Washington Apple Health: Hepatitis C Treatment Policy  
(September 2016)

Policy
Washington Apple Health determines medical necessity for the treatment of chronic hepatitis C infection based on criteria 1-5, except as noted in the “TREATMENT SPECIFIC EXCEPTIONS” section below. Washington Apple Health will approve coverage for all patients with chronic HCV infection regardless of fibrosis scoring.

1. Patient has chronic hepatitis C infection defined by:
   a. a liver fibrosis score ≥ F1 and a detectable and quantifiable HCV RNA (> 15 international units/ML) tests within the last 12 months; OR  
   b. a liver fibrosis score < F1; AND  
      i. a positive (i.e. reactive) HCV antibody test that is at least six months old; and has a detectable and quantifiable HCV RNA (> 15 international units/ML) six months after date of positive HCV antibody test; OR  
      ii. two detectable and quantifiable HCV RNA (> 15 international units/ML) tests at least six months apart; AND

2. Prescriber is:
   a. a specialist* in one of the following areas:
      i. Gastroenterologist  
      ii. Hepatologist  
      iii. HIV  
      iv. Infectious disease; OR  
   b. Prescriber is participating and consulting with Project ECHO or one of the specialists listed above (requires consultation note or documentation of phone call); AND

3. Required documentation and lab tests
   a. HCV Antibody test administered at least 6 months before request for treatment  
   b. HCV Genotype  
   c. HCV RNA Viral Load  
   d. Laboratory tests (e.g. APRI score or FibroSure®) to determine liver fibrosis staging are required to ensure the appropriate treatment regimen is used (e.g. patients with cirrhosis require longer treatment). Liver staging test results must be less than 2 years old;  
      i. If patient has cirrhosis must document if patient is compensated, currently decompensated, or has had previous episodes of decompensation.

* Exceptions may be made for other specialties or non-specialist providers who work in coordination with an organized system of care, have received training in hepatitis C diagnosis, staging and treatment protocols, and have ready access to specialists that treat HCV.
4. Patients with the following conditions are not eligible for HCV treatment until the condition is resolved. Patients who:
   a. Are taking medications that are contraindicated with or have a severe drug interaction with the prescribed HCV treatment
   b. Are pregnant or planning on becoming pregnant
   c. Have severe end organ disease and are not eligible for transplant (e.g. heart, lung, kidney)
   d. Have decompensated liver disease with CPT > 12 or MELD > 20
   e. Have a clinically-significant illness or any other major medical disorder that may interfere with patients’ ability to complete a course of treatment
   f. In the professional judgment of the primary treating clinician would not achieve a long term clinical benefit from HCV treatment (e.g. patients: with multisystem organ failure; receiving palliative care; significant pulmonary or cardiac disease; and malignancy outside of the liver not meeting oncologic criteria for cure)
   g. Have a MELD < 20\textsuperscript{16} and one of the following:
      i. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery
      ii. Malignancy outside the liver not meeting oncologic criteria for cure
      iii. Hepatocellular carcinoma with metastatic spread
      iv. Intrahepatic cholangiocarcinoma
      v. Hemangiosarcoma
      vi. Uncontrolled sepsis

5. Retreatment Criteria
   a. Re-treatment after failure of an interferon based treatment will be approved based on AASLD guidelines unless listed in the exceptions section below.
   b. Re-treatment after all- DAA regimen:
      i. All cases will be considered individually.
   c. Must provide prior treatment regimen including treatment regimen, length of treatment, response and date of treatment.
   d. Lab reports documenting presence or absence of resistant mutations
   e. Medical necessity will be based on expert recommendations that members not be re-treated with a regimen containing a drug they have failed or relapsed on:
   f. Patients having failed a regimen containing an NS3/4A protease inhibitor (boceprevir, telaprevir, simeprevir or paritaprevir) should not be re-treated with a regimen containing one of these agents. Harvoni\textsuperscript{®} (Ledipasvir/sofosbuvir) is suitable for retreatment in such cases unless contraindicated.
PREFERRED TREATMENT REGIMEN

Harvoni® is the preferred first line agent for Genotypes 1, 4, 5 and 6. Epclusa® is the preferred first line agent for the treatment of HCV genotype 2 and 3. Sovaldi® is a preferred agent when indicated in dual therapy or monotherapy to treat the appropriate HCV genotype when medically necessary.

TREATMENT SPECIFIC EXCEPTIONS

The following drugs require Harvoni® failure (when appropriate)

1. The use of Epclusa® (sofosbuvir/velpatasvir) with or without ribavirin may be considered medically necessary to treat patients with genotypes 2 and 3. It is not considered medically necessary to treat patients with all other genotypes since there is an equally or more effective less costly alternative, Harvoni® (ledipasvir/sofosbuvir).

2. The use of Technivie® (paritaprevir/ritonavir/ombitasvir) may be considered medically necessary to treat patients with the appropriate HCV genotype who do not have moderate to severe liver disease (Child-Pugh B/C/D) after failure of or intolerance to Harvoni® (ledipasvir/sofosbuvir), or if the CrCl is < 30 ml/min.

3. The use of Viekira Pak® (paritaprevir/ritonavir/ombitasvir/dasabuvir) may be considered medically necessary to treat patients with the appropriate HCV genotype who do not have moderate to severe liver disease (Child-Pugh B/C/D) after failure of or intolerance to Harvoni® (ledipasvir/sofosbuvir), or if patients creatinine clearance (CrCl) is < 30ml/min.

