Hepatitis B Management: Guidance for the Primary Care Provider

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The purpose of this document is to provide simplified, up-to-date, and readily accessible guidance for primary care medical providers and non-specialists related to the prevention, diagnosis, and management of hepatitis B virus (HBV) infection, including hepatocellular carcinoma surveillance.

About the HBV Primary Care Workgroup

This guidance was developed by the Hepatitis B Primary Care Workgroup, a multidisciplinary panel of national experts in the field of viral hepatitis B, including representation from primary care, hepatology, infectious diseases, public health, and community coalitions. The workgroup did not receive any outside funding for this project.

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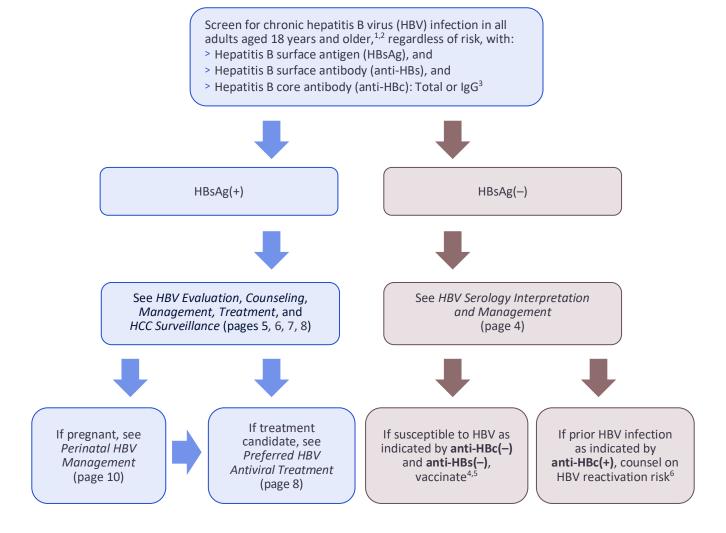
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Chronic Hepatitis B Testing and Management Algorithm



- ¹ HBV screening is recommended for all pregnant women, regardless of age and during each pregnancy, and for adults aged 18 years and older, regardless of risk (per U.S. Centers for Disease Control and Prevention recommendations).
- ² HBV testing is recommended for all persons with a risk of exposure, regardless of age; periodic testing is recommended for all persons susceptible to HBV infection with ongoing exposure(s) since last testing. (See CDC site for full list of exposures https://www.cdc.gov/mmwr/volumes/72/rr/rr7201a1.htm?s cid=rr7201a1 w)
- ³ During the typical course of chronic infection, total anti-HBc and HBsAg will persist, whereas IgM anti-HBc will disappear. IgM anti-HBc should be ordered only when acute HBV infection is a concern.
- ⁴ The CDC's Advisory Committee on Immunization Practices (ACIP) recommends hepatitis B vaccination for all persons younger than 60 years of age, and adults 60 years and older with risk factors for hepatitis B or without identified risk factors but seeking protection.
- ⁵ If screening and vaccination are done together, draw blood before vaccination. If vaccinated first, delay HBsAg testing by ≥4 weeks to avoid false positives. If HBsAg is positive, do not complete the vaccine series and link to care.
- ⁶ Check HBV DNA if isolated anti-HBc(+) in patients with immunosuppression to evaluate for occult hepatitis B.

Shared Management of Hepatitis B Between Primary Care and Specialty Settings

Primary Care or Non-Specialist Care

- > HBV Screening
- > HBV and HAV vaccination
- > Initial evaluation and counseling of HBsAg(+) patient
- > Screening for coinfection with HCV and/or HIV
- Management of metabolic syndrome risk factors (e.g., obesity, diabetes, hyperlipidemia, hypertension)
- > HBV lab monitoring every 6 months for patients not on treatment
- Liver cancer surveillance ultrasound and serum AFP every 6 months if indicated

Either Care Setting or Shared Management

- Initiation and monitoring of HBV treatment (including patients with compensated cirrhosis)
- Monitoring for planned
 HBV treatment withdrawal
- > Screening for coinfection with HDV
- > Perinatal HBV management
- Referral for HBV therapeutic clinical trials

Specialist Care (e.g., GI/Hepatology/ID)

- Decompensated cirrhosis evaluation
- > Management of coinfection with HDV
- Concern of antiviral resistance with persistent or increased viremia on treatment
- Persistent elevation of liver enzymes despite low HBV DNA levels and lack of other identifiable cause
- > Liver lesion on CT or MRI is suspicious for liver cancer
- Liver cancer evaluation and treatment with Hepatology/Surgery/ Oncology

