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

Related Policies

- Quality Care Dosing guidelines may apply to the following medications and can be found in Medical Policy #621A.

Prior Authorization Information

Policy	☒ Prior Authorization ☐ Step Therapy ☒ Quantity Limit ☐ Administrative	Reviewing Department	**Pharmacy Operations:** Tel: 1-800-366-7778 Fax: 1-800-583-6289
		Policy Effective Date	**7/2024**
Pharmacy (Rx) or Medical (MED) benefit coverage	☒ Rx ☐ MED	**To request for coverage:** Providers may call, fax, or mail the attached form (Formulary Exception/Prior Authorization form) 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 for the atypical patient:** Policy for requests that do not meet clinical criteria of this policy, see section labeled Individual Consideration	
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			

Summary

This is a comprehensive policy covering prior authorization requirements for medications used for the treatment of Hepatitis C.

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].

Formulary status and coverage requirements for medications affected by this policy:

Drug	Formulary Status (BCBSMA Commercial Plan)	Requirement
Epclusa ® (velpatasvir / sofosbuvir)	Covered, PA, QCD	PA required. See below for criteria.
Harvoni ™ (ledipasvir / sofosbuvir)	Covered, PA, QCD	
Vosevi ™ (sofosbuvir/velpatasvir/voxilaprevir)	NFNC, PA, QCD	
Sofosbuvir/velpatasvir (Authorized Epclusa Generic)	Covered, PA, QCD	
Ledipasvir/sofosbuvir (Authorized Harvoni Generic)	Covered, PA, QCD	
Mavyret ™ (glecaprevir and pibrentasvir)	NFNC, PA, QCD	
Sovaldi ™ (sofosbuvir)	NFNC, PA, QCD	
Zepatier ™ (elbasvir and grazoprevir)	NFNC, PA, QCD	

QCD - Quality Care Dosing (quantity limits policy #621B); PA – Prior Authorization; NFNC – Non-formulary / Non-Covered

Policy

Length of Approval	Varied, see criteria for each drug below.
Formulary Status	All requests must meet the Prior Authorizations requirement and for non-covered medications, the member **must** also have had a previous treatment failure with, or contraindication to, **at least two** covered formulary alternatives when available. See section on individual consideration for more information if you require an exception to any of these criteria requirements for an atypical patient.
Member cost share consideration	A higher non-preferred cost share may be applied if an exception request is approved for coverage of a non-preferred or a non-formulary/non-covered drug.

Prior Authorization Criteria

Required Information for Prior Authorization Review

The following clinical information must be provided with the Prior Authorization request form for all drugs to treat hepatitis C:

- Viral genotype and subtype; **AND**
- Cirrhosis status; **AND**
- Prior treatment for hepatitis C; **AND**
- Viral Load.

Epclusa ®

Epclusa may be considered **MEDICALLY NECESSARY** when ALL of the following criteria is met:

1. Documented diagnosis of Chronic Hepatitis C Genotype 1, 2, 3, 4, 5, or 6; **AND**
2. Age ≥ 3 years old or weight of at least 17 kg (over 37 pounds).

If above criteria are met, approval for **Epclusa** 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.

Sofosbuvir/velpatasvir – Authorized Epclusa Generic

Sofosbuvir/velpatasvir, the authorized generic for Epclusa, may be considered **MEDICALLY NECESSARY** when ALL of the following criteria is met:

1. Documented diagnosis of Chronic Hepatitis C Genotype 1, 2, 3, 4, 5, or 6, **AND**
2. Age ≥ 3 years old or weight of at least 17 kg (over 37 pounds).

If above criteria are met, approval for **Sofosbuvir/velpatasvir** 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 ™

Harvoni may be considered **MEDICALLY NECESSARY** when ALL of the following criteria is met:

1. Documented diagnosis of Chronic Hepatitis C Genotype 1, 4, 5, or 6, **AND**
2. Age ≥ 3 years old.

If above criteria are met, approval for **Harvoni** 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.

Ledipasvir/sofosbuvir – Authorized Harvoni Generic

Ledipasvir/sofosbuvir the authorized generic for Harvoni**,** may be considered **MEDICALLY NECESSARY** when ALL of the following criteria is met:

1. Documented diagnosis of Chronic Hepatitis C Genotype 1, 4, 5, or 6, **AND**
2. Age ≥ 3 years old.

If above criteria are met, approval for **Ledipasvir/sofosbuvir** 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

Mavyret ™

Mavyret may be covered when ALL of the following criteria are met:

1. Documented diagnosis of Chronic Hepatitis C Genotype 1,2,3,4,5 or 6, **AND**
2. Age ≥ 12 years old, **AND**
3. 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 for **Mavyret** will be given for up to 16 weeks of therapy.

