# Hepatitis B Virus Management: Who, When & How

A presentation for HealthTrust Members
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# Objectives for Pharmacists & Nurses

## Recall

- Recall evidenced-based guideline recommendations for hepatitis B virus (HBV) screening and patient eligibility for antivirals.

## Recognize

- Recognize serologic risk categories and specific needs for complex patients.

## Identify

- Identify methods for optimizing clinical outcomes for HBV patients.

# Objectives for Pharmacy Techs

## Recall

- Recall HBV vaccine schedules, indications and available vaccines to support immunization efforts.

## Identify

- Identify patterns of nonadherence to antiviral therapy to distinguish gaps in chronic therapy from short-term medications.

## Recognize

- Recognize strategies for effective education for patients receiving HBV vaccination series.

# Hepatitis

Hepatitis B Virus Management: Who, When, and How



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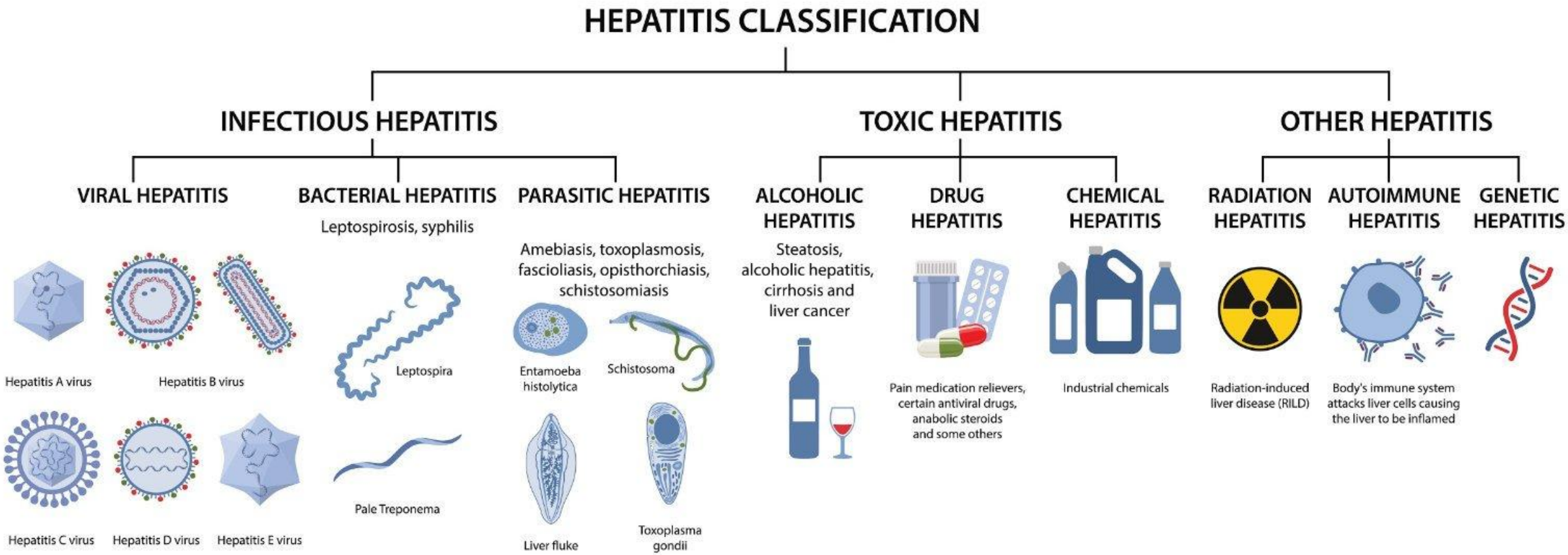
# Hepatitis: A Quick Overview




 | Image Source: Dakota Gastroenterology. Hepatitis. https://dakotagi.com/hepatitis/.



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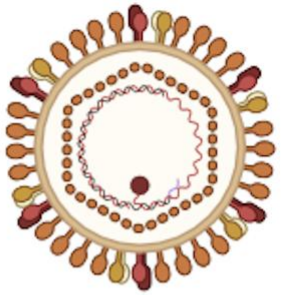
# Viral Hepatitis

| Hepatitis A<br>HAV | Hepatitis B<br>HBV | Hepatitis C<br>HCV | Hepatitis D<br>HDV | Hepatitis E<br>HEV |
|---|---|---|---|---|
|  |  |  |  |  |
| Route of Transmission<br>**Fecal-Oral** | Route of Transmission<br>**Parenteral**<br>**Sexual**<br>**Perinatal** | Route of Transmission<br>**Parenteral**<br>**Sexual**<br>**Perinatal** | Route of Transmission<br>**Parenteral**<br>**Sexual**<br>**Perinatal** | Route of Transmission<br>**Fecal-Oral** |
| **Acute**<br>**Self-Limiting** | **Acute and chronic infection** | **Acute and chronic infection** | **Requires HBV surface antigen** | **Acute**<br>**Self-Limiting** |

# Acute vs. Chronic Hepatitis

- Acute: inflammation of the liver lasting less than 6 months.
  - Symptoms vary; fever, nausea/vomiting, loss of appetite
- Chronic: persistent inflammation for 6 months or greater.
  - Chronic inflammation is often silent; symptoms signal cirrhosis.

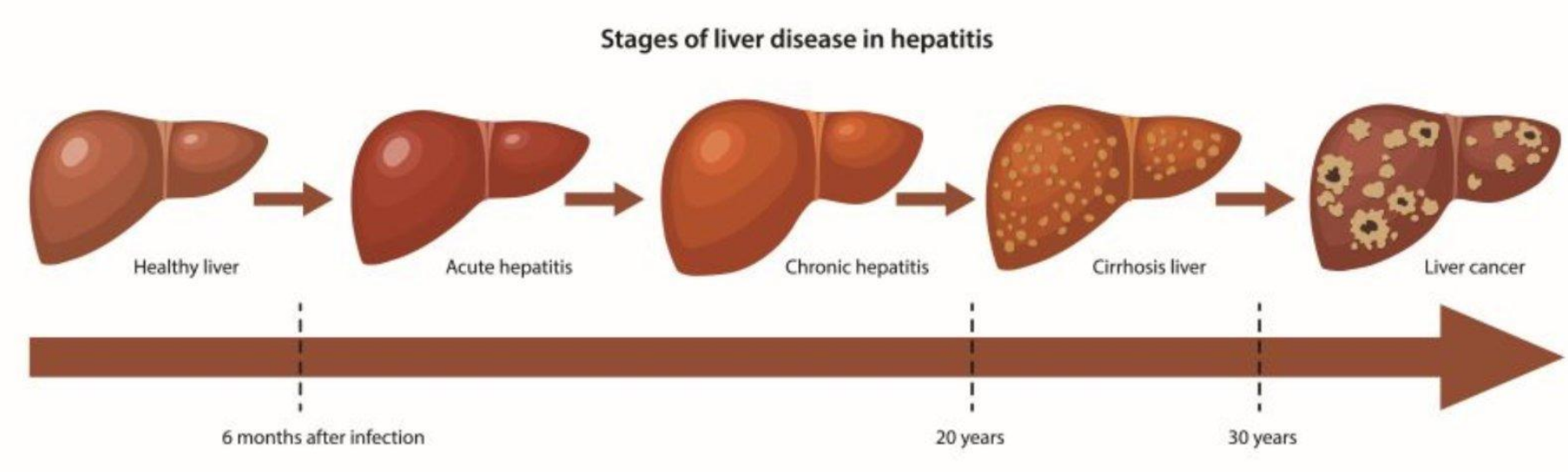



Image Source: Dakota Gastroenterology. Hepatitis. https://dakotagi.com/hepatitis/.

# Hepatitis B Virus

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# HBV Infection

- Hepatitis B virus (HBV) is an infection that can be acute or chronic
- Chronic HBV infection may progress to:
  - Liver fibrosis
  - Cirrhosis
  - Hepatocellular carcinoma (HCC)
- Currently, there is no definitive cure for chronic HBV

Source: WHO. Global hepatitis report 2024. Accessed January 12, 2026.

# HBV Infection

- The virus is highly infectious!
- It is considered 50-100 times more infectious than HIV
  - The highest exposure risk is to HBV-positive blood, it contains $10^9$ virions per mL of blood.
- A percutaneous exposure has a 6%–30% risk of contracting HBV from an infected patient.
  - The comparable risk for HIV from the same exposure is ~0.3%.


Source: Goldmann DA. J Allergy Clin Immunol. 2002;110(2 Suppl):S21-S26.

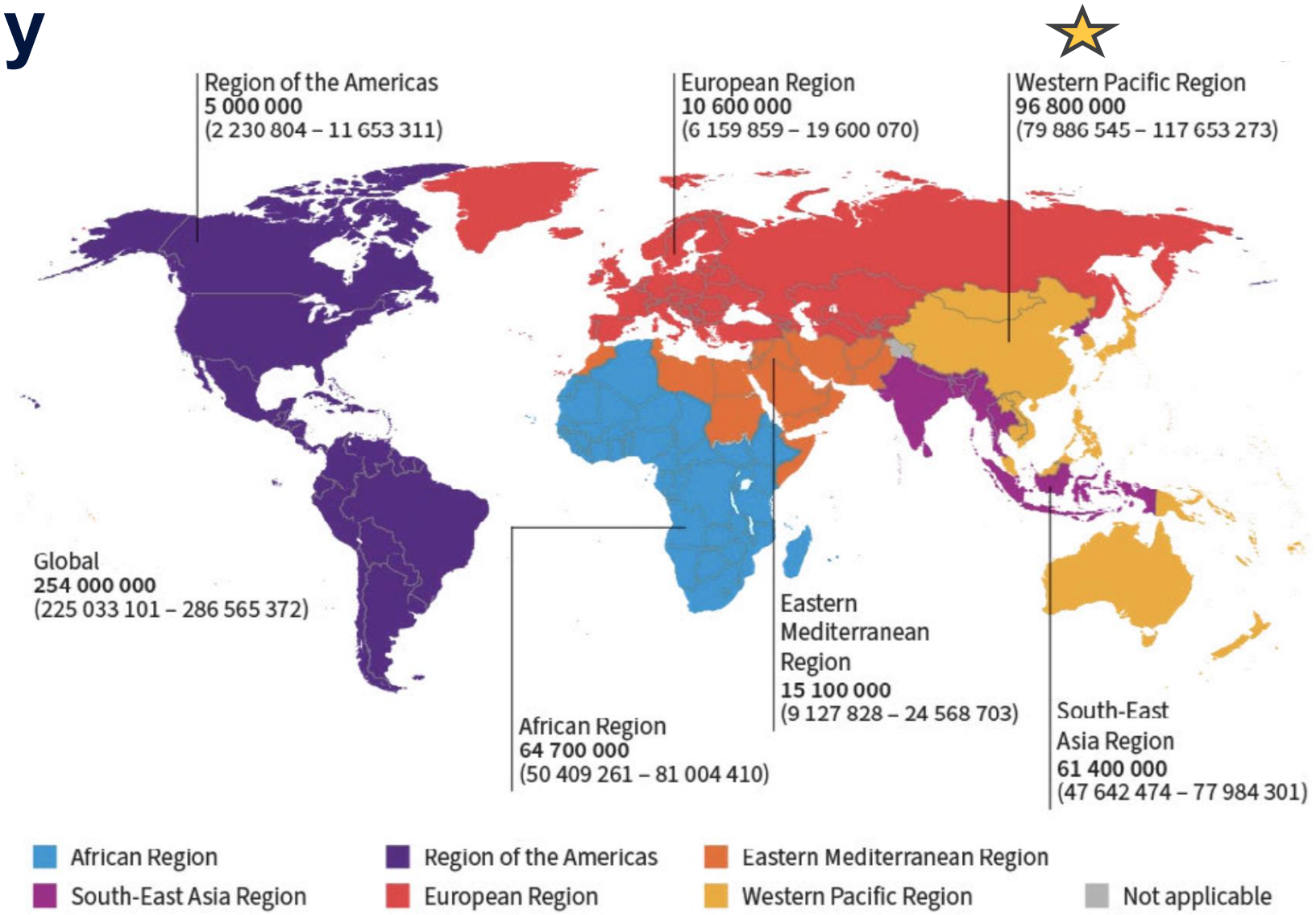
# Why Does it Matter?

- Estimated 1.3 million deaths in 2022 worldwide
- Estimated 1.2 million new infections each year
  - Many HBV cases remain undiagnosed
- Age determines chronicity
  - Fewer than 5% of adult-acquired infections become chronic
  - Around 90% of neonate infections become chronic
- Vaccine preventable

Source: WHO. Global hepatitis report 2024. Accessed January 12, 2026.

# Epidemiology

- ~254 million people live with chronic HBV worldwide (3.8% prevalence)
- The Western Pacific Region accounts for 47% of deaths while treatment remains low.




Source: WHO. Global hepatitis report 2024. Accessed January 12, 2026.





