

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 1180-10
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, 2/2025, 10/2025
Effective Date	1/1/2026

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.

2. Coverage Criteria^a:

<p>A. Authorization:</p> <p>1. Zepatier will be approved based on both of the following criteria:</p> <p style="padding-left: 40px;">a. Diagnosis of chronic hepatitis C genotype 1a, 1b, or 4 infection</p> <p style="text-align: center;">-AND-</p> <p style="padding-left: 40px;">b. Patient is not receiving Zepatier in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]</p> <p>Authorization will be issued for 12 months.</p> <p>^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.</p>

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. <https://www.hcvguidelines.org/> . Accessed September 8, 2025.

Program	Prior Authorization/Notification - Zepatier® (elbasvir/grazoprevir)
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.
2/2025	Annual review with no changes to coverage criteria. Updated references.
10/2025	Reorganized criteria so that chronic HCV infection for treatment-experienced patients as well as other specific populations are addressed in one section. Updated authorization to 12 months. Updated references.