Prior Authorization Conditions for Approval of Hepatitis C Agents

All requests for Hepatitis C Agents require a prior authorization and will be screened for medical necessity and appropriateness using the criteria listed below.

Coverage is provided for adult and pediatric members with chronic Hepatitis C Virus (HCV) Genotypes 1-6 in the following situations:

- The member is at least 12 years of age and older OR weighing at least 35kg
- The treatment regimen is being prescribed by a qualified specialist (infectious disease, gastroenterology, hepatology, transplant)
- The member has a documented diagnosis of chronic HCV and completed genotyping and meets the criteria for coverage based on HCV genotype as outlined below
- The dose and length of therapy prescribed is consistent with FDA approved labeling or peer-reviewed medical literature.
- The member has not previously had an incomplete course or treatment failure with the drug or any component of the regimen requested.
- The requested Hepatitis C Agent is a preferred product and if not, documentation by the prescriber as to why the preferred product is not appropriate.
- If the member has a history of failure with previous Hepatitis C treatment, documentation is provided that indicates the reason for failure, which may include (but is not limited to) non-compliance, safety, tolerability, or efficacy. In addition, documentation must be provided indicating that the reasons for the previous treatment failure have been addressed (e.g. re-education and review of the collaborative treatment agreement)
- For patients with Genotype 1a, documentation of NS5A resistance polymorphism testing has been submitted prior to starting treatment with Zepatier (if applicable).
- The member has documented liver biopsy or liver fibrosis panel results with a fibrosis score corresponding to Metavir F2 or greater and/or one of the following: HIV or Hepatitis B (HBV) coinfection, history of liver transplant, severe extrahepatic manifestations of Hepatitis C (i.e. type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations such as vasculitis; nephrotic syndrome, or membranoproliferative glomerulonephritis) otherwise demonstrating advanced liver fibrosis deeming treatment medically necessary per the terms below.
- Notwithstanding fibrosis score, treatment shall be covered upon a showing of medical necessity, which may include documentation of:
  o Extrahepatic symptoms that affect ADLs including but not limited to: fatigue, nausea, mental changes, joint pain, depression, sore muscles, arthritis, nerve damage and jaundice
  OR
  o Diagnosis of at least one (1) of the following co-morbidities:
    o HIV+
    o Hepatitis B infection
    o Lymphoma
    o Awaiting or post solid organ transplant (e.g. heart, kidney, liver)
    o Documentation of labs or biopsy showing fast progressing fibrosis that would require treatment earlier than the approved fibrosis stage
  OR
    o Other showing of medical necessity the prescriber is linking to Hepatitis C and is supported with appropriate physician documentation.
- If the member is actively abusing alcohol or IV drugs, or has a history of abuse, there is documentation of prescriber counseling regarding the risks of alcohol or IV drug abuse and an offer of referral for substance
abuse disorder treatment and case management.

- For regimens containing sofosbuvir, the member does not have renal impairment or end stage renal disease (GFR <30 mL/min/1.73m²)
- The member has committed in writing to the treatment agreement, acknowledging and agreeing to the planned treatment course, adherence to the planned medication regimen, on-time refills, and anticipated blood tests and office visits, both during and after treatment
- The member’s HCV RNA levels prior to treatment (within the past 3 months), their treatment status (naïve or experienced), the planned treatment regimen, the planned start date and documentation of a viral load two weeks after treatment is initiated to demonstrated drug utilization will be documented
- The member will be obtaining the medication from a qualified specialty pharmacy. Clients with co-morbid HIV must have undetectable HIV viral load or a CD4 count of at least 350 cells/µL. Coverage will be provided as long as the member satisfies the criteria for HCV mono-infected patients (based on genotype).
- In all situations where coverage is approved, authorizations will be provided for the length of their approved treatment duration.

Approval of a non-preferred agent requires

- A documented failure or contraindication to an alternative preferred regimen.
  - If the client has failed prior therapy, then documentation of the reason for failure is required. Simple noncompliance with previous therapy may be considered a contraindication to retreatment.
  - If a preferred regimen is contraindicated due to a comorbid condition, then documentation of the other condition is required.
- Documentation of an imminent need to initiate therapy such as cirrhosis or a pending liver transplant.
  - Cirrhosis can be documented based on a liver biopsy, or by other objective laboratory test demonstrating liver fibrosis corresponding to Metavir score of 2.
  - Alternatively, cirrhosis can be documented by a combination of an ultrasound or CT scan along with extrahepatic manifestations or clinical findings such as the presence of ascites.

