

Idaho Medicaid – Prior Authorization Therapeutic Criteria for Sofosbuvir (Sovaldi®)
Approved by the Pharmacy & Therapeutics Committee
May 23rd, 2014

DRUG NAME:

Sofosbuvir (Sovaldi®)

COVERED USES:

Sofosbuvir (Sovaldi®) 400mg/day is indicated for the treatment of chronic hepatitis-C (HCV) infection as a component of a combination antiviral treatment regimen or a diagnosis of HCV hepatic carcinoma awaiting liver transplantation.

AGE RESTRICTIONS:

FDA approved for ages 18 years or older.

PRESCRIBER RESTRICTIONS:

Sofosbuvir (Sovaldi®) is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

INCLUSION CRITERIA (All criteria must be met):

- Chronic infection with HCV genotype 1, 2, 3, or 4 or hepatic carcinoma secondary to HCV awaiting liver transplantation.
- Patient with advanced liver disease (Metavir stage F3-F4).
- Sofosbuvir (Sovaldi®) treatment in combination with ribavirin with or without peginterferon.
- Under the care of and/or collaboration with an experienced HCV practitioner.
- Provider has discussed with patient the potential risks and benefit of HCV therapy and progression of HCV disease and a shared decision has been made for antiviral treatment.
- Adherence counseling performed and documented understanding by patient.
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EXCLUSION CRITERIA:

- Non-FDA approved combinations or monotherapy with Sofosbuvir (Sovaldi®)
- Patients with severe renal impairment (<30mL/min/1.73m²), end-stage renal disease or on hemodialysis.
- Documented ongoing non-adherence to prior medications, medical treatment or failure to complete HCV disease evaluation appointments and procedures or patient is unable to commit to scheduled follow-up/monitoring for the duration of treatment.
- History of intravenous drug abuse/alcohol dependency WITHOUT documented evidence of successful completion of 6 months of abstinence for injection drug use and/or alcohol dependency.
- Known hypersensitivity to any component Sofosbuvir (Sovaldi®).
- Co-administration with drugs that are potent P-glycoprotein inducers in the intestine (e.g., rifampin, St. John's wort, carbamazepine).
- Decompensated liver disease.
- Patients with recurrent post-liver transplant HCV infection.
- Patients with chronic HCV with minimal fibrosis (Metavir stage F0-F2).
- Previous treatment of Hepatitis-C with Sofosbuvir (Sovaldi®).

REQUIRED MEDICAL INFORMATION:

- Diagnosis of chronic hepatitis C infection (ICD-9 070.4, 070.5, 070.7) with confirmed genotype of 1, 2, 3, or 4 or a diagnosis of hepatic carcinoma secondary to HCV awaiting liver transplantation (ICD-9 155.x).
- Documented evidence of compensated cirrhosis (Metavir score F3- F4 OR Batts-Ludwig scale 3-4 OR Fibroscan measurement >12.5 kPa OR ARFI value >1.75 meters/second OR radiographic imaging (CT/MRI) with features of portal hypertension, ascites, and hepatosplenomegaly OR APRI score >1.5 OR FIB-4 > 3.25).
- Documentation of recent laboratory values, within 6 months of request, including LFT's, CBC, genotype, HCV RNA viral count, negative pregnancy test (if applicable).
- Patients with a history of intravenous drug abuse/alcohol dependence will require documentation of successful completion of 6 months of abstinence for injection drug use and/or alcohol dependency.
- Previous history of HCV treatment (treatment naïve or treatment experienced).

COVERAGE DURATION:

Sofosbuvir (Sovaldi®) 400mg/day will be initially approved for 1 month of treatment with follow up HCV RNA reporting required before additional approvals will be allowed (refer to Treatment/Monitoring Criteria).

Approved combination treatments with Sofosbuvir (Sovaldi®) 400mg/day

Genotype	Combination Medication	Duration of Therapy
1 or 4	Pegylated interferon AND ribavirin	12 weeks
1-Interferon ineligible ¹	Ribavirin ONLY *	24 weeks
2	Ribavirin	12 weeks
3	Ribavirin	24 weeks
Hepatocellular carcinoma awaiting liver transplant	Ribavirin	48 weeks

*Combination with Simeprevir (Olysio®) is not a FDA approved treatment regimen.

