UnitedHealthcare Community Plan

# Clinical Pharmacy Program Guidelines for Hepatitis C Agents – CALIFORNIA

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|---|---|
| Program | Prior Authorization/Medical Necessity |
| Medication | Epclusa (sofosbuvir/velpatasvir), Harvoni™ (ledipasvir/sofosbuvir), ledipasvir/sofosbuvir (authorized generic of Harvoni), Mavyret™ (glecaprevir/pibrentasvir), sofosbuvir/velpatasvir (authorized generic of Epclusa), Sovaldi® (sofosbuvirVosevi™ (sofosbuvir/velpatasvir/voxilaprevir), Zepatier™ (elbasvir/grazoprevir) |
| Markets in Scope | California |

## 1. State Mandated Criteria - LOD

DHCS_Hep_C_Policy_7_1_18.pdf

## 2. Coverage Criteria:

1. Treatment considerations and choice of regimen for hepatitis C virus infected patients:

- Please refer to AASLD guidelines (hcvguidelines.org) for recommended treatment regimens and durations.

2. Identifying treatment candidates:

- Patient Readiness and Adherence:
  - Patients shall be evaluated for readiness to initiate treatment.
  - Patients selected for treatment shall be able and willing to strictly adhere to treatment protocols prescribed by their provider.
  - Caution shall be exercised with patients who have a history of treatment failure with prior hepatitis C treatment due to non-adherence with treatment regimen and appointments.
  - Patients shall be educated regarding potential risks and benefits of hepatitis C virus therapy, as well as the potential for resistance and failed therapy if medication is not taken as prescribed.
- Age requirements: Treatment candidate must be 12 years of age or older

3. Other considerations

- Laboratory Testing
  - Documentation of baseline hepatitis C virus-RNA level
  - Documentation of hepatitis C virus Genotype
  - Laboratory testing should be consistent with current AASLD/IDSA guidelines
- Populations Unlikely to Benefit from Hepatitis C Virus Treatment: According to AASLD/IDSA hepatitis C virus Guidelines, “patients with

limited life expectancy for whom hepatitis C virus therapy would not improve symptoms or prognosis do not require treatment. Chronic hepatitis C is associated with a wide range of comorbid conditions. Little evidence exists to support initiation of hepatitis C virus treatment in patients with limited life expectancy (less than 12 months) due to non– liver-related comorbid conditions. For these patients, the benefits of hepatitis C virus treatment are unlikely to be realized, and palliative care strategies should take precedence." In patients with a life expectancy less than 12 months, treatment is not recommended.

- Retreatment: Retreatment will be considered where there is evidence that such retreatment will improve patient outcomes. Please refer to AASLD guidelines for recommended retreatment regimens (hcvguidelines.org).
- Criteria for coverage of Investigational Services (Title 22 § 51303)
    - Investigational services are not covered except when it is clearly documented that all of the following apply:
    - Conventional therapy will not adequately treat the intended patient's condition;
    - Conventional therapy will not prevent progressive disability or premature death;
    - The provider of the proposed service has a record of safety and success with it equivalent or superior to that of other providers of the investigational service;
    - The investigational service is the lowest cost item or service that meets the patient's medical needs and is less costly than all conventional alternatives;
    - The service is not being performed as a part of a research study protocol;
    - There is a reasonable expectation that the investigational service will significantly prolong the intended patient's life or will maintain or restore a range of physical and social function suited to activities of daily living;
    - All investigational services require prior authorization. Payment will not be authorized for investigational services that do not meet the above criteria or for associated inpatient care when a beneficiary needs to be in the hospital primarily because she/he is receiving such non-approved investigational services.
- Unlabeled use of medication: Authorization for unlabeled use of drugs shall not be granted unless the requested unlabeled use represents reasonable and current prescribing practices. The determination of reasonable and current prescribing practices shall be based on:
    - Reference to current medical literature.
    - Consultation with provider organizations, academic and professional specialists.

