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PHARMACY POLICY – 5.01.636

Chronic Hepatitis B Antiviral Therapy

Effective Date:	Mar. 1, 2025	RELATED MEDICAL POLICIES:
Last Revised:	Feb. 24, 2025	5.01.606 Hepatitis C Antiviral Therapy
Replaces:	N/A	

Select a hyperlink below to be directed to that section.

∞ Clicking this icon returns you to the hyperlinks menu above.

Introduction

Hepatitis B is a vaccine-preventable liver infection that is caused by the hepatitis B virus (HBV). Most patients recover from the infection, but a small percentage goes on to develop chronic hepatitis B (CHB). This risk is higher in younger patients. In the early stage, the infection may show no symptoms or nonspecific symptoms such as fatigue. Later, the infection can have overlapping symptoms with liver disease as well as extrahepatic manifestations. The drugs used to treat hepatitis B include pegylated interferons and nucleoside/nucleotide analogs. The decision to initiate treatment is primarily based on the presence of cirrhosis, serum alanine aminotransferase (ALT) level, and the HBV DNA level. Other factors include malignancy and pregnancy. This policy describes the criteria when hepatitis B drugs may be considered medically necessary.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

Policy Coverage Criteria

Drug	Medical Necessity
Baraclude (entecavir) oral	**Baraclude (entecavir) may be considered medically necessary when all the following criteria are met:** • The individual is aged 2 years or older **AND** • Has a confirmed diagnosis of chronic hepatitis B virus (HBV) infection **AND** • Individuals aged 18 years or older with compensated or decompensated liver disease **OR** • Individuals aged 2 to 17 years with compensated liver disease **AND** • Has had inadequate response or intolerance to generic entecavir **AND** • Does not have a co-infection with human immunodeficiency virus (HIV) **OR** • Has a co-infection with HIV and is receiving highly active antiretroviral therapy
Epivir-HBV (lamivudine) oral	**Epivir-HBV (lamivudine) oral solution may be considered medically necessary when all the following criteria are met:** • The individual is aged 2 years or older **AND** • Has a confirmed diagnosis of chronic hepatitis B virus (HBV) infection **AND** • Has compensated liver disease **AND** • Documentation is provided that the oral solution is medically necessary (e.g., dosage is less than 100 mg daily, unable to swallow) **AND** • Does not have a co-infection with human immunodeficiency virus (HIV) **OR**

Drug	Medical Necessity
	• Has a co-infection with HIV and is receiving highly active antiretroviral therapy (HAART) **Epivir-HBV (lamivudine) oral tablet may be considered medically necessary when all the following criteria are met:** • The individual is aged 2 years or older **AND** • Has a confirmed diagnosis of chronic hepatitis B virus (HBV) infection **AND** • Has compensated liver disease **AND** • Has had inadequate response or intolerance to generic lamivudine **AND** • Does not have a co-infection with human immunodeficiency virus (HIV) **OR** • Has a co-infection with HIV and is receiving highly active antiretroviral therapy (HAART)
Pegasys (peginterferon alfa-2a) SC	**Pegasys (peginterferon alfa-2a) may be considered medically necessary for the treatment of chronic hepatitis B virus (HBV) infection in:** • Individuals aged 18 years or older with hepatitis B e-antigen (HBeAg) positive and HBeAg-negative chronic HBV infection who have compensated liver disease and evidence of viral replication and liver inflammation **OR** • Non-cirrhotic pediatric individuals aged 3 years or older with HBeAg-positive CHB and evidence of viral replication and elevations in serum alanine aminotransferase (ALT)
Vemlidy (tenofovir alafenamide) oral	**Vemlidy (tenofovir alafenamide) may be considered medically necessary when all the following criteria are met:** • The individual is aged 6 years or older **AND** • Has a confirmed diagnosis of chronic hepatitis B virus (HBV) infection

