![UnitedHealthcare logo]

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2053-18
Program	Prior Authorization/Medical Necessity
Medication	Sovaldi® (sofosbuvir)
P&T Approval Date	4/2015, 8/2015, 11/2015, 8/2016, 12/2016, 9/2017, 11/2018, 2/2019, 3/2020, 5/2021, 5/2022, 5/2023, 5/2024
Effective Date	8/1/2024

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 hepatitis C virus (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.

2. **Coverage Criteria[a]:**

A. For the treatment of chronic hepatitis C genotype 1 or 4 infection in peginterferon eligible patients who are without cirrhosis or have compensated cirrhosis, **Sovaldi in combination with peginterferon alfa and ribavirin** will be approved based on **all** of the following criteria:

1. **One** of the following:

a. Diagnosis of chronic hepatitis C genotype 1 infection

-OR-

b. Diagnosis of chronic hepatitis C genotype 4 infection

-AND-

2. Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

-AND-

3. Used in combination with peginterferon alfa and ribavirin

-AND-

4. **One** of the following:

    a.   Patient is without cirrhosis

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-OR-

</div>

    b.   Patient has compensated cirrhosis (Child-Pugh A)

<div align="center">

-AND-

</div>

5. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

<div align="center">

-AND-

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6. **One** of the following:

    a.   **All** of the following:

        (1) History of intolerance or contraindication to Epclusa (sofosbuvir/velpatasvir) therapy

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-AND-

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        (2) History of intolerance or contraindication to Harvoni (sofosbuvir/ledipasvir) therapy

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-AND-

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        (3) History of intolerance or contraindication to Mavyret (glecaprevir/pibrentasvir) therapy

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-AND-

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        (4) History of intolerance or contraindication to Zepatier (elbasvir/grazoprevir) therapy

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-OR-

</div>

    b.   Patient is currently on Sovaldi therapy

Authorization will be issued for 12 weeks.

B. For the treatment of chronic hepatitis C genotype 1 infection who are without cirrhosis or have compensated cirrhosis, **Sovaldi in combination with ribavirin** will be approved based on **all** of the following criteria:

1.   Diagnosis of chronic hepatitis C genotype 1 infection

-AND-

2. Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

-AND-

3. Used in combination with ribavirin

-AND-

4. Patient is ineligible for peginterferon alfa therapy

-AND-

5. **One** of the following:

    a. Patient is without cirrhosis

    -OR-

    b. Patient has compensated cirrhosis (Child-Pugh A)

    -AND-

6. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

-AND-

7. **One** of the following:

    a. **All** of the following:

        (1) History of intolerance or contraindication to Epclusa (sofosbuvir/velpatasvir) therapy

        -AND-

        (2) History of intolerance or contraindication to Harvoni (sofosbuvir/ledipasvir) therapy

        -AND-

        (3) History of intolerance or contraindication to Mavyret (glecaprevir/pibrentasvir) therapy

-AND-

    (4) History of intolerance or contraindication to Zepatier (elbasvir/grazoprevir) therapy

-OR-

    b. Patient is currently on Sovaldi therapy

Authorization will be issued for 24 weeks.

C. For the treatment of chronic hepatitis C genotype 2 infection who are without cirrhosis or have compensated cirrhosis, **Sovaldi in combination with ribavirin** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 2 infection

-AND-

2. Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

-AND-

3. Used in combination with ribavirin

-AND-

4. **One** of the following:

    a. Patient is without cirrhosis

-OR-

    b. Patient has compensated cirrhosis (Child-Pugh A)

-AND-

5. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

-AND-

6. **One** of the following:

    a. **Both** of the following:

        (1) History of intolerance or contraindication to Epclusa (sofosbuvir/velpatasvir)

therapy

-AND-

    (2) History of intolerance or contraindication to Mavyret (glecaprevir/pibrentasvir) therapy

-OR-

  b. Patient is currently on Sovaldi therapy

Authorization will be issued for 12 weeks.

