UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2052-17
Program	Prior Authorization/Medical Necessity
Medication	Harvoni® (ledipasvir/sofosbuvir)
P&T Approval Date	4/2015, 8/2015, 11/2015, 8/2016, 12/2016, 9/2017, 11/2017, 6/2019, 3/2020, 5/2021, 5/2022, 5/2023, 5/2024, 5/2025
Effective Date	8/1/2025

1. Background:

Harvoni® (ledipasvir/sofosbuvir) is a fixed-dose combination of ledipasvir, a hepatitis C virus (HCV) NS5A inhibitor, and sofosbuvir, an HCV nucleotide analog NS5B polymerase inhibitor, and is indicated for the treatment of chronic HCV in adults and pediatric patients 3 years of age and older:

- Genotype 1, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis
- Genotype 1 infection with decompensated cirrhosis, in combination with ribavirin
- Genotype 1 or 4 infection who are liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin.

2. Coverage Criteria[a]:

A. For the treatment of chronic hepatitis C genotype 1 infection in treatment-naïve patients without cirrhosis who have pre-treatment HCV RNA less than 6 million IU/mL, **Harvoni** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1 infection

-AND-

2. Patient is treatment-naive [patient has not experienced treatment failure (defined as viral relapse, breakthrough while on therapy, or non-responder to therapy) with peginterferon plus ribavirin or peginterferon plus ribavirin plus an HCV protease inhibitor (e.g., Incivek, Olysio, Victrelis) or Sovaldi (sofosbuvir)]

-AND-

3. Submission of laboratory report documenting a pre-treatment HCV RNA less than 6 million IU/mL

-AND-

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

-AND-

5. Patient is not receiving Harvoni in combination with another HCV direct acting antiviral

agent [e.g., Sovaldi (sofosbuvir)]

Authorization will be issued for 8 weeks.

B. For the treatment of chronic hepatitis C genotype 1 infection in treatment-naïve patients who are without cirrhosis and have a pre-treatment HCV RNA equal to or greater than 6 million IU/mL OR have compensated cirrhosis regardless of pre-treatment HCV RNA level, **Harvoni** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1 infection

-AND-

2. Patient is treatment-naive [patient has not experienced treatment failure (defined as viral relapse, breakthrough while on therapy, or non-responder to therapy) with peginterferon plus ribavirin or peginterferon plus ribavirin plus an HCV protease inhibitor (e.g., Incivek, Olysio, Victrelis) or Sovaldi (sofosbuvir)]

-AND-

3. **One** of the following:

   a. **Both** of the following:

      i. Patient is without cirrhosis

-AND-

      ii. Submission of laboratory report documenting a pre-treatment HCV RNA equal to or greater than 6 million IU/mL

-OR-

   b. Patient has compensated cirrhosis (Child-Pugh A)

-AND-

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

-AND-

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

-AND-

6. **One** of the following:

a. History of intolerance or contraindication to Epclusa therapy

-OR-

b. Patient is currently on Harvoni therapy

Authorization will be issued for 12 weeks.

C. For the treatment of chronic hepatitis C genotype 1 infection in treatment-naïve OR treatment-experienced patients with decompensated cirrhosis, **Harvoni** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1 infection

-AND-

2. **One** of the following:

a. Patient is treatment-naive [patient has not experienced treatment failure (defined as viral relapse, breakthrough while on therapy, or non-responder to therapy) with peginterferon plus ribavirin or peginterferon plus ribavirin plus an HCV protease inhibitor (e.g., Incivek, Olysio, Victrelis) or Sovaldi (sofosbuvir)]

-OR-

b. Patient has experienced treatment failure, defined as viral relapse/breakthrough while on therapy or non-responder to therapy, with a previous treatment regimen that included peginterferon plus ribavirin or an HCV protease inhibitor (e.g., Incivek, Olysio, Victrelis) plus peginterferon plus ribavirin or Sovaldi (sofosbuvir)

-AND-

3. **Both** of the following:

a. Patient has decompensated liver disease (Child-Pugh B or C)

-AND-

b. Used in combination with ribavirin

-AND-

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

-AND-

5. Patient is not receiving Harvoni in combination with another HCV direct acting antiviral

agent [e.g., Sovaldi (sofosbuvir)]

-AND-

6. **One** of the following:

   a. History of intolerance or contraindication to Epclusa therapy

   -OR-

   b. Patient is currently on Harvoni therapy

Authorization will be issued for 12 weeks.

