MEDICATION POLICY

Generic Name: Adefovir

Therapeutic Class or Brand Name: Hepsera®

Applicable Drugs (if Therapeutic Class)**:**

Preferred: Adefovir tablet (generic)

Non-Preferred: Hepsera® tablet

Date of Origin: 2/1/13 **Date Last Reviewed/Revised:** 9/22/16

GPI Code: 1235201510

Prior Authorization Criteria (may be considered medically necessary when criteria I through IV are met):

I. Documented diagnosis of Chronic Hepatitis B virus infection with evidence of active viral replication and ONE of criteria A OR B is met:
   A. Evidence of persistent elevations in serum aminotransferases (ALT or AST).
   B. Histologically active disease.

II. Minimum age requirement: 12 years old.

III. Prescriber is a Gastroenterologist, Infectious Disease Specialist, or Hepatologist.

IV. Non-preferred product (i.e. Hepsera® tablet) requires a documented clinical reason containing details as to why generic adefovir is not appropriate or is contraindicated.

Exclusion Criteria:

- Coadministration of Hepsera® with Viread® (tenofovir disoproxil fumarate) or any product containing tenofovir disoproxil fumarate including Atripla® (efavirenz/emtricitabine/tenofovir disoproxil fumarate), Complera® (emtricitabine/rilpivirine/tenofovir disoproxil fumarate), Stribild® (elvitegravir/cobicistat/ emtricitabine/tenofovir disoproxil fumarate), and Truvada® (emtricitabine/tenofovir disoproxil fumarate).

Other Criteria:

- N/A

Quantity/Days Supply Restrictions:

- Quantities of up to 30 tablets per 30 days.

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Approval Length:

- **Authorization:** 1 year.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing that current medical necessity criteria are met and that the medication is effective.

Appendix:

N/A

References:

1. http://onlinelibrary.wiley.com/doi/10.1002/hep.28156/epdf.
2. http://www.aasld.org/sites/default/files/guideline_documents/ChronicHepatitisB2009.pdf.
3. Medi-Span.
4. http://www.gilead.com/pdf/hepsera_pi.pdf.

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Historical Tracking Of Changes Made To Policy	
9/22/2016	1. **Added** "http://onlinelibrary.wiley.com/doi/10.1002/hep.28156/epdf" **under References**. 2. **Removed** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Hepsera.pdf" **from References** (link no longer valid).
2/24/2015	1. **Changed** "N/A" **to** "Preferred: Adefovir tablet (generic); Non-Preferred: Hepsera® tablet" **under Applicable Drugs (if Therapeutic Class)**. 2. **Reworded** "Documented diagnosis of chronic hepatitis B; Patient has evidence of active viral replication; Patient has either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease" **to** "Documented diagnosis of Chronic Hepatitis B virus infection with evidence of active viral replication and ONE of criteria A OR B is met: A. Evidence of persistent elevations in serum aminotransferases (ALT or AST); B. Histologically active disease" **under Prior Authorization Criteria**. 3. **Added** "Non-preferred product (i.e. Hepsera® tablet) requires a documented clinical reason containing details as to why generic adefovir is not appropriate or is contraindicated" **under Prior Authorization Criteria**. 4. **Added** "Coadministration of Hepsera® with Viread® (tenofovir disoproxil fumarate) or any product containing tenofovir disoproxil fumarate including Atripla® (efavirenz/emtricitabine/tenofovir disoproxil fumarate), Complera® (emtricitabine/rilpivirine/tenofovir disoproxil fumarate), Stribild® (elvitegravir/cobicistat/emtricitabine/tenofovir disoproxil fumarate), and Truvada® (emtricitabine/tenofovir disoproxil fumarate)" **under Exclusion Criteria**. 5. **Added** http://www.aasld.org/sites/default/files/guideline_documents/ChronicHepatitisB2009.pdf **under References**. 6. **Updated** "http://www.health.utah.gov/medicaid/pharmacy/priorauthorization/pdf/Hepsera.pdf" **to** "https://medicaid.utah.gov/pharmacy/priorauthorization/pdf/Hepsera.pdf" **under References**.
1/15/2014	1. **Adapted policy to new format.** 2. **Added GPI code**. 3. **Changed Prior Authorization Criteria from:** "Documented diagnosis of Hepatitis B; Failure on Epivir® (lamivudine); Minimum age requirement: 12 years old" **to:** "Documented diagnosis of chronic hepatitis B; Patient has evidence of active viral replication; Patient has either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease; Minimum age requirement: 12 years old; Prescriber is a Gastroenterologist, Infectious Disease Specialist, or Hepatologist". 4. **Changed Quantity/Days Supply Restrictions from** "Maximum dose: 10mg per day" **to** "Quantities of up to 30 tablets per 30 days". 5. **Changed Authorization under Approval Length from** "Initial authorization is for 12 weeks" **to** "1 year". 6. **Changed Re-Authorization under Approval Length from** "12 months with updated letter of medical necessity" **to** "An updated letter of medical necessity or progress notes showing that current medical necessity criteria are met and that the medication is effective". 7. **Updated references** to include Medi-Span.