D. For the treatment of chronic hepatitis C genotype 3 infection who are without cirrhosis or have compensated cirrhosis, **Sovaldi in combination with ribavirin** will be approved based on **all** of the following criteria:

  1. Diagnosis of chronic hepatitis C genotype 3 infection

-AND-

  2. Patient has not experienced failure with a previous treatment regimen that includes Sovaldi

-AND-

  3. Used in combination with ribavirin

-AND-

  4. **One** of the following:

    a. Patient is without cirrhosis

-OR-

    b. Patient has compensated cirrhosis (Child-Pugh A)

-AND-

  5. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

-AND-

  6. **One** of the following:

a. **Both** of the following:

    (1) History of intolerance or contraindication to Epclusa (sofosbuvir/velpatasvir) therapy

-AND-

    (2) History of intolerance or contraindication to Mavyret (glecaprevir/pibrentasvir) therapy

-OR-

b. Patient is currently on Sovaldi therapy

Authorization will be issued for 24 weeks.

E. For the treatment of chronic hepatitis C genotype 1, 2, 3, or 4 infection in patients with hepatocellular carcinoma awaiting liver transplantation. **Sovaldi in combination with ribavirin** will be approved based on **all** of the following criteria:

1. Diagnosis of hepatocellular carcinoma

-AND-

2. Patient is an active candidate on the waiting list for a liver transplant

-AND-

3. Patient is being managed in a liver transplant center

-AND-

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

-AND-

5. Used in combination with ribavirin

-AND-

6. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

-AND-

7. **One** of the following:

a. **Both** of the following:

   (1) Diagnosis of chronic hepatitis C genotype 1or 4

-AND-

   (2) **One** of the following:

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

- History of intolerance or contraindication to Harvoni (sofosbuvir/ledipasvir) therapy
- History of intolerance or contraindication to Epclusa (sofosbuvir/velpatasvir) therapy

-OR-

      (b) Patient is currently on Sovaldi therapy

-OR-

b. **Both** of the following:

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

-AND-

   (2) **One** of the following:

      (a) History of intolerance or contraindication to Epclusa (sofosbuvir/velpatasvir) therapy

-OR-

      (b) Patient is currently on Sovaldi therapy

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 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 March 26, 2024.

Program	Prior Authorization/Medical Necessity - Sovaldi (sofosbuvir)
Change Control	
4/2015	Coverage requirements for State of New Jersey effective 5/18/15.
8/2015	Added criteria for combination therapy with Daklinza (daclatasvir).
11/2015	Revised criteria to remove Sovaldi plus ribavirin step for cirrhotic patients in section M, merged section N into M, changed program title to include all lines of business and updated language regarding documentation of liver fibrosis.
7/2016	Added Indiana and West Virginia coverage information.
8/2016	Updated criteria to include Eplcusa as well as revisions to peginterferon eligibility requirements.
10/2016	Administrative change to correct formatting.
10/2016	Administrative change made for clarity.
11/2016	Added California coverage information.
12/2016	Removed abstinence-based criteria and replaced with treatment readiness screening criteria.
5/2017	Administrative update to reorder criteria. State mandate reference language updated.
9/2017	Revised step therapy criteria based on new product availability, included NY prescriber requirement, removed treatment readiness screening tools and removed medical record submission requirements.
11/2018	Annual review. Removed Olysio. Updated references.
2/2019	Revised step therapy to include Zepatier for genotypes 1 & 4.
3/2020	Annual review. Removed Daklinza as product is no longer available in market. Added requirement for peg-interferon ineligibility for genotype 1 + RBV. Removed Sovaldi + RBV for 24 weeks for GT 4 to align with current label and recommendations.
5/2021	Annual review. Removed prescriber requirement. Updated references.
5/2022	Reformatted criteria. Updated references.
5/2023	Annual review. Simplified peginterferon eligibility requirements. Clarified generic names for Harvoni and Epclusa. Updated references.
5/2024	Annual review. Removed liver disease staging criteria that was included for quality purposes rather than part of coverage decision. Updated references.