Abbreviations

AFP = alpha-fetoprotein CT = computed tomography GI = gastroenterology HAV = hepatitis A virus HBV = hepatitis B virus HCV = hepatitis C virus HDV = hepatitis D virus HIV = human immunodeficiency virus ID = infectious diseases MRI = magnetic resonance imaging

Hepatitis B Virus (HBV) Serology Interpretation and Management

HbsAg	Anti-HBc (Total or IgG)	Anti-HBs	Interpretation	Management
+	+	-/+	Current infection	 See Evaluation, Counseling, Management, Treatment, and HCC Surveillance (pages 5, 6, 7, 8) Refer household and sexual contacts for HBV screening; if susceptible, vaccinate
_	+	+	History of infection with immune control	 No transmission risk; HBV dormant in liver Reactivation risk if on select immunosuppressive medications¹
_	+	_	History of infection or occult infection ²	 If immunocompromised, check HBV DNA for occult infection² If immunocompetent, counsel as history of infection above Reactivation risk if on select immunosuppressive medications¹
_	_	+	Immune from prior vaccination	Protected. No need for booster vaccine
_	_	_	Susceptible	VACCINATE ^{3,4}

¹ See American Gastroenterological Association (AGA) HBV reactivation guidelines for list of medications and HBV reactivation risk levels with recommended management. (See AGA https://www.gastrojournal.org/article/S0016-5085(24)05744-5/fulltext#)

Post-Vaccination Serologic Testing

Response to HBV vaccination is assessed by an anti-HBs test between 1 and 2 months after the final dose of vaccine. Post-vaccination testing should be obtained in all of the following adult groups at high risk for HBV:

- > Health care personnel and public safety workers
- > Sexual and household contacts of HBsAg(+) persons
- > Hemodialysis patients
- > Persons with HIV and other immunocompromising conditions
- > Infants born HBsAg(+) mothers or mothers whose HBsAg status remains unknown (for infants, check HBsAg and anti-HBs)

Occult HBV infection is defined by the presence of detectable HBV DNA in persons who are negative for HBsAg. Patients with occult HBV infection should be managed similarly to those with current infection.

³ HBV vaccine options include 2-dose Heplisav-B given at least 4 weeks apart for adults >18 years of age, including pregnancy; 3-dose Engerix-B or Recombivax-B given over 6 months for all ages, including pregnancy; 2-dose Twinrix given 6 months apart with single HBV vaccine given between 1-2 months from first Twinrix dose. Heplisav-B can be used to complete a hepatitis B vaccine series if the previous vaccine was from a different manufacturer, but the reverse is not true for completing a series with Heplisav B.

⁴ For "susceptible" persons with documentation of complete vaccine series without follow-up serologic testing and considered low risk for HBV, revaccination is not required. Persons at high risk for HBV who previously received a complete vaccine series without follow-up serologic testing, acceptable management options include (a) give a booster vaccine dose followed by serologic testing 1 to 2 months later, with completion of a full vaccine series if the post-booster anti-HBs test remains negative or (b) give full vaccine series followed by post-vaccination serologic testing 1 to 2 months after the last vaccine dose. Consider 2-dose Heplisav-B if prior HBV vaccine was a 3-dose series.

Initial Evaluation of the HBsAg(+) Patient

History/Examination	Routine Laboratory Tests	Serology/Virology	Imaging/ Staging Studies
☐ Symptoms/signs of cirrhosis	☐ Complete blood count	☐ HBeAg/anti-HBe	☐ Abdominal ultrasound
	☐ Comprehensive	☐ HBV DNA	☐ Elastography (e.g.,
☐ Alcohol and metabolic risk factors	metabolic panel including: - AST/ALT - Total bilirubin - Alkaline phosphatase - Albumin - Creatinine	☐ Anti-HAV (total or IgG) to determine need for vaccination if not documented	FibroScan) or Serum fibrosis
☐ Family history of hepatocellular			assessment (e.g., APRI, FIB-4, FibroSure) ³
carcinoma (HCC)		☐ Anti-HCV¹	
☐ Hepatitis A vaccination status		☐ Anti-HDV, total or IgG ²	
		☐ HIV-1/2 Ag/Ab	

¹ If HCV antibody positive/reactive, check for HCV RNA for current HCV infection; consider ordering HCV RNA instead of anti-HCV if history of prior HCV treatment or possible exposure within past 6 months.

