

Sovaldi™ (Sofosbuvir) for Hepatitis C (HCV)

Criteria for Approval

1. Adult patient age \geq 18 years old; **AND**
2. Sofosbuvir treatment naïve; **AND**
3. Patient has abstained from the use of illicit drugs and alcohol for a minimum of three (3) months as evidenced by negative urine confirmation tests in each of the two months immediately prior to therapy (results must be submitted with request); **AND**
4. Meets the diagnosis and disease severity (cirrhosis or bridging fibrosis) criteria outlined in Table 1; **AND**
5. Agrees to complete regimen (i.e. dual or triple therapy as outlined in Table 1); **AND**
6. For HIV-1 co-infected patients, patients must have the following:
 - Documented HIV-1 diagnosis, **AND**
 - CD4 count greater than 500 cells/mm³, if patient is not taking antiretroviral therapy; **OR**
 - CD4 count greater than 200 cells/mm³, if patient is virologically suppressed (e.g., HIV RNA < 200 copies/mL)

Duration of Approval

1. Based on HCV genotype
 - a) Genotypes 1, 2, and 4 (including HCV-HIV-1 co-infection)
 - 12 weeks, maximum
 - b) Genotype 3 (including HCV-HIV-1 co-infection) and for dual therapy in Genotype 1 patients who are interferon ineligible
 - 12 weeks, with 1 renewal, maximum
 - c) Hepatocellular carcinoma awaiting liver transplant
 - 12 weeks, up to 3 renewals, maximum
2. Limits
 - a) As defined in 1.a), b), c) above
 - b) Retreatment not authorized within two (2) years
3. Lost or stolen medication
 - a) Lost or stolen medication replacement requests will not be authorized.

Quantity Limit

One 400 mg tablet per day (28 tablets/28 days)

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Table 1^{1,2,3,4,5,6}		
Documented HCV Genotype / Fibrosis Stage		
Diagnosis	Approved Treatment Regimen	Regimen Duration
<i>HCV genotype 1 / ≥ Stage F3 (cirrhosis or bridging fibrosis)</i>		
<ul style="list-style-type: none"> • HCV with or without compensated cirrhosis (incl. hepatocellular carcinoma [HCC]) • HCV/HIV-1 co-infection 	<i>Triple Therapy</i> sofosbuvir + peginterferon alfa + ribavirin [†]	12 weeks
<i>HCV genotype 1, interferon ineligible / ≥ Stage F3 (cirrhosis or bridging fibrosis)</i>		
<ul style="list-style-type: none"> • HCV with or without compensated cirrhosis (incl. HCC) 	<i>Dual Therapy</i> sofosbuvir + ribavirin [†]	24 weeks
<i>HCV genotype 2 / ≥ Stage F3 (cirrhosis or bridging fibrosis)</i>		
<ul style="list-style-type: none"> • HCV with or without compensated cirrhosis (incl. HCC) • HCV/HIV-1 co-infection 	<i>Dual Therapy</i> sofosbuvir + ribavirin [†]	12 weeks
<i>HCV genotype 3 / ≥ Stage F3 (cirrhosis or bridging fibrosis)</i>		
<ul style="list-style-type: none"> • HCV with or without compensated cirrhosis (incl. HCC) • HCV/HIV-1 co-infection 	<i>Dual Therapy</i> sofosbuvir + ribavirin [†]	24 weeks
<i>HCV genotype 4 / ≥ Stage F3 (cirrhosis or bridging fibrosis)</i>		
<ul style="list-style-type: none"> • HCV with or without compensated cirrhosis (incl. HCC) • HCV/HIV-1 co-infection 	<i>Triple Therapy</i> sofosbuvir + peginterferon alfa + ribavirin [†]	12 weeks
<i>HCV genotype 1, 2, 3, or 4</i>		
<ul style="list-style-type: none"> • Hepatocellular carcinoma awaiting liver transplantation AND • Meets Milan criteria: <ul style="list-style-type: none"> • In single hepatocellular (HC) carcinomas, tumor < 5 cm in diameter, OR • In multiple HC carcinomas, no more than 3 tumor modules, each < 3 cm in diameter, AND • No extrahepatic manifestations of the cancer and no evidence of vascular invasion of the tumor. 	<i>Dual Therapy</i> sofosbuvir + ribavirin [†]	48 weeks <i>or until the time of liver transplantation, whichever occurs first</i>

[†]Weight based ribavirin

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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** of the following clinical features:
 - Cirrhotic features on imaging
 - Ascites
 - Esophageal varices
 - Reversed AST:ALT ratio (> 1), thrombocytopenia ($< 130,000$ platelets/ μL), and coagulopathy (INR > 2)
2. Bridging fibrosis must be substantiated via biopsy.

Criteria for Denial

1. Patient is pregnant or lactating.
2. Patient is not abstaining from the use of illicit drugs and alcohol for at least three (3) months as evidenced by urine confirmation tests.
3. Patient is not sofosbuvir naïve.
4. Patient receiving concomitant hepatitis protease inhibitor therapy (e.g. telaprevir (Incivek[®]), boceprevir (Victrelis[®]), simeprevir (Olysio[™])).
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. HCV genotype is 5 or 6.
9. Patient is taking a concomitant medication that has a significant clinical interaction with sofosbuvir:
 - tipranavir/ritonavir
 - rifampin, rifabutin, rifapentine
 - carbamazepine, phenytoin, phenobarbital, oxcarbazepine
 - St. John's wort
10. Patient refuses treatment with Interferon but does not meet definition of Interferon Ineligibility.
Interferon Alfa Ineligible Defined:
 - Intolerance to interferon alfa
 - Autoimmune hepatitis and other autoimmune disorders
 - Hypersensitivity to peginterferon alfa or any of its components
 - Decompensated hepatic disease
 - Clinical features consistent with depression; history of depression, relative contraindication
 - A baseline neutrophil count below 1,500/ μL , a baseline platelet count below 90,000/ μL or baseline hemoglobin below 10 g/dL
 - A history of cardiac disease

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Additional Considerations

- 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.
- Sofosbuvir is a nucleotide analog NS5B polymerase inhibitor.

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.