Victrelis (boceprevir)

Effective: October 7, 2015

Clinical documentation and prior authorization required ✓ Type of review – case management

Not covered Type of review – clinical review
Fax: 617-673-0988 ✓

Pharmacy (RX) or medical (MED) benefit

OVERVIEW

FDA-APPROVED INDICATIONS
Victrelis (boceprevir) is a protease inhibitor, directly targeting the HCV protease, an enzyme essential for the virus to replicate. It is FDA-approved for the treatment of genotype-1 chronic HCV infection in patients who are treatment naïve or who have previously been treated. Victrelis must be given in combination with PEG-IFN and ribavirin to minimize the emergence of viral resistance.

PHARMACY COVERAGE GUIDELINES
Tufts Health Plan – Network Health may authorize coverage of Victrelis (boceprevir) for members when the following criteria are met and none of the limitations apply:

Initial Criteria
1. The member is 18 years of age or older, with a diagnosis of chronic hepatitis C, genotype 1 AND
2. The member has been evaluated by a gastroenterologist, infectious disease specialist or a physician specializing in the treatment of hepatitis AND
3. The member is not coinfected with HIV or hepatitis B AND
4. Boceprevir be used with ribavirin and peginterferon alfa, and initiated at treatment week 5, i.e. after 4 weeks of pegylated interferon/ribavirin therapy AND
5. The member has not previously used telaprevir (Incivek) or boceprevir (Victrelis) AND
6. The provider submits the member’s baseline HCV-RNA level.

Treatment weeks 12 through 14
1. The member has an HCV RNA level, i.e. viral load, of less than 100 IU/mL at treatment week 12, i.e. after 8 weeks of boceprevir therapy AND
2. The member is currently utilizing ribavirin and peginterferon.

Treatment weeks 24 through 26
3. The member has an undetectable HCV RNA level, i.e. viral load, at treatment week 24, i.e. after 20 weeks of boceprevir therapy (the HCV RNA Quantification assay ≤ 25IU/ml or the HCV RNA Qualification ≤ 10-15 IU/ml may be used to determine an undetectable level) AND
4. The member is currently utilizing ribavirin and peginterferon AND
5. The provider indicate the patient is one of the following:
   a. Treatment naïve and demonstrated interferon non-responsiveness at treatment week 4 (i.e. less than a 0.5 log decrease in HCV-RNA at week 4),
   b. Patient has compensated cirrhosis, OR
   c. Patient was a null responder (i.e. < 2 log reduction in HCV RNA at week 12) to a prior course of pegylated interferon/ribavirin therapy OR
6. The provider indicates that the patient is treatment naïve and demonstrated undetectable levels at treatment weeks 8, 12 and 24 OR
7. The provider indicates that the member had a partial response to a prior course of pegylated interferon/ribavirin therapy but demonstrated undetectable levels at treatment weeks 8, 12 and 24 with current boceprevir/pegylated interferon/ribavirin therapy OR
8. The provider indicates the member had a detectable level at treatment week 8, but undetectable levels at treatment weeks 12 and 24.
LIMITATIONS

1. Victrelis will not be covered for members who are concurrently taking any of the medications that are contraindicated with boceprevir. Medications that are contraindicated with Victrelis include, but are not limited to, carbamazepine, phenobarbital, phenytoin, droperidone-containing oral contraceptives, alfuzosin, the ergot alkaloids (dihydroergotamine, ergonovine, ergotamine, or methylergonovine), cisapride (not available in US), rifampin, St. John’s Wort, lovastatin, simvastatin, pimozide, sildenafil and tadalafil (when used at higher doses for PAH), triazolam or oral midazolam.

2. Authorizations will be as follows:
   a. Initial authorization: 12 tablets per day for 10 weeks.
   b. Treatment weeks 12-14: 12 tablets per day for 12 weeks.
   c. Treatment weeks 24-26: 12 tablets per day for the following durations:
      i. Member is treatment naive and demonstrated interferon non-responsiveness at treatment week 4, has compensated cirrhosis or was a null responder: 22 weeks.
      ii. Member is treatment naive and demonstrated undetectable levels at treatment weeks 8, 12 and 24: 2 weeks.
      iii. Member had a partial response to a prior course of pegylated interferon/ribavirin therapy but demonstrated undetectable levels at treatment weeks 8, 12 and 24 with current boceprevir/pegylated interferon/ribavirin therapy: 10 weeks.
      iv. Member had a detectable level at treatment week 8, but undetectable levels at treatment weeks 12 and 24: 10 weeks.

REFERENCES

Pharmacy Medication Request Guidelines apply to all insured offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable Preferred Drug List (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines, when applicable, and adherence to plan policies and procedures and claims editing logic.