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PHARMACY POLICY STATEMENT **Kentucky 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 patients 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:

1. Member must be between 12 and 17 years old (alternative preferred product includes Mavyret for all patients 18 years of age and older); AND
2. Member is treatment-naïve or treatment-experienced with genotype 2 or 3 (laboratory documentation required); AND
3. Medication must be used in combination with ribavirin; AND
4. Medication must be prescribed by a board certified hepatologist, gastroenterologist, infectious disease specialist or a nurse practitioner working with the above specialists; AND
5. Member's documented viral load taken within 6 months of beginning therapy and submitted with chart notes; AND
6. Member has documented current monthly negative urine drug and alcohol screens for 3 consecutive months (laboratory documentation required); AND
7. Member has evidence of liver fibrosis stage 3 or 4 confirmed by liver biopsy, or elastography only (lab chart notes required) unless **one** of the following (fibrosis stage F0-4 covered):
   a) Hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation);
   b) Post liver transplantation;
   c) Extrahepatic disease (i.e. kidney disease: proteinuria, nephrotic syndrome or membranoproliferative glomerulonephritis; cryoglobulinemia with end- organ manifestations (e.g. vasculitis));
   d) HIV or HBV coinfection; AND
8. Member does **not** have moderate to severe hepatic impairment (Child-Turcotte-Pugh B and C).
9. **Dosage allowed:** Sovaldi (one tablet once daily) + ribavirin for 12 weeks for genotype 2; Sovaldi (one tablet once daily) + ribavirin for 24 weeks for genotype 3.

Note: Member's life expectancy must be no less than one year due to non-liver related comorbidities.

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

For **reauthorization**:

1. Member is treatment experienced without cirrhosis or is treatment-experienced with compensated cirrhosis (Child-Turcotte-Pugh Class A); AND
2. Member must be in compliance with all other initial criteria; AND
3. Member is compliant with drug therapy regimen by paid pharmacy claims; AND
4. Member's HCV RNA greater than or equal to lower limit of quantification (LLOQ) of 25 IU per mL with 2 consecutive values during the post-treatment period after achieving HCV RNA less than LLOQ at end of treatment. Dates and HCV RNA values must be documented in chart notes; AND
5. Member must have a documented reason of treatment failure of previously tried medication.

If member meets all the reauthorization requirements listed above, the medication will be approved for an additional 12-24 weeks.

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.
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.

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: 12/13/2017
Revised date: 12/07/2017

Appendix. Treatment Duration

Genotype	Pediatric Patient Population 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