Sovaldi ™

Sovaldi may be considered **MEDICALLY NECESSARY** when ALL of the following criteria are met:

1. Documented diagnosis of Chronic Hepatitis C Genotype 2, 3, or 4 (including patients with hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation) and those with HCV/HIV-1 co-infection when), **AND**
2. Age ≥ 3 years old, **AND**
3. Administered in combination with ribavirin OR in combination with pegylated interferon and ribavirin, **AND**
4. 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 for **Sovaldi ™** will be given 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

Vosevi ™

Vosevi may be considered **MEDICALLY NECESSARY** when ALL of the following criteria is met:

1. Age ≥ 18 years old, **AND**
2. Previous treatment with, or contraindication to, Harvoni **AND** Epclusa, **AND**
3. Patient does not have cirrhosis or has compensated cirrhosis (Child-Pugh A), **AND either criteria 4 or 5 are met:**
4. Documented diagnosis of Chronic Hepatitis C Genotype 1, 2, 3, 4, 5, or 6, **AND**
   previously treated with an HCV regimen containing an NS5A inhibitor (ex: Harvoni, Epclusa, Zepatier); **OR**
5. Documented diagnosis of Chronic Hepatitis C Genotype 1a or 3, **AND**
   previously treated with an HCV regimen containing sofosbuvir without an NS5A inhibitor (ex: Sovaldi).

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

Zepatier ™

Zepatier ma may be considered **MEDICALLY NECESSARY** when ALL of the following criteria is met:

1. Documented diagnosis of Chronic Hepatitis C Genotype 1 or 4, **AND**
2. Age ≥ 18 years old, **AND**
3. 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.

Outpatient

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

	Outpatient
Commercial Managed Care (HMO and POS)	Prior authorization is **required**.
Commercial PPO and Indemnity	Prior authorization is **required**.

Provider Documentation Requirements

Documentation from the provider to support a reason preventing trial of formulary alternative(s) must include the name and strength of alternatives tried and failed (if alternatives were tried, including dates if available) and specifics regarding the treatment failure. Documentation to support clinical basis preventing switch to formulary alternative should also provide specifics around clinical reason.

The following clinical information must also be provided with the Prior Authorization request form for all drugs to treat hepatitis C:

- Viral genotype and subtype, **AND**

- Cirrhosis status, **AND**
- Prior treatment for hepatitis C, **AND**
- Viral Load.

Individual Consideration (For Atypical Patients)

Our medical policies are written for most people with a given condition. Each policy is based on peer reviewed clinical evidence. We also take into consideration the needs of atypical patient populations and diagnoses.

If the coverage criteria outlined is unlikely to be clinically effective for the prescribed purpose, the health care provider may request an exception to cover the requested medication based on an individual's unique clinical circumstances. This is also referred to as "individual consideration" or an "exception request."

Some reasons why you may need us to make an exception include: therapeutic contraindications; history of adverse effects; expected to be ineffective or likely to cause harm (physical, mental, or adverse reaction).

To facilitate a thorough and prompt review of an exception request, we encourage the provider to include additional supporting clinical documentation with their request. This may include:

- Clinical notes or supporting clinical statements;
- The name and strength of formulary alternatives tried and failed (if alternatives were tried) and specifics regarding the treatment failure, if applicable;
- Clinical literature from reputable peer reviewed journals;
- References from nationally recognized and approved drug compendia such as American Hospital Formulary Service® Drug Information (AHFS-DI), Lexi-Drug, Clinical Pharmacology, Micromedex or Drugdex®; and
- References from consensus documents and/or nationally sanctioned guidelines.

Providers may call, fax or mail relevant clinical information, including clinical references for individual patient consideration, to:

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

We may also use prescription claims records to establish prior use of formulary alternatives or to show if step therapy criteria has been met. We will require the provider to share additional information when prescription claims data is either not available or the medication fill history fails to establish use of preferred formulary medications or that step therapy criteria has been met.

Policy History

Date	Action
7/2024	Update to add Vosevi to NFNC and to cover ledipasvir/sofosbuvir and sofosbuvir/velpatasvir.
11/2023	Reformatted Policy.
10/2023	Reformatted Policy and updated IC to align with 118E MGL § 51A.
7/2023	Reformatted Policy.
8/2022	Updated to remove Daklinza, Olysio, Technivie, & Viekira as they were discontinued from the market.
6/2021	Clarified coding and updated age for Epclusa ™.
6/2020	Updated to include age change for Epclusa ™.

2/2020	Updated to remove specialist prescriber required criteria.
11/2019	Updated to add Age updates for Harvoni™ and Sovaldi™
7/2019	Updated age for 12 and older for Mavyret.
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.

Forms

To request prior authorization using the Massachusetts Standard Form for Medication Prior Authorization Requests (eForm), click the link below:

https://www.bluecrossma.org/medical-policies/sites/g/files/csphws2091/files/acquiadam-assets/023%20E%20Form%20medication%20prior%20auth%20instruction%20prn.pdf

OR

Print and fax, Massachusetts Standard Form for Medication Prior Authorization Requests #434

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4. Rosen HR. Clinical practice. Chronic hepatitis C infection. N Engl J Med 2011;364(25):2429-2438.
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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
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