- Follow the FDA approved labeling and guideline supported treatment regimen chart for adult HCV preferred coverage of genotypes 1-6 and unique patient populations.

<table>
<thead>
<tr>
<th>HCV Genotype</th>
<th>Specific Patient Population</th>
<th>Treatment Regimen</th>
<th>Treatment Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1,2,3,4,5 or 6</td>
<td>Treatment-naïve with no cirrhosis</td>
<td>Mavyret</td>
<td>8 weeks</td>
</tr>
<tr>
<td>1,2,3,4,5 or 6</td>
<td>Treatment-naïve with compensated cirrhosis (Child Pugh A)</td>
<td>Mavyret</td>
<td>12 weeks</td>
</tr>
<tr>
<td>1,2,4,5 or 6</td>
<td>Treatment-experienced with regimens containing interferon, pegylated interferon, ribavirin and/or sofosbuvir but no prior treatment with an HCV NS3/4A PI or NS5A inhibitor with no cirrhosis</td>
<td>Mavyret</td>
<td>8 weeks</td>
</tr>
<tr>
<td>1,2,4,5 or 6</td>
<td>Treatment-experienced with regimens containing interferon, pegylated interferon, ribavirin and/or sofosbuvir but no prior treatment with an HCV NS3/4A PI or NS5A inhibitor with compensated cirrhosis (Child Pugh A)</td>
<td>Mavyret</td>
<td>12 weeks</td>
</tr>
<tr>
<td>1</td>
<td>Treatment-experienced with an NS5A inhibitor without prior treatment with an NS3/4A protease inhibitor and with or without compensated cirrhosis (Child Pugh A)</td>
<td>Mavyret</td>
<td>16 weeks</td>
</tr>
</tbody>
</table>
### Table: HCV Genotype, Specific Patient Population, Treatment Regimen, and Treatment Duration

<table>
<thead>
<tr>
<th>HCV Genotype</th>
<th>Specific Patient Population</th>
<th>Treatment Regimen</th>
<th>Treatment Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A)</td>
<td>Harvoni</td>
<td>12 weeks</td>
</tr>
<tr>
<td>1</td>
<td>Treatment-experienced** without cirrhosis</td>
<td>Harvoni</td>
<td>12 weeks</td>
</tr>
<tr>
<td>1</td>
<td>Treatment-experienced ** with compensated cirrhosis (Child-Pugh A)</td>
<td>Harvoni</td>
<td>24 weeks</td>
</tr>
<tr>
<td>2</td>
<td>Treatment-naïve and treatment-experienced** without cirrhosis or with compensated cirrhosis (Child-Pugh A)</td>
<td>Sovaldi + ribavirin</td>
<td>12 weeks</td>
</tr>
<tr>
<td>3</td>
<td>Treatment-naïve and treatment-experienced** without cirrhosis or with compensated cirrhosis (Child-Pugh A)</td>
<td>Sovaldi + ribavirin</td>
<td>24 weeks</td>
</tr>
<tr>
<td>4,5 or 6</td>
<td>Treatment-naïve and treatment-experienced**, without cirrhosis or with compensated cirrhosis (Child-Pugh A)</td>
<td>Harvoni</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

** Treatment-experienced patients have failed an interferon based regimen with or without ribavirin.

### Table: Recommended Dosing for Ribavirin in Combination Therapy with Sovaldi for Pediatric Patients 12 Years of Age and Older or Weighing at least 35kg

<table>
<thead>
<tr>
<th>Body Weight (kg)</th>
<th>Ribavirin Daily dosage*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Less than 47</td>
<td>15mg/kg/day</td>
</tr>
<tr>
<td>47-49</td>
<td>600mg/day</td>
</tr>
<tr>
<td>50-65</td>
<td>800mg/day</td>
</tr>
<tr>
<td>66-80</td>
<td>1000mg/day</td>
</tr>
<tr>
<td>Greater than 80</td>
<td>1200mg/day</td>
</tr>
</tbody>
</table>

*The daily dosage of ribavirin is weight-based and is administered orally in two divided doses with food.

### Points to Note:
- Follow the FDA approved treatment regimen chart for pediatric HCV coverage of genotypes 1-6.
- For the treatment of HCV in members post-transplantation or with hepatocellular carcinoma with or without compensated cirrhosis awaiting liver transplantation, coverage is provided in the following situations:
- If the member fulfills MILAN criteria for liver transplantation **AND**
- Sovaldi and Daklinza is prescribed in combination with low initial dose of ribavirin for 12 weeks.
**Hepatitis C Agents – INITIAL AUTHORIZATION ONLY**

**PRIOR AUTHORIZATION FORM**

Please complete and **fax all requested information below including any progress notes, laboratory test results, or chart documentation as applicable** to Health Options Pharmacy Services.