Drug	Medical Necessity
	AND • Has compensated liver disease **AND** • Does not have a co-infection with human immunodeficiency virus (HIV) **OR** • Has a co-infection with HIV and is receiving highly active antiretroviral therapy (HAART) **AND** • For adults and pediatric individuals who weigh at least 35 kg, the individual has tried and had an inadequate response or intolerance to generic tenofovir disoproxil fumarate
Viread (tenofovir disoproxil fumarate) oral	**Viread (tenofovir disoproxil fumarate) may be considered medically necessary when all the following criteria are met:** • The individual is aged 2 years or older **AND** • Has a confirmed diagnosis of chronic hepatitis B virus (HBV) infection **OR** • Has a confirmed diagnosis of HIV-1 infection **AND** • For adults and pediatric individuals who weigh at least 35 kg, the individual has tried and had an inadequate response or intolerance to generic tenofovir disoproxil fumarate **OR** • Documentation is provided that the individual is not able to swallow tablets

Drug	Investigational
As listed	**The medications listed in this policy are subject to the product's US Food and Drug Administration (FDA) dosage and administration prescribing information.** **All other uses of the above-named agents when used for conditions not outlined in this policy or policy 5.01.606 Hepatitis C Antiviral Therapy are considered investigational.**

Length of Approval	
Approval	**Criteria**
Initial authorization	**Non-formulary exception reviews and all other reviews for drugs listed in this policy may be approved up to 12 months.**
Re-authorization criteria	**Non-formulary exception reviews and all other reviews for drugs listed in this policy may be approved up to 12 months as long as the medical necessity criteria are met and chart notes demonstrate that the individual continues to show a positive clinical response to therapy (e.g., a reduction in hepatitis B virus DNA levels).**

Documentation Requirements
The individual's medical records submitted for review for all conditions should document that medical necessity criteria are met. The record should include the following: • Office visit notes that contain the diagnosis, relevant history, physical evaluation, hepatitis B virus (HBV) DNA (viral load), and medication history

Coding

N/A

Related Information

Definition of Terms

Hepatitis B surface antigen (HBsAg): is found on the virus surface. All persons with HBsAg are infectious.

Hepatitis B e-antigen (HBeAg): is found in the inner core of the virus. All persons with positive HBeAg are most infectious.

Anti-Hepatitis B e-antigen (anti-HBe): antibodies to HBeAg, an indicator of resolution of acute infection.

HBV DNA: is a partially double-stranded DNA molecule found in the inner core of the virus. All persons with elevated HBV DNA are most infectious.

Chronic hepatitis B (CHB): HBsAg positive for at least 6 months; HBV DNA varies from undetectable to several billion IU/mL; persons can have HBeAg positive (typically associated with higher HBV DNA levels >20,000 IU/mL) and HBeAg negative (typically associated with lower HBV levels); ALT and/or ASL levels may be normal or elevated; liver biopsy results show chronic hepatitis with variable necroinflammation and/or fibrosis.

Immune-tolerant chronic hepatitis B: HBsAg present for at least 6 months; HBeAg positive; HBV DNA levels are very high (typically >1 million IU/mL); normal or minimally elevated ALT and/or AST; liver biopsy or noninvasive test results showing no fibrosis and minimal inflammation.

Immune-Active CHB: HBsAg present for at least 6 months; HBV DNA levels >20,000 IU/mL in HBeAg-positive CHB and >2,000 IU/mL in HBeAg-negative CHB; intermittently or persistently elevated ALT and/or AST levels; liver biopsy or noninvasive test results show CHB with moderate or severe necroinflammation and with or without fibrosis.

Inactive CHB: HBsAg present for at least 6 months; HBeAg negative and anti-HBe positive; HBV DNA levels <2,000 IU/mL; persistently normal ALT and/or AST levels; liver biopsy confirms absence of significant necroinflammation, and biopsy or noninvasive testing show variable levels of fibrosis.

HBeAg seroconversion: loss of HBeAg and detection of anti-HBe in a person who was previously HBeAg positive and anti-HBe negative.

Viral genotyping

There are 10 genotypes of HBV currently known, labeled A through J, with genotypes A, B, and C being most prevalent in the US Infection or immunization with 1 genotype usually provides immunity to all genotypes.

Benefit Application

Baraclude (entecavir), Epivir-HBV (lamivudine), Pegasys (peginterferon alfa-2a), Vemlidy (tenofovir alafenamide), and Viread (tenofovir disoproxil fumarate) are managed through the pharmacy benefit.

Evidence Review

Background

In 2015, the United States had approximately 2 million people with chronic hepatitis B with 847,000 people living with chronic HBV and 1.25 million people who were chronic HBV carriers. The prevalence rate was about 0.3%. Although the greatest incidence was in adults 30 to 39 years of age, infants and young children who were exposed to HBV had a greater chance of developing chronic hepatitis B. Non-Hispanic blacks had more than 2-fold higher rate of infection compared to other racial and ethnic populations in the US.

