Pharmacy Medical Policy
Hepatitis C Medication Management

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

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. Physicians may also submit requests for retail pharmacy exceptions via the web using Express PAth which can be found on the BCBSMA provider website or directly on the web at https://provider.express-path.com. 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></td>
<td>Standard</td>
</tr>
<tr>
<td></td>
<td>Formulary Status</td>
</tr>
<tr>
<td>Harvoni™ (ledipasvir / sofosbuvir)</td>
<td>PA Required</td>
</tr>
<tr>
<td>Daklinza™ (daclatasvir)</td>
<td>Not Covered</td>
</tr>
<tr>
<td>Epclusa® (velpatasvir / sofosbuvir)</td>
<td>PA Required</td>
</tr>
<tr>
<td>Mavyret™ (glecaprevir and pibrentasvir)</td>
<td>Not Covered</td>
</tr>
<tr>
<td>Olysio™ (simeprevir)</td>
<td>Not Covered</td>
</tr>
<tr>
<td>Sovaldi™ (sofosbuvir)</td>
<td>Not Covered</td>
</tr>
<tr>
<td>Technivie™ (ombitasvir / paritaprevir / ritonavir)</td>
<td>Not Covered</td>
</tr>
<tr>
<td>Viekira Pak™ (dasabuvir/ombitasvir/paritaprevir/ritonavir)</td>
<td>Not Covered</td>
</tr>
<tr>
<td>Viekira XR™ (dasabuvir/ombitasvir/paritaprevir/ritonavir)</td>
<td>Not Covered</td>
</tr>
<tr>
<td>Vosevi™ (sofosbuvir/velpatasvir/voxilaprevir)</td>
<td>PA Required</td>
</tr>
</tbody>
</table>
Zepatier™ (elbasvir and grazoprevir) | Not Covered

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 diagnosed;
- Prior treatment for hepatitis C.
- Viral Load

Daklinza™:
*We may cover Daklinza™ 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 3, and
- Administered in combination with sofosbuvir, and
- Daklinza™ is not used as monotherapy, and
- For Genotype 1: Previous treatment with or contraindication to Harvoni™ and Epclusa®, OR
- For Genotype 3: Previous treatment with or contraindication to Epclusa®

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

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
- Adult aged 18 and over
- Must be prescribed by board certified or eligible hepatologist, infectious disease specialists or gastroenterologist.
- Previous treatment with or contraindication to Harvoni™ if Genotype 1, 4, 5, or 6.

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:
  - Administered in combination with ribavirin, and
  - 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 12 and over
- Must be prescribed by board certified or eligible hepatologist, infectious disease specialists or gastroenterologist.

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:
  - Approval given for up to 12 weeks of therapy
- Patients who are treatment naïve without cirrhosis
  - Approval given for up to 8 weeks of therapy
- Patients who are treatment experienced* with cirrhosis:
  - 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 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
- Adult aged 18 and over, and
- Previous treatment with or contraindication to Harvoni™and Epclusa®,
- Must be prescribed by board certified or eligible hepatologist, infectious disease specialists or gastroenterologist.

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

We may cover Olysio™ 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
- Patient screened for and the absence of the NS3 Q80K polymorphism.
- Administered in combination with peginterferon alfa and ribavirin, and
- Previous treatment with or contraindication to Harvoni™and Epclusa®, And
- Olysio™ is not used as monotherapy

If above criteria are met, approval will be given for Olysio™ for up to 24 weeks of therapy.

We may cover Sovaldi™ for the treatment of Chronic Hepatitis C in Patients aged 12 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 soonerest</td>
</tr>
</tbody>
</table>

Olysio™ (simeprevir) will be considered in combination with Sovaldi™ (sofosbuvir) according to FDA (November 2014 FDA approval) approved usage for up to 24 weeks of combination therapy. We do not cover the above drugs for other conditions not listed above.

Technivie™:
We may cover Technivie™ for the treatment of Chronic Hepatitis C in adults when all of the following criteria are met:
- Documented diagnosis of Chronic Hepatitis C Genotype 4, and
- Administered in combination with ribavirin, and
- Previous treatment with or contraindication to Harvoni™and Epclusa®, and
- Technivie™ is not used as monotherapy
If above criteria are met, approval will be given for Technivie™ for up to 12 weeks of therapy.

**Viekira Pak™:**
We may cover Viekira Pak™ (with or without ribavirin) for the treatment of Hepatitis C when all of the following criteria are met:
- Documented diagnosis of Hepatitis C Genotype 1 including those with compensated cirrhosis
- Adult aged 18 and over
- Previous treatment with or contraindication to Harvoni™ and Epclusa®
- Must be prescribed by board certified or eligible hepatologist, infectious disease specialists or gastroenterologist.

We do not cover Viekira Pak™ for patients with decompensated cirrhosis.

