HEPATITIS B CLINICAL TRAINING SERIES

# Hepatitis B Pre-Treatment Evaluation and Treatment Initiation

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# Overarching Learning Objectives

By the end of this presentation, participants will be able to:

1. Describe the importance of interprofessional collaboration in effectively meeting the healthcare, educational, and psychosocial needs of patients living with hepatitis B
2. Describe the epidemiology and natural history of hepatitis B.
3. Use updated guidelines to identify patients at risk for hepatitis B infection and provide screening according to these guidelines.
4. Select appropriate antiviral treatments for people living with hepatitis including special populations such as people with advanced liver disease or HIV co-infection.
5. Explain the efficacy and safety of current and emerging therapies for hepatitis B including use in special populations such as people who use drugs or alcohol or have substance use disorders.
6. Illustrate how to counsel patients diagnosed with hepatitis B regarding risks and benefits of therapies and involve them in shared treatment decisions.

# Learning Objectives

By the end of this presentation, participants will be able to:

- Describe the epidemiology of hepatitis B (HBV) infection
- Understand the natural history of HBV infection
- Identify candidates for HBV vaccination
- Identify patients who should be screened for HBV and interpret HBV serology
- Educate patients on preventing HBV transmission
- Recall the role of the primary care provider (PCP) in HBV care

# Interpreting Hepatitis B Tests

| Clinical state | HBsAg | anti-HBs | anti-HBc | Action |
|---|---|---|---|---|
| Chronic infection | + | - | + | Link to HBV-directed care |
| Acute infection | + | - | + (IgM anti-HBc) | Provide or link to HBV-directed care |
| Resolved infection | - | + | + | Counseling, reassurance, monitor if undergoing Immunosuppressive Rx |
| Immune (immunization) | - | + | - | Reassurance |
| Susceptible (never infected or immunized) | - | - | - | Vaccinate |
| Unclear (maybe: false positive, resolved infection, “low level” chronic infection, or resolving acute infection) | - | - | + | Consider checking the HBV DNA |

Pre-Treatment
Evaluation

# History and Physical Examination

- Risk factors for viral hepatitis
- Risk factors for HIV co-infection
- Duration of infection
- Alcohol history
- Presence of comorbid diseases
- Family history of liver cancer

- Complete physical examination
  - Hepatomegaly
  - Splenomegaly
  - Jaundice
  - Distended abdomen
  - Spider angiomata

Martin P et al. Clin Gastroenterol Hepatol 2015;13:2071.

# Pre-Treatment Blood Tests

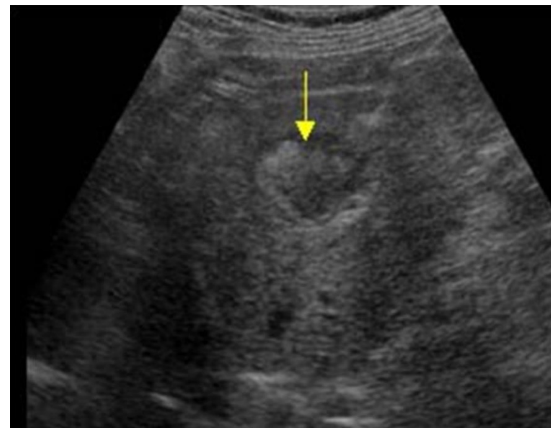
- Serial testing of ALT and HBV DNA level for 6 months
- CBC, Liver enzymes, prothrombin time/INR
- HBeAg and anti-HBeAb

- Testing for other viruses:
  - hepatitis A virus Ig G (vaccinate as needed)
  - HCV Ab
  - HDV Ab
  - HEV Ab (particularly in acute hepatitis)
  - HIV Ab
- Testing for other liver diseases in patients with abnormal liver tests:
  - ANA, ASMA
  - Fe/TIBC/ferritin

Martin P et al. Clin Gastroenterol Hepatol 2015;13:2071.

# Assessing Disease Severity

- Assess the severity of liver disease:
  - FIB-4, APRI, ELF
  - Transient elastography
  - MR elastography
- Screening for liver cancer
  - Ultrasound every-6-months
  - AFP every-6-months
  - **MRI with contrast in cirrhotics**



# Non-Invasive Formulas to Assess Severity of Fibrosis

## APRI

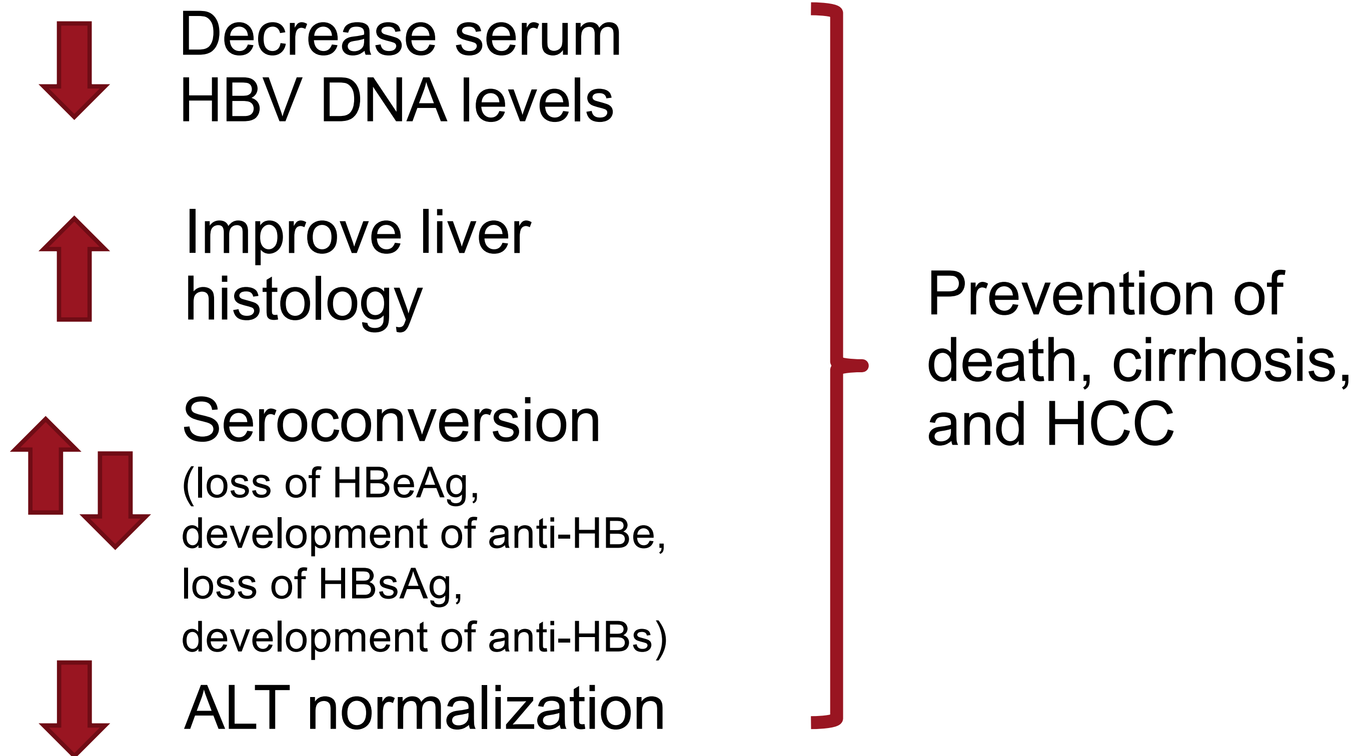
$$\text{APRI} = \frac{\dfrac{\text{AST Level } (IU/L)}{\text{AST (Upper Limit of Normal) } (IU/L)}}{\text{Platelet Count } (10^9/L)} \times 100 =$$