APRI calculator (https://www.hepatitisb.uw.edu/page/clinical-calculators/apri)

FIB-4 calculator (https://www.hepatitisb.uw.edu/page/clinical-calculators/fib-4)

FibroSure and FibroTest are commercially available blood tests that can be ordered as well.

Abbreviations

Ag/Ab = antigen/antibody ALT = alanine aminotransferase anti-HBe = antibody to hepatitis B e antigen APRI = AST to Platelet Ratio Index AST = aspartate aminotransferase HAV = hepatitis A virus HBeAg = hepatitis B e antigen HCV = hepatitis C virus HDV = hepatitis D virus HIV = human immunodeficiency virus IgG = immunoglobulin G

INR = international normalized ratio

² If HDV antibody positive, check HDV RNA to evaluate for active coinfection and refer to liver specialist for treatment if detectable.

³ AST to Platelet Ratio Index (APRI) and Fibrosis-4 (FIB-4) scores can be calculated using platelet count and AST and ALT from routine labs. Calculators with score interpretation are available. See Hepatitis B Online calculators:

Counseling of the HBsAg(+) Patient

1. Provide education on HBV transmission prevention, including safe practices and the importance of notifying close contacts, using non-stigmatizing language.

Persons with chronic HBV:

Should: > Verify that sexual contacts, household contacts, > Use condoms to prevent HBV transmission family members, or injection partners are screened during sexual intercourse with partners and vaccinated (if susceptible) who are susceptible to HBV infection > Cover open cuts and scratches > Clean blood spills with diluted (1:10) bleach Should > Participate in all daily and community activities, > Pursue educational or career opportunities feel free including contact sports without limitations, including work as a > Share food and utensils, or kiss others health care professional safely: > Pursue pregnancy (see Perinatal HBV Management section, page 10) Should > Share toothbrushes, razors, nail clippers, or earrings > Share glucose testing equipment NOT: with those susceptible/nonimmune to HBV > Donate blood, organs, or sperm > Share injection equipment

- 2. Co-develop a plan for follow-up care. Patients will need regular (approximately every 6 months) follow-up and monitoring for disease progression.
- 3. Educate patients on the potential long-term complications of chronic HBV infection, such as cirrhosis, hepatocellular carcinoma (HCC), and the risk of hepatitis D virus (HDV) coinfection.
- Encourage patients to inform all current and future medical providers of their HBsAg-positive status, particularly before starting treatment for cancer or autoimmune conditions (e.g., rheumatoid arthritis).
- 5. Counsel to limit alcohol consumption to reduce liver damage, and to avoid consumption if cirrhosis present.
- 6. Encourage patients to inform their medical provider about any use of herbal or over-the-counter medications to avoid potential liver toxicity.
- 7. Advise to optimize body weight and address metabolic complications, including control of diabetes and dyslipidemia (to prevent concurrent development of metabolic syndrome and fatty liver).
- 8. Emphasize that with proper monitoring and care, most people with hepatitis B can live long, healthy, and normal lives.

Management of the HBsAg(+) Patient

TREATMENT INDICATIONS

For Adolescents (age ≥12 years) and Adults with Chronic Hepatitis B

In principle, all HBsAg+ individuals with viremia are candidates for treatment. Factors to consider are fibrosis stage, HBV DNA, ALT, risk of disease progression and hepatocellular carcinoma (HCC), and patient preference.

Significant fibrosis or cirrhosis (≥F2; elastography >7 kPa or APRI >0.5¹)
 and
 Detectable HBV DNA

-OR-

 HBV DNA >2,000 IU/mL and Elevated ALT² or Family history of HCC

-OR-

- 3. Any of the following conditions:
 - > Immunosuppression³
 - > Viral coinfections (e.g., HIV, HDV, HCV treatment⁴)
 - > HBV transmission risk factors⁵
 - > Extrahepatic manifestations of HBV⁶

-OR-

4. Patient preference for treatment over monitoring only⁷

RECOMMENDED LAB MONITORING

For all with chronic HBV (patients on treatment and not on treatment):

- HBV DNA, ALT every 6 (may vary from 3 to 12) months*
- AST, platelet count, or elastography every 1 to 3 years

If HBV DNA undetectable:

