STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES
BUREAU FOR MEDICAL SERVICES

Office of Pharmacy Service
Prior Authorization Criteria

HARVONI® (ledipasvir/sofosbuvir) for Hepatitis C (HCV)

Harvoni is a two-drug fixed-dose combination product containing 90 mg ledipasvir and 400 mg sofosbuvir. Harvoni is indicated for the treatment of adult patients diagnosed with hepatitis C genotype 1.

Criteria for Approval

1) Patient must be eighteen (18) years of age or older; **AND**

2) Harvoni must be prescribed by, or in conjunction with, a board certified gastroenterologist, hepatologist or infectious disease physician; **AND**

3) Patient must be diagnosed with Hepatitis C Genotype 1; **AND**

4) Patient must have a documented diagnosis of **cirrhosis** or a **fibrosis level of F3 or greater** (see below under Diagnostic/Disease Severity Evidence); **AND**

5) Patient must be sofosbuvir (including Harvoni) treatment naïve; **AND**

6) Patient must **not** be co-infected with HIV; **AND**

7) Patient must **not** be awaiting liver transplant (Harvoni is not indicated in this population); **AND**

8) Patient has abstained from the use of illicit drugs and alcohol for a minimum of six (6) months, as indicated by the patient's signature on the Patient Consent form; **AND**

9) Patient must be vaccinated against Hepatitis A and Hepatitis B; **AND**

10) Patient must agree to complete the full regimen and the patient and the provider must agree that an SVR12 and SVR24 will be collected and submitted to WV Medicaid to verify therapy success;

Duration of Approval

- Initial approval is for 6 weeks and requires submission of the starting HCV RNA level (*See Table 1 for the list of accepted regimens)*.

- Continued coverage after week 6 depends upon receipt of an HCV RNA level at treatment week 4 (TW4), documentation of patient compliance, continued abstinence and an HCV RNA < 25 IU/ml. **Failure to obtain and report a treatment week 4 HCV RNA load will result in denial of further coverage.**

Table 1. Accepted Regimens and Treatment Duration for HCV Therapy

Diagnosis	Approved Regimen	Duration
Genotype 1 - Treatment Naïve - HCV RNA <6 mil IU/ml without cirrhosis	Harvoni	8 weeks
Genotype 1 - Treatment Naïve - HCV RNA >6 mil IU/ml OR who have compensated cirrhosis	Harvoni	12 weeks
Genotype 1 - Treatment Experienced[1] without cirrhosis	Harvoni	12 weeks
Genotype 1 - Treatment Experienced[1] with cirrhosis OR patients with decompensated cirrhosis	Harvoni + ribavirin	12 weeks

[1]**TREATMENT EXPERIENCED** patients are defined as those who have failed a previous regimen containing peginterferon alfa + ribavirin or an HCV protease inhibitor + peginterferon alfa + ribavirin. Patients previously treated with a sofosbuvir-containing regimen will not be covered except at the discretion of the Medical Director of the Bureau of Medical Services.

ALL OTHER REGIMEN REQUESTS WILL BE CONSIDERED ON A CASE-BY-CASE BASIS

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Diagnostic/Disease Severity Evidence (must be attached to request)

1) Cirrhosis may be substantiated either through biopsy or the presence of **at least two (2)** of the following clinical features:
    a. Cirrhotic features on imaging
    b. Ascites
    c. Esophageal varices
    d. Reversed AST:ALT ratio (> 1), thrombocytopenia (< 130,000 platelets/μL), and coagulopathy (INR > 2)

2) Fibrosis level must be substantiated via biopsy or other accepted method (e.g. FibroSure Assay)

Criteria for Denial

1) Prescription for any other HCV anti-viral medication.

2) Patient has HIV co-infection.

3) Diagnosis for any genotype other than GT 1.

4) Patient is awaiting liver transplant.

5) Patient is post-liver transplant (safety and efficacy have not been established).

6) Patient is not sofosbuvir naïve.

7) Prescriber has determined that the patient has not abstained from the use of illicit drugs and/or alcohol for at least six (6) months prior to the start of treatment.