## FIB-4

$$\text{FIB-4} = \frac{\text{Age } (years) \times \text{AST Level } (U/L)}{\text{Platelet Count } (10^9/L) \times \sqrt{\text{ALT } (U/L)}} =$$

Goals of
HBV Therapy

# Goals of HBV Therapy



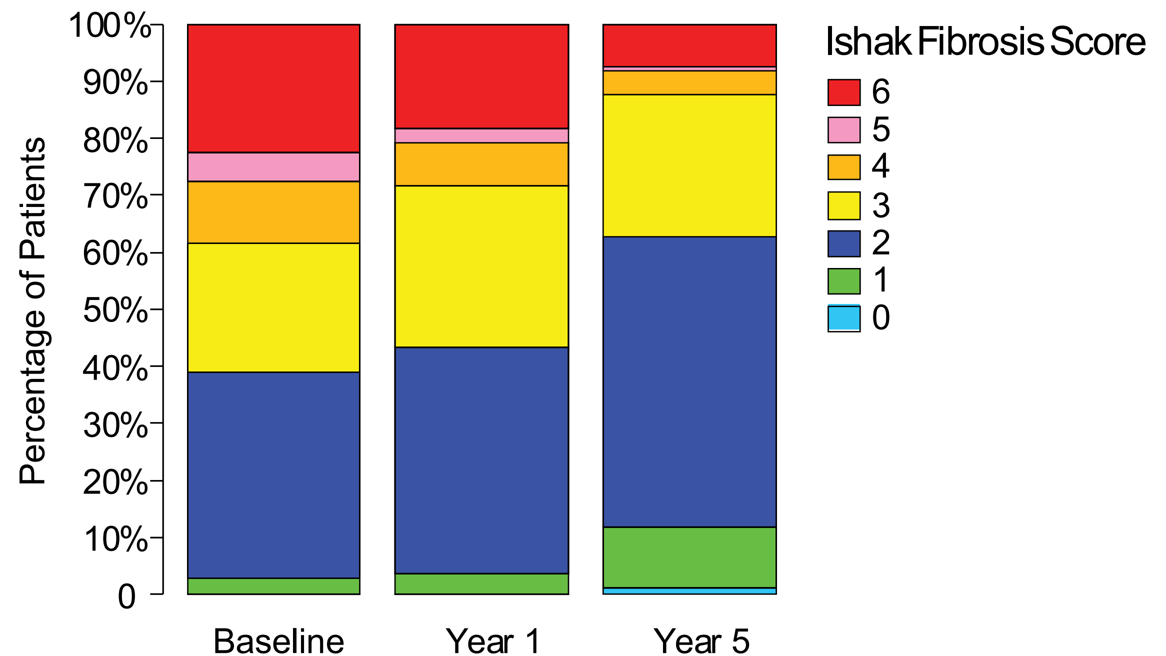
# What About A Cure? Types Of HBV Cure

- Inactive state
  - Sustained, off drug
    - No inflammation – Normal ALT
    - HBVDNA low or undetectable
    - HBsAg positive
- Functional Cure (Clinical Resolution)
  - Sustained, off drug
    - No inflammation – Normal ALT
    - HBsAg loss
    - Anti-HBs gain sometimes
- Complete Cure (Sterilizing Cure)
  - All of the above plus
  - Loss of cccDNA in the liver
  - Loss of integrated HBV DNA in hepatocytes

# HBV Therapy Reverses Fibrosis and Cirrhosis

489 patients complete 240 weeks (4.6 years) of treatment with tenofovir

- 348 patients have a biopsy at baseline and week 240
- 304 patients (87%) have histological improvement at week 240
- 176 patients (51%) have regression of fibrosis at week 240
- 71 / 96 (74%) with cirrhosis (Ishak Score ≥5) at baseline no longer had cirrhosis at week 240




Marcellin P et al. Lancet 2013;381:468.

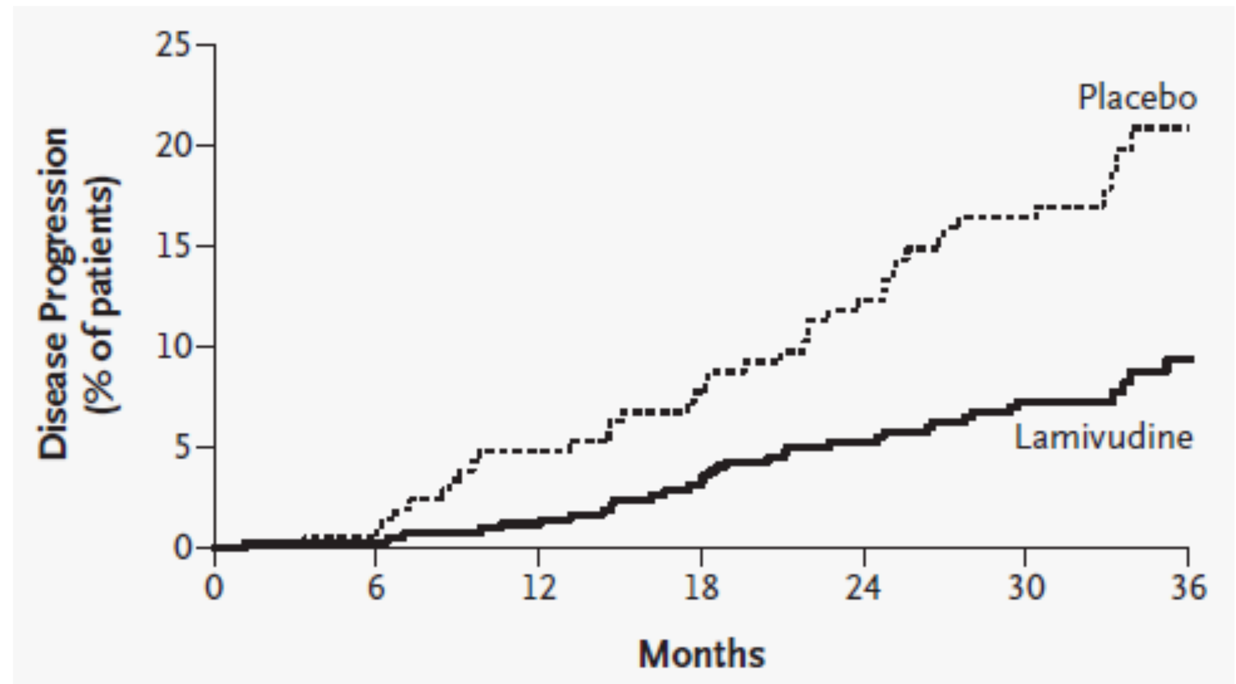
# HBV Therapy Reduces Risk of Disease Progression

