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

Prior Authorization Criteria
SOVALDI® (sofosbuvir) for Hepatitis C (HCV)

Prior Authorization Request Form
Prior Authorization Continuation Request Form

Criteria for Approval

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

2) Patient is sofosbuvir treatment naïve; **AND**

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

4) Patient may not be pregnant, as verified by a negative pregnancy test. In addition, the patient, and if applicable, the patient's partner, must attest that two forms of birth control will be used to prevent pregnancy during the treatment as indicated by the patient's signature on the Patient Consent Form; **AND**

5) 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**

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

7) Patient must have a fibrosis level of F3 or greater or have documented cirrhosis as indicated in the section entitled **Diagnostic/Disease Severity Evidence**; **AND**

8) Patient must agree to complete regimen (as outlined in Table 1) 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;

9) For HIV-1 co-infected patients, patients must have the following:
   a. CD4 count greater than 500 cells/mm3, if patient is not taking antiretroviral therapy; **OR**
   b. CD4 count greater than 200 cells/mm3, if patient is virologically suppressed (e.g., HIV RNA < 200 copies/mL)

Duration of Approval

- Initial approval is for 6 weeks.

- All indications require submission of an HCV RNA level at the start of therapy and at treatment week 4 (TW4).

- Continued coverage depends on 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.** Patients awaiting transplant must also submit HCV RNA levels at TW12, TW24 and TW36.

- Duration of coverage is based on HCV genotype **(Table 1 – Covered Regimens).**

- Patients with hepatic cellular carcinoma awaiting liver transplant may be eligible for coverage of Sovaldi + ribavirin for up to 48 weeks or until transplant, whichever comes first.

Table 1. Accepted Regimens and Treatment Duration for HCV Combination Therapy in HCV Mono-Infected and HCV/HIV-1 Co-Infected Patients

Diagnosis	Approved Regimen	Duration
Genotype 1 - HIV Co-Infection	Sovaldi + peginterferon alfa + ribavirin	12 weeks
Genotype 1 - HIV - Interferon Ineligible[1]	Sovaldi + ribavirin	24 weeks
Genotype 2	Sovaldi + ribavirin	12 weeks
Genotype 3	Sovaldi + peginterferon alfa + ribavirin	12 weeks
Genotype 3 - Interferon Ineligible[1]	Sovaldi + ribavirin	24 weeks
Genotype 4	Sovaldi + peginterferon alfa + ribavirin	12 weeks
Genotype 4 - Interferon Ineligible[1]	Sovaldi + ribavirin	24 weeks

[1]**INTERFERON-INELIGIBILITY** is defined under “CRITERIA FOR DENIAL”

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

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)

2) Fibrosis level must be substantiated via biopsy, FibroSure Assay or by Fibroscan.

Criteria for Denial

1) Patient is pregnant.

2) 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.

3) Patient is not sofosbuvir naïve.

4) Patient is receiving concomitant hepatitis protease inhibitor therapy (e.g. telaprevir (Incivek), boceprevir (Victrelis).

5) Patient has decompensated cirrhosis (defined as a Child-Pugh score greater than 6 [class B or C]).

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

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

8) Patient has HCV genotype 5 or 6.

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) Patient refuses treatment with Interferon but does not meet definition of Interferon Ineligibility. **Interferon Alfa Ineligible** is defined as:
    a. Documented intolerance to previous trial of interferon
    b. Autoimmune hepatitis and other autoimmune disorders
    c. Hypersensitivity to peginterferon alfa or any of its components
    d. Decompensated hepatic disease
    e. A baseline neutrophil count below 1,500/µL, a baseline platelet count below 90,000/µL or baseline hemoglobin below 10 g/dL

Additional Considerations

1) Sofosbuvir combination treatment with ribavirin or peginterferon alfa/ribavirin is contraindicated in women who are pregnant or may become pregnant and men whose female partners are pregnant because of the risks for birth defects and fetal death associated with ribavirin.

2) Sofosbuvir is a nucleotide analog NS5B polymerase inhibitor.

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) Sovaldi [package insert]. Foster City, CA; Gilead, December 2013.
2) FDA Antiviral Drugs Advisory Committee Meeting, October 25, 2013; Background Package for NDA 204671 sofosbuvir (GS-7977).
3) 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.
4) 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.
5) 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.
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) 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.