuries, organ transplantation and dialysis, and interpersonal contact through sharing items, such as razors or toothbrushes or contact with open sores of an infected person. Similar to HCV infection, 15% to 25% of people with chronic HBV infection develop chronic liver disease (CDC, 2020a).

The general route of transmission for the hepatitis A virus (HAV) is through the fecal-oral route by close person-to-person contact with an infected person, sexual contact with an infected person, or the ingestion of contaminated food or water, with the bloodborne transmission of HAV being uncommon (CDC, 2020a). Though death is uncommon and most people with acute HAV infection recover with no lasting liver damage, HAV remains a worldwide public health issue and is endemic in many low- to middle-income countries (CDC, 2020a; Keles et al., 2021).

For HCV and HBV screening in pregnant individuals, please see AHS-G2035-Prenatal Screening (Nongenetic).

II. Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual’s benefit coverage at the time of the request. Specifications pertaining to Medicare and Medicaid can be found in the “Applicable State and Federal Regulations” section of this policy document.

Hepatitis B

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- 1) For all individuals 18 years of age and older, triple panel testing (hepatitis B surface antigen [HBsAg], hepatitis B surface antibody [anti-HBs], total antibody to hepatitis B core antigen [anti-HBc]) for Hepatitis B (HBV) infection once per lifetime **MEETS COVERAGE CRITERIA.**
- 2) For asymptomatic, non-pregnant individuals, the following annual HBV infection screening **MEETS COVERAGE CRITERIA:**
 - a) HBsAg and hepatitis B surface antibody (anti-HBs) for infants born from an HBsAg-positive individual.
 - b) Triple panel testing (HBsAg, anti-HBs, anti-HBc) when **one** of the following high-risk situations is met:
 - i) For individuals born in or who have recently traveled to geographic regions with a HBV prevalence 2% or higher (see Note 1).
 - ii) For U.S.-born individuals not vaccinated as infants whose parents were born in geographic regions with an HBV prevalence 8% or higher (see Note 1).
 - iii) For individuals with a history of incarceration.
 - iv) For individuals infected with HIV.
 - v) For individuals with a history of sexually transmitted infections or multiple sex partners.
 - vi) For men who have sex with men.
 - vii) For household contacts, needle-sharing contacts, and sex partners of HBV-infected individuals.
 - viii) For injection-drug users.
 - ix) For individuals with an active hepatitis C virus infection or who have a history of hepatitis C virus infection.
 - x) For individuals with elevated liver enzymes.
 - xi) For individuals who are on long-term hemodialysis treatment.
 - xii) For individuals with diabetes.
 - xiii) For healthcare and public safety workers exposed to blood or body fluids.
- 3) For individuals who test positive for anti-HBc, follow up IgM antibody to anti-HBc (IgM anti-HBc) testing to distinguish between an acute or chronic infection **MEETS COVERAGE CRITERIA.**
- 4) For the confirmation of seroconversion after hepatitis B vaccination, anti-HBs testing **MEETS COVERAGE CRITERIA.**
- 5) For individuals who test positive for HBV by initial antibody screening and who will undergo immunosuppressive drug therapy, HBV DNA testing **MEETS COVERAGE CRITERIA.**

Hepatitis C

- 6) For all individuals 18 years of age and older, antibody testing for Hepatitis C (HCV) infection once per lifetime **MEETS COVERAGE CRITERIA.**
- 7) For any individual with the following recognized conditions or exposures, one-time, post-exposure antibody testing for HCV infection **MEETS COVERAGE CRITERIA:**

