UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3051-17
Program	Step Therapy
Medications	Hepatitis C Direct Acting Antivirals - Epclusa® (sofosbuvir/velpatasvir), Harvoni® (ledipasvir/sofosbuvir), Mavyret® (glecaprevir/pibrentasvir), Sovaldi® (sofosbuvir), Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets), Zepatier® (elbasvir/grazoprevir)
P&T Approval Date	1/2015, 2/2015, 8/2015, 2/2016, 8/2016, 9/2017, 11/2018, 2/2019, 3/2020, 7/2021, 7/2022, 7/2023, 7/2024
Effective Date	10/1/2024

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member with chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 infection to use Epclusa® (sofosbuvir/velpatasvir), Harvoni® (ledipasvir/sofosbuvir), Mavyret® (glecaprevir/pibrentasvir) and/or Zepatier® unless there is a history of intolerance or contraindication to Epclusa, Harvoni, Mavyret and/or Zepatier therapy.

Epclusa (sofosbuvir/velpatasvir) is a fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor, and is indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic HCV genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis, and with decompensated cirrhosis for use in combination with ribavirin.[1]

Harvoni (ledipasvir/sofosbuvir) is a fixed-dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and is indicated for the treatment of adults and pediatric patients 3 years of age and older with chronic HCV genotype 1, 4, 5 or 6 infection without cirrhosis or with compensated cirrhosis, genotype 1 infection with decompensated cirrhosis, in combination with ribavirin, and genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin.[2]

Mavyret (glecaprevir/pibrentasvir) is a fixed-dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor, and is indicated for the treatment of adult and pediatric patients 3 years and older with chronic HCV genotype (GT) 1, 2, 3, 4, 5 or 6 infection without cirrhosis and with compensated cirrhosis (Child-Pugh A). Mavyret is also indicated for the treatment of adult and pediatric patients 3 years and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.[3]

Sovaldi® (sofosbuvir) is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of 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. Sovaldi is also indicated for the treatment of 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.[4]

Viekira Pak® (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets) is indicated for the treatment of adult patients with chronic hepatitis C virus (HCV) genotype 1a without cirrhosis or with compensated cirrhosis for use in combination with ribavirin, and genotype 1b without cirrhosis or with compensated cirrhosis. Viekira Pak includes ombitasvir, a hepatitis C virus NS5A inhibitor, paritaprevir, a hepatitis C virus NS3/4A protease inhibitor, ritonavir, a CYP3A inhibitor and dasabuvir, a hepatitis C virus non-nucleoside NS5B palm polymerase inhibitor.[5]

Zepatier® (elbasvir/grazoprevir) is a fixed-dose combination product containing elbasvir, a hepatitis C virus (HCV) NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor, and is indicated for treatment of chronic HCV genotypes 1 or 4 infection in adult and pediatric patients 12 years of age and older or weighing at least 30 kgs. Zepatier is also indicated for use with ribavirin in certain patient populations.[6]

2. Coverage Criteria[a]:

A. <u>Chronic Hepatitis C Genotype 1</u>

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

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

      i. Genotype 1

      -AND-

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

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

            (1) History of intolerance or contraindication to Epclusa therapy

            -AND-

            (2) History of intolerance or contraindication to Harvoni therapy

            -AND-

            (3) History of intolerance or contraindication to Mavyret therapy

            -AND-

            (4) History of intolerance or contraindication to Zepatier therapy

         -OR-

         (b) Patient is currently on Sovaldi or Viekira Pak therapy

   -OR-

   b. **Sovaldi** is used in the treatment of any other genotype (not genotype 1, 2, 3, or 4)

-OR-

c. **Viekira Pak** is used in the treatment of any other genotype (not genotype 1)

Authorization will be issued for 12 months.

2. **Harvoni or Harvoni authorized generic** will be approved based on **one** of the following criteria:

a. **Both** of the following:

i. Genotype 1

-AND-

ii. Request is for 8 weeks

-OR-

b. **All** of the following:

i. Genotype 1

-AND-

ii. Request is for greater than 8 weeks of therapy

-AND-

iii. **One** of the following:

(a) History of intolerance or contraindication to Epclusa therapy

-OR-

(b) Patient is currently on Harvoni therapy

-OR-

c. All other genotypes (not genotype 1, 4, 5, or 6)

Authorization will be issued for 12 months.

