DIRECT ACTING ANTIVIRAL AGENTS FOR HEPATITIS C VIRUS (HCV):
DAKLINZA™ (daclatasvir) oral tablet
EPCLUSA® (velpatasvir, sofosbuvir) oral tablet
HARVONI® (ledipasvir, sofosbuvir) oral tablet
MAVYRET™ (glecaprevir, pibrentasvir) oral tablet
OLYSIO™ (simeprevir sodium) oral capsule
SOVALDI™ (sofosbuvir) oral tablet
TECHNIVIE™ (paritaprevir, ombitasvir, ritonavir) oral tablet
VIEKIRA PAK™ (paritaprevir, ombitasvir, dasabuvir, ritonavir) oral tablet therapy pack
VIEKIRA XR™ (paritaprevir, ombitasvir, dasabuvir, ritonavir) extended release oral tablet
VOSEVI™ (voxilaprevir, velpatasvir, sofosbuvir) oral tablet
ZEPATIER™ (grazoprevir, elbasvir) oral tablet

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Pharmacy Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Pharmacy Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Pharmacy Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Pharmacy Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

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DIRECT ACTING ANTIVIRAL AGENTS FOR HEPATITIS C VIRUS (HCV) (cont.)

This Pharmacy Coverage Guideline does not apply to FEP or other states’ Blues Plans.

Information about medications that require precertification is available at www.azblue.com/pharmacy.

Some large (100+) benefit plan groups may customize certain benefits, including adding or deleting precertification requirements.

All applicable benefit plan provisions apply, e.g., waiting periods, limitations, exclusions, waivers and benefit maximums.

Precertification for medication(s) or product(s) indicated in this guideline requires completion of the request form in its entirety with the chart notes as documentation. All requested data must be provided. Once completed the form must be signed by the prescribing provider and faxed back to BCBSAZ Pharmacy Management at (602) 864-3126 or emailed to Pharmacyprecert@azblue.com. Incomplete forms or forms without the chart notes will be returned.

Description:

The presence of hepatitis C (HCV) antibody and HCV RNA are used to support a diagnosis of HCV infection. There are at least six major genotypes and several subtypes of HCV. Baseline viral load by quantitative assay and genotype are necessary to guide therapeutic options.

Hepatitis C infection is a major cause of chronic liver disease and a leading reason for liver transplantation. Sequelae of chronic hepatitis may include liver fibrosis, cirrhosis, liver failure, and hepatocellular carcinoma. Hepatocellular carcinoma rarely progress without underlying fibrosis and cirrhosis.

During acute HCV infection, there is a 20-50% chance of spontaneous resolution of infection. In at least two-thirds of individuals, this will occur within 6 months of the estimated time of infection; only 11% of those who remain viremic at 6 months will spontaneously clear infection at some time later.

Treatment of HCV is rapidly evolving and clinical practice guidelines change as new agents and results of clinical studies become available. Newer agents alone or used in combination with other agents attempt to improve sustained virologic response (SVR) rates, reduce pill-burden, reduce drug-drug interactions, and improve patient tolerance to the medication. The American Association for the Study of Liver Diseases (AASLD) and the Infectious Disease Society of America (IDSA) jointly publish a guideline on the treatment of HCV that can be accessed at http://www.hcvguidelines.org/full-report-view. The guideline has recommendations for testing, managing, and treating all HCV genotypes. Treatment options should consider patient-specific factors such as HCV genotype, prior treatment history, presence or absence of compensated or decompensated cirrhosis. The guidance uses evidence-based information.

Ribavirin in combination with an interferon or non-interferon oral anti-hepatitis C antiviral medications is indicated for the treatment of chronic hepatitis C viral (HCV) infection in patients with compensated liver disease. Ribavirin is a synthetic nucleoside analog (purine analog) with antiviral activity. It inhibits replication of RNA and DNA viruses, it inhibits influenza virus RNA polymerase activity and it inhibits the initiation and elongation of RNA fragments resulting in inhibition of viral protein synthesis.
HCV is an RNA virus that utilizes several important enzymes for reproduction. One is a NS3/4A serine protease enzyme that acts to cut large HCV encoded proteins into smaller pieces that are used to build new viruses. It is essential for viral replication. An additional enzyme that is essential for viral replication is NS5B RNA-dependent RNA polymerase that synthesizes the viral genome. The RNA polymerase initiates RNA synthesis by forming a bond between nucleotides that also begins the elongation process of RNA synthesis. A third enzyme, NS5A functions through interaction with other NS viral proteins and other cellular proteins that play a role in mediating host cell function and HCV viral replication, assembly, and egress. Cross-resistance is possible between HCV NS3/4A protease inhibitors and between HCV NS5A inhibitors by class.

