

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)				

Reference #
4976-D

EXCEPTIONS CRITERIA HEPATITIS B ANTIVIRAL PRODUCTS

PREFERRED PRODUCTS: ENTECAVIR, LAMIVUDINE, TENOFOVIR DISOPROXIL FUMARATE AND VEMLIDY

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

	Products
Preferred*	- entecavir (generic) - lamivudine (generic) - tenofovir disoproxil fumarate (generic) Vemlidy (tenofovir alafenamide)
Targeted	Baraclude tablets (entecavir) Epivir-HBV tablets (lamivudine)

*: 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 Baraclude tablets 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.

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	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)							

- Member has a documented inadequate virologic response, resistance, or intolerable adverse event to at least one of the preferred products other than generic entecavir.

B. Epivir-HBV tablets

Coverage for Epivir-HBV tablets is provided when both of the following criteria are met:

- Member has had a documented intolerable adverse event to generic lamivudine, 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 intolerable adverse event to at least two of the preferred products other than generic lamivudine.

REFERENCES

- Baraclude [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; November 2019.
- Entecavir [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; April 2022.
- Epivir-HBV [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2021.
- Lamivudine [package insert]. Mason, OH: Prasco Laboratories; June 2022.
- Tenofovir disoproxil fumarate [package insert]. Warren, NJ: Cipla USA, Inc.; December 2022.
- Vemlidy [package insert]. Foster City, CA: Gilead Sciences, Inc.; October 2022.