According to the AASLD 2018 Hepatitis B Guidance, preferred approved antiviral therapies for CHB treatment in adults and children include peg-interferon alpha-2a, entecavir, tenofovir disoproxil fumarate, and tenofovir alafenamide. Nonpreferred therapies include lamivudine, adefovir, and telbivudine.

Summary of Evidence

Coinfection with Hepatitis C Virus (HCV)

Direct-acting antiviral (DAA) HCV therapy has been reported to increase HBV DNA levels in HBsAg-positive individuals and elevate ALT levels concurrently with HBV reactivation. In HCV/HBV coinfected persons, HBV antiviral therapy should be started concurrently with DAA therapy. Entecavir, tenofovir disoproxil fumarate, or tenofovir alafenamide are preferred agents.

Coinfection with Human Immunodeficiency Virus (HIV)

The prevalence of HBV infection among HIV patients is 5-10% with the highest rate occurring in mem who have sex with men and IV drug users. Lamivudine, emtricitabine, and tenofovir are nucleoside analogues with activity against both HIV and HBV. However, due to resistance against lamivudine monotherapy, HIV/HBV-coinfected persons should receive two-drug antiretroviral therapy regimen.

Coinfection with Hepatitis Delta Virus (HDV)

Persons with HIV infection, persons who inject drugs, men who have sex with men, and immigrants from areas of high HDV endemicity with positive HBsAg should be tested for HDV.

Baraclude (entecavir)

Baraclude is a deoxyguanosine nucleoside analogue that inhibits HBV DNA synthesis via its activity against HBV reverse transcriptase.

The efficacy of Baraclude was evaluated in three phase 3 active-controlled trials. Study AI463022 compared Baraclude 0.5 mg once daily to lamivudine 100 mg once daily for 52 weeks in 709 nucleoside-inhibitor-naïve subjects with HBeAg-positive chronic HBV infection and compensated liver disease. Study AI463027 compared Baraclude 0.5mg to lamivudine 100mg once daily for 52 weeks in 638 nucleoside-inhibitor-naïve subjects with HBeAg-negative chronic HBV infection and compensated liver disease. The proportion of subjects who achieved undetectable HBV DNA (<300 copies/mL) was 67% and 90% in Baraclude-treated group in Study AI463022 and Study AIU463027, respectively, compared to 36% and 72% in lamivudine-treated groups. Study AI463026 evaluated the efficacy of Baraclude in lamivudine-refractory chronic HBV infection and compensated liver disease. Subjects either switched to Baraclude 1 mg once daily (no washout period, n=124) or continued on lamivudine 100 mg (n=116) for 52 weeks. At week 48, 19% of Baraclude-treated group achieved undetectable HBV DNA (<300 copies/mL) versus 1% of lamivudine-treated group.

Study AI463048 compared Baraclude 1 mg once daily (n=100) to adefovir dipivoxil 10 mg once daily (n=91) in adults with HBeAg-positive or HBeAg-negative chronic HBV infection and decompensated liver disease, defined as Child-Turcotte-Pugh score of 7 or higher. At week 48, 57% of Baraclude-treated individuals achieved undetectable HBV DNA while 20% of adefovir-treated individuals.

The efficacy and safety of Baraclude in the pediatric population was evaluated in Study AI463189 which included nucleoside-inhibitor-treatment-naïve subjects 2 to less than 18 years of age with HBeAg-positive chronic HBV infection, compensated liver disease, and elevated ALT. At week 48, 58% of treatment-naïve subjects and 47% of lamivudine-experienced subjects achieved HBV DNA <50 IU/mL. Individuals either received Baraclude 0.015 mg/kg up to 0.5 mg/day (n=120) or placebo (n=60). At week 48, 46% of Baraclude-treated group achieved HBV DNA <50 IU/mL compared to 2% in placebo-treated group.

Epivir-HBV (lamivudine)

Epivir-HBV is a nucleoside analogue reverse transcriptase inhibitor. Lamivudine is converted to an active metabolite that inhibits RNA- and DNA-dependent polymerase activities of HBV reverse transcriptase via DNA chain termination.

