VENTURA COUNTY
HEALTH CARE PLAN

Prior Authorization DRUG Guidelines

Sovaldi® (sofosbuvir tablets – Gilead)

Effective Date:7/24/2018
Date Developed: 7/24/2018 by Catherine Sanders, MD and ESI P&T
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(Formulary Exclusion – For Exception Review Use Only)
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Sovaldi is a hepatitis C virus (HCV) nucleotide analog non-serine (NS)5B polymerase inhibitor indicated for the treatment of genotype 1, 2, 3 or 4 chronic HCV infection as a component of a combination antiviral treatment.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Sovaldi is recommended in those who meet the following criteria:

Food and Drug Administration (FDA)-Approved Indications

1. **Chronic Hepatitis C Virus (HCV) Genotype 1, Adults.** Approve for the specified duration below if the patient meets all of the following criteria (A, B, and C):
   - **A)** The patient is ≥ 18 years of age; AND
   - **B)** Sovaldi is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
   - **C)** The patient has a fibrosis score of ≥ 2, AND
   - **D)** The patient meets ONE of the following (i or ii):
     - **i.** **Approve for 12 weeks** in patients who meet ONE of the following (a or b):
       - **a)** Sovaldi will be prescribed **in combination with Olysio (simeprevir capsules)** AND the patient does not have cirrhosis (for patient with cirrhosis, see *Criterion Cii* below); OR
       - **b)** Sovaldi will be prescribed **in combination with Daklinza (daclatasvir tablets)** AND the patient meets one of the following criteria ([1], [2] or [3]):
         - **(1)** The patient does not have cirrhosis; OR
         - **(2)** The patient has compensated cirrhosis (Child-Pugh A); OR
         - **(3)** The patient has decompensated cirrhosis (Child Pugh B or C) AND Sovaldi will be prescribed **in combination with Daklinza AND ribavirin**; OR
     - **ii.** **Approve for 24 weeks** if Sovaldi will be prescribed **in combination with Olysio** AND the patient has cirrhosis

2. **Chronic HCV Genotype 2, Pediatric Patients.** Approve for 12 weeks if the patient meets all of the following criteria (A, B, C, D and E):
   - **A)** The patient is ≥ 12 years of age OR weighs ≥ 35 kg; AND
   - **B)** Sovaldi is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
   - **C)** Sovaldi will be prescribed **in combination with ribavirin**; AND

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D) The patient has a fibrosis score of ≥ 2, AND
E) The patient does not have decompensated cirrhosis (Child-Pugh B or C). [Coverage is provided for patients without cirrhosis or with compensated {Child-Pugh A} cirrhosis].

3. **Chronic HCV Genotype 3, Pediatrics Patients.** Approve for 24 weeks if the patient meets all of the following criteria (A, B, C, D and E):
   A) The patient is ≥ 12 years of age OR weighs ≥ 35 kg; AND
   B) Sovaldi is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
   C) The patient has a fibrosis score of ≥ 2, AND
   D) Sovaldi will be prescribed **in combination with ribavirin**; AND
   E) The patient does not have decompensated cirrhosis (Child-Pugh B or C). [Coverage is provided for patients without cirrhosis or with compensated {Child-Pugh A} cirrhosis].

4. **Chronic HCV Genotype 3, Adults.** Approve for 12 weeks if the patient meets all of the following criteria (A, B, C and D):
   A) The patient is ≥ 18 years of age; AND
   B) Sovaldi is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
   C) The patient has a fibrosis score of ≥ 2, AND
   D) Sovaldi is prescribed **in combination with Daklinza (daclatasvir tablets)** AND the patient meets one of the following (i or ii):

      i. The patient does not have cirrhosis; OR
      ii. The patient has cirrhosis (this includes patients with compensated [Child-Pugh A] OR decompensated [Child-Pugh B or C] cirrhosis) AND Daklinza and Sovaldi will be prescribed **in combination with ribavirin**.

Other Uses with Supportive Evidence

5. **Recurrent Hepatitis C Virus (HCV) Post-Liver Transplantation, Genotypes 1, 2, and 3, Adults.** Approve for the specified duration below if the patient meets all of the following criteria (A, B, C, and D):
   A) The patient is ≥ 18 years of age; AND
   B) The patient has recurrent HCV after a liver transplantation; AND

   C) Sovaldi is prescribed by or in consultation with one of the following prescribers who is affiliated with a transplant center: a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
   D) The patient meets ONE of the following conditions (i, ii, or iii):
      i. Genotype 1 recurrent HCV: Approve if the patient meets one of the following (a or b):
         a) Sovaldi is prescribed **in combination with Olysio**: **Approve for 12 weeks.**
         b) Sovaldi is prescribed in combination with **Daklinza AND ribavirin: Approve for 12 weeks.**
      ii. Genotype 2 recurrent HCV: If Sovaldi is prescribed **in combination with Daklinza AND ribavirin**, **approve for 12 weeks**.

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iii. **Genotype 3 recurrent HCV** if Sovaldi is prescribed **in combination with Daklinza AND ribavirin**, **approve for 12 weeks**.

6. **Patient Has Been Started on Sovaldi.** Approve for an indication or condition addressed as an approval in the Recommended Authorization Criteria section (FDA-Approved Indications or Other Uses with Supportive Evidence). Approve the duration described above to complete a course therapy (e.g., a patient who should receive 12 weeks, and has received 3 weeks should be approved for 9 weeks to complete their 12-week course).

   Sovaldi is not approved for the following: HCV (any genotype), Combination use with Direct-Acting Antivirals (DAAs) Other than Daklinza, Olysio, or ribavirin; Life Expectancy < 12 Months Due to Non-Liver Related Comorbidities; Monotherapy with Sovaldi; Pediatric Patients (Age < 12 years OR weighing < 35 kg).

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