1. Interferon ineligible

- Autoimmune hepatitis or autoimmune disorders (eg, dermatomyositis, immune [idiopathic] thrombocytopenic purpura, inflammatory bowel disease, interstitial lung disease, interstitial nephritis, polymyositis, psoriasis, rheumatoid arthritis, sarcoidosis, and systemic lupus erythematosus)
- Major uncontrolled depressive illness
- History of psychosis, schizophrenia, bipolar disorder, schizoaffective disorder, or suicidal ideation
- Uncontrolled seizures
- Moderate or severe retinopathy
- Poorly controlled diabetes
- Baseline neutrophil count below 750 cells/mm³
- Baseline platelet count below 75,000 cells/mm³
- Baseline hemoglobin below 10 g/dL
- Significant ischemic cardiac disease
- Prior intolerance or hypersensitivity (urticaria, angioedema, bronchoconstriction, anaphylaxis, or Stevens-Johnson syndrome) to interferon therapy
- Symptomatic hepatitis C induced cryoglobulinemia

TREATMENT/MONITORING CRITERIA:

- For genotype 1 and 4, Sovaldi must be used in combination of weight-based ribavirin (less than 75 kg, 1000 mg; 75 kg or greater, 1200 mg) plus weekly peginterferon.
- For genotype 2 or 3, Sovaldi must be used in combination of weight-based ribavirin (less than 75 kg, 1000 mg; 75 kg and greater, 1200 mg).
- Healthcare provider must submit an HCV RNA viral count at 2 weeks of treatment for all genotypes to determine compliance and efficacy of treatment.
- Healthcare provider must submit an HCV RNA viral count at week 4 and 8 for 12-WEEK TREATMENT REGIMEN of Sofosbuvir (Sovaldi®).
- Healthcare provider must submit an HCV RNA viral count at weeks 4 ,8 and 12 for 24-WEEK TREATMENT REGIMEN of Sofosbuvir (Sovaldi®).
- Requests for renewal will be denied in patients who have not achieved HCV RNA below the limit of detection after 4 weeks of therapy or in patients who have not demonstrated a decrease in HCV RNA (response) after 4 weeks.
- All treatment must be discontinued if HCV RNA is >25 IU/ml at week 4 or at any other time point thereafter.
- Drug treatment approval will be denied if there is a discontinuation or dose reduction of any component of combination treatment plan.
- Urine/Blood toxicology testing for drug abuse/alcohol must be submitted on a monthly basis in patients with a history of drug abuse/alcohol dependence.
- Healthcare provider must submit a sustained viral response (SVR) at week 12 and week 24 after successful completion of treatment.

OTHER:

The criteria for Sofosbuvir (Sovaldi®) are based upon the most current evidence provided. There is limited data on the efficacy of Sofosbuvir (Sovaldi®) in treatment experienced patients and requests will be evaluated on a case-by-case basis.

Idaho Medicaid recognizes as new information becomes available these criteria may change and will be revised when necessary.

REFERENCES:

1. Recommendations from the Department of Veterans Affairs National Hepatitis C Resource Center Program and the Office of Public Health (March 27, 2014; data last reviewed on March 6, 2014) <http://www.hepatitis.va.gov/pdf/2014hcv.pdf>
2. Product Information: SOVALDI(TM) oral tablets, sofosbuvir oral tablets. Gilead Sciences, Inc. Foster City, CA, 2013.
3. EASL Recommendations on Treatment of Hepatitis C 2014. <http://www.easl.eu/newsroom/latest-news/easl-recommendations-on-treatment-of-hepatitis-c-2014>:
4. AASLD/IDSA 2014 Recommendations for Testing, Managing, and Treating Hepatitis C. <http://www.hcvguidelines.org/full-report-view>
5. WHO: 2014 Guidelines for the Screening, Care and Treatment of Persons with Hepatitis C Infection. <http://www.who.int/hiv/pub/hepatitis/hepatitis-c-guidelines/en/>
6. The Comparative Clinical Effectiveness and Value of Simeprevir and Sofosbuvir in the Treatment of Chronic Hepatitis C infection. http://www.ctaf.org/sites/default/files/u119/CTAF_Hep_C_Apr14_final.pdf

Idaho Medicaid – Prior Authorization Therapeutic Criteria for Simeprevir (Olysio®)
Approved by the Pharmacy & Therapeutics Committee
May 23rd, 2014

DRUG NAME:

Simeprevir (Olysio™)

COVERED USES:

Simeprevir (Olysio™) 150mg/day is indicated for the treatment of chronic hepatitis-C (HCV) genotype 1 infection as a component of a combination antiviral treatment regimen with peginterferon alfa and ribavirin.

AGE RESTRICTIONS:

FDA approved for ages 18 years or older.

PRESCRIBER RESTRICTIONS:

Simeprevir (Olysio™) is prescribed by or in consultation with a gastroenterologist, hepatologist, or an infectious diseases physician.

INCLUSION CRITERIA (All criteria must be met):

- Simeprevir (Olysio™) is prescribed in combination with peginterferon and ribavirin for HCV genotype 1 infection.
- Patient with advanced liver disease (Metavir stage F3-F4).
- Under the care of and/or collaboration with an experienced HCV practitioner.
- Provider has discussed with patient the potential risks and benefit of HCV therapy and progression of HCV disease and a shared decision has been made for antiviral treatment.
- Adherence counseling performed and documented understanding by patient.

