

This policy applies to the following:

✓	Standard Opt-in	PDPD	Marketplace	Medical Benefit	Medicare Part B	Reference #
	Standard Opt-out	ACSF	MMT	Medical Benefit: Biosimilars First	Medicare Part B: Biosimilars First	3159-D
	VF	Balanced	Medical Benefit: Managed Medicaid	Medical Benefit: Add-on	Medicare Part B: Add-on	

EXCEPTIONS CRITERIA HEPATITIS B ANTIVIRAL AGENTS

PREFERRED PRODUCTS: ENTECAVIR 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 agents specified in this policy. Coverage for targeted product 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	<ul style="list-style-type: none"> entecavir Vemlidy (tenofovir alafenamide)
Targeted	<ul style="list-style-type: none"> Baraclude (entecavir)

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:

- 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.
- Member has a documented inadequate virologic response, resistance or intolerable adverse event to the preferred product, Vemlidy.

REFERENCES

- Baraclude [package insert]. Princeton, NJ: Bristol-Myers Squibb Company; November 2019.
- entecavir [package insert]. East Windsor, NJ: Aurobindo Pharma USA, Inc.; January 2020.
- Vemlidy [package insert]. Foster City, CA: Gilead Sciences, Inc.; August 2020.