Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

catamaran™

VICTRELIS™ (boceprevir)

GPI CODING:

12353015000120

DESCRIPTION:

VICTRELIS (boceprevir) 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 (≥ 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

CRITERIA FOR VICTRELIS

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 the following drugs:
   A. Adcirca (tadalafil) or Revatio (sildenafil)
   B. Uroxatral (alfuzosin)
   C. Carbamazepine
   D. Phenytoin
   E. Phenobarbital
   F. Ergot derivatives (e.g. 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
IX. A sensitive real-time RT-PCR assay will be used for monitoring HCV RNA levels:
   A. Quantitative limit of detection ≤ 25 IU/MI **OR**
   B. Qualitative limit of detection: 10- 15 IU/MI

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 (i.e., <1.0-$\log_{10}$ 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 <u>and</u> 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 <u>not</u> have a null response to prior HCV therapy (i.e., <2-$\log_{10}$ 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 (i.e. ≥ 2-$\log_{10}$ 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 (i.e., <1.0-$\log_{10}$ 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 <u>and</u> 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