Pharmacy Policy

Hepatitis C Agents

Policy Number: 9.123  
Version Number: 20.0  
Version Effective Date: 3/1/2018

Product Applicability  □ All Plan* Products

Well Sense Health Plan
☐ New Hampshire Medicaid  
☐ NH Health Protection Program  

Boston Medical Center HealthNet Plan
☒ MassHealth  
☒ Qualified Health Plans/ConnectorCare/Employer Choice Direct
☐ Senior Care Options
☐ ____________________________

Note: Disclaimer and audit information is located at the end of this document.

Policy Summary

The Plan may authorize coverage of specific medications used in the treatment of Hepatitis C when appropriate criteria are met.

Description of Item or Service

Chronic Hepatitis C

The treatment of chronic hepatitis C is rapidly changing as new medications are approved and guidelines are updated. As a result, this summary may not reflect the most up-to-date recommendations from the American Association for Study of Liver Disease (AASLD) or the latest iteration of the various products’ prescribing information. This policy will be updated as new hepatitis C medications become available and guideline recommendations change.

* Plan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.
Treatment is indicated for patients with chronic hepatitis C, circulating HCV RNA, evidence of moderate to severe hepatitis (e.g. METAVIR score exhibiting bridging fibrosis or cirrhosis), compensated liver disease, and the ability to adhere to a treatment regimen. It is also appropriate to offer treatment to patients with milder disease (e.g. milder histologic changes, normal aminotransferase) when it is determined that there is an urgency for treatment initiation. For patients who choose to defer therapy, periodic laboratory and histologic monitoring should be arranged by their treating physician.

The previous standard of care for treatment of chronic hepatitis C consisted of a combination of injectable peginterferon (weekly) and oral ribavirin therapy (daily). This regimen is no longer recommended by the AASLD and the Infectious Diseases Society of America (IDSA) due to the low sustained virologic response (SVR) compared with newer regimens that include Direct Acting Antivirals (DAAs).

The use of a DAA in combination with peginterferon and/or ribavirin is known to be a more effective regimen than peginterferon/ribavirin alone. DAAs target the HCV life cycle directly, and they are FDA-approved for the treatment of chronic hepatitis C in patients with compensated liver disease who are treatment naïve or have failed previous therapy. Victrelis® (boceprevir) and Incivek® (telaprevir) were the first generation DAAs and had SVR rates of up to 75% in clinical trials compared to approximately 40% with peginterferon/ribavirin therapy alone. Victrelis® and Incivek® are no longer considered the standard of care in the treatment of hepatitis C and both have been discontinued with the advent of new DAAs.

The second generation DAAs include Olysio™ (simeprevir), Sovaldi® (sofosbuvir), Harvoni™ (ledipasvir/sofosbuvir), Daklinza™ (daclatasvir), TECHNIVIE™ (ombitasvir/paritaprevir/ritonavir), Zepatier™ (elbasvir/grazoprevir), Viekira Pak™ (ombitasvir/paritaprevir/ritonavir/dasabuvir), Mavyret® (glecaprevir/pibrentasvir), and Vosevi® (sofosbuvir/velpatasvir/voxilaprevir).

Daklinza™ is an NS5A inhibitor indicated for use with Sovaldi® for the treatment of chronic hepatitis C genotypes 1 and 3. The typical dose of Daklinza™ is 60 mg once daily administered at the same time as Sovaldi®. However, if Daklinza™ is administered concomitantly with a CYP3A4 inhibitor or inducer, the dose may need to be decreased to 30 mg once daily or 90 mg once daily (refer to table 9 for dosing recommendations and interacting medications).

Sovaldi® is a nucleotide polymerase inhibitor that targets HCV NS5B RNA-dependent RNA polymerase. It disrupts the viral replication process and has been shown to have activity against hepatitis C genotypes 1, 2, 3, and 4, including those resistant to protease inhibitors. Sovaldi® is approved in combination with peginterferon and ribavirin for the treatment of genotypes 1 and 4. It is also approved as a dual regimen with ribavirin for genotypes 2 and 3, and for all chronic hepatitis C genotypes with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation). Sovaldi® can also be used in patients with HCV/HIV-1 co-infection.

Epclusa® is a fixed-dose, single tablet, interferon-free regimen consisting of sofosbuvir (NS5B polymerase inhibitor) and velpatasvir (NS5A inhibitor). It is indicated for the treatment of adults patients with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis. The FDA-approved treatment duration is 12 weeks regardless of the presence or absence of cirrhosis. The addition of ribavirin is recommended in patients with decompensated cirrhosis and in select patients with HCV genotype 3 infection. The recommended dose is one tablet (400mg sofosbuvir/100mg velpatasvir) taken once daily with or without food.

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**Harvoni™** is a single tablet, interferon-free regimen consisting of sofosbuvir and ledipasvir. Ledipasvir inhibits HCV NS5A, which is a viral phosphoprotein involved in viral replication, assembly, and secretion. Harvoni™ is approved to treat HCV genotypes 1, 4, 5 and 6.

**Zepatier™** (elbasvir/grazoprevir) is the newest DAA and is approved for treatment of genotypes 1 and 4. Elbasvir is an HCV NS5A inhibitor and grazoprevir is an HCV NS3/4A protease inhibitor. Zepatier™ is taken once daily with or without food. Depending on specific patient characteristics, Zepatier™ regimens may include ribavirin. In clinical trials, patients with genotype 1a who had one or more baseline NS5A resistance-associated polymorphisms at amino acid positions 28, 30, 31, or 93 and received Zepatier™ for 12 weeks had lower SVR12 rates. Prior to starting therapy, it is recommended that patients with genotype 1a be tested for the presence of the virus with NS5A resistance-associated polymorphisms in order to determine the dosage regimen and duration. The safety and efficacy of Zepatier™ has not been established in patients awaiting liver transplant or in liver transplant recipients.

**Mavyret®** (glecaprevir/pibrentasvir) is a once-daily combination of glecaprevir, an NS3/4A protease inhibitor (PI), and pibrentasvir, an HCV NS5A inhibitor. It is indicated for the treatment of chronic HCV genotype 1 through 6 infection in adults, including patients with moderate to severe renal impairment. It is also approved for adults with HCV genotype 1 who have been previously treated with an HCV NS5A inhibitor or an NS3/4A PI, but not both. The recommended treatment duration is eight, 12 or 16 weeks depending on various clinical factors.

**Vosevi®** (sofosbuvir/velpatasvir/voxilaprevir) is a once-daily combination of sofosbuvir, velpatasvir, and a novel NS3/4A PI, voxilaprevir. It is indicated for the treatment of chronic HCV genotype 1 through 6 infection in adults who have been previously treated with a DAA regimen containing sofosbuvir or an NS5A inhibitor. The FDA-approved treatment duration is 12 weeks.

The addition of a second generation DAA to peginterferon/ribavirin therapy provides a treatment option with an SVR greater than 90%. It also potentially shortens treatment duration from 48 weeks to 12 weeks, depending on the choice of the DAA agent and the patient’s HCV genotype. Other agents like Daklinza™, Harvoni™, TECHNIVIE™, and Viekira Pak™ have allowed for the elimination of peginterferon altogether. The goal of HCV therapy is to achieve a sustained virologic response (SVR) at least 12 weeks after completing therapy.

Due to the side effects and contraindications associated with peginterferon and ribavirin therapy, candidates for therapy must be carefully screened and monitored throughout their course of therapy. Contraindications to therapy include decompensated cirrhosis, pregnancy, uncontrolled depression or severe mental illness, active substance abuse in the absence of concurrent participation in a drug treatment program, advanced cardiac or pulmonary disease, severe cytopenias, poorly controlled diabetes, retinopathy, seizure disorders, immunosuppressive treatment, autoimmune diseases, or other inadequately controlled comorbid conditions.

MassHealth has selected **Harvoni®** (ledipasvir/sofosbuvir), **Epclusa®** (sofosbuvir/velpatasvir), **Mavyret®** (glecaprevir/pibrentasvir), and **Vosevi®** (sofosbuvir/velpatasvir/voxilaprevir) as the preferred combination products. The following is a general guide to when a step through the preferred product(s) applies in the prior authorization criteria: - Epclusa® (sofosbuvir/velpatasvir), an eight-week Harvoni® (ledipasvir/sofosbuvir) and an eight-week Mavyret® (glecaprevir/pibrentasvir) regimens are at parity and do not require a step through another hepatitis C product when prior authorization criteria are met. - Most requests for other regimens must provide a clinical rationale for use of a non-preferred regimen instead of one or more preferred regimens above.

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Although FDA-approved, the following regimens are not recommended by the AASLD/IDSA guidelines for routine use in the treatment of chronic hepatitis C. Requests for new starts will generally be denied. Requests for continuation of therapy and requests documenting medical necessary for use over combination regimens recommended for routine use can be discussed with a clinical reviewer: Peginterferon alfa as monotherapy, Sovaldi® plus Daklinza® or Olysio® for HCV genotype 1, Sovaldi® or Olysio® plus peginterferon alfa and ribavirin, Sovaldi® plus ribavirin for 24 weeks, Technivie®, Viekira Pak®, Viekira XR®.

