Antivirals - Hepatitis C Treatment

Medical policy no. 12.35.30.99

Effective July 1, 2019

Medical necessity

<table>
<thead>
<tr>
<th>Drug</th>
<th>Medical Necessity</th>
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</table>
| Preferred  
Glecaprevir/pibrentasvir (MAVYRET) | MAVYRET is preferred and covered without authorization. |
| Non-preferred  
Daclatasvir dihydrochloride (DAKLINZA)  
Elbasvir/grazoprevir (ZEPATIER)  
Ledipsvir/sofosbuvir (HARVONI)  
Ombitasvir/paritaprevir/ritonavir (TECHNIVIE)  
Ombitas/paritapr/riton and dasab pak (VIEKIRA)  
Sofosbuvir (SOVALDI)  
Sofosbuvir/velpatasvir (EPCLUSA)  
Sofosbuvir/velpatasvir/voxilaprevir (VOSEVI) | All non-preferred antiviral products for the treatment of Hepatitis C virus (HCV) will be considered on a case-by-case basis. |

Non-preferred HCV antivirals may be considered medically necessary for the treatment of chronic HCV infection when Mavyret is not indicated and the clinical criteria listed below are met.

Requests for brand-name medications with a generic equivalent available must also meet the criteria described in the Brands with Generic Equivalents policy (Non-Clinical Policy No. 0001).

Clinical policy:

<table>
<thead>
<tr>
<th>Drug</th>
<th>Clinical Criteria (Initial Approval)</th>
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| Daclatasvir dihydrochloride (DAKLINZA)  
Elbasvir/grazoprevir (ZEPATIER)  
Glecaprevir/pibrentasvir (MAVYRET)  
Ledipsvir/sofosbuvir (HARVONI)  
Ombitasvir/paritaprevir/ritonavir (TECHNIVIE)  
Ombitas/paritapr/riton and dasab pak (VIEKIRA)  
Sofosbuvir (SOVALDI)  
Sofosbuvir/velpatasvir (EPCLUSA)  
Sofosbuvir/velpatasvir/voxilaprevir (VOSEVI) | 1. Patient has confirmed diagnosis of Hepatitis C and a quantifiable HCV RNA test >15 IU/mL within the last 12 months.  
2. Required documentation and lab tests:  
   a. HCV Genotype.  
   b. Current HCV RNA Viral Load less than 12 months old.  
   c. Fibrosis staging test (e.g. FibroScan® or FibroSURE®) to determine liver fibrosis level required to ensure the appropriate treatment regimen is used (e.g. patients with cirrhosis and/or decompensation may require longer treatment and/or ribavirin). Fibrosis staging test results must be less than 2 years old.  
   d. Documentation of decompensation (or previous episodes of decompensation) if fibrosis level is F4 or cirrhosis.  
   e. Documentation of treatment-experienced status including prior treatment regimen, length of treatment, response, and dates of treatment. |
f. Lab reports, if available, documenting presence or absence of resistant mutations in treatment-experienced patients.

3. Patients with the following conditions are not eligible for HCV treatment until the condition is resolved. Patients who:
   a. Are taking medications that are contraindicated with or that have a severe drug interaction with the prescribed HCV treatment.
   b. Are pregnant or planning on becoming pregnant.
   c. Have severe end organ disease and are not eligible for transplantation (e.g. heart, lung, kidney)
   d. Have a clinically-significant illness or any other major medical disorder that may interfere with patients’ ability to complete a course of treatment.
   e. In the professional judgment of the primary treating clinician, would not achieve a long-term clinical benefit from HCV treatment (e.g. patients with multisystem organ failure, receiving palliative care, with significant pulmonary or cardiac disease, or with malignancy outside of the liver not meeting oncologic criteria for cure).
   f. Have a MELD score <20 and one of the following:
      i. Cardiopulmonary disease that cannot be corrected and is a prohibitive risk for surgery
      ii. Malignancy outside the liver not meeting oncologic criteria for cure
      iii. Hepatocellular carcinoma with metastatic spread
      iv. Intrahepatic cholangiocarcinoma
      v. Hemangiosarcoma
      vi. Uncontrolled sepsis

