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. Hepatitis C Virus (HCV) Direct Acting Antivirals

3. 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

4. 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/pharmacyservices/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 into account whether the recipient:

1. Has a diagnosis of chronic Hepatitis C with documented genotyping

AND

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

AND

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

AND

4. Is 18 years of age or older

AND

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

AND

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

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

    AND

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

AND

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

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

    b. An invasive test such as a liver biopsy

AND

8. Does not have a limited life expectancy of less than 12 months due to non-liver-related comorbid conditions

AND

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

AND

10. Does not have a history of previously failed therapy for hepatitis C with a treatment regimen that included the requested HCV direct acting antiviral

AND

11. Does not have a history of an incomplete course of therapy for Hepatitis C with a treatment regimen that included the requested HCV direct acting antiviral due to non-compliance with medications and/or Hepatitis C therapy management.

AND

12. 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

13. For combination therapy, including sofosbuvir:

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

    AND

    b. Has a diagnosis of Genotype1 and is:

        i. HCV treatment naive without cirrhosis and prescribed ledipasvir/sofosbuvir (Harvoni) for 8 weeks if HCV RNA levels are less than 6 million IU/mL or 12 weeks if ≥6 million IU/mL **OR**

        ii. HCV treatment naive with cirrhosis and prescribed ledipasvir/sofosbuvir (Harvoni) for 12 weeks **OR**

        iii. HCV treatment experienced without cirrhosis and is prescribed ledipasvir/sofosbuvir (Harvoni) for 12 weeks **OR**

        iv. HVC treatment experienced with cirrhosis and prescribed ledipasvir/sofosbuvir (Harvoni) monotherapy for 24 weeks

OR

c. Has a diagnosis of Genotype 2 and is prescribed sofosbuvir (Sovaldi) in combination with ribavirin

OR

d. Has a diagnosis of Genotype 3 and is prescribed sofosbuvir (Sovaldi) in combination with:

i. Pegylated interferon alpha and ribavirin, **OR**

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

OR

e. Has a diagnosis of Genotype 4 and is prescribed sofosbuvir (Sovaldi) in combination with pegylated interferon alpha and ribavirin

AND

14. When prescribed interferon:

a. Was counseled about the risks and benefits of initiating current treatment or deferring for future treatment

AND

b. 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

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

AND

15. When prescribed ribavirin:

a. Has a pretreatment platelet count ≥ 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. 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

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

OR

17. 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

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, a HCV direct acting antiviral, 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, a HCV direct acting antiviral, , 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. Merk & 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. Merk & 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.