Hepatitis C Medications Prior Authorization Criteria

Harvoni® (ledipasvir/sofosbuvir), Sovaldi® (sofosbuvir), Olysio® (simeprevir), pegylated interferon (Pegasys® & Peg-Intron®), Viekira Pak® (ombitasvir/paritaprevir/ritonavir; dasabuvir) and ribavirin

# Olysio regimens are non-preferred but are reviewed on a case by case basis.
*NHP requires all patients who are genotype 1 to begin treatment with either a Harvoni or Sovaldi-containing regimen before using a Viekira Pak-containing regimen.

All hepatitis C medications are specialty products; dispensing is available only via BriovaRx specialty pharmacy.

How do I obtain a prior authorization for a hepatitis C medication or medication regimen?

• Download a BriovaRx fax form & send to (800) 218-3221 (hyperlink to PA fax form).
• Contact BriovaRx at (800) 850-9122 or NHP at (855) 444-4NHP (4647) for questions.

Approvable Diagnosis

• Chronic hepatitis C (CHC) infection

Approval Criteria

• Patient is new to NHP and has already been started and stabilized on a regimen of hepatitis C medication as part of an appropriate treatment regimen (e.g. genotype, combination therapy, dose, treatment duration, etc.) for chronic hepatitis C infection

OR

• Patient has a diagnosis of chronic hepatitis C (CHC) infection AND
• The request is being prescribed by or in consultation with a GI specialist, hepatologist, or infectious disease specialist AND
• Patient has documented compensated liver disease† AND
• Patient has documented liver fibrosis Metavir stage F3-4 by biopsy and/or Fibroscan® result greater than 10.3 KiloPascals and/or at least 2 blood tests [such as FibroTest® score > 0.75 AND an AST:platelet ratio index (APRI) greater than 2.0]; or severe extra hepatic manifestations/symptoms AND
• Patient has demonstrated understanding of the proposed treatment plan and has displayed the ability to adhere to clinical appointments AND
• For patients with past or current issues with alcohol abuse or substance use: patient is participating in supportive care and has documented abstinence from injection drug use and/or excessive alcohol use/abuse for at least 6 months AND
• For patients with current or past behavioral health history including depression: patient is currently stable and/or receiving behavioral health care AND
• The requested dose and duration of therapy are consistent with published treatment guidelines as outlined below in Tables 1 through 3.**
• All other requests will be reviewed on a case-by-case basis.

† Treatment of decompensated cirrhosis including Child-Turcotte-Pugh class B or C will be considered on a case by case basis, and should be directed by highly-experienced HCV providers (i.e Transplant Hepatologist).