**Acute Hepatitis C**

Patients with acute Hepatitis C have a high risk of developing chronic Hepatitis C, as HCV infection will spontaneously clear in only 20% to 50% of patients. Testing for HCV antibody and HCVRNA is recommended when acute infection is suspected, as this expedites linkage to care, counseling on high-risk behavior, and other important interventions that will reduce viral transmission and disease progression. When medically managing an acute hepatitis C infection, the AASLD guidelines recommends regularly monitoring HCVRNA every 4 to 8 weeks for 6 to 12 months to determine whether the patient has spontaneously cleared the virus or if a chronic infection has developed. At this time, data documenting the safety and efficacy of acute hepatitis C with interferon-sparing therapy are not available. If there is a detectable HCVRNA at 6 months after the time of infection, then treatment as described from chronic hepatitis C can be recommended. If a decision is made to initiate treatment during the acute infection period, the same regimens recommended for chronic HCV infection are recommended for acute infection.

**Policy**

The Plan may authorize coverage of specific hepatitis C products for members meeting the following criteria:

**Policy Applicability by Product**

<table>
<thead>
<tr>
<th>Medications</th>
<th>BMC HealthNet Plan</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>MassHealth</td>
</tr>
<tr>
<td>Daklinza™</td>
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<tr>
<td>Epclusa® (preferred)</td>
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</tr>
<tr>
<td>Harvoni™ (preferred)</td>
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</tr>
<tr>
<td>Mavyret® (preferred)</td>
<td>X</td>
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<td>X</td>
</tr>
<tr>
<td>Rebetol sol</td>
<td>X</td>
</tr>
<tr>
<td>Brand name* ribavirin convenience pack</td>
<td>X</td>
</tr>
<tr>
<td>Sovaldi® (preferred)</td>
<td>X</td>
</tr>
<tr>
<td>Vosevi® (preferred)</td>
<td>X</td>
</tr>
<tr>
<td>Zepatier™</td>
<td>X</td>
</tr>
</tbody>
</table>

*= brand name with interchangeable generic available will be reviewed under mandatory generic policy

**Prior Authorization** - (Treatment regimen >12 weeks meeting approval criteria will be approved in 12 week increments, Quantity limits apply – see Appendix A)

**Criteria Index**

0BSection 1. Harvoni (ledipasvir/sofosbuvir) – Approval Criteria

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Hepatitis C
Section 1. Harvoni (ledipasvir/sofosbuvir) – Approval Criteria
Genotype 1, 4, 5, or 6

A. Genotype 1: Treatment-naïve members without cirrhosis

Documentation of all of the following:
1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
2. Genotype 1
3. Member ≥12 years of age*
4. Requested dose is 90 mg/400 mg once daily
5. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
6. Stage of liver disease is early stage (e.g. Metavir Score F0 to F2) or advanced stage (e.g. Metavir Score F3)
7. ONE of the following:
   a. Member ≥12 and <18 years old and requested duration is 12 weeks*
   b. Member ≥18 years of age AND ONE of the following:
      i. Baseline viral load (within the last six months) < 6 million IU/mL and requested duration is eight weeks†
      ii. BOTH of the following:
         1. Baseline viral load (within the last six months) ≥ 6 million IU/mL and requested duration is 12 weeks‡
         2. Clinical rationale for use instead of Epclusa®
8. Treatment will be discontinued if viral load is detectable at week 4 of treatment AND has increased by greater than 10-fold (>1 log10 IU/mL) on repeat testing at week 6 (or thereafter).

* Requests for members <12 years old who weigh ≥35 kg can be reviewed in the same manner as requests for members ≥12 and <18 years of age.
† Requests for 12 weeks documenting that member has HIV-coinfection, is African-American, black, or has IL28B

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Section 1. Harvoni (ledipasvir/sofosbuvir) – Approval Criteria

Genotype 1, 4, 5, or 6

polyorphism CT or TT (anywhere on PA or medical records) can be approved even if viral load is <6 million (if all other criteria are met). Requests for 8 weeks for members with HIV-coinfection, s/p liver transplant, or decompensated cirrhosis should be denied due to lack of studies supporting this treatment duration in these populations. All other requests for 8 weeks meeting criteria above can be approved, regardless of ethnicity/race or IL28B polymorphism.

B. Genotype 1: Treatment-naïve members with compensated cirrhosis (Child Turcotte Pugh [CTP] class A) OR treatment-experienced members without cirrhosis

Documentation of ALL of the following:

1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
2. Genotype 1
3. **ONE** of the following:
   a. Member ≥18 years of age and clinical rationale for use instead of Epclusa®
   b. Member ≥12 and <18 years of age*
4. Requested dose is 90 mg/400 mg once daily
5. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
6. Stage of liver disease is early stage (e.g. Metavir Score F0 to F2) or advanced stage (e.g. Metavir Score F3 to F4, documentation of cirrhosis)
7. Requested duration is 12 weeks
8. Treatment will be discontinued if viral load is detectable at week 4 of treatment AND has increased by greater than 10-fold (>1 log_{10} IU/mL) on repeat testing at week 6 (or thereafter).

C. Genotype 1: Treatment-experienced† members with compensated cirrhosis (Child Turcotte Pugh [CTP] class A)

Documentation of ALL of the following:

1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
2. Genotype 1
3. **ONE** of the following:
   a. Member ≥18 years of age and clinical rationale for use instead of Epclusa®
   b. Member ≥12 and <18 years of age*
4. Requested dose is 90 mg/400 mg once daily
5. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
6. **ONE** of the following:
   a. Member ≥12 and <18 years of age and requested duration is 24 weeks*
   b. Member ≥18 years of age AND **ALL** of the following:
      i. Requested regimen includes ribavirin
      ii. Requested duration is 12 weeks
   c. Member ≥18 years of age AND **ALL** of the following:
      i. Requested duration is 24 weeks

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## Section 1. Harvoni (ledipasvir/sofosbuvir) – Approval Criteria

### Genotype 1, 4, 5, or 6

7. **One** of the following:
   a. Documentation that this is the initiation of treatment
   b. Requests for continuation of treatment beyond 12 weeks should provide HCV RNA lab values at weeks 4 and 6 (if HCV RNA is detectable at week 4) supporting continued use

8. Treatment will be discontinued if viral load is detectable at week 4 of treatment **AND** has increased by greater than 10-fold (>1 log$_{10}$ IU/mL) on repeat testing at week 6 (or thereafter)

† Treatment-experienced members are those who have failed treatment with an interferon based regimen with or without ribavirin (age ≥12 and <18 years), or failed treatment with peginterferon alfa and ribavirin with or without a protease inhibitor (age ≥18 years old)

### Genotype 4, 5, or 6

D. **Genotype 4, 5, or 6: Treatment-naïve or treatment-experienced members without cirrhosis or with compensated cirrhosis (Child Turcotte Pugh [CTP] class A**

Documentation of **ALL** of the following:
1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
2. Genotype 4, 5, or 6
3. **One** of the following:
   a. Member ≥18 years of age and clinical rationale for use instead of Epclusa®
   b. Member ≥12 and <18 years of age*
4. Requested dose is 90 mg/400 mg once daily
5. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
6. Stage of liver disease is early stage (e.g. Metavir Score F0 to F2) or advanced stage (e.g. Metavir Score F3 to F4, documentation of cirrhosis)
7. Requested duration is 12 weeks
8. Treatment will be discontinued if viral load is detectable at week 4 of treatment **AND** has increased by greater than 10-fold (>1 log$_{10}$ IU/mL) on repeat testing at week 6 (or thereafter).

## Section 3. Vosevi® (sofosbuvir/velpatasvir/voxilaprevir) – Approval Criteria

A. **Treatment-experienced (failed treatment with an HCV NS5A inhibitor)** members with or without compensated cirrhosis (Child Turcotte Pugh [CTP] class A)

Documentation of **ALL** of the following:

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Hepatitis C

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### Section 3. Vosevi® (sofosbuvir/velpatasvir/voxilaprevir) – Approval Criteria

1. Diagnosis of chronic hepatitis C
2. Genotype 1, 2, 3, 4, 5, or 6
3. Member ≥18 years of age
4. Requested dose is 400 mg/100 mg/100 mg once daily
5. For members with genotype 3 and compensated cirrhosis, requested regimen includes ribavirin†
6. Requested duration is 12 weeks
7. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
8. Stage of liver disease is early stage (e.g. Metavir Score F0 to F2) or advanced stage (e.g. Metavir Score F3 to F4, documentation of cirrhosis)
9. Treatment will be discontinued if viral load is detectable at week 4 of treatment AND has increased by greater than 10-fold (≥1 log_{10} IU/mL) on repeat testing at week 6 (or thereafter).