651 patients with HBV cirrhosis

- 436 receive lamivudine
- 215 receive placebo

Primary end point = development of:

- Deteriorating liver function
- Variceal bleed
- Spontaneous bacterial peritonitis
- Hepatocellular carcinoma
- Death due to liver disease




Liaw YF et al. N Engl J Med. 2004;351:1521.

# HBV Therapy Reduces Liver Cancer Risk

| Reference | Treated pts/ Untreated pts | Type of study | NUC used | Median follow-up | Incidence of HCC: % treated / % untreated | *P* value |
|---|---|---|---|---|---|---|
| Liaw, 2004 | 436/215 | RCT, prospective | LAM vs. placebo | 2.7 years | **3.9% / 7.4%** | 0.047 |
| Yuen, 2007 | 142/104 | Prospective | LAM | 8.2 years | **0.7% / 2.4%** | 0.005 |
| Papatheodoridis, 2010 | 21 studies 3881/534 | Systematic review | LAM | 3.8 years | **2.8% / 6.4%** | 0.003 |
| Singal, 2013 | 49 studies 10025/3571 | Meta-analysis | LAM, ADV, ETV, LdT, TDF | --- | **3.3 vs. 9.7 per 100 person years** | < 0.0001 |

*Hepatic decompensation, HCC, spontaneous bacterial peritonitis, bleeding gastroesophageal varices, or death related to liver disease.

Rapti I, Hadziyannis S. World J Hepatol 2015;7:1064.

Making A Decision
To Treat

# New Nomenclature For Chronic Hepatitis B

| | HBeAg positive | | HBeAg negative | | |
|---|---|---|---|---|---|
| | **Chronic infection** *Phase 1* | **Chronic hepatitis** *Phase 2* | **Chronic infection** *Phase 3* | **Chronic hepatitis** *Phase 4* | **Resolved infection** *Phase 5* |
| **HBsAg** | High | High/ intermediate | Low | Intermediate | Negative |
| **HBeAg** | Positive | Positive | Negative | Negative | Negative |
| **HBV DNA** | $>10^7$ IU/mL | $10^4$–$10^7$ IU/mL | <2,000 IU/mL* | >2,000 IU/mL | <10 IU/mL‡ |
| **ALT** | Normal | Elevated | Normal | Elevated† | Normal |
| **Liver disease** | None/minimal | Moderate/ severe | None | Moderate/ severe | None§ |
| ***Old terminology*** | *Immune tolerant* | *Immune reactive HBeAg positive* | *Inactive carrier* | *HBeAg negative chronic hepatitis* | *HBsAg negative /anti-HBc positive* |

*HBV DNA levels can be between 2,000 and 20,000 IU/mL in some patients without signs of chronic hepatitis;
†Persisitently or intermittently, based on traditional ULN (~40 IU/L). ‡cccDNA can frequently be detected in the liver;
§Residual HCC risk only if cirrhosis has developed before HBsAg loss.

European Association for the Study of the Liver. J Hepatol 2017;67:370.

# HBV Treatment and Monitoring: EASL Recommendations

- All patients with HBeAg-positive or -negative chronic hepatitis B, defined by HBV DNA >2,000 IU/ml, ALT >ULN and/or at least moderate liver necroinflammation or fibrosis, should be treated.
- Patients with compensated or decompensated cirrhosis need treatment, with any detectable HBV DNA level and regardless of ALT levels.
- Patients who are not candidates for antiviral therapy should be monitored with periodical assessments of serum ALT and HBV DNA levels as well as for liver fibrosis severity by non-invasive markers.

European Association for the Study of the Liver. J Hepatol 2017;67:370.

# Simplified approach to HBV Elimination

**CONSULT WITH HBV SPECIALIST**

- Cirrhosis and/or liver mass
- Platelets < 100 x $10^9$/L
- HDV, HCV, and/or HIV coinfection
- Pregnancy
- Lack of response to treatment or rebound of HBV DNA levels[j]

**SCREENING**

Universal, one-time HBV screening in all adults[a]
(HBsAg, anti-HBs, and total anti-HBc)

