

This policy applies to the following:

	Standard Control (SF)		Managed Medicaid Template (MMT)	✓	ACSF Chart (ACSFC)		Medical Benefit		Medicare Part B	Reference #
	Preferred Drug Plan Design (PDPD)		Marketplace (MF)		SF Chart (SFC)		Medical Benefit: Biosimilars First		Medicare Part B: Biosimilars First	4976-D
✓	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		Medicare Part B: Add-on	
			IVL							

## EXCEPTIONS CRITERIA HEPATITIS B ANTIVIRAL PRODUCTS

**PREFERRED PRODUCTS: BARACLUDE SOLUTION, 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
<b>Preferred*</b>	<ul style="list-style-type: none"> <li>• Baraclude solution (entecavir)</li> <li>• entecavir</li> <li>• lamivudine</li> <li>• tenofovir disoproxil fumarate</li> <li>• Vemlidy (tenofovir alafenamide)</li> </ul>
<b>Targeted</b>	<ul style="list-style-type: none"> <li>• Baraclude tablets (entecavir)</li> <li>• Epivir-HBV tablets (lamivudine)</li> <li>• Hepsera (adefovir dipivoxil)</li> </ul>

\*: 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.

##### A. Baraclude tablets

Coverage for the targeted product is provided when the member meets all of the following criteria:

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1. Member has had a documented intolerable adverse event to entecavir or Baraclude solution, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
2. Member has a documented inadequate virologic response, resistance or intolerable adverse event to at least two of the preferred products other than entecavir or Baraclude solution.

#### B. Epivir-HBV tablets

Coverage for the targeted product is provided when the member meets all of the following criteria:

1. Member has had a documented intolerable adverse event to lamivudine, and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information.
2. Member has a documented inadequate virologic response, resistance or intolerable adverse event to at least two of the preferred products other than lamivudine.

#### C. Hepsera

Coverage for the targeted product is provided when the member has a documented inadequate virologic response, resistance or intolerable adverse event to at least three of the preferred products.

### 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.
3. Hepsera [package insert]. Foster City, CA: Gilead Sciences, Inc.; December 2018.
4. tenofovir disoproxil fumarate [package insert]. Warren, NJ: Cipla USA, Inc.; October 2019.
5. Vemlidy [package insert]. Foster City, CA: Gilead Sciences, Inc.; September 2021.
6. entecavir [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; April 2022.
7. lamivudine [package insert]. Mason, OH: Prasco Laboratories; June 2022.