

## Specialty Pharmacy Program

### Victrelis™ (boceprevir)

#### DESCRIPTION

Victrelis is a hepatitis C virus (HCV) NS3/4A protease inhibitor indicated for the treatment of chronic hepatitis C genotype 1 infection, in combination with peginterferon alfa and ribavirin, in adult patients (≥18 years of age) with compensated liver disease, including cirrhosis, who are previously untreated or who have failed previous interferon and ribavirin therapy.

#### APPROVAL DURATION

New start: Up to 8 weeks

First renewal: Up to 20 weeks total

Second renewal: Up to 44 weeks total

#### APPROVAL CRITERIA

Victrelis will be approved if the patient meets the following criteria:

- I. Patient has a diagnosis of chronic hepatitis C confirmed by the presence of HCV in serum **AND**
- II. Victrelis was prescribed by, or in consultation with, a gastroenterologist, hepatologist, or infectious disease specialist **AND**
- III. Patient has a HCV genotype 1 infection **AND**
- IV. Patient is not co-infected with HIV or hepatitis B, and is not an organ transplant recipient **AND**
- V. Patient is naïve to HCV protease inhibitor therapy **AND**
- VI. Victrelis will be given in combination with PEG-IFN and RBV **AND**
- VII. Victrelis will not be used in combination with any of following drugs:
  - A. Adcirca (tadalafil) or Revatio (sildenafil)
  - B. Uroxatral (alfuzosin)
  - C. Carbamazepine
  - D. Phenytoin
  - E. Phenobarbital
  - F. Ergot derivatives (eg, dihydroergotamine)
  - G. Lovastatin or simvastatin
  - H. Oral midazolam or triazolam
  - I. Pimozide
  - J. Rifampin
  - K. St. John's wort
  - L. Drospirenone**AND**
- VIII. Patient will receive 4 weeks of PEG-IFN and RBV prior to starting Victrelis **AND**

- IX. A sensitive real-time RT-PCR assay will be used for monitoring HCV RNA levels:
  - A. Quantitative limit of detection:  $\leq 25$  IU/mL **OR**
  - B. Qualitative limit of detection: 10-15 IU/mL **AND**
- X. HCV RNA levels will be measured at weeks 4, 8, 12, and 24 of treatment.
  
- XI. Criteria for patients who are HCV treatment naïve
  - A. HCV RNA level is measured at weeks 4 and 8 of treatment **AND**
  - B. HCV RNA is undetectable or level is  $<100$  IU/mL at week 12 of treatment **AND**
  - C. HCV RNA is undetectable at week 24 of treatment
  - D. Patients with cirrhosis or a poor response to PEG-IFN at week 4 (ie,  $<1.0\text{-log}_{10}$  decrease in HCV RNA) will be authorized for up to 44 weeks of Victrelis and up to 48 weeks of PEG-IFN and RBV therapy
  - E. Patients with undetectable HCV RNA at weeks 8 and 24 will be authorized for up to 24 weeks of Victrelis and up to 28 weeks of PEG-IFN and RBV therapy
  - F. Other patients meeting A through C above will be authorized for up to 32 weeks of Victrelis and up to 48 weeks of PEG-IFN and RBV therapy
  
- XII. Criteria for prior relapse patients and patients who were nonresponders to previous HCV treatment
  - A. Patient did not have a null response to prior HCV therapy (ie,  $<2\text{-log}_{10}$  decrease in HCV RNA by week 12 of therapy)
    - 1. Victrelis may be approved for previously-treated patients with:
      - a. Relapse after prior treatment (HCV RNA was undetectable by end of treatment but was detectable during follow up) **OR**
      - b. Partial response to prior treatment (ie,  $\geq 2\text{-log}_{10}$  decrease in HCV RNA by week 12 of therapy)
  - AND**
  - B. HCV RNA level is measured at weeks 4 and 8 of treatment **AND**
  - C. HCV RNA is undetectable or level is  $<100$  IU/mL at week 12 of treatment **AND**
  - D. HCV RNA is undetectable at week 24 of treatment
  - E. Patients with cirrhosis or a poor response to PEG-IFN at week 4 (ie,  $<1.0\text{-log}_{10}$  decrease in HCV RNA) will be authorized for up to 44 weeks of Victrelis and up to 48 weeks of PEG-IFN and RBV therapy
  - F. Patients with undetectable HCV RNA at weeks 8 and 24 will be authorized for up to 32 weeks of Victrelis and up to 36 weeks of PEG-IFN and RBV therapy
  - G. Other patients meeting A through D above will be authorized for up to 32 weeks of Victrelis and up to 48 weeks of PEG-IFN and RBV therapy