HBsAg negative → See Table 1

HBsAg positive ↓

**DIAGNOSTIC WORKUP**

At minimum *(see Table 2 for full evaluation)*

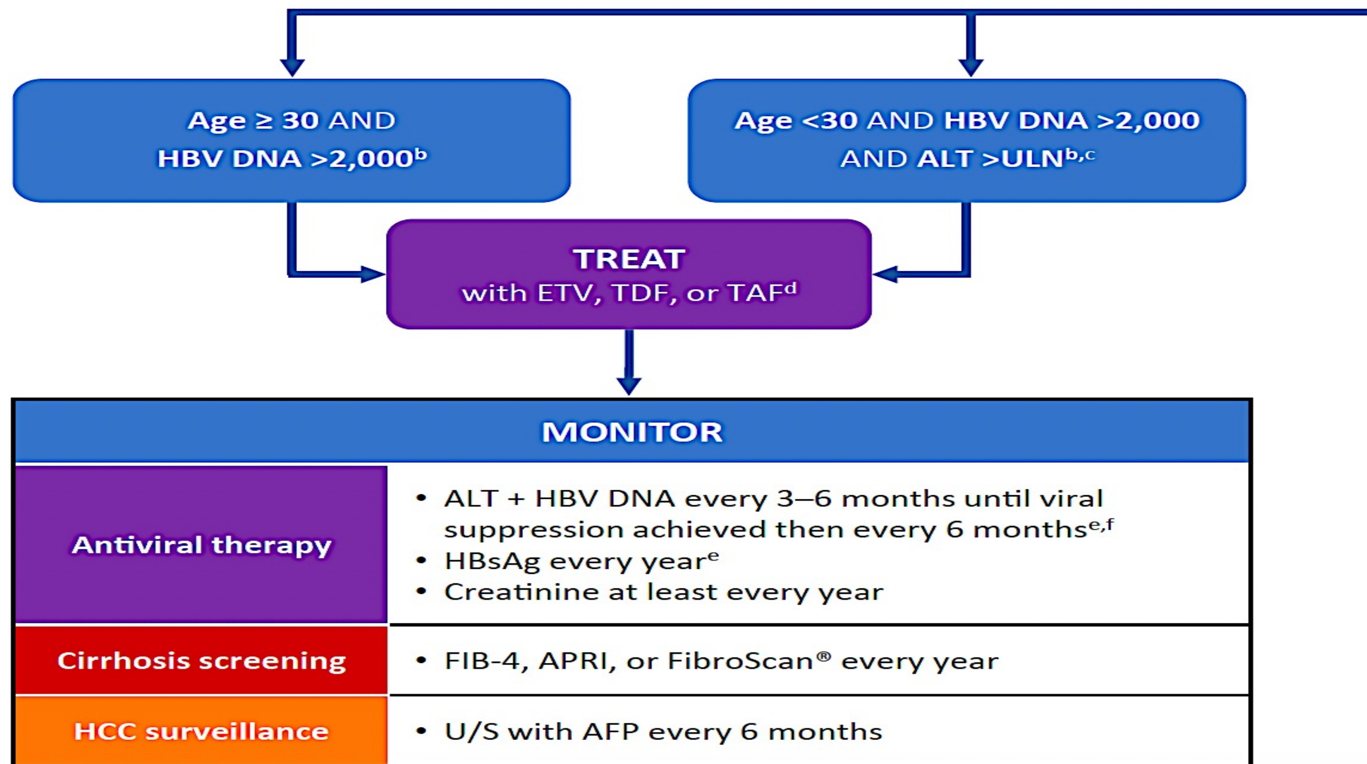
**HBV:** HBV DNA, ALT, AST, platelets

**Cirrhosis screening:** Noninvasive tests such as FIB-4, APRI, or FibroScan®

**HCC surveillance:** Baseline U/S of liver with AFP

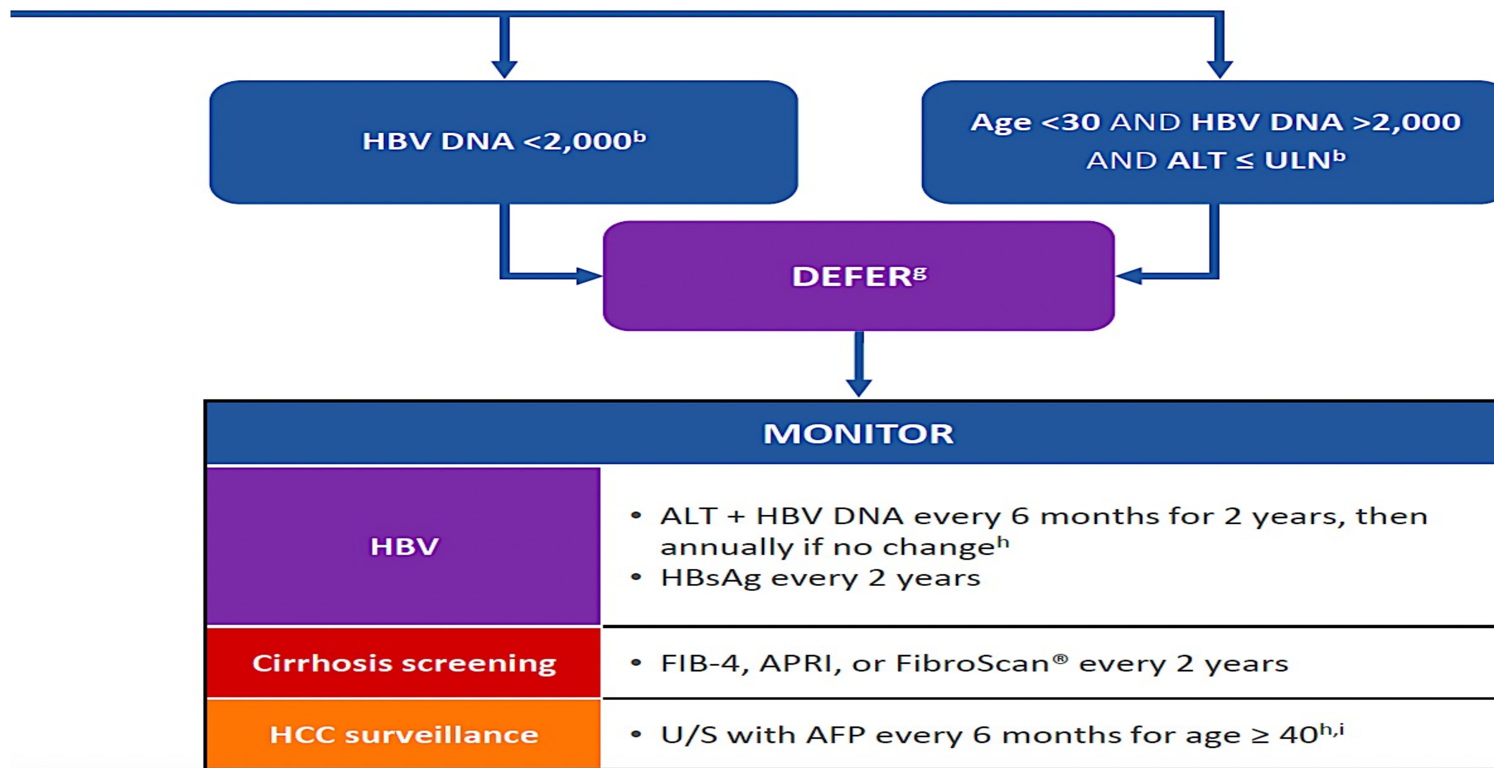
Gastro Hep Advanced 2023;2:209-218

# Simplified approach to HBV Elimination




Gastro Hep Advanced 2023;2:209-218

# Simplified approach to HBV Elimination




Gastro Hep Advanced 2023;2:209-218

HBV Management in
Primary Care

# Role of Primary Care and Specialists in HBV Management

| What can be managed in primary care? | What should be referred to a liver specialist? |
|---|---|
| • HBV screening and interpretation for all patients<br>• HBV and HAV vaccination for all patients<br>• Initial evaluation and counseling of the HBsAg(+) patients<br>• Initiation of and monitoring on HBV antiviral treatment<br>• Perinatal HBV management<br>• Substance use screening/harm reduction counseling<br>• Smoking cessation<br>• Alcohol moderation/abstinence counseling<br>• Management of metabolic syndrome risk factors<br>• HBV lab monitoring every 6 months<br>• Liver cancer surveillance | • Liver lesion on imaging suspicious for HCC (e.g. US LI-RADS3, CT-MRI LI-RADS 5)<br>• Compensated and decompensated cirrhosis<br>• Hepatitis D co-infection<br>• Persistent elevation of liver enzymes that do not correlate with HBV DNA levels or metabolic syndrome risk factors |
| | |

Wang et al, *Current Hepatology Reports* 2021.

