

This document applies to the following:

Formulary	Applies
Standard Control (SF)	<input type="checkbox"/>
Standard Control – Choice (SCCF)	<input type="checkbox"/>
Preferred Drug Plan Design (PDPD)	<input type="checkbox"/>
Advanced Control Specialty (ACSF)	<input type="checkbox"/>
Advanced Control Specialty – Choice (ACSCF)	<input 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"/>
Aetna Individual Lives (IVL)	<input type="checkbox"/>
Value (VF)	<input checked="" 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"/>
Medical Benefit: Managed Medicaid (MMMB)	<input type="checkbox"/>
Medicare Part B	<input type="checkbox"/>
Medicare Part B: Advanced Biosimilars First	<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: Value Formulary (VF).

Plan Design Summary

This program applies to the hepatitis B virus antiviral products specified in this document. Coverage for 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 members who are new to treatment with Baraclude solution for the first time. This program applies to all members requesting treatment with all other targeted products.

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.

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

Exception Criteria

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

Baraclude Solution

Coverage for Baraclude solution is provided when any of the following criteria is met:

- Member is currently receiving treatment with Baraclude solution, excluding when Baraclude solution is obtained as samples or via manufacturer's patient assistance programs.
- Member is unable to reliably swallow tablets.
- Member meets both of the following criteria:
 - 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 has a documented inadequate virologic response, resistance, or intolerable adverse event to the preferred product tenofovir disoproxil fumarate or Vemlidy.⁶

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 has a documented inadequate virologic response, resistance, or intolerable adverse event to the preferred product tenofovir disoproxil fumarate or Vemlidy.⁶

References

1. Baraclude [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; November 2019.

Reference number(s)
5907-D

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. Tenofovir disoproxil fumarate [package insert]. Warren, NJ: Cipla USA, Inc.; March 2024.
5. Vemlidy [package insert]. Foster City, CA: Gilead Sciences, Inc.; March 2024.