About 10-15% of HCV genotype 1 infected patients without prior exposure to NS5A inhibitors will have detectable HCV NS5A resistance associated substitutions (RASs) prior to treatment. The presence of baseline NS5A RASs can cause a large reduction in the activity (> 5 fold) of NS5A inhibitors that potentially adversely impact response to NS5A containing regimens. Given that baseline NS5A RASs are one of the strongest pretreatment predictors of treatment outcome with certain regimens, testing for these RASs prior to deciding on a therapeutic course is now recommended in select situations. Patients with genotype 1a may have higher rates of failure than genotype 1b and RASs testing is recommended for genotype 1a. If the genotype cannot be subtyped recommendations from AASLD is to treat as a genotype 1a infection.

Definitions:

Direct acting antiviral agents for hepatitis C, oral:

**NS3/4A serine protease inhibitors:**
- Boceprevir – found in Victrelis, no longer available on the market
- Glecaprevir – found in Mavyret
- Grazoprevir – found in Zepatier
- Paritaprevir – found in Viekira Pak, Viekira XR, and Technivie
- Simeprevir – found in Olysio
- Telaprevir – found in Incivek, no longer available on the market
- Voxilaprevir – found in Vosevi

**NS5A inhibitors:**
- Daclatasvir – found in Daklinza
- Elbasvir – found in Zepatier
- Ledipasvir – found in Harvoni
- Ombitasvir – found in Viekira Pak, Viekira XR, and Technivie
- Pibrentasvir – found in Mavyret
- Velpatasvir – found in Epclusa, Vosevi

**NS5B polymerase inhibitors:**
- Dasabuvir – non-nucleoside inhibitor found in Viekira Pak and Viekira XR
- Sofosbuvir – nucleotide inhibitor found in Sovaldi, Harvoni, Epclusa, and Vosevi

**CYP3A inhibitors:**
- Ritonavir – inhibitor of metabolism, found in Viekira Pak, Viekira XR, and Technivie
The Child-Pugh classification system
The Child-Pugh classification is a scoring system used to determine the prognosis of chronic liver disease and cirrhosis. Scoring is based upon several factors: albumin, total bilirubin, prothrombin time or international normalized ratio, and degrees of ascites and encephalopathy.

<table>
<thead>
<tr>
<th>Child-Pugh Classification</th>
<th>Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>A: Well compensated</td>
<td>5-6</td>
</tr>
<tr>
<td>B: Significant functional compromise</td>
<td>7-9</td>
</tr>
<tr>
<td>C: Decompensated</td>
<td>10-15</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Parameter/Factor</th>
<th>1 point each</th>
<th>2 points each</th>
<th>3 points each</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total Bilirubin, mg/dL</td>
<td>&lt; 2 (or &lt; 34)</td>
<td>2-3 (or 34-50)</td>
<td>&gt;3 or (&gt; 50)</td>
</tr>
<tr>
<td>Albumin, g/dL</td>
<td>&gt;3.5 (or &gt; 35)</td>
<td>2.8-3.5 (or 28-35)</td>
<td>&lt; 2.8 (or &lt; 28)</td>
</tr>
<tr>
<td>Prothrombin time prolongation</td>
<td>1-3</td>
<td>4-6</td>
<td>&gt; 6</td>
</tr>
<tr>
<td>INR</td>
<td>&lt; 1.7</td>
<td>1.71-2.3</td>
<td>&gt; 2.3</td>
</tr>
<tr>
<td>Ascites</td>
<td>Absent</td>
<td>Slight/Mild</td>
<td>Moderate to severe</td>
</tr>
<tr>
<td>Encephalopathy</td>
<td>None</td>
<td>Grade 1-2 (or suppressed with medication)</td>
<td>Grade 3-4 (or refractory)</td>
</tr>
</tbody>
</table>