** For patients with genotype 1 HCV infection who have compensated cirrhosis and who have failed prior PEG-IFN and ribavirin with or without an HCV protease inhibitor – must begin treatment with Harvoni and ribavirin for 12 weeks unless patient is ribavirin ineligible or intolerant.
<table>
<thead>
<tr>
<th>Genotype 1a</th>
<th>Treatment History</th>
<th>Regimen</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Treatment Naïve</strong></td>
<td>Without cirrhosis</td>
<td>Daily fixed-dose Harvoni</td>
<td>8-12 weeks</td>
</tr>
<tr>
<td></td>
<td>Without cirrhosis</td>
<td>HCVRNA &lt; 6,000,000 IU/mL (8 weeks)</td>
<td>8-12 weeks</td>
</tr>
<tr>
<td></td>
<td>Without cirrhosis</td>
<td>HCVRNA &lt; 6,000,000 IU/mL (12 weeks)</td>
<td>12 weeks*</td>
</tr>
<tr>
<td></td>
<td>With compensated cirrhosis</td>
<td>Daily fixed-dose Harvoni</td>
<td>12 weeks</td>
</tr>
<tr>
<td></td>
<td>With compensated cirrhosis</td>
<td>Daily fixed-dose Viekira Pak + weight-based RBV</td>
<td>24 weeks*</td>
</tr>
<tr>
<td><strong>Prior PEG-IFN + RBV failed</strong></td>
<td>Without cirrhosis</td>
<td>Daily fixed-dose Harvoni</td>
<td>24 weeks**</td>
</tr>
<tr>
<td></td>
<td>Without cirrhosis</td>
<td>Daily fixed-dose Viekira Pak + weight-based RBV</td>
<td>12 weeks</td>
</tr>
<tr>
<td></td>
<td>With compensated cirrhosis</td>
<td>Daily fixed-dose Harvoni</td>
<td>24 weeks**</td>
</tr>
<tr>
<td></td>
<td>With compensated cirrhosis</td>
<td>Daily fixed-dose Harvoni + weight-based RBV</td>
<td>12 weeks</td>
</tr>
<tr>
<td></td>
<td>With compensated cirrhosis</td>
<td>Daily fixed-dose Viekira Pak + weight-based RBV</td>
<td>24 weeks*</td>
</tr>
<tr>
<td><strong>Prior PEG-IFN, RBV, + HCV protease inhibitor regimen failed</strong></td>
<td>Without cirrhosis</td>
<td>Daily fixed-dose Harvoni</td>
<td>12 weeks</td>
</tr>
<tr>
<td></td>
<td>With cirrhosis</td>
<td>Daily fixed-dose Harvoni</td>
<td>24 weeks**</td>
</tr>
<tr>
<td></td>
<td>With cirrhosis</td>
<td>Daily fixed-dose Harvoni + weight-based RBV</td>
<td>12 weeks</td>
</tr>
<tr>
<td><strong>Prior sofosbuvir-containing regimen failed</strong></td>
<td>Without advanced fibrosis</td>
<td>Based on the limited data available for effective therapy, patients without an urgent need for HCV treatment should defer antiviral therapy pending additional data or consider treatment within clinical trial settings.</td>
<td>24 weeks</td>
</tr>
<tr>
<td></td>
<td>With advanced fibrosis/ cirrhosis</td>
<td>Daily fixed-dose Harvoni +/- weight-based RBV</td>
<td>24 weeks</td>
</tr>
</tbody>
</table>

* Please note: NHP requires all patients who are genotype 1 to begin treatment with either a Harvoni or Sovaldi-containing regimen before using a Viekira Pak-containing regimen.

** For patients with genotype 1 HCV infection who have compensated cirrhosis and who have failed prior PEG-IFN and ribavirin with or without an HCV protease inhibitor – must begin treatment with Harvoni and ribavirin for 12 weeks unless patient is ribavirin ineligible or intolerant.
<table>
<thead>
<tr>
<th>Genotype 1b</th>
<th>Treatment History</th>
<th>Without cirrhosis</th>
<th>Regimen</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior PEG-IFN + RBV failed</td>
<td>Daily fixed-dose Harvoni</td>
<td>12 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>With compensated cirrhosis</td>
<td>Daily fixed-dose Harvoni</td>
<td>24 weeks**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior PEG-IFN, RBV, + HCV protease inhibitor regimen failed</td>
<td>Daily fixed-dose Harvoni</td>
<td>12 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>With compensated cirrhosis</td>
<td>Daily fixed-dose Harvoni + weight-based RBV</td>
<td>12 weeks</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Daily fixed-dose Viekira Pak + weight-based RBV</td>
<td>12 weeks*</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prior sofosbuvir-containing regimen failed</td>
<td>Based on the limited data available for effective therapy, patients without an urgent need for HCV treatment should defer antiviral therapy pending additional data or consider treatment within clinical trial settings.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>With advanced fibrosis/cirrhosis</td>
<td>Daily fixed-dose Harvoni +/- weight-based RBV</td>
<td>24 weeks</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* Please note: NHP requires all patients who are genotype 1 to begin treatment with either a Harvoni or Sovaldi-containing regimen before using a Viekira Pak-containing regimen.