The safety of Epivir-HBV was evaluated in 3 clinical trials including subjects with CHB and compensated liver disease. Trial 1 compared Epivir-HBV 100 mg once daily (n=62) to placebo (n=63) in treatment-naïve US subjects for 52 weeks followed by 16 weeks of no-treatment period. Trial 2 compared Epivir-HBV 25 mg once daily and Epivir-HBV 100 mg once daily (total n=131) to placebo (n=68) in Asian subjects for 52 weeks. Trial 3 compared Epivir-HBV 100 mg once daily in North American and European subjects for 52 weeks, followed by either Epivir-HBV 100 mg once daily (n=110) or placebo (n=54) for 16 weeks. At week 52, histologic response (defined as greater than or equal to 2-point decrease in the Knodell Histologic Activity Index compared to baseline) showed improvement in 55%, 56%, and 56% of Epivir-HBV-treated group in Trials 1, 2, and 3, respectively, compared to 25%, 26%, and 26% of placebo-treated group. The majority of Epivir-HBV treated individuals showed a decrease in HBV DNA levels to below the assay limit early in the course of therapy, but only one-third had undetectable HBV DNA levels after the initial response.

The safety and efficacy of Epivir-HBV in pediatric subjects were evaluated in a double-blind clinical trial including 286 subjects of 2 to 17 years of age with CHB and compensated liver disease. Individuals either received Epivir-HBV 3 mg/kg once daily up to 100 mg once daily or placebo. At week 52, 23% of Epivir-HBV-treated group and 13% of placebo-treated group achieved loss of HBeAg and undetectable HBV DNA. Adolescents aged 13 to 17 years showed less evidence of treatment effect than younger pediatric patients.

Pegasys (peginterferon alfa-2a)

Pegasys is a recombinant human interferon alfa-2a that binds to the human type 1 interferon receptor leading to receptor dimerization, activating transduction pathways mediated by JAK/STAT pathway. Pegasys has activity against both hepatitis B and C viruses.

The efficacy of Pegasys was evaluated in Study 8 (HBeAg-positive) and Study 9 (HBeAg-negative) individuals with CHB and compensated liver disease. In Study 8, subjects were randomized to receive Pegasys 180mcg SC once weekly (n=271) or lamivudine 100mg once daily (n=272). At week 48, 32% of Pegasys-treated group achieved HBV DNA <100,000 copies/mL compared to 62% of lamivudine-treated group. In Study 9, subjects were randomized to receive Pegasys 180mcg SQ once weekly (n=177) or lamivudine once daily (n=181). At week 48, 43% of Pegasys-treated group achieved HBV DNA <20,000 copies/mL compared to 85% of lamivudine-treated group.

Study 10 evaluated the efficacy of Pegasys in pediatric subjects aged 3 to less than 18 years with HBeAg-positive CHB in the immune-active phase and no cirrhosis. Individuals were randomized to receive Pegasys (n=101) or no treatment (n=50). At week 48, Pegasys-treated group had 34% achieve HBV DNA <20,000 IU/mL and 29% achieve HBV DNA <20,000 IU/mL, compared to 4% and 2% of the untreated group, respectively.

In Studies 8 and 9, the most common serious adverse reactions were infections, hepatitis B flares, and thrombotic thrombocytopenic purpura happening in <1% of subjects. Other non-serious common adverse events included pyrexia, headache, fatigue, myalgia, alopecia, and anorexia.

Vemlidy (tenofovir alafenamide)

Vemlidy is a hepatitis B virus (HBV) nucleoside analog reverse transcriptase inhibitor. Tenofovir alafenamide is a phosphonamidite prodrug of tenofovir, which is then converted to an active metabolite that incorporates into viral DNA reverse transcriptase, inhibiting HBV replication.

The efficacy of Vemlidy in the treatment of adults with CHB and compensated liver disease is based on 48-week data from 2 randomized, double-blind, active-controlled trials including both treatment-naïve and treatment-experienced adults. In trial 108, HBeAg-negative individuals either received Vemlidy 25 mg (n=285) once daily or tenofovir disoproxil fumarate (TDF) 300mg (n=140) once daily. In trial 110, HBeAg-positive individuals either received Vemlidy 25mg once daily (n=581) or TDF 300mg (n=292) once daily. The efficacy endpoint in both trials was the proportion of subjects with plasma HBV DNA levels below 29 IU/mL at week 48. In trial 108, 92%

of Vemlidy-treated adults and 93% of TDF-treated adults achieved HBV DNA <29 IU/mL. The corresponding proportions in trial 110 were 63% and 67% in the Vemlidy-treated group and TDF-treated group, respectively.

