

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2053-20
Program	Prior Authorization/Medical Necessity
Medication	Sovaldi® (sofosbuvir)
P&T Approval Date	4/2015, 8/2015, 11/2015, 8/2016, 12/2016, 9/2017, 11/2018, 2/2019, 3/2020, 5/2021, 5/2022, 5/2023, 5/2024, 5/2025, 10/2025
Effective Date	1/1/2026

1. Background:

Sovaldi® (sofosbuvir) is a hepatitis C virus (HCV) nucleotide analog NS5B polymerase inhibitor indicated for the treatment of:

- Adult patients with genotype 1, 2, 3 or 4 chronic hepatitis C virus (HCV) infection without cirrhosis or with compensated cirrhosis as a component of a combination antiviral treatment regimen.
- Pediatric patients 3 years of age and older with genotype 2 or 3 chronic HCV infection without cirrhosis or with compensated cirrhosis in combination with ribavirin.

2. Coverage Criteria^a:

<p>A. Authorization</p> <p>1. Sovaldi will be approved based on all of the following criteria:</p> <p style="padding-left: 40px;">a. Diagnosis of chronic hepatitis C genotype 1, 2, 3, or 4 infection</p> <p style="text-align: center;">-AND-</p> <p style="padding-left: 40px;">b. Used in combination with ribavirin</p> <p style="text-align: center;">-AND-</p> <p style="padding-left: 40px;">c. Patient has not experienced failure with a previous treatment regimen that includes Sovaldi</p> <p style="text-align: center;">-AND-</p> <p style="padding-left: 40px;">d. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen</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>
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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. Sovaldi [package insert]. Foster City, CA: Gilead Sciences, Inc.; December 2024.
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 September 8, 2025.

Program	Prior Authorization/Medical Necessity - Sovaldi (sofosbuvir)
Change Control	
4/2015	Coverage requirements for State of New Jersey effective 5/18/15.
8/2015	Added criteria for combination therapy with Daklinza (daclatasvir).
11/2015	Revised criteria to remove Sovaldi plus ribavirin step for cirrhotic patients in section M, merged section N into M, changed program title to include all lines of business and updated language regarding documentation of liver fibrosis.
7/2016	Added Indiana and West Virginia coverage information.
8/2016	Updated criteria to include Eplcusa as well as revisions to peginterferon eligibility requirements.
10/2016	Administrative change to correct formatting.
10/2016	Administrative change made for clarity.
11/2016	Added California coverage information.
12/2016	Removed abstinence-based criteria and replaced with treatment readiness screening criteria.
5/2017	Administrative update to reorder criteria. State mandate reference language updated.
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.
11/2018	Annual review. Removed Olysio. Updated references.
2/2019	Revised step therapy to include Zepatier for genotypes 1 & 4.
3/2020	Annual review. Removed Daklinza as product is no longer available in market. Added requirement for peg-interferon ineligibility for genotype 1 + RBV. Removed Sovaldi + RBV for 24 weeks for GT 4 to align with current label and recommendations.
5/2021	Annual review. Removed prescriber requirement. Updated references.
5/2022	Reformatted criteria. Updated references.
5/2023	Annual review. Simplified peginterferon eligibility requirements. Clarified generic names for Harvoni and Eplcusa. Updated references.
5/2024	Annual review. Removed liver disease staging criteria that was included for quality purposes rather than part of coverage decision. Updated

	references.
5/2025	Annual review without changes to coverage criteria. Updated references.
10/2025	Simplified criteria so that chronic HCV infection for specific populations are addressed in one section. Updated authorization to 12 months. Updated references.