CareSource

PHARMACY POLICY STATEMENT **Ohio Medicaid**	
DRUG NAME	Sovaldi (sofosbuvir)
BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
COVERAGE REQUIREMENTS	Prior Authorization Required (Non-Preferred Product) Alternative preferred product includes Mavyret for all members 18 years of age and older QUANTITY LIMIT— 28 for a 28 day supply
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

Sovaldi (sofosbuvir) is a **non-preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

HEPATITIS C (without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A))

For **initial** authorization:
Member must meet all criteria below Step 1 and Step 2 and Step 3.

Step 1 (evaluation of member's readiness):

1. Member must be 12 years of age or older (or must weigh at least 35 kg); AND
2. Member must be free for 6 months from alcohol use, controlled drug abuse, and illicit drug use before consideration of therapy (laboratory documentation required for month 1 and for month 6 and for one additional month between month 2-5); AND
3. Member must meet kidney function as indicated in package labeling for product (No dosage adjustment of Sovaldi is required for members with mild or moderate renal impairment. The safety and efficacy of Sovaldi have not been established in members with severe renal impairment (eGFR less than 30 mL/min/1.73 m^2) or ESRD requiring hemodialysis.); AND
4. Member must not be concomitantly taking drugs that have significant clinical interaction as described in the prescribing information (Sovaldi used in combination with peginterferon alfa/ribavirin or ribavirin alone, all contraindications to peginterferon alfa and/or ribavirin also apply to Sovaldi combination therapy; see additional notes in Appendix[1]); AND
5. Member must agree to be adherent with office visits, lab testing, imaging, procedures and, if deemed a candidate, the HCV medication regimen. Prescribers must submit documentation demonstrating the member attests to meet these requirements (Office notes documenting this are sufficient to meet this criteria); AND

Step 2 (clinical assessment of disease):

6. If member is 18 years of age and older must tried and failed course of treatment with Mavyret (Dates and HCV RNA values must be documented in chart notes); AND
7. Member has confirmation of chronic hepatitis C (CHC):
   a) Hepatitis C Virus (HCV) antibody test reactive; AND
   b) Provide HCV RNA load measured within 90 days prior to starting DAA therapy; AND
   c) Specify the Genotype (choose one of the following statuses):

i) Adult members with genotype 1, 2, 3 or 4 chronic hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis
ii) Pediatric members 12 years of age and older or weighing at least 35 kg with genotype 2 or 3 without cirrhosis or with compensated cirrhosis (must be used in combination with ribavirin); AND

8. Member has documented progression of disease:
   a) Document the degree of liver fibrosis:
      i) Liver biopsy; OR
      ii) One radiological and one serological test; AND
   b) If cirrhosis is present, indicate whether cirrhosis is compensated or decompensated and provide the Child-Turcotte-Pugh (CTP) score; AND
   c) If pediatric member Sovaldi must be prescribed in combination with ribavirin. If ribavirin ineligible must submit documentation of ONE of the following results obtained within the past month:
      i) History of severe or unstable cardiac disease
      ii) Pregnant women and men with pregnant partners
      iii) Diagnosis of hemoglobinopathy (e.g., thalassemia major, sickle cell anemia)
      iv) Hypersensitivity to ribavirin
      v) Baseline platelet count <70,000 cells/mm^3
      vi) ANC <1500 cells/mm^3
      vii) Hb <12 gm/dL in women or <13 g/dL in men; AND
9. Document that member does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions; AND
10. Document any previously tried Hepatitis C treatments, dates treated, and response/outcome (member will not be approved if any other HCV treatments have been used in the last 6 months); AND

Step 3 (Direct Acting Antivirals (DAA) conditions for coverage):

11. Medication must be prescribed by, or in consultation with, a hepatologist, gastroenterologist, or infectious disease specialist; AND
12. Member's documented HCV RNA testing is required every 4 weeks and submitted with chart notes; AND
13. Providers of HIV/HCV-coinfected persons should recognize and manage interactions with other antiretroviral medications (e.g. DAAs); AND
14. Only regimens listed as recommended or alternative in the current AASLD guidance (http://hcvguidelines.org) will be approved with duration of approval based upon guidelines. Regimens listed as not recommended will not be approved.
15. **Dosage allowed:** Pediatric and adult members: Sovaldi (one tablet once daily) + ribavirin for 12 weeks for genotype 2; Sovaldi (one tablet once daily) + ribavirin for 24 weeks for genotype 3. Adult members: Sovaldi (one tablet once daily) + peginterferon alfa + ribavirin for 12 weeks for genotype 1 or 4.

If member meets all the requirements listed above, the medication will be approved for 12-24 weeks, see Appendix[2] below.

For **reauthorization**:

1. Medication will not be reauthorized.

CareSource considers Sovaldi (sofosbuvir) not medically necessary for the treatment of the diseases that are not listed in this document.

DATE	ACTION/DESCRIPTION
05/09/2017	New policy for Sovaldi created. Criteria coverage was adjusted for age, alternative products were indicated. Hep B test requirement was added. Drug and alcohol screens for 3 consecutive months required for all regardless of abuse history. Evidence of liver fibrosis exceptions was expanded. Reauthorization requirement of 2 consecutive values of HCV RNA ≥25 IU per mL during the post-treatment period and documented reason of treatment failure were added.
06/08/2017	Fibrosis stage 2 and above covered.
11/22/2017	Substance abuse program information is no longer required. Criterion on absence of moderate to severe liver impairment was added.
12/07/2017	Criterion of "life expectancy not less than one year due to non-liver related comorbidities" removed from criteria and added in a form of the note. Hepatitis B testing is no longer required.
12/17/2018	Criteria changed per Ohio Department of Medicaid requirement. Minimum of 3 months of "drug/alcohol free period" criterion changed to 6 months; no fibrosis score required, but documentation of degree liver fibrosis changed; kidney function and clinical interactions addressed; HCV RNA load measurement prior to starting DAA therapy changed from "within 6 months" to "within 90 days"; cirrhosis score required; prescribers specialty changed; HCV RNA testing is now required every 4 weeks; reauthorization criteria removed.

References:

1. Sovaldi [package Insert]. Foster City, CA: Gilead Sciences, Inc.; November, 2017.
2. Hepatitis C Information | Division of Viral Hepatitis | CDC. (2015, May 31). Retrieved from https://www.cdc.gov/hepatitis/hcv/index.htm.
3. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (AASLD) and Infectious Diseases Society of America (IDSA). HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C; 2017. Available at: https://www.hcvguidelines.org/.
4. Afdhal, N. (2012). Fibroscan (Transient Elastography) for the Measurement of Liver Fibrosis. Gastroenterology & Hepatology, 8(9), 605-607.

Effective date: 01/01/2019
Revised date: 12/17/2018

Appendix. Current Medication List and Treatment Duration

[1]Current medication list that does NOT include: carbamazepine, phenytoin, phenobarbital, oxcarbazepine, rifabutin, rifampin, rifapentine, St. John's Wort, or tipranavir/ritonavir.

[2]Treatment Duration

Genotype	**Adult Members**	**Regimen and Duration**
Genotype 1 or 4	Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + peginterferon alfa + ribavirin 12 weeks
Genotype 2	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin 12 weeks
Genotype 3	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin 24 weeks

Genotype	**Pediatric Members 12 Years of Age and Older or Weighing at Least 35 kg**	**Regimen and Duration**
Genotype 2	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin 12 weeks
Genotype 3	Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A)	Sovaldi + ribavirin 24 weeks