EXCLUSION CRITERIA:

- Non-FDA approved combinations or monotherapy with Simeprevir (Olysio™).
- Documented ongoing non-adherence to prior medications, medical treatment or failure to complete HCV disease evaluation appointments and procedures or patient is unable to commit to scheduled follow-up/monitoring for the duration of treatment.
- History of intravenous drug abuse/alcohol dependency WITHOUT documented evidence of successful completion of 6 months of abstinence for injection drug use and/or alcohol dependency.
- Known hypersensitivity to any component Simeprevir (Olysio™).
- Coadministration with moderate or strong inducers or inhibitors of cytochrome P450 3A.
- Decompensated liver disease.
- Patient co-infected with HIV.
- Patients with recurrent post-liver transplant HCV infection.
- Patients with chronic HCV with minimal fibrosis (Metavir stage F0-F2).
- Previously failed a course of HCV therapy with a NS3-4A protease inhibitor (boceprevir or telaprevir).
- Positive test of HCV virus with the presence of NS3 Q80K polymorphism

REQUIRED MEDICAL INFORMATION:

- Diagnosis of chronic hepatitis C infection (ICD-9 070.4, 070.5, 070.7) with confirmed genotype 1 infection.
- Screening for HCV Genotype 1a infection for the presence of virus with the NS3 Q80K polymorphism at baseline.
- Documented evidence of compensated cirrhosis (Metavir score F3- F4 OR Batts-Ludwig scale 3-4 OR Fibroscan measurement >12.5 kPa OR ARFI value >1.75 meters/second OR radiographic imaging (CT/MRI) with features of portal hypertension, ascites, and hepatosplenomegaly OR APRI score >1.5 OR FIB-4 > 3.25).
- Documentation of recent laboratory values, within 6 months of request, including LFT's, CBC, genotype, HCV RNA viral count, negative pregnancy test (if applicable).
- Patients with a history of intravenous drug abuse/alcohol dependence will require documentation of successful completion of 6 months of abstinence for injection drug use and/or alcohol dependency.
- Previous history of HCV treatment (treatment naïve or treatment experienced).

COVERAGE DURATION:

Recommended Treatment Duration with Simeprevir (Olysio™)			
HCV Treatment Status	Triple Therapy	Treatment Peginterferon and Ribavirin only	Total Length of Therapy
Treatment Naïve and patient with prior relapse ¹ .	Simeprevir, peginterferon alfa, and ribavirin for 12 weeks	Additional 12 weeks	24 weeks
Treatment for patients with prior nonresponse (partial/null) ² .	Simeprevir, peginterferon alfa, and ribavirin for 12 weeks	Additional 36 weeks	48 weeks
1. Prior relapse=Patient with undetectable HCV RNA at end of prior interferon-based therapy, but with detectable HCV RNA during follow-up. 2. Prior partial responder=Patient having a 2 log IU/ml or greater reduction from baseline HCV RNA at week 12 and detectable HCV RNA at the end of prior interferon-based therapy. Prior null responder=Patient a reduction of HCV RNA of less than 2 log IU/ml from baseline at week 12 during prior interferon-based therapy.			

TREATMENT/MONITORING CRITERIA:

- HCV RNA will be monitored at week 4, 12, and 24. If HCV RNA is > 25 IU/ml at any of these time points, triple therapy will be discontinued.
- Simeprevir (Olysio™) therapy must be stopped in patients who discontinue peginterferon alfa or ribavirin for any reason. To prevent treatment failure, the dose of Simeprevir (Olysio®) must not be reduced or interrupted. If Simeprevir (Olysio®) is discontinued for any reason (eg. adverse reaction or inadequate treatment response), treatment with Simeprevir (Olysio®) must not be reinitiated.
- Urine/Blood toxicology testing for drug abuse/alcohol must be submitted on a monthly basis in patients with a history of drug abuse/alcohol dependence.
- Healthcare provider must submit a sustained viral response (SVR) at week 12 and week 24 after successful completion of treatment.

REFERENCES:

1. Recommendations from the Department of Veterans Affairs National Hepatitis C Resource Center Program and the Office of Public Health (March 27, 2014; data last reviewed on March 6, 2014) <http://www.hepatitis.va.gov/pdf/2014hcv.pdf>
2. AASLD/IDSA 2014 Recommendations for Testing, Managing, and Treating Hepatitis C. <http://www.hcvguidelines.org/full-report-view>
3. Olysio™ (simeprevir) product labeling. Janssen Therapeutics, Division of Janssen Products, LP. Titusville, NJ November 2013.