### B. Treatment-experienced (failed treatment with sofosbuvir† without an HCV NS5A inhibitor) members with or without compensated cirrhosis (Child Turcotte Pugh [CTP] class A)

Documentation of ALL of the following:

1. Diagnosis of chronic hepatitis C
2. Genotype 1a or 3§
3. Member ≥18 years of age
4. Requested dose is 400 mg/100 mg/100 mg once daily
5. Requested duration is 12 weeks
6. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
7. Stage of liver disease is early stage (e.g. Metavir Score F0 to F2) or advanced stage (e.g. Metavir Score F3 to F4, documentation of cirrhosis)
8. Treatment will be discontinued if viral load is detectable at week 4 of treatment AND has increased by greater than 10-fold (≥1 log_{10} IU/mL) on repeat testing at week 6 (or thereafter).

* In clinical trials, prior NSSA inhibitors included daclatasvir, elbasvir, ledipasvir, ombitasvir, or velpatasvir. Requests noting prior Mavyret® or Vosevi® failure – Consult clinical reviewer
† Requests for ribavirin products on PA – see FAQ document
‡ In clinical trials, prior sofosbuvir-containing regimens included peginterferon alfa/ribavirin, ribavirin, and HCV protease inhibitor (boceprevir, simeprevir or telaprevir).
§ Requests for members with genotype 4, 5, or 6 who have failed sofosbuvir-containing regimen(s) without HCV NS5A inhibitor can be evaluated using criteria above.
Requests for members with genotype 3 who are treatment-experienced (PEG/REBV only) with compensated cirrhosis should provide clinical rationale for use instead of Epclusa® plus ribavirin for 12 weeks.
### Section 4. Mavyret® (glecaprevir/pibrentasvir) – Approval Criteria

#### A. Treatment-naive members with or without compensated cirrhosis (Child Turcotte Pugh [CTP] class A)

Documentation of **ALL** of the following:

1. Diagnosis of chronic hepatitis C
2. Genotype 1, 2, 3, 4, 5, or 6
3. Member ≥18 years of age
4. Requested dose is three glecaprevir/pibrentasvir 100 mg/40 mg tablets once daily

5. **ONE** of the following:
   
   a. Absence of cirrhosis and requested duration is eight weeks
   
   b. **ALL** of the following:
      
      i. Compensated cirrhosis and requested duration is 12 weeks
      
      ii. Clinical rationale for use instead of Epclusa®
      
      iii. For genotype 1, 4, 5, or 6, clinical rationale for use instead of Harvoni®

6. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)

7. Stage of liver disease is early stage (e.g. Metavir Score F0 to F2) or advanced stage (e.g. Metavir Score F3 to F4, documentation of cirrhosis)

8. Treatment will be discontinued if viral load is detectable at week 4 of treatment **AND** has increased by greater than 10-fold (>1 log10 IU/mL) on repeat testing at week 6 (or thereafter).

#### B. Treatment-experienced (failed treatment with interferon, peginterferon, ribavirin only) members with or without compensated cirrhosis (Child Turcotte Pugh [CTP] class A)

Documentation of **ALL** of the following:

1. Diagnosis of chronic hepatitis C
2. Genotype 1, 2, 3, 4, 5, or 6
3. Member ≥18 years of age
4. Requested dose is three glecaprevir/pibrentasvir 100 mg/40 mg tablets once daily

5. For genotype 1, 2, 4, 5, or 6, **ONE** of the following:
   
   a. Absence of cirrhosis and requested duration is eight weeks
   
   b. **ALL** of the following:
      
      i. Compensated cirrhosis and requested duration is 12 weeks
      
      ii. Clinical rationale for use instead of Epclusa®
      
      iii. For genotype 1, 4, 5, or 6, clinical rationale for use instead of Harvoni®

6. For genotype 3, **BOTH** of the following:
   
   a. Requested duration is 16 weeks
   
   b. Clinical rationale for use instead of Epclusa®

7. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)

8. Stage of liver disease is early stage (e.g. Metavir Score F0 to F2) or advanced stage (e.g. Metavir Score F3 to F4, documentation of cirrhosis)

9. **ONE** of the following:
   
   a. Documentation that this is the initiation of treatment

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### Section 4. Mavyret® (glecaprevir/pibrentasvir) – Approval Criteria

<table>
<thead>
<tr>
<th>Approval Criteria</th>
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<tbody>
<tr>
<td>b. Requests for continuation of treatment beyond 12 weeks should provide HCV RNA lab values at weeks 4 and 6 (if HCV RNA is detectable at week 4) supporting continued use</td>
</tr>
<tr>
<td>10. Treatment will be discontinued if viral load is detectable at week 4 of treatment AND has increased by greater than 10-fold (&gt;1 log\textsubscript{10} IU/mL) on repeat testing at week 6 (or thereafter).</td>
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</table>

### C. Treatment-experienced (failed treatment with sofosbuvir plus simeprevir or an HCV protease inhibitor plus peginterferon alfa and ribavirin only) members with or without compensated cirrhosis (Child Turcotte Pugh [CTP] class A)

Documentation of ALL of the following:

1. Diagnosis of chronic hepatitis C
2. Genotype 1
3. For members with genotype 1b who failed treatment with sofosbuvir and simeprevir, clinical rationale for use instead of Epclusa®
4. For members who previously failed treatment with an HCV protease inhibitor plus peginterferon alfa and ribavirin, clinical rationale for use instead of Epclusa® and Harvoni®*
5. Member ≥18 years of age
6. Requested dose is three glecaprevir/pibrentasvir 100 mg/40 mg tablets once daily
7. Requested duration is 12 weeks
8. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
9. Stage of liver disease is early stage (e.g. Metavir Score F0 to F2) or advanced stage (e.g. Metavir Score F3 to F4, documentation of cirrhosis)
10. Treatment will be discontinued if viral load is detectable at week 4 of treatment AND has increased by greater than 10-fold (>1 log\textsubscript{10} IU/mL) on repeat testing at week 6 (or thereafter).

### D. Treatment-experienced (failed treatment with sofosbuvir plus peginterferon and ribavirin or sofosbuvir plus ribavirin only) members with or without compensated cirrhosis (Child Turcotte Pugh [CTP] class A)

Documentation of ALL of the following:

1. Diagnosis of chronic hepatitis C
2. Genotype 1, 2, 3, 4, 5, or 6
3. Member ≥18 years of age
4. Requested dose is three glecaprevir/pibrentasvir 100 mg/40 mg tablets once daily
5. For genotype 1, 2, 4, 5, or 6, ONE of the following:
   a. Absence of cirrhosis and requested duration is eight weeks
   b. BOTH of the following:
      i. Compensated cirrhosis and requested duration is 12 weeks
      ii. For genotype 1b or 2, clinical rationale for use instead of Epclusa®
6. For genotype 3, requested duration is 16 weeks
7. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
8. Stage of liver disease is early stage (e.g. Metavir Score F0 to F2) or advanced stage (e.g.

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### Section 4. Mavyret® (glecaprevir/pibrentasvir) – Approval Criteria

**Metavir Score F3 to F4, documentation of cirrhosis**

9. **ONE** of the following:
   - Documentation that this is the initiation of treatment
   - Requests for continuation of treatment beyond 12 weeks should provide HCV RNA lab values at weeks 4 and 6 (if HCV RNA is detectable at week 4) supporting continued use

10. Treatment will be discontinued if viral load is detectable at week 4 of treatment **AND** has increased by greater than 10-fold ($>1 \log_{10} \text{IU/mL}$) on repeat testing at week 6 (or thereafter).

E. **Treatment-experienced (failed treatment with an HCV NSSA inhibitor without an HCV protease inhibitor) members with or without compensated cirrhosis (Child Turcotte Pugh [CTP] class A)**

Documentation of **ALL** of the following:

1. Diagnosis of chronic hepatitis C
2. Genotype 1
3. Member ≥18 years of age
4. Requested dose is three glecaprevir/pibrentasvir 100 mg/40 mg tablets once daily
5. Requested duration is 16 weeks
6. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
7. Stage of liver disease is early stage (e.g. Metavir Score F0 to F2) or advanced stage (e.g. Metavir Score F3 to F4, documentation of cirrhosis)

8. **ONE** of the following:
   - Documentation that this is the initiation of treatment
   - Requests for continuation of treatment beyond 12 weeks should provide HCV RNA lab values at weeks 4 and 6 (if HCV RNA is detectable at week 4) supporting continued use

9. Treatment will be discontinued if viral load is detectable at week 4 of treatment **AND** has increased by greater than 10-fold ($>1 \log_{10} \text{IU/mL}$) on repeat testing at week 6 (or thereafter).

* A trial with Harvoni® can be bypassed in members with genotype 1a who are treatment-experienced (prior peginterferon and ribavirin with or without protease inhibitor) with cirrhosis and also have baseline NSSA resistance. A trial with Harvoni® can also be bypassed in members with genotype 1 who are treatment-experienced (prior peginterferon and ribavirin with or without protease inhibitor) with cirrhosis and have a contraindication to ribavirin.