The efficacy of switching from TDF to Vemlidy in virologically suppressed adults with CHB infection was evaluated in a 48-week, randomized, double-blind, active-controlled trial requiring subjects to have been taking TDF 300 mg once daily for at least 12 months with HBV DNA <20 IU/mL at screening. Individuals were then randomized to receive Vemlidy 25 mg once daily (n=243) or TDF 300mg once daily (n=245). The primary endpoint was the proportion of adults with plasma HBV DNA levels of ≥20 IU/mL at week 48. Both groups had <1% who achieved the primary endpoint.

Trial 4035 evaluated the efficacy and safety of switching from TDF and/or other antivirals to Vemlidy in an open-label study of adults with virological suppression and moderate to severe renal impairment (Cohort 1, n=78) or end-stage renal disease (ESRD) on hemodialysis (Cohort 2, n=15). At week 24, 98% of subjects achieved HBV DNA <20 IU/mL. There were no significant differences in mean change from baseline in ALT values and mean change in HBsAg level from baseline between these groups.

Trial 1092 was a randomized, double-blind, placebo-controlled study that evaluated the efficacy and safety of Vemlidy in subjects 12 to 18 years of age weighing at least 35 kg with CHB infection. Individuals either received Vemlidy (n=47) or placebo (n=23) once daily. At week 24, 21% of Vemlidy-treated group achieved HBV DNA <20 IU/mL versus 0% in placebo-treated group. ALT normalization (according to AASLD criteria) was achieved in 44% of Vemlidy-treated group and 0% in placebo-treated group.

The safety of Vemlidy was assessed based on pooled data of 1298 patients from Trial 108 and Trial 110 who continued treatment through week 120. Week 97 analysis showed that the most common adverse reactions reported in at least 10% of subjects was headache, similarly in both Vemlidy- and TDF-treated groups. Other adverse reactions reported in at least 5% of subjects included abdominal pain, cough, back pain, fatigue, nausea, arthralgia, diarrhea, and dyspepsia.

Practice Guidelines

Update on prevention, diagnosis, and treatment of chronic hepatitis B: AASLD 2018 hepatitis guidance

The American Association for the Study of Liver Diseases (AASLD) approved this practice guidelines on December 4, 2017, to complement the AASLD 2016 Practice Guidelines for Treatment of Chronic Hepatitis B. The 2018 update in available on the Internet at **https://www.aasld.org/practice-guidelines/chronic-hepatitis-b** and included (1) the use of tenofovir alafenamide; (2) guidance on screening, counseling, and prevention; (3) specialized virological and serological tests; (4) monitoring of untreated patients; and (5) treatment of hepatitis B in special populations, including persons with viral coinfections, acute hepatitis B, recipients of immunosuppressive therapy, and transplant recipients.

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History

Date	Comments
11/01/23	New policy, approved October 10, 2023, effective for dates of service on or after November 1, 2023. Add to Prescription Drug section. Added coverage criteria for Baraclude, Epivir-HBV, Hepsera, and Vemlidy for the treatment of chronic hepatitis B. Moved Pegasys (peginterferon alfa-2a) policy criteria for the treatment of chronic hepatitis B from 5.01.606 Hepatitis C Antiviral Therapy to 5.01.636 Chronic Hepatitis B Antiviral Therapy.
06/01/24	Annual Review, approved May 14, 2024. Removed Hepsera (adefovir dipivoxil) as it was withdrawn from the market. Updated Vemlidy (tenofovir alafenamide) age requirement from 12 years and older to 6 years and older and added generic tenofovir disoproxil fumarate trial first requirement.
07/01/24	Interim Review, approved June 11, 2024. Added coverage criteria for Viread (tenofovir disoproxil fumarate).
03/01/25	Annual Review, approved February 24, 2025. Clarified that non-formulary exception review authorizations for all drugs listed in this policy may be approved up to 12 months. Clarified that the medications listed in this policy are subject to the product's FDA dosage and administration prescribing information.

Scope: Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.