- HBsAg once yearly for HBsAg loss
- * Depending on factors such as recent treatment initiation, liver enzymes, and viral load, patients may need to be monitored more or less frequently.
- ¹ If APRI > 0.5, discuss treatment and either initiate treatment or get transient elastography to confirm need for treatment, depending on patient preference and resource availability.
- ² Elevated ALT defined as >25 U/L in females and >35 U/L in males that is persistent for at least 3 to 6 months.
- ³ Refer to AGA Clinical Practice Guideline on the Prevention and Treatment of HBV Reactivation for list of immunosuppressive medications posing moderate to high risk for HBV reactivation. https://www.gastrojournal.org/article/S0016-5085(24)05744-5/fulltext.
- ⁴ HBV antiviral treatment is recommended during HCV direct-acting antiviral (DAA) treatment to prevent HBV reactivation.
- ⁵ Transmission factors include pregnancy with HBV DNA >200,000 IU/mL, sexual or close contact with someone who is nonimmune or unknown HBV status or immunocompromised, and health care worker doing Society for Healthcare Epidemiology of America (SHEA) category 3 exposure-prone procedures (e.g., procedures with a higher likelihood of healthcare personnel-to-patient bloodborne pathogen transmission, specifically when the health care worker's hands, even when gloved, may come into contact with sharp instruments, needle tips, or bone spicules within a poorly visualized or confined anatomical site).
- ⁶ Extrahepatic manifestations of HBV include glomerulonephritis, polyarteritis nodosa, serum sickness-like syndrome, vasculitis.
- Patient prefers long-term treatment over monitoring-only approach after discussion of risk and benefits, including risk of post-treatment flare if treatment is prematurely discontinued.

Abbreviations

ALT = alanine aminotransferase APRI = AST to Platelet Ratio Index AST = aspartate aminotransferase HBsAg = hepatitis B surface antigen HCC = hepatocellular cancer HCV = hepatitis C virus HDV = hepatitis D virus

Preferred Antiviral Treatment of the HBsAg(+) Patient

Drug	Adult dose	Pregnancy category ¹	Side effects	Monitoring on treatment
Entecavir ² Baraclude	 Standard: 0.5 mg by mouth daily Take 2 hours before or after food Decompensated liver disease³ or lamivudine- resistant or lamivudine- experienced individuals: 1 mg by mouth daily 	 Formerly FDA category C Limited pregnancy exposure, pregnancy exposure registry available Insufficient human data to assess risk of major birth defects No adverse effects observed in animal studies 	 Headache, fatigue, dizziness, nausea reported in ≤3% Post-marketing surveillance includes rare reports of: lactic acidosis severe hepatomegaly 	 Adjust dose with CrCl <50 mL/min Lactic acid levels if clinical concern
Tenofovir disoproxil fumarate ² (TDF) Viread	 300 mg by mouth daily Take without regard to food 	 Formerly FDA category B Pregnancy exposure registry available Extensive data from pregnant women with HIV or HBV infections indicate no increase in pregnancy complications or major birth defects 	 Nausea (9%) Post-marketing surveillance includes infrequent reports of: nephropathy Fanconi syndrome osteomalacia lactic acidosis 	 Adjust dose with CrCl <50 mL/min Serum creatinine at baseline; if at risk for renal impairment, serum creatinine and phosphorus, and urine glucose and protein at least annually Consider bone density study at baseline and during treatment in persons with history of fracture or risks for osteopenia Lactic acid levels if clinical concern
Tenofovir alafenamide (TAF) Vemlidy	 25 mg by mouth daily Take with food 	 Pregnancy exposure registry available⁴ First-trimester exposure to TAF is not associated with increased risk of congenital anomalies⁴ No adverse effects observed in animal studies 	 Headache (12%) Lactic acidosis/ severe hepatomegaly with steatosis is a warning for TAF due to rare reports with use of TDF 	 Avoid with CrCl <15 mL/min if not receiving hemodialysis Dose after hemodialysis in those on hemodialysis If at risk for renal impairment, serum creatinine and phosphorus, and urine glucose and protein, as clinically indicated. Lactic acid levels if clinical concern

¹ In 2015, the US FDA replaced the pregnancy risk designation by letters A, B, C, D, and X with more specific language on pregnancy and lactation. This new labeling is being phased in gradually and, to date, only tenofovir alafenamide includes these additional data.

Abbreviations

CrCl = creatinine clearance

² Available as generic medications

³ Decompensated liver disease is defined as Child-Turcotte-Pugh (CTP) ≥7 (see Hepatitis B Online CTP calculator).

⁴ Pregnancy data for TAF from the antiretroviral pregnancy registry: https://www.apregistry.com/HCP.aspx.