### Section 3. Daklinza® (daclatasvir) – Approval Criteria

**A. Genotype 3: Treatment-naïve members without cirrhosis**

Documentation of all of the following:

1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)

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Section 3. Daklinza® (daclatasvir) – Approval Criteria

2. HCV genotype 3
3. Contraindication to ALL combination products FDA-approved for the treatment of HCV genotype 3 infection (e.g., Epclusa®, Mavyret®)Member ≥18 years of age
4. ONE of the following:
   a. Requested dose is 60 mg once daily
   b. Medical necessity for requested dose of either 30 mg or 90 mg once daily
5. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
6. Stage of liver disease is early stage (e.g. Metavir Score F0 to F2) or advanced stage (e.g., Metavir Score F3)
7. Requested regimen includes sofosbuvir 400 mg once daily and requested duration is 12 weeks
8. Treatment will be discontinued if viral load is detectable at week 4 of treatment AND has increased by greater than 10-fold (>1 log10 IU/mL) on repeat testing at week 6 (or thereafter).

B. Genotype 3: Treatment-naïve members with compensated cirrhosis (Child Turcotte Pugh [CTP] class A)

Documentation of all of the following:
1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
2. HCV genotype 3
3. Contraindication to ALL combination products FDA-approved for the treatment of HCV genotype 3 infection (e.g., Epclusa®, Mavyret®)
4. Member ≥18 years of age
5. ONE of the following:
   a. Requested dose is 60 mg once daily
   b. Medical necessity for requested dose of either 30 mg or 90 mg once daily
6. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
7. Requested regimen includes sofosbuvir 400 mg once daily and requested duration is 24 weeks
8. ONE of the following:
   a. Testing results document absence of NS5A Y93H resistance-associated polymorphism
   b. Testing results document presence of NS5A Y93H resistance-associated polymorphism and requested regimen includes ribavirin†
9. ONE of the following:
   a. Documentation that this is the initiation of treatment
   b. Requests for continuation of treatment beyond 12 weeks should provide HCV RNA lab values at weeks 4 and 6 (if HCV RNA is detectable at week 4) supporting continued use
10. Treatment will be discontinued if viral load is detectable at week 4 of treatment AND has increased by greater than 10-fold (>1 log10 IU/mL) on repeat testing at week 6 (or thereafter).

† Requests for ribavirin products on PA
**Section 3. Daklinza® (daclatasvir) – Approval Criteria**

**C. Genotype 3: Treatment-experienced (failed treatment with peginterferon alfa and ribavirin) members without cirrhosis**

Documentation of all of the following:

1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
2. HCV genotype 3
3. Contraindication to ALL combination products FDA-approved for the treatment of HCV genotype 3 infection (e.g., Epclusa®, Mavyret®)
4. Member ≥18 years of age
5. **ONE** of the following:
   a. Requested dose is 60 mg once daily
   b. Medical necessity for requested dose of either 30 mg or 90 mg once daily
6. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
7. Stage of liver disease is early stage (e.g., Metavir Score F0 to F2) or advanced stage (e.g., Metavir Score F3)
8. Requested regimen includes sofosbuvir 400 mg once daily and requested duration is 12 weeks
9. **ONE** of the following
   a. Testing results document absence of NS5A Y93H resistance-associated substitution
   b. Testing results document presence of NS5A Y93H resistance-associated substitution and requested regimen includes **ribavirin**†
10. Treatment will be discontinued if viral load is detectable at week 4 of treatment AND has increased by greater than 10-fold (>1 log_{10} IU/mL) on repeat testing at week 6 (or thereafter).

† Requests for ribavirin products on PA

**D. Genotype 3: Treatment-experienced (failed treatment with peginterferon alfa and ribavirin) members with compensated cirrhosis (Child Turcotte Pugh [CTP] class A)**

Documentation of all of the following:

1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
2. HCV genotype 3
3. Contraindication to ALL combination products FDA-approved for the treatment of HCV genotype 3 infection (e.g., Epclusa®, Mavyret®)
4. Member ≥18 years of age
5. **ONE** of the following:
   a. Requested dose is 60 mg once daily
   b. Medical necessity for requested dose of either 30 mg or 90 mg once daily
6. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
7. Requested regimen includes sofosbuvir 400 mg once daily and ribavirin
8. Requested duration is 24 weeks

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### Section 3. Daklinza® (daclatasvir) – Approval Criteria

9. **ONE** of the following:
   - Documentation that this is the initiation of treatment
   - Requests for continuation of treatment beyond 12 weeks should provide HCV RNA lab values at weeks 4 and 6 (if HCV RNA is detectable at week 4) supporting continued use
10. Treatment will be discontinued if viral load is detectable at week 4 of treatment **AND** has increased by greater than 10-fold (>1 log₁₀ IU/mL) on repeat testing at week 6 (or thereafter).

### Section 4. Sovaldi (sofosbuvir) – Approval Criteria

**A. Genotype 3: Treatment-naïve members without cirrhosis**

Documentation of **ALL** of the following:

1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
2. HCV genotype 3
3. Clinical rationale for use instead of Epclusa®
4. Member ≥18 years of age
5. Requested dose is 400 mg once daily
6. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
7. Stage of liver disease is early stage (e.g. Metavir Score F0 to F2) or advanced stage (e.g., Metavir Score F3)
8. Requested duration is 12 weeks and requested regimen includes daclatasvir
9. Treatment will be discontinued if viral load is detectable at week 4 of treatment **AND** has increased by greater than 10-fold (>1 log₁₀ IU/mL) on repeat testing at week 6 (or thereafter).

**B. Genotype 3: Treatment-naïve members with compensated cirrhosis (Child Turcotte Pugh [CTP] class A)**

Documentation of **ALL** of the following:

1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
2. HCV genotype 3
3. Clinical rationale for use instead of Epclusa®
4. Member ≥18 years of age
5. Requested dose is 400 mg once daily
6. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
7. **ONE** of the following:
   - Requested duration is 24 weeks requested regimen includes daclatasvir, and testing results document absence of NS5A Y93H resistance-associated substitution
   - Requested duration is 24 weeks, requested regimen includes daclatasvir and **ribavirin†**, and testing results document presence of NS5A Y93H resistance-associated substitution

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### Section 4. Sovaldi (sofosbuvir) – Approval Criteria

8. **ONE of the following:**
   a. Documentation that this is the initiation of treatment
   b. Requests for continuation of treatment beyond 12 weeks should provide HCV RNA lab values at weeks 4 and 6 (if HCV RNA is detectable at week 4) supporting continued use

9. Treatment will be discontinued if viral load is detectable at week 4 of treatment **AND** has increased by greater than 10-fold ($>1 \log_{10} \text{IU/mL}$) on repeat testing at week 6 (or thereafter).

† Requests for ribavirin products on PA

### C. Genotype 3: Treatment-experienced (failed treatment with peginterferon alfa and ribavirin) members without cirrhosis

**Documentation of all of the following:**

1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
2. HCV genotype 3
3. Clinical rationale for use instead of Epclusa
4. Member ≥18 years of age
5. Requested dose is 400 mg once daily
6. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
7. Stage of liver disease is early stage (e.g. Metavir Score F0 to F2) or advanced stage (e.g., Metavir Score F3)
8. **ONE** of the following:
   a. Requested duration is 12 weeks, requested regimen includes daclatasvir, and testing results document absence of NS5A Y93H resistance-associated substitution
   b. Requested duration is 12 weeks, requested regimen includes daclatasvir and ribavirin†, and testing results document presence of NS5A Y93H resistance-associated substitution

9. Treatment will be discontinued if viral load is detectable at week 4 of treatment **AND** has increased by greater than 10-fold ($>1 \log_{10} \text{IU/mL}$) on repeat testing at week 6 (or thereafter).

### D. Genotype 3: Treatment-experienced (failed treatment with peginterferon alfa and ribavirin) members with compensated cirrhosis (Child Turcotte Pugh [CTP] class A)

**Documentation of all of the following:**

1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
2. HCV genotype 3

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Section 4. Sovaldi (sofosbuvir) – Approval Criteria

3. Clinical rationale for use instead of Epclusa®

4. Member ≥18 years of age

5. Requested dose is 400 mg once daily

6. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)

7. Requested duration is 24 weeks and requested regimen includes Daklinza® and ribavirin

8. **ONE** of the following:
   - a. Documentation that this is the initiation of treatment
   - b. Requests for continuation of treatment beyond 12 weeks should provide HCV RNA lab values at weeks 4 and 6 (if HCV RNA is detectable at week 4) supporting continued use

9. Treatment will be discontinued if viral load is detectable at week 4 of treatment **AND** has increased by greater than 10-fold (>1 log_{10} IU/mL) on repeat testing at week 6 (or thereafter).