4. The use of combination Olysio® (simeprevir) and Sovaldi® (sofosbuvir) to treat HCV is considered not medically necessary, since there is an equally or more effective less costly alternative, Harvoni® (ledipasvir/sofosbuvir).

5. The use of combination Daklinza® (daclatasvir) plus Sovaldi® (sofosbuvir) to treat HCV is considered not medically necessary, since there is an equally or more effective less costly alternative, Epclusa® (sofosbuvir/velpatasvir).

6. The use of Zepatier® (elbasvir/grazoprevir) may be considered medically necessary to treat patients with the appropriate HCV genotype when ALL of the following criteria have been met:
   a. Documentation of genotype 1a resistance testing showing no NS5A resistance-associated polymorphisms (at amino acid positions 28,30,31, or 93) in treatment naïve and treatment experienced patients; AND
   b. The patient tried and failed Harvoni® (ledipasvir/sofosbuvir) therapy; OR
   c. the patient is NOT a suitable candidate for treatment with Harvoni® (ledipasvir/sofosbuvir) for the following reasons:
      i. CrCl < 30 ml/min; OR
      ii. Intolerance to Harvoni® (ledipasvir/sofosbuvir); AND
d. The patient does NOT have moderate to severe liver disease (Child-Pugh B/C/D). Hepatic testing prior to therapy initiation showed no clinically significant Liver Function Test (ALT) elevations. Hepatic testing should be repeated at 8 weeks for a 12 week course of therapy and at 12 weeks for a 16 week course of therapy.

7. Length of Therapy Exceptions
   a. Although Harvoni® (ledipasvir/sofosbuvir) was approved by the FDA for a 12-week course of therapy, based on the clinical trials and as noted in the FDA approved label for Harvoni® (ledipasvir/sofosbuvir), an 8-week course may be considered in patients with baseline viral load less than 6 million units/mL.
      i. ION-3 excluded patients with cirrhosis and investigated shortening therapy from 12 weeks to 8 weeks (with or without RBV). (Kowdley, 2014) SVR12 rate was 93% to 95% across all arms, with no difference in SVR in the intention-to-treat analysis. However, relapse rates were higher in the 8-week arms (20 of 431) regardless of RBV use compared with the 12-week arm (3 of 216). Post hoc analyses of the 2 RBV-free arms assessed baseline predictors of relapse and identified lower relapse rates in patients receiving 8 weeks of ledipasvir/sofosbuvir who had baseline HCV RNA levels below 6 million IU/mL (2%; 2 of 123), and was the same for patients with similar baseline HCV RNA levels who received 12 weeks (2%; 2 of 131). This analysis was not controlled and thus substantially limits the generalizability of this approach to clinical practice. Shortening treatment to less than 12 weeks for patients without cirrhosis should be done with caution and performed at the discretion of the practitioner.
   
   b. All other deviations from the length of therapy recommended by the AASLD guidelines are considered investigational.

Table 1. HCA accepted diagnostic tests and scores to stage liver fibrosis in patients with chronic HCV infection

<table>
<thead>
<tr>
<th>Metavir Score</th>
<th>Biopsy</th>
<th>Fibroscan</th>
<th>Elastography (ARFI/PSWE)</th>
<th>FibroSure</th>
<th>APRI</th>
<th>Other Imaging</th>
</tr>
</thead>
<tbody>
<tr>
<td>F4</td>
<td>F4</td>
<td>≥ 12.5 kPa</td>
<td>≥ 2.34 m/s</td>
<td>≥ 0.75</td>
<td>≥ 2.0</td>
<td>Cirrhosis</td>
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<tr>
<td>F3</td>
<td>F3</td>
<td>9.6 – 12.4 kPa</td>
<td>2.01 – 2.33 m/s</td>
<td>0.58 – 0.74</td>
<td>1.5 – 1.9</td>
<td></td>
</tr>
<tr>
<td>F2</td>
<td>F2</td>
<td>7.1 – 9.5 kPa</td>
<td>1.38 – 2.0 m/s</td>
<td>0.49 – 0.57</td>
<td>1.0 – 1.4</td>
<td></td>
</tr>
<tr>
<td>F1</td>
<td>F1</td>
<td>≤ 7.0 kPa</td>
<td>≤ 1.37 m/s</td>
<td>0.23 - 0.48</td>
<td>≤ 0.9</td>
<td></td>
</tr>
</tbody>
</table>

Washington Apple Health  Hepatitis C Treatment Policy Last Revised September 30, 2016
References:


49. Kwo P, Gitlin N, Nahass R, et al. A phase 3, randomized, open-label study to evaluate the efficacy and safety of 8 and 12 weeks fo Simeprevir (SMV) plus sofosbuvir (SOF) in treatment-naïve and experienced patients with chronic HCV genotype 1 infection without cirrhosis: OPTIMIST-1. 50th Annual Meeting of the European Association for the Study of the Liver (EASL). April 22-26, 2015; S270; Vienna, Austria.


54. Bourliere M, Bronowicki J, de Ledinghen V, et al. Ledipasvir/sofosbuvir fixed dose combination is safe and efficacious in cirrhotic patients who have previously failed protease-inhibitor based triple therapy. [Abstract LB-6.] 65th annual Meeting of the American Association for the Study of Liver Diseases (AASLD). November 7-11, 2014; Boston, MA.


