



## Preferred Drug List

### NEW DRUG REVIEW

**Proprietary Name:** Tyzeka™

**Common Name:** Telbivudine Tablets

**PDL Category:** Hepatitis B Only

<u>Comparable Products</u>	<u>Preferred Drug List/ Recommended Drug List Status</u>
Baraclude®	Preferred
Hepsera®	Preferred*

#### Summary

**Indications and Usage:** Chronic Hepatitis B

**Mechanism of Action:** Inhibits hepatitis B virus DNA polymerase by competing with the natural substrate.

**Dosage Forms:** Tablets; 600mg

**Recommended Dosage:** One 600mg tablet by mouth once daily

**Common Adverse Drug Reactions:** Creatine kinase elevation, URI, fatigue/malaise, abdominal pain, headache

**Contraindications:** Previous hypersensitivity to any component of the product

**Manufacturer:** Novartis

**Analysis:** Tyzeka™ is a once-a-day therapy for treatment of chronic hepatitis B infection. While initially only compared to lamivudine in clinical trials, after one year of treatment with Tyzeka™, 75% of patients who were HBeAg-positive or HBeAg-negative experienced viral suppression, in addition to either ALT improvement or loss of serum hepatitis B antigen. These same studies report a histologic improvement (defined as a two point decrease in Knodell Necroinflammatory Score from baseline) in 69% of patients who were HBeAg-positive or negative. By comparison, in placebo-controlled studies with Hepsera®, 53%-59% of HBeAg-positive patients and 64% of HBeAg-negative patients experienced histological improvement. Similar studies comparing Baraclude® to lamivudine report a 72% histologic improvement in HBeAg-positive patients and 70% histologic improvement in HBeAg-negative patients receiving Baraclude®. Tyzeka™ is a cost-effective choice for the treatment of chronic hepatitis B infection.

**IME Recommendation:**

<input checked="" type="checkbox"/>	Preferred Drug	<input type="checkbox"/>	Recommended Drug
<input type="checkbox"/>	Non-Preferred Drug	<input type="checkbox"/>	Non-Recommended Drug
<input type="checkbox"/>	Preferred Drug with Conditions		

\*Is being recommended to change to Non-Preferred Status