Pharmacy Policy

Hepatitis C

Policy Number: 9.123
Version Number: 19.0
Version Effective Date: 07/17/2017

Product Applicability  □ All Plan* Products

<table>
<thead>
<tr>
<th>Well Sense Health Plan</th>
<th>Boston Medical Center HealthNet Plan</th>
</tr>
</thead>
<tbody>
<tr>
<td>□ New Hampshire Medicaid</td>
<td>□ MassHealth</td>
</tr>
<tr>
<td>□ NH Health Protection Program</td>
<td>□ Qualified Health Plans/ConnectorCare/Employer Choice Direct</td>
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<td></td>
<td>□ Senior Care Options</td>
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</tbody>
</table>

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.

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Treatment is indicated for patients with chronic hepatitis C, circulating HCVRNA, 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), and Viekira Pak™ (ombitasvir/paritaprevir/ritonavir/dasabuvir).

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).

Olysio™ is approved by the FDA for the treatment of chronic hepatitis C genotype 1 in adult patients with compensated liver disease, including cirrhosis. Use of Olysio™ in patients with moderate to severe hepatic impairment is not recommended. Olysio™ is a HCV NS3/4A protease inhibitor and is approved for use in combination with Sovaldi®. Screening patients with genotype 1a at baseline for the presence of the NS3 Q80K polymorphism is strongly recommended when Olysio™ is used in combination with interferon and ribavirin. Alternative regimens should be considered for patients that are Q80K polymorphism positive. Olysio™ has not been studied in patients who have had a previous exposure to a protease inhibitor (e.g. boceprevir, telaprevir) and it therefore should not be used in patients with previous HCV protease inhibitor exposure. The combination of Sovaldi® and Olysio™ in genotype 1 has been approved by the FDA and the AASLD guidelines do recommend Sovaldi® and Olysio™ with or without ribavirin in certain patients. However, Zepatier™ and Harvoni™ are more cost-effective interferon-free treatment options with decreased pill burden.

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.

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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.

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.

Technivie™, like Viekira Pak™, consists of ombitasvir/paritaprevir/ritonavir tablets; however, Technivie™ does not include dasabuvir. Technivie™ is approved by the FDA for the treatment of genotype 4 without cirrhosis. Tablets are dispensed in a monthly carton. Patients are to take two tablets once daily. Like Viekira Pak™, Technivie™ should be administered with a meal without regard to fat or calorie content, is contraindicated with severe hepatitis impairment, and is recommended by to be administered in combination with ribavirin. Both Technivie™ and Viekira Pak™ are contraindicated in patients with moderate to severe hepatic impairment (Child Pugh B and C). Hepatic decompensation and hepatic failure (including liver transplantation or fatal outcomes) have been reported postmarketing. Technivie™ is not indicated for cirrhosis. The labeling for Viekira Pak™ recommends routine monitoring for hepatic decompensation in patients who have cirrhosis, and therapy discontinuation in patients who develop evidence of hepatic decompensation while on Viekira Pak™.

Viekira Pak™ consists of ombitasvir/paritaprevir/ritonavir tablets and dasabuvir tablets; it is approved for the treatment of chronic hepatitis C genotype 1. Ombitasvir is an HCV NS5A inhibitor, paritaprevir is an NS3/4A inhibitor, and dasabuvir is an NS5B inhibitor. Ritonavir has no activity against HCV itself. Instead, it inhibits paritaprevir metabolism, increasing peak and trough drug exposure and allowing once daily dosing of paritaprevir. Two ombitasvir/paritaprevir/ritonavir tablets are taken once daily in the morning and one dasabuvir tablet is taken twice daily (once in the morning, once in the evening). Viekira Pak™ should be taken with a meal, but fat or calorie content does not need to be taken into account. Viekira Pak™ is not recommended in the presence of decompensated liver disease. Patients with particular characteristics (genotype subtype and presence of cirrhosis) do need to administer ribavirin in conjunction with Viekira Pak™.

Viekira XR® consists of dasabuvir/ombitasvir/paritaprevir/ritonavir extended-release. It is approved for patients with chronic HCV genotype 1 infection including those with compensated cirrhosis) with or without ribavirin. The FDA-approved treatment duration is 12 or 24 weeks depending on prior treatment history and cirrhosis status. It is a fixed-dose, once-daily combination of dasabuvir, an HCV non-nucleoside NS5B palm polymerase inhibitor, ombitasvir, an HCV NS5A inhibitor, paritaprevir, an HCV NS3/4A protease inhibitor, and ritonavir, a CYP3A inhibitor.

