1. **Background:**

   Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member with chronic hepatitis C genotype 1, 3, 4, 5 or 6 infection to use Harvoni™ (ledipasvir/sofosbuvir) and/or Epclusa® (sofosbuvir/velpatasvir) unless there is a history of intolerance or contraindication to Harvoni and/or Epclusa therapy.

   Epclusa® (sofosbuvir/velpatasvir) is a fixed-dose combination of sofosbuvir, a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor, and velpatasvir, an HCV NS5A inhibitor, and is indicated for the treatment of adult patients with chronic HCV genotype 1, 2, 3, 4, 5 or 6 infection:
   - without cirrhosis or with compensated cirrhosis
   - with decompensated cirrhosis for use in combination with ribavirin

   Harvoni™ (ledipasvir/sofosbuvir) is a fixed-dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and is indicated for the treatment of chronic hepatitis C (CHC) genotype 1, 4, 5 or 6 infection in adults.

   Daklinza® (daclatasvir) is a hepatitis C virus (HCV) NS5A inhibitor indicated for use with Sovaldi® (sofosbuvir), with or without ribavirin, for the treatment of chronic HCV genotype 1 or 3 infection.

   Olysio® (simeprevir) is a hepatitis C virus (HCV) NS3/4A protease inhibitor indicated for the treatment of chronic hepatitis C (CHC) genotype 1 infection as a component of a combination antiviral treatment regimen.

   Sovaldi® (sofosbuvir) is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of chronic hepatitis C (CHC) infection as a component of a combination antiviral treatment regimen.

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Technivie™ (ombitasvir, paritaprevir, and ritonavir tablets) is a fixed-dose combination of ombitasvir, a hepatitis C virus NS5A inhibitor, paritaprevir, a hepatitis C virus NS3/4A protease inhibitor, and ritonavir, a CYP3A inhibitor and is indicated in combination with ribavirin for the treatment of patients with genotype 4 chronic hepatitis C virus (HCV) infection without cirrhosis.6

Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets) and Viekira XR™ (dasabuvir, ombitasvir, paritaprevir, and ritonavir extended-release tablets) with or without ribavirin are indicated for the treatment of patients with genotype 1 chronic hepatitis C virus (HCV) infection including those with compensated cirrhosis. Viekira Pak and Viekira XR include ombitasvir, a hepatitis C virus NS5A inhibitor, paritaprevir, a hepatitis C virus NS3/4A protease inhibitor, ritonavir, a CYP3A inhibitor and dasabuvir, a hepatitis C virus non-nucleoside NS5B palm polymerase inhibitor.7,8

Zepatier™ (elbasvir/grazoprevir) is a fixed-dose combination product containing elbasvir, a hepatitis C virus (HCV) NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor, and is indicated with or without ribavirin for treatment of chronic HCV genotypes 1 or 4 infection in adults.9

2. Coverage Criteria a,b,c:

A. Chronic Hepatitis C Genotype 1

1. Daklinza, Olysio, Sovaldi, Viekira Pak, or Viekira XR will be approved based on one of the following criteria:

   a. Both of the following:

      i. Genotype 1

      -AND-

      ii. One of the following:

         (a) Both of the following:

            (1) History of intolerance or contraindication to Harvoni therapy

            -AND-

            (2) History of intolerance or contraindication to Epclusa therapy

            -OR-

            (b) Patient is currently on Daklinza, Olysio, Sovaldi, Viekira Pak, or Viekira XR therapy

            -OR-

   b. All other genotypes (not genotype 1 or 2)
Authorization will be issued for 12 months.

2. **Epclusa** will be approved based on **one** of the following criteria:
   a. **Both** of the following:
      i. Genotype 1
      
      -AND-

      ii. **One** of the following:
         (a) History of intolerance or contraindication to Harvoni therapy
         
         -OR-

         (b) Patient is treatment-experienced with cirrhosis
         
         -OR-

         (c) Patient is currently on Epclusa therapy
         
         -OR-

   b. All other genotypes (not genotype 1 or 2)

   Authorization will be issued for 12 months.

