Reference number(s)
6557-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☑
Standard Control – Choice (SCCF)	☑
Preferred Drug Plan Design (PDPD)	☐
Advanced Control Specialty (ACSF)	☑
Advanced Control Specialty – Choice (ACSCF)	☑
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☐
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☐
Advanced Control Specialty Formulary Chart (ACSFC)	☐
Value Formulary Chart (VFC)	☐
Medical Benefit	☐
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

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 product 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	• entecavir (generic) • lamivudine (generic) • tenofovir disoproxil fumarate (generic) • Vemlidy (tenofovir alafenamide)
Target	• Baraclude tablets (entecavir)

Exception Criteria

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

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 tenofovir disoproxil fumarate or Vemlidy.

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