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.

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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. Currently, AALSD guidelines recommend regimens with a second generation DAA as the first therapy choice for chronic hepatitis C. 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. The table below lists common side effects associated with interferon and ribavirin. Table 12 lists the common side effects with interferon and ribavirin therapy, while table 13 lists the AASLD definition of “interferon-ineligible”.

**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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<tbody>
<tr>
<td></td>
<td>MassHealth</td>
<td>QHP</td>
<td></td>
</tr>
<tr>
<td>Daklinza™ (preferred)</td>
<td>X</td>
<td>X</td>
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</tr>
<tr>
<td>Epclusa® (preferred)</td>
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<td></td>
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<tr>
<td>Harvoni™ (preferred)</td>
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</tr>
<tr>
<td>Olysio™</td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Pegasys®</td>
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<td>X</td>
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<tr>
<td>Peg-Intron®</td>
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<td></td>
</tr>
<tr>
<td>Rebetol® sol</td>
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<td></td>
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<tr>
<td>Brand name® ribavirin convenience pack</td>
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</tr>
<tr>
<td>TECHNIVIE™</td>
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<tr>
<td>Viekira Pak™</td>
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</table>

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Hepatitis C

4 of 42
Prior Authorization- (Treatment regimen >12 weeks meeting approval criteria will be approved in 12 week increments, Quantity limits apply – see Appendix A)

Criteria Index

Section 1. Harvoni (ledipasvir/sofosbuvir) – Approval Criteria ................................................................. 5
Section 2. Viekira Pak and Viekira XR – Approval Criteria ........................................................................... 9
Section 3. Daklinza® (daclatasvir) – Approval Criteria ................................................................................. 11
Section 4. Sovaldi (sofosbuvir) – Approval Criteria .................................................................................... 15
Section 5. Zepatier® (elbasvir/grazoprevir) – Approval Criteria ................................................................. 20
Section 6. Eclusa® (sofosbuvir/velpatasvir) – Approval Criteria ................................................................. 22
Section 7. Technivie® (ombitasvir/paritaprevir/ritonavir) – Approval Criteria ................................................. 25
Section 8. Olysio® (simeprevir) – Approval Criteria ..................................................................................... 25
Section 9. Pegasys® (peginterferon alfa-2a) or PegIntron® (peginterferon alfa-2b) ............................................. 26
Section 10. Requests Noting Prior Failure with Direct-Acting Antivirals (DAAs) – not otherwise addressed in drug specific sections above ......................................................................................................................... 26
Section 11. Non-preferred therapies for HCV genotype 1 or 4 s/p liver transplant for members without decompensated cirrhosis .................................................................................................................. 28
Section 12. HCV members with Decompensated Cirrhosis ........................................................................... 29
Section 13. Other HCV Genotypes ............................................................................................................... 32
Section 14. Preferred and non-preferred regimens for members with patients with CrCl<30ml/min ..................... 33
Section 15. Continuation Criteria for Regimens >12 weeks (must have met Plan criteria for the initial 12 weeks) .......... 33
Section 16. Brand name ribavirin convenience packaged products – Approval Criteria ................................. 34
Section 16. Rebetol® Solution – Approval Criteria ........................................................................................ 34

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

1. **Genotype 1: Treatment-naive members without cirrhosis**

   Documentation of all of the following:

   2. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
   3. Genotype 1
   4. Member ≥18 years of age
   5. Requested dose is 90 mg/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:

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

<table>
<thead>
<tr>
<th>Section</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>a.</td>
<td>Baseline viral load (within the last six months) &lt; 6 million IU/mL and requested duration is eight weeks‡</td>
</tr>
<tr>
<td>b.</td>
<td>Baseline viral load (within the last six months) ≥ 6 million IU/mL and requested duration is 12 weeks</td>
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</tbody>
</table>

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).

‡Requests for 12 weeks documenting that member has HIV-coinfection, is African-American, black, or has IL28B polymorphism 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.

### A. Genotype 1: Treatment-naïve members with compensated cirrhosis (Child Turcotte Pugh [CTP] class A) OR treatment-experienced members without cirrhosis OR Prior failure of HCV protease inhibitor (BOC+PEG+RBV or TLV+PEG+RBV) 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 ≥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).

