Custom Criteria for
BlueCross Blue Shield of Rhode Island Commercial

catamaran

INCIVEK® (telaprevir)

GPI CODING:

12353085000320

DESCRIPTION:

INCIVEK (telaprevir) is a hepatitis C virus (HCV) NS3/4A protease inhibitor indicated, in combination with peginterferon alfa (PEG-IFN) and ribavirin (RBV), for the treatment of genotype 1 chronic hepatitis C in adult patients with compensated liver disease, including cirrhosis, who are treatment-naïve or who have been previously treated with interferon-based treatment, including prior null responders, partial responders, and relapsers.

APPROVAL DURATION:

New start: Up to 4 weeks
Renewal: Up to 12 weeks total

CRITERIA FOR INCIVEK

I. Patient has a diagnosis of chronic hepatitis C confirmed by the presence of HCV in serum **AND**
II. Incivek 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. Incivek will be given in combination with PEG-IFN and RBV **AND**
VII. Incivek will not be used in combination with any of the following drugs:
   A. Adcirca (tadalafil) or Revatio (sildenafil)
   B. Uroxatral (alfuzosin)
   C. Atorvastatin, lovastatin, or simvastatin
   D. Ergot derivatives (e.g. dihydroergotamine)
   E. Oral midazolam or triazolam
   F. Pimozide
   G. Rifampin
   H. St. John's wort

AND

VIII. A sensitive real-time RT-PCR assay will be used for monitoring HCV RNA levels:
   A. Quantitative limit of detection: ≤ 25 IU/mL **OR**
   B. Qualitative limit of detection: 10- 15 IU/mL

AND

IX. HCV RNA levels will be measured at weeks 4, 12, and 24 of treatment

X. Criteria for patients who are HCV treatment naïve and prior relapse patients
   A. HCV RNA is undetectable or level is ≤ 1000 IU/mL at weeks 4 and 12 of treatment
   B. HCV RNA is undetectable at week 24 of treatment (for continuation of PEG-IFN and RBV)

C. Patients with undetectable HCV RNA at weeks 4 and 12 (i.e. extended rapid virologic response) will be authorized for up to 12 weeks of Incivek and up to 24 weeks of PEG-IFN and RBV therapy
D. Patients with cirrhosis and other patients meeting A and B above will be authorized for up to 12 weeks of Incivek and up to 48 weeks of PEG-IFN and RBV therapy

XI. Criteria for patients who were nonresponders to previous HCV treatment (including partial responders and null responders)
A. HCV RNA is undetectable or level is ≤ 1000 IU/MI at weeks 4 and 12 of treatment
B. HCV RNA is undetectable at week 24 of treatment (for continuation of PEG-IFN and RBV)
C. Patients meeting A and B above will be authorized for up to 12 weeks of Incivek and up to 48 weeks of PEG-IFN and RBV therapy