3. **Zepatier** will be approved based on **one** of the following criteria:
   a. **Both** of the following:
      i. Genotype 1
      
      -AND-

      ii. **One** of the following:
         (a) History of intolerance or contraindication to Harvoni therapy
         
         -OR-

         (b) Patient is currently on Zepatier therapy
         
         -OR-

   b. All other genotypes (not genotype 1 or 2)
Authorization will be issued for 12 months.

B. **Chronic Hepatitis C Genotype 3**

1. **Daklinza or Sovaldi** will be approved based on **one** of the following criteria:
   
a. **Both** of the following:
   
i. Genotype 3 -AND-
   
ii. **One** of the following:

   (a) History of intolerance or contraindication to Epclusa therapy -OR-
   
   (b) Patient is currently on Daklinza or Sovaldi therapy -OR-

   b. All other genotypes (not genotype 2 or 3)

   **Authorization will be issued for 12 months.**

C. **Chronic Hepatitis C Genotype 4**

1. **Epclusa or Zepatier** will be approved based on **one** of the following criteria:
   
a. **Both** of the following:
   
i. Genotype 4 -AND-
   
ii. **One** of the following:

   (a) History of intolerance or contraindication to Harvoni therapy -OR-
   
   (b) Patient is currently on Epclusa or Zepatier therapy -OR-

   b. All other genotypes (not genotype 2 or 4)

   **Authorization will be issued for 12 months.**
2. Technivie will be approved based on one of the following criteria:

   a. Both of the following:
      
      i. Genotype 4  
         -AND-  
      
      ii. One of the following:
           
           (a) Both of the following:
               
               (1) History of intolerance or contraindication to Harvoni therapy  
               -AND-  
               
               (2) History of intolerance or contraindication to Epclusa therapy  
               -OR-  
           
           (b) Patient is currently on Technivie therapy  
           -OR-  

   b. All other genotypes (not genotype 2 or 4)

   Authorization will be issued for 12 months.

D. Chronic Hepatitis C Genotype 5 or 6

1. Epclusa will be approved based on one of the following criteria:

   a. Both of the following:
      
      i. One of the following:
         
         (a) Genotype 5  
         -OR-  
      
      (b) Genotype 6  
      -AND-  

   ii. One of the following:
       
       (a) History of intolerance or contraindication to Harvoni therapy  
       -OR-  
   
       (b) Patient is currently on Epclusa therapy
-OR-

b. All other genotypes (not genotype 2, 5 or 6)

**Authorization will be issued for 12 months.**

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\(^a\) For Maryland, requests for continuation of therapy may also be approved if the provider confirms the patient has been on the medication in the past 180 days and that the medication is effective in treating the patient’s condition. Please see Maryland Continuation of Care guideline.

\(^b\) For Indiana (effective 7/1/16) and West Virginia (effective 1/1/17), step therapy requirements may be approved if the patient has previously received either a documented step one prescription drug or another prescription drug that has the same mechanism of action as a preceding prescription drug, and the prescription drug was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event. For West Virginia (effective 1/1/17) members only, coverage may also be provided for continuation of therapy if the member is currently stabilized on the requested medication for the same medical condition.

\(^c\) For California, requests for continuation of therapy may also be approved if the provider confirms the patient has been on the medication, it is appropriately prescribed, and that the medication is considered safe and effective in treating the patient’s condition.

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3. **Additional Clinical Rules:**
   Supply limits and/or Prior Authorization may be in place.

4. **References:**
**Program** | **Step Therapy – Hepatitis C Direct Acting Antivirals - Daklinza® (daclatasvir), Olysio® (simeprevir), Sovaldi® (sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir tablets), Victrelis® (boceprevir), Viekira Pak™ (ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets), Zepatier™ (elbasvir/grazoprevir)**  
---|---  
**Change Control** |  
1/2015 | New step therapy program that requires the use of Harvoni for treatment of chronic hepatitis c genotype 1 before other treatments are covered.  
2/2015 | Revised formatting.  
8/2015 | Added Technivie. Added Maryland Continuation of Care.  
2/2016 | Added Daklinza and Zepatier. Removed Victrelis Updated references.  
7/2016 | Added Indiana and West Virginia coverage information.  
8/2016 | Added new step criteria to include Epclusa and Viekira XR.  
10/2016 | Administrative change to correct current therapy for Daklinza or Sovaldi (Section B).  
11/2016 | Administrative change. Added California coverage information