

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2019 P 3051-11
Program	Step Therapy
Medications	Hepatitis C Direct Acting Antivirals - Daklinza® (daclatasvir), Epclusa® (sofosbuvir/velpatasvir), 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
Effective Date	5/1/2019; Oxford only: N/A

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 adult patients with chronic HCV genotype 1, 2, 3, 4, 5 or 6 infection¹:

- Without cirrhosis or with compensated cirrhosis
- With decompensated cirrhosis for use in combination with ribavirin

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 chronic hepatitis C (CHC) genotype 1, 4, 5 or 6 infection.²

Daklinza® (daclatasvir) is a hepatitis C virus (HCV) NS5A inhibitor indicated for use with Sovaldi® (sofosbuvir), with or without ribavirin, for the treatment of chronic HCV genotype 1 or 3 infection.³

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 patients 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 patients 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.⁴

Sovaldi® (sofosbuvir) is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen.⁵

Viekira Pak® (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets) with or without ribavirin is indicated for the treatment of patients with genotype 1 chronic hepatitis C virus (HCV) infection including those 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 polymerase inhibitor.⁶

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 with or without ribavirin for treatment of chronic HCV genotypes 1 or 4 infection in adults.⁷

2. Coverage Criteria^a:

A. Chronic Hepatitis C Genotype 1

1. **Daklinza, Sovaldi, or Viekira Pak** will be approved based on **one** of the following criteria:

a. **Both** of the following:

i. Genotype 1

-AND-

ii. **One** 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 Daklinza, Sovaldi, or Viekira Pak therapy

-OR-

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

Authorization will be issued for 12 months.

C. Chronic Hepatitis C Genotype 3

1. **Daklinza or 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 Daklinza or Sovaldi therapy

-OR-

b. All other genotypes (not genotype 3, 5 or 6)

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, 5 or 6)

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.; November 2017.
2. Harvoni [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2017.
3. Daklinza [package insert]. Princeton, NJ : Bristol-Myers Squibb ; November 2017.
4. Mavyret [package insert]. North Chicago, IL: AbbVie Inc.; August 2018.
5. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2017.
6. Viekira Pak [package insert]. North Chicago, IL: AbbVie, Inc.; July 2018.
7. Zepatier [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; June 2018.

Program	Step Therapy – Hepatitis C Direct Acting Antivirals - Daklinza [®] (daclatasvir), Sovaldi [®] (sofosbuvir), Viekira Pak [™] (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets)
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.
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