# HBV Primary Care Workgroup Recommendations: Assessing for Treatment Response

**Assessing for treatment response**

- After initiation of HBV antiviral therapy:
  - Recheck HBV DNA every 3 months until undetectable
  - Once undetectable, recheck HBV DNA every 6 months
- Refer to specialist or obtain expert consultation if:
  - Patient does not achieve undetectable HBV DNA after 1 year of antiviral therapy
  - HBV DNA levels are not trending down

https://www.hepatitisb.uw.edu/page/primary-care-workgroup/guidance

# HBV Primary Care Workgroup Recommendations: Endpoints for Antiviral Discontinuation

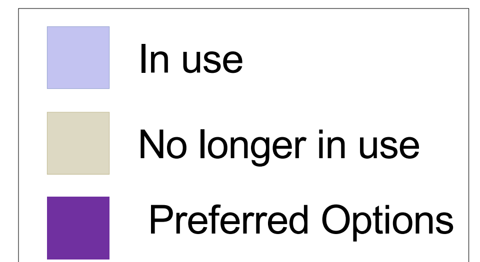
| Cirrhosis | HBeAg | Endpoint for Antiviral Discontinuation |
|---|---|---|
| Yes | | Do not stop antiviral treatment, unless guided by expert consultation |
| No | Positive at baseline | Patients with the following may trial off antiviral treatment:<br>• persistent undetectable HBV DNA<br>• normal ALT<br>• persistent HBeAg(-) and anti-HBe(+) 1 year after HBeAg seroconversion [from HBeAg(+)/anti-HBe(-) to HBeAg(-)/anti-HBe(+)] |
| No | Negative at baseline | Continue antiviral treatment until HBsAg clearance |

https://www.hepatitisb.uw.edu/page/primary-care-workgroup/guidance

HBV Treatment
Options

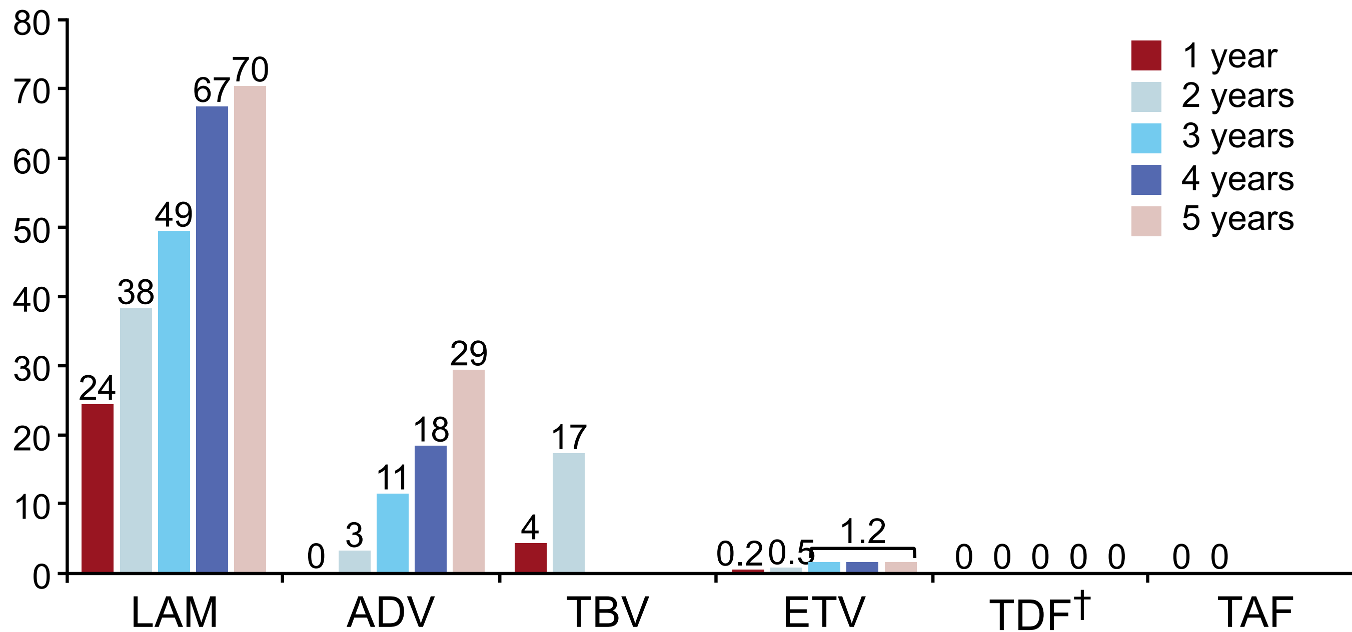
# Evolution of Hepatitis B Therapy

| Year | Therapy | Status |
| --- | --- | --- |
| 1991 | Interferon alfa-2b (Intron A®) | No longer in use |
| 1998 | Lamivudine (Epivir®)* | In use |
| 2002 | Adefovir (Hepsera®)* | In use |
| 2005 | Peginterferon alfa-2a. (Pegasys®) | In use |
| 2005 | Entecavir (Baraclude®) | Preferred Options |
| 2006 | Telbivudine (Tyzeka®)* | No longer in use |
| 2008 | Tenofovir disoproxil fumarate (Viread®) | Preferred Options |
| 2016 | Tenofovir alafenamide (Vemlidy®) | Preferred Options |



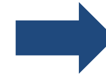
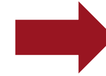
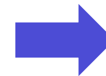

