MDWISE PRIOR AUTHORIZATION CRITERIA

**HEPSERA (adefovir dipivoxil)** Tablet: 10mg  
**FORMULARY STATUS** Preferred

**PA CRITERIA FOR APPROVAL**

- Member has documented diagnosis of chronic hepatitis B.  
  AND
- Submitted current laboratory values indication evidence of active viral replication.  
  AND
- Submitted current laboratory values indicating persistent elevations in ALT or AST or histologically active disease.  
  AND
- Documented treatment failure with contraindication to Baraclude Therapy.  
  AND
- Patient under the care of a gastroenterologist.

If the above conditions are met, the request will be approved with a 12 month duration; if the above conditions are not met, the request will be referred to a Medical Director for medical necessity review.

**FDA INDICATIONS**

Hepsera is indicated for the treatment of chronic hepatitis B in patients 12 years of age and older with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease. This indication is based on histological, virological, biochemical, and serological responses in adult patients with HBeAg+ and HBeAg- chronic hepatitis B with compensated liver function, and with clinical evidence of lamivudine-resistant hepatitis B virus with either compensated or decompensated liver function. For patients 12 to <18 years of age, the indication is based on virological and biochemical responses in patients with HBeAg+ chronic hepatitis B virus infection with compensated liver function.

**DOSAGE AND ADMINISTRATION**

The recommended dose of adefovir in chronic hepatitis B patients with adequate renal function is 10 mg once daily taken orally without regard to food. The optimal duration of treatment is unknown.  
Dose adjustment in renal impairment: Adjust the dosing interval of adefovir in patients with baseline creatinine clearance (Ccr) less than 50 ml/min using the following suggested guidelines.  
Dosing Interval Adjustment of Adefovir in Patients with Renal Impairment Ccr (ml/min):

<table>
<thead>
<tr>
<th>Creatinine Clearance (mL/min)</th>
<th>Hemodialysis Patients</th>
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<tbody>
<tr>
<td>≥50</td>
<td>10 mg every 24 hours</td>
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<tr>
<td>30-49</td>
<td>10 mg every 48 hours</td>
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<tr>
<td>10-29</td>
<td>10 mg every 72 hours</td>
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<tr>
<td></td>
<td>10 mg every 7 days following dialysis</td>
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**BLACK BOX WARNING:**

- Severe acute exacerbations of hepatitis have been reported in patients who have discontinued anti-hepatitis B therapy, including therapy with adefovir dipivoxil. Closely monitor hepatic function in patients who discontinue anti-hepatitis B therapy. If appropriate, resumption of anti-hepatitis B therapy may be warranted.
- In patients at risk of or having underlying renal dysfunction, chronic administration of adefovir dipivoxil may result in nephrotoxicity. Closely monitor these patients for renal function and adjust dose as required.
- Human Immunodeficiency Virus (HIV) resistance may emerge in chronic hepatitis B patients with unrecognized or untreated HIV infection treated with anti-hepatitis B therapies, such as therapy with adefovir dipivoxil that may have activity against HIV.
- Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogs alone or in combination with other antiretrovirals.

**REFERENCES**

5. Davis GL. Update on the management of chronic hepatitis B. Rev Gastroenterol Disord (United States), Summer 2002, 2(3) p106-15

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