4. **One** of the following:

a. **All** of the following:

(1) The request is for Mavyret

**-AND-**

(2) The requested regimen is an approvable regimen, as outlined below, based on patient genotype and characteristics

**Treatment Naïve Patients**

| HCV Genotype | Treatment Duration | |
|---|---|---|
| | No cirrhosis | Compensated cirrhosis (Child-Pugh A) |
| 1, 2, 3, 4, 5, or 6 | 8 weeks | 8 weeks |

**Treatment Experienced Patients**

| | | Treatment Duration | |
|---|---|---|---|
| **HCV Genotype** | **Patients previously treated with a regimen containing:** | **No cirrhosis** | **Compensated cirrhosis (Child-Pugh A)** |
| 1 | An NS5A inhibitor[1] without prior treatment with an NS3/4A protease inhibitor | 16 weeks | 16 weeks |
| | An NS3/4A PI[2] without prior treatment with an NS5A inhibitor | 12 weeks | 12 weeks |
| 1, 2, 4, 5, or 6 | PRS[3] | 8 weeks | 12 weeks |
| 3 | PRS[3] | 16 weeks | 16 weeks |

1. In clinical trials, subjects were treated with prior regimens containing ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin.

2. In clinical trials, subjects were treated with prior regimens containing simeprevir and sofosbuvir, or simeprevir, boceprevir, or telaprevir with pegylated interferon and

ribavirin.

3. PRS = prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor.

**Kidney Transplant Recipients**

| **HCV Genotype** | **Treatment Duration** | |
|---|---|---|
| | No cirrhosis | Compensated cirrhosis (Child-Pugh A) |
| 1, 2, 3, 4, 5, or 6 | 12 weeks | 12 weeks |

**-OR-**

b. **All** of the following:

(1) The request is for Epclusa or sofosbuvir/velpatasvir (authorized generic of Epclusa)

**-AND-**

(2) The requested regimen is an approvable regimen, as outlined below, based on patient genotype and characteristics:

| **Patient Population** | **Recommended Treatment Regimen** |
|---|---|
| Treatment-naïve and treatment experienced[1] without cirrhosis and with compensated cirrhosis (Child-Pugh A) | EPCLUSA for 12 weeks |
| Treatment-naïve and treatment experienced[1] with decompensated cirrhosis (Child-Pugh B and C) | EPCLUSA + ribavirin for 12 weeks |

1 = In clinical trials, regimens contained peginterferon alfa/ribavirin with or without an HCV NS3/4A protease inhibitor (boceprevir, simeprevir, or telaprevir)

NOTE: RPh will review for preferred authorized generic drug and determine if non-preferred (brand name) is appropriate. If brand is requested, the provider must submit explanation of medical necessity for brand versus authorized generic.

**-OR-**

c. **All** of the following:

(1) The request is for Harvoni or ledipasvir/sofosbuvir (authorized generic of Harvoni)

**-AND-**

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

(a) Patient is genotype 1 or 4and has a history of intolerance or contraindication to all of the following: sofosbuvir/velpatasvir (authorized generic of Epclusa), Mavyret and Zepatier

**-OR-**

(b) Patient is genotype 5 or 6 and has a history of intolerance or contraindication to both of the following: sofosbuvir/velpatasvir (authorized generic of Epclusa) and Mavyret

**-OR-**

(c) Patient is currently on Harvoni therapy

**-AND-**

(3) The requested regimen is an approvable regimen, as outlined below, based on patient genotype and characteristics

**Recommended adult treatment regimen and duration:**

| Genotype | Patient Population | Regimen and Duration |
|---|---|---|
| Genotype 1 | Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A) | HARVONI 12 weeks* |
| | Treatment-experienced** without cirrhosis | HARVONI 12 weeks |
| | Treatment-experienced** with compensated cirrhosis (Child-Pugh A) | HARVONI 24 weeks |

| | | |
|---|---|---|
| | Treatment-naïve and treatment-experienced** with decompensated cirrhosis (Child-Pugh B or C) | HARVONI + ribavirin 12 weeks |
| Genotype 1 or 4 | Treatment-naïve and treatment-experienced** liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A) | HARVONI + ribavirin 12 weeks |
| Genotype 1 or 4 | Treatment-naïve and treatment-experienced kidney transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A) | HARVONI 12 weeks |
| Genotype 4, 5, or 6 | Treatment-naïve and treatment-experienced** without cirrhosis or with compensated cirrhosis (Child-Pugh A) | HARVONI 12 weeks |

*HARVONI for 8 weeks can be considered in treatment-naïve patients without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/mL

**Treatment-experienced patients have failed a peginterferon alfa + ribavirin based regimen with or without an HCV protease inhibitor

