

FORMULARY EXCEPTION POLICY

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

DATE REVISED: 11/12/2020

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 for 12 weeks if the patient meets the following criteria (A, B, C, D, and E):
 - A. Patient is \geq 18 years of age; AND
 - B. Patient does not have compensated (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis (See *Criteria 3*); AND
 - C. 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 the patient did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required]**. AND
 - D. The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
 - E. The medication will be prescribed in combination with Daklinza.

- 3. Chronic Hepatitis C Virus (HCV) Genotype 1, Compensated or Decompensated Cirrhosis, Adults.** Approve for 12 weeks in patients who meet the following criteria (A, B, C, D and E):
 - A. Patient is \geq 18 years of age; AND
 - B. Patient has compensated (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis **[documentation required]**; AND
 - C. Patient has completed a course of therapy with ONE of Epclusa (brand or generic) or Harvoni (brand or generic) and has documentation that the patient did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required]**. AND
 - D. The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
 - E. Patient meets ONE of the following criteria (i or ii below):
 - i) Patient has decompensated (Child-Pugh B or C) cirrhosis AND Sovaldi will be prescribed in combination with Daklinza AND ribavirin; OR
 - ii) 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 for 12 weeks if the patient meets the following criteria (A, B, C, and D):
 - A. Patient is ≥ 3 years of age; AND
 - B. The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
 - C. The medication will be prescribed in combination with ribavirin; AND
 - D. 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 for 24 weeks if the patient meets the following criteria (A, B, C, and D):
 - A. Patient is ≥ 3 years of age; AND
 - B. The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
 - C. The medication will be prescribed in combination with ribavirin; AND
 - D. 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 for 12 weeks if the patient meets the following criteria (A, B, C, D, and E):
 - A. Patient is ≥ 18 years of age; AND
 - B. Patient does not have compensated (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis (See *Criteria 7*); AND
 - C. Patient has completed a course of therapy with ONE of Epclusa (brand or generic) or Vosevi and has documentation that the patient did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required]**. AND
 - D. The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
 - E. The medication is prescribed in combination with Daklinza.

7. **Chronic Hepatitis C Virus (HCV) Genotype 3, Adults, Compensated or Decompensated Cirrhosis.** Approve for 12 weeks if the patient meets the following criteria (A, B, C, D, and E):
 - A. Patient is ≥ 18 years of age; AND
 - B. Patient has compensated (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis **[documentation required]**; AND
 - C. Patient has completed a course of therapy with Epclusa (brand or generic) and has documentation that the patient 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. The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
 - E. The medication 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 12 weeks if the patient meets the following criteria (A, B, C, and D):
 - A. Patient is ≥ 18 years of age; AND
 - B. Patient has recurrent HCV after a liver transplantation; AND
 - C. The medication 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 medication 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).

HISTORY

Type of Revision	Summary of Changes*	Lay Criteria Effective Date
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	Chronic Hepatitis C Virus (HCV) Genotype 2, Pediatric Patients: Age indication revised to include patients \geq 3 years of age. Chronic Hepatitis C Virus (HCV) Genotype 3, Pediatric Patients: Age indication revised to include patients \geq 3 years of age. 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. "brand or generic" was added to criteria in which Harvoni or Epclusa trial is required.	09/04/2019
DEU revision	Chronic Hepatitis C Virus (HCV) Genotype 1, No Cirrhosis, Adults: Reference to he/she was changed to" the patient". Chronic Hepatitis C Virus (HCV) Genotype 1, Compensated or Decompensated Cirrhosis, Adults: Reference to he/she was changed to" the patient". Chronic Hepatitis C Virus (HCV) Genotype 3, Adults, No Cirrhosis: Reference to he/she was changed to" the patient". Chronic Hepatitis C Virus (HCV) Genotype 3, Adults, Compensated or Decompensated Cirrhosis: Reference to he/she was changed to" the patient".	11/12/2020