Clinical Policy: Telbivudine (Tyzeka)

Reference Number: HIM.PA.95
Effective Date: 12/14
Last Review Date: 08/17 Revision Log
Line of Business: Health Insurance Marketplace

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Telbivudine (Tyzeka™) is a synthetic thymidine nucleoside analogue with activity against hepatitis B virus (HBV).

FDA approved indication
Tyzeka is indicated for the treatment of chronic hepatitis B in adult patients with evidence of viral replication and either evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease.

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

I. Initial Approval Criteria

A. Chronic Hepatitis B (must meet all)**:**

1. Diagnosis of chronic hepatitis B infection with evidence of viral replication and one of the following (a or b):
   a. Member is HBeAg-positive with HBV DNA < 9 $\log_{10}$ copies per mL and ALT ≥ 2 times upper limit of normal;
   b. Member is HBeAg-negative with HBV DNA < 7 $\log_{10}$ copies per mL;
2. Member meets one of the following (a or b):
   a. Evidence of persistent elevations in serum aminotransferases (ALT or AST);
   b. Disease is histologically active;
3. Dose does not exceed 600 mg/day (1 tablet/day).

Approval duration: 24 weeks

B. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Chronic Hepatitis B (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. HBV DNA is not detectable (HBV DNA < 300 copies per mL);
3. Dose does not exceed 600 mg/day (1 tablet/day).

Approval duration: 24 weeks

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

1. Currently receiving medication via health plan benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to HIM.PA.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized)

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 policy – HIM.PA.21 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation Key
ALT: alanine aminotransferase
AST: aspartate aminotransferase
HBeAg: hepatitis B e antigen
HBV: hepatitis B virus

V. References

1. Tyzeka Prescribing Information. East Hanover, NJ: Novartis Pharmaceutical Corporation; January 2013. Available at: https://dailymed.nlm.nih.gov/dailymed/. Accessed January 13, 2017.
2. Terrault NA, Bzowej NH, Chang K, Hwang JP, Jonas JM, Murad MH. AASLD guidelines for treatment of chronic hepatitis B. Hepatology. 2016; 63(1): 261-283.
3. Epivir HBV Prescribing Information. Research Triangle Park, NC: GlaxoSmithKline; December 2013. Available at: https://www.gsksource.com/pharma/content/dam/GlaxoSmithKline/US/en/Prescribing_Information/Epivir-HBV/pdf/EPIVIR-HBV-PI-PIL.PDF. Accessed January 13, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Reformatted guideline to new format. Added Workflow reference document.	12/15	12/15
Updated verbiage and references. Added requirement for HBV DNA and ALT levels prior to initiation based on HBeAg status per PI. Added criteria to allow re-auth as there is no conclusive duration of treatment per PI (per PI, treatment can be continued until HBV DNA is detectable). Continued approval duration is set at 24 weeks per PI and AASLD guideline recommendations for HBV DNA monitoring. Removed workflow document.	09/16	11/16
Converted to new template	04/17	08/17

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 policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.