

Clinical Policy: Entecavir (Baraclude)

Reference Number: HIM.PA.08

Effective Date: 06.01.19

Last Review Date: 05.20

Line of Business: HIM

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Entecavir (Baraclude[®]) is a hepatitis B virus nucleoside analogue reverse transcriptase inhibitors.

FDA Approved Indication(s)

Baraclude is indicated for the treatment of chronic hepatitis B virus infection in adults and children at least 2 years of age with evidence of active viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Baraclude is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Hepatitis B Infection (must meet all):

1. Diagnosis of hepatitis B virus infection;
2. Prescribed by or in consultation with a gastroenterologist, hepatologist, or infectious disease specialist;
3. Age \geq 2 years;
4. Evidence of active viral replication;
5. Member meets one of the following (a or b):
 - a. Evidence of persistent elevations in serum aminotransferases (ALT or AST);
 - b. Histologically active disease;
6. Dose does not exceed (a or b):
 - a. 1 mg (1 tablet) per day;
 - b. 20 mL per day (3 bottles per month).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy

A. Hepatitis B Infection (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed (a or b):
 - a. 1 mg (1 tablet) per day;
 - b. 20 mL per day (3 bottles per month).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace.

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PHAR.21 for health insurance marketplace or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

AST: aspartate aminotransferase

ALT: alanine aminotransferase

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s):
 - Severe acute exacerbation of hepatitis B
 - Potential for development of resistance to HIV nucleoside reverse transcriptase inhibitors
 - Lactic acidosis and hepatomegaly

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose																											
Hepatitis B infection	<p><u>Adults and adolescents ≥ 16 years</u> Nucleoside inhibitor treatment-naïve: 0.5 mg PO QD</p> <p>History of hepatitis B viremia while receiving lamivudine, known lamivudine/telbivudine resistance substitutions rtM204I/V, or decompensated liver disease: 1 mg PO QD</p> <p><u>Pediatric patients ≥ 2 years to < 16 years</u> Weight-based dose PO QD:</p> <table border="1"> <thead> <tr> <th>Body weight (kg)</th> <th>Treatment-Naïve</th> <th>Lamivudine-Experienced</th> </tr> </thead> <tbody> <tr> <td>10 – 11</td> <td>3 mL</td> <td>6 mL</td> </tr> <tr> <td>> 11 – 14</td> <td>4 mL</td> <td>8 mL</td> </tr> <tr> <td>> 14 – 17</td> <td>5 mL</td> <td>10 mL</td> </tr> <tr> <td>> 17 – 20</td> <td>6 mL</td> <td>12 mL</td> </tr> <tr> <td>> 20 – 23</td> <td>7 mL</td> <td>14 mL</td> </tr> <tr> <td>> 23 – 26</td> <td>8 mL</td> <td>16 mL</td> </tr> <tr> <td>> 26 – 30</td> <td>9 mL</td> <td>18 mL</td> </tr> <tr> <td>> 30</td> <td>10 mL</td> <td>20 mL</td> </tr> </tbody> </table>	Body weight (kg)	Treatment-Naïve	Lamivudine-Experienced	10 – 11	3 mL	6 mL	> 11 – 14	4 mL	8 mL	> 14 – 17	5 mL	10 mL	> 17 – 20	6 mL	12 mL	> 20 – 23	7 mL	14 mL	> 23 – 26	8 mL	16 mL	> 26 – 30	9 mL	18 mL	> 30	10 mL	20 mL	1 mg/day or 20 mL/day
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VI. Product Availability

- Tablets: 0.5 mg, 1 mg
- Oral solution: 0.05 mg/mL

VII. References

1. Baraclude Prescribing Information. Princeton, NJ: Bristol-Myers Squibb Company; November 2019. Available at: www.baraclude.com. Accessed January 24, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	03.05.19	05.19
2Q 2020 annual review: no significant changes; corrected dosing from 18 mL/day to 20 mL/day per PI; updated Section V with pediatric weight-based dosing; references reviewed and updated.	01.24.20	05.20

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical

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