*If above criteria are met, approval timeframes will be given according to the following criteria:*
- Patients with Genotype 1a without cirrhosis with concomitant ribavirin
  - Approval given for up to 12 weeks of therapy
- Patients with Genotype 1a with cirrhosis with concomitant ribavirin
  - Approval given for up to 24 weeks of therapy
- Patients with Genotype 1b without cirrhosis
  - Approval given for up to 12 weeks of therapy
- Patients with Genotype 1b with cirrhosis with concomitant ribavirin
  - Approval given for up to 12 weeks of therapy
- Patients with unknown Genotype 1 subtype or mixed infection Genotype 1 without cirrhosis with concomitant ribavirin
  - Approval given for up to 12 weeks of therapy
- Patients with unknown Genotype 1 subtype or mixed infection Genotype 1 with cirrhosis with concomitant ribavirin
  - Approval given for up to 24 weeks of therapy
- Patients with Genotype 1 with liver transplant, Metavir fibrosis score ≤ 2 with concomitant ribavirin
  - Approval given for up to 24 weeks of therapy

**Viekira XR™:**
We may cover Viekira XR™ (with or without ribavirin) for the treatment of Hepatitis C when all of the following criteria are met:
- Documented diagnosis of Hepatitis C Genotype 1 including those with compensated cirrhosis
- Adult aged 18 and over
- Previous treatment with or contraindication to Harvoni™ and Epclusa®
- Must be prescribed by board certified or eligible hepatologist, infectious disease specialists or gastroenterologist.

We do not cover Viekira XR™ for patients with decompensated cirrhosis.

*If above criteria are met, approval timeframes will be given according to the following criteria:*
- Patients with Genotype 1a without cirrhosis with concomitant ribavirin
  - Approval given for up to 12 weeks of therapy
- Patients with Genotype 1a with compensated cirrhosis with concomitant ribavirin
  - Approval given for up to 24 weeks of therapy
- Patients with Genotype 1b with or without compensated cirrhosis
  - Approval given for up to 12 weeks of therapy

**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, Daklinza, Technivie, Viekira Pak, Viekira XR, & Zepatier)
OR

- genotype 1a or 3 infection

AND

- have previously been treated with an HCV regimen containing sofosbuvir without an NS5A
  inhibitor. (Sovaldi)

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>Genotype 1a:</td>
<td>ZEPATIER</td>
<td>Up to 12 weeks</td>
</tr>
<tr>
<td>Treatment-naïve or</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PegIFN/RBVexperienced* without baseline NS5A polymorphisms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genotype 1a:</td>
<td>ZEPATIER + ribavirin</td>
<td>Up to 16 weeks</td>
</tr>
<tr>
<td>Treatment-naïve or</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PegIFN/RBVexperienced* with baseline NS5A polymorphisms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genotype 1b:</td>
<td>ZEPATIER</td>
<td>Up to 12 weeks</td>
</tr>
<tr>
<td>Treatment-naïve or</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PegIFN/RBVexperienced</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genotype 1a or 1b:</td>
<td>ZEPATIER + ribavirin</td>
<td>Up to 12 weeks</td>
</tr>
<tr>
<td>PegIFN/RBV/PI-experienced</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genotype 4:</td>
<td>ZEPATIER</td>
<td>Up to 12 weeks</td>
</tr>
<tr>
<td>Treatment-naïve</td>
<td></td>
<td></td>
</tr>
<tr>
<td>PegIFN/RBV-experienced</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Genotype 4:</td>
<td>ZEPATIER + ribavirin</td>
<td>Up to 16 weeks</td>
</tr>
<tr>
<td>PegIFN/RBV-experienced</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
Managed Care Authorization Instructions
- Prior authorization is required for all outpatient sites of service.
- For retail pharmacy requests, physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients.
  
  Pharmacy Operations: (800)366-7778
- For all outpatient sites of service, physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients.
- For all outpatient sites of service, physicians may also submit requests for retail pharmacy exceptions via the web using Express PAth which can be found on the BCBSMA provider website or directly on the web at https://provider.express-path.com

PPO and Indemnity Authorization Instructions
- Prior authorization is required when these medications are processed under the retail pharmacy benefit and home infusion therapy benefit.
- Prior authorization is not required when these drugs are purchased by the physician and administered in the office in accordance with this medical policy.
- For retail pharmacy requests, physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients.
  
  Pharmacy Operations: (800)366-7778
- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients.
- Physicians may also submit requests for retail pharmacy exceptions via the web using Express PAth which can be found on the BCBSMA provider website or directly on the web at https://provider.express-path.com

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>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 SovaldiTM 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 Eclusa® and Viekira XR™</td>
</tr>
<tr>
<td>6/2016</td>
<td>Updated to add Zepateri™ 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>Date</td>
<td>Description</td>
</tr>
<tr>
<td>------------</td>
<td>-------------------------------------------------------------------------------------------------</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 PegIntron® 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:

- Use **Internet Explorer 7, 8, 9, or Firefox**. You may not be able to see or submit the eForm if you use another browser.
- If you use **Internet Explorer 8.0**, select “No” when you see a pop-up box that says, “Stop running this script” so you can continue with your submission.

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.