### B. 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. 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. **ONE** of the following:

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Hepatitis C

6 of 42
### Section 1. Harvoni (ledipasvir/sofosbuvir) – Approval Criteria

#### a. ALL of the following:
   - i. Requested regimen includes ribavirin
   - ii. Requested duration is 12 weeks

#### b. ALL of the following:
   - i. Requested duration is 24 weeks
   - ii. Clinical rationale for use over 12-week treatment with Harvoni® (ledipasvir/sofosbuvir) and 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)

### C. Genotype 2 (In combination with Ribavirin; non-preferred therapy)

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 (documentation of prior treatment, if any, should be provided)
3. Member without decompensated cirrhosis (Child-Pugh score B or C)
4. Member is not s/p liver transplant
5. Member >18 years of age
6. Requested dose is 90 mg/400 mg once daily
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. Requested regimen includes ribavirin and requested duration is 12 weeks
10. If member is treatment-experienced (prior failure of peginterferon and ribavirin only) with cirrhosis, prescriber should provide contraindication to ALL of the following†:
   - a. SOF/VEL+RBV x 12 weeks
   - b. DCV+SOF+RBV x 24 weeks
   - c. SOF+RBV x 24 weeks
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).

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Hepatitis C

7 of 42
Section 1. Harvoni (ledipasvir/sofosbuvir) – Approval Criteria

**Genotype 4, 5, or 6**

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

**E. Genotype 1 or 4: Members s/p liver transplant including members s/p liver transplant with decompensated cirrhosis**

Documentation of the 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 is s/p liver transplant
4. Member ≥18 years of age
5. Requested dose is 90 mg/400 mg once daily
6. **ONE** of the following:
   a. Requested regimen includes ribavirin and requested duration is 12 weeks
   b. Requested duration is 24 weeks (without ribavirin) and contraindication or prior intolerance 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).

**F. Genotype 4: Members with decompensated cirrhosis who have failed sofosbuvir based regimen**

Documentation of all of the following:

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Hepatitis C

8 of 42
Section 1. Harvoni (ledipasvir/sofosbuvir) – Approval Criteria

1. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
2. Genotype 4
3. Member is >18 years of age
4. Clinical rationale for use instead of Epclusa
5. Requested dose is 90 mg/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 to F4, documentation of cirrhosis)
8. Requested duration is 24 weeks and requested regimen includes ribavirin
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).

Section 2. Viekira Pak and Viekira XR – Approval Criteria

A. Genotype 1: Treatment-naïve 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 1
3. Member ≥18 years of age
4. Clinical rationale for use instead of Harvoni*
5. For Viekira Pak requests, requested dose is two ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg tablets once daily and one dasabuvir 250 mg tablet twice daily; or For Viekira XR® requests, requested dose is three dasabuvir/ombitasvir/paritaprevir/ritonavir 200 mg/8.33 mg/50 mg/33.33 mg tablets once daily
6. For members with genotype 1a only: requested regimen includes ribavirin
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. Requested duration is 12 weeks
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).

1. Genotype 1: Treatment-experienced members without cirrhosis

Documentation of all of the following:
2. Diagnosis of chronic hepatitis C
3. Genotype 1
4. Member ≥18 years of age

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Section 2. Viekira Pak and Viekira XR– Approval Criteria

5. Clinical rationale for use instead of Harvoni®.

6. **For Viekira Pak requests**, requested dose is two ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg tablets once daily and one dasabuvir 250 mg tablet twice daily; or

**For Viekira XR® requests**, requested dose is three dasabuvir/ombitasvir/paritaprevir/ritonavir 200 mg/8.33 mg/50 mg/33.33 mg tablets once daily

7. For members with genotype 1a only: requested regimen includes ribavirin

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)

10. Member has not been previously treated with a regimen containing an HCV protease inhibitor (e.g., boceprevir, grazoprevir, paritaprevir, simeprevir, or telaprevir)

11. Requested duration is 12 weeks

12. 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).

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

   Documentation of all of the following:
   
   2. Diagnosis of chronic hepatitis C
   3. Genotype 1
   4. Clinical rationale for use instead of Harvoni®
   5. Member >18 years of age

6. **For Viekira Pak requests**, requested dose is two ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg tablets once daily and one dasabuvir 250 mg tablet twice daily; or

**For Viekira XR® requests**, requested dose is three dasabuvir/ombitasvir/paritaprevir/ritonavir 200 mg/8.33 mg/50 mg/33.33 mg tablets once daily

7. For members with genotype 1a only: requested regimen includes ribavirin

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. Member has not been previously treated with a regimen containing an HCV protease inhibitor (e.g., boceprevir, grazoprevir, paritaprevir, simeprevir, or telaprevir)

10. **ONE** of the following:
   
   a. For genotype 1b, requested duration is 12 weeks
   b. For genotype 1a with history of relapse or partial response to prior peginterferon and ribavirin treatment, requested duration is 12 weeks
   c. For genotype 1a with history of null response to prior peginterferon and ribavirin treatment, requested duration is 24 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