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Section 5. Zepatier® (elbasvir/grazoprevir) – Approval Criteria

A. **Genotype 1: Treatment-naïve or treatment-experienced members (failed treatment with peginterferon alfa and ribavirin only)**

Documentation of the following:

1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)

2. HCV genotype 1

3. Contraindication to ALL combination products FDA-approved for the treatment of HCV genotype 1 infection (e.g., Epclusa®, Harvoni®, Mavyret®)

4. Member ≥18 years of age

5. Requested dose is 50 mg/100 mg once daily

6. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)

7. Stage of liver disease is early stage (e.g. Metavir Score F0 to F2) or advanced stage (e.g. Metavir Score F3 to F4, documentation of cirrhosis)

8. Member does not have decompensated cirrhosis (Child Turcotte Pugh Class B or C)

9. **ONE** of the following:
   - a. Request is for genotype 1a and **BOTH** of the following:
     - i. Testing results document **absence of NS5A resistance-associated substitutions** at amino acid positions 28, 30, 31, and 93
     - ii. Requested duration is 12 weeks
   - b. Request is for genotype 1a and **BOTH** of the following:
     - i. Testing results document **presence of NS5A resistance-associated substitutions** at amino acid positions 28, 30, 31, or 93
     - ii. Requested regimen includes ribavirin and requested duration is 16 weeks
   - c. Request is for genotype 1b and requested duration is 12 weeks

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Section 5. Zepatier® (elbasvir/grazoprevir) – Approval Criteria

10. **ONE** of the following:
   a. Documentation that this is the initiation of treatment
   b. Requests for continuation of treatment beyond 12 weeks should provide HCV RNA lab values at weeks 4 and 6 (if HCV RNA is detectable at week 4) supporting continued use

11. Treatment will be discontinued if viral load is detectable at week 4 of treatment **AND** has increased by greater than 10-fold (>1 log_{10} IU/mL) on repeat testing at week 6 (or thereafter)

### B. Genotype 1: Treatment-experienced members (failed treatment with an HCV protease inhibitor (boceprevir or telaprevir) plus peginterferon alfa and ribavirin only) without cirrhosis

Documentation of the following:

1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
2. HCV genotype 1
3. Contraindication to ALL combination products FDA-approved for the treatment of HCV genotype 1 infection (e.g., Epclusa®, Harvoni®, Mavyret®)
4. Member ≥18 years of age
5. Requested dose is 50 mg/100 mg once daily
6. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
7. Stage of liver disease is early stage (e.g. Metavir Score F0 to F2) or advanced stage (e.g. Metavir Score F3 to F4, documentation of cirrhosis)
8. Member does not have decompensated cirrhosis (Child Turcotte Pugh Class B or C)
9. Requested regimen includes ribavirin †
10. **ONE** of the following:
   a. Request is for genotype 1a and **BOTH** of the following:
      i. Testing results document absence of NS5A resistance-associated substitutions at amino acid positions 28, 30, 31, and 93
      ii. Requested duration is 12 weeks
   b. Request is for genotype 1a and **BOTH** of the following:
      i. Testing results document presence of NS5A resistance-associated substitutions at amino acid positions 28, 30, 31, or 93
      ii. Requested duration is 16 weeks
   c. Request is for genotype 1b and requested duration is 12 weeks
11. **ONE** of the following:
   a. Documentation that this is the initiation of treatment
   b. Requests for continuation of treatment beyond 12 weeks should provide HCV RNA lab values at weeks 4 and 6 (if HCV RNA is detectable at week 4) supporting continued use
12. Treatment will be discontinued if viral load is detectable at week 4 of treatment **AND** has increased by greater than 10-fold (>1 log_{10} IU/mL) on repeat testing at week 6 (or thereafter)

† Requests for ribavirin products on PA
Section 5. Zepatier® (elbasvir/grazoprevir) – Approval Criteria

C. **Genotype 4: Treatment-naïve or treatment-experienced members (failed treatment with peginterferon alfa and ribavirin only) including compensated liver disease and no prior history of liver transplant**

Documentation of all of the following:

1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
2. Genotype 4
3. Contraindication to ALL combination products FDA-approved for the treatment of HCV genotype 4 infection (e.g., Epclusa®, Harvoni®, Mavyret®)
4. Member ≥18 years of age
5. Requested dose is 50 mg/100 mg once daily
6. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
7. Stage of liver disease is early stage (e.g. Metavir Score F0 to F2) or advanced stage (e.g. Metavir Score F3 to F4, documentation of cirrhosis)
8. Member does not have decompensated cirrhosis (Child Turcotte Pugh Class B or C)
9. **ONE** of the following:
   a. Member is treatment-naïve or has a history of relapse to prior peginterferon and ribavirin treatment and requested duration is 12 weeks
   b. Member has a history of on-treatment virologic failure (failure to suppress or breakthrough) while on peginterferon and ribavirin treatment **AND BOTH** of the following:
      i. Requested regimen includes ribavirin
      ii. Requested duration is 16 weeks
10. **ONE** of the following:
    a. Documentation that this is the initiation of treatment
    b. Requests for continuation of treatment beyond 12 weeks should provide HCV RNA lab values at weeks 4 and 6 (if HCV RNA is detectable at week 4) supporting continued use
11. Treatment will be discontinued if viral load is detectable at week 4 of treatment **AND has increased by greater than 10-fold (>1 log_{10} IU/mL) on repeat testing at week 6 (or thereafter)**

Section 6. Epclusa® (sofosbuvir/velpatasvir) – Approval Criteria

Genotype 1, 2, 3, 4, 5, or 6

A. **Treatment-naïve members or treatment-experienced* members with or without compensated cirrhosis (Child Turcotte Pugh [CTP] class A)**

Documentation of ALL of the following:

1. Diagnosis of chronic hepatitis C
2. Genotype 1, 2, 3, 4, 5, or 6
3. Member ≥18 years of age
4. Requested dose is 400 mg/100 mg once daily

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Section 6. Epclusa® (sofosbuvir/velpatasvir) – Approval Criteria
Genotype 1, 2, 3, 4, 5, or 6

5.Requested duration is 12 weeks
6. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
7. Stage of liver disease is early stage (e.g., Metavir Score F0 to F2) or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis)
8. For genotype 3 only, ONE of the following
   a. Member is treatment-naïve without cirrhosis
   b. Member is treatment-naïve with compensated cirrhosis or treatment-experienced with or without compensated cirrhosis and testing results document absence of NS5A Y93H resistance-associated substitution
   c. Requested regimen includes ribavirin and ONE of the following
      i. Member is treatment-naïve with compensated cirrhosis or treatment-experienced without cirrhosis and testing results document presence of NS5A Y93H resistance-associated substitution
      ii. Member is treatment-experienced with compensated cirrhosis
9. Treatment will be discontinued if viral load is detectable at week 4 of treatment AND has increased by greater than 10-fold (>1 log_{10} IU/mL) on repeat testing at week 6 (or thereafter).

* Treatment-experienced members are those who have failed treatment with peginterferon alfa and ribavirin (with or without protease inhibitor). Requests for members with genotypes 1b or 2 who have failed sofosbuvir-containing regimen(s) without HCV NS5A inhibitor can be evaluated using criteria above.

Section 9. Pegasys® (peginterferon alfa-2a) or PegIntron® (peginterferon alfa-2b)

A. Hepatitis B – Pegasys® (peginterferon alfa 2a) only:
1. Diagnosis of Hepatitis B

Section 10. Requests Noting Prior Failure with Direct-Acting Antivirals (DAAs) – not otherwise addressed in drug specific sections above

A. Other Therapies: Genotype 1 – Prior failure of other HCV protease inhibitor (SOF +RBV, SOF+PEG+RBV, SOF+SIM+/−RBV, DCV+SOF, LDV+SOF, SOF+VEL, Viekira Pak, or Zepatier)
1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
2. Genotype 1

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Section 10. Requests Noting Prior Failure with Direct-Acting Antivirals (DAAs) – not otherwise addressed in drug specific sections above

3. Member ≥18 years of age

4. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)

5. Stage of liver disease is early stage (e.g., Metavir Score F0 to F2) or advanced stage (e.g. Metavir Score F3 to F4, documentation of cirrhosis)

6. ONE of the following:
   a. Documentation of ALL of the following:
      i. Prior failure of ONE of the following sofosbuvir-containing regimens:
         Sofosbuvir with ribavirin for 24 weeks, sofosbuvir plus peginterferon with ribavirin for 12 weeks, or sofosbuvir plus simprevir for 12-24 weeks
      ii. Requested regimen is Harvoni® plus ribavirin for 12 weeks (no cirrhosis) or 24 weeks (compensated or decompensated cirrhosis)
   b. Documentation of ALL of the following:
      i. Prior failure of ONE of the following NS5A inhibitor-containing regimens (with or without RBV): Harvoni®, Daklinza® plus Sovaldi®, Epclusa®, Viekira Pak®, Zepatier®
      ii. Resistance testing for susceptibility to NS5A inhibitors and to NS3 protease inhibitors (e.g., Q80K if genotype 1a)
      iii. If NS5A resistance is not detected, requested regimen is Harvoni® once daily plus ribavirin (with or without peginterferon alfa) for 24 weeks
      iv. If NS5A resistance is detected, but no NS3 resistance detected, requested regimen is Sovaldi® once daily plus Olysio® once daily plus ribavirin (with or without peginterferon alfa) for 24 weeks
      v. If both NS5A resistance AND NS3 resistance is detected, requested regimen is one of the following:
         1) Zepatier® plus Sovaldi® with ribavirin for 12 weeks
         2) Viekira Pak® plus Sovaldi® with ribavirin for 24 weeks (genotype 1a)
         3) Viekira Pak® plus Sovaldi® for 12 weeks (genotype 1b)
         4) Epclusa® with ribavirin for 24 weeks