Liver Cancer Surveillance

Indications for Liver Cancer (Hepatocellular Carcinoma) Surveillance

Persons with chronic HBV at increased risk for hepatocellular carcinoma (HCC) who require routine surveillance, including after observed HBsAg loss:

- > All persons with cirrhosis
- > The following populations, even in the absence of cirrhosis:
 - Men over 40 years of age¹
 - Women over 50 years of age¹
 - Persons with a family history of HCC
 - Persons with hepatitis D virus or HIV² coinfection

Recommended HCC Surveillance Method

HCC surveillance should be performed in the primary care setting with liver ultrasound with serum alphafetoprotein (AFP)³ every 6 months. More frequent monitoring or other imaging modalities, such as computed tomography (CT) or magnetic resonance imaging (MRI), with and without contrast, may be indicated to further evaluate new liver lesions.

When to Stop HCC Surveillance?

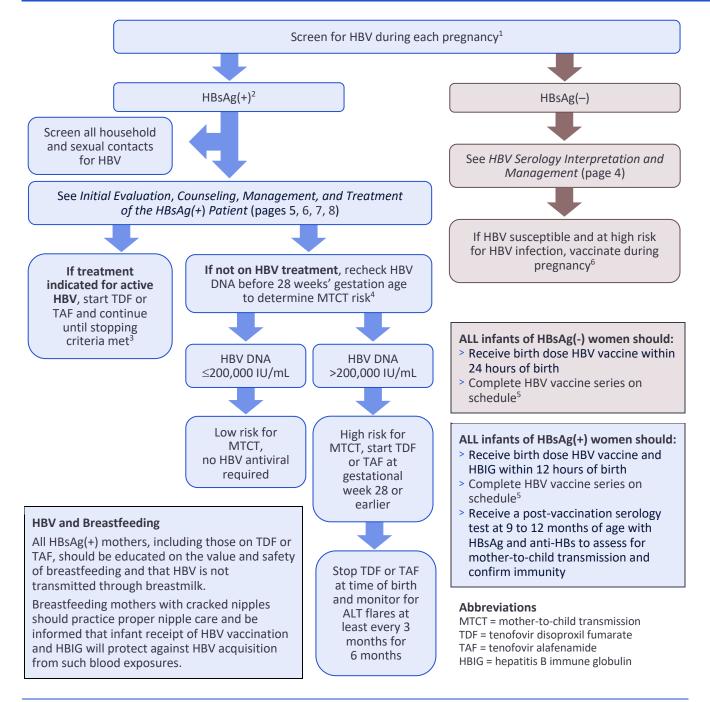
HCC surveillance can be stopped in persons with limited life expectancy or who would not tolerate treatment for HCC, if found. Persons with observed HBsAg loss before 50 years of age and without cirrhosis are at low risk for HCC and may stop HCC surveillance.

¹ Consider earlier HCC surveillance (younger than standard age cutoffs) for persons from Africa (e.g., as early as 30 years of age, given median 46 years of age at HCC diagnosis), persons with genotypes or viral features linked to early HCC, persons with high HCC risk scores (e.g., REACH-B or PAGE-B, and based on patient preferences for surveillance). AASLD recommends HCC surveillance in men >40 years of age from endemic regions and women >50 years of age from endemic regions.

² AASLD recommends HCC surveillance in male-born persons >18 years of age and female-born persons >40 years of age with HBV-HIV coinfection.

³ Wait at least 6 months after pregnancy before using AFP for HCC surveillance.

Perinatal HBV Management



- ¹ All pregnant women should be screened for HBV (with HBsAg at minimum) during each pregnancy, regardless of prior HBV screening results. For complete HBV profile, add anti-HBs to determine immunity and anti-HBc IgG or total for evidence of prior infection.
- ² All HBsAg(+) mothers should be educated on the importance of regular follow-up during and after the pregnancy so that appropriate HBV monitoring can occur, especially since the postpartum period is a time of increased risk for hepatitis B flares.
- ³ If an HBsAg(+) woman is taking entecavir when she becomes pregnant, the antiviral regimen should immediately be switched to tenofovir disoproxil fumarate (TDF) or tenofovir alafenamide (TAF) if she is not already taking one of these medications.
- ⁴ If HBV DNA <200,000 IU/mL in first trimester, consider retesting in second trimester as viral load may rise.
- ⁵ For infants weighing less than 2,000 grams, the birth dose does not count toward the vaccine series, and the infant should receive another HBV vaccine one month after birth
- ⁶ Engerix-B, Recombivax-HB, Heplisav-B, and Twinrix are safe to give at any time during pregnancy; however Heplisav-B and Twinrix are approved for use among those aged 18 years and older.

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