B. Chronic Hepatitis C Genotype 2

1. **Sovaldi** will be approved based on **one** of the following criteria:

a. **Both** of the following:

i. Genotype 2

-AND-

ii. **One** of the following:

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

(1) History of intolerance or contraindication to Epclusa therapy

-AND-

(2) History of intolerance or contraindication to Mavyret therapy

-OR-

(b) Patient is currently on Sovaldi therapy

-OR-

b. All other genotypes (not genotype 2, 1, 3, or 4)

Authorization will be issued for 12 months.

C. Chronic Hepatitis C Genotype 3

1. **Sovaldi** will be approved based on **one** of the following criteria:

a. **Both** of the following:

i. Genotype 3

-AND-

ii. **One** of the following:

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

(1) History of intolerance or contraindication to Epclusa therapy

-AND-

(2) History of intolerance or contraindication to Mavyret therapy

-OR-

(b) Patient is currently on Sovaldi therapy

-OR-

b. All other genotypes (not genotype 3, 1, 2, or 4)

Authorization will be issued for 12 months.

D. Chronic Hepatitis C Genotype 4

1. **Sovaldi** will be approved based on **one** of the following criteria:

   a. **Both** of the following:

      i. Genotype 4

      -AND-

      ii. **One** of the following:

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

            (1) History of intolerance or contraindication to Epclusa therapy

            -AND-

            (2) History of intolerance or contraindication to Harvoni therapy

            -AND-

            (3) History of intolerance or contraindication to Mavyret therapy

            -AND-

            (4) History of intolerance or contraindication to Zepatier therapy

            -OR-

         (b) Patient is currently on Sovaldi therapy

      -OR-

   b. All other genotypes (not genotype 4, 1, 2, or 3)

   Authorization will be issued for 12 months.

2. **Harvoni** or **Harvoni authorized generic** will be approved based on **one** of the following criteria:

   a. **Both** of the following:

      i. Genotype 4

      -AND-

      ii. **One** of the following:

         (a) History of intolerance or contraindication to Epclusa therapy

         -OR-

         (b) Patient is currently on Harvoni therapy

-OR-

b. All other genotypes (not genotype 4, 1, 5, or 6)

Authorization will be issued for 12 months.

E. Chronic Hepatitis C Genotype 5 or 6

1. **Harvoni** or **Harvoni authorized generic** will be approved based on **one** of the following criteria:

a. **Both** of the following:

i. Genotype 5 or 6

-AND-

ii. **One** of the following:

(a) History of intolerance or contraindication to Epclusa therapy

-OR-

(b) Patient is currently on Harvoni therapy

-OR-

b. All other genotypes (not genotype 5, 6, 1, or 4)

Authorization will be issued for 12 months.

[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 and/or Prior Authorization may be in place.

4. References:

1. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2022.
2. Harvoni [package insert]. Foster City, CA: Gilead Sciences, Inc.; March 2020.
3. Mavyret [package insert]. North Chicago, IL: AbbVie Inc.; October 2023.
4. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; March 2020.
5. Viekira Pak [package insert]. North Chicago, IL: AbbVie, Inc.; December 2019.
6. Zepatier [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; May 2022.

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Change Control	
1/2015	New step therapy program that requires the use of Harvoni for treatment of chronic hepatitis c genotype 1 before other treatments are covered.
2/2015	Revised formatting.
8/2015	Added Technivie. Added Maryland Continuation of Care.
2/2016	Added Daklinza and Zepatier. Removed Victrelis Updated references.
7/2016	Added Indiana and West Virginia coverage information.
8/2016	Added new step criteria to include Epclusa and Viekira XR.
10/2016	Administrative change to correct current therapy for Daklinza or Sovaldi (Section B).
11/2016	Administrative change. Added California coverage information
9/2017	Updated step criteria based on approval of new agent
11/2017	Administrative change for continuation of therapy
11/2018	Annual review. Removed Olysio. Updated references.
2/2019	Removed Technivie and Viekira XR because products were withdrawn from the market. Updated step requirement for Zepatier.
3/2020	Annual review. Removed Daklinza as product was withdrawn from the market. Added step requirement for Harvoni and AG >8 weeks therapy.
7/2020	Administrative change to list Harvoni in medication list of header.
7/2021	Annual review. No changes to coverage criteria. Updated background and references.
7/2022	Annual review. Revised listing of genotypes as exceptions in criteria to avoid allowing for approvals without routing through the appropriate criteria. No changes to clinical intent. Updated Zepatier indication in background section to align with label and updated references.
7/2023	Annual review. No changes to coverage criteria.
7/2024	Annual review. Updated background and references.