7. ONE of the following:
   a. Documentation that this is the initiation of treatment
   b. Requests for continuation of treatment beyond 12 weeks should provide HCV RNA lab values at weeks 4 and 6 (if HCV RNA is detectable at week 4) supporting continued use

8. Treatment will be discontinued if viral load is detectable at week 4 of treatment AND has increased by

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Section 10. Requests Noting Prior Failure with Direct-Acting Antivirals (DAAs) – not otherwise addressed in drug specific sections above

greater than 10-fold (>1 log_{10} IU/mL) on repeat testing at week 6 (or thereafter)

B. Epclusa plus Ribavirin or Daklinza plus Sovaldi with or without Ribavirin: Genotype 2: Prior failure of SOF+RBV

Documentation of the following:

1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
2. HCV genotype 2
3. Member >18 years of age
4. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
5. Stage of liver disease is early stage (e.g. Metavir Score F0 to F2) or advanced stage (e.g., Metavir Score F3 to F4, documentation of cirrhosis)
6. **ONE** of the following:
   a. Requested regimen is sofosbuvir/velpatasvir once daily plus ribavirin for 12 weeks
   b. **ALL** of the following
      i. Requested regimen is sofosbuvir 400 mg plus daclatasvir at an appropriate dose for 24 weeks
      ii. Clinical rationale for use instead of sofosbuvir/velpatasvir plus ribavirin for 12 weeks (e.g., contraindication to ribavirin)
7. **ONE** of the following:
   a. Documentation that this is the initiation of treatment
   b. Requests for continuation of treatment beyond 12 weeks should provide HCV RNA lab values at weeks 4 and 6 (if HCV RNA is detectable at week 4) supporting continued use
8. Treatment will be discontinued if viral load is detectable at week 4 of treatment **AND** has increased by greater than 10-fold (>1 log_{10} IU/mL) on repeat testing at week 6 (or thereafter).

Section 11. Non-preferred therapies for HCV genotype 1 or 4 s/p liver transplant for members without decompensated cirrhosis

- Requests for (Daklinza® plus Sovaldi® plus ribavirin) for 12 weeks must provide contraindication to Harvoni® with ribavirin for 12 weeks and Harvoni® for 24 weeks.
- Requests for (Daklinza® plus Sovaldi®) x 24 weeks must provide contraindication to **ALL** of the following

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- **(listed in order of preference).**
  - Harvoni® with ribavirin for 12 weeks **AND**
  - Harvoni® for 24 weeks **AND**
  - Daklinza® plus Sovaldi® with ribavirin for 12 weeks
- **Request for (Sovaldi® plus Olysio®) for 12 weeks for HCV genotype 1 infection without decompensated cirrhosis must provide contraindication to ALL of the following (listed in order of preference)**
  - Harvoni® with ribavirin for 12 weeks **AND**
  - Harvoni® for 24 weeks **AND**
  - Daklinza® plus Sovaldi® with ribavirin for 12 weeks
- **Requests for (Viekira Pak® plus ribavirin) x 24 weeks for HCV genotype 1 infection without decompensated cirrhosis must provide contraindication to ALL of the following (listed in order of preference).**
  - Harvoni® with ribavirin for 12 weeks **AND**
  - Harvoni® for 24 weeks **AND**
  - Daklinza® plus Sovaldi® with ribavirin for 12 weeks **AND**
  - Sovaldi® plus Olysio® (with or without ribavirin) for 12 weeks

### Section 12. HCV members with Decompensated Cirrhosis

**A. Harvoni® for Genotype 1 or 4: Treatment naïve members with decompensated cirrhosis who are treatment-naïve or failed prior peginterferon and ribavirin +/- protease inhibitor**

Documentation of all of the following:

1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
2. Genotype 1 or 4
3. Member ≥18 years of age
4. Requested dose is 90 mg/400 mg once daily
5. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
6. Member with decompensated cirrhosis (Child Pugh Class B or C)
7. Member is not s/p liver transplant
8. **ONE** of the following:
   a. Requested regimen includes ribavirin and requested duration is 12 weeks
   b. Requested duration is 24 weeks and contraindication or prior intolerance to ribavirin

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### Section 12. HCV members with Decompensated Cirrhosis

9. **ONE** of the following:
   - Documentation that this is the initiation of treatment
   - Requests for continuation of treatment beyond 12 weeks should provide HCV RNA lab values at weeks 4 and 6 (if HCV RNA is detectable at week 4) supporting continued use

10. Treatment will be discontinued if viral load is detectable at week 4 of treatment **AND** has increased by greater than 10-fold ($>1 \log_{10} \text{IU/mL}$) on repeat testing at week 6 (or thereafter)

### B. Other HCV Genotype 1 and 4 Requests for members with Decompensated Cirrhosis

**Epclusa plus ribavirin for 12 weeks:**
- Documentation of contraindication to all of the following (listed in order of preference)
  - **Harvoni® plus ribavirin for 12 weeks AND**
  - **Harvoni® for 24 weeks**

**Epclusa for 24 weeks**
- Documentation of contraindication to all of the following (listed in order of preference)
  - **Harvoni® plus ribavirin for 12 weeks AND**
  - **Harvoni® for 24 weeks**
  - **Epclusa® plus ribavirin for 12 weeks**
  - **Daklinza® plus Sovaldi® plus ribavirin for 12 weeks**

**Daklinza plus Sovaldi plus ribavirin for 12 weeks**
- Documentation of contraindication to all of the following (listed in order of preference)
  - **Harvoni® plus ribavirin for 12 weeks AND**
  - **Harvoni® for 24 weeks AND**
  - **Epclusa® plus ribavirin for 12 weeks**

**Daklinza plus Sovaldi for 24 weeks**
- Documentation of contraindication to all of the following (listed in order of preference)
  - **Harvoni® plus ribavirin for 12 weeks**
  - **Harvoni® for 24 weeks**
  - **Epclusa® plus ribavirin for 12 weeks**
  - **Daklinza® plus Sovaldi® plus ribavirin for 12 weeks**
  - **Epclusa® for 24 weeks**

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Section 12. HCV members with Decompensated Cirrhosis

C. Epclusa or Sovaldi plus Daklinza for Genotype 2: Decompensated Cirrhosis

Documentation of all of the following:

1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
2. HCV genotype 2
3. Member ≥18 years of age
4. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
5. Member with decompensated cirrhosis (Child Pugh Class B or C)
6. Member is not s/p liver transplant
7. ONE of the following:
   a. Requested regimen is Epclusa® once daily plus ribavirin for 12 weeks
   b. Requested regimen is Epclusa® once daily for 24 weeks and contraindication or prior intolerance to ribavirin
   c. ALL of the following:
      i. Requested regimen is Sovaldi® once daily plus Daklinza® once daily at an appropriate dose plus ribavirin and requested duration is 12 weeks
      ii. Contraindication to Epclusa® plus ribavirin for 12 weeks
   d. ALL of the following:
      i. Requested regimen is Sovaldi® once daily plus Daklinza® once daily at an appropriate dose and requested duration is 24 weeks
      ii. Contraindication or prior intolerance to ribavirin
      iii. Contraindication to Epclusa® for 24 weeks
8. ONE of the following:
   a. Documentation that this is the initiation of treatment
   b. Requests for continuation of treatment beyond 12 weeks should provide HCV RNA lab values at weeks 4 and 6 (if HCV RNA is detectable at week 4) supporting continued use
9. Treatment will be discontinued if viral load is detectable at week 4 of treatment AND has increased by greater than 10-fold (>1 log_{10} IU/mL) on repeat testing at week 6 (or thereafter).

D. Epclusa or Sovaldi plus Daklinza for Genotype 3 with Decompensated Cirrhosis

Documentation of all of the following:

1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
Section 12. HCV members with Decompensated Cirrhosis

2. HCV genotype 3
3. Member ≥18 years of age
4. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
5. Member with decompensated cirrhosis (Child Pugh Class B or C)
6. Member is not s/p liver transplant
7. **ONE** of the following:
   a. Requested regimen is Epclusa® once daily plus ribavirin for 12 weeks
   b. Requested regimen is Epclusa® once daily for 24 weeks and contraindication or prior intolerance to ribavirin
   c. Requested regimen is Sovaldi® once daily plus Daklinza® once daily at an appropriate dose* plus ribavirin and requested duration is 12 weeks
   d. **ALL** of the following:
      i. Requested regimen is Sovaldi® once daily plus Daklinza® once daily at an appropriate dose and requested duration is 24 weeks
      ii. Contraindication or prior intolerance to ribavirin
8. **ONE** of the following:
   a. Documentation that this is the initiation of treatment
   b. Requests for continuation of treatment beyond 12 weeks should provide HCV RNA lab values at weeks 4 and 6 (if HCV RNA is detectable at week 4) supporting continued use
9. Treatment will be discontinued if viral load is detectable at week 4 of treatment **AND** has increased by greater than 10-fold (>1 log$_{10}$ IU/mL) on repeat testing at week 6 (or thereafter).