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Section 2. Viekira Pak and Viekira XR– Approval Criteria

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

1. **Genotype 4: Members with no prior history of liver transplant**
   2. Diagnosis of chronic hepatitis C (either by direct notation on request form or lab data noting HCV RNA levels)
   3. Genotype 4
   4. Clinical rationale for use instead of Harvoni®
   5. Member ≥18 years of age
   6. **For Viekira Pak requests**, requested dose is two ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg tablets once daily and one dasabuvir 250 mg tablet twice daily; or
      **For Viekira XR® requests**, requested dose is three dasabuvir/ombitasvir/paritaprevir/ritonavir 200 mg/8.33 mg/50 mg/33.33 mg tablets once daily
   7. Member is not s/p liver transplant
   8. Member without decompensated cirrhosis (Child Pugh B or C)
   9. Medical records and results of diagnostic tests assessing hepatic fibrosis including tests supporting liver disease staging (e.g., APRI, Fibroscan, Fibrosure, FIB-4)
   10. Stage of liver disease is early stage (e.g. Metavir Score F0 to F2) or advanced stage (e.g. Metavir Score F3 or F4)
   11. Member has not been previously treated with a regimen containing an HCV protease inhibitor (e.g., boceprevir, grazoprevir, paritaprevir, simeprevir, or telaprevir)
   12. Requested regimen includes ribavirin and requested duration is 12 weeks
   13. 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).

Section 3. Daklinza® (daclatasvir) – Approval Criteria

A. **Genotype 1**
   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 has a contraindication to **ALL** combination products FDA-approved for the treatment of HCV genotype 1 infection (i.e., Harvoni®, Viekira Pak®, Viekira XR®, Zepatier®, Epclusa®)
   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

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Hepatitis C

11 of 42
Section 3. Daklinza® (daclatasvir) – Approval Criteria

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. Requested regimen includes sofosbuvir 400 mg once daily
9. ONE of the following:
   a. Absence of cirrhosis and requested duration is 12 weeks
   b. Compensated cirrhosis (Child Turcotte Pugh [CTP] class A) and requested duration is 24 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)

B. Genotype 2: Treatment-naïve or treatment experienced (Non-preferred therapy)

Documentation of all of the following:
1. Diagnosis of chronic hepatitis C
2. Member without decompensated cirrhosis (Child-Pugh score B or C)
3. Member is not s/p liver transplant
4. HCV genotype 2
5. Clinical rationale for use instead of Epclusa®
6. Member ≥18 years of age
7. ONE of the following:
   a. Requested Daklinza® dose is 60 mg once daily
   b. Medical necessity for requested Daklinza® dose of either 30 mg or 90 mg once daily
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 or F4, documentation of cirrhosis)*
10. ONE of the following
    a. If member is treatment-naïve or treatment-experienced (prior peginterferon and ribavirin only) without cirrhosis, requested regimen includes sofosbuvir 400 mg once daily and requested duration is 12 weeks
    b. If member is treatment-naïve or treatment-experienced (prior peginterferon and

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Section 3. Daklinza® (daclatasvir) – Approval Criteria

ribavirin only) with compensated cirrhosis (Child-Pugh score A), requested regimen includes sofosbuvir 400 mg once daily and requested duration is 16 or 24 weeks, as requested.

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).

C. **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. 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 log_{10} IU/mL) on repeat testing at week 6 (or thereafter).

D. **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. 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. Requested regimen includes sofosbuvir 400 mg once daily and requested duration is 24 weeks
7. **ONE** of the following:

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

| 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 |

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 log₁₀ IU/mL) on repeat testing at week 6 (or thereafter).

**E. 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. 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. sofosbuvir 400 mg once daily and requested duration is 12 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. 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).

**F. 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. Member ≥ 18 years of age
4. **ONE** of the following:

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Section 3. Daklinza® (daclatasvir) – Approval Criteria

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. Requested regimen includes sofosbuvir 400 mg once daily and ribavirin
7. Requested duration is 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).

G. Genotype 3: Treatment-experienced (prior sofosbuvir and ribavirin failure) 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. HCV genotype 3
3. 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 to F4, documentation of cirrhosis)
7. Requested regimen includes sofosbuvir 400 mg once daily and ribavirin
8. Requested duration is 24 weeks
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 log_{10} IU/mL) on repeat testing at week 6 (or thereafter).

