



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: 12/1/17

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

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Historical Tracking Of Changes Made To Policy	
12/1/2017	1. Policy reviewed: no changes made.
9/22/2016	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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	<ol style="list-style-type: none"> 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.

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