Clinical Policy: Sofosbuvir (Sovaldi)

Reference Number: PA.CP.PHAR.281
Effective Date: 01/18
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Description
Sofosbuvir (Sovaldi®) is a nucleotide analog inhibitor of hepatitis C virus (HCV) NS5B polymerase.

FDA-Approved Indication
Sovaldi is indicated for the treatment of:

- Adult patients with genotype 1, 2, 3 or 4 chronic HCV infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen.
- Pediatric patients 12 years of age and older or weighing at least 35 kg with genotype 2 or 3 chronic HCV infection without cirrhosis or with compensated cirrhosis in combination with ribavirin (RBV).

Policy/Criteria
It is the policy of Pennsylvania Health and Wellness ® that Sovaldi is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria
*** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria ***

A. Chronic Hepatitis C Infection (must meet all)**:**

1. Diagnosis of chronic hepatitis C virus (HCV) infection with documented genotyping;
2. If actively abusing alcohol or IV drugs, or has a history of abuse, has documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse and an offer of a referral for substance use disorder treatment;
3. Has a Metavir fibrosis score documented by a recent noninvasive test such as a blood test or imaging, a Fibroscan, or findings on physical examination;
4. Has documented completion of the following (a or b, c, d, and e):
   a. Hepatitis B immunization series; or
   b. Hepatitis B screening (sAb/sAg and cAb);
   c. If positive for hepatitis B sAg, quantitative HBV DNA results;
   d. If there is detectable HBV DNA, a treatment plan for hepatitis B consistent with AASLD recommendations; and
   e. If negative for hepatitis B sAb, a hepatitis B immunization plan or counseling to receive the hepatitis B immunization series;
5. Has a documented HIV screening (HIV Ag/Ab) and if confirmed positive by HIV-1/HIV-2 differentiation immunoassay meets the following (a or b):
   a. Is being treated for HIV or is not being treated for HIV; or
   b. The medical record documents the rationale for not being treated;
6. Has documentation of AASLD-recommended resistance- associated substitution (RAS) testing and is prescribed a drug regimen in accordance with AASLD guidance;

7. If genotype 1a, or had a previous treatment failure with a direct-acting antiretroviral (DAA) regimen, is prescribed an AASLD recommended drug regimen based on the documented results of a NS5A RAS screening;
8. Does not have a life expectancy of less than 12 months due to non-liver-related comorbid conditions;
9. Has a documented quantitative HCV RNA at baseline that was tested within the past 3 months;
10. Has corrected or addressed the causes of non-adherence to a previously prescribed Hepatitis C treatment regimen if the member has a history of failed treatment due to non-adherence;
11. Had all potential drug interactions addressed by the prescriber;
12. Prescribed regimen is consistent with an FDA or AASLD-IDSA recommended regimen (*see Section V Dosage and Administration for reference)*;
    a. If a lower cost alternative regimen carries an equal or higher AASLD-IDSA rating, a clinical contraindication or intolerance must be present for the alternative regimen prior to the approval of a Sovaldi-based regimen;
13. If prescribed with ribavirin, no changes will be required of therapy;
14. Has a documented commitment to adherence with the planned course of treatment and appropriate monitoring;
15. Dose does not exceed 400 mg (1 tablet) per day.
    a. If request exceeds limit, refer to PA.CP.PMN.53.

Approval duration: up to 24 weeks*(*Approved duration should be consistent with a regimen in Section V Dosage and Administration)*
Approval duration for Pediatrics: 12 weeks for genotype 2; 24 weeks for genotype 3

B. Other diagnoses/indications: Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Approval

*** Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria ***

A. Chronic Hepatitis C Infection (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Dose does not exceed 400 mg (1 tablet) per day.

Approval duration for Adults: up to a total of 24 weeks*
*(*Approved duration should be consistent with a regimen in Section V Dosage and Administration)*
Approval duration for Pediatrics: up to 12 weeks for genotype 2; up to 24 weeks for genotype 3

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

2. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices

Appendix A: Abbreviation Key

ALT: alanine aminotransferase
APRI: AST to platelet ratio
AASLD: American Association for the Study of Liver Diseases
CTP: Child Turcotte Pugh
CrCl: creatinine clearance
DAA: direct acting antiviral
FIB-4: Fibrosis-4 index
HBeAg: hepatitis B virus envelope antigen
HBV: hepatitis B virus
HCC: hepatocellular carcinoma
HCV: hepatitis C virus
IDSA: Infectious Diseases Society of America
MRE: magnetic resonance elastography
NS3/4A, NS5A/B: nonstructural protein
Peg-IFN: pegylated interferon
PI: protease inhibitor
RBV: ribavirin
RNA: ribonucleic acid

Appendix B: General Information

- Hepatitis B Reactivation is a Black Box Warning for all direct-acting antiviral drugs for the treatment of HCV. The provider must provide either:
  - Documentation of absence of concurrent HBV infection as evidenced by laboratory values showing absence of hepatitis B virus envelope antigen (HBeAg) and HBV DNA (deoxyribonucleic acid);
  - Documentation that HBV co-infected patient may not be candidates for therapy as evidenced by one of the following:
    - Absence of HBeAg, HBV DNA less than 2,000 international units/mL, and alanine aminotransferase (ALT) level within 1 to 2 times the upper limit of normal;
    - HBeAg-positive and HBV DNA greater than 1,000,000 international units/mL and ALT level within 1 to 2 times the upper limit of normal;
  - Documentation that concurrent HBV infection is being treated (e.g., tenofovir alafenamide, adefovir, entecavir), unless contraindicated or clinically significant adverse effects are experienced.
- The 2016 AASLD/IDSA treatment guideline for HBV consider ALT levels <30 U/L for men and <19 U/L for women as upper limits of normal.
- The 2016 AASLD/IDSA treatment guideline for HBV recommend adults with compensated cirrhosis, even with low levels of viremia (<2,000 IU/mL) be treated with antiviral therapy to reduce the risk of decompensation, regardless of ALT level. The recommendation extends to adults with decompensated cirrhosis be treated with antiviral

therapy indefinitely regardless of HBV DNA level, HBeAg status, or ALT level to decrease the risk of worsening liver-related complications.

Appendix C: Direct-Acting Antivirals (DAAs) for Treatment of HCV Infection

Brand Name	Drug Class				
	NS5A Inhibitor	Nucleotide Analog NS5B Polymerase Inhibitor	Non-Nucleoside NS5B Palm Polymerase Inhibitor	NS3/4A Protease Inhibitor (PI)**	CYP3A Inhibitor
Daklinza	Daclatasvir				
Epclusa*	Velpatasvir	Sofosbuvir			
Harvoni*	Ledipasvir	Sofosbuvir			
Olysio				Simeprevir	
Sovaldi		Sofosbuvir			
Technivie*	Ombitasvir			Paritaprevir	Ritonavir
Viekira XR/PAK*	Ombitasvir		Dasabuvir	Paritaprevir	Ritonavir
Zepatier*	Elbasvir			Grazoprevir	

*Combination drugs
**Additional PIs no longer recommended: Victrelis (boceprevir), Incivek (telaprevir)

V. Dosage and Administration

A. **AASLD/IDSA treatment guidelines for chronic hepatitis C infection are updated at irregular intervals; refer to the most updated AASLD/IDSA guideline for most accurate treatment regimen.*

VI. Product Availability

Tablet: 400 mg

Updated policy to incorporate DUR Memo dated 12.10.18.	1.7.2019	
3Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	07/17/19	

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