

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

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| Program Number | 2024 P 1180-8 |
| Program | Prior Authorization/Notification |
| Medication | Zepatier® (elbasvir/grazoprevir) |
| P&T Approval Date | 2/2016, 9/2018, 2/2019, 2/2020, 2/2021, 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 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.¹

2. Coverage Criteria^a:

A. Chronic Hepatitis C - Genotype 1a -Treatment-Naïve or PegIFN/RBV-experienced without baseline NS5A polymorphisms:

1. **Zepatier** will be approved based on **all** of the following criteria:

a. Diagnosis of chronic hepatitis C genotype 1a infection

-AND-

b. **One** of the following:

(1) Patient is treatment-naïve

-OR-

(2) Patient has prior failure to peginterferon alfa plus ribavirin treatment

-AND-

c. **Both** of the following:

(1) Patient has been tested for the presence of NS5A resistance-associated polymorphisms

-AND-

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

-AND-

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

Authorization will be issued for 12 weeks.

B. Chronic Hepatitis C - Genotype 1a - Treatment-Naïve or PegIFN/RBV-experienced with baseline NS5A polymorphisms:

1. Zepatier will be approved based on **all** of the following criteria:

- a. Diagnosis of chronic hepatitis C genotype 1a infection

-AND-

- b. **One** of the following:

- (1) Patient is treatment-naive

-OR-

- (2) Patient has prior failure to peginterferon alfa plus ribavirin treatment

-AND-

- c. **Both** of the following:

- (1) Patient has been tested for the presence of NS5A resistance-associated polymorphisms

-AND-

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

-AND-

- d. Used in combination with ribavirin

-AND-

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

Authorization will be issued for 16 weeks

C. Chronic Hepatitis C - Genotype 1b - Treatment-Naïve or PegIFN/RBV-experienced:

1. **Zepatier** will be approved based on all of the following criteria:

a. Diagnosis of chronic hepatitis C genotype 1b infection

-AND-

b. **One** of the following:

(1) Patient is treatment- naïve

-OR-

(2) Patient has prior failure to peginterferon alfa plus ribavirin treatment

-AND-

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

Authorization will be issued for 12 weeks

D. Chronic Hepatitis C - Genotype 1a or 1b - PegIFN/RBV/protease inhibitor-experienced:

1. **Zepatier** will be approved based on all of the following criteria:

a. Diagnosis of chronic hepatitis C genotype 1a or 1b infection

-AND-

b. 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-

c. Used in combination with ribavirin

-AND-

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

Authorization will be issued for 12 weeks

E. Chronic Hepatitis C - Genotype 4 -Treatment-naïve:

1. **Zepatier** will be approved based on **all** of the following criteria:

a. Diagnosis of chronic hepatitis C genotype 4 infection

-AND-

b. Patient is treatment-naïve

-AND-

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

Authorization will be issued for 12 weeks

F. Chronic Hepatitis C - Genotype 4 -PegIFN/RBV-experienced:

1. **Zepatier** will be approved based on **all** of the following criteria:

a. Diagnosis of chronic hepatitis C genotype 4 infection

-AND-

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

-AND-

c. Used in combination with ribavirin

-AND-

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

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.
- Medical necessity 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/Notification - Zepatier® (elbasvir/grazoprevir) |
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| Change Control | |
| 2/2016 | New program. |
| 9/2018 | Annual review with no changes to coverage criteria. Updated references. |
| 2/2019 | Removed Olysio from examples and updated references. |
| 2/2020 | Annual review with no changes to coverage criteria. Updated references. |
| 2/2021 | Annual review with no changes to coverage criteria. Updated references. |
| 2/2022 | Annual review. Updated background and references with no change to clinical criteria. |
| 2/2023 | Annual review with no changes to coverage criteria. Added state mandate and updated references. |
| 2/2024 | Annual review. Updated polymorphism criteria for treatment of chronic hepatitis C genotype 1a infection in treatment-naïve, PegIFN/RBV-experienced patients with baseline NS5A polymorphisms to include “one or more”. Added treatment -_naïve requirement in criteria for Chronic Hepatitis C - Genotype 4 -Treatment-naïve patients. |