Pharmacy Medical Policy
Hepatitis C Medication Management

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Policy Number: 344
BCBSA Reference Number: N.A.

Prior Authorization Information
☒ Prior Authorization
☐ Step Therapy
☐ Quality Care Dosing

Policy Effective Date 7/1/2023

Policy applies to Commercial Members:
• Managed Care (HMO and POS),
• PPO and Indemnity
• MEDEX with Rx plan
• Managed Major Medical with Custom BCBSMA Formulary
• Comprehensive Managed Major Medical with Custom BCBSMA Formulary
• Managed Blue for Seniors with Custom BCBSMA Formulary

Policy does NOT apply to:
• Medicare Advantage

To request for coverage: Physicians may call, fax, or mail the attached form (Massachusetts Hep C Form for Medication Prior Authorization Requests) to the address below.

Blue Cross Blue Shield of Massachusetts
Pharmacy Operations Department
25 Technology Place
Hingham, MA 02043
Tel: 1-800-366-7778
Fax: 1-800-583-6289

Individual Consideration: Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration
**Summary**

Hepatitis C is a viral disease that causes inflammation of the liver that can lead to diminished liver function or liver failure. Most people infected with hepatitis C virus (HCV) have no symptoms of the disease until liver damage becomes apparent, which may take several years. Some people with chronic HCV infection develop scarring and poor liver function (cirrhosis) over many years, which can lead to complications such as bleeding, jaundice (yellowish eyes or skin), fluid accumulation in the abdomen, infections, or liver cancer. 21

**Policy**

**Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity**

Note: All requests for outpatient retail pharmacy for indications listed and not listed on the medical policy guidelines may be submitted to BCBSMA Clinical Pharmacy Operations by completing the Prior Authorization Form on the last page of this document. Physicians may also call BCBSMA Pharmacy Operations department at (800)366-7778 to request a prior authorization/formulary exception verbally. Patients must have pharmacy benefits under their subscriber certificates.

Non formulary medications are covered when a formulary exception request is submitted to BCBSMA Pharmacy Operations and criteria below are met.

<table>
<thead>
<tr>
<th>Drug</th>
<th>Formulary Information</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Harvoni™</strong> (ledipasvir / sofosbuvir)</td>
<td>PA Required</td>
</tr>
<tr>
<td><strong>Epclusa®</strong> (velpatasvir / sofosbuvir)</td>
<td>PA Required</td>
</tr>
<tr>
<td><strong>Ledipasvir/sofosbuvir</strong> (Authorized Harvoni Generic)</td>
<td>Not Covered</td>
</tr>
<tr>
<td><strong>Mavret™</strong> (glecaprevir and pibrentasvir)</td>
<td>Not Covered</td>
</tr>
<tr>
<td><strong>Sofosbuvir/velpatasvir</strong> (Authorized Epclusa Generic)</td>
<td>Not Covered</td>
</tr>
<tr>
<td><strong>Sovaldi™</strong> (sofosbuvir)</td>
<td>Not Covered</td>
</tr>
<tr>
<td><strong>Vosevi™</strong> (sofosbuvir/velpatasvir/voxilaprevir)</td>
<td>PA Required</td>
</tr>
<tr>
<td><strong>Zepatier™</strong> (elbasvir and grazoprevir)</td>
<td>Not Covered</td>
</tr>
</tbody>
</table>

Prerequisite clinical and other information required to be provided on Prior Authorization Form for all drugs to treat hepatitis C:
- Viral genotype and subtype;
- Cirrhosis status;
- Prior treatment for hepatitis C.
- Viral Load

**Epclusa®**

*We may cover Epclusa® for the treatment of Hepatitis C when all of the following criteria are met:*
- Documented diagnosis of Hepatitis C Genotype 1, 2, 3, 4, 5, or 6 infection
- Children and Adult aged 3 and over or weighing at least 17 kg (over 37 pounds)

*If above criteria are met, approval timeframes will be given according to the following criteria:*
- Patients without cirrhosis and patients with compensated cirrhosis:
  - Approval given for up to 12 weeks of therapy
• Patients with decompensated cirrhosis:
  o Administered in combination with ribavirin, and
  o Approval given for up to 12 weeks of therapy.

**Harvoni™:**
We may cover **Harvoni™** for the treatment of Hepatitis C when all of the following criteria are met:
• Documented diagnosis of Hepatitis C Genotype 1, 4, 5, or 6 infection
• Patients aged 3 (Harvoni™ pellets) and over

If above criteria are met, approval timeframes will be given according to the following criteria:
• Patients who are treatment naïve with cirrhosis or treatment experienced without cirrhosis:
  o Approval given for up to 12 weeks of therapy
• Patients who are treatment naïve without cirrhosis
  o Approval given for up to 8 weeks of therapy
• Patients who are treatment experienced* with cirrhosis:
  o Approval given for up to 24 weeks of therapy.