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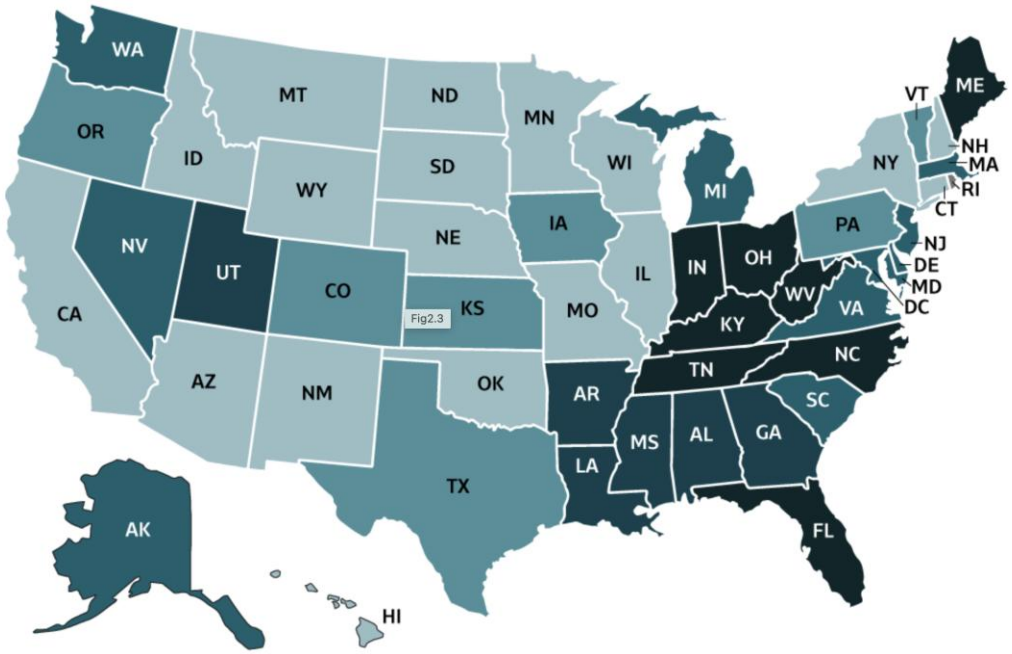
# Epidemiology

- United States
  - ~14,000 acute infections annually
  - ~850,000 to 2.4 million people with chronic HBV
  - Highest prevalence
    - Born in HBV-endemic countries
    - People who inject drugs
    - Men who have sex with men (MSM)
    - Those who are immunocompromised or have HIV

| Color Key | Cases/100,000 Population |
|---|---|
| | 0-0.3 |
| | >0.3-0.6 |
| | >0.6-0.9 |
| | >0.9-2.0 |
| | >2.0-7.3 |
| | No reported cases |

Figure 2.3. Rates of reported acute hepatitis B, by state or jurisdiction — United States, 2018




 | Source: Figure adapted from: CDC, 2018 Surveillance Report on Hepatitis B

# HBV Virology

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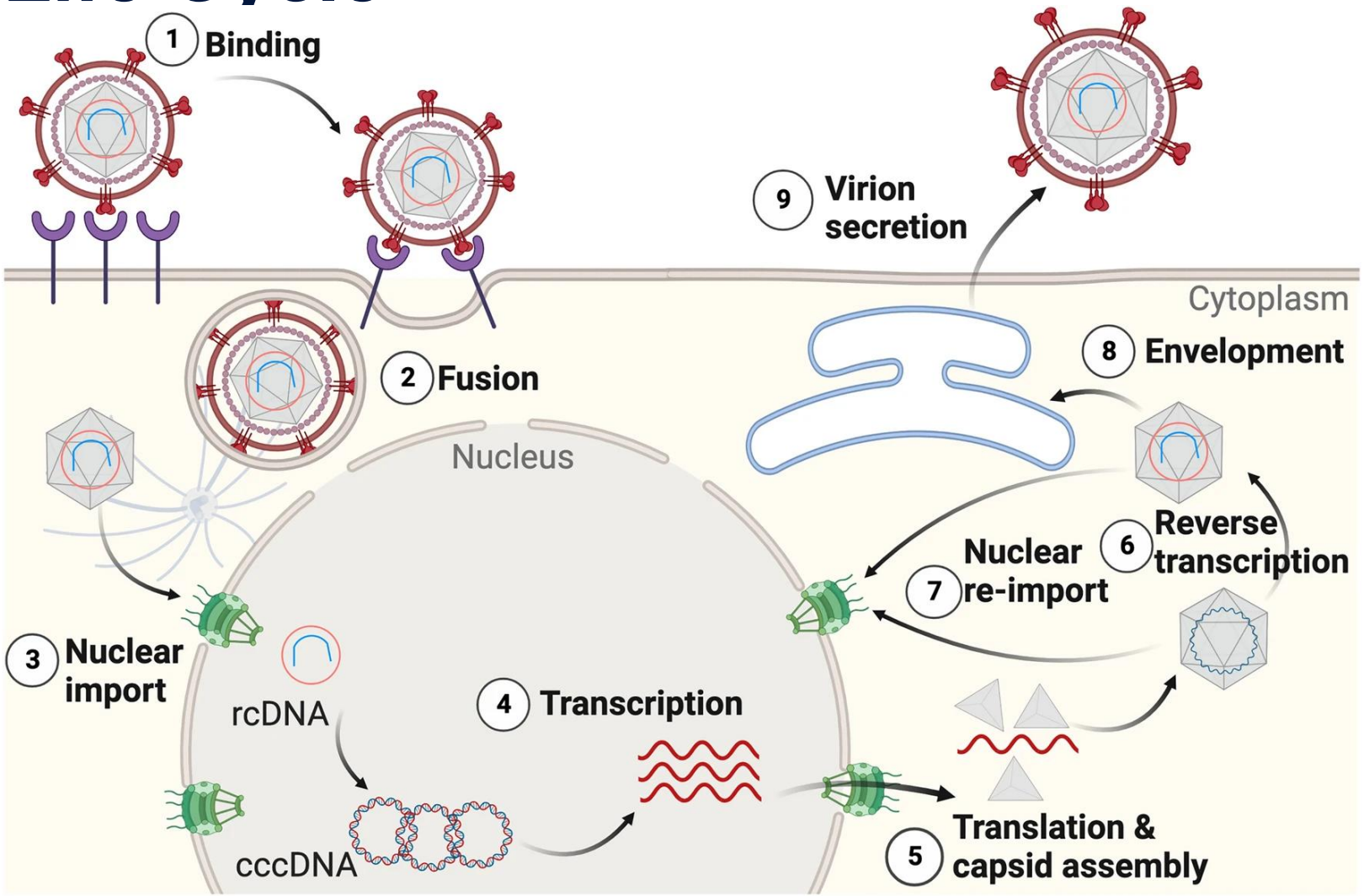
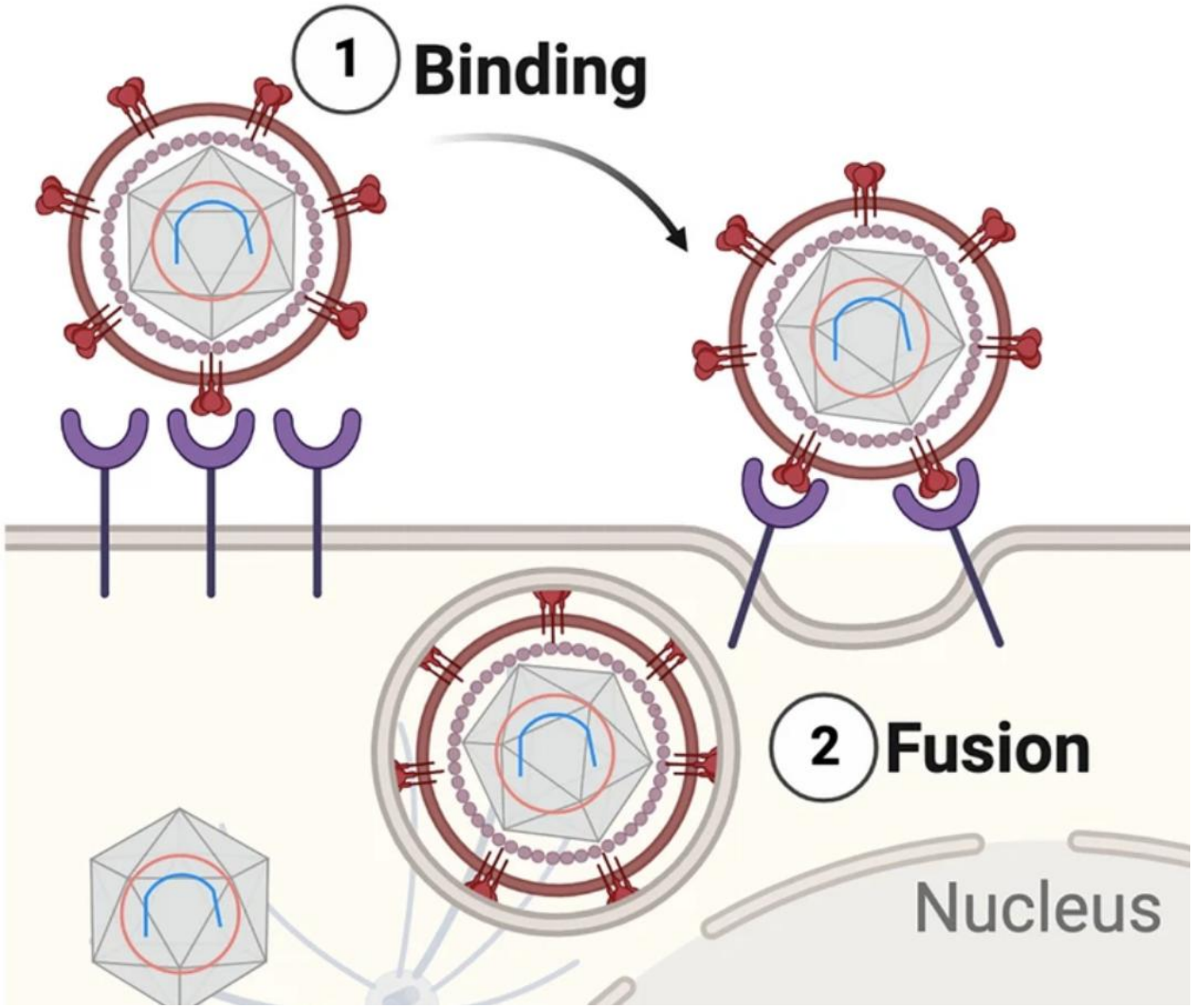
# HBV Life Cycle




 | Source: Adapted from Ghaemi et al., Sci Rep, 2023.

# Attachment & Entry

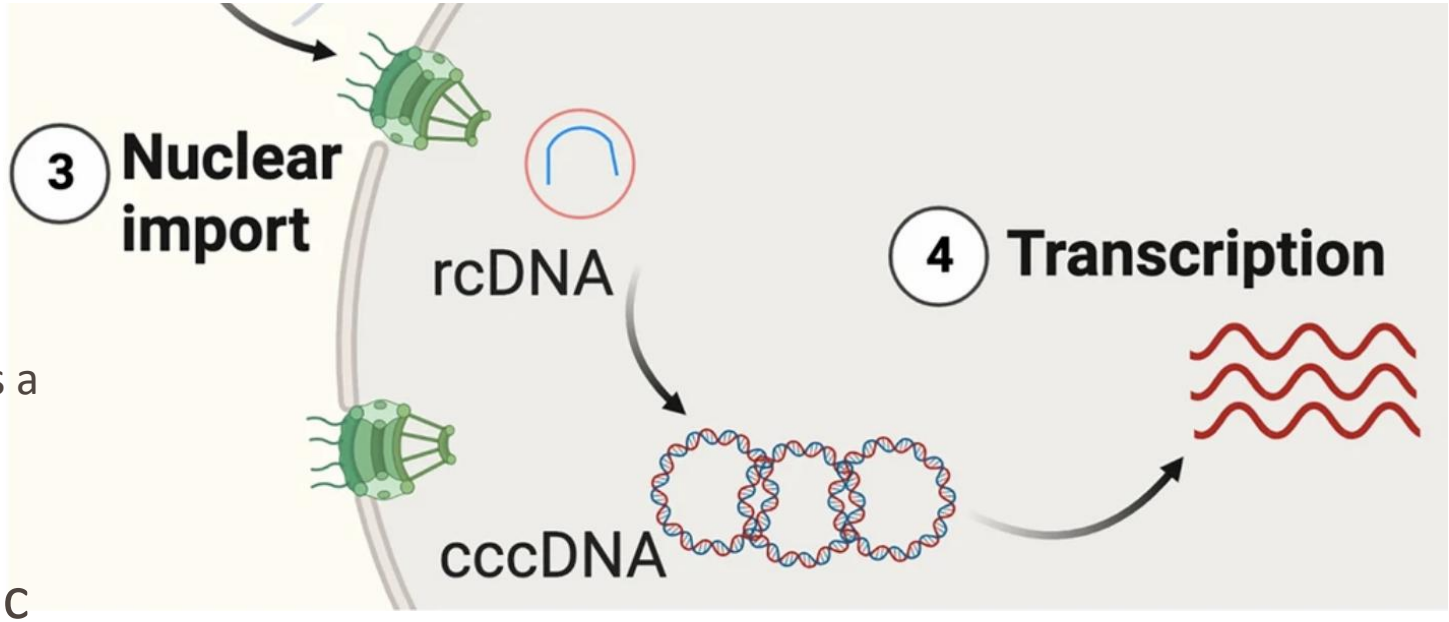
- HBV attaches to hepatocytes via the sodium taurocholate co-transporting polypeptide receptor
- The virus enters the cell through endocytosis
- The envelope is removed, releasing the nucleocapsid into the cytoplasm




 | Source: Adapted from Ghaemi et al., Sci Rep, 2023.