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- a) For individuals who have used illicit intranasal or injectable drugs.
- b) For individuals who have received clotting factor concentrates produced before 1987.
- c) For individuals with a history of hemodialysis.
- d) For individuals with evidence of liver disease (based on clinical presentation, persistently abnormal ALT levels, or abnormal liver function studies).
- e) For individuals infected with HIV.
- f) For individuals who received an organ transplant before July 1992.
- g) For individuals who received a blood transfusion or blood component before July 1992.
- h) For individuals notified that they received blood from a donor who later tested positive for an HCV infection.
- i) For individuals with a history of incarceration.
- j) For individuals who received a tattoo in an unregulated setting.
- k) For healthcare, emergency medical, and public safety workers after needle sticks, sharps, or mucosal exposures to HCV-positive blood.
- l) For children born from an HCV-positive individual.
- m) For current sexual partners of HCV-infected persons.
- 8) Routine periodic antibody testing for HCV **MEETS COVERAGE CRITERIA** for individuals with **any** of the following ongoing risk factors (while risk factors persist):
 - a) For individuals who currently inject drugs and share needles, syringes, or other drug preparation equipment.
 - b) For individuals who are receiving ongoing hemodialysis.
 - c) For individuals engaging in high-risk sexual behavior.
- 9) Qualitative nucleic acid testing for HCV **MEETS COVERAGE CRITERIA** in **any** of the following situations:
 - a) As a follow up for individuals who test positive for HCV by initial antibody screening (to differentiate between active infection and resolved infection).
 - b) One time screening for perinatally exposed infants who are 2-6 months of age.
- 10) Prior to the initiation of direct acting anti-viral (DAA) treatment, one time testing for HCV genotype to guide selection of the most appropriate antiviral regimen **MEETS COVERAGE CRITERIA**.
- 11) Testing for HCV viral load with a quantitative nucleic acid test **MEETS COVERAGE CRITERIA** in **any** of the following situations:
 - a) Prior to the initiation of DAA therapy.
 - b) After four weeks of DAA therapy.
 - c) At the end of treatment.
 - d) Twelve, twenty-four, and forty-eight weeks after completion of treatment.

Hepatitis A

- 12) For individuals with signs and symptoms of acute viral hepatitis and who have tested negative for HBV and HCV, testing for IgM anti-hepatitis A (HAV) or qualitative testing for HAV RNA **MEETS COVERAGE CRITERIA**.

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13) Quantitative nucleic acid testing for HAV viral load **DOES NOT MEET COVERAGE CRITERIA.**

Hepatitis D

14) For individuals who have tested positive for HBV, testing for hepatitis D virus (HDV) antibody (anti-HDV) or qualitative testing for HDV RNA **MEETS COVERAGE CRITERIA.**

15) Quantitative nucleic acid testing for HDV viral load **DOES NOT MEET COVERAGE CRITERIA.**

NOTES:

Note 1: The CDC defines HBsAg prevalence by geographic region: <https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/hepatitis-b>.

III. Applicable State and Federal Regulations

DISCLAIMER: If there is a conflict between this Policy and any relevant, applicable government policy for a particular member [e.g., Local Coverage Determinations (LCDs) or National Coverage Determinations (NCDs) for Medicare and/or state coverage for Medicaid], then the government policy will be used to make the determination. For the most up-to-date Medicare policies and coverage, please visit the Medicare search website: <https://www.cms.gov/medicare-coverage-database/search.aspx>. For the most up-to-date Medicaid policies and coverage, visit the applicable state Medicaid website.

Food and Drug Administration (FDA)

Many labs have developed specific tests that they must validate and perform in house. These laboratory-developed tests (LDTs) are regulated by the Centers for Medicare and Medicaid (CMS) as high-complexity tests under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88). LDTs are not approved or cleared by the U. S. Food and Drug Administration; however, FDA clearance or approval is not currently required for clinical use.

IV. Applicable CPT/HCPCS Procedure Codes

CPT	Code Description
86692	Antibody; hepatitis, delta agent
86704	Hepatitis B core antibody (HBcAb); total
86705	Hepatitis B core antibody (HBcAb); IgM antibody
86706	Hepatitis B surface antibody (HBsAb)
86708	Hepatitis A antibody (HAAb)
86709	Hepatitis A antibody (HAAb), IgM antibody

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CPT	Code Description
86803	Hepatitis C antibody
86804	Hepatitis C antibody; confirmatory test (eg, immunoblot)
87340	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; hepatitis B surface antigen (HBsAg)
87341	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; hepatitis B surface antigen (HBsAg) neutralization
87380	Infectious agent antigen detection by immunoassay technique, (eg, enzyme immunoassay [EIA], enzyme-linked immunosorbent assay [ELISA], fluorescence immunoassay [FIA], immunochemiluminometric assay [IMCA]) qualitative or semiquantitative; hepatitis, delta agent
87516	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis B virus, amplified probe technique
87517	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis B virus, quantification
87520	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, direct probe technique
87521	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, amplified probe technique, includes reverse transcription when performed
87522	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis C, quantification, includes reverse transcription when performed
87523	Infectious agent detection by nucleic acid (DNA or RNA); hepatitis D (delta), quantification, including reverse transcription, when performed
87799	Infectious agent detection by nucleic acid (DNA or RNA), not otherwise specified; quantification, each organism
87902	Infectious agent genotype analysis by nucleic acid (DNA or RNA); Hepatitis C virus
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), 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

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Procedure codes appearing in Medical Policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

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V. Evidence-based Scientific References

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