Oscar Clinical Guideline: Vemlidy (tenofovir alafenamide) (PG010, Ver. 5)

Vemlidy (tenofovir alafenamide)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Hepatitis B is a viral infection that targets the liver, leading to either acute or chronic disease. Acute infections are often self-limiting and do not always require treatment; however, a small fraction can progress to chronic hepatitis B. Chronic infections pose significant health risks as they can result in serious liver complications, such as cirrhosis and hepatocellular carcinoma.

Vemlidy (tenofovir alafenamide), granted FDA approval in 2016, is a nucleotide analog reverse transcriptase inhibitor employed to manage chronic hepatitis B infection in adults with compensated liver disease. It shares a similar mechanism of action with tenofovir disoproxil fumarate (Viread), another variant of tenofovir used in managing chronic hepatitis B. Yet, Vemlidy is linked to fewer adverse effects on kidneys and bones, making it a preferable treatment option in certain patient populations.

In addition to its role in managing chronic hepatitis B, Vemlidy also has an important place in prophylaxis against hepatitis B virus reactivation in immunocompromised patients, and hepatitis B virus reinfection post liver transplant, further broadening its clinical utility.

Definitions

"**Albumin**" is a type of protein made by the liver that often decreases with liver disease.

"**Anti-CD20 Therapy**" is a type of drug that targets CD20, a protein found on the surface of B cells. It is used in certain types of cancers and autoimmune diseases.

"**Antibody to Hepatitis B core Antigen (Anti-HBc)**" is an antibody that is part of the body's immune response to a hepatitis B infection.

"**ARV Treatment Regimen**" refers to the use of Antiretroviral (ARV) medications, which are a class of drugs utilized in the management and treatment of Human Immunodeficiency Virus (HIV). A fully suppressive regimen is one that effectively minimizes the viral load in a patient's body to levels that are undetectable, thereby helping to prevent progression of the disease and transmission of the virus.

"**Ascites**" refers to an abnormal buildup of fluid in the abdomen, often due to severe liver disease.

"**Chronic Hepatitis B**" is a long-lasting infection of the liver caused by the hepatitis B virus, defined by the persistence of the virus for six months or more. It is typically diagnosed through detection of hepatitis B surface antigen (HBsAg) in the blood.

"**Decompensated Liver Disease**" is a severe stage of chronic liver disease characterized by the presence of complications such as variceal bleeding, ascites, hepatic encephalopathy, or abnormal liver function tests. It indicates a failure of the liver to perform its normal metabolic and synthetic functions.

"**Hepatitis B surface Antigen (HBsAg)**" is a surface antigen of the hepatitis B virus; its presence indicates active infection.

"**Hepatic Encephalopathy**" is a decline in brain function that occurs as a result of severe liver disease. It can lead to symptoms like confusion and poor coordination.

"**Hepatitis B Flare**" is a sudden increase in liver inflammation, typically measured by a rise in alanine aminotransferase (ALT) levels, in a person with chronic hepatitis B.

"**Hepatitis B Virus Reactivation**" is a sudden increase in hepatitis B virus in the bloodstream, which can occur spontaneously or as a result of medical or immunological triggers.

"**Direct-acting antivirals (DAAs)**" are a group of medications used to treat hepatitis C. They directly target the hepatitis C virus to stop it from making copies of itself.

"**Immunosuppressive or Cytotoxic Therapy**" are treatments that reduce the activity of the body's immune system, often used in conditions like cancer and autoimmune diseases.

"**International Normalized Ratio (INR)**" is a standardized measurement of the time it takes for blood to clot. It's used to monitor and adjust dosing of anticoagulant therapy.

"**Lamivudine-resistance**" arises when the hepatitis B virus mutates after exposure to the antiviral drug lamivudine over a prolonged period. These mutations enable the virus to resist the effects of the drug, leading to an increase in viral replication and potentially resulting in the failure of lamivudine treatment.

"**Prophylaxis**" is the prevention of disease. In this context, Vemlidy is being used to prevent the reactivation or reinfection of the hepatitis B virus.

"**Variceal Bleeding**" refers to bleeding from enlarged veins (varices) usually found in the esophagus or stomach. It is a serious complication of liver cirrhosis.