# Nuclear Transport & cccDNA Formation

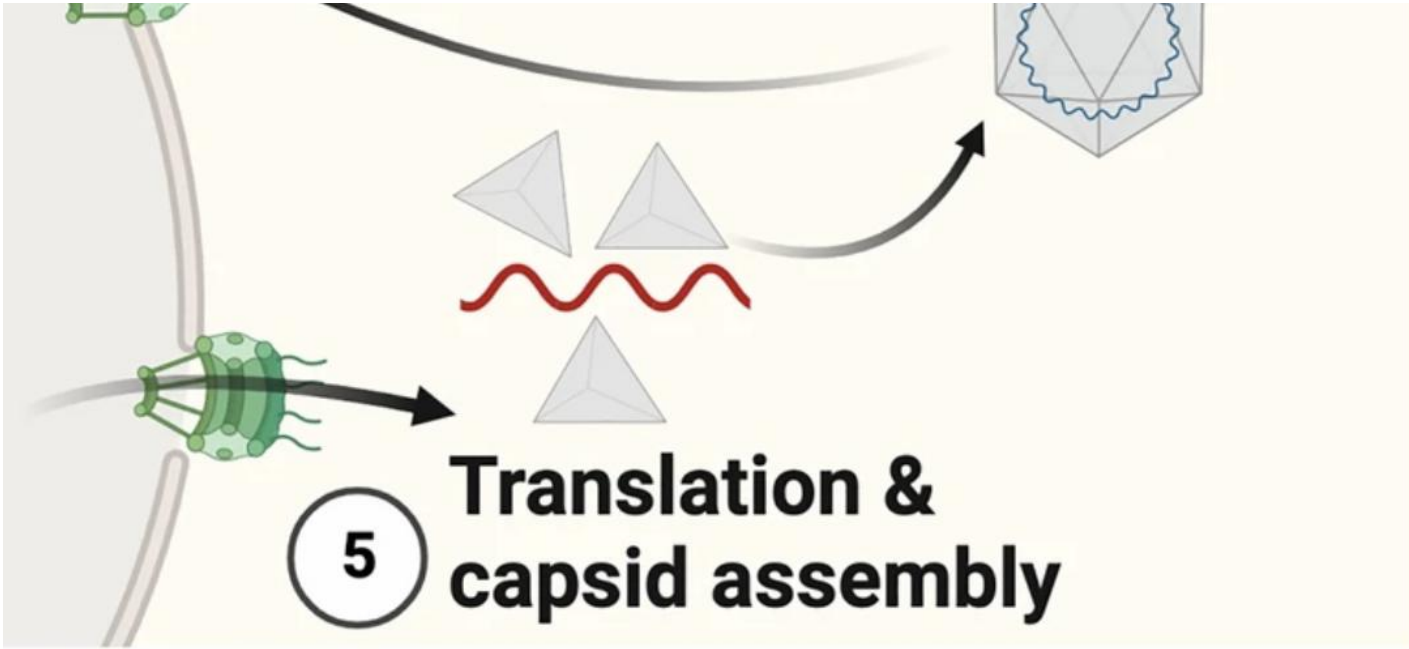
- Nucleocapsid travels to the nucleus and viral DNA enters
  - Enters as partially double-stranded DNA
- Enzymes repair it into covalently closed circular DNA (cccDNA)
  - cccDNA persists in the nucleus and serves as a persistent viral genome reservoir
    - This is a barrier to curing HBV
- cccDNA is transcribed to pregenomic RNA (pgRNA)




 | Source: Adapted from Ghaemi et al., Sci Rep, 2023.

# Translation & Capsid Formation

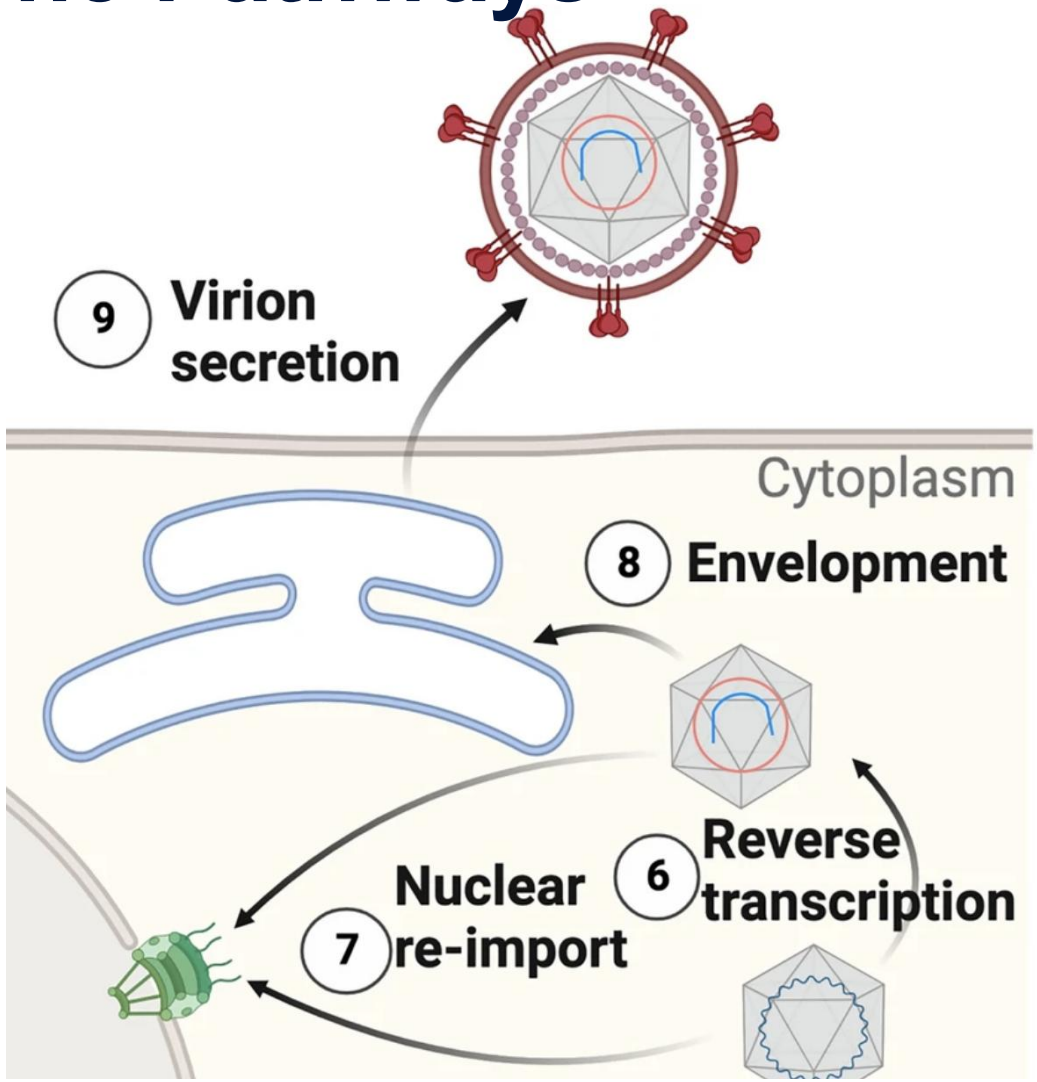
- Viral mRNAs move to the cytoplasm
- Host ribosomes produce:
  - Core protein (HBcAg)
  - Surface proteins (HBsAg)
  - Polymerase
  - Regulatory proteins
- pgRNA + viral polymerase are packaged into a new nucleocapsid




 | Source: Adapted from Ghaemi et al., Sci Rep, 2023.

# Reverse Transcription & The Pathways

- Inside the capsid:
  - pgRNA → negative-strand DNA
  - Partial positive-strand DNA is synthesized
- Recycling pathway
  - Nucleocapsid returns to the nucleus
  - Increases the pool of cccDNA (maintains chronic infection)
- Secretion pathway
  - Nucleocapsid acquires an envelope with surface antigens
  - Mature virion is released from the cell




 | Source: Adapted from Ghaemi et al., Sci Rep, 2023.

# HBV Persistence Ex Vivo

- HBV remains infectious on environmental surfaces for ≥7 days
  - Bond et al., 1981 found that dried HBV-positive human plasma caused active infection in chimpanzees.
- Highly stable DNA virus → greater environmental resilience
- Clinical significance:
  - Highlights the risk of environmental contamination in healthcare settings and need for practices to prevent nosocomial and occupational transmission.


Sources: Than TT et al. J Infect Dis. 2019;219:1044-1048.
Bond WW et al. HBV survival after drying. Lancet. 1981.

# Screening & Testing

Hepatitis B Virus Management: Who, When, and How



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# HBV Screening: Who & When

- Universal Screening
  - Who: All adults aged 18 years and older
  - When: At least once in a lifetime
  - Tests: Use the Triple Panel (HBsAg, anti-HBs, total anti-HBc)
- Pregnancy Screening
  - Who: All pregnant individuals
  - When: During every pregnancy, ideally in the 1st trimester
    - Note: Screen regardless of vaccination status or prior negative results

Sources: Conners EE, et al. MMWR Recomm Rep. Published online Mar 10, 2023.
Terrault NA et al. AASLD 2018 hepatitis B guidance. Clin Liver Dis. 2018.

# HBV Screening: Who and When

- Risk-Based Testing
  - Who: Persons with ongoing risk factors, including:
    - People born in regions with HBsAg prevalence ≥ 2%
    - People who inject drugs (current or former)
    - MSM
    - People with HIV or Hepatitis C
    - Incarcerated persons (current or former)
    - People who live with or have sex with someone who has hepatitis B
- Clinical Triggers
  - Who: Anyone with elevated ALT/AST of unknown etiology.
  - When: Prior to initiating immunosuppressive therapy (to prevent HBV reactivation).

Sources: Conners EE, et al. MMWR Recomm Rep. Published online Mar 10, 2023.
Terrault NA et al. AASLD 2018 hepatitis B guidance. Clin Liver Dis. 2018.

# Antigens, Antibodies, and Other Measures

| Test | Type | What it Means (Simplified) |
|---|---|---|
| HBsAg (Surface Antigen) | Antigen | Positive = Current HBV infection (acute or chronic) |
| HBeAg (Envelope-Antigen) | Antigen | Positive = High replication → more contagious |
| Anti-HBs (Surface Antibody) | Antibody | Positive = Immunity (vaccine or recovered infection) |
| Anti-HBc (Core Antibody) | Antibody | Positive = Exposure (past or current infection; NOT from vaccine) |
| IgM Anti-HBc | Antibody | Positive IgM anti-HBc = recent infection / acute HBV |
| IgG Anti-HBc | Antibody | Positive IgG anti-HBc = prior exposure to HBV (past or chronic infection) |
| HBV DNA (Viral Load) | Viral measure | High = active replication; Low/undetectable = suppressed |
| ALT | Liver enzyme | High = liver inflammation/injury |

# Serologic Interpretation

| | | |
|---|---|---|
| **HBsAg**<br>**anti-HBc**<br>**anti-HBs** | negative<br>negative<br>negative | Susceptible |
| **HBsAg**<br>**anti-HBc**<br>**anti-HBs** | negative<br>positive<br>positive | Immune due to natural infection |
| **HBsAg**<br>**anti-HBc**<br>**anti-HBs** | negative<br>negative<br>positive | Immune due to hepatitis B vaccination |
| **HBsAg**<br>**anti-HBc**<br>**IgM anti-HBc**<br>**anti-HBs** | positive<br>positive<br>positive<br>negative | Acutely infected |
| **HBsAg**<br>**anti-HBc**<br>**IgM anti-HBc**<br>**anti-HBs** | positive<br>positive<br>negative<br>negative | Chronically infected |


Source: CDC. Interpretation of hepatitis B serologic test results. 2013. Accessed 2026.

# Phases of HBV Infection

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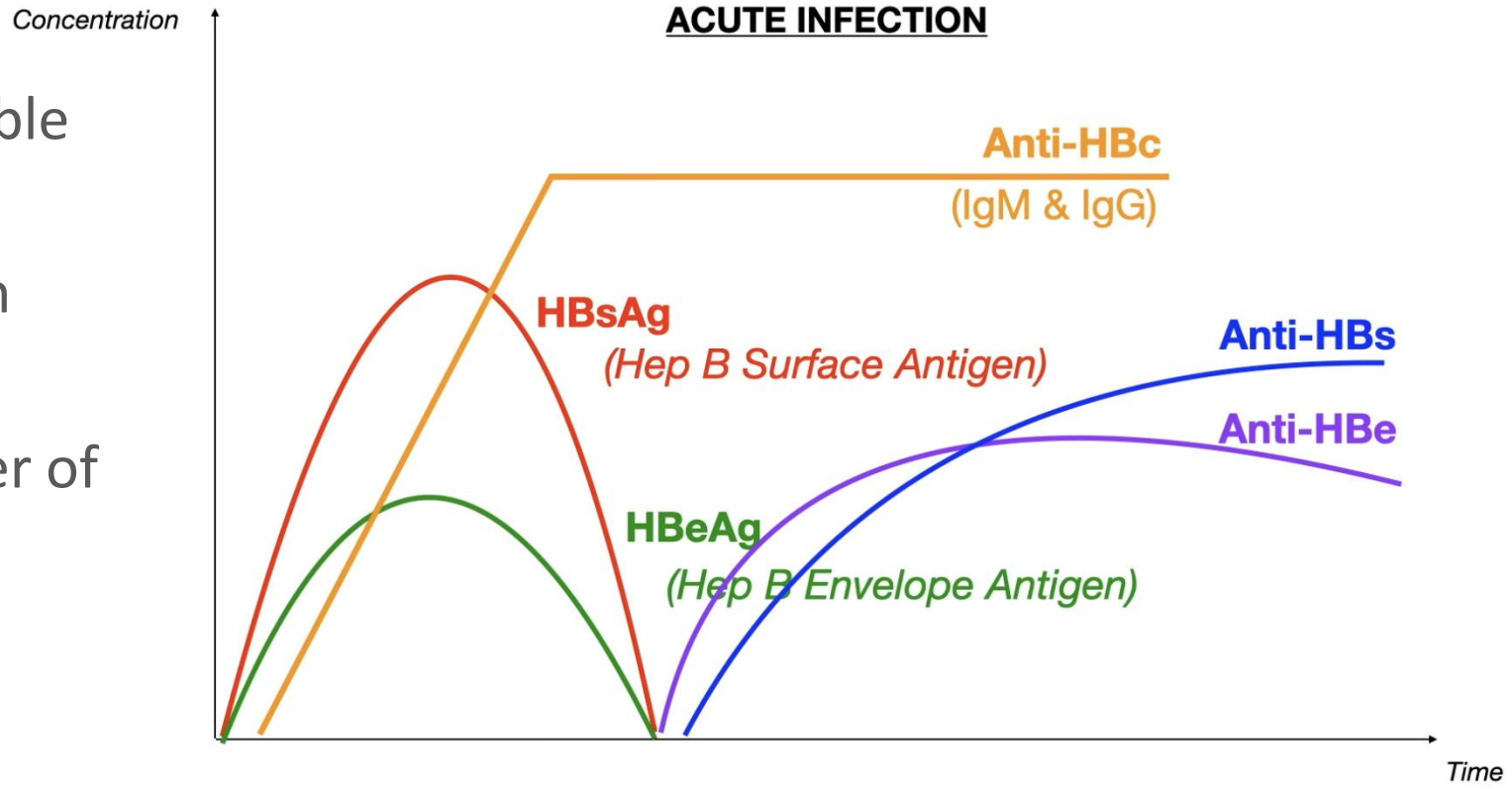
# Acute HBV Infection

- **Occurs within 6 months of exposure**
- HBsAg is the first detectable marker after exposure
- HBeAg is positive early on
  - Indicates high infectivity
- Anti-HBc IgM = key marker of acute infection





Source: Adapted from Schillie et al., ACIP/CDC, 2018.