**Criteria (Reauthorization)**
See treatment experienced dosing guidelines below.

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### Preferred Therapies:

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Preferred For</th>
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<tr>
<td>Glecaprevir/pibrentasvir (MAVYRET)</td>
<td>Patients with or without compensated cirrhosis (Child-Pugh A) that are:</td>
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<td>• treatment naïve patients with genotypes 1, 2, 3, 4, 5, and 6; or</td>
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<tr>
<td></td>
<td>• patients with genotypes 1, 2, 3, 4, 5, and 6 with prior treatment with</td>
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<td>peg-interferon, ribavirin, or sofosbuvir, but no prior treatment with a</td>
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<td>NSSA inhibitor or an NS3/4A protease inhibitor; or</td>
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<td>• patients with genotype 1 with prior treatment with an NSSA inhibitor but</td>
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<td>not an NS3/4A protease inhibitor; or</td>
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<td>• patients with genotype 1 with prior treatment with an NS3/4A protease</td>
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<td>inhibitor but not an NSSA inhibitor.</td>
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Sofosbuvir/velpatasvir (EPCLUSA)  
Sofosbuvir/velpatasvir/voxilaprevir (VOSEVI)  
Will be considered on a case-by-case basis when treatment with Mavyret is not indicated.

### Dosage and quantity limits

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<tr>
<th>Drug Name</th>
<th>Dose and Quantity Limits</th>
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| Glecaprevir/pibrentasvir (MAVYRET) | Treatment Naïve Genotypes 1, 2, 3, 4, 5, 6  
  - 8 weeks without cirrhosis  
  - 12 weeks with compensated cirrhosis  

  **Treatment Experienced**  
  - With peg-interferon, ribavirin, or sofosbuvir, but no prior treatment with an NS5A inhibitor or an NS3/4A protease inhibitor  
    - Genotypes 1, 2, 4, 5, 6  
      - 8 weeks without cirrhosis  
      - 12 weeks with compensated cirrhosis  
    - Genotype 3  
      - 16 weeks with or without compensated cirrhosis  
  - With an NS5A inhibitor without an NS3/4A protease inhibitor  
    - 16 weeks for Genotype 1 with or without compensated cirrhosis  
  - With an NS3/4A protease inhibitor without an NS5A inhibitor  
    - 12 weeks for Genotype 1 with or without compensated cirrhosis  

Sofosbuvir/velpatasvir (EPCLUSA)  
Sofosbuvir/velpatasvir/voxilaprevir (VOSEVI)  
Will be determined on a case-by-case basis when treatment with Mavyret is not indicated.

### References


49. Kwo P, Gitlin N, Nahass R, et al. A phase 3, randomized, open-label study to evaluate the efficacy and safety of 8 and 12 weeks fo Simeprevir (SMV) plus sofosbuvir (SOF) in treatment-naive and experienced patients with chronic HCV genotype 1 infection without cirrhosis: OPTIMIST-1. 50th Annual Meeting of the European Association for the Study of the Liver (EASL). April 22-26, 2015; S270; Vienna, Austria.
54. Bourliere M, Bronowicki J, de Ledinghen V, et al. Ledipasvir/sofosbuvir fixed dose combination is safe and efficacious in cirrhotic patients who have previously failed protease-inhibitor based triple therapy. [Abstract LB-6.] 65th annual Meeting of the American Association for the Study of Liver Diseases (AASLD). November 7-11, 2014; Boston, MA.

**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Action and Summary of Changes</th>
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<tbody>
<tr>
<td>06-07-2019</td>
<td>• Updated policy for preferred therapies and formatting.</td>
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<tr>
<td>Date</td>
<td>Updates</td>
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<tr>
<td>07-08-2019</td>
<td>• Placed in updated policy format</td>
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<tr>
<td></td>
<td>• Removed prescriber specialty requirement</td>
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<td>• Removed proof of chronic HCV infection</td>
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<td>• Added all drugs to the policy</td>
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<td>• Mavyret only preferred agent</td>
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<td>• Added treatment regimens</td>
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<tr>
<td>07-23-2019</td>
<td>Updated policy to reflect Mavyret covered without authorization</td>
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