Pharmacy Medical Necessity Guidelines: Hepatitis C Virus

Effective: February 1, 2017

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<th>Prior Authorization Required</th>
<th>Type of Review – Care Management</th>
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Pharmacy (RX) or Medical (MED) Benefit

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<th>RX Department to Review</th>
<th>RXUM</th>
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This Pharmacy Medical Necessity Guideline applies to the following:

INTotal Health Medicaid Plan
INTotal Health Medicaid Plan
INTotal Health FAMIS Plan
INTotal Health FAMIS Plan

Fax Numbers:
RXUM: 855-762-5205

OVERVIEW
Per the Centers for Disease Control and Prevention, "Hepatitis C is a liver infection caused by the Hepatitis C virus (HCV). Hepatitis C is a blood-borne virus. Today, most people become infected with the Hepatitis C virus by sharing needles or other equipment to inject drugs. For some people, hepatitis C is a short-term illness but for 70%–85% of people who become infected with Hepatitis C, it becomes a long-term, chronic infection. Chronic Hepatitis C is a serious disease than can result in long-term health problems, even death. The majority of infected persons might not be aware of their infection because they are not clinically ill. There is no vaccine for Hepatitis C. The best way to prevent Hepatitis C is by avoiding behaviors that can spread the disease, especially injecting drugs.”

FDA-APPROVED MEDICATIONS FOR HEPATITIS C VIRUS

- Zepatier (Elbasvir + Grazoprevir)
- Harvoni (Ledipasvir + Sofosbuvir)
- Sovaldi (Sofosbuvir)
- Daklinza (Daclatasvir)
- Olysio (Simeprevir)
- Technivie (Ombitasvir + Paritaprevir + Ritonavir)
- Viekira (Ombitasvir + Paritaprevir + Ritonavir + Dasabuvir)
- Epclusa (Sofobuvir + Velpatasvir)
COVERAGE GUIDELINES
INTotal Health may provide medication therapy coverage for qualifying members meeting all guidelines as outlined by DMAS criteria:

1. All requests will be reviewed for FDA approved label indications and guidelines; AND

2. Member must be 18 years of age or older; AND

3. Prescriber must be a gastroenterologist, hepatologist, infectious disease specialist or transplant specialist; AND

4. A baseline HCV-RNA (within 4 weeks of request) must be obtained before treatment initiation.

   4.1. At TW4, if the HCV RNA is ≥25 IU/mL, or at any time point thereafter, all treatment should be reevaluated; AND

5. Prescriber must review the Hepatitis C Therapy Patient Treatment Agreement with the patient, and the prescriber and member must sign the agreement to acknowledge he/she has been informed about the requirements of the treatment program and understand the expectations set forth in the agreement. [see attached agreement form]; AND

6. Members must be evaluated for decompensated cirrhosis (which is defined as a Child-Pugh score greater than 6 [class B or C]); AND

7. Members must be evaluated for severe renal impairment (eGFR <30 mL/min/1.73m²) or end stage renal disease (ESRD) requiring hemodialysis; AND

8. If member’s life expectancy is less than a year they do not qualify for hepatitis C treatment

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<tr>
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<th>GT3</th>
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<td>Epclusa 12 wk</td>
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<td>Sovaldi + Daklinza 12wk*</td>
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<td>Harvoni 12wk</td>
<td>Harvoni 12wk</td>
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* 1a w th baseline NS5A polymorphisms Epclusa 12wk is preferred
* w th compensated cirrhosis 24wk

FDA approved indications for treatment naïve

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* 1a w th baseline NS5A polymorphisms Epclusa 12wk is preferred
* w th compensated cirrhosis 24wk

AASLD/IDSA Update: July 6, 2016

Hepatitis C Medical Necessity Guidelines
Individual Drug coverage criteria

**ZEPATIER (elbasvir and grazoprevir)**
The plan may authorize coverage for Zepatier when all of the above criteria for therapy inclusion are met

AND

1. Zepatier will not be given in combination with any of the following drugs that are organic anion transporting polypeptides 1B1/3 (OATP1B1/3) inhibitors, strong inducers of CYP3A or efavirenz: Phenytoin, carbamazepine, rifampin, St. John’s Wort, efavirenz, atazanavir, darunavir, lopinavir, saquinavir, tipranavir, or cyclosporine.