# Acute to Chronic Conversion

- **Chronic infection is defined by the presence of HBsAg for ≥ 6 month.**
- Factors influencing progression to chronic infection:
  - Age at time of infection (strongest predictor)
    - McMahon BJ et al.: Chronic HBV was more common when infection occurred early in life
    - 28.8% ≤4 years vs 7.7% ≥30 years
  - Immunosuppression
    - Increased risk of progression (ex: HIV co-infection)

Sources: McMahon BJ et al. Age and outcomes of acute HBV infection. J Infect Dis. 1985
Bodsworth NJ et al. HIV infection and HBV carrier state. J Infect Dis. 1991.







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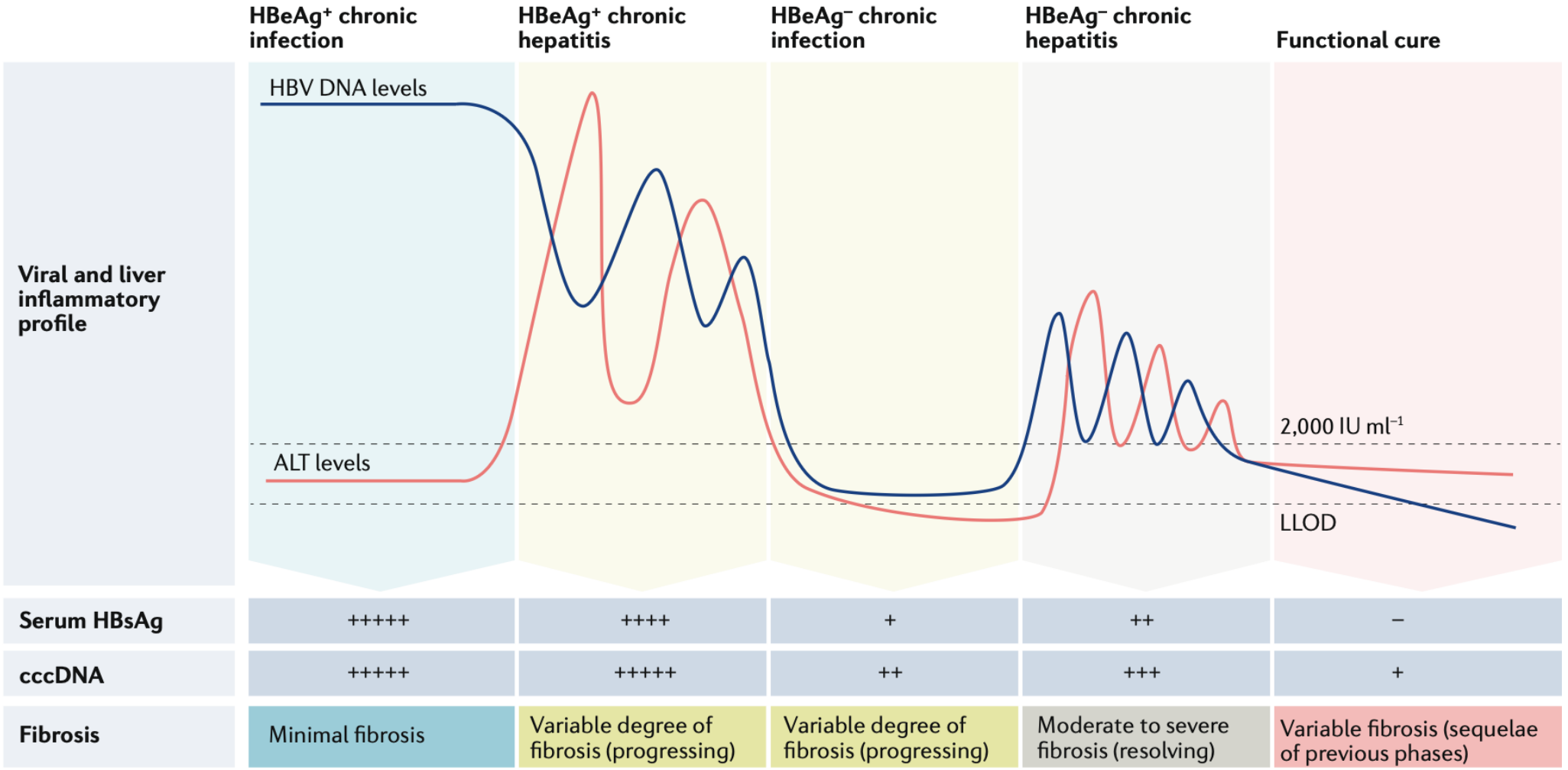
# Chronic Phases of Infection




 | Source: Fanning et al., Nat Rev Drug Discov, 2019.



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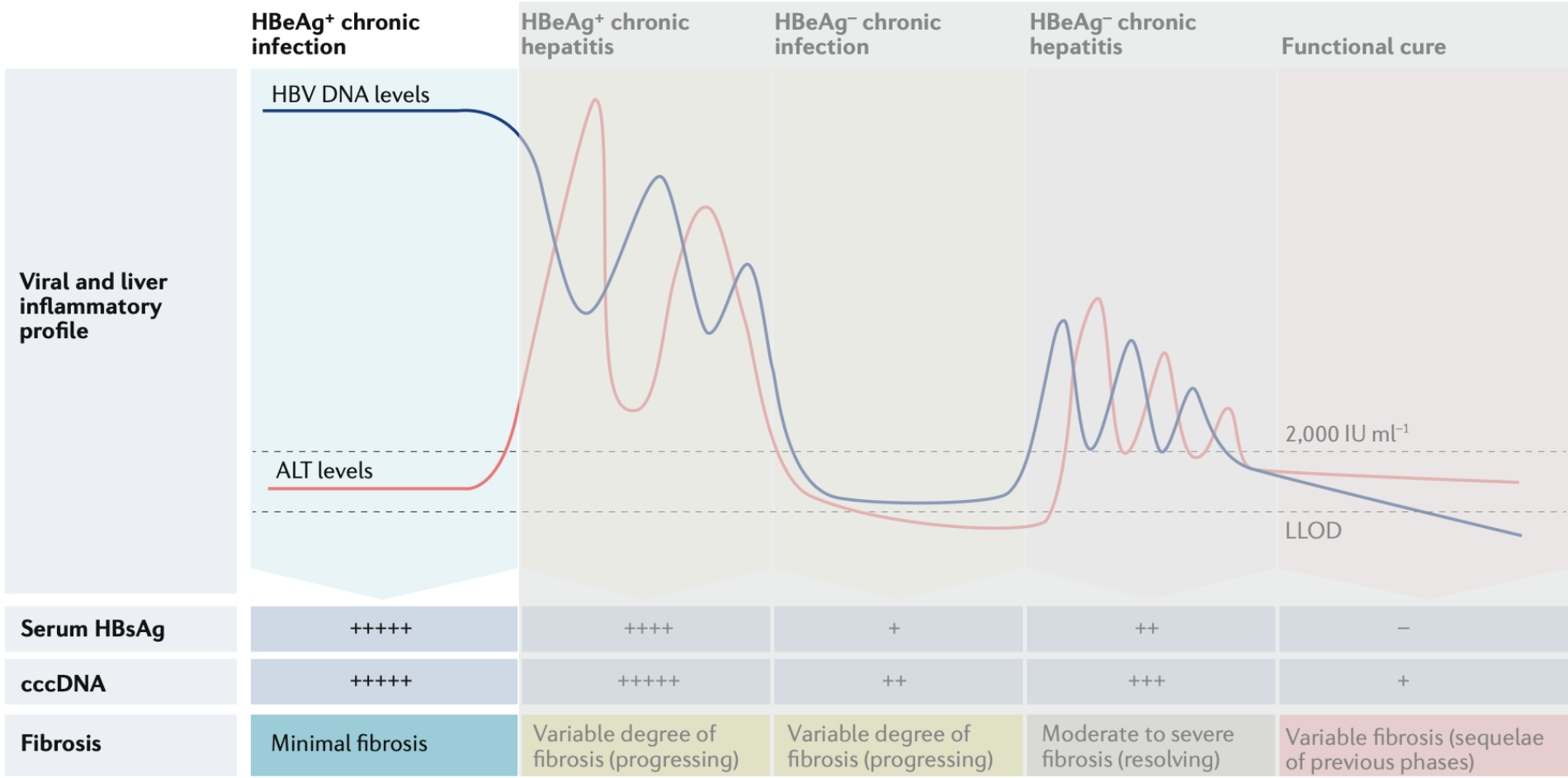
# HBeAg-Positive Chronic Infection

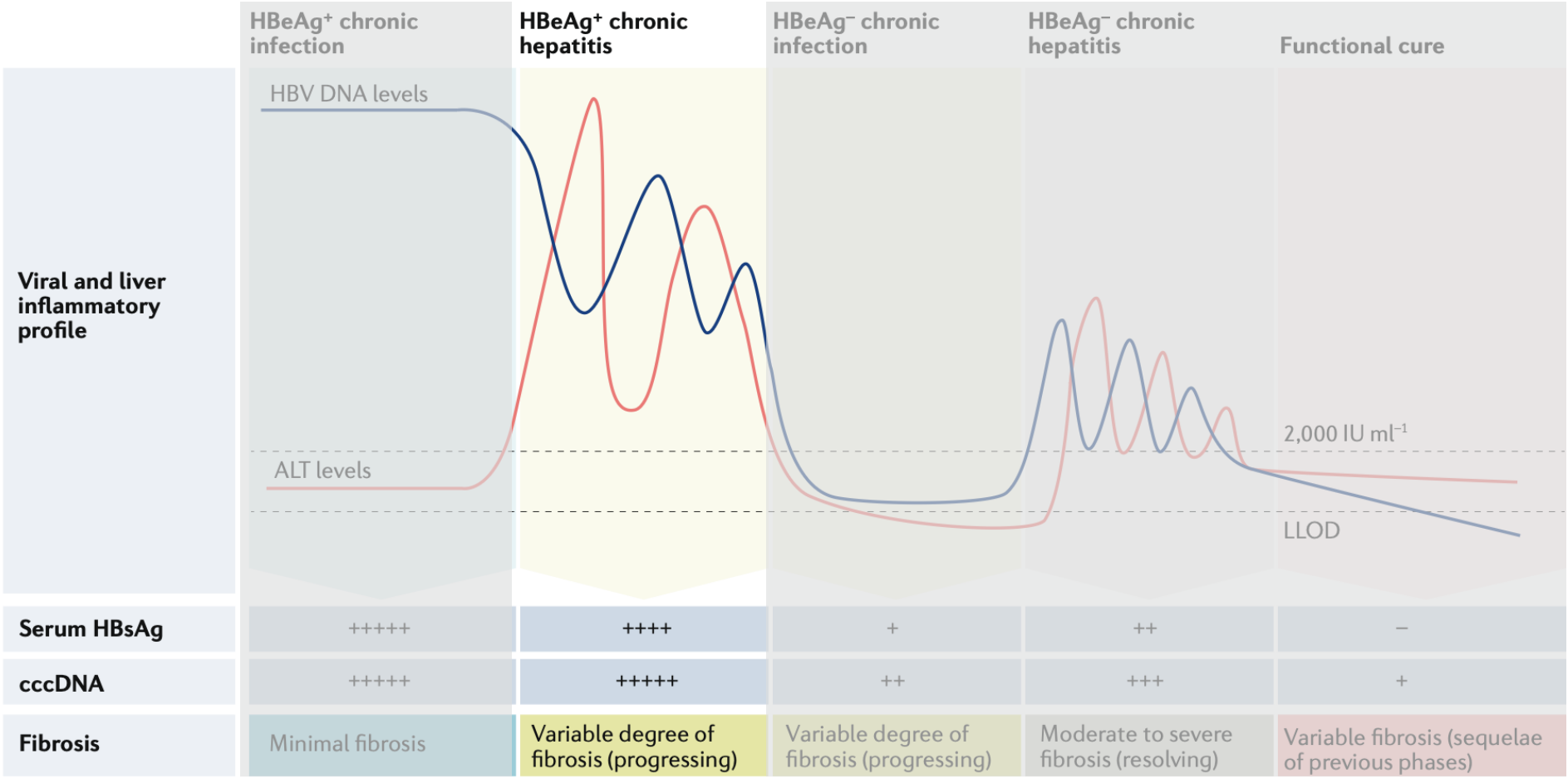
- There is a lack of host immune response against the virus
- High levels of HBV DNA and HBeAg
- ALT is normal; fibrosis is absent or minimal.




 | Source: Fanning et al., Nat Rev Drug Discov, 2019.