Hepatitis C Treatment Naive – Preferred Oral Agents

<table>
<thead>
<tr>
<th>Genotype 1</th>
<th>Genotype 2</th>
<th>Genotype 3</th>
<th>Genotype 4</th>
<th>Genotype 5</th>
<th>Genotype 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Epclusa</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Harvoni</td>
<td>X</td>
<td></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Mavyret†</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
</tbody>
</table>

Harvoni is not FDA approved for genotypes 2,3
† No cirrhosis or compensated cirrhosis (Child-Pugh A)

Hepatitis C Treatment Experienced – Preferred Oral Agent: Mavyret
Without cirrhosis or with compensated cirrhosis (Child-Pugh A) only

<table>
<thead>
<tr>
<th>Genotype 1, 2, 3, 4, 5, 6</th>
<th>Treatment naïve patients</th>
<th>Genotype 1</th>
<th>Genotype 1</th>
<th>Genotype 1, 2, 4, or 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior NS3/4A but without prior NS5A</td>
<td>8 weeks (without cirrhosis) or 12 weeks (with compensated cirrhosis [Child-Pugh A])</td>
<td>12 weeks</td>
<td>8 weeks no cirrhosis</td>
<td></td>
</tr>
<tr>
<td>Prior NS5A but without prior NS3/4A</td>
<td>16 weeks</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior PRS (peg-interferon, ribavirin, sofosbuvir)*</td>
<td>12 weeks compensated cirrhosis (C-P Class A)</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
DIRECT ACTING ANTIVIRAL AGENTS FOR HEPATITIS C VIRUS (HCV) (cont.)

Genotype 3
Prior PRS (peg-interferon, ribavirin, sofosbuvir)* 16 weeks

* No prior NS3/4A protease inhibitor or NS5A inhibitor experience

Mavyret (glecaprevir [NS3/4A inhibitor] and pibrentasvir [NS5A inhibitor])
NS3/4A inhibitors: boceprevir, grazoprevir, paritaprevir, simeprevir, telaprevir, voxilaprevir
NS5A inhibitors: daclatasvir, elbasvir, ledipasvir, ombitasvir, velpatasvir
NS5B inhibitors: dasabuvir, sofosbuvir

HCV treatment options by genotype:

<table>
<thead>
<tr>
<th>FDA-Approved indications</th>
<th>Genotype 1</th>
<th>Genotype 2</th>
<th>Genotype 3</th>
<th>Genotype 4</th>
<th>Genotype 5</th>
<th>Genotype 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daklinza + Sovaldi + RBV</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Epclusa</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Harvoni</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Mavyret†</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Olysio* + RBV / Peg-INF</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>Olysio* + Sovaldi</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sovaldi + RBV / Peg-INF</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Sovaldi + RBV</td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technivie + RBV</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Viekira Pak + RBV &amp;</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Viekira XR + RBV</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vosevi*</td>
<td>X*</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Zepatier**</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

† It is indicated for treatment-naive genotype 1-6 patients without cirrhosis or with compensated cirrhosis (C-P Class A) and also indicated for genotype 1 patients without cirrhosis or with compensated cirrhosis (C-P Class A) previously treated for HCV infection with a regimen that contained NS3/4A protease inhibitor or NS5A inhibitor, but not both and for genotypes 1-6 previously treated with pegylated interferon, ribavirin, and/or sofosbuvir, but no prior NS3/4 or NS5A inhibitors

* No Q80K substitution

+ It is indicated for individuals previously treated a HCV regimen: for genotypes 1-6 without cirrhosis or with compensated cirrhosis (C-P Class A) whose previous regimen contained a NS5A inhibitor and for genotype 1a or 3 whose regimen contained sofosbuvir without an NS5A inhibitor

** No baseline NS5A RASs at amino acid positions M28, Q30, L31, and Y93 for genotype 1a

Duration of treatment, depending on regimen, can be as short as weeks 8 weeks but usually ranges 12-24 weeks, and is influenced by genotype, agent(s) selected, prior treatment, presence of compensated or decompensated cirrhosis, and other patient specific factors

RBV = Ribavirin
Peg-INF = pegylated interferon
Ribavirin intolerance or ineligibility – requirements
- Platelets < 50,000 cell/mm³
- Neutrophils < 750 cell/mm³
- Hemoglobin < 10 g/dL
- Autoimmune hepatitis or other autoimmune condition known to be exacerbated by ribavirin