AND

2. Zepatier will not be given in combination with Hepatitis C protease inhibitor (e.g., telprevir [Lincivek], simpeprevir [Olysio], sofosbuvir [Sovaldi], Harvoni, Viekira

AND

3. Member has been shown to have HCV Genotype 1a, 1b, or 4:

For **Genotype 1a:**

4. Member has tested negatively for the presence of baseline NS5A resistance-associated polymorphisms

OR

5. Member has had an inadequate response, intolerance or contraindication to the preferred product Epclusa

For **Genotype 1b:**

6. Member is treatment-naïve, treatment experienced with PEG-IFN and ribavirin

OR

7. Member is treatment experienced with PEG-IFN and ribavirin and NS3/4 protease inhibitor

For **Genotype 4:**

8. Member is treatment-naïve

OR

9. Member failed prior treatment with PEG-IFN and ribavirin (virologic relapse after treatment)

OR

10. Member failed prior treatment with PEG-IFN and ribavirin (on-treatment virologic failure)

AND

11. Member has had an inadequate response, intolerance or contraindication to the preferred product Epclusa

**EPCLUSA (sofosbuvir and velpatasvir)**
The plan may authorize coverage for Epclusa when all of the above criteria for therapy inclusion are met

AND

1. Epclusa will not be used in combination with other drugs containing sofosbuvir, including Sovaldi

AND

2. IF the member has HIV coinfection, Epclusa will not be used in combination with cobicistat and tenofovir disoproxil fumarate

AND
3. Member will not be receiving treatment with tipranavir
   AND
4. Member has been shown to have HCV Genotype 1a, 1b, 2, 3, 4, 5, or 6

**For Genotype 1a:**

5. Member was tested for baseline NS5A resistance-associated polymorphisms
   AND
6. One or more baseline NS5A resistance-associated polymorphisms are present
   OR
7. No NS5A polymorphisms are present
   AND
8. Member has had an inadequate response, intolerance or contraindication to the preferred product [Zepatier]

**For Genotype 1b:**

9. Member has had an inadequate response, intolerance or contraindication to the preferred product [Zepatier]

**For Genotype 2:**

10. Member is treatment naïve
    OR
11. Member failed prior treatment with PEG-IFN and ribavirin
    OR
12. Member failed prior treatment with sofosbuvir and ribavirin

**For Genotype 3:**

13. Member is treatment naïve
    OR
14. Member failed prior treatment with PEG-IFN and ribavirin, no cirrhosis
    OR
15. Member failed prior treatment with PEG-IFN and ribavirin, compensated cirrhosis
    OR
16. Member failed prior treatment with sofosbuvir and ribavirin

**For Genotype 4:**

17. Member is treatment naïve
    OR
18. Member failed prior treatment with PEG-IFN and ribavirin (virologic relapse after treatment)
    AND
19. Member has had an inadequate response, intolerance or contraindication to the preferred product [Zepatier]
    OR
20. Member failed prior treatment with PEG-IFN and ribavirin (on-treatment virologic failure)

**For Genotype 5 or 6:**

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Hepatitis C Medical Necessity Guidelines
21. Member is treatment naïve
   OR
22. Member failed prior treatment with PEG-IFN and ribavirin

**SOVALDI (sofosbuvir) with DAKLINZA (daclatasvir)**
The plan may authorize coverage for Sovaldi with Daklinza when all of the above criteria for therapy inclusion are met

1. IF Member has HIV coinfection, Member will not be receiving treatment with tipranavir
   AND
2. Member has been shown to have HCV Genotype 2 or 3
   AND
3. Member has had an inadequate response, intolerance or contraindication to the preferred product [Epclusa]
   AND
4. Daklinza will be used in combination with Sovaldi