# HBeAg-Positive Chronic Hepatitis

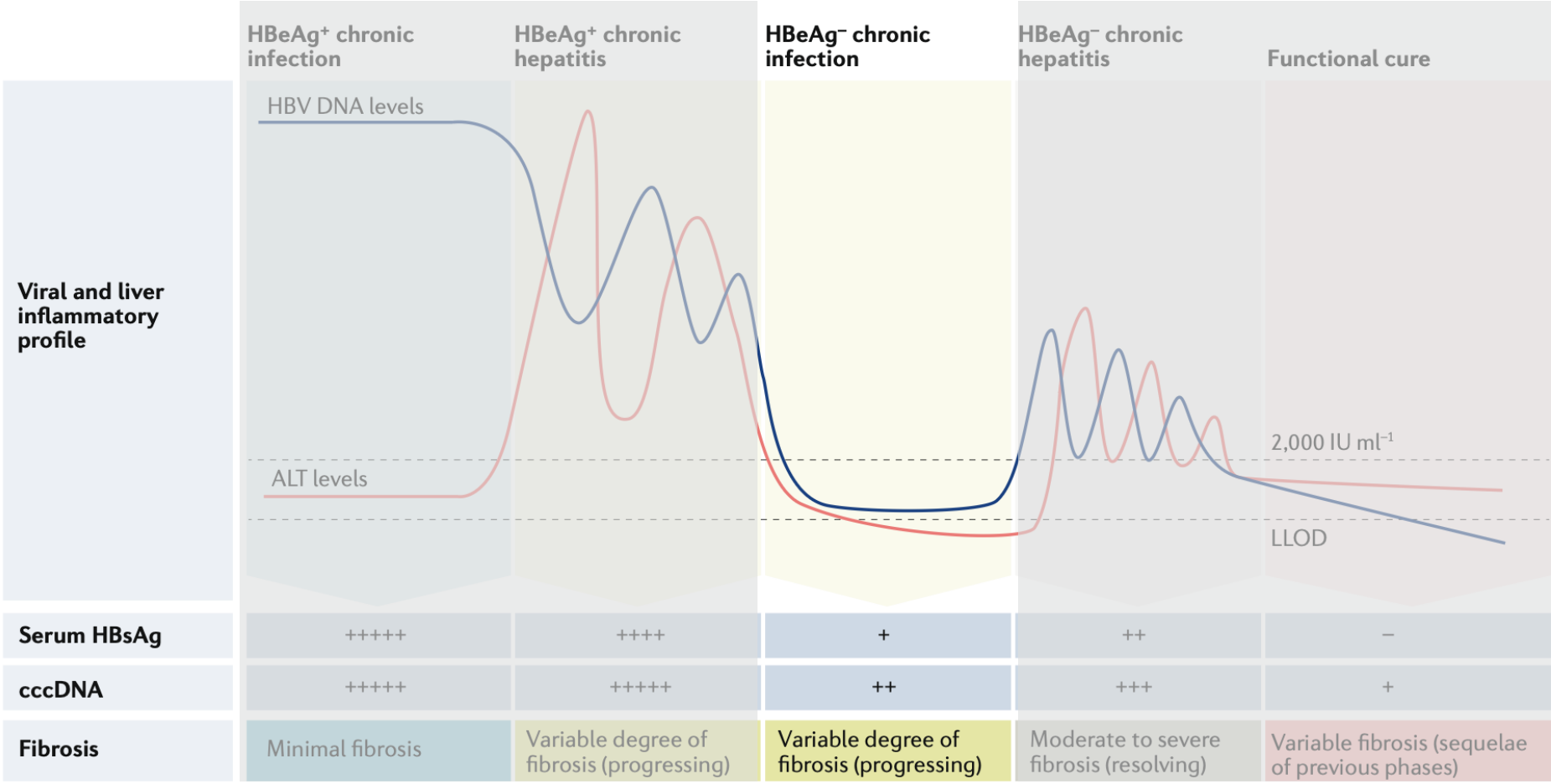
- Beginning of immune-mediated response
- HBV DNA remains high but begins to fluctuate as infected cells are targeted.
- Elevated ALT; progressive fibrosis begins here.




 | Source: Fanning et al., Nat Rev Drug Discov, 2019.

# HBeAg-Negative Chronic Infection

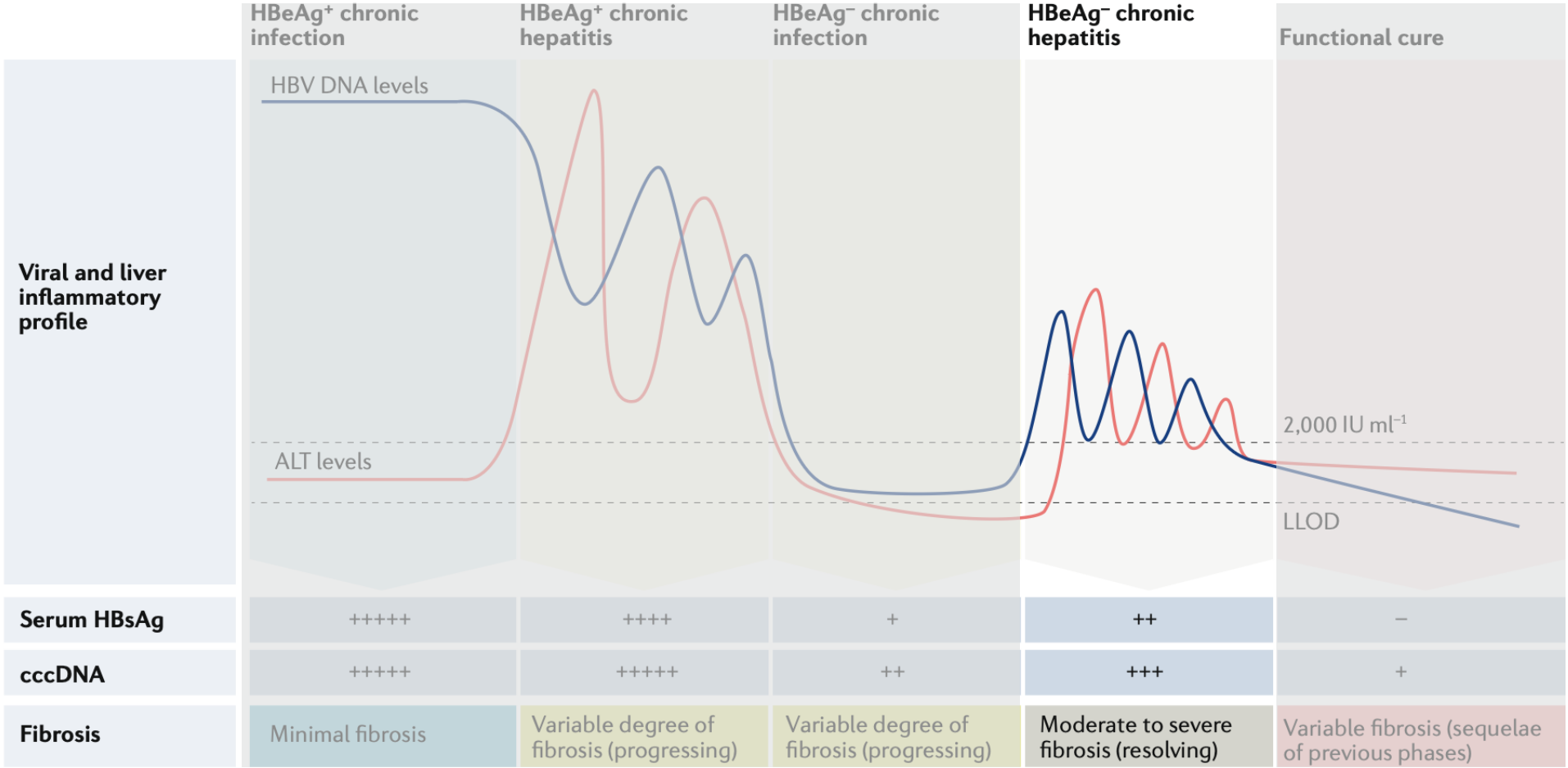
- Host has gained partial control, low-level viral replication
- HBeAg is lost (seroconversion to anti-HBe).
- HBV DNA is low or undetectable (<2,000 IU/mL).
- ALT normalizes; fibrosis typically stabilizes.




 | Source: Fanning et al., Nat Rev Drug Discov, 2019.

# HBeAg-Negative Chronic Hepatitis (Reactivation)

- The virus “escapes” immune control
- HBV DNA rises again, but the patient remains HBeAg-negative.
- ALT elevations return; fibrosis can progress rapidly toward cirrhosis.




 Source: Fanning et al., Nat Rev Drug Discov, 2019.



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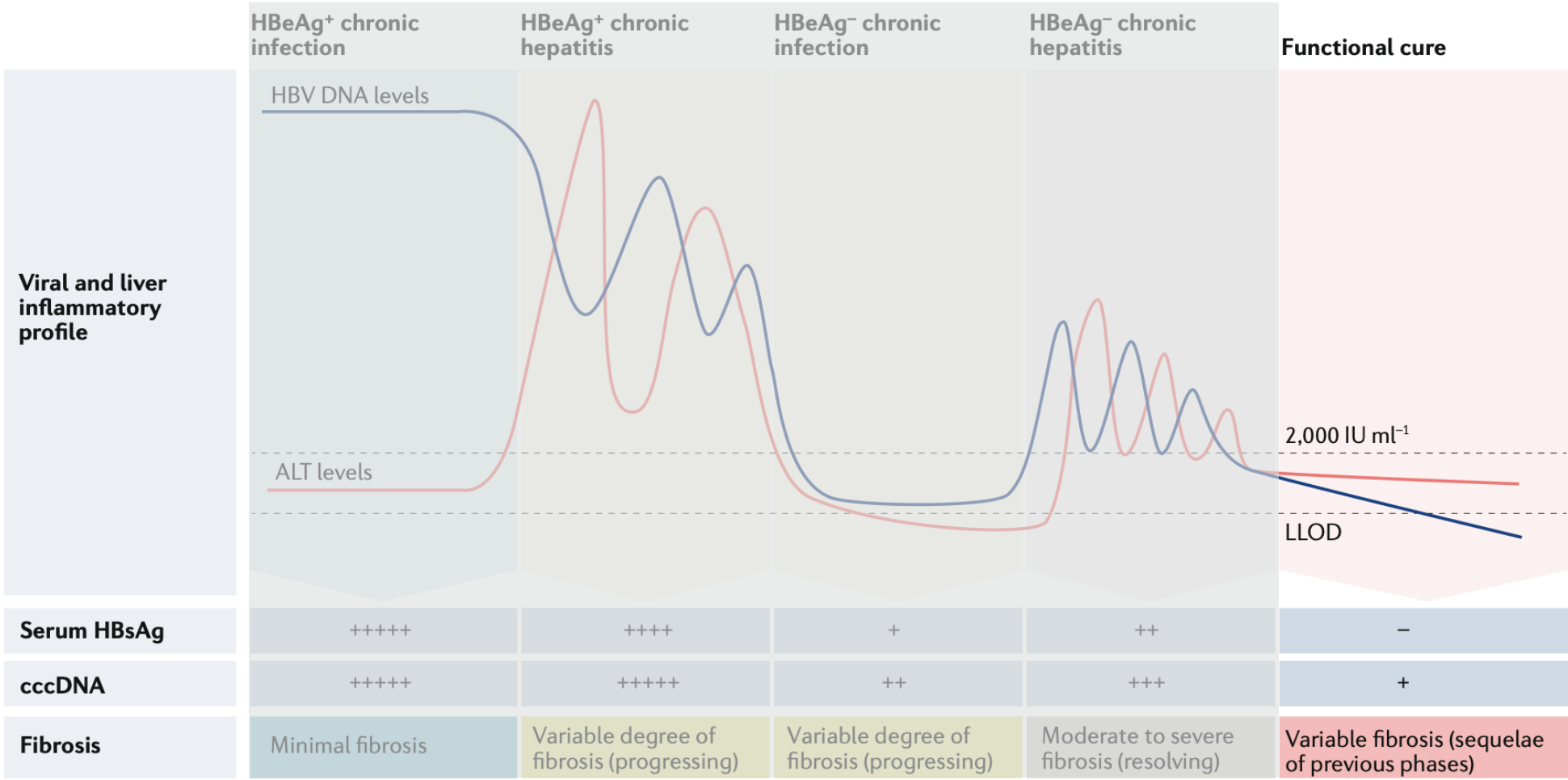
# Functional Cure (HBsAg Loss)

- Clinical goal
- Sustained loss of HBsAg from the serum. HBV DNA is undetectable in the blood.
- ALT is normal; fibrosis may slowly regress over years.




 | Source: Fanning et al., Nat Rev Drug Discov, 2019.