Section 4. Sovaldi (sofosbuvir) – Approval Criteria

1. A. Genotype 1: In combination with Daklinza® (daclatasvir)

Documentation of all of the following:

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Section 4. Sovaldi (sofosbuvir) – Approval Criteria

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 has a contraindication to ALL combination products FDA-approved for the treatment of HCV genotype 1 infection (i.e., Harvoni®, Epclusa®, Viekira Pak®, Viekira XR®, Zepatier®)
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 to F4, documentation of cirrhosis)
8. Requested regimen includes daclatasvir
9. ONE of the following:
   a. Absence of cirrhosis and requested duration is 12 weeks
   b. Compensated cirrhosis (Child Turcotte Pugh [CTP] class A) and requested duration is 24 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)

B. Genotype 1: In combination with Olysio® (simeprevir)
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 has a contraindication to ALL other all-oral regimens FDA-approved for the treatment of HCV genotype 1 infection (i.e., Harvoni®, Epclusa®, Viekira Pak®, Viekira XR®, Zepatier®, and Daklinza® plus Sovaldi®)
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 to F4, documentation of cirrhosis)
8. Member does not have decompensated cirrhosis (Child Turcotte Pugh Class B or C)
9. Member has not been previously treated with a regimen containing an HCV protease inhibitor (e.g., boceprevir, grazoprevir, paritaprevir, simeprevir, or telaprevir)
10. Requested regimen includes simeprevir 150 mg once daily
11. ONE of the following:

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Section 4. Sovaldi (sofosbuvir) – Approval Criteria

a. For genotype 1a or 1b without cirrhosis, requested duration is 12 weeks
b. For genotype 1a with cirrhosis, documentation of absence of NS3 Q80K polymorphism and requested duration is 24 weeks
c. For genotype 1b with cirrhosis, requested duration is 24 weeks

12. 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

13. 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 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. Member ≥18 years of age
4. Requested dose is 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. Requested duration is 12 weeks and requested regimen includes daclatasvir
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).

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

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 3
3. Member ≥18 years of age
4. Requested dose is 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. Requested duration is 24 weeks requested regimen includes daclatasvir, and testing results document absence of NS5A Y93H resistance-associated polymorphism
7. Requested duration is 24 weeks, requested regimen includes daclatasvir and ribavirin, and testing results document presence of NS5A Y93H resistance-associated polymorphism ONE of the following:

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

**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<sub>10</sub> IU/mL) on repeat testing at week 6 (or thereafter).

### E. 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. Member ≥18 years of age
4. Requested dose is 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. Requested duration is 12 weeks, requested regimen includes daclatasvir, and testing results document absence of NS5A Y93H resistance-associated polymorphism
   
   b. Requested duration is 12 weeks, requested regimen includes daclatasvir and ribavirin†, and testing results document presence of NS5A Y93H resistance-associated polymorphism

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<sub>10</sub> IU/mL) on repeat testing at week 6 (or thereafter).

### F. 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. Member ≥18 years of age
4. Requested dose is 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. **Requested duration is 24 weeks** and **requested regimen includes Daklinza® and ribavirin**
7. **ONE** of the following:

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Hepatitis C

18 of 42
Section 4. Sovaldi (sofosbuvir) – Approval Criteria

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).

G. Genotype 3: Treatment-experienced (prior sofosbuvir and ribavirin failure) 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. HCV genotype 3
3. Member ≥18 years of age
4. Requested dose is 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 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).

H. Genotype 2 or 3: Members s/p liver transplant (Request in combination with Daklinza)

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 or 3
3. Member is s/p liver transplant
4. Member ≥18 years of age
5. Requested Sovaldi® dose is 400 mg once daily
6. ONE of the following:
   a. Member without decompensated cirrhosis (Child Pugh B or C) and ONE of the following:
      i. Requested regimen includes Daklinza® at an appropriate dose* plus ribavirin and requested duration is 12 weeks
      ii. Requested regimen includes ribavirin, requested duration is 24 weeks, and prescriber documents contraindication to Daklinza® plus Sovaldi® plus ribavirin for 12 weeks

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Section 4. Sovaldi (sofosbuvir) – Approval Criteria

iii. Requested regimen includes Daklinza® at an appropriate dose*, requested duration is 24 weeks, and prescriber documents contraindication to ribavirin
   b. Member with decompensated cirrhosis (Child Pugh B or C), requested regimen includes ribavirin, and requested duration is 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 greater than 10-fold (>1 log<sub>10</sub> IU/mL) on repeat testing at week 6 (or thereafter).