[+]HARVONI + ribavirin for 12 weeks can be considered in treatment-experienced genotype 1 patients with cirrhosis who are eligible for ribavirin

**Recommended treatment duration for pediatric patients 12 years of age and older or weighing at least 35kg:**

| | **Pediatric patient population 12 years of age and older or weighing at least 35kg** | **Regimen and Duration** |
|---|---|---|
| Genotype 1 | Treatment naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A) | HARVONI 12 weeks |
| | Treatment-experienced[1] without cirrhosis | HARVONI 12 weeks |
| | Treatment-experienced[1] with compensated cirrhosis (Child-Pugh A) | HARVONI 24 weeks |
| | Treatment naïve and | HARVONI |

| | | |
|---|---|---|
| Genotype 4, 5, or 6 | treatment experienced[1] without cirrhosis or with compensated cirrhosis (Child-Pugh A) | 12 weeks |

1 = Treatment-experienced patients have failed an interferon based regiment with or without ribavirin

NOTE: RPh will review for preferred authorized generic drug and determine if non-preferred (brand name) is appropriate. If brand is requested, the provider must submit explanation of medical necessity for brand versus authorized generic.

d. **All** of the following:

(1) The request is for Sovaldi

**-AND-**

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

(a) Patient is genotype 1 or 4and has a history of intolerance or contraindication to all of the following: sofosbuvir/velpatasvir (authorized generic of Epclusa), Mavyret and Zepatier

**OR-**

(b) Patient is genotype 2 or 3 and has a history of intolerance or contraindication to both of the following: sofosbuvir/velpatasvir (authorized generic of Epclusa) and Mavyret

**-OR-**

(c) Patient is currently on Sovaldi therapy

**-AND-**

(3) The requested regimen is an approvable regimen, as outlined below, based on patient genotype and characteristics

**Recommended Adult Treatment Regimen and Duration**

| | **Adult Patient Population** | **Regimen and Duration** |
|---|---|---|
| | Treatment naïve without | SOVALDI + peginterferon |

| | | |
|---|---|---|
| Genotype 1 or 4 | cirrhosis or with compensated cirrhosis (Child-Pugh A) | alfa + ribavirin 12 weeks |
| Genotype 2 | Treatment naïve and treatment experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A) | SOVALDI + ribavirin 12 weeks |
| Genotype 3 | Treatment naïve and treatment experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A) | SOVALDI + ribavirin 24 weeks |

SOVALDI in combination with ribavirin for 24 weeks can be considered for adult patients with genotype 1 infection who are interferon ineligible.
SOVALDI should be used in combination with ribavirin for treatment of HCV in adult patients with hepatocellular carcinoma awaiting liver transplantation for up to 48 weeks or until liver transplantation, whichever occurs first.
*Treatment-experienced patients have failed an interferon based regimen with or without ribavirin

**Recommended Treatment Regimen and Duration for Pediatric Patients 12 Years of Age and Older or Weighing at Least 35kg**

| | **Pediatric Patient Population 12 Years of Age and Older or Weighing at Least 35kg** | **Regimen and Duration** |
|---|---|---|
| Genotype 2 | Treatment naïve and treatment experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A) | SOVALDI + ribavirin 12 weeks |
| Genotype 3 | Treatment naïve and treatment experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A) | SOVALDI + ribavirin 24 weeks |

*Treatment experienced patients have failed an interferon based regimen with or without ribavirin

**-OR-**

e. **All** of the following:

(1) The request is for Vosevi

**-AND-**

(2) The patient is without cirrhosis or has compensated cirrhosis (Child-Pugh A)

**-AND-**

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

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

- Patient is genotype 1, 2, 3, 4, 5, or 6 and had virologic failure after completing previous treatment of at least 4 weeks' duration with an HCV regimen containing an NS5A inhibitor
- If patient is genotype 1 and has not been previously treated with an NS3/4A inhibitor, history of intolerance or contraindication to Mavyret

**-OR-**

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

- Patient is genotype 1a or 3 and had virologic failure after completing previous treatment of at least 4 weeks' duration with an HCV regimen containing sofobuvir without an NS5A inhibitor
- If patient is genotype 1a and has been treated with or without an NS3/4A inhibitor, history of intolerance or contraindication to Mavyret
- If patient is genotype 3 and has not been treated with an NS3/4A inhibitor, history of intolerance or contraindication to Mavyret

