

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2020 P 3051-13
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
Effective Date	6/1/2020; 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 infection without cirrhosis or with compensated cirrhosis, and with decompensated cirrhosis for use in combination with ribavirin.<sup>1</sup>

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 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.<sup>2</sup>

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 and pediatric patients 12 years of age or older or weighing at least 45 kg 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.<sup>4</sup>

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.<sup>5</sup>

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 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.<sup>6</sup>

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 adults. It is also indicated for use with ribavirin in certain patient populations.<sup>7</sup>

## 2. Coverage Criteria<sup>a</sup>:

### A. Chronic Hepatitis C Genotype 1

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

**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-**

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

**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. **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, 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.**

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 2, 3, or 4)

**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 2, 3, 5, or 6)

**Authorization will be issued for 12 months.**

<sup>a</sup> 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 2019.
2. Harvoni [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2019.
3. Mavyret [package insert]. North Chicago, IL: AbbVie Inc.; January 2020.
4. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; September 2019.
5. Viekira Pak [package insert]. North Chicago, IL: AbbVie, Inc.; December 2019.
6. Zepatier [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; December 2019.

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<b>Change Control</b>	
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.