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# HBV Prevention

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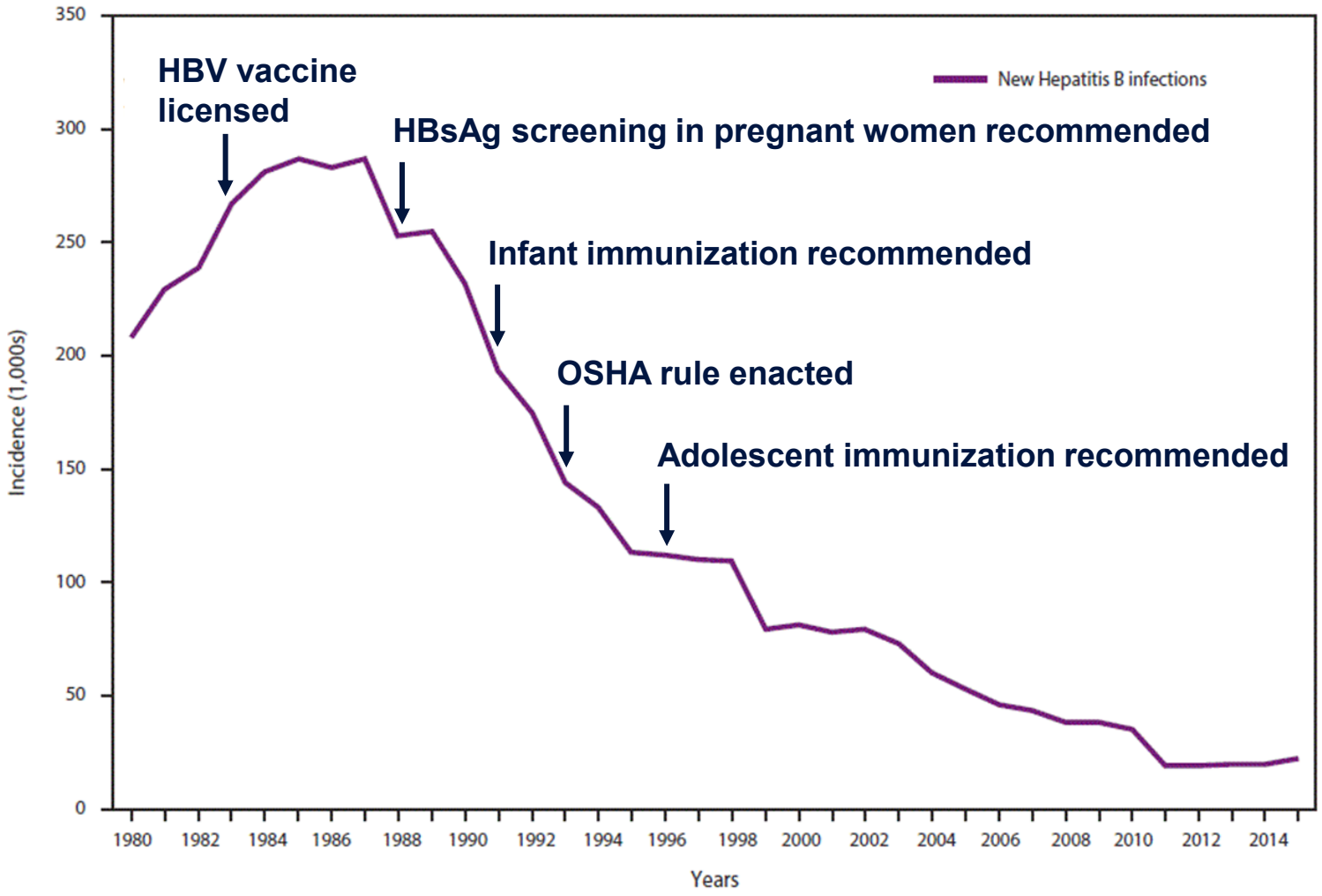
# Incidence of HBV infection — National Notifiable Diseases Surveillance System (US) 1980–2015




**However…**
**↑ 2016-2018 due to IVDU**



Sources: Figure adapted from: Schille S, et al. *MMWR Recomm Rep* 2018;67(No. RR-1):1-31



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# CDC Adopts Individual-Based Decision-Making for Hepatitis B Immunization for Infants Born to Women Who Test Negative for the Hepatitis B Virus

**FOR IMMEDIATE RELEASE**

**December 16, 2025**

# Prevention: Vaccination

- HBV vaccines prevent infection by inducing protective antibodies (anti-HBs ≥10 mIU/mL)
  - Protect from chronic HBV, HCC, and HBV-induced cirrhosis
- Vaccines contain recombinant HBsAg
  - Not a live vaccine
- Long lasting immunity
  - Studies have shown immune memory > 30 years

- Who: The Advisory Committee on Immunization Practices (ACIP) recommends
  - All infants: individual-based decision-making for HBV negative mothers
    - Previously: born dose within 24 hours
  - Unvaccinated children younger than 19 years of age
  - Adults 19–59 years
  - Adults 60 years and older with risk factors for hepatitis B
    - Adults 60 years and older without risk factors **may also** receive vaccination
  - Health care and safety personnel

Sources: Cocchio S et al. Persistence of anti-HBs after HBV vaccination. Vaccines (Basel). 2021.
CDC. Hepatitis B vaccine administration. Accessed 2026.

# Monovalent HBV Vaccines

| Vaccine | Age Group | Doses | Schedule | Key Notes |
|---|---|---|---|---|
| Engerix-B | Infants, children, adults | 3 | 0, 1, 6 months | Standard HepB vaccine |
| Recombivax HB | Infants, children, adults | 3 | 0, 1, 6 months | Pediatric & adult formulations |
| Heplisav-B | Adults ≥18 yrs | 2 | 0, 1 month | Faster protection; higher seroconversion |

# Combination HBV Vaccines

| Vaccine | Includes | Age Group | Doses | Schedule | Key Notes |
|---|---|---|---|---|---|
| Pediarix | HepB + DTaP + IPV | Infants | 3 | 2, 4, 6 months | Not for birth dose |
| Vaxelis | HepB + DTaP + IPV + Hib | Infants | 3 | 2, 4, 6 months | Not for birth dose |
| Twinrix | HepA + HepB | Adults ≥18 yrs | 3 | 0, 1, 6 months | Dual hepatitis protection |
| Twinrix (Accelerated) | HepA + HepB | Adults ≥18 yrs | 4 | 0, 7, 21–30 days + 12 mo booster | Travel / rapid immunity |

 Source: CDC. Hepatitis B vaccine administration. Accessed 2026.

# Infants Born to Mothers who Have Hepatitis B

- Hepatitis B Immune Globulin
  - Provides immunity; contains anti-HBs antibodies
  - Immediate but short-term protection
  - Most efficacious if given within 12 hours of birth
  - IMPORTANT: Must be given in different sites (i.e. separate limbs) to minimize interactions

| Maternal HBsAg Status | At Birth (≤12 hours) | Vaccine Series Completion | Post-Vaccination Testing |
|---|---|---|---|
| HBsAg-Positive | HepB vaccine + HBIG | Complete HepB series by 6 months | HBsAg & anti-HBs at 9–12 months |
| Unknown Status | HepB vaccine within 12 hours (± HBIG if available) | Complete HepB series by 6 months | Test mother ASAP; infant testing if indicated |



Sources : CDC. ACIP recommendations for prevention of hepatitis B virus infection. 2018.

# HBV Therapy Overview

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# Management Guidelines

- **American Association for the Study of Liver Diseases (AASLD)**
  - Currently used for screening and diagnosis of HBV
  - The 2025 update includes the Infectious Disease Society of America (IDSA) and addresses new treatment questions
- **American College of Obstetricians and Gynecologists (ACOG)**
  - Focuses on pregnant or postpartum individuals who screen positive for viral hepatitis infections
- **American Gastroenterology Association (AGA)**
  - Focuses on prevention and treatment of hepatitis B reactivation

Sources: Terrault NA et al. Hepatology. 2018;67:1560-1599.
ACOG. Clinical guidance and practice resources. Accessed 2026.

# HBV Therapy

- Goals of therapy
  - Suppress HBV DNA replication
  - Reduce inflammation and fibrosis to prevent progression to cirrhosis, liver failure, and HCC
- Who should be treated? (Not all patients require treatment)
  - Elevated HBV DNA + elevated ALT
  - Moderate–severe fibrosis or cirrhosis
  - High-risk populations, such as:
    - Immunosuppressed patients (risk of HBV reactivation)
    - Pregnancy with high viral load (to reduce vertical transmission)
- Therapy Options
  - Antivirals, interferon, HBIG


Sources: Terrault NA et al. Hepatology. 2018;67:1560-1599.

# Entecavir (ETV)

| | |
|---|---|
| Brand Name | Baraclude |
| MOA | Guanosine nucleoside analog → inhibits HBV DNA polymerase (blocks viral DNA synthesis) |
| Dosing | 0.5 mg to 1 mg by mouth once daily |
| Adverse Effects | Headache, fatigue, dizziness, and nausea. |
| Renal Adjustment | Adjust if CrCl is less than 50 mL/min |

# Tenofovir disoproxil fumarate (TDF)

| | |
|---|---|
| Brand Name | Viread |
| MOA | Nucleotide analog → inhibits HBV reverse transcriptase / DNA polymerase (causes DNA chain termination) |
| Dosing | 300 mg orally once daily with or without food |
| Adverse Effects | Abdominal pain, nausea, insomnia, itching, vomiting, dizziness, and fever. |
| Renal Adjustment | Adjust if CrCl is less than 50 mL/min |

# Tenofovir alafenamide (TAF)

| | |
|---|---|
| Brand Name | Vemlidy |
| MOA | Tenofovir prodrug → inhibits HBV reverse transcriptase/DNA polymerase (DNA chain termination) |
| Dosing | 25 mg by mouth once daily with food |
| Adverse Effects | Headache. |
| Renal Adjustment | Not recommended in CrCl less that 15 mL/min in patients who are not receiving chronic hemodialysis. |

| | TDF | TAF |
|---|---|---|
| Prodrug type | Oral prodrug of tenofovir | Newer oral prodrug of tenofovir |
| Plasma tenofovir levels | Higher systemic exposure | ~90% lower exposure |
| Renal safety | Risk of nephrotoxicity: proximal tubular | Improved renal safety |
| Bone effects | ↓ Bone mineral density | Less BMD loss |
| Lipid effects | Lipid-lowering | ↑ LDL & total cholesterol |
| Use in renal impairment | Avoid if CrCl <50 mL/min | Usable if CrCl ≥15 mL/min |
| HBV efficacy | Highly effective | Noninferior to TDF |
| **Cost** | **Generic available** | **Brand only (may be $$$)** |

Sources: Chan HL et al. TAF vs TDF for chronic hepatitis B. N Engl J Med. 2016.
Gupta SK et al. Renal safety of TAF vs TDF. Clin Infect Dis. 2019.
FDA. Viread (tenofovir disoproxil fumarate) PI.
FDA. Vemlidy (tenofovir alafenamide) PI.

# Peginterferon alfa-2a

| | |
|---|---|
| Brand Name | Pegasys |
| MOA | Peginterferon alfa-2a binds to the human type 1 interferon receptor and induces the innate antiviral immune response |
| Dosing | 180 mcg subQ once a week for 48 weeks |
| Adverse Effects | The most common adverse reactions (incidence greater than 40%) are fatigue/asthenia, pyrexia, myalgia, and headache |
| Contraindicated | Severe or decompensated liver disease<br>Severe psychiatric disorders – MDD with suicidal ideation, psychosis<br>Neonates/infants – benzyl alcohol |
| Renal Adjustment | Adjust if CrCl is less than 30 mL/min or ESRD requiring hemodialysis |

 Sources: FDA. Pegasys PI. 2011.

# Acute HBV Treatment

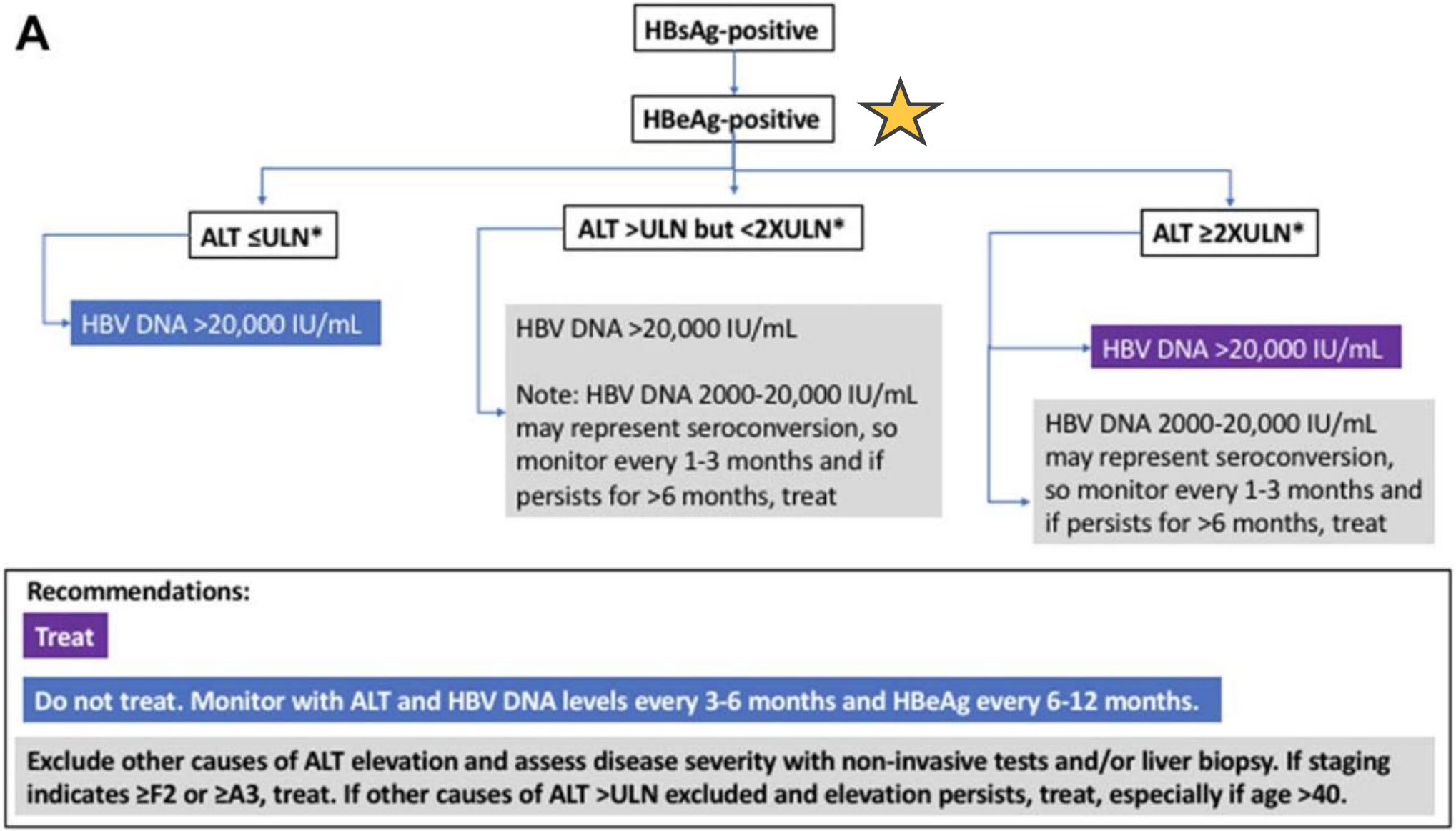
- Not typically indicated as 95% of cases recover spontaneously.
- Treat severe/fulminant acute HBV per AASLD:
  - Total bilirubin >3 mg/dL (or direct >1.5 mg/dL)
  - INR >1.5
  - Encephalopathy or ascites
- Preferred agents: TDF/TAF or Entecavir
- Continue therapy until HBsAg clearance is confirmed


Sources: Terrault NA et al. Hepatology. 2018;67:1560-1599.

