Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Victrelis™

Common Name: boceprevir

PDL Category: Hepatitis C Agents

Comparable Products	Preferred Drug List Status
Incivek™	Non-Preferred Recommendation

Summary

Indications and Usage: Indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous interferon and ribavirin therapy.[1]

Mechanism of Action: Acts directly on the hepatitis C virus protease, an enzyme essential for viral replication. [1]

Dosage Forms: Capsules: 200mg

Recommended Dosage: Recommended dose is 800mg three times daily with food. Must be administered with both peginterferon alfa and ribavirin. Treatment duration is dependent on treatment response and prior treatment.[1]

Common Adverse Drug Reactions: Anemia, fatigue, nausea, headache, dysgeusia.[1]

Contraindications: Pregnant women and men whose female partners are pregnant. Coadministration with drugs that are highly dependent on CYP3A4/5 for clearance, and for which elevated plasma concentrations are associated with serious and/or life-threatening events. Potent CYP3A4/5 inducers where significantly reduced boceprevir plasma concentrations may be associated with reduced efficacy.[1]

Manufacturer: Merck & Co., Inc.

Analysis: Victrelis™ is the first protease inhibitor indicated in combination with peginterferon alfa and ribavirin, the current standard therapy, for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease regardless if previously treated. In the two studies used to gain FDA approval, Victrelis™ increased viral cure rates and decreased treatment duration in some patients. Both of the studies included two treatment arms with Victrelis™, a response-guided therapy (RGT) arm in which patients with undetectable virus at treatment week 8 were eligible for shorter treatment duration and a 48 week treatment arm. The studies also included a control arm of standard therapy. Both studies included a 4 week standard therapy lead-in. In the SPRINT-2 trial, including treatment naïve patients, sustained virologic response (SVR) rates were 63% in the RGT arm, 66% for the 48-week treatment arm, and 38% for control. Fifty-seven percent of patients in the RGT arm were considered early responders and were eligible to stop treatment at week 28. In the RESPOND-2 trial, including patients who previously failed standard therapy, SVR rates were 59% for the RGT arm, 66% for the 48-week treatment arm, and 23% for control. Forty-six percent of patients in the RGT arm were considered early responders and were eligible to stop treatment at week 36. Victrelis™ has not been studied in patients considered to be null responders to previous standard therapy. Victrelis™ is only indicated for use in patients with genotype 1 chronic hepatitis C with compensated liver disease as a combination therapy due to resistance. Therefore, it is recommended that Victrelis™ be added as a non-preferred drug to verify diagnosis of use, combination therapy, and duration of use. In addition, it is recommended to refer to the Drug Utilization Review (DUR) Commission for criteria development.

IME Recommendation:

- ☐ Preferred Drug
- ☒ Non-Preferred Drug
- ☐ Recommended Drug
- ☐ Non-Recommended Drug
- ☒ Refer to DUR for PA criteria

1. Victrelis™ [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; 2011.