This policy applies to the following:

✓	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit		Medicare Part B
✓	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First		Medicare Part B: Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

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EXCEPTIONS CRITERIA

HEPATITIS B ANTIVIRAL PRODUCTS

PREFERRED PRODUCTS: ENTECAVIR, LAMIVUDINE AND TENOFOVIR DISOPROXIL FUMARATE

POLICY

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

I. PLAN DESIGN SUMMARY

This program applies to the hepatitis B antiviral products specified in this policy. 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 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 Antiviral Products

	Product(s)
Preferred*	• entecavir (generic) • lamivudine (generic) • tenofovir disoproxil fumarate (generic)
Targeted	• **Baraclude tablets** (entecavir) • **Vemlidy** (tenofovir alafenamide)

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

II. EXCEPTION CRITERIA

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

A. Baraclude tablets

Coverage for the targeted product is provided when both of the following criteria are met:

1. 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.
2. Member meets either of the following criteria:
   a. Member has a documented inadequate virologic response, resistance, or intolerable adverse event to the preferred product tenofovir disoproxil fumarate, or

This policy applies to the following:

✓	Standard Control (SF)		Managed Medicaid Template (MMT)		ACSF Chart (ACSFC)		Medical Benefit		Medicare Part B
✓	Standard Control – Choice (SCCF)		Marketplace (MF)		SF Chart (SFC)		Medical: Advanced Biosimilars First		Medicare Part B: Biosimilars First
	Preferred Drug Plan Design (PDPD)		Aetna Health Exchange (AHE)		VF Chart (VFC)		Medical Benefit: Managed Medicaid		Medicare Part B: Advanced Biosimilars First
	Advanced Control Specialty (ACSF)		IVL		New to Market (NTM)		Medical Benefit: Add-on		
	Advanced Control Specialty – Choice (ACSCF)		Value (VF)						

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b. 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).

B. Vemlidy

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

1. Member has a documented inadequate virologic response, resistance, or intolerable adverse event to the preferred products entecavir and tenofovir disoproxil fumarate.
2. Member meets both of the following criteria:
   a. 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), and
   b. Member has a documented inadequate virologic response, resistance, or intolerable adverse event to the preferred product entecavir.

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 [package insert]. Mason, OH: Prasco Laboratories; June 2022.
4. Tenofovir disoproxil fumarate [package insert]. Warren, NJ: Cipla USA, Inc.; December 2022.
5. Vemlidy [package insert]. Foster City, CA: Gilead Sciences, Inc.; October 2022.