*Usual dose is 60mg in the absence of drug interactions.*

Section 13. Other HCV Genotypes

**Genotype 5 or 6:**
Please see section for Epclusa® and Harvoni® for genotype 5 or 6 infection with compensated liver disease and no prior history of liver transplant.
**Section 14. Preferred and non-preferred regimens for members with patients with CrCl<30ml/min**

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Preferred regimens</th>
<th>Alternative regimens</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1a, 1b, or 4</td>
<td>EBR/GZR x 12 weeks*</td>
<td>Viekira Pak+RBV x 12 weeks (genotype 1a only)</td>
</tr>
<tr>
<td></td>
<td>*No strong recommendation on NS5A resistance testing can be made</td>
<td></td>
</tr>
<tr>
<td>Genotype 1b</td>
<td>Viekira Pak x 12 weeks</td>
<td>None</td>
</tr>
<tr>
<td>Genotype 2, 3, 4, 5, or 6</td>
<td>PEG/RBV</td>
<td>None</td>
</tr>
</tbody>
</table>

**Section 15. Continuation Criteria for Regimens >12 weeks (must have met Plan criteria for the initial 12 weeks)**

Documentation of **ONE** of the following:

1. Undetectable HCV RNA viral load at treatment week 4, or
2. Detectable HCV RNA viral load at treatment week 4 **AND** HCV RNA increased by ≤10-fold (≤1 log_{10} IU/mL) on repeat testing at treatment week 6 (or thereafter), or
3. HCV RNA testing at treatment week 4 (or week 6 if HCV RNA was detectable at week 4) was not performed (reason should be provided)

**Section 16. Brand name ribavirin convenience packaged products – Approval Criteria**

Documentation of the following:

- The above criteria for dual or triple therapy have been met; **AND**
- A failed trial of individually prescribed generic ribavirin due to poor adherence

*Note: brand name with interchangeable generic available will be reviewed under mandatory generic policy*

**Section 17. Rebetol® Solution – Approval Criteria**

Documentation of the following:

1. The above criteria for dual or triple therapy have been met; **AND**
2. Swallowing difficulties due to a clinical condition

*Note: Rebetol® Solution does not require PA for members less than or equal to 12 years of age.*

**Appendix A – Quantity Limitations**

<table>
<thead>
<tr>
<th>Medication Name</th>
<th>Quantity Limit</th>
</tr>
</thead>
</table>

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Hepatitis C
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| Daklinza™ 30 mg, 60 mg tablets | 28 tablets per 28 days |
| Epclusa® 400 mg/100 mg tablet | 28 tablets per 28 days |
| Harvoni™ 90 mg/400 mg tablets | 28 tablets per 28 days |
| Pegasys® 135 mcg/0.5 mL, 180 mcg/0.5 mL syringe | 4 syringes per 28 days |
| Peg-Intron® 50 mcg/0.5 mL, 80 mcg/0.5 mL, 120 mcg/0.5 mL, 150 mcg/mL pen | 4 pens per 28 days |
| Olysio™ 150 mg tablet | 28 tablets per 28 days |
| Sovaldi® 400 mg tablet | 28 tablets per 28 days |
| TECHNIVIE™ 12.5 mg/75 mg/50 mg tablet | 1 carton (56 tablets) per 28 days |
| Viekira Pak™ 12.5 mg/75 mg/50 mg tablets and 250 mg tablets | 1 pack (112 tablets) per 28 days |
| **Viekira XR** | 28 tablets per 28 days |
| Zepatier™ 50 mg/100 mg | 28 tablets per 28 days |

**Glossary of Terms**

### Commonly Used Hepatitis C Regimen Abbreviations

- **BOC** = boceprevir (Victrelis®)
- **DCV+SOF** = daclatasvir (Daklinza™) plus sofosbuvir (Sovaldi®)
- **SOF+SMV** = sofosbuvir (Sovaldi®) plus simeprevir (Olysio™)
- **EBR/GZR** = elbasvir/grazoprevir (Zepatier®)
- **LDV/SOF** = ledipasvir/sofosbuvir (Harvoni®)
- **PEG/RBV** = peginterferon plus ribavirin
- **PrO** = paritaprevir/ritonavir/ombitasvir (Technivie®)
- **PrOD** = paritaprevir/ritonavir/ombitasvir plus dasabuvir (Viekira Pak®)
- **SOF/VEL** = sofosbuvir/velpatasvir (Epclusa®)
- **TLV** = telaprevir (Incivek®)

### Other Terms

<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute Hepatitis C</td>
<td>A short-term illness that usually occurs within the first six months after someone is exposed to the HCV</td>
</tr>
<tr>
<td>Chronic Hepatitis C</td>
<td>A long-term illness that occurs when HCV infection lasts longer than six months</td>
</tr>
<tr>
<td>Cirrhosis</td>
<td>Late stage of progressive hepatic fibrosis; generally irreversible</td>
</tr>
<tr>
<td>Fibrosis</td>
<td>Scarring caused by repair of tissue damage; can lead to cirrhosis</td>
</tr>
<tr>
<td>Null Response</td>
<td>Failure to reduce HCV RNA by at least 2 log_{10} (100 times) after 12 weeks of prior treatment.</td>
</tr>
<tr>
<td>Partial Response</td>
<td>At least a 2 log_{10} (100 times) decrease in HCV RNA during treatment for hepatitis C, but inability to fully remove the virus from the blood by week 24</td>
</tr>
<tr>
<td>Non-responder</td>
<td>Either null or partial responder (see definitions above)</td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>Relapse</th>
<th>Undetectable HCV RNA at the end of treatment, but lack of SVR (negative HCV RNA 24 weeks after completing treatment)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sustained Virological Response (SVR), or Viral Cure</td>
<td>HCV RNA remains undetectable 12 weeks after the end of treatment</td>
</tr>
<tr>
<td>Treatment-experienced</td>
<td>Historically referred to prior interferon plus ribavirin failure; but with the availability of direct-acting antivirals, could also refer to failure with other drugs (e.g., protease inhibitor, sofosbuvir, ledipasvir). If treatment was discontinued (e.g., due to an adverse event) while patient was responding to therapy based on viral load, patient may be considered treatment-naïve; requests noting response could not be determined will be evaluated on a case-by-case basis.</td>
</tr>
</tbody>
</table>

**Limitations**

The Plan will *not* approve coverage of the above treatment of Hepatitis C in the following instances:

- Diagnoses not listed in the policy
- When the above criteria have not been met
- Members < 3 years of age for peginterferon
- Member is pregnant
- Any regimen combination or monotherapy not addressed with specific approval criteria in the policy
- Newly approved regimens for chronic hepatitis C that do not meet required clinical justification as to why none of the preferred and non-preferred regimens in this policy are appropriate for the member
- Retreatment following completion of therapy will be evaluated on a case-by-case basis unless specifically addressed in the policy

**Clinical Background Information and References**


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46. Lawitz E, Gane E, Pearlman B, Tam E, Ghesquiere W, Guyader D, et al. Efficacy and safety of 12 weeks versus 18 weeks of treatment with grazoprevir (MK-5172) and elbasvir (MK-8742) with or without ribavirin for hepatitis C genotype 1 infection in previously untreated patients with cirrhosis and patients with previous null response with or without cirrhosis (C-WORTHY): a randomized, open-label phase 2 trial. *Lancet*. 2015;385:1075-1086.

