

# Drug Therapy Guidelines

Sovaldi™ (sofosbuvir)

*Applicable*

Medical Benefit		Effective: 11/1/18
Pharmacy- Formulary 1	x	Next Review: 9/19
Pharmacy- Formulary 2	x	Date of Origin: 3/13
Pharmacy- Formulary 3/Exclusive	x	Review Dates: 12/13, 10/14, 12/14, 1/15, 9/15, 9/16, 9/17, 9/18
Pharmacy- Formulary 4/AON	x	

## I. Medication Description

Sofosbuvir is a direct-acting antiviral agent against the hepatitis C virus. It is an inhibitor of the HCV NS5B RNA-dependent RNA polymerase, which is essential for viral replication. Sovaldi should be used as a component of a combination antiviral treatment regimen.

## II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

## III. Policy

Coverage of Sovaldi can be granted if the following criteria are met:

- Member's age is
  - 18 or older for genotypes 1, 2, 3, or 4 **OR**
  - 12 years or older for genotypes 2 and 3 **OR**
  - Younger than 12 years old and weighing at least 35 kg for genotypes 2 and 3 **AND**
- Medication is prescribed by a:
  - hepatologist, gastroenterologist, infectious disease specialist, transplant physician, healthcare practitioner under the direct supervision of one of the preceding listed specialists, or a healthcare practitioner experienced and trained in the treatment of HCV infection prescriber working in collaboration with one of these specialists, or a prescriber who has clinical experience with the management and treatment of HCV infection (defined as the management AND treatment of at least 10 patients with HCV infection within the past 12 months and at least 10 HCV-related CME credits in the last 12 months) **OR**
  - healthcare professional in partnership (defined as consultation, preceptorship, or via telemedicine) with an experienced HCV provider who meets the above criteria **AND**
- A diagnosis of chronic hepatitis C has been established and baseline viral load reported **AND**
- Genotype and subgenotype (if available) is confirmed and documented **AND**
- Usage (medication combination, dose and duration) is in accordance with current AASLD/IDSA treatment guidelines for chronic hepatitis C (<http://www.hcvguidelines.org>)

## IV. Quantity Limitations

Coverage is provided for up to 28 tablets per each 28 days.

V. Coverage Duration

Coverage duration will be determined in accordance with medication prescribing information and recommendations from current AASLD/IDSA treatment guidelines for chronic hepatitis C (<http://www.hcvguidelines.org>).

VI. Coverage Renewal Criteria

n/a

VII. Billing/Coding Information

Sovaldi is available as 400mg tablets, 28 tablets per bottle.

VIII. Summary of Policy Changes

- 3/15/14: new policy
- 4/16/14: updated to reflect changes in AASLD/IDSA guidelines
- 12/1/14: prioritization of members based on disease severity added
- 12/23/14: updated to reflect changes in AASLD/IDSA guidelines
- 3/1/15: ViekiraPak is preferred agent for the treatment of genotype 1 disease
- 3/15/15: no policy changes
- 4/15/15: guideline updated to reflect changes in recommendations for the use of ViekiraPak outside of genotype 1 disease
- 7/1/15: formulary distinctions made
- 8/1/15: preferred status of ViekiraPak removed
- 9/1/15: coverage criteria opened to treat less urgent-need members
- 12/15/15: no policy changes
- 4/22/16: coverage criteria opened to allow consideration despite disease severity; specialist qualifications clarified
- 8/23/16: Epclusa listed as a preferred product for appropriate clinical scenarios
- 9/15/16: no policy changes
- 4/12/17: updated to include pediatric indication
- 5/1/17: step therapy criteria added
- 10/19/17: age requirements updated; step criteria removed
- 11/1/18: no policy changes

IX. References

1. Prescribing information: Sovaldi™ (sofosbuvir). Gilead Sciences, Inc. Foster City, CA 94404. Revised 11/2017.
2. Clinical Pharmacology online: sofosbuvir. Elsevier/Gold Standard. Accessed online 7/2018.
3. Micromedex: sofosbuvir. Accessed online 7/2018.
4. Lawitz E, et al. Sofosbuvir for Previously Untreated Chronic Hepatitis C Infection. N Engl J Med 2013; 368:1878-1887.
5. Gane E, et al. Nucleotide Polymerase Inhibitor Sofosbuvir plus Ribavirin for Hepatitis C. N Engl J Med 2013; 368:34-44.
6. Jacobson I, et al. Sofosbuvir for Hepatitis C Genotype 2 or 3 in Patients without Treatment Options. N Engl J Med 2013; 368:1867-1877.
7. HCVguidelines.org. Launched January 29, 2014. Accessed 7/2018.

*The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.*

*The preceding policy applies only to members for whom the above named pharmacy benefit medications are included on their covered formulary. Members with closed formulary benefits are subject to trying all appropriate formulary alternatives before a coverage exception for a non-formulary medication will be considered. The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.*