**Direct acting antiviral agents for hepatitis C, oral:**

**Daklinza (daclatasvir)**

**Epclusa (velpatasvir, sofosbuvir)**

**Harvoni (ledipasvir, sofosbuvir)**

**Mavyret (gelcaprevir, pibrentasvir)**

**Olysio (simeprevir sodium)**

**Sovaldi (sofosbuvir)**

**Technivie (paritaprevir, ombitasvir, ritonavir)**

**Viekira Pak (paritaprevir, ombitasvir, dasabuvir, ritonavir)**

**Viekira XR (paritaprevir, ombitasvir, dasabuvir, ritonavir)**

**Vosevi (voxilaprevir, velpatasvir, sofosbuvir)**

**Zepatier (grazoprevir, elbasvir)**

**Medication class:**
Direct Acting Antiviral Agents

**FDA-approved indication(s):**
- Treatment of Hepatitis C infection

**Recommended Dose:**
- Dosing and duration of treatment vary according to product, Hepatitis C genotype, presence or absence of cirrhosis, whether the cirrhosis is compensated or decompensated, patient characteristics and other co-morbidities

**Maximum dosage**
- Product dependent

**Available Dosage Forms:**

**Daklinza:** 30 mg, 60 mg, and 90 mg tablets

**Epclusa:** 100 mg velpatasvir + 400 mg sofosbuvir tablet

**Harvoni:** 90 mg ledipasvir + 400 mg sofosbuvir tablets

**Mavyret:** 100 mg voxilaprevir + 100 mg velpatasvir + 400 mg sofosbuvir tablets

**Olysio:** 150 mg capsule

**Sovaldi:** 400 mg tablet

**Technivie:** 75 mg paritaprevir + 12.5 mg ombitasvir + 50 mg ritonavir tablet

**Viekira Pak:** 75 mg paritaprevir + 12.5 mg ombitasvir + 50 mg ritonavir tablet and 250 mg dasabuvir tablet

**Viekira XR:** 50 mg paritaprevir + 8.33 mg ombitasvir + 33.33 mg ritonavir tablet and 200 mg dasabuvir tablet

**Vosevi:** 100 mg voxilaprevir + 100 mg velpatasvir + 400 mg sofosbuvir tablet
DIRECT ACTING ANTIVIRAL AGENTS FOR HEPATITIS C VIRUS (HCV) (cont.)

**Zepatier**: 100 mg grazoprevir + 50 mg elbasvir tablet

**Warnings and Precautions:**
- Woman of child bearing potential who is pregnant unless is using effective contraception
- Woman who is breast feeding an infant or child

**Ribavirin:**
- **Copegus (ribavirin)**
- **Moderiba (ribavirin)**
- **Rebetol (ribavirin)**
- **Ribasphere (ribavirin)**
- **Ribasphere Ribapak (ribavirin)**
- **RibaTab (ribavirin)**
- **Ribavirin**

**Medication class:**
Antihepaciviral, nucleoside (Anti-HCV)

**FDA-approved indication(s):**
- Treatment of chronic hepatitis C virus (HCV) infection and treatment of HCV with HIV co-infection

**Limitations of use:**
- Ribavirin monotherapy is not effective for the treatment of chronic hepatitis C virus (HCV) infection and should not be used alone for this indication
- Safety and efficacy of ribavirin have been established when used with interferon-based HCV therapies and non-interferon containing regimens in the treatment of chronic HCV infection

**Recommended Dose:**
- Dosing and duration of treatment vary according to product, Hepatitis C genotype, presence or absence of cirrhosis, whether the cirrhosis is compensated or decompensated, patient characteristics and other co-morbidities
  - See American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) recommendations at [https://www.hcvguidelines.org/](https://www.hcvguidelines.org/)

**Maximum dosage**
- Not stated

**Available Dosage Forms:**
- 200 mg, 400 mg, and 600 mg capsules and tablets depending on formulation
- 40 mg/mL oral solution

**Warnings, Precautions, and other Clinical Information:**
- Discontinue therapy in patients who develop hepatic decompensation during treatment
- The primary toxicity of ribavirin is hemolytic anemia, hemoglobin and hematocrit should be monitored
DIRECT ACTING ANTIVIRAL AGENTS FOR HEPATITIS C VIRUS (HCV) (cont.)

