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.

BLUE CROSS®, BLUE SHIELD® and the Cross and Shield Symbols are registered service marks of the Blue Cross and Blue Shield Association, an association of independent Blue Cross and Blue Shield Plans. All other trademarks and service marks contained in this guideline are the property of their respective owners, which are not affiliated with BCBSAZ.

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

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.

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

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 RAS testing is recommended for genotype 1a. If the genotype cannot be subtyped recommendations from AASLD is to treat as a genotype 1a infection.

Daklinza (daclatasvir) is an NS5A inhibitor. Epclusa is a fixed-dose combination of velpatasvir (an NS5A inhibitor) and sofosbuvir (an NS5B polymerase inhibitor). Harvoni is a fixed-dose combination of sofosbuvir and ledipasvir (an NS5A inhibitor). Mavyret is a fixed-dose combination of glecaprevir (an NS3/4A inhibitor) and pibrentasvir (an NS5A inhibitor). Olysio (simeprevir) is an inhibitor of the HCV NS3/4A serine protease. Inhibition results in immature forms of the NS4A, NS4B, NS5A and NS5B proteins that are needed for viral replication. Protease inhibitors (PIs) must not be used as monotherapy; they must only be used in combination with other antiviral agents used to treat HCV. Sovaldi (sofosbuvir) is a nucleotide pro-drug that is incorporated into NS5B polymerase and acts as analog inhibitor of the enzyme resulting in termination of RNA synthesis. Sovaldi must not be used as monotherapy. Depending upon HCV genotype, it is used in combination with other agents. Technivie is a fixed-dose combination of ombitasvir (an NS5A inhibitor), paritaprevir (an NS3/4A protease inhibitor), and ritonavir a CYP3A inhibitor. Viekira Pak & Viekira XR is a fixed-dose combination of ombitasvir, paritaprevir, ritonavir, and dasabuvir (a non-nucleoside NS5B polymerase inhibitor). Vosevi is a fixed-dose combination product containing sofosbuvir, velpatasvir, and voxilaprevir (an NS3/4A protease inhibitor). Zepatier is a fixed-dose combination of elbasvir (an NS5A inhibitor) and grazoprevir (an NS3/4A protease inhibitor) indicated for use with or without ribavirin.

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

**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 (or μmol/L)</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 (or g/L)</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></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Seconds over control</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>
### DIRECT ACTING ANTIVIRAL AGENTS FOR HEPATITIS C VIRUS (HCV) (cont.)

**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></td>
<td></td>
<td></td>
<td></td>
<td></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>8 weeks (without cirrhosis) or 12 weeks (with compensated cirrhosis [Child-Pugh A])</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1</td>
<td>Prior NS3/4A but without prior NS5A</td>
<td>12 weeks</td>
</tr>
<tr>
<td></td>
<td>Prior NS5A but without prior NS3/4A</td>
<td>16 weeks</td>
</tr>
<tr>
<td>Genotype 1, 2, 4, or 6</td>
<td>Prior PRS (peg-interferon, ribavirin, sofosbuvir)*</td>
<td>8 weeks no cirrhosis</td>
</tr>
<tr>
<td></td>
<td>Prior PRS (peg-interferon, ribavirin, sofosbuvir)*</td>
<td>12 weeks compensated cirrhosis (C-P Class A)</td>
</tr>
<tr>
<td>Genotype 3</td>
<td>Prior PRS (peg-interferon, ribavirin, sofosbuvir)*</td>
<td>16 weeks</td>
</tr>
</tbody>
</table>

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

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>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Epclusa</td>
<td>X</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></td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Mavyrett†</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Olysio* + RBV / Peg-INF</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td></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></td>
<td>X</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Technivie + RBV</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
<td></td>
<td></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>X</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>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Zepatier**</td>
<td></td>
<td>X</td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

† It is indicated for treatment-naïve 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 VIRUS (HCV) (cont.)

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

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

- 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
  - 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

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

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 drug/alcohol screen completed within the past 90 days.

8. Laboratory results for 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:


AASLD/IDSA/IAS–USA. Recommendations for Testing, Managing, and Treating Hepatitis C.

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


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**

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>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Member Name (first &amp; last):</strong></td>
</tr>
<tr>
<td><strong>Address:</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Prescribing Provider Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Provider Name (first &amp; last):</strong></td>
</tr>
<tr>
<td><strong>Office Address:</strong></td>
</tr>
<tr>
<td><strong>Office Contact:</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Dispensing Pharmacy Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Pharmacy Name:</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Requested Medication Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medication Name:</strong></td>
</tr>
<tr>
<td><strong>Directions for Use:</strong></td>
</tr>
</tbody>
</table>

- [ ] Check if requesting **brand** only  
- [ ] Check if requesting **generic**

- [ ] Check if requesting continuation of therapy (prior authorization approved by BCBSAZ expired)

### Turn-Around Time For Review

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

<table>
<thead>
<tr>
<th>Clinical Information</th>
</tr>
</thead>
</table>
| 1. **What is the diagnosis?** Please specify below.  
  **ICD-10 Code:** ___________________________  
  **Diagnosis Description:** ___________________________ |
| 2. [ ] Yes  
  [ ] No  
  **Was this medication started on a recent hospital discharge or emergency room visit?** |
| 3. [ ] Yes  
  [ ] No  
  **There is absence of ALL contraindications.** |

| 4. **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.  
  **Medication Name, Strength, Frequency** | **Dates started and stopped** <br> **or Approximate Duration** | **Describe response, reason for failure, or allergy** |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Medication Name, Strength, Frequency</strong></td>
<td><strong>Dates started and stopped</strong> &lt;br&gt; <strong>or Approximate Duration</strong></td>
<td><strong>Describe response, reason for failure, or allergy</strong></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| 5. **Are there any supporting labs or test results?** Please specify below.  
  **Date** | **Test** | **Value** |
<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Blue Cross Blue Shield of Arizona, Mail Stop A115, P.O. Box 13466, Phoenix, AZ 85002-3466  
Page 1 of 2
6. **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.