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Clinical Guideline

Oscar Clinical Guideline: Adefovir Dipivoxil (Hepsera) (PG081, Ver. 5)

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

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

Hepatitis B (HBV) is a viral liver infection that can cause acute and/or chronic infections. Acute infections often do not require treatment and infrequently turn into a chronic disease. Chronic infections (6 months or more) can have long-term consequences on the liver including cirrhosis and liver cancer. Treatment of chronic HB is complicated, and usually should be managed by a specialist such as a gastroenterologist, hepatologist or an infectious disease specialist. The American Association for the Study of Liver Diseases (AASLD) has published recommendations for management of HBV at https://www.aasld.org.

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 with evidence (viral laboratory test results required) of active HBV replication and **ONE** (1) of the following:
    a. persistent elevations in serum aminotransferase (ALT or AST) concentrations; ***or***
    b. histologic evidence of active liver disease; ***AND***
4. The member is unable to use or has tried and failed entecavir or tenofovir; ***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 6 months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 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).

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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2. Hepsera (adefovir) [prescribing information]. Foster City, CA: Gilead Sciences Inc; December 2018.
3. Sigmapharm Laboratories. Adefovir dipivoxil tablet [prescribing information]. Bensalem, PA; 2016 Aug.
4. Terrault NA, Bzowej NH, Chang KM et al. AASLD guidelines for treatment of chronic hepatitis B. Hepatology. 2016; 63:261-83.
5. Terrault NA, Lok ASF, McMahon BJ, et al. Update on prevention, diagnosis, and treatment of chronic hepatitis B: AASLD 2018 hepatitis B guidance. Hepatology. 2018;67(4):1560-1599. doi:10.1002/hep.29800
6. World Health Organization. Guidelines for the prevention, care and treatment of persons with chronic hepatitis B infection. March 2015. Geneva: World Health Organization; 2015.

Clinical Guideline Revision / History Information

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