

Title: *adefovir (Hepsera®)*

Origination: 09/18/96	Revised: 05/27/09	Annual Review: 12/15/11
------------------------------	--------------------------	--------------------------------

Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Medication Summary

- Adefovir is a nucleotide analogue used for the treatment of Hepatitis B virus (HBV). It slows the progression of chronic hepatitis B and improves liver inflammation and fibrosis by inhibiting HBV DNA polymerase (reverse transcriptase), by competing with the natural substrate deoxyadenosine triphosphate, and by causing DNA chain termination after it is incorporated into viral DNA.

Reference Statement

- Guidelines will be compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Eligibility Criteria

- Member must be eligible and have applicable benefits.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusions

- Member is less than 12 years of age.
- Member has severe renal dysfunction (CrCl <10 ml/min without hemodialysis).

Title: adefovir (Hepsera®)

Procedure:

- 1.0 Request for *initial therapy* for the treatment of Hepatitis B virus (HBV) requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying **ALL** of the following:
 - 1.1 Member has a positive (+) Hepatitis B surface antigen (**HbsAg positive**);
 - 1.2 Member has a detectable serum HBV DNA viral load of at least 2,000 IU/ml (confirmed via quantitative measurement);
 - 1.3 Member has a persistent or intermittent elevation in ALT liver enzyme (reference range will vary per laboratory utilized – normal: ALT: 7-56 U/L);
 - 1.4 If the Member meets all of the above criteria, may approve up to 10mg per day (#30 tablets per month) for 12 months.

- 2.0 Request for *continuation therapy* beyond the initial authorization period requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying **ALL** of the following:
 - 2.1 Member has a repeat HBV DNA viral load undetectable **OR** decreased at least 10-fold (2 log drop) from pre-treatment HBV DNA viral load;
 - 2.2 Member has a repeat ALT (liver enzymes) in the normal range **OR** significantly decreased from pre-treatment level;
 - 2.3 If the Member meets all of the above criteria, may approve up to 10mg per day (#30 tablets per month) for 12 months.

Title: adefovir (Hepsera®)

References:

1. Lok ASF, McMahon BJ. AASLD Practice Guidelines: Chronic Hepatitis B. *Hepatology* 2001; 1225-1241.
2. Lok AS, McMahon BJ. *Chronic Hepatitis B: Update of Recommendations. AASLD Practice Guideline. Hepatology* 2004;39:857-861.
3. Lok ASF, McMahon BJ. *AASLD Practice Guidelines: Chronic Hepatitis B. Hepatology* 2007; 45:507-39.
4. Gilead Sciences, Inc., Hepsera® (adefovir dipivoxil). Full Prescribing information. Foster City, CA. Revised May 2008.
5. Gold Standard, Clinical Pharmacology: Hepsera® monograph, accessed on March 2009.

Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.