MASSACHUSETTS

Blue Cross Blue Shield of Massachusetts is an Independent Licensee of the Blue Cross and Blue Shield Association

Pharmacy Medical Policy

Hepatitis C Medication Management

Table of Contents

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.

Drug	Formulary Information
	Standard
	Formulary Status
Harvoni™ (ledipasvir / sofosbuvir)	PA Required
Daklinza™ (daclatasvir)	Not Covered
Epclusa® (velpatasvir / sofosbuvir)	PA Required
Ledipasvir/sofosbuvir (Authorized Harvoni Generic**)**	Not Covered
Mavyret™ (glecaprevir and pibrentasvir)	Not Covered
Olysio™ (simeprevir)	Not Covered
Sofosbuvir/velpatasvir (Authorized Epclusa Generic**)**	Not Covered
Sovaldi™ (sofosbuvir)	Not Covered
Technivie™ (ombitasvir / paritaprevir / ritonavir)	Not Covered
Viekira Pak™ (dasabuvir/ombitasvir/paritaprevir/ritonavir)	Not Covered

Viekira XR™ (dasabuvir/ombitasvir/paritaprevir/ritonavir)	Not Covered
Vosevi™ (sofosbuvir/velpatasvir/voxilaprevir)	PA Required
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 Genotype1 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 **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 12 and over, and
- Previous treatment with or contraindication to Harvoni™ **and** Epclusa® if over 17 years of age
- *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.*

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 **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*
- 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 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.*

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:

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

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 ribavirn
    - 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:

Patient Population	Treatment	Duration

Genotype 1a: Treatment-naïve or PegIFN/RBVexperienced* without baseline NS5A polymorphisms	ZEPATIER	Up to 12 weeks
Genotype 1a: Treatment-naïve or PegIFN/RBVexperienced* with baseline NS5A polymorphisms	ZEPATIER + ribavirin	Up to 16 weeks
Genotype 1b: Treatment-naïve or PegIFN/RBVexperienced	ZEPATIER	Up to 12 weeks
Genotype 1a or 1b: PegIFN/RBV/PI-experienced	ZEPATIER + ribavirin	Up to 12 weeks
Genotype 4: Treatment-naïve	ZEPATIER	Up to 12 weeks
Genotype 4: PegIFN/RBV-experienced	ZEPATIER + ribavirin	Up to 16 weeks

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

Managed Care Authorization Instructions
- Prior authorization is required for all out patient 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

Date	Action
2/2019	Updated to include at not covered the Authorized generics of Harvoni and Epclusa.
1/2018	Updated to include Mavyret as non-preferred.
11/2017	Updated to include Vosevi™ as part of the policy plus update Walgreens Specialty and added the Mass Standard PA form.
7/2017	Updated criteria for age change in Sovaldi™ and Harvoni® plus added AllCare to Specialty Pharmacy list.
6/2017	Updated Pharmacy Ops address.
1/1/2017	Updated to include Epclusa® and Viekira XR™
6/2016	Updated to add Zepatier™ and Remove Victrelis™.
4/2016	Updated to include new Harvoni® indications and add Daklinza™ & Technivie™.
7/2015	Added Genotype 1 to Sovaldi™ table.
2/2015	Updated to include Harvoni® and Viekira Pak™ and criteria.
1/2015	Updated to remove Pegylated Interferons requiring PA and changes to Olysio.
7/2014	Updated to include ICD-10 and added Sovaldi™ and Olysio™.
2/2014	Updated Onco360 name and removed Curascript in Specialty Pharmacy section.
1/2014	Updated to remove Blue Value.
1/2013	Updated coverage criteria for PegIntron® to require previous treatment failure with Pegasys.®
8/2012	Updated to include Pegasys® ProClick™.
11/2011-4/2012	Medical policy ICD 10 remediation: Formatting, editing and coding updates. No changes to policy statements.
1/1/2012	New policy, effective 1/1/2012, describing covered and non-covered indications.

References

1. Incivek™ [package insert]. Cambridge, MA: Vertex Pharmaceuticals Incorporated; May, 2011.

2. Victrelis™ [package insert]. Whitehouse Station, NJ: Merck &Co, Inc.; May, 2011.
3. Pearlman BL, Traub N. Sustained virologic response to antiviral therapy for chronic hepatitis C virus infection: a cure and so much more. Clin Infect Dis 2011;52(7):889-900.
4. Rosen HR. Clinical practice. Chronic hepatitis C infection. N Engl J Med 2011;364(25):2429-2438.
5. Poordad F, McCone J, Jr., Bacon BR, et al. Boceprevir for untreated chronic HCV genotype 1 infection. N Engl J Med 2011;364(13):1195-1206.
6. Bacon BR, Gordon SC, Lawitz E, et al. Boceprevir for previously treated chronic HCV genotype 1 infection. N Engl J Med 2011;364(13):1207-1217.
7. Jacobson IM, McHutchison JG, Dusheiko G, et al. Telaprevir for previously untreated chronic hepatitis C virus infection. N Engl J Med 2011;364(25):2405-2416.
8. Zeuzem S, Andreone P, Pol S, et al. Telaprevir for retreatment of HCV infection. N Engl J Med 2011;364(25):2417-2428.
9. Kwo PY, Lawitz EJ, McCone J, et al. Efficacy of boceprevir, an NS3 protease inhibitor, in combination with peginterferon alfa-2b and ribavirin in treatment-naive patients with genotype 1 hepatitis C infection (SPRINT-1): an open-label, randomised, multicentre phase 2 trial. Lancet 2010;376(9742):705-716.
10. Sovaldi™ [package insert]. Foster City, CA: Gilead Sciences Incorporated; Dec, 2013.
11. Olysio™ [package insert]. Titusville, NJ: Janssen Therapeutics; Nov, 2013.
12. AASLD, IDSA, IAS–USA. Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. Accessed June 10, 2014.
13. Harvoni™ [package insert] Gilead, Forest City, CA. Accessed October 2014.
14. Viekira Pak™ [package insert] AbbVie N. Chicago IL Accessed January 2015
15. Daklinza™ [package insert] Bristol-Myers Squibb Company. Princeton, NJ Accessed January 2016
16. Technivie™ [package insert] AbbVie N. Chicago IL Accessed January 2016
17. Zepatier™ [package insert] Whitehouse Station, NJ: Merck &Co, Inc.; January 2016.
18. Epclusa® [package insert] Gilead, Forest City, CA ; June 2016
19. Viekira XR™ [package insert] AbbVie N. Chicago IL ; July 2016
20. Vosevi™ [package insert] Gilead, Forest City, CA ; July 2017

Endnotes

1. Based on BCBSA Technology Evaluation Center Specialty Pharmacy Combined Capacity (SPCC) Report #8-2011 and #9-2011 Hepatitis C Drugs Boceprevir (Victrelis™) Telaprevir (Incivek™), reviewed June 2011.

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.