



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



Office of Pharmacy Services Prior Authorization Criteria

HARVONI® (ledipasvir/sofosbuvir)

Effective 2/19/2016

[Prior Authorization Request Form](#)
[Prior Authorization Continuation Request Form](#)
[Patient Consent Form](#)
[Preferred HepC Regimens \(Attachment A\)](#)

Harvoni® is a two-drug fixed-dose combination product containing 90 mg ledipasvir (a hepatitis C virus (HCV) NS5A inhibitor), and 400 mg sofosbuvir (an HCV nucleotide analog NS5B polymerase inhibitor). Harvoni is indicated for the treatment of adult patients diagnosed with chronic hepatitis C genotype 1, 4, 5 or 6 infection.

Criteria for Approval

- 1) All documentation must be fully completed, including the patient consent form. A fibrosis score substantiated by a validated evidence-based method must be reported when requesting prior authorization; **AND**
- 2) Patient must have a documented **fibrosis level \geq F3**; **AND**
- 3) Patient must be eighteen (18) years of age or older; **AND**
- 4) Harvoni must be prescribed by, or in conjunction with, a board certified gastroenterologist, hepatologist or infectious disease physician; **AND**
- 5) Patient must be diagnosed with chronic Hepatitis C Genotype 1, 4, 5, or 6; **AND**
- 6) Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months, as indicated by their signature on the Patient Consent form; **AND**
- 7) 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

- A list of accepted regimens and treatment duration for chronic Hepatitis C therapy may be found in [Attachment A](#).
- Initial approval is for 6 weeks and requires submission of the starting HCV RNA level
- 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.**



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



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

- 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 (MRI, ultrasound, or CT)
 - b. Ascites
 - c. Esophageal varices
 - d. Reversed AST:ALT ratio (> 1), thrombocytopenia ($< 130,000$ platelets/ μL), and coagulopathy (INR > 2)

Criteria for Denial

- 1) Requests submitted with incomplete documentation will be denied.
- 2) Failure to report a fibrosis score.
- 3) Evidence exists that the patient has abused any illicit substance or alcohol in the past three (3) months.
- 4) Patient has severe renal impairment (eGFR < 30 mL/min/1.73m²) or end stage renal disease (ESRD) requiring hemodialysis.
- 5) Patient has been previously treated with **ledipasvir/sofosbuvir**.
- 6) 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
- 7) **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) It is highly recommended that the patient vaccinated against Hepatitis A and Hepatitis B.
- 2) Sofosbuvir is a nucleotide analog NS5B polymerase inhibitor.
- 3) Ledipasvir is an inhibitor of the hepatitis C virus NS5A protein.



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



- 4) **For HCV/HIV co-infections all requests must be reviewed for drug-drug interactions prior to approval. Please submit a list of the patient's current HIV regimen along with your request for coverage of Harvoni.**
- 5) 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.
- 6) Lost or stolen medication replacement request will not be authorized.

References

- 1) Harvoni [package insert]. Foster City, CA; Gilead, February 2016.
- 2) FDA Antiviral Drugs Advisory Committee Meeting, October 25, 2013; Background Package for NDA 204671 sofosbuvir (GS-7977).
- 3) 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 23, 2015.
- 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) 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.
- 7) 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
- 8) Heidelbaugh JJ and Bruderly M. Cirrhosis and Chronic Liver Failure: Part I. Diagnosis and Evaluation. *Am Fam Physician*. 2006 Sep 1;74(5):756-762.