** For patients with genotype 1 HCV infection who have compensated cirrhosis and who have failed prior PEG-IFN and ribavirin with or without an HCV protease inhibitor – must begin treatment with Harvoni and ribavirin for 12 weeks unless patient is ribavirin ineligible or intolerant.
<table>
<thead>
<tr>
<th>Genotype</th>
<th>Treatment Experienced</th>
<th>Prior PEG-IFN + RBV failed</th>
<th>Treatment</th>
<th>Prior treatment failed</th>
<th>Prior treatment failed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 4</td>
<td>Prior PEG-IFN + RBV failed</td>
<td>Daily fixed-dose Harvoni</td>
<td>12 weeks</td>
<td>Daily fixed-dose Viekira Pak + weight-based RBV</td>
<td>12 weeks²</td>
</tr>
<tr>
<td>Treatment Experienced</td>
<td></td>
<td>Daily Sovaldi + weight-based RBV + weekly PEG-IFN (if eligible to receive IFN)</td>
<td>12 weeks</td>
<td>Daily Sovaldi + weight-based RBV + weekly PEG-IFN</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Genotype 5</td>
<td>Treatment Naïve</td>
<td>+/- compensated cirrhosis</td>
<td>12 weeks</td>
<td>Weekly PEG-IFN + weight-based RBV</td>
<td>48 weeks</td>
</tr>
<tr>
<td>Treatment Experienced</td>
<td>Prior treatment failed</td>
<td>Daily Sovaldi + weight-based RBV + weekly PEG-IFN (if eligible to receive IFN)</td>
<td>12 weeks</td>
<td>Weekly PEG-IFN + weight-based RBV (if eligible to receive IFN)</td>
<td>48 weeks</td>
</tr>
<tr>
<td>Genotype 6</td>
<td>Treatment Naïve</td>
<td>+/- compensated cirrhosis</td>
<td>12 weeks</td>
<td>Alternative: Daily Sovaldi + weight-based RBV + weekly PEG-IFN</td>
<td>12 weeks</td>
</tr>
<tr>
<td>Treatment Experienced</td>
<td>Prior treatment failed</td>
<td>Daily fixed-dose Harvoni</td>
<td>12 weeks</td>
<td>Alternative: Daily Sovaldi + weight-based RBV + weekly PEG-IFN (if eligible to receive IFN)</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

¹ For patients with genotype 3 HCV infection who are treatment naïve and without cirrhosis – note that Sovaldi, PEG-IFN, and ribavirin for 12 weeks is preferred unless patient is ribavirin ineligible or intolerant. Patients who are treatment naïve and have cirrhosis must begin treatment with Sovaldi, PEG-IFN, and ribavirin for 12 weeks unless patient is ribavirin ineligible or intolerant.

*** For patients with genotype 3 HCV infection who are treatment experienced – must begin treatment with Sovaldi, PEG-IFN, and ribavirin for 12 weeks unless patient is ribavirin ineligible or intolerant.

% Please note: NHP requires all patients who are genotype 4 to begin treatment with either a Harvoni or Sovaldi-containing regimen before using a Viekira Pak-containing regimen.

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**Table 2: Hepatitis C Regimens for HIV/HCV Co-Infected Patients**

Antiretroviral drug switches, when needed, should be done in collaboration with the HIV practitioner. For HIV antiretroviral and HCV direct-acting antiviral combinations not addressed below, expert consultation is recommended.

Fixed-dose combination of Harvoni (Because ledipasvir increases tenofovir levels, concomitant use mandates consideration of creatinine clearance (CrCl) rate and should be avoided in those with CrCl below 60 mL/min. Because potentiation of this effect is expected when tenofovir is used with ritonavir-boosted HIV protease inhibitors, ledipasvir should be avoided with this combination (pending further data) unless antiretroviral regimen cannot be changed and the urgency of treatment is high.)

For combinations expected to increase tenofovir levels, baseline and ongoing assessment for tenofovir nephrotoxicity is recommended.

Daily fixed-dose of Viekira Pak*

Olysio should only be used with antiretroviral drugs with which it does not have clinically significant interactions: raltegravir (and probably dolutegravir), rilpivirine, maraviroc, enfuvirtide, tenofovir, emtricitabine, lamivudine, + abacavir.
Viekira Pak and dasabuvir should be used with antiretroviral drugs with which it does not have substantial interactions: raltegravir (and probably dolutegravir), enfuvirtide, tenofovir, emtricitabine, lamivudine, and atazanavir. The dose of ritonavir used for boosting of HIV protease inhibitors may need to be adjusted (or held) when administered with Viekira Pak and dasabuvir and then restored when HCV treatment is completed. The HIV protease inhibitor should be administered at the same time as the fixed-dose HCV combination.