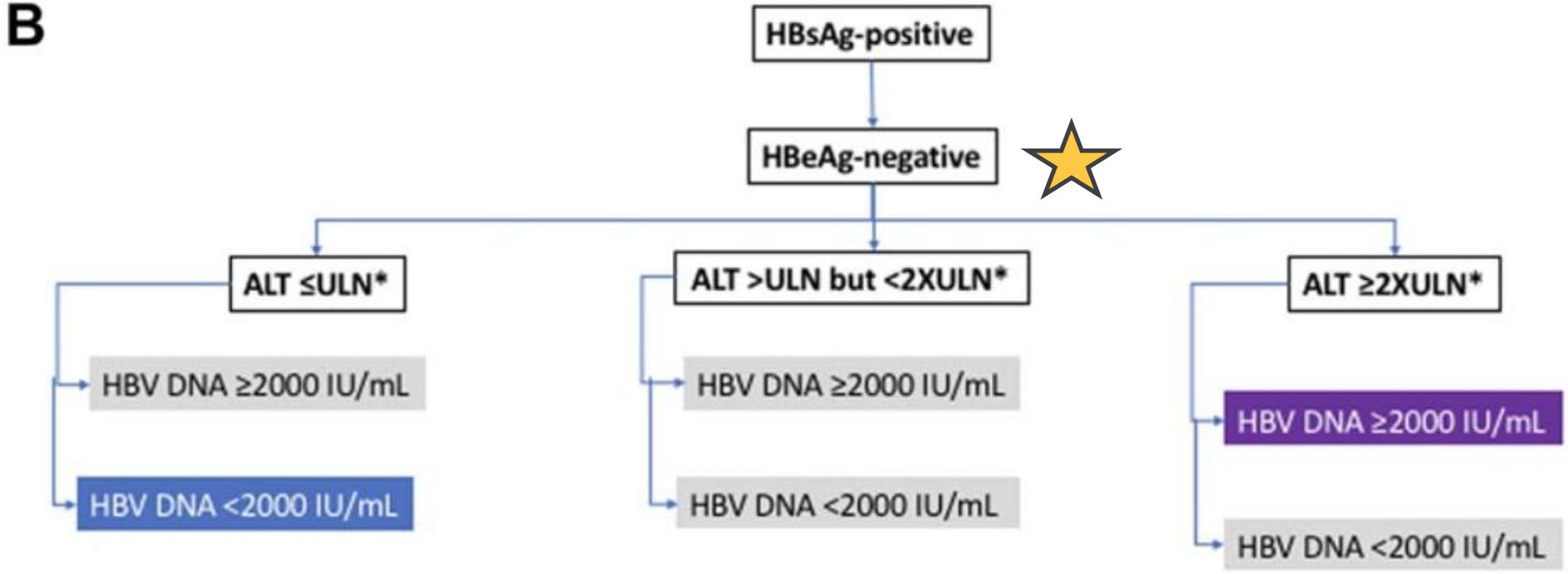
# Lamivudine in Acute Hepatitis B

- Lamivudine in Acute Hepatitis B
  - Randomized controlled trial
    - Lamivudine 100 mg daily × 3 months (n=31) vs placebo (n=40)
    - Included moderate–severe acute HBV (bilirubin >5 mg/dL)
  - Virologic outcomes
    - Greater HBV DNA decline at week 4 with lamivudine
    - No difference in HBV DNA levels after week 4
- Serologic outcomes
  - HBsAg loss at 12 months:
    - Lamivudine 93.5% vs placebo 96.7%
  - Protective anti-HBs at 12 months:
    - Lamivudine 67.7% vs placebo 85% (P=0.096)
- Conclusion: Lamivudine lowers HBV DNA faster but **does not improve clinical** or biochemical recovery compared with placebo in acute hepatitis B

 Sources: Kumar M, et al. Hepatology 2007;45(1):97




 Sources: Terrault NA et al. Hepatology. 2018;67:1560-1599.




**Recommendations:**

Treat

Do not treat. Monitor with ALT and HBV DNA levels every 3-6 months and HBsAg annually.

**If ALT ≤ULN, monitor ALT and HBV DNA every 3 months for 1 year, then every 6 months.**
**If ALT elevated, exclude other causes of ALT elevation and assess disease severity with non-invasive tests and/or liver biopsy. If staging indicates ≥F2 or ≥A3, treat. If persistent ALT >ULN with HBV DNA ≥2000 IU/mL, treat, especially if age >40.**

**The upper limits of normal for ALT in healthy adults is reported to be 29 to 33 U/L for males and 19 to 25 U/L for females. An upper limit of normal for ALT of 35 U/L for males and 25 U/L for females is recommended to guide management decisions.*


Sources: Terrault NA et al. Hepatology. 2018;67:1560-1599.

# Treatment Duration per AASLD/IDSA

**HBeAg-Positive (Without Cirrhosis)**

- Treat until all of the following:
  - HBeAg loss and anti-HBe seroconversion
  - Undetectable HBV DNA
  - ≥ 12 months of consolidation
- After stopping therapy:
  - Monitor ALT and HBV DNA every 1-3 months ≥ 12 months

**HBeAg-Negative (Without Cirrhosis)**

- Indefinite therapy is common
  - Discontinuation may be considered in:
    - On NA therapy ≥3 years
    - Persistently undetectable HBV DNA
    - No cirrhosis
- After stopping therapy:
  - Monitor ALT and HBV DNA every 1-3 months ≥ 12 months

**Cirrhosis (Compensated or Decompensated)**

- Indefinite therapy
  - Discontinuation of therapy is not recommended

**HBsAg Loss (Functional Cure)**

- Can discontinue after confirmed HBsAg loss.

Sources: Terrault NA et al. Hepatology. 2018;67:1560-1599.
AASLD. New practice guideline on treatment of chronic hepatitis B. Accessed 2026.

# Tenofovir vs Entecavir in Chronic Hepatitis B

- Study design
  - Retrospective cohort study
    - US Veterans Affairs (VA) database
    - Electronic health record–based analysis
  - Population
    - Adults (18–90 years) with chronic hepatitis B
  - Predominantly male (95%), mean age 57 years
  - Treatment-naïve at index
    - TDF: 1,769
    - ETV: 1,966
  - Primary outcome: incident HCC
  - HCC incidence (overall follow-up):
    - TDF: 1.16–1.34% per 1,000 person-years
    - ETV: 1.25–1.55% per 1,000 person-years
  - Overall: Long-term TDF use was associated with an ~11–12% relative reduction in HCC risk compared with ETV
- Author's conclusions:
  - Tenofovir may offer a slight HCC risk advantage
  - Clinical significance unclear, and unlikely alone to justify practice change


Sources: Kramer JR et al. Clin Gastroenterol Hepatol, 2023.

# Pregnancy and Postpartum

- All pregnant women should be screened for HBsAg.
- HBIG and HBV vaccine should be administered to their newborn <12 hours after delivery.
- **Antiviral therapy in the third trimester is recommended if serum HBV DNA >200,000 IU/mL**
- Recent guideline change:
  - 2018 AASLD: preferred TDF over lamivudine/telbivudine
  - 2025 update: recommends TDF or TAF starting around 28 weeks gestation (or earlier if HBIG unavailable)


Sources: Terrault NA et al. Hepatology. 2018;67:1560-1599.

# Patient Cases

Hepatitis B Virus Management: Who, When, and How



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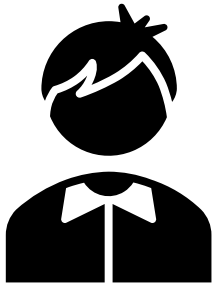
# Patient Case: AS



| | |
|---|---|
| Age | 29 yrs |
| Gender | M |
| Race | White |
| Ethnicity | Non-Hispanic |
| Insurance | None |

**Presents to PSL ED with jaundice, loss of appetite, abdominal pain, and fever**

| | |
|---|---|
| Medical Hx | Seasonal allergies, IVDA |
| Social Hx | **EtOH**: 2-3 drinks/day, binge drinking 1 x month<br>**Illicit DU**: IV methamphetamine daily x 1 year, marijuana (smoking) daily x "many years"<br>**Tobacco**: former 1 PPD x 4 years |
| Family Hx | Mother: Breast CA s/p mastectomy<br>Father: HTN, HLD |
| Home Rx | Loratadine 10 mg PO daily<br>Ibuprofen 200-400 mg PO daily PRN |
| All./ADR | [hives] cat dander |

# Patient Case: AS

| | |
|---|---|
| Na (mmol/L) | 130 (L) |
| K (mmol/L) | 3.5 |
| Cl (mmol/L) | 107 |
| CO2 (mmol/L) | 26 |
| BUN (mg/dL) | 40 (H) |
| SCr (mg/dL) | 1.4 (H) |
| Ca (mg/dL) | 8.4 |
| Alb (g/dL) | 3.4 |
| T bili (mg/dL) | 8.5 (H) |
| AST (U/L) | 2152 (H) |
| ALT (U/L) | 3817 (H) |
| Alk phos (U/L) | 176 |

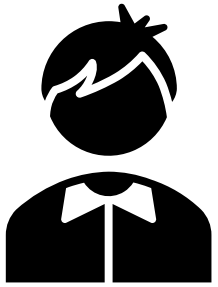
| | |
|---|---|
| WBC ($10^9$/L) | 10.6 |
| Hgb (g/dL) | 12.7 |
| Hct (%) | 40.2 |
| Plt ($10^9$/L) | 371 |

| | |
|---|---|
| INR | 1.1 |

| | |
|---|---|
| Temp (°C) | 37.1 |
| HR (bpm) | 95 |
| RR (bpm) | 16 |
| BP (mmHg) | 142/84 (H) |
| O2 Sat (%) | 94 |
| Resp status | Room air |

| | |
|---|---|
| HBV DNA | Positive |
| HBsAg | Positive |
| Anti-HBs | Negative |
| Anti-HBc IgM | Positive |
| Anti-HBc IgG | Negative |
| HBeAg | Positive |
| Anti-HBe | Negative |

# Patient Case: AS



## Does AS need treatment for HBV? If so, with what?

- Immunocompetent adults:
  - <1% likelihood of acute liver failure
  - <5% likelihood of progression to CHB
  - Lamivudine v placebo (n=71):
    - ↓ HBV DNA at 4 weeks
    - No difference in other lab values at 4 weeks
    - No difference in HBsAg loss at 12 months
- Interferon:
  - Contraindicated due to risk of worsening hepatitis
- Unknown benefits for antivirals:
  - Immunocompromised patient
  - Concurrent HCV, HIV
  - Older age
  - Existing liver disease
- Consider entecavir, tenofovir:
  - INR >1.5
  - T bili >3 mg/dL for >4 weeks
  - Acute liver failure (encephalopathy, coagulopathy)

AS: INR 1.1, T bili 8.5 mg/dL: **monitor**


Sources: Kumar M, et al. *Hepatology* 2007;45(1):97
Terrault N et al. *Hepatology* 2018;67:1560

# Patient Case: VL

| | |
|---|---|
| Age | 34 yrs |
| Gender | F |
| Race | Other |
| Ethnicity | Hispanic |
| Insurance | Commercial |

| | |
|---|---|
| Medical Hx | Pre-DM, MDD/anxiety<br>Pregnancy (GA 18 weeks); G2P0A1 |
| Social Hx | **EtOH**: denies<br>**Illicit DU**: denies<br>**Tobacco**: vaped nicotine ~2 years, stopped 4 years ago |
| Family Hx | Mother: obesity<br>Father: IDDM, HLD |
| Home Rx | Prenatal MVI PO daily<br>Sertraline 100 mg PO daily |
| All./ADR | [throat swelling] kiwi |

**Presents to PSL hepatology clinic following referral from OBGYN for (+) HBV testing**

# Patient Case: VL

| | |
|---|---|
| Na (mmol/L) | 135 |
| K (mmol/L) | 3.5 |
| Cl (mmol/L) | 107 |
| CO2 (mmol/L) | 26 |
| BUN (mg/dL) | 16 |
| SCr (mg/dL) | 0.9 |
| Ca (mg/dL) | 8.4 |
| Alb (g/dL) | 4.8 (H) |
| T bili (mg/dL) | 0.9 |
| AST (U/L) | 21 |
| ALT (U/L) | 25 |
| Alk phos (U/L) | 176 |

| | |
|---|---|
| WBC ($10^9$/L) | 10.6 |
| Hgb (g/dL) | 12.7 |
| Hct (%) | 40.2 |
| Plt ($10^9$/L) | 371 |

| | |
|---|---|
| Temp (°C) | 37.1 |
| HR (bpm) | 95 |
| RR (bpm) | 16 |
| BP (mmHg) | 125/64 |
| O2 Sat (%) | 96 |
| Resp status | Room air |

| | |
|---|---|
| HBV DNA (IU/mL) | 375,000 |
| HBsAg | Positive |
| Anti-HBs | Negative |
| Anti-HBc IgM | Negative |
| Anti-HBc IgG | Positive |
| HBeAg | Positive |
| Anti-HBe | Negative |

# Patient Case: VL

## How should VL be managed for HBV to reduce vertical transmission?

- Perinatal transmission:
  - 8-10% with HBV DNA >200,000 IU/mL
- Initiate TDF or TAF
  - At gestational week 28 + infant HBIG and HBV vaccination
  - At gestational week 16 + infant vaccination if HBIG unavailable
- TAF: New with 2025 updates!
  - Meta-analysis of 31 studies:
    - TDF (n=2588) v TAF (n=280) v no antivirals (n=1600)
    - TDF and TAF equivalent
      - Vertical transmission: RR 1.09 (95% CI 0.15-7.65)
    - Infant safety:
      - TDF studies: 3 fetal deaths
      - TAF studies: no fetal deaths
      - Prematurity risk with TAF v TDF: RR 1.9 (95% CI 0.51-6.99)
      - Congenital abnormalities: no difference between no antivirals and TDF (p=0.89) or TDF and TAF (p=0.34)