**HARVONI (ledipasvir and sofosbuvir)**
The plan may authorize coverage for Harvoni when all of the above criteria for therapy inclusion are met

1. Harvoni will not be used in combination with other drugs containing sofosbuvir, including Sovaldi
   AND
2. IF the member has HIV coinfection, Harvoni will not be used in combination with cobicistat and tenofovir disoproxil fumarate
   AND
3. Member will not be receiving treatment with tipranavir
   AND
4. Member has been shown to have HCV Genotype 1a, 1b, 4, 5, or 6

**For Genotype 1a:**

5. Member was tested for baseline NS5A resistance-associated polymorphisms
   AND
6. One or more baseline NS5A resistance-associated polymorphisms are present
   AND
7. Member has had an inadequate response, intolerance or contraindication to the preferred product [Epclusa]
   OR
8. No NS5A polymorphisms are present
   AND
9. Member has had an inadequate response, intolerance or contraindication to the preferred product [Zepatier]
   AND
10. Member has had an inadequate response, intolerance or contraindication to the preferred product [Epclusa]
    AND
11. Harvoni will not be prescribed in combination with ANY of the following:
    - Amiodarone
Hepatitis C Medical Necessity Guidelines

- Hepatitis C protease inhibitors (e.g., telaprevir [Incivek], simeprevir [Olysio], sofosbuvir [Sovaldi], elbasvir/grazoprevir [Zepatier], Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir [Viekira Pak])

AND

12. Member is treatment-naive

OR

13. Member is treatment experienced, without cirrhosis

OR

14. Member is treatment experienced, with compensated cirrhosis (Child Turcotte Pugh [CTP] class A)

Genotype 1b:

15. Member has had an inadequate response, intolerance or contraindication to the preferred product [Zepatier]

AND

16. Member has had an inadequate response, intolerance or contraindication to the preferred product [Epclusa]

AND

17. Harvoni will not be prescribed in combination with ANY of the following:
   - Amiodarone
   - Hepatitis C protease inhibitors (e.g., telaprevir [Incivek], simeprevir [Olysio], sofosbuvir [Sovaldi], elbasvir/grazoprevir [Zepatier], Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir [Viekira Pak])

AND

18. Member is treatment-naive

OR

19. Member is treatment experienced, without cirrhosis

OR

20. Member is treatment experienced, with compensated cirrhosis (Child Turcotte Pugh [CTP] class A)

Genotype 4:

21. Member has had an inadequate response, intolerance or contraindication to the preferred product [Zepatier]

AND

22. Member has had an inadequate response, intolerance or contraindication to the preferred product [Epclusa]

AND

23. Harvoni will not be prescribed in combination with ANY of the following:
   - Amiodarone
   - Hepatitis C protease inhibitors (e.g., telaprevir [Incivek], simeprevir [Olysio], sofosbuvir [Sovaldi], elbasvir/grazoprevir [Zepatier], Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir [Viekira Pak])

AND

24. Member is treatment-naive

OR

25. Member is treatment experienced, without cirrhosis

OR

26. Member is treatment experienced, with compensated cirrhosis (Child Turcotte Pugh [CTP] class A)
Genotype 5 or 6:

27. Member has had an inadequate response, intolerance or contraindication to the preferred product [Epclusa]

AND

28. Harvoni will not be prescribed in combination with ANY of the following:
   • Amiodarone
   • Hepatitis C protease inhibitors (e.g., telaprevir [Incivek], simeprevir [Olysio], sofosbuvir [Sovaldi], elbasvir/grazoprevir [Zepatier], Ombitasvir/Paritaprevir/Ritonavir/Dasabuvir [Viekira Pak])