- Cardiac disease may be worsened by drug-induced anemia, patients with a history of significant or unstable cardiac disease should not use ribavirin
- Severe acute hypersensitivity reactions have occurred during alpha-interferon and ribavirin therapy
- Dyspnea, pulmonary infiltrates, pneumonitis, pulmonary hypertension, and pneumonia have been reported during therapy with ribavirin and interferon
- Pancytopenia and bone marrow suppression have been reported with pegylated interferon, ribavirin, and azathioprine therapy
- Pancreatitis may occur with ribavirin and pegylated interferon
- A negative pregnancy test is required immediately before initiation, monthly during therapy, and for 6 months after treatment is discontinued
- Woman of child bearing potential should avoid becoming pregnant, treatment of HCV is not recommended for women who are already pregnant
- Woman of child bearing potential should use 2 effective forms of contraception
- Males with female partners of reproductive potential should use effective contraception

Criteria:

- **Criteria for initial therapy:** Daklinza, Epclusa, Harvoni, Mavyret, Olysio, Sovaldi, Technivie, Viekira Pak, Viekira XR, Vosevi, and Zepatier for treatment Hepatitis C infection with or without ribavirin is considered **medically necessary** and will be approved when ALL of the following criteria are met:

  1. Prescriber is a Gastroenterologist, Hepatologist, or Infectious Disease provider
  2. Individual is 18 years of age for Daklinza, Epclusa, Mavyret, Olysio, Technivie, Viekira Pak, Viekira XR, Vosevi, and Zepatier or 12 years of age or older for Harvoni and Sovaldi
  3. A confirmed diagnosis of chronic hepatitis C virus (HCV)
  4. Individual with past Hepatitis C treatment has been compliant with previous and/or current drug therapy
  5. There must be no alcohol and/or no substance abuse in the past 6 months
  6. There must be no contraindications for use of agent(s) requested
  7. There are no significant interacting drugs
  8. For treatment- for HCV for non-preferred drugs: Failure, Contraindication or intolerance to at least 2 of the preferred agent by HCV genotype and treatment history

    - Preferred agents for treatment naïve HCV per genotype include:
      - Genotype 1: Harvoni, Epclusa, Mavyret
      - Genotype 2: Epclusa, Mavyret
      - Genotype 3: Epclusa, Mavyret
      - Genotype 4: Harvoni, Epclusa, Mavyret
      - Genotype 5: Harvoni, Epclusa, Mavyret
      - Genotype 6: Harvoni, Epclusa, Mavyret
9. For HCV treatment requiring concurrent use of ribavirin: Individual has failure, contraindication or intolerance to **generic ribavirin 200mg**

10. Duration of treatment is consistent with product labeling, current clinical guideline recommendation from AASLD / IDSA for the specific HCV genotype, liver evaluation, individual’s treatment status, individual’s prior treatment history, and comorbidities

- For **Harvoni**: PREFERRED
  - Genotype 1: without cirrhosis, HCV RNA level < 6 million IU/mL, HIV-uninfected, non-black: 8 weeks
  - Genotype 1: treatment-naïve, without cirrhosis or compensated cirrhosis, one or more of the following (HCV RNA level ≥ 6 million IU/mL, HIV-positive, black): 12 weeks
  - Genotype 1: treatment-experienced, with decompenated cirrhosis (Child-Pugh B & C): 12 weeks with ribavirin
  - Genotype 1 or 4: Treatment-naïve and treatment-experienced liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh class A): 12 weeks with ribavirin
  - Genotype 4,5,6: Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh class A) : 12 weeks

- For **Epclusa**: PREFERRED
  - Genotypes 1,2,3,4,5,&6: Without cirrhosis or with **compensated cirrhosis** (Child-Pugh class A): 12 weeks
  - Genotypes 1,2,3,4,5,&6: With **decompensated cirrhosis** (Child-Pugh class B or C): 12 weeks with ribavirin

- For **Mavyret**: PREFERRED-Without cirrhosis or with compensated cirrhosis (Child-Pugh A)
  - Genotype 1,2,3,4,5,6: treatment naïve: 8 weeks
  - Genotype 1 & prior NS3/4A inhibitor but no prior NS5A inhibitor: 12 weeks
  - Genotype 1 & prior NS5A inhibitor but no prior NS3/4A inhibitor: 16 weeks
  - Genotype 3: prior pegylated interferon + ribavirin + sofosbuvir (PRS), no prior NS3/4A or NS5A inhibitor: 16 weeks
  - Genotype 1,2,4,5,6: prior PRS, no prior NS3/4A or NS5A inhibitor: 12 weeks
  - Genotype 1,2,4,5,6: no cirrhosis, prior PRS, no prior NS3/4A or NS5A inhibitor: 8 weeks

