

## Hepatitis B Antivirals

### Goal(s):

- Approve treatment supported by medical evidence and consensus guidelines
- Cover preferred products when feasible for covered diagnosis

### Length of Authorization:

- Up to 12 months; quantity limited to a 30-day supply per dispensing.

### Requires PA:

- All nonpreferred Hepatitis B antivirals

### Covered Alternatives:

- Preferred alternatives listed at <http://www.orpd.org/drugs/>

### Pediatric Age Restrictions:

- lamivudine (Epivir HBV) –  $\geq 2$  years
- adefovir dipivoxil (Hepsera) –  $\geq 12$  years
- entecavir (Baraclude) –  $\geq 2$  years
- tenofovir disoproxil fumarate (Viread) –  $\geq 2$  years and weight  $\geq 10$  kg
- tenofovir alafenamide (Vemlidy) –  $\geq 6$  years and  $\geq 25$  kg

### Approval Criteria

1. What diagnosis is being treated?	Record ICD10 code	
2. Is the request for an antiviral for the treatment of HIV/AIDS?	<b>Yes:</b> Approve for up to 12 months	<b>No:</b> Go to #3
3. Is the request for treatment of chronic Hepatitis B Virus infection?	<b>Yes:</b> Go to #4	<b>No:</b> Pass to RPh. Deny; medical appropriateness
4. Is the request for a pediatric patient?	<b>Yes:</b> Go to #5	<b>No:</b> Go to #6
5. Does the pediatric patient meet the age and weight requirements for the requested drug (see Pediatric Age Restrictions above).	<b>Yes:</b> Go to #6	<b>No:</b> Pass to RPh. Deny; medical appropriateness
6. Is this a continuation of current therapy previously approved by the FFS program (i.e. filled prescription within prior 90 days)? Verify via pharmacy claims.	<b>Yes:</b> Go to Renewal Criteria	<b>No:</b> Go to #7

## Approval Criteria

7. Has the client tried and is intolerant to, resistant to, or has a contraindication to the preferred products?	<b>Yes:</b> Document intolerance, resistance, or contraindication. Approve requested treatment for 6 months with monthly quantity limit of 30-day supply.	<b>No:</b> Go to #8
8. Will the prescriber consider a change to a preferred product?	<b>Yes:</b> Inform prescriber of covered alternatives in class	<b>No:</b> Approve requested treatment for 6 months with monthly quantity limit of 30-day supply

## Renewal Criteria

1. Is the patient adherent with the requested treatment (see refill history)?	<b>Yes:</b> Go to #2	No: Deny; Pass to RPh for provider consult
2. Is HBV DNA undetectable (below 10 IU/mL by real time PCR) or the patient has evidence of cirrhosis?  Note: Antiviral treatment is indicated irrespective of HBV DNA level in patients with cirrhosis to prevent reactivation.	<b>Yes:</b> Approve for up to 1 year with monthly quantity limit of 30-day supply	No: Deny; pass to RPh for provider consult

P&T Review: 8/25 (DM); 3/17(MH); 3/12  
Implementation: 9/15/25; 4/1/17; 5/29/14; 1/13