* Nucleoside/nucleotide analogues with a low barrier against HBV resistance

# HBV Resistance To Nucleoside / Nucleotide Analogues



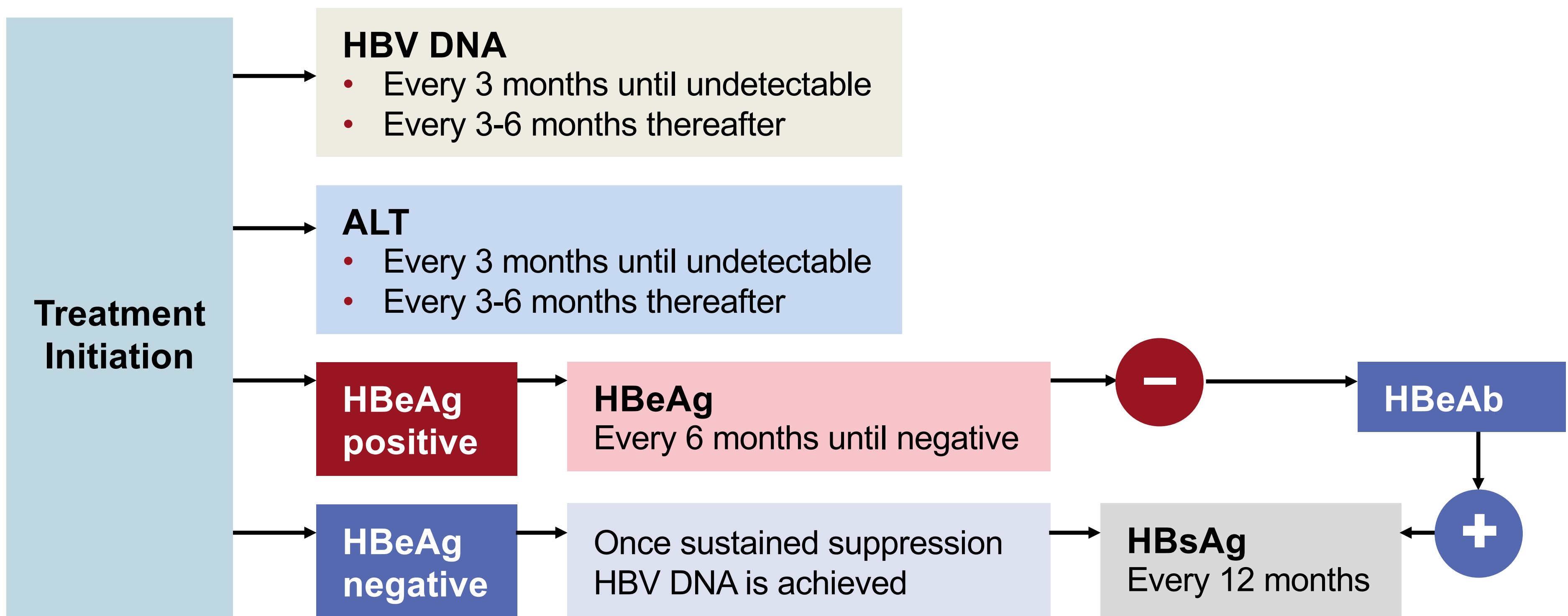

*Evidence level I, grade of recommendation 1; †Collation of currently available data – not from head-to-head studies;
‡No evidence of resistance has been shown after 8 years of TDF treatment
EASL CPG HBV. J Hepatol 2017;67:370–98

# Selecting A Medication

| Condition | | Recommendation |
| --- | --- | --- |
| **Prior exposure to a nucleoside/ nucleotide analogue** |  | Prefer TAF to ETV |
| **Bone disease**<br>• Chronic steroid use<br>• Osteoporosis<br>• History of compression fracture |  | Prefer ETV or TAF to TDF |
| **Renal dysfunction**<br>• GFR < 60 ml/min/1.73m$^2$<br>• Albuminuria > 30 mg/24 h<br>• Low phosphate (< 2.5 mg/dL)<br>• Hemodialysis |  | Prefer ETV or TAF to TDF |
| **? Age > 60 years ?** | | Prefer ETV or TAF to TDF |

EASL CPG HBV.
J Hepatol
2017;67:370–98

# Monitoring of CHB Patients on Treatment



# Monitoring of Renal Function

- No formal recommendations at this time
- Renal dysfunction can be seen in patients on NAs, particularly for patients on tenofovir disoproxil fumarate (TDF).
- Consider every 6 month check of:
  - Serum phosphorus
  - Serum uric acid
  - Urinalysis

# When To Stop Treatment

| | |
|---|---|
| **HBeAg positive** | • Can consider stopping therapy if eAg-/eAb+ seroconversion occurs but only after further consolidation therapy for at least 1-2 years<br>• If stopping therapy, monitor for relapse:<br>– Seroconversion to HBeAg positivity<br>– Reappearance of HBV DNA<br>– ALT elevation |
| **HBeAg negative** | • Continue antiviral therapy for life<br>• Treatment may be stopped if:<br>– If HBsAg becomes negative and HBsAb becomes positive following a year of consolidation therapy<br>– If HBV DNA is undetectable for ≥ 3 years.*<br>• Monitor closely for relapse |
| **Cirrhosis** | • Continue antiviral therapy for life |

Terrault NA et al. Hepatology 2016;63:261. *EASL CPG HBV. J Hepatol 2017;67:370–98

# Case Study

- 36 year old Asian women
- History of hepatitis B with risk factor pre-natal transmission
- Feels well
- ALT 55
- HBV DNA 120,000 IU
- Platelet count 185,000
- HBsAg+
- HBeAg+
- F1 on transient elastography

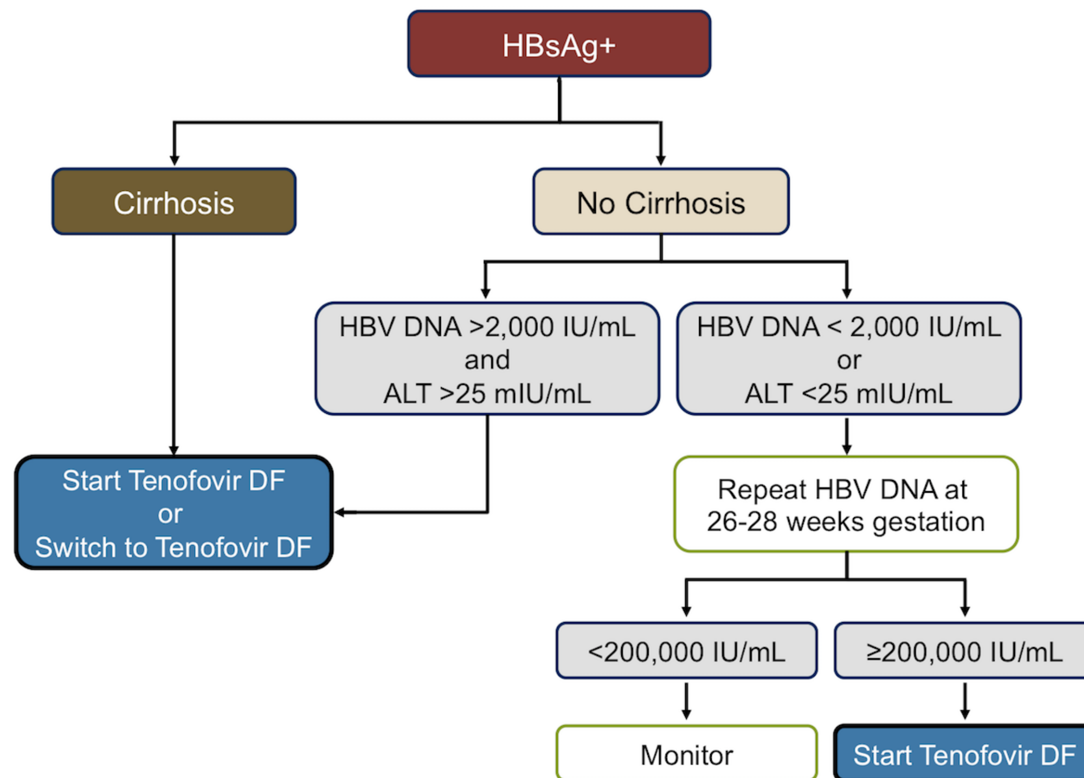
- What do you do now?
  - Initiate HBV anti-viral therapy
  - Recheck HBV DNA every 3 months until undetectable
  - Once undetectable, recheck HBV DNA every 6 months
  - Monitor ALT
  - Contact screening and vaccination

