**UnitedHealthcare Individual & Family ACA Marketplace Plans**
**Clinical Pharmacy Program Guidelines for Hepatitis B**

| Program | Step Therapy |
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| Medication | Vemlidy® (tenofovir alafenamide) |
| Issue Date | 11/2020 |
| Pharmacy and Therapeutics Approval Date | 3/2022 |
| Effective Date | 5/2022 |

1.      **Background:**

Entecavir is a hepatitis B virus (HBV) nucleoside analogue reverse transcriptase inhibitor indicated for the treatment of chronic hepatitis B virus infection in adults and children at least 2 years of age with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.[1]

Vemlidy (tenofovir alafenamide) is an HBV nucleoside analogue reverse transcriptase inhibitor and is indicated for the treatment of chronic hepatitis B virus infection in adults with compensated liver disease.[2]

Viread (tenofovir disoproxil fumarate) is an HBV nucleoside analogue reverse transcriptase inhibitor and is indicated for the treatment of chronic hepatitis B in adults and pediatric patients 2 years of age and older weighing at least 10 kg.[3]

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. This program requires a member to try entecavir oral tablets or tenofovir disoproxil fumarate 300mg before providing coverage for Vemlidy® (tenofovir alafenamide).

2.      **Coverage Criteria [a]:**

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**A. Treatment-Naïve Chronic Hepatitis B Infection:**

1. **Vemlidy** will be approved based on the following criterion:

   a.   Patient has a contraindication to entecavir therapy

   **Authorization will be issued for 12 months**

**B. Treatment-Experienced Chronic Hepatitis B Infection:**

1. **Vemlidy** will be approved based on **<u>one</u>** of the following criteria:

   a.   Patient has a history of failure, intolerance or contraindication to entecavir therapy

   **-OR-**

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b. **Both** of the following:

    (1) Patient is currently on tenofovir disoproxil fumarate 300mg therapy

        **-AND-**

    (2) **One** of the following:

        (a) Patient has an estimated glomerular filtration rate below 90 mL/minute

            **-OR-**

        (b) Patient has a diagnosis of osteoporosis

            **-OR-**

c. Patient is currently on Vemlidy therapy

    **Authorization will be issued for 12 months**

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

**3.**     **Additional Clinical Rules:**
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

**4.**     **References:**
1. Baraclude [package insert].  Princeton, NJ:  Bristol-Myers Squibb Company; December 2018.
2. Vemlidy [package insert]. Foster City, CA: Gilead Sciences, Inc.; February 2019.
3. Viread [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2019.

| Program | Step Therapy – Hepatitis B |
|---|---|
| **Change Control** | |
| 6/2017 | New step therapy program that requires the use of entecavir or Viread before benefit coverage of Vemlidy. |
| 10/2018 | Annual review with update to references. |
| 10/2019 | Annual review with no changes to coverage criteria.  Updated references. |
| 12/2020 | Renamed policy to Step Therapy Hepatitis B, revised authorization duration to 12 months and alternatives to include entecavir oral tablets and tenofovir disoproxil fumarate 300mg exclusively for |

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| | application to UnitedHealthcare Value & Balance Exchange for 1/2021 implementation. |
| 2/2021 | Clean up disoproxil fumarate spelling. |
| 9/2021 | Updated background removing automation language. |
| 3/2022 | Removed the formulary box and renamed the policy to remove Washington from the name. Updated renal cut off to estimated GFR less than or equal to 90 mL/min. |