UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 2053-15
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
Effective Date	8/1/2021; Oxford only: 8/1/2021

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 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. Diagnosis of chronic hepatitis C genotype 1 infection

-AND-

2. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

3. Used in combination with peginterferon alfa and ribavirin

-AND-

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

-AND-

5. **One** of the following:

a. Patient is without cirrhosis

-OR-

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

-AND-

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

-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 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. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

3. Used in combination with ribavirin

-AND-

4. Patient is ineligible for peginterferon alfa therapy as evidenced by **one** of the following:

    a. Autoimmune hepatitis or autoimmune disorders (e.g., dermatomyositis, immune [idiopathic)] thrombocytopenic purpura, inflammatory bowel disease, interstitial lung disease, interstitial nephritis, polymyositis, psoriasis, rheumatoid arthritis, sarcoidosis, and systemic lupus erythematosus)
    b. Major uncontrolled depressive illness
    c. History of psychosis, schizophrenia, bipolar disorder, schizoaffective disorder, suicidal ideation
    d. Uncontrolled seizures
    e. Moderate or severe retinopathy
    f. Poorly controlled diabetes
    g. Baseline neutrophil count below 1,500/ µL
    h. Baseline platelet count below 70,000/ µL
    i. Baseline hemoglobin below 10 g/dL
    j. Significant ischemic cardiac disease
    k. Prior intolerance or hypersensitivity (urticaria, angioedema, bronchoconstriction, anaphylaxis, or Stevens-Johnson syndrome) to interferon therapy

-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. Patient is without cirrhosis
    b. Patient has compensated cirrhosis (Child-Pugh A)

-AND-

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

-AND-

8. **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. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

3. Used in combination with ribavirin

-AND-

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

-AND-

5. **<u>One</u>** of the following:

   a. Patient is without cirrhosis

   -OR-

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

   -AND-

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

-AND-

7. **<u>One</u>** of the following:

   a. **<u>Both</u>** 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 **<u>all</u>** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 3 infection

-AND-

2. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be

considered as part of the coverage decision

-AND-

3. Used in combination with ribavirin

-AND-

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

-AND-

5. **One** of the following:

   a. Patient is without cirrhosis
   b. Patient has compensated cirrhosis (Child-Pugh A)

-AND-

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

-AND-

7. **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 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. Diagnosis of chronic hepatitis C genotype 4 infection

-AND-

2. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

3. Used in combination with peginterferon alfa and ribavirin

-AND-

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

-AND-

5. **One** of the following:

   a. Patient is without cirrhosis
   b. Patient has compensated cirrhosis (Child-Pugh A)

-AND-

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

-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 12 weeks.

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

1. **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) **All** of the following

- History of intolerance or contraindication to Harvoni therapy
- History of intolerance or contraindication to Epclusa 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) **Both** of the following

- History of intolerance or contraindication to Epclusa therapy

-OR-

(b) Patient is currently on Sovaldi therapy

-AND-

2. Used in combination with ribavirin

-AND-

3. Diagnosis of hepatocellular carcinoma

-AND-

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

-AND-

5. Patient is being managed in a liver transplant center

-AND-

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

-AND-

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

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 24, 2021.

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.