**FAX:** 1-855-476-4158

If needed, you may call to speak to a Pharmacy Services Representative.

**PHONE:** 1-844-325-6251  Monday through Friday 8:30am to 5:00pm

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### PROVIDER INFORMATION

- **Requesting Physician:**
- **NPI:**
- **Physician Specialty:**
- **Office Contact:**
- **Office Address:**
- **Office Phone:**
- **Office Fax:**

### MEMBER INFORMATION

- **Patient Name:**
- **DOB:**
- **Health Options ID:**
- **Weight (kg):**

### REQUESTED DRUG INFORMATION

- **Medication:**
- **Strength:**
- **Frequency:**
- **Duration:**
- **Planned HCV Treatment Regimen:**

### MEDICAL HISTORY

- **Diagnosis:**
- **Hepatitis C Virus**
- **Other:**
- **HCV Genotype:**
- **Hepatitis C Viral Load:**
- **Has the patient had a liver biopsy or liver fibrosis panel?**
- **Yes**
- **No**
- **If Yes, please list METAVIR Score**

- **Does the patient have hepatocellular carcinoma and awaiting liver transplant?**
- **Yes**
- **No**

- **What is the patient’s HCV treatment status?**
- **Treatment-Naïve**
- **Treatment-experienced**

- **If the patient is treatment-experienced, please list the previous treatment regimens used and the reasons for failure:**

- **Is the patient co-infected with HIV?**
- **Yes**
- **No**

- **If yes, please list CD4 Cell Count**

- **Does the patient have a known substance or alcohol abuse diagnosis or is actively abusing alcohol or IV drugs?**
- **Yes**
- **No**

- **If YES, has the patient been counseled by the prescriber regarding the risks of alcohol or IV drug abuse and been offered a referral for substance use disorder treatment?**
- **Yes**
- **No**

- **What is the start date of the patient’s HCV Treatment Regimen?**

### SUPPORTING INFORMATION or CLINICAL RATIONALE

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<table>
<thead>
<tr>
<th>Prescribing Physician Signature</th>
<th>Date</th>
</tr>
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Hepatitis C Agents – REAUTHORIZATION ONLY

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<td>Frequency:</td>
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</table>

MEDICAL HISTORY

What treatment regimen is the patient taking?

- Mavyret x 8 weeks
- Mavyret x 12 weeks
- Mavyret x 16 weeks
- Epclusa in combination with Ribavirin x 12 weeks
- Harvoni x 12 weeks (pediatric members only)
- Harvoni x 24 weeks (pediatric members only)
- Sovaldi in combination with Ribavirin x 12 weeks (pediatric members only)
- Sovaldi in combination with Ribavirin x 24 weeks (pediatric members only)
- Hepatocellular carcinoma awaiting liver transplant – Sovaldi and Daklinza in combination with Ribavirin for 12 weeks

What date did the patient begin treatment with the indicated regimen?

<table>
<thead>
<tr>
<th>Re-Authorization</th>
<th>Date of Last Office Visit or Patient Contact</th>
<th>Has the patient been adherent to the prescribed treatment regimen? (Please provide supporting information)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Re-Authorization #1 (Weeks 5-8)</td>
<td></td>
<td>[ ] Yes [ ] No</td>
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<tr>
<td>Re-Authorization #2 (Weeks 9-12)</td>
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<td>[ ] Yes [ ] No</td>
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<tr>
<td>Re-Authorization #3 (Weeks 13-16)</td>
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<td>Re-Authorization #4 (Weeks 17-20)</td>
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<td>[ ] Yes [ ] No</td>
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<tr>
<td>Re-Authorization #5 (Weeks 21-24)</td>
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<td>[ ] Yes [ ] No</td>
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<tr>
<td>Re-Authorization #6 (Weeks 25-28)</td>
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<td>[ ] Yes [ ] No</td>
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<tr>
<td>Re-Authorization #7 (Weeks 29-32)</td>
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<td>[ ] Yes [ ] No</td>
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<tr>
<td>Re-Authorization #8 (Weeks 33-36)</td>
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<td>[ ] Yes [ ] No</td>
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<tr>
<td>Re-Authorization #9 (Weeks 37-40)</td>
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<td>[ ] Yes [ ] No</td>
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<td>Re-Authorization #10 (Weeks 41-44)</td>
<td></td>
<td>[ ] Yes [ ] No</td>
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<tr>
<td>Re-Authorization #11 (Weeks 45-48)</td>
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