UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2078-11
Program	Prior Authorization/Medical Necessity
Medication	Zepatier® (elbasvir/grazoprevir)
P&T Approval Date	2/2016, 12/2016, 9/2017, 2/2019, 4/2020, 5/2021, 2/2022, 2/2023, 2/2024
Effective Date	5/1/2024

1. Background:

Zepatier® (elbasvir/grazoprevir) is a fixed-dose combination product containing elbasvir, a hepatitis C virus (HCV) NS5A inhibitor, and grazoprevir, an HCV NS3/4A protease inhibitor, and is indicated for treatment of chronic HCV genotypes 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.

2. Coverage Criteria [a]:

A. For the treatment of chronic hepatitis C genotype 1a infection in treatment-naïve, PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced patients without baseline NS5A polymorphisms, **Zepatier** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1a infection

-AND-

2. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

3. **Both** of the following:

   a. Patient has been tested for the presence of NS5A resistance-associated polymorphisms

   -AND-

   b. Patient is without baseline NS5A resistance-associated polymorphisms (i.e., polymorphisms at amino acid positions 28, 30, 31, or 93)

-AND-

4. **One** of the following:

a. Patient is treatment naïve or has prior failure to peginterferon alfa plus ribavirin treatment

-OR-

b. **Both** of the following:

(1) Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (eg, boceprevir, simeprevir, or telaprevir)

-AND-

(2) Used in combination with ribavirin

-AND-

5. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

-AND-

6. Patient is not receiving Zepatier in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

-AND-

7. Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C)

Authorization will be issued for 12 weeks

B. For the treatment of chronic hepatitis C genotype 1a infection in treatment-naïve, PegIFN/RBV-experienced, or PegIFN/RBV/protease inhibitor-experienced patients with baseline NS5A polymorphisms, **Zepatier** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1a infection

-AND-

2. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

3. **Both** of the following:

a. Patient has been tested for the presence of NS5A resistance-associated polymorphisms

-AND-

b. Patient has one or more baseline NS5A resistance-associated polymorphisms (i.e., polymorphisms at amino acid positions 28, 30, 31, or 93)

-AND-

4. Used in combination with ribavirin

-AND-

5. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

-AND-

6. Patient is not receiving Zepatier in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir),]

-AND-

7. Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C)

Authorization will be issued for 16 weeks

C. For the treatment of chronic hepatitis C genotype 1b infection in treatment-naïve, PegIFN/RBV-experienced or PegIFN/RBV/protease inhibitor-experienced patients, **Zepatier** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1b infection

-AND-

2. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

3. **One** of the following:

a. Patient is treatment naïve or has prior failure to peginterferon alfa plus ribavirin treatment

-OR-

b. **Both** of the following:

(1) Patient has prior failure to treatment with peginterferon alfa plus ribavirin plus a HCV NS3/4A protease inhibitor (e.g., boceprevir, simeprevir, or telaprevir)

-AND-

(2) Used in combination with ribavirin

-AND-

5. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

-AND-

6. Patient is not receiving Zepatier in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)

-AND-

7. Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C)

Authorization will be issued for 12 weeks

D. For the treatment of chronic hepatitis C genotype 4 infection in treatment-naïve patients, **Zepatier** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 4 infection

-AND-

2. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

3. Patient is treatment-naïve

-AND-

4. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

-AND-

5. Patient is not receiving Zepatier in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

-AND-

6. Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C)

Authorization will be issued for 12 weeks

E. For the treatment of chronic hepatitis C genotype 4 infection in PegIFN/RBV-experienced patients, **Zepatier** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 4 infection

-AND-

2. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

3. Patient has prior failure to peginterferon alfa plus ribavirin treatment

-AND-

4. Used in combination with ribavirin

-AND-

5. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

-AND-

6. Patient is not receiving Zepatier in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]

-AND-

7. Patient does not have moderate to severe hepatic impairment (e.g., Child-Pugh Class B or C)

Authorization will be issued for 16 weeks.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply Limits may be in place.

4. References:

1. Zepatier [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; May 2022.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. http://www.hcvguidelines.org/full-report-view. Accessed December 20, 2023.

Program	Prior Authorization/Medical Necessity – Zepatier® (elbasvir/grazoprevir)
Change Control	
2/2016	New program.
7/2016	Added Indiana and West Virginia coverage information.
11/2016	Added California coverage information.
12/20/16	Removed abstinence-based criteria and replaced with treatment readiness screening criteria.
9/2017	Revised step therapy criteria based on new product availability, included NY prescriber requirement, removed treatment readiness screening tools and removed medical record submission requirements.
2/2019	Removed step therapy criteria. Updated references.
4/2020	Annual review with no changes to clinical coverage criteria.
5/2021	Removed prescriber requirement. Updated references.
2/2022	Updated background and references with no change to clinical criteria.
2/2023	Annual review with no change to clinical coverage criteria. Updated background per FDA label. Updated references.
2/2024	Annual review. Updated polymorphism criteria for treatment of chronic hepatitis C genotype 1a infection in treatment-naïve, PegIFN/RBV-experienced, or PegIFN/RBV/protease inhibitor-experienced patients with baseline NS5A polymorphisms to include “one or more”.