8) Patient has severe renal impairment (eGFR < 30 mL/min/1.73m2) or end stage renal disease (ESRD) requiring hemodialysis.

9) Patient is taking a concomitant medication that has a significant clinical interaction with sofosbuvir:
    a. tipranavir/ritonavir
    b. rifampin, rifabutin, rifapentine
    c. carbamazepine, phenytoin, phenobarbital, oxcarbazepine
    d. St. John's wort

10) **Requests for continuation of coverage will be denied if the patient has an HCV RNA level >25 IU/ml OR if the prescriber has not submitted or has not obtained a viral load at treatment week 4.**

Additional Considerations

1) Sofosbuvir is a nucleotide analog NS5B polymerase inhibitor.

2) Ledipasvir is an inhibitor of the hepatitis C virus NS5A protein.

3) Coverage shall be for one successful course of therapy in a lifetime. Success of therapy shall be judged by undetectable SVR12 and SVR24 HCV RNA levels. If RNA levels have not been submitted, then it will be assumed that therapy was successful. Re-infection will not be covered. Exceptions may be allowed on a case-by-case basis.

4) Lost or stolen medication replacement request will not be authorized.

References

1) Harvoni [package insert]. Foster City, CA; Gilead, October 2014.
2) Sovaldi [package insert]. Foster City, CA; Gilead, December 2013.
3) FDA Antiviral Drugs Advisory Committee Meeting, October 25, 2013; Background Package for NDA 204671 sofosbuvir (GS-7977).
4) Lawitz E, Mangia A, Wyles D, et al. Sofosbuvir for previously untreated chronic hepatitis C infection. *N Engl J Med*. 2013; 368:1878-87. doi: 10.1056/NEJMoa1214853. Available at: http://www.nejm.org/doi/pdf/10.1056/NEJMoa1214853. Accessed January 2, 2014.
5) Jacobson IM, Gordon SC, Kowdley KV, et al. Sofosbuvir for hepatitis C genotype 2 or 3 in patients without treatment options. *N Engl J Med.* 2013;368:1867-77. doi: 10.1056/NEJMoa1214854. Available at: http://www.nejm.org/doi/pdf/10.1056/NEJMoa1214854. Accessed January 2, 2014.
6) American Association for the Study of Liver Diseases Infectious Diseases Society of America: Recommendations for testing, managing and treating hepatitis C. Available at: http://www.hcvguidelines.org/. Accessed February 18, 2014.
7) Poynard T, Ratziu V, Benmanov Y, DiMartino V, Bedossa P, Opolon P. Fibrosis in patients with hepatitis c: detection and significance. *Semin Liver Dis*. 2000;20(1). Retrieved from www.medscape.com. Accessed February 26, 2014.
8) Flamm SL, Everson GT, Charlton M et al. Ledipasvir/sofosbuvir with ribavirin for the treatment of HCV in patients with decompensated cirrhosis: preliminary results of a prospective, multicenter study. 65th Annual Meeting of the American Association for the Study of Liver Diseases (AASLD). November 1-5, 2014; Boston, MA

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Viekira Pak™ (ombitasvir/paritaprevir/ritonavir + dasabuvir)

Viekira Pak™ with or without ribavirin is indicated for the treatment of patients with genotype 1 chronic hepatitis C virus (HCV) infection including those with compensated cirrhosis. The product includes ombitasvir, a hepatitis C virus NS5A inhibitor, paritaprevir, a hepatitis C virus NS3/4A protease inhibitor, ritonavir, a CYP3A inhibitor (used as a booster), and dasabuvir, a hepatitis C virus non-nucleoside NS5B palm polymerase inhibitor.

