

This document applies to the following:

Formulary	Applies
Standard Control (SF)	<input checked="" type="checkbox"/>
Standard Control – Choice (SCCF)	<input checked="" type="checkbox"/>
Preferred Drug Plan Design (PDPD)	<input type="checkbox"/>
Advanced Control Specialty (ACSF)	<input checked="" type="checkbox"/>
Advanced Control Specialty – Choice (ACSCF)	<input checked="" type="checkbox"/>
Managed Medicaid Template (MMT)	<input type="checkbox"/>
Marketplace (MF)	<input type="checkbox"/>
Aetna Small Group Affordable Care Act (SG ACA)	<input type="checkbox"/>
Aetna Health Exchange (AHE)	<input type="checkbox"/>
Value (VF)	<input type="checkbox"/>

Formulary	Applies
New to Market (NTM)	<input type="checkbox"/>
Standard Formulary Chart (SFC)	<input type="checkbox"/>
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	<input type="checkbox"/>
Advanced Control Specialty Formulary Chart (ACSFC)	<input type="checkbox"/>
Value Formulary Chart (VFC)	<input type="checkbox"/>
Medical Benefit	<input type="checkbox"/>
Medical Benefit: Advanced Biosimilars First	<input type="checkbox"/>
Combined Benefit Medical (CBM)	<input type="checkbox"/>
Combined Benefit Medical Pharmacy (CBMP)	<input type="checkbox"/>
Medical Benefit: Managed Medicaid (MMMB)	<input type="checkbox"/>

Exceptions Criteria

Hepatitis B Antiviral Products

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Advanced Control Specialty Formulary (ACSF), and Advanced Control Specialty – Choice Formulary (ACSCF).

Plan Design Summary

This program applies to the hepatitis B virus antiviral products specified in this document. Coverage for the targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Hepatitis B Virus Antiviral Products

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

	Product(s)
Preferred	<ul style="list-style-type: none"> entecavir (generic) lamivudine (generic) tenofovir disoproxil fumarate (generic)
Target	<ul style="list-style-type: none"> Baraclude tablets (entecavir) Vemlidy (tenofovir alafenamide)

Exception Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Baraclude Tablets

Coverage for Baraclude tablets is provided when both of the following criteria are met:

- Member has had a documented intolerable adverse event to generic entecavir, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
- Member meets either of the following criteria:
 - Member has documented bone loss and mineralization defects or is at risk for bone loss and mineralization defects (e.g., history of fragility fractures, advanced age, frailty, chronic glucocorticoid use, low T-scores, or increased fall risk).
 - Member has a documented inadequate virologic response, resistance, or intolerable adverse event to tenofovir disoproxil fumarate.

Vemlidy

Coverage for Vemlidy is provided when either of the following criteria is met:

- Member has a documented inadequate virologic response, resistance, or intolerable adverse event to both of the preferred products entecavir and tenofovir disoproxil fumarate.
- Member meets both of the following criteria:
 - Member has documented bone loss and mineralization defects or is at risk for bone loss and mineralization defects (e.g., history of fragility fractures, advanced age, frailty, chronic glucocorticoid use, low T-scores, or increased fall risk).
 - Member has a documented inadequate virologic response, resistance, or intolerable adverse event to the preferred product entecavir.

Reference number(s)
7170-D

References

1. Baraclude [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; November 2019.
2. Entecavir [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; April 2022.
3. Lamivudine tablet [package insert]. Mason, OH: Prasco Laboratories; June 2022.
4. Lamivudine solution [package insert]. Congers, NY: Chartwekk RX, LLC.; February 2025.
5. Tenofovir disoproxil fumarate [package insert]. Warren, NJ: Cipla USA, Inc.; March 2024.
6. Vemlidy [package insert]. Foster City, CA: Gilead Sciences, Inc.; March 2024.