*Treatment experienced is defined as patients who have failed treatment with either a regimen of peginterferon alfa and ribavirin or a regimen of an HCV protease inhibitor and peginterferon alfa and ribavirin

We may cover **Ledipasvir/sofosbuvir** (Authorized Harvoni Generic) for the treatment of Chronic Hepatitis C in adults when all of the following criteria are met:
• Documented diagnosis of Chronic Hepatitis C Genotype 1,4,5 or 6, and
• Adult aged 3 and over, and
• Previous treatment with or contraindication to Harvoni™ and Epclusa®

If above criteria are met, approval timeframes will be given according to the following criteria:
• Patients who are treatment naïve with cirrhosis or treatment experienced without cirrhosis:
  o Approval given for up to 12 weeks of therapy
• Patients who are treatment naïve without cirrhosis
  o Approval given for up to 8 weeks of therapy
• Patients who are treatment experienced* with cirrhosis:
  o Approval given for up to 24 weeks of therapy.

We may cover **Mavyret™** for the treatment of Chronic Hepatitis C in adults when all of the following criteria are met:
• Documented diagnosis of Chronic Hepatitis C Genotype 1,2,3,4,5 or 6, and
• Adults and those aged 12 and over, and
• For Genotype 1 or 4, 5 & 6: Previous treatment with or contraindication to Harvoni™ and Epclusa® OR
  • For Genotype 2 or 3: Previous treatment with or contraindication to Epclusa®

If above criteria are met, approval will be given for Mavyret™ for up to 16 weeks of therapy.

We may cover **Sofosbuvir/velpatasvir** (Authorized Epclusa Generic) for the treatment of Chronic Hepatitis C in adults when all of the following criteria are met:
• Documented diagnosis of Chronic Hepatitis C Genotype 1,2,3,4,5 or 6, and
• Patients aged 3 and over or weighing at least 17 kg (over 37 pounds), and
• Previous treatment with or contraindication to Harvoni™ and Epclusa®

If above criteria are met, approval timeframes will be given according to the following criteria:
• Patients without cirrhosis and patients with compensated cirrhosis:
o Approval given for up to 12 weeks of therapy

Patients with decompensated cirrhosis:

o Administered in combination with ribavirin, and

o Approval given for up to 12 weeks of therapy.

We may cover Sovaldi™ for the treatment of Chronic Hepatitis C in Patients aged 3 (Sovaldi ™ pellets) or older including those with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection when all of the following criteria are met:

- Documented diagnosis of Chronic Hepatitis C Genotype 2, 3 or 4 and administered in combination with ribavirin or in combination with pegylated interferon and ribavirin, and
- Sovaldi™ is not used as monotherapy; and
- For Genotype 1 or 4: Previous treatment with or contraindication to Harvoni™ and Epclusa® OR
- For Genotype 2 or 3: Previous treatment with or contraindication to Epclusa®

If above criteria are met, approval will be given for Sovaldi™ as follows:

<table>
<thead>
<tr>
<th>HCV Mono-infected and HCV/HIV-1 Co-infected</th>
<th>Treatment</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Genotype 1 or 4</td>
<td>Sovaldi™ + peg-interferon alfa + ribavirin</td>
<td>Up to 12 weeks</td>
</tr>
<tr>
<td>Genotype 2</td>
<td>Sovaldi™ + ribavirin</td>
<td>Up to 12 weeks</td>
</tr>
<tr>
<td>Genotype 3</td>
<td>Sovaldi™ + ribavirin</td>
<td>Up to 24 weeks</td>
</tr>
<tr>
<td>All Genotypes (Hepatocellular carcinoma awaiting liver transplantation)</td>
<td>Sovaldi™ + ribavirin</td>
<td>Up to 48 weeks or until liver transplant whichever soonest</td>
</tr>
</tbody>
</table>

We do not cover the above drugs for other conditions not listed above.

Vosevi™

We may cover Vosevi™ for the treatment of adult patients with chronic hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis (Child-Pugh A) when all of the following criteria are met:

- genotype 1, 2, 3, 4, 5, or 6 infection, AND
- have previously been treated with an HCV regimen containing an NS5A inhibitor (Harvoni, Epclusa & Zepatier)

OR

- genotype 1a or 3 infection, AND
- have previously been treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor. (Sovaldi)

If above criteria are met, approval will be given for Vosevi™ for up to 12 weeks of therapy.

We may cover Zepatier™ for the treatment of Chronic Hepatitis C in adults when all of the following criteria are met:

- Documented diagnosis of Chronic Hepatitis C Genotype 1 or 4 and
- Previous treatment with or contraindication to Harvoni™ and Epclusa®

If above criteria are met, approval will be given for Zepatier™ as follows:

<table>
<thead>
<tr>
<th>Patient Population</th>
<th>Treatment</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Other Information

Blue Cross Blue Shield of Massachusetts (BCBSMA*) members (other than Medex®; Blue MedicareRx, Medicare Advantage plans that include prescription drug coverage) will be required to fill their prescriptions for the above medications at one of the providers in our retail specialty pharmacy network, see link below:

[Link to Specialty Pharmacy List](#)

### Individual Consideration

All our medical policies are written for the majority of people with a given condition. Each policy is based on medical science. For many of our medical policies, each individual’s unique clinical circumstances may be considered in light of current scientific literature. Physicians may send relevant clinical information for individual patients for consideration to:

Blue Cross Blue Shield of Massachusetts  
Clinical Pharmacy Department  
25 Technology Place  
Hingham, MA 02043  
Tel: 1-800-366-7778  
Fax: 1-800-583-6289

### Prior Authorization Information

#### Outpatient

For services described in this policy, see below for products where prior authorization **IS REQUIRED** if the procedure is performed **outpatient**.

