Adefovir Dipivoxil (Hepsera)

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 (HBV) 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, defined as the persistence of hepatitis B surface antigens present after 6 months, pose significant health risks as they can result in serious liver complications, such as cirrhosis and hepatocellular carcinoma (HCC). The goal of HBV treatment is to reduce the risk of HCC, however initiation of therapy is based on several factors including presence or absence of cirrhosis, alanine aminotransferase levels (a liver enzyme test, with higher levels indicating liver damage or disease) and HBV DNA levels. Management of chronic HBV includes treatment with either pegylated interferon or nucleoside/nucleotide analogs (i.e., entecavir [Baraclude] or Vemlidy [tenofovir alafenamide]). The American Association for the Study of Liver Diseases (AASLD) has published recommendations for management of HBV at https://www.aasld.org.

Adefovir Dipivoxil (Hepsera) Oral tablet is an antiviral medicine approved for the treatment of chronic hepatitis B virus (HBV) infections in those 12 years and older. It is usually taken once daily, however, dosing interval adjustments may be required in certain individuals with renal impairments, such as those on hemodialysis. While adefovir (Hepsera) is approved to treat hepatitis B infection, according to major

guidelines it is not preferred for chronic hepatitis B treatment due to its high rate of resistance with long-term use. Other drugs with a higher barrier to drug resistance are usually recommended, such as tenofovir (Vemlidy) or entecavir (Baraclude).

Definitions

"ALT and AST" refers to liver enzymes aspartate transaminase (AST) and alanine aminotransferase (ALT) that are indicators of liver damage or injury from different types of diseases or conditions.

"Creatinine clearance" (CrCl) is the volume of blood plasma cleared of creatinine, a waste product from the body, per unit of time. It is an indicator or measurement of kidney function.

"DNA" refers to Deoxyribonucleic Acid, a small molecule inside of cells that contain genetic information.

"Nucleoside analog" is a class of drugs used to treat viral infections that work by inhibiting the ability of the virus to replicate.

Medical Necessity Criteria for Initial Authorization

The Plan considers Adefovir (Hepsera) medically necessary when ALL of the following criteria are met:

1. The requested medication is being prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist; *AND*
2. The member is 12 years of age or older; *AND*
3. The member has a documented diagnosis of chronic hepatitis B virus (HBV) infection confirmed by appropriate laboratory test(s); *AND*
4. The member is unable to use or has tried and failed entecavir (Baraclude) or tenofovir (Vemlidy); *AND*
5. Chart documentation and supporting laboratory test results are provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, Adefovir Dipivoxil (Hepsera) will be approved for up to 6 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for up to 12 months will be granted if recent (within the last 3 months) chart and laboratory test results documentation shows the member has experienced therapeutic response to the requested medication as evidenced by ONE (1) of the following:

1. A decrease or suppression of serum HBV DNA levels (viral load, reported in international units/mL or in copies/mL) compared to baseline (pre-treatment); *OR*

2. A decrease or normalization of serum aminotransferase (ALT or AST) concentrations compared to baseline (pre-treatment); *OR*
3. Undetectable levels of serum HBV DNA or only minimal histologic evidence of liver injury.

Experimental or Investigational / Not Medically Necessary

Adefovir Dipivoxil (Hepsera) 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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