**-OR-**

(c) Patient is currently on Vosevi therapy

**-AND-**

(4) The requested regimen is an approvable regimen, as outlined below,

based on patient genotype and characteristics

| Genotype | Patients previously treated with an HCV regimen containing: | VOSEVI Duration |
|---|---|---|
| 1, 2, 3, 4, 5, or 6 | An NS5A inhibitor[1] | 12 weeks |
| 1a or 3 | Sofosbuvir without an NS5A inhibitor[2] | 12 weeks |

1. In clinical trials, prior NS5A inhibitor experience included daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir.
2. In clinical trials, prior treatment experience included sofosbuvir with or without any of the following: peginterferon alfa/ribavirin, ribavirin, HCV NS3/4A protease inhibitor (boceprevir, simeprevir or telaprevir).

**-OR-**

f. **All** of the following:

(1) The request is for Zepatier

**-AND-**

(2) The requested regimen is an approvable regimen, as outlined below, based on patient genotype and characteristics

**Dosage Regimens and Durations for ZEPATIER in Patients with Genotype 1 or 4 HCV with or without Cirrhosis**

| Patient Population | Treatment | Duration |
|---|---|---|
| Genotype 1a: treatment naïve or PegIFN/RBV experienced* without baseline NS5A polymorphisms[+] | ZEPATIER | 12 weeks |
| Genotype 1a: treatment naïve or PegIFN/RBV experienced* with baseline NS5A polymorphisms[+] | ZEPATIER + ribavirin | 16 weeks |
| Genotype 1b: treatment naïve or PegIFN/RBV experienced* | ZEPATIER | 12 weeks |
| Genotype 1a or 1b: PegIFN/RBV/PI experienced[++] | ZEPATIER + ribavirin | 12 weeks |

| | | |
|---|---|---|
| Genotype 4: treatment naïve | ZEPATIER | 12 weeks |
| Genotype 4: PegIFN/RBV experienced* | ZEPATIER + ribavirin | 16 weeks |

*Peginterferon alfa + ribavirin
+Polymorphisms at amino acid positions 28, 30, 31, or 93
++Peginterferon alfa + ribavirin + HCV NS3/4 A protease inhibitor

**3. UnitedHealthcare Community Plan PDL Placement:**

| UnitedHealthcare Pharmacy – Community and State Preferred Products | | | | | | |
|---|---|---|---|---|---|---|
| | Genotype | | | | | |
| | 1 | 2 | 3 | 4 | 5 | 6 |
| Epclusa | | | | | | |
| Harvoni | | | | | | |
| Ledipasvir/sofosbuvir (authorized generic of Harvoni) | | | | | | |
| Mavyret | X | X | X | X | X | X |
| Sofosbuvir/velpatasvir (authorized generic of Epclusa) | X | X | X | X | X | X |
| Solvadi | | | | | | |
| Vosevi | | | | | | |
| Zepatier | X | | | X | | |

## 3. 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. Mavyret [package insert]. North Chicago, IL: AbbVie, Inc.; September 2019.
4. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2017.
5. Vosevi [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2017.
6. Zepatier [package insert]. Whitehouse Station, NJ: Merck & Co.; June 2018.


| Program | Prior Authorization |
|---|---|
| **Change Control** | |
| 9/2017 | New policy hepatitis C policy created to incorporate all direct acting antiviral agents. Mavyret will be the preferred product for all genotypes starting 1/1/18. |
| 7/2018 | Removed section pertaining to identification of patients for treatment. Changed minimum age requirement to 12 years. |
| 12/2018 | Removed Olysio, Technivie, and Viekira/XR from the program since the medications are no longer available. Added clarifying notes about treatment regimens per package inserts. Removed additional Mavyret characteristics from criteria since it is outlined in the approvable regimens. Added authorized generics for Epclusa and Harvoni to the program. Revised step component since Zepatier moving to preferred status. |
| 7/2019 | Removed Daklinza from the policy since the product is discontinued. Revised preferred products to reflect authorized generic of Epclusa will become a preferred product on 10/1/19. |
| 11/2019 | Changed Mavyret treatment-naïve compensated cirrhosis treatment duration from 12 weeks to 8 weeks to align with updated label. Updated references. |