Sources: Terrault N et al. *Hepatology* 2018;67:1560
Ghany M, et al. *Hepatology* Published online Nov. 4, 2025.
Funk A, et al. *Lancet Infect Dis* 2021;21:70-84
Pan X, et al. *Sci Rep* 2020;10:13631
Pan C, et al. *Clin Infect Dis* 2024;79:953-964

# Patient Case: VL

## When can VL stop antivirals?

- Can stop at delivery in absence of other indications than vertical transmission prevention

- 6-month monitoring (Q1-3 months):
  - HBV DNA
  - ALT
  - Reinitiate treatment if ALT ≥5 x ULN

- Breastfeeding:
  - No increase in HBV transmission risk
    - Breastfeeding v non-breastfeeding infants HBV infections OR 1.01 (95% CI 0.75-1.36)
  - TDF and TAF safe
    - TDF (HIV data):
      - Infants exposed to 0.01-0.04% of weight-adjusted therapeutic dose
      - Breastfed infants exposed to 0.5-16% of fetal doses via placental transfer
    - TAF:
      - Infants receive 0.005% of maternal dose

Sources: Terrault N et al. *Hepatology* 2018;67:1560
Ghany M, et al. *Hepatology* Published online Nov. 4, 2025.
Shi Z, et al. *Arch Pediatr Adolesc Med* 2011;165:837-846
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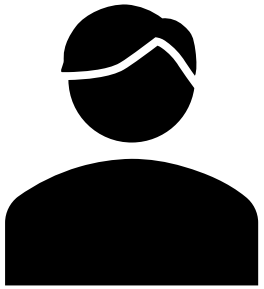
# Patient Case: BR

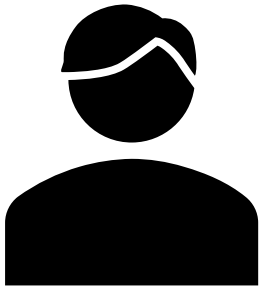


| | |
|---|---|
| Age | 44 yrs |
| Gender | M |
| Race | Asian/P.I. |
| Ethnicity | Non-Hispanic |
| Insurance | Commercial |

**Presents to PSL hepatology clinic to establish care of HBV while initiating therapies for Crohn's disease**

| | |
|---|---|
| Medical Hx | HBV, HTN, Crohn's disease |
| Social Hx | **EtOH**: occasional ~1 drink/month<br>**Illicit DU**: denies<br>**Tobacco**: denies |
| Family Hx | Mother: anxiety, HBV<br>Father: T2DM |
| Home Rx | Lisinopril 10 mg PO daily<br>*Not yet initiated:*<br>**Azathioprine 50 mg PO daily**<br>**Adalimumab SUBQ 160 mg, 80 mg (day 15), 40 mg Q14D (day 29)** |
| All./ADR | [N/V] penicillin |

# Patient Case: BR



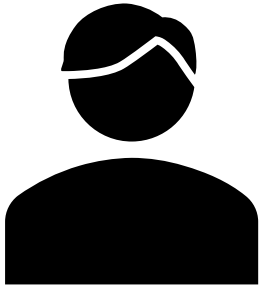
| | |
|---|---|
| Na (mmol/L) | 135 |
| K (mmol/L) | 3.5 |
| Cl (mmol/L) | 107 |
| CO2 (mmol/L) | 26 |
| BUN (mg/dL) | 16 |
| SCr (mg/dL) | 0.9 |
| Ca (mg/dL) | 8.4 |
| Alb (g/dL) | 3.5 (L) |
| T bili (mg/dL) | 0.2 |
| AST (U/L) | 12 |
| ALT (U/L) | 17 |
| Alk phos (U/L) | 86 |

| | |
|---|---|
| WBC ($10^9$/L) | 10.8 |
| Hgb (g/dL) | 8.7 (L) |
| Hct (%) | 30.3 (L) |
| Plt ($10^9$/L) | 371 |

| | |
|---|---|
| Temp (°C) | 37.1 |
| HR (bpm) | 95 |
| RR (bpm) | 16 |
| BP (mmHg) | 125/64 |
| O2 Sat (%) | 96 |
| Resp status | Room air |

| | |
|---|---|
| HBV DNA (IU/mL) | 60 (H) |
| HBsAg | Positive |
| Anti-HBs | Negative |
| Anti-HBc IgM | Negative |
| Anti-HBc IgG | Positive |
| HBeAg | Negative |
| Anti-HBe | Positive |

# Patient Case: BR



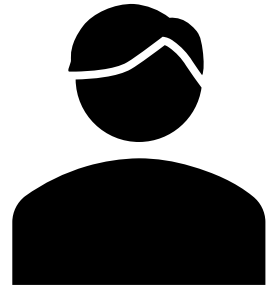
## Question 1: Does BR need antivirals for his HBV?

- Labs:
  - HBsAg: positive
  - HBV DNA: 60 IU/mL
  - Anti-HBc
    - IgM: negative – no current acute infection
    - IgG: positive – prior exposure and chronic infection
  - HBeAg: negative
  - Anti-HBs: negative, HBsAg still positive
- Using the algorithm, these labs are indicative of **monitoring**.

- However,
  - Will initiate therapies for Crohn's Disease
    - Adalimumab SUBQ 160 mg, 80 mg (day 15), 40 mg Q14D (day 29)
    - Azathioprine 50 mg PO daily
- The AASLD guidelines recommend starting antiviral prophylaxis before immunosuppressive therapy.
  - Typically started 7 days prior to immunosuppression

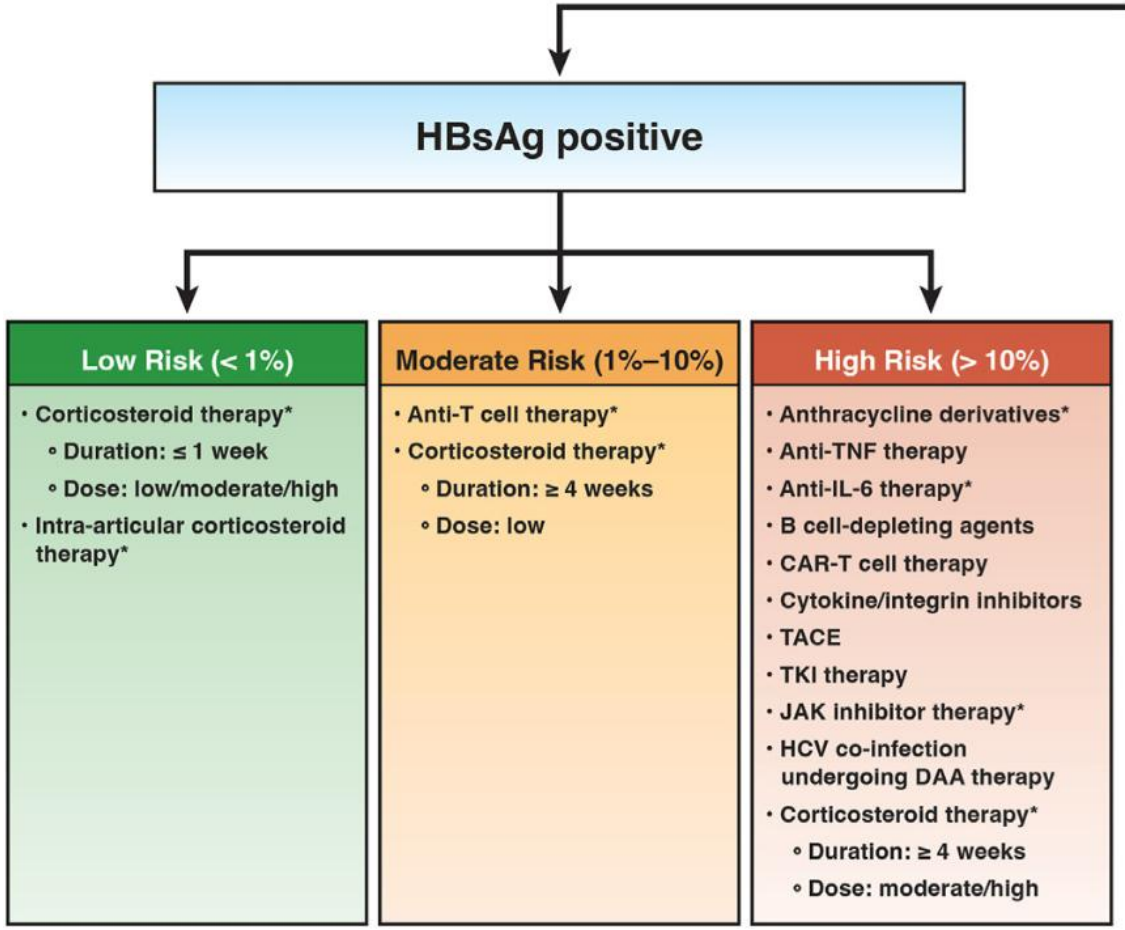

Sources: Terrault NA et al. Hepatology. 2018;67:1560-1599.

# Patient Case: BR



## Question 2: When would he be a candidate for stopping antivirals?

- The commonly recommended duration of prophylactic antiviral therapy is 6-12 months
- Our patient is at a high risk of HBV reactivation:
  - HBsAg positive + anti-TNF therapy (high risk)
- AGA guidelines recommend antiviral prophylaxis for ≥6 months after risk therapy ends.




Sources: Terrault NA et al. Hepatology. 2018;67:1560-1599.
AGA Institute. HBV reactivation during immunosuppressive therapy. Gastroenterology. 2025.





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# Assessment Questions

## Assessment Question 1:
## Which of the following best describes current evidence-based guideline recommendations for HBV screening and patient eligibility for antivirals?

a) Screen only if ALT is elevated; treat all HBsAg-positive patients

b) Screen only pregnant patients and people who inject drugs; treat if HBV DNA is detectable.

c) One-time screening with HBsAg only; treat all anti-HBc–positive patients.

d) Broad (often one-time adult) screening using HBsAg + anti-HBc + anti-HBs; treat immune-active disease, cirrhosis, or high-risk groups

## Assessment Question 1: Correct Response

Which of the following best describes current evidence-based guideline recommendations for hepatitis B virus (HBV) screening and patient eligibility for antivirals?

a) Screen only if ALT is elevated; treat all HBsAg-positive patients

b) Screen only pregnant patients and people who inject drugs; treat if HBV DNA is detectable.

c) One-time screening with HBsAg only; treat all anti-HBc–positive patients.

d) Broad (often one-time adult) screening using HBsAg + anti-HBc + anti-HBs; treat immune-active disease, cirrhosis, or high-risk groups

Assessment Question 2:

For pregnant women with HBV DNA >200,000 IU/mL, which therapy is recommended during the third trimester to reduce perinatal transmission?

a) Lamivudine
b) Interferon
c) Telbivudine
d) Tenofovir alafenamide

## Assessment Question 2: Correct Response

For pregnant women with HBV DNA >200,000 IU/mL, which therapy is recommended during the third trimester to reduce perinatal transmission?

a) Lamivudine

b) Interferon

c) Telbivudine

d) Tenofovir alafenamide

## Assessment Question 3:
## Which statement regarding HBV antivirals is true?

a) Tenofovir disoproxil fumarate does not have safety data for pregnancy
b) Tenofovir reduces the incidence of hepatocellular carcinoma more than entecavir
c) Acute HBV infections are best managed with interferon
d) Lamivudine is first-line treatment for chronic HBV in the AASLD guidelines

## Assessment Question 3: Correct Response
## Which statement regarding HBV antivirals is true?

a) Tenofovir disoproxil fumarate does not have safety data for pregnancy

b) Tenofovir reduces the incidence of hepatocellular carcinoma more than entecavir

c) Acute HBV infections are best managed with interferon

d) Lamivudine is first-line treatment for chronic HBV in the AASLD guidelines

## Assessment Question 4:
## Which of the following indicates a patient has completed the full HBV vaccine series?

a) Received 2 doses of Heplisav-B administered at least 4 weeks apart
b) Received 3 doses of Engerix-B at 0, 1, and 6 months
c) Received 3 doses of Twinrix at 0, 1, and 6 months
d) Received 4 doses of accelerated Twinrix at 0, 7, 21-30 days, plus a 12-month booster
e) All of the above

## Assessment Question 4: Correct Response

Which of the following indicates a patient has completed the full HBV vaccine series?

a) Received 2 doses of Heplisav-B administered at least 4 weeks apart

b) Received 3 doses of Engerix-B at 0, 1, and 6 months

c) Received 3 doses of Twinrix at 0, 1, and 6 months

d) Received 4 doses of accelerated Twinrix at 0, 7, 21-30 days, plus a 12-month booster

e) All of the above

## Assessment Question 5:
## When reviewing refill history for a patient on tenofovir, which pattern is most concerning for nonadherence?

a) Refills consistently every 30–31 days

b) One-time early refill for travel

c) Last refill was 45 days ago and no refill since

d) Switched to 90-day supply and now refills every 3 months

## Assessment Question 5: Correct Response

When reviewing refill history for a patient on tenofovir, which pattern is most concerning for nonadherence?

a) Refills consistently every 30–31 days

b) One-time early refill for travel

c) Last refill was 45 days ago and no refill since

d) Switched to 90-day supply and now refills every 3 months

Assessment Question 6:

A patient comes to the pharmacy asking about HBV vaccines for their child that will be attending college in the fall. Which of the following is **NOT** true regarding HBV vaccines?

a) There are multiple vaccinations available that are effective at preventing HBV infection
b) HBV vaccination was previously recommended for all infants upon birth, so they may already have an HBV series
c) HBV vaccines are only necessary in those that have chronic HBV
d) The fastest HBV vaccine series is Heplisav-B with 2 doses

## Assessment Question 6: Correct Response

A patient comes to the pharmacy asking about HBV vaccines for their child that will be attending college in the fall. Which of the following is **NOT** true regarding HBV vaccines?

a) There are multiple vaccinations available that are effective at preventing HBV infection

b) HBV vaccination was previously recommended for all infants upon birth, so they may already have an HBV series

c) HBV vaccines are only necessary in those that have chronic HBV

d) The fastest HBV vaccine series is Heplisav-B with 2 doses

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# Thank You!

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