<table>
<thead>
<tr>
<th></th>
<th>Outpatient</th>
</tr>
</thead>
<tbody>
<tr>
<td>Commercial Managed Care (HMO and POS)</td>
<td>Prior authorization is required.</td>
</tr>
<tr>
<td>Commercial PPO and Indemnity</td>
<td>Prior authorization is required.</td>
</tr>
</tbody>
</table>
CPT Codes / HCPCS Codes / ICD-9 Codes
The following codes are included below for informational purposes. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member’s contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

CPT Codes
There is no specific CPT code for this service.

Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>7/2023</td>
<td>Reformatted Policy.</td>
</tr>
<tr>
<td>8/2022</td>
<td>Updated to remove Daklinza, Olysio, Technivie, &amp; Viekira as they were discontinued from the market.</td>
</tr>
<tr>
<td>6/2021</td>
<td>Clarified coding and updated age for Epclusa™.</td>
</tr>
<tr>
<td>6/2020</td>
<td>Updated to include age change for Epclusa™.</td>
</tr>
<tr>
<td>2/2020</td>
<td>Updated to remove specialist prescriber required criteria.</td>
</tr>
<tr>
<td>11/2019</td>
<td>Updated to add Age updates for Harvoni™ and Sovaldi™.</td>
</tr>
<tr>
<td>7/2019</td>
<td>Updated age for 12 and older for Mavryet.</td>
</tr>
<tr>
<td>2/2019</td>
<td>Updated to include at not covered the Authorized generics of Harvoni and Epclusa.</td>
</tr>
<tr>
<td>1/2018</td>
<td>Updated to include Mavyret as non-preferred.</td>
</tr>
<tr>
<td>11/2017</td>
<td>Updated to include Vosevi™ as part of the policy plus update Walgreens Specialty and added the Mass Standard PA form.</td>
</tr>
<tr>
<td>7/2017</td>
<td>Updated criteria for age change in Sovaldi™ and Harvoni® plus added AllCare to Specialty Pharmacy list.</td>
</tr>
<tr>
<td>6/2017</td>
<td>Updated Pharmacy Ops address.</td>
</tr>
<tr>
<td>1/1/2017</td>
<td>Updated to include Epclusa® and Viekira XR™.</td>
</tr>
<tr>
<td>6/2016</td>
<td>Updated to add Zepatier™ and Remove Victrelis™.</td>
</tr>
<tr>
<td>4/2016</td>
<td>Updated to include new Harvoni® indications and add Daklinza™ &amp; Technivie™.</td>
</tr>
<tr>
<td>7/2015</td>
<td>Added Genotype 1 to Sovaldi™ table.</td>
</tr>
<tr>
<td>2/2015</td>
<td>Updated to include Harvoni® and Viekira Pak™ and criteria.</td>
</tr>
<tr>
<td>1/2015</td>
<td>Updated to remove Pegylated Interferons requiring PA and changes to Olysio.</td>
</tr>
<tr>
<td>7/2014</td>
<td>Updated to include ICD-10 and added Sovaldi™ and Olysio™.</td>
</tr>
<tr>
<td>2/2014</td>
<td>Updated Onco360 name and removed Curascript in Specialty Pharmacy section.</td>
</tr>
<tr>
<td>1/2014</td>
<td>Updated to remove Blue Value.</td>
</tr>
<tr>
<td>1/2013</td>
<td>Updated coverage criteria for Peglntron® to require previous treatment failure with Pegasys®.</td>
</tr>
<tr>
<td>8/2012</td>
<td>Updated to include Pegasys® ProClick™.</td>
</tr>
<tr>
<td>1/1/2012</td>
<td>New policy, effective 1/1/2012, describing covered and non-covered indications.</td>
</tr>
</tbody>
</table>

References

Endnotes
Massachusetts Standard Form for HEP C Prior Authorization Requests (eForm)

Browser information:

If NOT logged into Provider Central use this link:

Massachusetts Standard Form for Hep C Medications Prior Authorization Requests eForm

(Can also be found on Provider Central at Forms > Authorization – Pharmacy)

If logged into Provider Central use this link:

Provider Central Link to Pharmacy Forms

(Also found on Provider Central by clicking Forms on the top of the page, then choose Authorization – Pharmacy)

Tips for using this eForm:

- Fill out completely and submit it. You won't be able to start the form and save it for later.
- You can attach documents to support your request. Please have them ready.
- You'll be able to print a copy for your patient's medical record at the end.