Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines: Zepatier® (elbasvir/grazoprevir)

Effective: July 8, 2025

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Drug	Indication
Zepatier (elbasvir/grazoprevir)	• Treatment of chronic hepatitis C virus (HCV) genotype 1 or 4 infection in adult and pediatric patients 12 years of age and older or weighing at least 30 kg. Zepatier is indicated for use with ribavirin in certain patient populations.

Clinical Guideline Coverage Criteria

Zepatier (elbasvir/grazoprevir) – Genotype 1a, treatment-naïve or treatment experienced (peginterferon/ribavirin or peginterferon/ribavirin/protease inhibitor) without baseline NS5A polymorphisms

The plan may authorize coverage of Zepatier for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of chronic hepatitis C virus

AND

2. Documentation of genotype 1a

AND

3. Documentation of **one (1)** of the following:
   a. The patient is treatment-naïve
   b. Both of the following
      i. The patient has prior failure to treatment peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., Olysio)
      ii. The requested agent will be used in combination with ribavirin

AND

4. Documentation of **both** of the following:
   a. The patient has been tested for the presence of NS5A resistance-associated polymorphisms
   b. The patient is without baseline NS5A resistance-associated polymorphisms (i.e., polymorphisms at amino acid position 28, 30, 31, or 93)

AND

5. Documentation the patient does not have moderate to severe hepatic impairment (Child-Pugh Class B or C)

AND

6. Documentation the patient is not receiving the requested agent in combination with another HCV direct acting antiviral agents (e.g., Sovaldi)

AND

7. Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist

AND

8. Documentation of **one (1)** of the following:
    a. Both of the following
        i. Trial and failure or intolerance to one, or contraindication to both of the following: Brand Epclusa, Brand Harvoni
        ii. Trial and failure or intolerance to, or contraindication to the following: Mavyret
    b. The patient is new to the plan and stable on the requested medication

Approval Duration = 12 weeks

Zepatier (elbasvir/grazoprevir) – Genotype 1a, treatment-naïve or treatment experienced (peginterferon/ribavirin or peginterferon/ribavirin/protease inhibitor) with baseline NS5A polymorphisms

The plan may authorize coverage of Zepatier for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of chronic hepatitis C virus

AND

2. Documentation of genotype 1a

AND

3. Documentation of **one (1)** of the following:
    a. The patient is treatment-naïve
    b. The patient has prior failure to peginterferon alfa plus ribavirin treatment
    c. The patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., Olysio)

AND

4. Documentation of **both** of the following:
    a. The patient has been tested for the presence of NS5A resistance-associated polymorphisms
    b. The patient has baseline NS5A resistance-associated polymorphisms (i.e., polymorphisms at amino acid position 28, 30, 31, or 93)

AND

5. Documentation the requested agent will be used in combination with ribavirin

AND

6. Documentation the patient does not have moderate to severe hepatic impairment (Child-Pugh Class B or C)

AND

7. Documentation the patient is not receiving the requested agent in combination with another HCV direct acting antiviral agents (e.g., Sovaldi)

AND

8. Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist

AND

9. Documentation of **one (1)** of the following:
    a. Both of the following
        i. Trial and failure or intolerance to one, or contraindication to both of the following: Brand Epclusa, Brand Harvoni
        ii. Trial and failure or intolerance to, or contraindication to the following: Mavyret
    b. The patient is new to the plan and stable on the requested medication

Approval Duration = 16 weeks

Zepatier (elbasvir/grazoprevir) – Genotype 1b, treatment-naïve or treatment experienced (peginterferon/ribavirin or peginterferon/ribavirin/protease inhibitor)

The plan may authorize coverage of Zepatier for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of chronic hepatitis C virus

AND

2. Documentation of genotype 1b

AND

3. Documentation of **one (1)** of the following:
    a. The patient is treatment-naïve

b. The patient has prior failure to peginterferon alfa plus ribavirin treatment
c. Both of the following:
    i. The patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., Olysio)
    ii. The requested agent will be used in combination with ribavirin

AND

4. Documentation the patient does not have moderate to severe hepatic impairment (Child-Pugh Class B or C)

AND

5. Documentation the patient is not receiving the requested agent in combination with another HCV direct acting antiviral agents (e.g., Sovaldi)

AND

6. Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist

AND

7. Documentation of **one (1)** of the following:
    a. Both of the following
        i. Trial and failure or intolerance to one, or contraindication to both of the following: Brand Epclusa, Brand Harvoni
        ii. Trial and failure or intolerance to, or contraindication to the following: Mavyret
    b. The patient is new to the plan and stable on the requested medication

Approval Duration = 12 weeks

Zepatier (elbasvir/grazoprevir) – Genotype 4, treatment-naïve

The plan may authorize coverage of Zepatier for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of chronic hepatitis C virus

AND

2. Documentation of genotype 4

AND

3. Documentation the patient is treatment-naïve

AND

4. Documentation the patient does not have moderate to severe hepatic impairment (Child-Pugh Class B or C)

AND

5. Documentation the patient is not receiving the requested agent in combination with another HCV direct acting antiviral agents (e.g., Sovaldi)

AND

6. Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist

AND

7. Documentation of **one (1)** of the following:
    a. Both of the following
        i. Trial and failure or intolerance to one, or contraindication to both of the following: Brand Epclusa, Brand Harvoni
        ii. Trial and failure or intolerance to, or contraindication to the following: Mavyret
    b. The patient is new to the plan and stable on the requested medication

Approval Duration = 12 weeks

Zepatier (elbasvir/grazoprevir) – Genotype 4, treatment-experienced (peginterferon/ribavirin)

The plan may authorize coverage of Zepatier for Members when **ALL** of the following criteria are met:

1. Documented diagnosis of chronic hepatitis C virus

AND

2. Documentation of genotype 4

AND

3. Documentation the patient has prior failure to peginterferon alfa plus ribavirin treatment

AND

4. Documentation the requested agent will be in combination with ribavirin

AND

5. Documentation the patient does not have moderate to severe hepatic impairment (Child-Pugh Class B or C)

AND

6. Documentation the patient is not receiving the requested agent in combination with another HCV direct acting antiviral agents (e.g., Sovaldi)

AND

7. Prescribed by or in consultation with a hepatologist, gastroenterologist, or infectious disease specialist

AND

8. Documentation of **one (1)** of the following:
    a. Both of the following
        i. Trial and failure or intolerance to one, or contraindication to both of the following: Brand Epclusa, Brand Harvoni
        ii. Trial and failure or intolerance to, or contraindication to the following: Mavyret
    b. The patient is new to the plan and stable on the requested medication

Approval Duration = 16 weeks

Limitations

1. Zepatier will be authorized 12 or 16 weeks based on package labeling.
2. For a non-formulary medication request, please refer to the Pharmacy Medical Necessity Guidelines for Formulary Exceptions and submit a formulary exception request to the plan as indicated.

Codes

None

References

1. Zepatier (elbasvir and grazoprevir) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; May 2022.
2. AASLD-IDSA. HCV Guidance: Recommendations for testing, managing, and treating hepatitis C. http://www.hcvguidelines.org. v2025.1. Accessed: June 2025.

Approval And Revision History

September 13, 2022: Reviewed by the Pharmacy & Therapeutics Committee.

- August 8, 2023: No changes
- June 11, 2024: No changes
- July 8, 2025: No changes. (eff 7/8/2025).

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.