



FORMULARY EXCEPTION POLICY

POLICY: Sovaldi® (sofosbuvir tablets and oral pellets – Gilead)

DATE REVISED: 09/04/2019

Documentation: Documentation will be required for patients requesting Sovaldi where noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts and/or laboratory data.

CRITERIA

- 1. Hepatitis C virus (HCV) any genotype.** Patients who meet any of the following criteria do not qualify for treatment with Sovaldi (A, B, C, or D): [Note: for patients who do not meet one of the following criteria A through D, review using the appropriate criteria 2 through 8 below]:
 - A. Combination use with direct-acting antivirals (DAAs) other than Daklinza and ribavirin; OR
 - B. Life expectancy < 12 months due to non-liver related comorbidities; OR
 - C. Monotherapy with Sovaldi; OR
 - D. Age < 3 years.

- 2. Chronic Hepatitis C Virus (HCV) Genotype 1, No Cirrhosis, Adults.** Approve Sovaldi for the specified duration if the patient meets the following criteria (A, B, C, D, and E):
 - A. The patient is ≥ 18 years of age; AND
 - B. The patient does not have compensated (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis (See *Criteria 3*); AND
 - C. The patient has completed a course of therapy with ONE of Epclusa (brand or generic), Harvoni (brand or generic), Zepatier, or Vosevi and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required]**. AND
 - D. Sovaldi is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
 - E. **Approve for 12 weeks** in patients who meet ONE of the following (i or ii below):
 - i. Sovaldi will be prescribed **in combination with Daklinza**.

- 3. Chronic Hepatitis C Virus (HCV) Genotype 1, Compensated or Decompensated Cirrhosis, Adults.** Approve Sovaldi for 12 weeks in patients who meet the following criteria (A, B, C, D and E):
 - A. The patient is ≥ 18 years of age; AND
 - B. The patient has compensated (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis **[documentation required]**; AND
 - C. The patient has completed a course of therapy with ONE of Epclusa (brand or generic) or Harvoni (brand or generic) and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required]**. AND
 - D. Sovaldi is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
 - E. The patient meets ONE of the following criteria (i or ii below):
 - i) The patient has decompensated (Child-Pugh B or C) cirrhosis AND Sovaldi will be prescribed **in combination with Daklinza AND ribavirin**; OR
 - ii) The patient has compensated (Child-Pugh A) cirrhosis AND Sovaldi will be prescribed **in combination with Daklinza**.

4. **Chronic Hepatitis C virus (HCV) Genotype 2, Pediatric patients.** Approve Sovaldi for 12 weeks in the patient meets the following criteria (A, B, C, and D):
 - A. The patient is ≥ 3 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. Sovaldi will be prescribed in combination with ribavirin; AND
 - D. 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]

5. **Chronic Hepatitis C virus (HCV) Genotype 3, Pediatric patients.** Approve Sovaldi for 24 weeks in the patient meets the following criteria (A, B, and C):
 - A. The patient is ≥ 3 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. Sovaldi will be prescribed in combination with ribavirin; AND
 - D. 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]

6. **Chronic Hepatitis C Virus (HCV) Genotype 3, Adults, No Cirrhosis.** Approve Sovaldi for 12 weeks if the patient meets the following criteria (A, B, C, D and E):
 - A. The patient is ≥ 18 years of age; AND
 - B. The patient does not have compensated (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis (See Criteria 7); AND
 - C. The patient has completed a course of therapy with ONE of Epclusa (brand or generic) or Vosevi and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required]**. AND
 - D. Sovaldi is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
 - E. Sovaldi is prescribed in combination with **Daklinza**.

7. **Chronic Hepatitis C Virus (HCV) Genotype 3, Adults, Compensated or Decompensated Cirrhosis.** Approve Sovaldi for 12 weeks if the patient meets the following criteria (A, B, C, and D):
 - A. The patient is ≥ 18 years of age; AND
 - B. The patient has compensated (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis **[documentation required]**; AND
 - C. The patient has completed a course of therapy with Epclusa (brand or generic) and has documentation that he/she did not achieve a sustained viral response (SVR, virus undetectable 12 weeks following completion of therapy) with Epclusa (brand or generic) **[documentation required]**; AND
 - D. Sovaldi is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
 - E. Sovaldi will be prescribed **in combination with Daklinza AND ribavirin**.

8. **Recurrent Hepatitis C Virus (HCV) Post-Liver Transplant Genotype 1, 2, or 3, Adults.** Approve Sovaldi 12 weeks in patients who meet 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. Sovaldi is prescribed **in combination with Daklinza AND ribavirin**

8. Patient Has Been Started on Sovaldi. Approve for an indication or condition above. 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).

***Note: Treatment-naïve includes patients who are in the middle of their first HCV treatment course and prior to their current course of therapy have not been treated for HCV. Treatment-naïve also includes patients who have not started HCV therapy and have never previously been treated for HCV.*

HISTORY

Type of Revision	Summary of Changes*	Lay Criteria Effective Date
New Policy	--	01/01/2017
DEU revision	Added approval criteria for patients ≥ 12 years of age or ≥ 35 kg with genotype 2 or 3 chronic HCV. Modified exclusion for patients < 18 years of age to agree with updated age indication for Sovaldi.	In Progress
DEU revision	Genotype 1 chronic HCV, no cirrhosis, criteria were modified to add Epclusa, Mavyret, and Vosevi to the list of one DAA the patient must try before Sovaldi. Genotype 1 chronic HCV with compensated or decompensated cirrhosis, criteria were modified to add Epclusa to the list of DAAs the patient must try one of before Sovaldi. Genotype 3 chronic HCV without cirrhosis, criteria were added to indicate with or without cirrhosis, and for patients without cirrhosis requirement that patients try one of Epclusa, Mavyret, or Vosevi was added (documentation required). Genotype 3 chronic HCV with compensated or decompensated cirrhosis, criteria were created that require a patient to try Epclusa prior to Sovaldi (documentation required).	In Progress
DEU revision	Genotype 2 recurrent HCV: removed criteria for approval with ribavirin for 24 weeks and added criteria for approval with Daklinza and ribavirin for 12 weeks.	In Progress
DEU revision	Trial of Mavyret removed from Chronic Genotype 3, Adults. Viekira and Viekira XR removed from the policy.	01/01/2019
DEU revision	Genotype 1 chronic HCV: Criteria to approve Sovaldi with Olysio were removed. Genotype 1 recurrent HCV: Criteria to approve Sovaldi with Olysio were removed. "Combination use with direct-acting antivirals (DAAs) other than Daklinza, Olysio, and ribavirin", Olysio was removed from this statement.	02/13/2019

DEU revision	<p>Chronic Hepatitis C Virus (HCV) Genotype 2, Pediatric Patients: Age indication revised to include patients \geq 3 years of age.</p> <p>Chronic Hepatitis C Virus (HCV) Genotype 3, Pediatric Patients: Age indication revised to include patients \geq 3 years of age.</p> <p>For patients who do not qualify for Sovaldi, Pediatric patients age < 12 years OR weighing < 35 kg was revised to < 3 years of age and the weight requirement was removed.</p> <p>“brand or generic” was added to criteria in which Harvoni or Epclusa trial is required.</p>	09/04/2019
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