



PHARMACY COVERAGE GUIDELINES
SECTION: DRUGS

NEXT REVIEW DATE: 4th Quarter 2012

ORIGINAL EFFECTIVE DATE: 1-1-2012
LAST REVIEW DATE: New
LAST CRITERIA REVISION DATE: New
ARCHIVE DATE: NA

HEPATITIS C VIRUS (HCV) NS3/4A SERINE PROTEASE INHIBITORS

Incivek™ (Telaprevir)
Victrelis™ (Boceprevir)

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as "**Description**" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "**Criteria**" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational & thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Hepatitis C virus (HCV) protease plays an important role in the reproduction of HCV in genotype 1. HCV protease is an enzyme that acts to cut large proteins into smaller pieces that are used to build new viruses. It is essential for viral replication. Incivek™ and Victrelis™ are inhibitors of the HCV NS3/4A serine protease that is necessary for the proteolytic cleavage of the HCV encoded polyprotein into mature forms of the NS4A, NS4B, NS5A and NS5B proteins. Hepatitis C virus protease inhibitors must not be administered as monotherapy and must only be prescribed with both pegylated interferon alfa and ribavirin. The use of these agents for the treatment of other HCV genotypes has not been fully evaluated at this time. There are no clinical data on re-treating individuals who have failed an HCV NS3/4A protease inhibitor-based treatment, nor are there data on repeated courses.

Precertification:

Precertification* for Incivek™ and Victrelis™ is required for members with a Blue Cross Blue Shield of Arizona (BCBSAZ) retail and mail order prescription benefit. Medications requiring precertification are identified on the following list located on the Internet at <http://www.azblue.com/pdfs/medications/pharmacy/QILList.pdf>:



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"Prescription Limitations and Precertification Requirements for Retail and Mail Order Prescriptions"

This list may also be requested by calling (602) 864-4273 or (800) 232-2345, ext. 4273.

Please refer to this list for other IncivekTM and VictrelisTM prescription claim limitations where applicable.

- * Precertification will not be required for certain individuals who are already receiving IncivekTM and VictrelisTM. Members having at least one BCBSAZ paid claim for IncivekTM and VictrelisTM within the three months preceding the initial effective date of this guideline will not need to obtain precertification.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

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Incivek™ (Telaprevir)

Victrelis™ (Boceprevir)

(cont.)

[Date to be determined]

Criteria:

Incivek™ (Telaprevir)

- FDA-approved dosage of Incivek™ (Telaprevir), in combination with pegylated interferon alfa and ribavirin, is considered **medically necessary** for treatment of chronic hepatitis C virus (HCV) genotype 1 infection in adult patients (18 years of age and older) with compensated liver disease, including cirrhosis, who are treatment-naïve or who have previously been treated with interferon-based treatment, including prior null responders, partial responders, and relapsers and documentation of:
 - Negative pregnancy test prior to initiating therapy with monthly pregnancy tests during treatment for female patients and female partners of male patients
 - Use of at least 2 effective methods of contraception
 - Breast feeding has been discontinued prior to initiation of therapy
 - Individual has no contraindication to both pegylated interferon alfa and ribavirin

Incivek™ (Telaprevir) for all other indications not previously listed, including:

- Co-infection of HCV and HIV
- Co-infection of HCV and Hepatitis B virus
- HCV genotypes other than genotype 1
- Individuals with solid organ transplants
- Individuals with moderate or severe hepatic impairment (Child-Pugh B or C, score greater than or equal to 7)
- Individuals with decompensated liver disease

is considered experimental or investigational based upon;

1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
2. Insufficient evidence to support improvement of the net health outcome, and
3. Insufficient evidence to support improvement of the net health outcome as much as, or more than established alternatives

Criteria:

Victrelis™ (Boceprevir)

- FDA-approved dosage of Victrelis™ (Boceprevir), in combination with pegylated interferon alfa and ribavirin, is considered **medically necessary** for treatment of chronic hepatitis C virus (HCV) genotype 1 infection in adult patients (18 years of age and older) with compensated liver disease, including cirrhosis, who are previously untreated or who have failed interferon and ribavirin therapy, including prior partial responders, and relapsers and documentation of:
 - Negative pregnancy test prior to initiating therapy with monthly pregnancy tests during treatment for female patients and female partners of male patients
 - Use of at least 2 effective methods of contraception



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- Breast feeding has been discontinued prior to initiation of therapy
- Individual has no contraindication to both pegylated interferon alfa and ribavirin

Victrelis™ (Boceprevir) for all other indications not previously listed, including:

- Co-infection of HCV and HIV
- Co-infection of HCV and Hepatitis B virus
- HCV null responders to previous prgylated interferon alfa and ribavirin
- HCV genotypes other than genotype 1
- Individuals with solid organ transplants
- Individuals with decompensated liver disease

is considered experimental or investigational based upon;

1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
2. Insufficient evidence to support improvement of the net health outcome, and
3. Insufficient evidence to support improvement of the net health outcome as much as, or more than established alternatives

History:

Date:

Activity:

Pharmacy and Therapeutics review	August 2011	Adopted guideline
Director Pharmacy Mgmt review	August 2011	Development

Criteria Revisions:



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Incivek™ (Telaprevir)

Victrelis™ (Boceprevir)

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Resources:

Incivek™ (Telaprevir) package insert issued May 2011, review on June 28, 2011

Victrelis™ (Boceprevir) package insert (34965510T) issued May 2011, review on June 28, 2011

FDA Product Approval Information for Incivek™ (Telaprevir):

FDA-approved indication: For the treatment chronic hepatitis C virus (HCV) genotype 1 infection in adult patients (18 years of age and older) with compensated liver disease, including cirrhosis, who are treatment-naïve or who have previously been treated with interferon-based treatment, including prior null responders, partial responders, and relapsers.

The recommended dose of Incivek™ tablets is 750 mg (two 375-mg tablets) taken orally 3 times a day (7-9 hours apart) with food (not low fat). The dose of Incivek™ must not be reduced or interrupted.

In patients who respond to therapy, the duration of Incivek™ combination therapy is 12 weeks. After the first 12 weeks, patients should receive an additional 12 weeks or 36 weeks of pegylated interferon and ribavirin treatment depending upon response to treatment and use of previous HCV therapy.

FDA Product Approval Information for Victrelis™ (Boceprevir):

FDA-approved indication: For the treatment of chronic hepatitis C virus (HCV) genotype 1 infection in adult patients (18 years of age and older) with compensated liver disease, including cirrhosis, who are previously untreated or who have failed interferon and ribavirin therapy, including prior partial responders, and relapsers.

The dose of Victrelis™ is 800 mg (four 200-mg capsules) three times daily (every 7-9 hours) with food [a meal or light snack]. The dose of Victrelis™ must not be reduced or interrupted.

The duration of Victrelis™ combination therapy will depend upon response to therapy and use of previous HCV therapy and will range from 24 weeks to 44 weeks for patients who respond to therapy.



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