This policy applies to the following:

	Standard Opt-in	✓	ACSF		VF		Marketplace
	Standard Opt-in NTMB		PDPD		MMT		Medical Benefit
	Standard Opt-out		Generics First				Medical Benefit: Managed Medicaid

Reference #
3035-D

EXCEPTIONS CRITERIA
HEPATITIS B ANTIVIRAL AGENTS

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 agents 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 Agents

	Product(s)
Preferred	• **entecavir** • **lamivudine** • **tenofovir disoproxil fumarate**
Targeted	• **Baraclude** (entecavir) • **Epivir-HBV** (lamivudine) • **Hepsera** (adefovir dipivoxil) • **Vemlidy** (tenofovir alafenamide)

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 all of the following criteria are met:

A. Baraclude and Epivir-HBV
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 the respective generic preferred product, 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 all of the other preferred products.

This policy applies to the following:

	Standard Opt-in	✓	**ACSF**		**VF**		**Marketplace**
	Standard Opt-in NTMB		**PDPD**		**MMT**		**Medical Benefit**
	Standard Opt-out		**Generics First**				**Medical Benefit: Managed Medicaid**

Reference #
3035-D

B. Vemlidy

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

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

C. Hepsera

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

REFERENCES

1. Baraclude [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; December 2018.
2. Epivir-HBV [package insert]. Research Triangle Park, NC: GlaxoSmithKline; November 2018.
3. Hepsera [package insert]. Foster City, CA: Gilead Sciences, Inc.; December 2018.
4. tenofovir disoproxil fumarate [package insert]. North Wales, PA: Teva; November 2018.
5. Vemlidy [package insert]. Foster City, CA: Gilead Sciences, Inc.; February 2019.