

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

I. Requirements for Prior Authorization of Hepatitis C Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Interferon, HCV Protease Inhibitors, and non-preferred Hepatitis C Agents must be prior authorized. See the most recent version of the Preferred Drug List (PDL), which includes a list of preferred Hepatitis C Agents, at:

www.providersynergies.com/services/documents/PAM_PDL.pdf

B. Review of Documentation for Medical Necessity

In evaluating an initial request for prior authorization of a prescription for an Interferon, an HCV Protease Inhibitor, or a non-preferred Hepatitis C Agent, the determination of whether the recipient:

1. Has a documented history of a pattern of abstinence from alcohol and drugs prior to treatment; for recipients with a history of substance dependency, the abstinence is supported by lab testing (such as blood alcohol level [BAL] and urine drug screen [UDS])

AND

2. Was determined to be a candidate for Hepatitis C treatment as follows:
 - a. Was evaluated and treated by a psychiatrist if the recipient has a history of prior suicide attempt, bipolar disorder, major depressive disorder, schizophrenia, substance dependency disorders, anxiety disorders, borderline personality disorder or antisocial personality disorder

OR

- b. For all others, had a mental health evaluation performed by the prescriber

AND

3. Is compliant with treatment if currently being treated for substance dependency

AND

4. Is prescribed a dose and length of therapy that is consistent with FDA approved labeling

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AND

5. Has a diagnosis of chronic Hepatitis C

AND

6. Is prescribed the medication by a specialist (infectious disease, gastroenterology, hepatology, transplant)

AND

7. Has a documented Hepatitis C genotyping

AND

8. Has a documented quantitative HCV RNA at baseline that was tested within the past 3 months

AND

9. Does not have a contraindication or intolerance of Hepatitis C Agents, such as but not limited to, autoimmune hepatitis or hepatic decompensation

AND

10. If taking any agent in combination with ribavirin:

- a. Has a pretreatment platelet count $\geq 90,000$ cells/mm³

AND

- b. Has a pretreatment absolute neutrophil count (ANC) ≥ 1500 cells/mm³

AND

- c. Has a pretreatment hemoglobin of at least 10 g/dL

AND

- d. If female:

- i. Has had a negative pregnancy test immediately prior to initiating therapy

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AND

- ii. Will be using two or more forms of contraception

AND

- iii. Will have monthly pregnancy tests during therapy

AND

11. For Pegasys - Whether the recipient:

- a. Is 5 years of age or older

AND

- b. Does not have a history of treatment failure with pegylated interferon in combination with ribavirin unless being used for retreatment with a HCV Protease Inhibitor, or recipient has a contraindication to HCV Protease Inhibitor, and retreatment is supported by current AASLD guideline

AND

12. For non-preferred ribavirin products, a documented history of contraindication or intolerance of a preferred ribavirin product

AND

13. For Infergen:

- a. Is 18 years of age or older

AND

- b. Has a documented history of a contraindication or intolerance of a preferred and non-preferred pegylated interferon

OR

- c. Has a history of treatment failure with pegylated interferon in combination with ribavirin and has a contraindication to HCV Protease Inhibitor

AND

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14. For Peg-Intron and Peg-Intron Redipens:

- a. Is 3 years of age or older and is receiving combination therapy with ribavirin

AND

- b. Does not have a history of treatment failure with pegylated interferon in combination with ribavirin unless being used for retreatment with a HCV Protease Inhibitor, or recipient has a contraindication to HCV Protease Inhibitor, and retreatment is supported by current AASLD guideline

AND

15. For a HCV Protease Inhibitor:

- a. Has a diagnosis of chronic hepatitis C genotype 1

AND

- b. Is 18 years of age or older

AND

- c. Does not have a history of solid organ transplant

AND

- d. Is not co-infected with HIV

AND

- e. Is being prescribed an HCV Protease Inhibitor by one of the following specialists: infectious disease, gastroenterology or hepatology

AND

- f. Is being prescribed an HCV Protease Inhibitor for use in combination with pegylated interferon alpha and ribavirin

AND

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- g. Does not have a history of previously failed therapy for hepatitis C with a treatment regimen that includes Victrelis, Incivek or another HCV Protease Inhibitor

AND

- h. Does not have a history of an incomplete course of therapy for hepatitis C with a treatment regimen that includes HCV Protease Inhibitor due to non-compliance with medications and/or Hepatitis C therapy management.