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

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. Clinical rationale for use instead of Harvoni®
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 polymorphisms 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 polymorphisms 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

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

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<sub>10</sub> IU/mL) on repeat testing at week 6 (or thereafter)

### B. Genotype 1: Treatment-experienced members (failed treatment with 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. Clinical rationale for use instead of Harvoni®
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 polymorphisms 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 polymorphisms 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<sub>10</sub> IU/mL) on repeat testing at week 6 (or thereafter)

### 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)

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

2. Genotype 4  
3. Clinical rationale for use instead of Harvoni®  
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

A. **Genotype 1, 2, 3,4, 5, or 6:** 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 (either by direct notation on request form or lab data noting HCV RNA levels)  
2. Genotype 1, 2, 3, 4, 5, or 6  
3. For genotype 1, 4, 5, or 6 only, clinical rationale for use instead of Harvoni®  
4. Member ≥18 years of age  
5. Requested dose is 400 mg/100 mg once daily  
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. **For genotype 3 only, ONE of the following**

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Hepatitis C  
22 of 42
Section 6. Epclusa® (sofosbuvir/ velpatasvir) – Approval Criteria

a. Member is treatment-naive without cirrhosis
b. Member is treatment-naive with compensated cirrhosis or treatment-experienced with or without compensated cirrhosis and testing results document absence of NS5A Y93H resistance-associated polymorphism

c. Requested regimen includes ribavirin and ONE of the following
   i. Member is treatment-naive with compensated cirrhosis or treatment-experienced without cirrhosis and testing results document presence of NS5A Y93H resistance-associated polymorphism
   ii. Member is treatment-experienced with compensated 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 log₁₀ IU/mL) on repeat testing at week 6 (or thereafter).

B. Genotype 1: Prior failure of HCV protease inhibitor (BOC+PEG+RBV or TLV+PEG+RBV)

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. For genotype 1, clinical rationale for use instead of Harvoni*
4. Member ≥18 years of age
5. Requested dose is 400 mg/100 mg once daily
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. For genotype 3 only, ONE of the following
    a. Member is treatment-naive without cirrhosis
    b. Member is treatment-naive with compensated cirrhosis or treatment-experienced without cirrhosis and testing results document absence of NS5A Y93H resistance-associated polymorphism
    c. Requested regimen includes ribavirin AND ONE of the following:
       i. Member is treatment-naive with compensated cirrhosis or treatment-experienced without cirrhosis and testing results document presence of NS5A Y93H resistance-associated polymorphism
       ii. Member is treatment-experienced with compensated 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 log₁₀ IU/mL) on repeat testing at week 6 (or thereafter).

C. Genotype 3: Prior failure of sofosbuvir and ribavirin

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

2. Genotype 3
3. Member ≥18 years of age
4. Requested dose is 400 mg/100 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 and requested regimen includes ribavirin
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).

D. Genotype 4: 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, 5 or 6
3. Clinical rationale for use instead of Harvoni®
4. Member ≥18 years of age
5. Requested dose is 400 mg/100 mg once daily
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 log₁₀ IU/mL) on repeat testing at week 6 (or thereafter).

E. Genotype 4: Prior failure of sofosbuvir based regimen 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)
2. Genotype 4
3. Member is >18 years of age
4. Requested dose is 400 mg/100 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 24 weeks and requested regimen includes ribavirin
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).

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Section 7. Technivie® (ombitasvir/paritaprevir/ritonavir) – Approval Criteria

A. Genotype 4: (including compensated liver disease and no prior history of liver transplant)

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. Genotype 4
3. Clinical rationale for use instead of Harvoni®
4. Member >18 years of age
5. Requested dose is two ombitasvir/paritaprevir/ritonavir 12.5/75/50 mg tablets 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 cirrhosis
9. Member has not been previously treated with a regimen containing an HCV protease inhibitor (e.g., boceprevir, grazoprevir, paritaprevir, simeprevir, or telaprevir)
10. Requested regimen includes ribavirin and requested duration is 12 weeks
11. 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 8. Olysio® (simeprevir) – Approval Criteria

A. Genotype 1: In combination with Sovaldi® (sofosbuvir)

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 has a contraindication to ALL other all-oral regimens FDA-approved for the treatment of HCV genotype 1 infection (i.e., Harvoni®, Viekira Pak®, Viekira XR, Zepatier®, Epclusa®, Daklinza® plus Sovaldi®)
4. Member >18 years of age
5. Requested dose is 150 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. Member has not been previously treated with a regimen containing an HCV protease inhibitor (e.g., boceprevir, grazoprevir, paritaprevir, simeprevir, or telaprevir)

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Section 8. Olysio® (simeprevir) – Approval Criteria

