UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1127-15
Program	Prior Authorization/Notification
Medication	Sovaldi® (sofosbuvir)
P&T Approval Date	2/2014, 4/2014, 5/2014, 8/2014, 2/2015, 8/2015, 2/2016, 2/2017, 2/2018, 2/2019, 2/2020, 2/2021, 2/2022, 2/2023, 5/2023
Effective Date	8/1/2023; Oxford only: N/A

1. Background:

Sovaldi® (sofosbuvir) is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of: [1]

- Adult patients with genotype 1, 2, 3, or 4 chronic HCV infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen.
- Pediatric patients 3 years of age and older with genotype 2 or 3 chronic HCV infection without cirrhosis or with compensated cirrhosis in combination with ribavirin.

Sovaldi's efficacy has been established in subjects with HCV genotype 1, 2, 3 or 4 infection, including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection.[1]

The following points should be considered when initiating treatment with Sovaldi:[1]

- Monotherapy of Sovaldi is not recommended for treatment of chronic hepatitis C (CHC).
- Treatment regimen and duration are dependent on both viral genotype and patient population.
- Treatment response varies based on baseline host and viral factors

2. Coverage Criteria[a]:

A. <u>Sovaldi in combination with ribavirin with or without peginterferon alfa:</u>

1. **Sovaldi** will be approved based on **<u>one</u>** of the following criteria:

   a. **<u>All</u>** of the following:

      (1) Diagnosis of chronic hepatitis C <u>genotype 1 or 4</u> infection

      -AND-

      (2) Used in combination with ribavirin

      -AND-

      (3) **<u>One</u>** of the following:

         (a) Used in combination with peginterferon alfa

         -OR-

(b) **Both** of the following:

1) Patient is ineligible for peginterferon alfa therapy

-AND-

2) Patient has genotype 1 infection

-AND-

(4) Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

-AND-

(5) Patient is without decompensated liver disease (e.g., Child-Pugh B or C)

-OR-

b. **All** of the following:

(1) Diagnosis of chronic hepatitis C genotype 2 or 3 infection

-AND-

(2) Used in combination with ribavirin

-AND-

(3) Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

-OR-

c. **All** of the following:

(1) Diagnosis of chronic hepatitis C genotype 1, 2, 3, or 4 infection

-AND-

(2) One of the following:

(a) Diagnosis of hepatocellular carcinoma

-OR-

(b) Patient has decompensated liver disease (e.g., Child-Pugh Class B or C)

-AND-

(3) Patient is an active candidate on the waiting list for a liver transplant

-AND-

(4) Used in combination with ribavirin

-AND-

(5) Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

For GENOTYPES 1 and 4 in combination with peginterferon alfa and ribavirin: Authorization will be issued for 12 weeks.

For GENOTYPE 1 in combination with ribavirin and ineligible for pegylated interferon alfa: Authorization will be issued for 24 weeks.

For GENOTYPE 2 in combination with ribavirin: Authorization will be issued for 12 weeks.

For GENOTYPE 3 in combination with ribavirin: Authorization will be issued for 24 weeks.

For GENOTYPES 1, 2, 3, or 4 in combination with ribavirin in patients with hepatocellular carcinoma OR decompensated liver disease and awaiting liver transplantation: Authorization will be issued for 48 weeks.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits, step therapy and medical necessity may be in place.

4. References:

1. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; March 2020.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. http://www.hcvguidelines.org/full-report-view. Accessed April 3, 2023.

Program	Prior Authorization/Notification - Sovaldi™ (sofosbuvir)
Change Control	
2/2014	New program.
4/2014	Added criteria for Sovaldi + pegineterferon alfa + ribavirin for genotype 3. Added criteria for Sovaldi + ribavirin for genotype 4. Added criteria for HCV reinfection after liver transplantation.
5/2014	Added criterion requiring that the patient has not tried a previous regimen with Sovaldi or has demonstrated intolerance to Sovaldi/interferon/ribavirin.
8/2014	Removed symptomatic hepatitis C induced cryoglobulinemia as an option to prove interferon ineligibility. Added criterion requiring that patient is without decompensated disease throughout, except where criteria has been revised to allow in decompensated patients awaiting liver transplant.
12/2014	Administrative correction.
2/2015	Updated background and references. Revised Sovaldi in combination with Olysio section to reflect revised Olysio prescribing information.
8/2105	Added criteria for combination therapy with Daklinza (daclatasavir).
2/2016	Annual review with no clinical changes. Updated references.
2/2017	Annual review. Removal of Sovaldi/ribavirin combination for post transplant therapy in genotypes 1, 3, and 4 as no longer recommended by guidelines. Updated approval duration to 24 weeks for genotype 2 post liver transplant. Added genotype 1 to criteria for combination therapy with Daklinza (daclatasavir).
2/2018	Annual review with no change to coverage criteria. Updated references.
2/2019	Removed use with Olysio (simeprevir) to reflect market withdrawal. Updated criteria to remove reinfection after liver transplant for genotype 2. Updated approval durations.
2/2020	Annual review. Clarification to genotype 1 or 4 length of therapy with ribavirin +/- peginterferon. Removed criteria for use with Daklinza, as Daklinza is now off the market. Updated background and references.
2/2021	Annual review. No changes to clinical coverage criteria. Background and references updated.
2/2022	Annual review. No changes to clinical coverage criteria. References updated.
2/2023	Annual review without changes to clinical coverage criteria. Added state mandate and updated references.
5/2023	Simplified peginterferon eligibility requirements. Updated references.