

Specialty Pharmacy Program

Incivek™ (telaprevir)

DESCRIPTION

Incivek 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 (continuation of Incivek therapy): Up to 12 weeks total

(Additional renewals are required for continuation of PEG-IFN and RBV)

APPROVAL CRITERIA

Incivek 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. 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 following drugs:
 - A. Adcirca (tadalafil) or Revatio (sildenafil)
 - B. Uroxatral (alfuzosin)
 - C. Atorvastatin, lovastatin, or simvastatin
 - D. Ergot derivatives (eg, 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 (ie, 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/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 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