10. Requested regimen includes sofosbuvir 400 mg once daily

11. ONE of the following:
   a. For genotype 1a or 1b without cirrhosis, requested duration is 12 weeks
   b. For genotype 1a with cirrhosis, documentation of absence of NS3 Q80K polymorphism and requested duration is 24 weeks
   c. For genotype 1b with cirrhosis, requested duration is 24 weeks

12. 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

13. 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 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
   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
Section 10. Requests Noting Prior Failure with Direct-Acting Antivirals (DAAs) – not otherwise addressed in drug specific sections above

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b. Documentation of ALL of the following:

i. Prior failure of ONE of the following NS5A inhibitor-containing regimes (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 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

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

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\textsubscript{10} IU/mL) on repeat testing at week 6 (or thereafter).

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

- Requests for (Daklinza\textsuperscript{*} plus Sovaldi\textsuperscript{*} plus ribavirin) for 12 weeks must provide contraindication to Harvoni\textsuperscript{*} with ribavirin for 12 weeks and Harvoni\textsuperscript{*} for 24 weeks.
- Requests for (Daklinza\textsuperscript{*} plus Sovaldi\textsuperscript{*}) x 24 weeks must provide contraindication to **ALL** of the following (listed in order of preference).
  - Harvoni\textsuperscript{*} with ribavirin for 12 weeks **AND**
  - Harvoni\textsuperscript{*} for 24 weeks **AND**
  - Daklinza\textsuperscript{*} plus Sovaldi\textsuperscript{*} with ribavirin for 12 weeks
- Request for (Sovaldi\textsuperscript{*} plus Olysio\textsuperscript{*}) 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\textsuperscript{*} with ribavirin for 12 weeks **AND**
  - Harvoni\textsuperscript{*} for 24 weeks **AND**
  - Daklinza\textsuperscript{*} plus Sovaldi\textsuperscript{*} with ribavirin for 12 weeks

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Hepatitis C

- 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
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 log_{10} 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:

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Section 12. HCV members with Decompensated Cirrhosis

a. 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

a. 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

a. 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 for 24 weeks

a. 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

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
### Section 12. HCV members with Decompensated Cirrhosis

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 log₁₀ 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)
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

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Hepatitis C

31 of 42
**Section 12. HCV members with Decompensated Cirrhosis**

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} 1U/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.

*Mixed genotype:*

*Epclusa® or Harvoni® plus ribavirin for Mixed Genotype 1 AND 2:*

Prescriber provides 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 AND 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 or F4)

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

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Hepatitis C

32 of 42
### Section 13. Other HCV Genotypes

7. Member is not s/p liver transplant

8. **ONE** of the following:
   a. Member does not have cirrhosis and is either treatment-naïve or treatment-experienced with peginterferon and ribavirin dual therapy only and requested regimen is Harvoni® once daily plus ribavirin for 12 weeks
   b. Member has compensated cirrhosis and requested regimen is Epclusa® once daily for 12 weeks.

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 log_{10} IU/mL) on repeat testing at week 6 (or thereafter)

### 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)

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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 16. 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>
<tbody>
<tr>
<td>Daklinza™ 30 mg, 60 mg tablets</td>
<td>28 tablets per 28 days</td>
</tr>
<tr>
<td>Epclusa® 400 mg/100 mg tablet</td>
<td>28 tablets per 28 days</td>
</tr>
<tr>
<td>Harvoni™ 90 mg/400 mg tablets</td>
<td>28 tablets per 28 days</td>
</tr>
<tr>
<td>Pegasys®135 mcg/0.5 mL, 180 mcg/0.5 mL syringe</td>
<td>4 syringes per 28 days</td>
</tr>
<tr>
<td>Peg-Intron® 50 mcg/0.5 mL, 80 mcg/0.5 mL, 120 mcg/0.5 mL, 150 mcg/mL pen</td>
<td>4 pens per 28 days</td>
</tr>
<tr>
<td>Olysio™ 150 mg tablet</td>
<td>28 tablets per 28 days</td>
</tr>
<tr>
<td>Sovaldi® 400 mg tablet</td>
<td>28 tablets per 28 days</td>
</tr>
<tr>
<td>TECHNIVIE™ 12.5 mg/75 mg/50 mg tablet</td>
<td>1 carton (56 tablets) per 28 days</td>
</tr>
<tr>
<td>Viekira Pak™ 12.5 mg/75 mg/50 mg tablets and 250 mg tablets</td>
<td>1 pack (112 tablets) per 28 days</td>
</tr>
<tr>
<td>Viekira XR®</td>
<td>28 tablets per 28 days</td>
</tr>
<tr>
<td>Zepatier™ 50 mg/100 mg</td>
<td>28 tablets per 28 days</td>
</tr>
</tbody>
</table>