AND

29. Member is treatment-naïve

OR

30. Member is treatment experienced, without cirrhosis

OR

31. Member is treatment experienced, with compensated cirrhosis (Child Turcotte Pugh [CTP] class A)

**LIMITATIONS**

1. Approval duration as per table.

2. Quantity limits standard daily dosing.

<table>
<thead>
<tr>
<th>GENOTYPE 1A:</th>
<th>ZEPATIER</th>
<th>EPCLUSA</th>
<th>SOVALDI+ DAKLINZA</th>
<th>HARVONI</th>
<th>RIBAVIRIN</th>
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<td>Treatment Naïve with baseline NS5A Polymorphisms</td>
<td>16 weeks*</td>
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<td>16 weeks*</td>
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<tr>
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<tr>
<td>Treatment Experienced with PEG-IFN and Ribavirin without cirrhosis with baseline NS5A Polymorphisms</td>
<td>16 weeks*</td>
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<td>12 weeks</td>
<td>16 weeks*</td>
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<tr>
<td>Treatment Experienced with PEG-IFN and Ribavirin without cirrhosis &amp; without baseline NS5A Polymorphisms</td>
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<td>Treatment 2</td>
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<tr>
<td>Experienced with PEG-IFN and Ribavirin with compensated cirrhosis, with baseline NS5A Polymorphisms</td>
<td>16 weeks*</td>
<td>12 weeks</td>
<td>12 weeks**</td>
<td>16 weeks*</td>
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<tr>
<td>Experienced with PEG-IFN and Ribavirin with compensated cirrhosis &amp; without baseline NS5A Polymorphisms</td>
<td>12 weeks</td>
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<td>12 weeks*</td>
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<tr>
<td>Experienced with PEG-IFN and Ribavirin and NS3/4 protease inhibitor, with baseline NS5A Polymorphisms</td>
<td>16 weeks*</td>
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<tr>
<td>Experienced with PEG-IFN and Ribavirin and NS3/4 protease inhibitor, without baseline NS5A Polymorphisms</td>
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**GENOTYPE 1B:**

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<tbody>
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<tr>
<td>Experienced with PEG-IFN and Ribavirin and NS3/4 protease inhibitor</td>
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<td>12 weeks*</td>
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<tr>
<td>Experienced with compensated cirrhosis</td>
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<tr>
<td>Experienced with compensated cirrhosis</td>
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**GENOTYPE 2:**

| Hepatitis C Medical Necessity Guidelines |
### Hepatitis C Medical Necessity Guidelines

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<th>Treatment Status</th>
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<tbody>
<tr>
<td>Treatment Naive</td>
<td>12 weeks</td>
<td></td>
</tr>
<tr>
<td>Treatment Experienced with PEG-IFN and ribavirin</td>
<td>12 weeks</td>
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<tr>
<td>Failed prior treatment with sofosbuvir and ribavirin</td>
<td>12 weeks*</td>
<td>12 weeks*</td>
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<tr>
<td>Without cirrhosis</td>
<td>12 weeks</td>
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<td>With compensated cirrhosis</td>
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#### GENOTYPE 3:

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<tr>
<td>Treatment Experienced with PEG-IFN and ribavirin without cirrhosis</td>
<td>12 weeks</td>
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</tr>
<tr>
<td>Treatment Experienced with PEG-IFN and ribavirin with compensated cirrhosis</td>
<td>12 weeks*</td>
<td>12 weeks*</td>
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<tr>
<td>Failed prior treatment with sofosbuvir and ribavirin</td>
<td>12 weeks*</td>
<td>12 weeks*</td>
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<tr>
<td>Treatment experienced without cirrhosis</td>
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#### GENOTYPE 4:

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<td>Failed prior treatment with PEG-IFN and ribavirin (virologic relapse after treatment)</td>
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<td>Failed prior treatment with PEG-IFN and ribavirin (on-treatment virologic failure)</td>
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<td>Treatment experienced without cirrhosis</td>
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*indicates concomitant therapy

**CODES**

None.

**REFERENCES**


**APPROVAL HISTORY**

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Hepatitis C Medical Necessity Guidelines