# HBV Treatment Access

- Uninsured or underinsured patients may not be able to afford costs of specialty care, including co-payment and co-insurance
- Uninsured or underinsured patients may benefit from HBV patient assistance programs: https://www.hepb.org/treatment-and-management/treatment/patient-assistance-programs-in-the-u-s/
- HBV patient navigators can help uninsured or underinsured patients access treatment
  - Check Hep B Patient Navigation offers multilingual patient navigation services to people living with HBV in NYC: https://hepfree.nyc/check-hep-b-patient-navigation-program/

HBV Treatment During Pregnancy

# Treatment Approach to HBsAg-Positive Mothers During Pregnancy




https://www.hepatitisb.uw.edu/go/prevention-hbv/preventing-perinatal-transmission-hbv/core-concept/all

# Perinatal HBV Treatment and Monitoring

| Patients who do not meet criteria for antiviral therapy for maternal benefit | Patients who meet criteria for antiviral therapy for maternal benefit |
|---|---|
| • Monitor ALT for hepatitis flares due to pregnancy-associated immunologic changes<br>– Every 3 months during pregnancy and for 6 months postpartum<br>• Check HBV DNA at 26 to 28 weeks gestation to determine need for antiviral (Tenofovir DF) initiation which may be discontinued following delivery | • Continue on therapy<br>– Treatment endpoints for pregnant people is same as for nonpregnant people<br>• Tenofovir DF preferred agent as safe during pregnancy and for breastfeeding<br>– After breastfeeding stops, consider switching to either tenofovir alafenamide or entecavir if indicated or preferred |

New HBV Guidelines coming out to support TAF during pregnancy and in breastfeeding

https://www.hepatitisb.uw.edu/go/prevention-hbv/preventing-perinatal-transmission-hbv/core-concept/all

# Prevention of Secondary HBV Transmission During and After Pregnancy

| Contact | Prevention strategy |
|---|---|
| **Newborn** | • Treatment of mother (if HBV DNA >200,000 IU/mL)<br>• HBIG and HBV vaccine first dose within 12 hours<br>• Can complete full vaccination series at 6 months<br>• Post-vaccination serology testing at 9 months or after |
| **Other children and household contacts** | • Screen for HBV susceptibility<br>• Full vaccination series |
| **Sexual partner(s)** | • Screen for HBV susceptibility<br>• Full vaccination series<br>• Safe sex methods until immunity confirmed |
| **Drug sharing partner(s)** | • Screen for HBV susceptibility<br>• Full vaccination series<br>• Harm reduction |

Utilize the NYC Health Department Perinatal HBV Prevention Program to support case management of contact screening and vaccination: https://www1.nyc.gov/site/doh/providers/health-topics/hepatitis-b-and-pregnancy.page.

Prevention of
HBV Reactivation During
Immunosuppressive
Drug Therapy

# Patients Undergoing Immunosuppressive Therapy or Chemotherapy

**Case:**

- 40-year-old woman with rheumatoid arthritis has an inadequate response to anti-TNF agents.
- Rheumatology plans to start rituximab in combination with methotrexate next week.
- Labs:
  - Liver chemistries: normal.
  - HBcAb (total): positive.
  - HBsAg: negative.
  - HBsAb: negative.
- What is your response?

Rajender Reddy K et al. American Gastroenterological Association Institute guideline on the prevention and treatment of hepatitis B virus reactivation during immunosuppressive drug therapy. Gastroenterol 2015;148:215.

# Monitoring HBV-Exposed Patients on Immunosuppression: Treat Prophylactically?

High-risk (>10%)  Moderate-risk (1-10%)  Low-risk (<1%)

| | HBsAg+/ HBcAb+ | HBsAg-/ HBcAb+ |
|---|---|---|
| B cell-depleting agents (eg, rituximab, ofatumumab) | High-risk | High-risk |
| Anthracycline derivatives (eg, doxorubicin, epirubicin) | High-risk | Moderate-risk |
| High-dose (> 20 mg prednisone daily or equivalent) corticosteroids daily for ≥ 4 weeks | High-risk | Moderate-risk |
| Moderate-dose (10–20 mg prednisone daily or equivalent) corticosteroids daily for ≥ 4 weeks | High-risk | Moderate-risk |
| TNF alpha inhibitors (eg, etanercept, adalimumab, certolizumab, infliximab) | Moderate-risk | Moderate-risk |
| Cytokine or integrin inhibitors (eg, abatacept, ustekinumab, natalizumab, vedolizumab) | Moderate-risk | Moderate-risk |
| Tyrosine kinase inhibitors (eg, imatinib, nilotinib) | Moderate-risk | Moderate-risk |
| Low-dose (< 10 mg prednisone daily or equivalent) corticosteroids for duration of ≥ 4 weeks | Moderate-risk | Low-risk |
| Any dose of oral corticosteroids daily for ≤ 1 week | Low-risk | Low-risk |
| Intra-articular corticosteroids | Low-risk | Low-risk |
| Traditional immunosuppressive agents (eg, azathioprine, 6-mercaptopurine, methotrexate) | Low-risk | Low-risk |

HBVR, HEPATITIS B VIRUS REACTIVATION; HBCAB+, ANTI-HBC-POSITIVE
REDDY KR, ET AL. *GASTROENTEROLOGY.* 2015;148:215–219.

# AGA Guideline on Prophylaxis of HBV Reactivation During Immunosuppressive Drug Therapy

| | High-Risk | Moderate-Risk | Low-Risk |
|---|---|---|---|
| Anticipated incidence of HBVr | > 10% | 1 – 10% | < 1% |
| AGA Recommendation | Antiviral prophylaxis during IS & for at least 6–12 months after D/C of IS therapy | Antiviral prophylaxis during IS & for at least 6 months after D/C of IS therapy | No antiviral prophylaxis |

- AGA suggests to use antiviral drugs with a high barrier to resistance
- No recommendation for a strategy of HBV DNA monitoring followed by rescue therapy as an alternative to antiviral prophylaxis

**HBVr, hepatitis B virus reactivation; D/C, discontinuation; IS, immunosuppressive**
**High-risk group: HBsAg+/HBcAb+ or HBsAg-/HBcAb+ treated with B cell-depleting agents, or HBsAg+/HBcAb+ treated with anthracycline derivatives, moderate- or high-dose corticosteroids daily for ≥ 4 weeks**
**Moderate-risk group: HBsAg+/HBcAb+ or HBsAg-/HBcAb+ treated with TNF alpha inhibitors, other cytokine or integrin inhibitors, tyrosine kinase inhibitors, HBsAg+/HBcAb+ treated with low-dose corticosteroids for duration of ≥ 4 weeks, HBsAg-/HBcAb+ treated with moderate- or high-dose corticosteroids daily for ≥ 4 weeks or anthracycline derivatives**
**Low-risk group: HBsAg+/HBcAb+ or HBsAg-/HBcAb+ treated with traditional immunosuppressive agents, intra-articular corticosteroids, any dose of oral corticosteroids daily for ≤ 1 week, or HBsAg-/HBcAb+ treated with low-dose corticosteroids for ≥ 4 weeks**
**Reddy KR, et al. *Gastroenterology.* 2015;148:215–219.**

HBVR, HEPATITIS B VIRUS REACTIVATION; HBCAB+, ANTI-HBC-POSITIVE
REDDY KR, ET AL. *GASTROENTEROLOGY.* 2015;148:215–219.