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®)

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<table>
<thead>
<tr>
<th>Term</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>LDV/SOF=ledipasvir/sofosbuvir (Harvoni*)</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>PEG/RBV=peginterferon plus ribavirin</td>
<td>A long-term illness that occurs when HCV infection lasts longer than six months</td>
</tr>
<tr>
<td>PrO=paritaprevir/ritonavir/ombitasvir (Technivie*)</td>
<td>Cirrhosis Late stage of progressive hepatic fibrosis; generally irreversible</td>
</tr>
<tr>
<td>PrOD=paritaprevir/ritonavir/ombitasvir plus dasabuvir (Viekira Pak*)</td>
<td>Fibrosis Scarring caused by repair of tissue damage; can lead to cirrhosis</td>
</tr>
<tr>
<td>SOF/VEL=sofosbuvir/velpatasvir (Epclusa*)</td>
<td>Partial Response 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>TLV=telaprevir (Incivek*)</td>
<td>Non-responder Either null or partial responder (see definitions above)</td>
</tr>
<tr>
<td></td>
<td>Relapse Undetectable HCV RNA at the end of treatment, but lack of SVR (negative HCV RNA 24 weeks after completing treatment)</td>
</tr>
<tr>
<td></td>
<td>Sustained Virological Response (SVR), or Viral Cure HCV RNA remains undetectable 12 weeks after the end of treatment</td>
</tr>
<tr>
<td></td>
<td>Treatment-experienced 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).</td>
</tr>
<tr>
<td></td>
<td></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

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• 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


20. Bourliere M, Bronowicki J, de Ledinghen, et al. Ledipasvir/sofosbuvir fixed dose combination is safe and efficacious in cirrhotic patients who have previously failed protease-inhibitor based triple therapy. Program and

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Hepatitis C

36 of 42
abstracts of the 65th Annual Meeting of the American Association for the Study of Liver Diseases; November 7-11, 2014; Boston, Massachusetts. Abstract LB-6.


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46. Lawitz E, Gane E, Pearlman B, Tam E, Ghersique 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.


<table>
<thead>
<tr>
<th>Original Approval Date</th>
<th>Original Effective Date</th>
<th>Policy Owner</th>
<th>Approved by</th>
</tr>
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<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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</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>
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<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”,</td>
<td>01/01/2008</td>
<td>P&amp;T Committee</td>
</tr>
</tbody>
</table>

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Hepatitis C

38 of 42
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### Policy Revisions History

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
<th>Date</th>
<th>Event Description</th>
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</thead>
<tbody>
<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>
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<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 Incivek® triple therapy for patients with compensated cirrhosis, minor formatting changes throughout.</td>
<td>11/01/2013</td>
<td>P&amp;T Committee</td>
</tr>
<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</td>
<td>11/12/2014</td>
<td>P&amp;T Committee</td>
</tr>
</tbody>
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Hepatitis C

39 of 42
<table>
<thead>
<tr>
<th>Date</th>
<th>Description</th>
<th>Date</th>
<th>Responsible Party</th>
</tr>
</thead>
<tbody>
<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 decompensated liver disease as it pertains to Olysio™, Viekira Pak™, or pegylated interferon, added Harvoni™ and Viekira Pak™ to the list of medications that not approvable for members less than 18 years of age, and addressed concomitant use of Sovaldi® and Olysio™ in the limitations section</td>
<td>05/05/2015</td>
<td>P&amp;T Committee</td>
</tr>
<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>
</tr>
<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™,</td>
<td>10/05/2015 (BMCHP); 11/4/2015 (Well Sense)</td>
<td>P&amp;T Committee NH DHHS</td>
</tr>
</tbody>
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<tr>
<th>Date</th>
<th>Description</th>
<th>Date</th>
<th>Referenced Committee</th>
</tr>
</thead>
<tbody>
<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 limitations section for newly approved hepatitis C medications</td>
<td>10/05/2015 (BMCHP); 11/4/2015 (Well Sense)</td>
<td>P&amp;T Committee</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>
</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>
</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</td>
<td>07/17/2017</td>
<td>P&amp;T Committee</td>
</tr>
</tbody>
</table>

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**Hepatitis C**

**Policy Revisions History**

| Preferred in plan applicability chart. |

**Next Review Date**

07/13/2017

**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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Hepatitis C

42 of 42