

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 Hepatitis C Agents that meet any of the following conditions must be prior authorized:

1. Interferon
2. HCV Protease Inhibitors
3. Sofosbuvir (Sovaldi)
4. Non-preferred Hepatitis C Agents - 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
5. A prescription for a Hepatitis C Agent with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at:
<http://www.dpw.state.pa.us/provider/doingbusinesswithdpw/pharmaservices/quantitylimitslist/index.htm>

B. Review of Documentation for Medical Necessity

In evaluating an initial request for prior authorization of a prescription for a Hepatitis C Agent, the determination of whether the requested prescription is medically necessary will take in account the following:

1. For combination therapy, including sofosbuvir (Solvaldi), whether the recipient:
 - a. Has a diagnosis of chronic Hepatitis C with documented genotyping

AND

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

AND

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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

AND

d. Is 18 years of age or older

AND

e. Does not have severe renal impairment or end stage renal disease

AND

f. Has a documented history of a pattern of abstinence from alcohol and drugs for at least 6 months prior to treatment.

AND

g. For a recipient with a history of substance dependence:

i. Has lab testing (such as blood alcohol level [BAL] and urine drug screen [UDS]) that support abstinence

AND

ii. Is compliant with treatment if currently being treated for substance dependence

AND

h. Has a Metavir fibrosis score of F3 or F4 documented by a recent:

i. Non-invasive test such as a blood test depicting liver fibrosis or a fibroscan **OR**

ii. An invasive test such as a liver biopsy

AND

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

AND

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- j. Does not have a history of previously failed therapy for hepatitis C with a treatment regimen that included sofosbuvir (Sovaldi)

AND

- k. Does not have a history of an incomplete course of therapy for Hepatitis C with a treatment regimen that included sofosbuvir (Sovaldi) due to non-compliance with medications and/or Hepatitis C therapy management.

AND

- l. Had all 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

- m. When prescribed interferon:
 - i. Was counseled about the risks and benefits of initiating current treatment or deferring for future treatment

AND

- ii. Was evaluated and treated by a psychiatrist if the recipient has a history of any of the following: prior suicide attempt, bipolar disorder, major depressive disorder, schizophrenia, substance dependence disorder, anxiety disorder, borderline personality disorder or antisocial personality disorder

OR

- iii. Had a mental health evaluation performed by the prescriber if the recipient does not have any of the diagnoses listed above

AND

- n. When prescribed ribavirin:
 - i. Has a pretreatment platelet count $\geq 90,000$ cells/mm³

AND

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- ii. Has a pretreatment absolute neutrophil count (ANC) \geq 1500 cells/mm³

AND

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

AND

- iv. If female:

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

AND

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

AND

- iii. Will have monthly pregnancy tests during therapy

AND

- o. For a diagnosis of Genotype 1, is prescribed :sofosbuvir (Sovaldi) in combination with;

- i. Pegylated interferon alpha and ribavirin

OR

- ii. Simeprevir (Olysio) if interferon ineligible

NOTE: Interferon ineligible is defined as one or more of the following:

- Autoimmune hepatitis and other autoimmune disorders
- Hypersensitivity to interferon or any of its components
- Decompensated hepatic disease
- History of depression with suicidality or resulting in hospital admission and the recipient is currently receiving antidepressant therapy

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- A baseline neutrophil count below 1500/ μ L, a baseline platelet count below 90,000/ μ L or baseline hemoglobin below 10 g/dL
- A history of preexisting unstable cardiac disease

AND

- p. For a diagnosis of Genotype 2, is prescribed sofosbuvir (Sovaldi) in combination with ribavirin

AND

- q. For a diagnosis of Genotype 3, is prescribed sofosbuvir (Sovaldi) in combination with:

- i. Pegylated interferon alpha and ribavirin

OR

- ii. Ribavirin if interferon ineligible

AND

- r. For a diagnosis of Genotype 4, is prescribed sofosbuvir (Sovaldi) in combination with pegylated interferon alpha and ribavirin

AND

2. For combination therapy including simeprevir (Olysio) whether the recipient:

- a. Has a diagnosis of chronic hepatitis C, Genotype 1

AND

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

AND

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

AND

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

d. Is 18 years of age or older

AND

e. Has a documented history of a pattern of abstinence from alcohol and drugs for at least 6 months prior to treatment.

AND

f. For recipients with a history of substance dependence:

i. Has lab testing (such as blood alcohol level [BAL] and urine drug screen [UDS]) that support abstinence

AND

ii. Is compliant with treatment if currently being treated for substance dependence

AND

g. Has a documented non-invasive liver fibrosis panel or liver biopsy

AND

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

AND

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

AND

j. Had all 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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

- k. When prescribed in combination with interferon and ribavirin, does not have HCV genotype 1a with an NS3 Q80K polymorphism

AND

- l. When prescribed interferon:

- i. Was counseled about the risks and benefits of initiating current treatment or deferring for future treatment without interferon

AND

- ii. Was evaluated and treated by a psychiatrist if the recipient has a history of any of the following: prior suicide attempt, bipolar disorder, major depressive disorder, schizophrenia, substance dependency disorders, anxiety disorders, borderline personality disorder or antisocial personality disorder was evaluated and treated by a psychiatrist,

OR

- iii. Had a mental health evaluation performed by the prescriber, if the recipient does not have any of the diagnoses listed above

AND

- m. When prescribed ribavirin:

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

AND

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

AND

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

AND

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

iv. If female:

a) Had a negative pregnancy test immediately prior to initiating therapy

AND

b) Will be using two or more forms of contraception

AND

c) Will have monthly pregnancy tests during therapy

AND

3. For non-preferred Hepatitis C Agents, whether the recipient has a documented history of therapeutic failure, contraindication or intolerance to the preferred Hepatitis C Agents.

OR

4. 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 addition, if a prescription for either a preferred or non-preferred Hepatitis C Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

IN EVALUATING A REQUEST FOR PRIOR AUTHORIZATION OF A PRESCRIPTION FOR RE-TREATMENT OF HEPATITIS C 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 as listed above

AND

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

OR

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

3. 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 for prior authorization of a prescription for an Interferon, an HCV Protease Inhibitor, sofosbuvir (Sovaldi), 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 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, sofosbuvir (Sovaldi), 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

MEDICAL ASSISTANCE HANDBOOK
PRIOR AUTHORIZATION OF PHARMACEUTICAL SERVICES

4. Victrelis prescribing information. Merck & Co. Inc. Whitehouse Station, NJ. May 2011
5. US Department of Veteran Affairs, Management and Treatment of Hepatitis C Viral Infection, October 2006
6. Ghany et.al. AASLD Practice Guidelines Diagnosis, Management, and Treatment of Hepatitis C: An Update. Hepatology, April 2009, 1335-1374
7. Incivek prescribing information. Vertex Pharmaceuticals Inc. Cambridge, MA. 2011
8. Victrelis prescribing information. Merck & Co. Inc. Whitehouse Station, NJ. May 2011
9. Olysio prescribing information. Janssen Therapeutics. Titusville, NJ. November 2013
10. Sovaldi prescribing information. Gilead Sciences Inc. Foster City, CA. December 2013
11. Use in Patients With HCV and HIV Coinfection—OLYSIO. JanssenMD, Professional Information Recourse. Janssen Scientific Affairs, modified on November 27, 2013.
12. Davis et.al. AASLD/IDSA Recommendations for Testing, Managing, and Treating Hepatitis C. www.hcvguidelines.org. Accessed January 30, 2014.