AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: **The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request**. All other information may be filled in by office staff; **fax to 1-305-671-0200**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: adefovir dipivoxil (ADV, generic Hepsera)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Recommended Dosage: 10 mg once daily

Quantity Limit: 30 tablets per 30 days

CLINICAL CRITERIA: Check below all that apply. **All criteria must be met for approval.** To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

Complete SECTION I and SECTION II for Initial Approval

SECTION I. DIAGNOSIS CRITERIA

- ❑ Prescribed by or in consultation with a specialist in gastroenterology, hepatology, infectious disease, or knowledgeable in treating patients with Hepatitis B and disease monitoring

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- ❑ Member has a diagnosis of Chronic Hepatitis B confirmed by **ALL** of the following **(applicable laboratory documentation and results from a Hepatitis B panel must be submitted)**:
  - ❑ HBsAg positive or negative for at least 6 months
  - ❑ There is documented evidence of active viral replication (HBeAg+ and HBV DNA> 100,000 copies/mL)
  - ❑ There is documented evidence of active liver disease as demonstrated by persistent elevation in serum alanine aminotransferase (ALT) (greater than 2 times upper limit of normal) or moderate to severe hepatitis on biopsy
- ❑ Current levels of alanine aminotransferase (ALT) and Hepatitis B DNA have been measured and meet **ONE** of the following **(must submit lab results)**:
  - ❑ For serological status of HBeAntigen-postive, the alanine aminotransferase (ALT) level is found to be 2 or more times greater than the upper limit of normal, and levels of Hepatitis B DNA are greater than 20,000IU/mL
  - ❑ For serological status of HBeAntigen-negative, the alanine aminotransferase (ALT) level is found to be 2 or more times greater than the upper limit of normal, and levels of Hepatitis B DNA are greater than 2,000IU/mL
- ❑ Clinical markers are outside of those listed above, but at least one patient variable exists to recommend treatment **(chart notes must be submitted to confirm patient variables)**:
  - ❑ Age: older age (>40 years) is associated with a higher likelihood of significant histological disease
  - ❑ Family history of cirrhosis or HCC
  - ❑ Previous treatment history
  - ❑ Serological and virological benefits of peg-IFN occur after treatment discontinuation (delayed)
  - ❑ Past nucleoside/nucleotide analogue exposure is a risk for drug resistance
  - ❑ Presence of extrahepatic manifestations: indication for treatment independent of liver disease severity
  - ❑ Presence of cirrhosis

SECTION II. DRUG CRITERIA

- ❑ Member is 18 years of age or older
- ❑ Adefovir dipivoxil will not be used concurrently with tenofovir or any product containing tenofovir
- ❑ Member has an estimated creatinine clearance (CrCl) ≥ 50 mL/minute. If CrCl is < 50 mL/minute, dosage will be adjusted to 10 mg every 48 hours for CrCl 30-49 mL/min, or 10 mg every 72 hours for CrCl 10-29 mL/min
- ❑ Provide clinical rationale, medical necessity, pertinent past medical history, and documented previous treatments as to why adefovir must be used in lieu of the other clinically preferred treatments **(NOTE: Adefovir dipivoxil is a nonpreferred drug for the treatment of Chronic Hepatitis B according to the most current recommendations published by the American Association for the Study of Liver Diseases):**

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_____

_____

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Reauthorization - 12 months. All criteria must be checked for approval. To support each line checked, all documentation (lab results, diagnostics, and/or chart notes) must be provided or request may be denied.

- ❑ Member's renal function has been monitored during treatment, and the most recent estimated creatinine clearance is ≥ 50 mL/minute. If CrCl is < 50 mL/minute, dosage will be adjusted to 10 mg every 48 hours for CrCl 30-49 mL/min, or 10 mg every 72 hours for CrCl 10-29 mL/min
- ❑ Therapy discontinuation is not appropriate at this time due to **ONE** of the following:
  - ❑ Disease state/phase requires ongoing treatment **(attach most recently monitored levels of HBV DNA, ALT, HBeAg status, anti-HBe status)**
  - ❑ Seroconversion on therapy occurred, but treatment consolidation period not met **(attach most recently monitored levels of HBV DNA, ALT, HBeAg status, anti-HBe status)**

Medication being provided by a Specialty Pharmacy - PropriumRx

Not all drugs may be covered under every Plan.

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.****

****Previous therapies will be verified through pharmacy paid claims or submitted chart notes.****

***Approved by Pharmacy and Therapeutics Committee**: 9/10/2021
REVISED/UPDATED: ~~12/9/2021;12/23/2021;~~ **10/25/2023**