Table 3: Hepatitis C Regimens for Patients with Renal Impairment

<table>
<thead>
<tr>
<th>Recommended dosage adjustments for patients with renal impairment, including severe renal impairment (creatinine clearance [CrCl] &gt;30 mL/min) or end-stage renal disease (ESRD).</th>
</tr>
</thead>
<tbody>
<tr>
<td>For patients with mild to moderate renal impairment (CrCl &gt;30 mL/min), no dosage adjustment is required when using Sovaldi, Olysio, fixed-dose combination of Harvoni, or fixed-dose of Viekira Pak + twice-daily dosed dasabuvir to treat or retreat HCV infection in patients with appropriate genotypes.</td>
</tr>
<tr>
<td>For patients with CrCl below 30 mL/min, treatment can be contemplated after consultation with an expert, because safety and efficacy data are not available for these patients.</td>
</tr>
</tbody>
</table>

**Notes**

- **Non-responders, or null responders**, are defined as those who experienced less than a 2 log decline in viral load during a previous 12 week treatment course (viral load was never undetectable). Partial responders experienced greater viral load suppression than non-responders, but viral load was never undetectable during treatment. These individuals have lower re-treatment success.
- **Relapsers** are defined as those who achieved undetectable HCV blood levels during previous treatment who relapsed after treatment cessation. Relapsers should be treated as if they are naïve to therapy. These individuals tend to do well with re-treatment.
- **Interferon ineligible** is defined as one or more of the following:
  - Intolerance to interferon
  - Autoimmune hepatitis or other severe autoimmune conditions known to be exacerbated by interferon
  - Untreated thyroid disease
  - Severe concurrent disease including uncontrolled hypertension, heart failure, or significant coronary artery disease
  - Decompensated hepatic disease
  - A baseline neutrophil count < 1500/μL,
  - A baseline platelet count < 90,000/μL,
  - A baseline hemoglobin <10 g/dL
  - Major uncontrolled depressive illness or a history of interferon-induced severe depression (past or current history of stabilized depression on therapy does not qualify)
- For patients who are currently taking an antacid, H2 antagonist, or proton pump inhibitor and require a Harvoni-containing regimen, NHP requires documentation of how this drug interaction will be managed.

References


• Foster g, Abstract L05: SOFOSBUVIR + PEGINTERFERON/RIBAVIRIN FOR 12 WEEKS VS SOFOSBUVIR + RIBAVIRIN FOR 16 OR 24 WEEKS IN GENOTYPE 3 HCV INFECTED PATIENTS AND TREATMENT-EXPERIENCED CIRRHOTIC PATIENTS WITH GENOTYPE 2 HCV: THE BOSON STUDY, European Association for the Study of the Liver, The International Liver Congress 2015, Vienna, Austria; April 22–26, 2015.


• HARVONI Prescribing Information. Gilead Sciences. Foster City, CA. October 2014.


• Sulkowski M, Rodriguez-Torres M, Lalezari J, et al. All-oral therapy with sofosbuvir plus ribavirin for the treatment of HCV genotype 1, 2, and 3 infection in patients co-infected with HIV (PHOTON-1). Data presented at the Annual Meeting of the American Association for the Study of Liver Diseases (AASLD), November 1-5, 2013, Washington, DC.
• Viekira Pak™ [package insert]. North Chicago (IL): AbbVie; Feb 2015.
• Zhong-Hua Lin, Yong-Ning Xin, Quan-Jiang Dong et al., Performance of the aspartate aminotransferase-to-platelet ratio index for the staging of hepatitis C-related fibrosis: An updated meta-analysis, Hepatology 2011; 53: 726-736.

**Healthwise Knowledgebase**

- The Knowledgebase contains patient educational material about formulary medications in English and Spanish.
- Drug information is directly accessible by visiting [Healthwise Knowledgebase](http://www.uptodate.com) (link).