# Tyzeka (telbivudine)

| Override(s) | Approval Duration |
|---|---|
| Prior Authorization<br>Quantity Limit | 1year |

| Medications | Quantity Limit |
|---|---|
| Tyzeka† (telbivudine) | May be subject to quantity limit |

†Tyzeka was discontinued by the manufacturer as of 11-2016. It will remain in the edit as claims can adjudicate up to 3 years after discontinuation.

## APPROVAL CRITERIA

Requests for Tyzeka (telbivudine) may be approved for individuals who meet the following criteria:

I. Individual is 16 years of age or older; **AND**
II. Individual has a diagnosis of chronic Hepatitis B; **AND**
III. Individual has had a previous trial and inadequate response or intolerance to or has a contraindication to an alternative antiviral agent with a higher genetic barrier to resistance for Hepatitis B [such as entecavir or tenofovir] (AASLD 2016).

Note: Tyzeka (telbivudine) has black box warnings for severe exacerbations of hepatitis, lactic acidosis, and severe hepatomegaly with steatosis. Hepatic function should be monitored for several months after discontinuation of therapy to assess for severe exacerbation of hepatitis.

| State Specific Mandates | | |
|---|---|---|
| State name<br>N/A | Date effective<br>N/A | Mandate details (including specific bill if applicable)<br>N/A |

**Key References**:


Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2017. URL: http://www.clinicalpharmacology.com. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed January 30, 2017.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2017; Updated periodically.