

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2078-13
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, 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 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:

<p>A. Authorization</p> <p>1. Zepatier will be approved based on all 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. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen</p> <p style="text-align: center;">-AND-</p> <p style="padding-left: 40px;">c. Patient is not receiving Zepatier in combination with another HCV direct acting antiviral agent [e.g., Sovaldi (sofosbuvir)]</p> <p style="text-align: center;">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>
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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. <https://www.hcvguidelines.org/>. Accessed December 19, 2024.

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”.
2/2025	Annual review. Removed liver disease staging criteria that was included for quality purposes rather than part of coverage decision. 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.