- For **Vosevi**: NOT PREFERRED-Without cirrhosis or with compensated cirrhosis (Child-Pugh A)
  - Genotype 1,2,3,4,5,6: treatment naïve): Prior treatment with NS5A inhibitor: 12 weeks
  - Genotype 1a & 3: prior treatment with sofosbuvir but without NS5A inhibitor: 12 weeks

- For **Zepatier**: NOT PREFERRED
  - Genotype 1a, no NS5A polymorphism, treatment-naïve or prior interferon/ribavirin: 12 weeks
  - Genotype 1a, with NS5A polymorphism, treatment-naïve or prior interferon/ribavirin: 16 weeks
  - Genotype 1b, treatment-naïve or prior interferon/ribavirin: 12 weeks
  - Genotype 1a or b, treatment-naïve or prior interferon/ribavirin/NS3/4A inhibitor: 12 weeks when used with ribavirin
  - Genotype 4, treatment naïve: 12 weeks
  - Genotype 4, prior interferon/ribavirin: 16 weeks
DIRECT ACTING ANTIVIRAL AGENTS FOR HEPATITIS C VIRUS (HCV) (cont.)

Approval duration: Per HCV genotype and patient specific factors
Prescribing provider must submit viral load after 12 weeks of completion of therapy (SVR12)

REQUIRED DOCUMENTATION FOR SUBMISSION OF HCV PRIOR AUTHORIZATION REQUESTS
In order for a prior authorization request for HCV medications to be considered, the following minimum information must be submitted for the member:

1. Evidence of liver fibrosis and presence of cirrhosis plus if it is compensated or decompensated
2. HCV treatment history and responses.
3. Evidence of Hepatitis A & B vaccinations or laboratory evidence of immunity.
5. There must be an abstinence contract signed by the patient and provider.
6. An HIV test must be done within 90 days of request for treatment of HCV, if positive, a treatment plan for HCV and HIV therapies must be sent.
7. Laboratory results for and drug/alcohol screen completed within the past 90 days.
8. Laboratory results HCV screen, genotype and current baseline viral load within last 90 days.
9. Laboratory results for total bilirubin, albumin, INR, CrCl or GFR, LFTs, CBC within past 90 days.
10. There must be a negative pregnancy test in a woman of child bearing potential, unless is using adequate contraception.

Resources:


UpToDate: Ribavirin (systemic): Drug information. https://www.uptodate-com.mwu.idm.oclc.org/contents/ribavirin-systemic-drug-information?search=ribavirin&source=search_result&selectedTitle=1~149&usage_type=default&display_rank=1
Fax completed prior authorization request form to 602-864-3126 or email to pharmacyprecert@azblue.com. Call 866-325-1794 to check the status of a request. All requested data must be provided. **Incomplete forms or forms without the chart notes will be returned.** Pharmacy Coverage Guidelines are available at [www.azblue.com/pharmacy](http://www.azblue.com/pharmacy).

# Pharmacy Prior Authorization Request Form

**Direct Acting Antiviral Agents for Hepatitis C Virus (HCV)**

Do not copy for future use. Forms are updated frequently.

**REQUIRED:** Office notes, labs, and medical testing relevant to the request that show medical justification are required.

<table>
<thead>
<tr>
<th>Member Information</th>
<th>Date of Birth:</th>
<th>Gender:</th>
<th>BCBSAZ ID#:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Member Name (first &amp; last):</td>
<td>Address:</td>
<td>City:</td>
<td>State:</td>
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<thead>
<tr>
<th>Prescribing Provider Information</th>
<th>Specialty:</th>
<th>NPI#:</th>
<th>DEA#:</th>
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<tbody>
<tr>
<td>Provider Name (first &amp; last):</td>
<td>Office Address:</td>
<td>City:</td>
<td>State:</td>
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<tr>
<td>Office Contact:</td>
<td>Office Phone:</td>
<td>Office Fax:</td>
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<tr>
<th>Dispensing Pharmacy Information</th>
<th>Pharmacy Name:</th>
<th>Pharmacy Phone:</th>
<th>Pharmacy Fax:</th>
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<tr>
<th>Requested Medication Information</th>
<th>Strength:</th>
<th>Dosage Form:</th>
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<tbody>
<tr>
<td>Medication Name:</td>
<td>Directions for Use:</td>
<td>Quantity:</td>
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</table>