Criteria for Approval

1) Documented failure or contraindication to a preferred HCV therapy; **AND**

2) Patient must be eighteen (18) years of age or older; **AND**

3) Viekira Pak™ must be prescribed by, or in conjunction with, a board certified gastroenterologist, hepatologist or infectious disease physician; **AND**

4) Patient must be diagnosed with Hepatitis C Genotype 1; **AND**

5) Patient must have a documented diagnosis of **compensated cirrhosis** or a **fibrosis level of F3 or greater** (see below under Diagnostic/Disease Severity Evidence); **AND**

6) Patient has abstained from the use of illicit drugs and alcohol for a minimum of six (6) months, as indicated by the patient's signature on the Patient Consent form; **AND**

7) Patient must be vaccinated against Hepatitis A and Hepatitis B; **AND**

8) Patient must agree to complete the full regimen and the patient and the provider must agree that an SVR12 and SVR24 will be collected and submitted to WV Medicaid to verify therapy success;

Duration of Approval

- Initial approval is for 6 weeks and requires submission of the starting HCV RNA level (*See Table 1 for the list of accepted regimens)*.

- Continued coverage after week 6 depends upon receipt of an HCV RNA level at treatment week 4 (TW4), documentation of patient compliance, continued

abstinence and an HCV RNA < 25 IU/ml. **Failure to obtain and report a treatment week 4 HCV RNA load will result in denial of further coverage.**

Table 1. FDA Approved Regimens and Treatment Duration for Treatment Naïve or Interferon Experienced Patients**

Diagnosis	Approved Regimen	Duration
Genotype 1a – without cirrhosis	Viekira Pak™ + ribavirin	12 weeks
Genotype 1a – with cirrhosis	Viekira Pak™ + ribavirin	12 or 24 weeks*
Genotype 1b – without cirrhosis	Viekira Pak™	12 weeks
Genotype 1b – with cirrhosis	Viekira Pak™ + ribavirin	12 weeks
HCV/HIV-1 Co-Infection	Appropriate monotherapy listed above	12 or 24 weeks
(Post) Transplant Patients	Viekira Pak™	24 weeks

***Null Responders who have previously been treated with another HCV regimen shall be eligible for 24 weeks of coverage.**

****REGIMENS NOT LISTED ABOVE WILL BE CONSIDERED ON A CASE BY CASE BASIS WITH SUPPORTING DOCUMENTATION**

<u>Diagnostic/Disease Severity Evidence (must be attached to request)</u>

1) Cirrhosis may be substantiated either through biopsy or the presence of **at least two** of the following clinical features:
    a. Cirrhotic features on imaging
    b. Ascites
    c. Esophageal varices
    d. Reversed AST:ALT ratio (> 1), thrombocytopenia (< 130,000 platelets/μL), and coagulopathy (INR > 2)

2) Fibrosis level must be substantiated via biopsy or other accepted method (e.g. FibroSure Assay)

Criteria for Denial

1) Prescription for any other HCV anti-viral medication.

2) Diagnosis for any genotype other than GT 1.

3) Patient has Child-Pugh score of B or C.

4) Patient has not received a preferred regimen of HCV therapy or has no contra-indication to a preferred regimen.

5) Patient has been previously treated with Viekira Pak™.

6) Prescriber has determined that the patient has not abstained from the use of illicit drugs and/or alcohol for at least six (6) months prior to the start of treatment.

7) Patient is on dialysis.

8) Patient is taking a concomitant medication that has a significant clinical interaction with Viekira Pak™ (refer to package insert for a listing of interacting medications).

9) **Requests for continuation of coverage will be denied if the patient has an HCV RNA level >25 IU/ml OR if the prescriber has not submitted or has not obtained a viral load at treatment week 4.**

Additional Considerations

1) Coverage shall be for one successful course of therapy in a lifetime. Success of therapy shall be judged by undetectable SVR12 and SVR24 HCV RNA levels. If RNA levels have not been submitted, then it will be assumed that therapy was successful. Re-infection will not be covered. Exceptions may be allowed on a case-by-case basis.

2) Lost or stolen medication replacement request will not be authorized.

References

9) Viekira Pak™ [package insert]. Abbvie, Revised 2/2015
10) AASLD 2015 Recommendations for Testing, Managing and Treating Hepatitis C (http://www.hcvguidelines.org)

Version 4 – DUR Board reviewed and approved with changes (02-25-2015)
ersion 4.2 - created 03-09-2015 (BMT)