This policy applies to the following:

	Standard Control (SF)	1	Managed Medicaid Template (MMT)	√	ACSF Chart (ACSFC)	Medical Benefit	Medicare Part B
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)	Medical Benefit: Biosimilars First	Medicare Part B: Biosimilars First
~	Advanced Control Specialty (ACSF)		New to Market (NTM)	~	VF Chart (VFC)	Medical Benefit: Add-on	Medicare Part B: Advanced Biosimilars First
	Value (VF)		Aetna Health Exchange (AHE)			Medical Benefit: Managed Medicaid	
			IVL				

Reference #

3319-D

EXCEPTIONS CRITERIA HEPATITIS B LIQUID ANTIVIRAL PRODUCTS

PREFERRED PRODUCT: BARACLUDE SOLUTION

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 liquid antiviral products specified in this policy. Coverage for the targeted product is provided based on clinical circumstances that would exclude the use of the preferred product 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 a targeted product for the first time.

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

Table. Hepatitis B Liquid Antiviral Products

	Product(s)
Preferred*	Baraclude solution (entecavir)
Targeted	Epivir-HBV solution (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 the preferred product.

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

- A. Member is currently receiving treatment with the targeted product, excluding when the requested targeted product is obtained as samples or via manufacturer's patient assistance programs.
- B. Member has a documented weight of less than 10 kg.
- C. Member has a documented inadequate virologic response, resistance, or intolerable adverse event with the preferred product.

REFERENCES

- 1. Baraclude [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; November 2019.
- 2. Epivir-HBV [package insert]. Research Triangle Park, NC: GlaxoSmithKline; December 2021.

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This policy applies to the following:

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

Reference #

3319-D

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