47. Sulkowski M, Hezode C, Gerstoft J, Vierling JM, Mallolas J, Pol S, et a.. Efficacy and safety of 8 weeks versus 12 weeks of treatment with grazoprevir (MK-5172) and elbasvir (MK-8742) with or without ribavirin in patients with

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<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date</th>
<th>Policy Owner</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>09/08/2003</td>
<td>01/01/2004</td>
<td>Pharmacy Services</td>
<td>Pharmacy &amp; Therapeutics (P&amp;T) Committee</td>
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</tbody>
</table>

**Policy Revisions History**

<table>
<thead>
<tr>
<th>Review Date</th>
<th>Summary of Revisions</th>
<th>Revision Effective Date</th>
<th>Approved by</th>
</tr>
</thead>
<tbody>
<tr>
<td>07/14/2005</td>
<td>P&amp;T Annual Review – Added additional criteria to the “Clinical Coverage Criteria”, and approvable Hepatitis B criteria for treatment.</td>
<td>11/01/2005</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>09/12/2005</td>
<td>Policy Revision - Added approvable criteria for non-Hepatitis indications</td>
<td>11/01/2005</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>09/27/2007</td>
<td>P&amp;T Annual review, -Specialty requirements for prescribers removed, -Lower age limit added for interferon/ribavirin therapy, -Title changed from, “Hepatitis” to Hepatitis C”, -Criteria for non-Hepatitis C indications removed</td>
<td>01/01/2008</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>07/10/2008</td>
<td>P&amp;T Annual Review, no changes required.</td>
<td>11/01/2008</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>07/09/2009</td>
<td>P&amp;T Annual Review, criteria added for extended therapy for “slow responders”, criteria added for acute hepatitis C</td>
<td>11/01/2009</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>07/08/2010</td>
<td>P&amp;T Annual Review, no changes required.</td>
<td>11/01/2010</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>07/14/2011</td>
<td>P&amp;T Annual Review, criteria added for Victrelis®, Incivek®, Ribapak® Pak, and Rebetol® policy applied to Commercial</td>
<td>11/01/2011</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>07/12/2012</td>
<td>P&amp;T Annual Review, modified criteria language for Ribapak® Pak, and Rebetol®</td>
<td>11/01/2012</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>07/11/2013</td>
<td>P&amp;T Annual Review, increased initial treatment duration for all components of Incivek® triple therapy to 8 weeks, included black box warning for Incivek® into background information, modified criteria and treatment duration for Victrelis® triple therapy for patients with compensated cirrhosis, minor formatting changes throughout.</td>
<td>11/01/2013</td>
<td>P&amp;T Committee</td>
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</tbody>
</table>

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Hepatitis C
### Policy Revisions History

<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
<th>Effective Date</th>
<th>Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>12/13/2013</td>
<td>Policy Revision, policy applied to ConnectorCare/Qualified Health Plan (QHP)</td>
<td>01/01/2014</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>03/13/2014</td>
<td>Policy Revision, added criteria for Sovaldi and Olysio, removed section for dual therapy of peginterferon in combination with ribavirin, and section for monotherapy of interferon alfacon (case by case review since these are no longer recommended by AASLD; added general coverage requirements and limitations applicable to all hepatitis C regimen request</td>
<td>04/19/2014</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>07/10/2014</td>
<td>P&amp;T Annual Review. Defined interferon ineligibility, added criteria for Sovaldi and Olysio combination, added continuation criteria and adjusted approval durations for initial and continuation criteria, added criteria regarding antiretroviral drug-drug interactions for Sovaldi and Olysio, added extended approval criteria for Sovaldi and ribavirin in genotype 2 with cirrhotic treatment experienced patients, added a time frame of 6 months for absence of substance/alcohol abuse, added requirement of no history of medication and appointment nonadherence for initial approval criteria, added pregnancy as a limitation</td>
<td>11/12/2014</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>11/13/2014</td>
<td>Policy Review, added approval criteria for Harvoni™; removed decompensated liver disease from general approval criteria; added chart with “preferred regimens” and “non-preferred” treatment regimens; removed Incivek® from policy due to product discontinuation; updated diagnoses indicating an urgency for treatment; added the following items to the limitations section: treatment regimen containing Victrelis, newly approved hepatitis C medications, previous treatment with HCV DAA.</td>
<td>12/01/2014</td>
<td>P&amp;T Committee</td>
</tr>
<tr>
<td>03/12/2015</td>
<td>Policy Revision, added approval criteria for Viekira Pak™, edited preferred and non-preferred regimens, updated limitation section to address presence of</td>
<td>05/05/2015</td>
<td>P&amp;T Committee</td>
</tr>
</tbody>
</table>

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<thead>
<tr>
<th>Date</th>
<th>Description</th>
<th>Date</th>
<th>Description</th>
<th>Committee</th>
</tr>
</thead>
<tbody>
<tr>
<td>05/29/2015</td>
<td>Policy applied to NH Medicaid</td>
<td>09/01/2015</td>
<td>P&amp;T Committee NH DHHS</td>
<td></td>
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<tr>
<td>07/09/2015</td>
<td>P&amp;T Annual Review; removed Infergen from policy due to product discontinuation; minor rephrasing of criteria regarding adherence and uncontrolled depression; added treatment regimens after failure of a direct acting antiviral (DAA); modified preferred treatment regimens for genotype 3; removed peginterferon as treatment for acute hepatitis C from the policy; added quantity limits for Sovaldi®, Olysio™, Harvoni™, Viekira Pak™, Pegasys®, and Peg-Intron®; added use of Harvoni™, Viekira Pak™, or Olysio™ for the treatment of chronic hepatitis C genotype 2 or 3 to the limitations section, added the regimens Sovaldi/RBV, Sovaldi/PEG/RBV, and Olysio/PEG/RBV for the treatment of genotype 1 to the limitations section; removed previous treatment with HCV DAA from limitations section</td>
<td>10/05/2015</td>
<td>(BMCHP); 11/4/2015 (Well Sense)</td>
<td>P&amp;T Committee NH DHHS</td>
</tr>
<tr>
<td>09/10/2015</td>
<td>Policy Revision; added approval criteria for Daklinza™ to the policy for the treatment of genotypes 1, 2, 3, and 4; added TECHNIVIE™ to the policy for the treatment of genotype 4; divided non-preferred regimens into second line regimens and third line regimens; removed Viekira Pak™ for the treatment of genotype 4; removed Sovaldi/Olysio regimen from the limitations section and added it as a non-preferred regimen for the treatment of genotype 1 and genotype 4; added quantity limits for Daklinza™ and TECHNIVIE™; modified wording in ƒPlan refers to Boston Medical Center Health Plan, Inc. and its affiliates and subsidiaries offering health coverage plans to enrolled members. The Plan operates in Massachusetts under the trade name Boston Medical Center HealthNet Plan and in other states under the trade name Well Sense Health Plan.</td>
<td>10/05/2015</td>
<td>(BMCHP); 11/4/2015 (Well Sense)</td>
<td>P&amp;T Committee</td>
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<tr>
<td>Date</td>
<td>Action</td>
<td>Effective Date</td>
<td>Responsible Party</td>
<td></td>
</tr>
<tr>
<td>------------</td>
<td>------------------------------------------------------------------------</td>
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<td>-------------------------</td>
<td></td>
</tr>
<tr>
<td>07/14/2016</td>
<td>Policy Revision; adopted MassHealth Pharmacy Program Hepatitis C clinical criteria to be used for BMCHP MassHealth requests. Removed Victrelis® from the policy due to product discontinuation; added approval criteria, limitations, and quantity limit for Epclusa® and Zepatier™; removed policy applicability to Well Sense</td>
<td>08/01/2016</td>
<td>P&amp;T Committee</td>
<td></td>
</tr>
<tr>
<td>09/08/2016</td>
<td>P&amp;T annual review, removed advanced liver disease restriction, substance abuse requirements for QHP to match MassHealth criteria</td>
<td>09/15/2016</td>
<td>P&amp;T Committee</td>
<td></td>
</tr>
<tr>
<td>03/09/2017</td>
<td>Policy Revision; policy updated to include Viekira XR with criteria similar to Viekira Pak except for dosing schedule. Criteria for the following treatments no longer recommended by AASLD/IDSA guidelines were removed-Pegasys, PegIntron, Sovaldi or Olysio in combination with peginterferon and ribavirin, and Sovaldi plus ribavirin for genotype 2 or 3 removed; Epclusa was indicated as preferred in plan applicability chart.</td>
<td>07/17/2017</td>
<td>P&amp;T Committee</td>
<td></td>
</tr>
<tr>
<td>09/14/2017</td>
<td>P&amp;T Annual Review, preferred drug designation removed for Daklinza, step through Epclusa® has been implemented for all genotype 3 requests; updated criteria to reflect FDA-approval of Harvoni® and Sovaldi® in children ≥12 years old.</td>
<td>01/01/2018</td>
<td>P&amp;T Committee</td>
<td></td>
</tr>
<tr>
<td>03/08/2017</td>
<td>Policy Revision; removed the criteria for combinations no longer recommended by guidelines for routine use (Viekira Pak/XR, Sovaldi plus Daklinza or Olysio for genotype 1, and Technivie). Criteria were updated to reflect the selection of Epclusa, Harvoni, Mavyret, Sovaldi, and Vosevi as the preferred products. Epclusa, Mavyret for eight weeks, and Harvoni for eight weeks do not require a step through another hepatitis C product.</td>
<td>03/01/2018</td>
<td>P&amp;T Committee</td>
<td></td>
</tr>
</tbody>
</table>

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Next Review Date

09/13/2018

Other Applicable Policies

9.002 Mandatory Generic Substitution Policy
OCA 3.14 Medically Necessary Policy

Reference to Applicable Laws and Regulations, If Any

MassHealth Pharmacy Program Hepatitis C Guidelines – version 7.4

Disclaimer Information

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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