☐ Check if requesting **brand** only ☐ Check if requesting **generic**

☐ Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

**Preferred agents are Mavyret, Harvoni, and Epclusa**

## Turn-Around Time For Review

☐ Standard ☐ Urgent. Sign here: _______________________________ ☐ Exigent (requires prescriber to include a written statement)

## Clinical Information

1. **What is the diagnosis?** Please specify below.
   - ☐ Chronic Hepatitis C Virus (HCV)
   - ☐ Other diagnosis: **ICD-10 Code:** __________ **Diagnosis Description:** __________

2. **What is the individual’s specific genotype?**
   - ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

3. **What is the individual’s HCV treatment status?**
   - ☐ Naive ☐ Relapse ☐ Non-responder

4. **What is the prescriber’s specialty?**
   - ☐ Gastroenterologist ☐ Hepatologist ☐ Infectious Disease ☐ Other: __________

5. ☐ Yes ☐ No **Individual has abstained from alcohol and/or substance abuse in the past 6 months.**

6. ☐ Yes ☐ No **For individuals with past HCV treatment:** Individual has been compliant with previous and/or current drug therapy.

7. ☐ Yes ☐ No **For HCV treatment requiring concurrent use of ribavirin:** Individual has failure, contraindication or intolerance to generic ribavirin 200mg.

8. ☐ Yes ☐ No **There is absence of all contraindications for use of agent(s) requested.**

9. ☐ Yes ☐ No **There is absence of all significant interacting drugs.**

10. ☐ Yes ☐ No **Required documentation:** Evidence of liver fibrosis and presence of cirrhosis; plus, if it is compensated or decompensated.

11. ☐ Yes ☐ No **Required documentation:** HCV treatment history and responses.

12. ☐ Yes ☐ No **Required documentation:** Child-Pugh score - total bilirubin, albumin, INR within past 90 days plus status of ascites and encephalopathy.

13. ☐ Yes ☐ No **Required documentation:** Evidence of Hepatitis A & B vaccinations or laboratory evidence of immunity.
14. ☐ Yes ☐ No  Required documentation: Current medication list.

15. ☐ Yes ☐ No  Required documentation: Abstinence contract signed by the patient and provider.

16. ☐ Yes ☐ No  Required documentation: An HIV test must be done within 90 days of request for treatment of HCV; if positive, a treatment plan for HCV and HIV therapies must be sent.

17. ☐ Yes ☐ No  Required documentation: Laboratory results for and drug/alcohol screen completed within the past 90 days.

18. ☐ Yes ☐ No  Required documentation: Laboratory results HCV screen, genotype and current baseline viral load within last 90 days.

19. ☐ Yes ☐ No  Required documentation: Laboratory results for CrCl or GFR, LFTs, CBC within past 90 days.

20. ☐ Yes ☐ No  Required documentation (if applicable): A negative pregnancy test in a woman of child bearing potential, unless is using adequate contraception.

21. What medication(s) has the individual tried and failed for this diagnosis? Please specify below. Important note: Samples provided by the provider are not accepted as continuation of therapy or as an adequate trial and failure.

<table>
<thead>
<tr>
<th>Medication Name, Strength, Frequency</th>
<th>Dates started and stopped or Approximate Duration</th>
<th>Describe response, reason for failure, or allergy</th>
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22. Are there any supporting labs or test results? Please specify below.

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<tr>
<th>Date</th>
<th>Test</th>
<th>Value</th>
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23. Is there any additional information the prescribing provider feels is important to this review? Please specify below. For example, explain the negative impact on medical condition, safety issue, reason formulary agent is not suitable to a specific medical condition, expected adverse clinical outcome from use of formulary agent, or reason different dosage form or dose is needed.

Signature affirms that information given on this form is true and accurate and reflects office notes

Prescribing Provider’s Signature: ___________________________ Date: ___________________________

Please note: Some medications may require completion of a drug-specific request form.

Incomplete forms or forms without the chart notes will be returned.

Office notes, labs, and medical testing relevant to the request that show medical justification are required.