# Case Study

- 43-year-old Asian woman sent to specialist for chronic HBV and liver lesions
  - Diagnosed with chronic HBV at prenatal checkup 9 years ago. Mother died of liver cancer at age of 58. Patient started on TDF in 2015 at outside facility but took it irregularly. On TDF for 8 months and self-discontinued in 2016 when she ran out of medications and felt fine.
- Patient was hospitalized (1/30-2/2/2017) for abdominal pain
  - Abdominal MRI revealed 7.2 cm LI-RADS 4 left hepatic mass, additional satellite lesions
  - Labs: AST 51, ALT 24, HBsAg positive, eAg negative, anti-HBe positive, HBV DNA 26 (IU/ml), AFP 387,800, INR 1.0, WBC 8.4, Hb 15.7, platelets 246,000, anti-HCV negative, and HCV RNA negative, immune to HAV

# Case Study

- Restarted on TDF, seen by surgical oncology, IR, and oncology, scheduled for left trisegmentectomy for multifocal bilobar HCC.
  - At ex-lap, it showed additional segment 7 lesion; patient deemed inoperable.
  - Segment 6 wedge resection revealed moderately differentiated HCC and liver biopsy showed chronic HBV with focal bridging fibrosis.
  - Patient was referred to liver transplant for evaluation.

# Summary

- Effective therapies are available to treat chronic HBV infection
- HBV is not a curable disease at this time
- Appropriate patients should be placed on HBV therapy
- HBV therapy is usually lifelong
- All patients, whether on therapy or not, should be monitored for the development of HCC
- Hepatitis B therapy may be indicated in pregnant people to prevent parent-to-child transmission

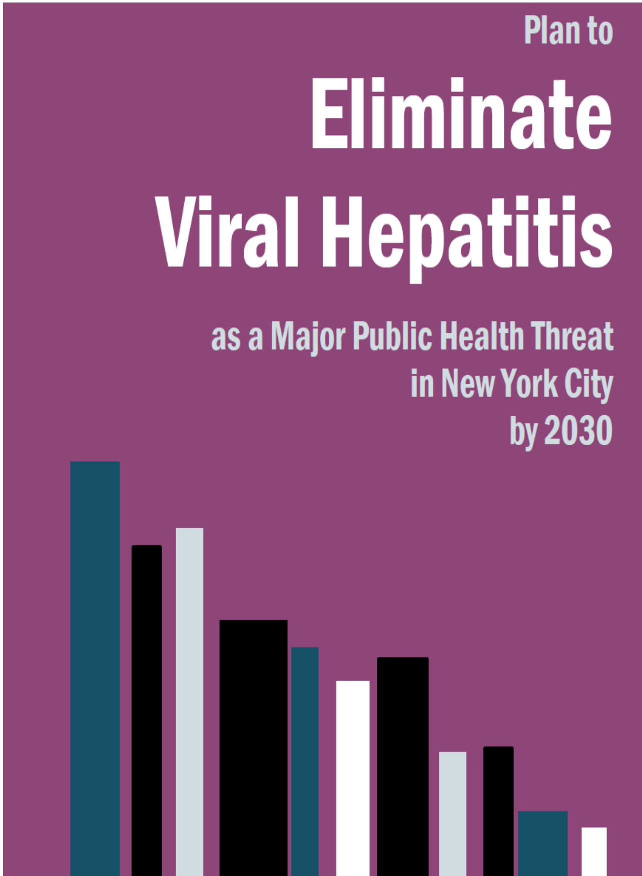
# Hepatitis B Treatment Guidelines and Resources

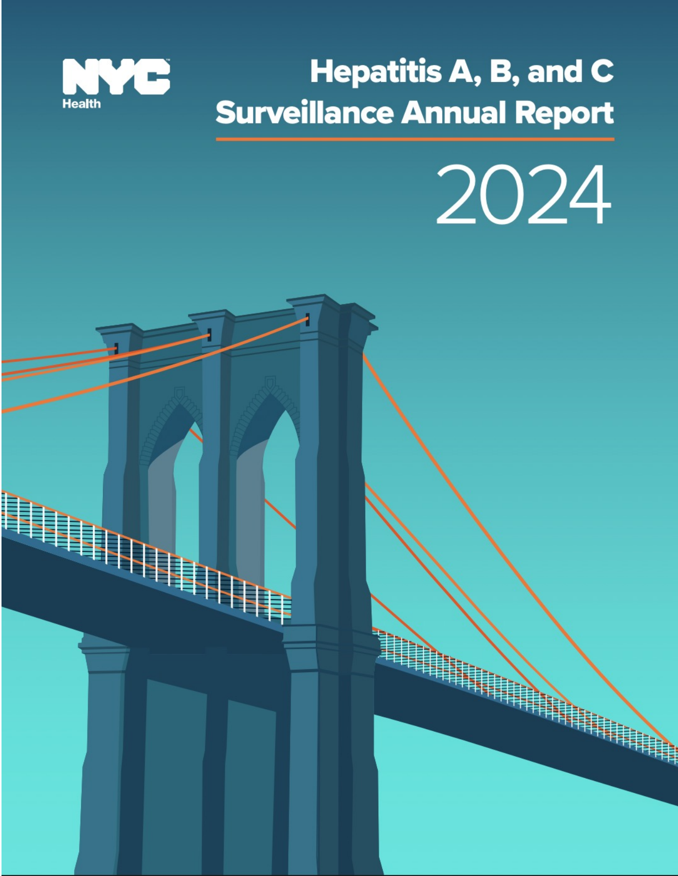
- Treatment Guidelines - AASLD
- Drug-Drug Interactions - https://www.hep-druginteractions.org/

# Hepatitis B Resources

- www.HepFree.NYC
  - Hep B Coalition
  - Clinical Resources
  - Capacity building tools
  - Advocacy Committee
- Hepatitis B patient information page: www.nyc.gov/health/hepb
  - Free or low-cost testing and treatment

# Elimination Plan and Annual Report



# Contact Us

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