AND

- i. Does not have a contraindication to the requested HCV Protease Inhibitor

AND

- j. Had any potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the recipient of the risks associated with the use of both medications when they interact)

AND

- k. If taking a buprenorphine agent or methadone, was cleared for treatment of hepatitis by the prescriber of buprenorphine or methadone

AND

- l. If female, will be using two non-hormonal forms of contraception

OR

- 16. Does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

In evaluating a request for a renewal of prior authorization of a prescription for an interferon, a HCV Protease Inhibitor or a non preferred ribavirin product, the determination of whether the requested prescription is medically necessary will take into account whether the recipient:

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1. Meets the medical necessity guidelines for the specific medication as listed above

AND

2. For any agent taken in combination with ribavirin, had:
 - a. A CBC at weeks 4, 8, and 12 of therapy and any signs of neutropenia or anemia have been addressed

AND

- b. If female, documentation of monthly pregnancy tests during therapy

AND

3. Has genotype 1, and if treated with:
 - a. Interferon monotherapy or interferon/ribavirin dual therapy, has a documented quantitative HCV RNA tested at week 12 of therapy **AND**
 - i. Achieved undetectable serum HCV RNA at treatment week 12 compared to baseline

OR

- ii. Achieved at least a 2-log reduction in serum HCV RNA that remains detectable at treatment week 12 compared to baseline

AND

- iii. Achieved undetectable HCV RNA at treatment week 24

OR

- b. Victrelis, has a documented quantitative HCV RNA tested at treatment weeks 4, 8, 12, and 24 of therapy **AND** has not met fertility rules for the medication

OR

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- c. Incivek, has a documented quantitative HCV RNA tested at treatment weeks 4, 12, and 24 of therapy AND has not met futility rules for the medication

OR

- 4. Has genotype 4, **AND**

- a. Achieved undetectable serum HCV RNA at treatment week 12 compared to baseline

OR

- b. Achieved at least a 2-log reduction in serum HCV RNA at treatment week 12 compared to baseline

AND

- c. Achieved undetectable HCV RNA at treatment week 24

OR

- 5. Has genotype 2 or 3, in which case the request will be referred to a physician reviewer for a determination of medical necessity

OR

- 6. Does not meet the guidelines listed above, the request for renewal of prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient

In evaluating a request for prior authorization of a prescription for an interferon, a HCV protease inhibitor, or a non-preferred ribavirin product for re-treatment with a Hepatitis C Agent, the determination of whether the requested prescription is medically necessary will take into account whether the recipient:

- 1. Meets the medical necessity guidelines for an initial request for prior authorization

AND

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2. Corrected or addressed causes of non-compliance if the recipient has a history of failed treatment due to noncompliance

AND

3. Does not have a history of hospitalization due to side effects of the Hepatitis C Agent such as optic nerve changes, suicidal ideation, attempted suicide or manic episode attributable to interferon treatment.

AND

4. Completed:
 - a. A course of treatment with a non-pegylated interferon and the request is for a pegylated interferon

OR

- b. A monotherapy course of treatment with a pegylated interferon, and will now be treated with combination pegylated interferon and ribavirin

OR

- c. A course of treatment with a non-pegylated or pegylated interferon and the request is for a HCV NS3/4A HCV Protease Inhibitor

OR

5. Does not meet the guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient

C . Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of an initial request and a request for a renewal of prior authorization of a prescription for an Interferon, an HCV Protease Inhibitor, or a non-preferred Hepatitis C Agent. If the guidelines in Section B are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the

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physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

All requests for prior authorization of a prescription for an interferon, an HCV Protease Inhibitor, or a non-preferred Hepatitis C Agent for re-treatment with a Hepatitis C Agent will be automatically forwarded to a physician reviewer for a medical necessity determination.

The physician reviewer will prior authorize the prescription when:

1. The guidelines for re-treatment in Section B. are met, **OR**
2. In the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

D. Dose and Duration of Therapy

Approvals of requests for prior authorization of Hepatitis C Agents will be consistent with package labeling.

E. Resources

1. US Department of Veteran Affairs, Management and Treatment of Hepatitis C Viral Infection, October 2006
2. Ghany et.al. AASLD Practice Guidelines Diagnosis, Management, and Treatment of Hepatitis C: An Update. Hepatology, April 2009, 1335-1374
3. Incivek prescribing information. Vertex Pharmaceuticals Inc. Cambridge, MA. 2011
4. Victrelis prescribing information. Merck & Co. Inc. Whitehouse Station, NJ. May 2011