Medical Necessity Criteria for Initial Authorization

The Plan considers **Vemlidy (tenofovir alafenamide)** medically necessary when **ALL** the following criteria are met for the applicable indication listed below:

Treatment of chronic hepatitis B virus infection

1. The member is 12 years of age or older; ***AND***
2. The member has a diagnosis of chronic hepatitis B confirmed by appropriate laboratory test; ***AND***
3. The member has tested negative for HIV-1 virus; ***AND***
4. The member meets **ONE** of the following conditions regarding previous therapies:
    a. The member has been previously treated with lamivudine, or with a strain known to have lamivudine resistance variants; ***or***
    b. The member is unable to use, or has tried and failed entecavir; ***AND***
5. The member does **NOT** have decompensated liver disease, demonstrated by meeting **ALL** of the following:

a. No variceal bleeding; ***and***
b. No ascites; ***and***
c. No hepatic encephalopathy; ***and***
d. International normalized ratio (INR) less than 1.5x upper limit of normal (ULN); ***and***
e. Total bilirubin less than 2.5x upper limit of normal (ULN); ***and***
f. Albumin level greater than or equal to 3 g/dL; ***AND***

6. Chart documentation and supporting laboratory work are provided for review to substantiate the above listed requirements.

<u>Hepatitis B Virus Reactivation Prophylaxis</u>

1. The member is 18 years of age or older***; AND***
2. Prescribed by or in consultation with an oncologist, gastroenterologist, hepatologist, infectious disease specialist, or transplant specialist***; AND***
3. Vemlidy is being used for prophylaxis against hepatitis B reactivation***; AND***
4. Information reviewed does not indicate **ANY** of the following:
    a. The member is currently experiencing a Hepatitis B flare; ***or***
    b. The member has known contraindications to the use of Vemlidy***; AND***
5. The member fulfills **ONE** of the following conditions:
    a. Is anti-HBc-positive, HBsAg-positive **AND** undergoing immunosuppressive or cytotoxic therapy***; or***
    b. Is anti-HBc-positive, HBsAg-negative **AND** undergoing stem cell transplantation or receiving anti-CD20 therapy such as rituximab***; AND***
6. If coinfected with HIV or chronic HCV, the member meets **ONE** of the following:
    a. The member has hepatitis B and HIV coinfection **AND** is receiving a fully suppressive ARV treatment regimen for HIV***; or***
    b. The member is coinfected with hepatitis B and chronic HCV and is currently receiving a hepatitis C DAA therapy***; AND***
7. Chart documentation and supporting laboratory work are provided for review to substantiate the above listed requirements.

<u>Hepatitis B Virus Reinfection Prophylaxis Post Liver Transplant</u>

1. The member is 18 years of age or older***; AND***
2. Prescribed by or in consultation with a gastroenterologist, hepatologist, infectious disease specialist, or transplant specialist***; AND***

3. Vemlidy is being used for prophylaxis against HBV reinfection***; AND***
4. The member has a documented history of chronic Hepatitis B infection and has undergone a liver transplant***; AND***
5. If coinfected with HIV or chronic HCV, the member meets **ONE** of the following:
    a. The member has hepatitis B and HIV coinfection **AND** is receiving a fully suppressive ARV treatment regimen for HIV***; or***
    b. The member is coinfected with hepatitis B and chronic HCV and is currently receiving a hepatitis C DAA therapy***; AND***
6. The member does not have contraindications to Vemlidy***; AND***
7. Chart documentation and supporting laboratory work are provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, Vemlidy (tenofovir alafenamide) will be approved for 6 months.

Medical Necessity Criteria for Reauthorization

Reauthorization of 12 months will be granted if the following criteria are met:

For Treatment of Chronic Hepatitis B Virus Infection:

1. The member continues to meet all initial authorization criteria*; AND*
2. The member has documented clinical improvement, or maintenance, in disease activity, as evidenced by **ANY** of the following parameters:
    a. Reduction in HBV DNA levels***; or***
    b. Loss or reduction of HBeAg or HBsAg***; or***
    c. Normalization of ALT levels*; AND*
3. Chart documentation and supporting laboratory work are provided for review to substantiate the above listed requirements.

For Hepatitis B Virus Reactivation Prophylaxis:

1. The member continues to meet all initial authorization criteria*; AND*
2. The member has no evidence of Hepatitis B reactivation*; AND*
3. If coinfected with HIV or chronic HCV, the member continues to receive an effective treatment regimen for these conditions*; AND*
4. Chart documentation and supporting laboratory work are provided for review to substantiate the above listed requirements.

For Hepatitis B Virus Reinfection Prophylaxis Post Liver Transplant:

1. The member continues to meet all initial authorization criteria*; AND*
2. The member shows no signs of Hepatitis B virus reinfection*; AND*
3. If coinfected with HIV or chronic HCV, the member continues to receive an effective treatment regimen for these conditions*; AND*
4. Chart documentation and supporting laboratory work are provided for review to substantiate the above listed requirements.

Experimental or Investigational / Not Medically Necessary

Vemlidy (tenofovir alafenamide) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

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Clinical Guideline Revision / History Information

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