D. For the treatment of chronic hepatitis C genotype 1 infection in treatment-experienced patients without cirrhosis, **Harvoni** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1 infection

-AND-

2. Patient has experienced treatment failure, defined as viral relapse/breakthrough while on therapy or non-responder to therapy, with a previous treatment regimen that included peginterferon plus ribavirin or an HCV protease inhibitor (e.g., Incivek, Olysio, Victrelis) plus peginterferon plus ribavirin or Sovaldi (sofosbuvir)

-AND-

3. Patient is without cirrhosis

-AND-

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

-AND-

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

-AND-

6. **One** of the following:

   a. History of intolerance or contraindication to Epclusa therapy

   -OR-

   b. Patient is currently on Harvoni therapy

Authorization will be issued for 12 weeks.

E. For the treatment of chronic hepatitis C genotype 1 infection in treatment-experienced patients with compensated cirrhosis, **Harvoni** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1 infection

-AND-

2. Patient has experienced treatment failure, defined as viral relapse/breakthrough while on therapy or non-responder to therapy, with a previous treatment regimen that included peginterferon plus ribavirin or an HCV protease inhibitor (e.g., Incivek, Olysio, Victrelis) plus peginterferon plus ribavirin or Sovaldi (sofosbuvir)

-AND-

3. Patient has compensated cirrhosis (Child-Pugh A)

-AND-

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

-AND-

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

-AND-

6. **One** of the following:

   a. History of intolerance or contraindication to Epclusa therapy

   -OR-

   b. Patient is currently on Harvoni therapy

Authorization will be issued for 24 weeks.

F. For the treatment of chronic hepatitis C genotype 1 or 4 infection in treatment-naïve and treatment-experienced liver transplant recipients who are without cirrhosis or have compensated cirrhosis, **Harvoni** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1 or 4 infection

-AND-

2. **One** of the following:

   a. Patient is treatment-naive [patient has not experienced treatment failure (defined as viral relapse, breakthrough while on therapy, or non-responder to therapy) with peginterferon plus ribavirin or peginterferon plus ribavirin plus an HCV protease inhibitor (e.g., Incivek, Olysio, Victrelis) or Sovaldi (sofosbuvir)]

   -OR-

   b. Patient has experienced treatment failure, defined as viral relapse/breakthrough while on therapy or non-responder to therapy, with a previous treatment regimen that included peginterferon plus ribavirin or an HCV protease inhibitor (e.g., Incivek, Olysio, Victrelis) plus peginterferon plus ribavirin or Sovaldi (sofosbuvir)

-AND-

3. **Both** of the following:

   a. Patient has received a liver transplant

   -AND-

   b. Used in combination with ribavirin

-AND-

4. **One** of the following:

   a. Patient is without cirrhosis

   -OR-

   b. Patient has compensated cirrhosis (Child-Pugh A)

-AND-

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

-AND-

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

-AND-

7. **One** of the following:

   a. History of intolerance or contraindication to Epclusa therapy

   -OR-

   b. Patient is currently on Harvoni therapy

Authorization will be issued for 12 weeks.

G. For the treatment of chronic hepatitis C genotype 4, 5 or 6 infection in treatment-naïve or treatment-experienced patients who are without cirrhosis or have compensated cirrhosis, **Harvoni** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 4, 5 or 6 infection

   -AND-

2. **One** of the following:

   a. Patient is without cirrhosis

   -OR-

   b. Patient has compensated cirrhosis (Child-Pugh A)

   -AND-

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

   -AND-

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

   -AND-

5. **One** of the following:

   a. History of intolerance or contraindication to Epclusa therapy

   -OR-

   b. Patient is currently on Harvoni therapy

Authorization will be issued for 12 weeks.

H. For the treatment of chronic hepatitis C genotype 1, 4, 5, or 6 infection in treatment-naïve and non-direct acting antiviral treatment-experienced kidney transplant recipients who are without cirrhosis or have compensated cirrhosis, **Harvoni** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1, 4, 5, or 6 infection

-AND-

2. **One** of the following:

   a. Patient is treatment-naive [patient has not experienced treatment failure (defined as viral relapse, breakthrough while on therapy, or nonresponder to therapy) with peginterferon plus ribavirin or peginterferon plus ribavirin plus an HCV protease inhibitor (e.g., Incivek, Olysio, Victrelis) or Sovaldi (sofosbuvir)]

-OR-

   b. Patient has not been previously treated with a direct acting antiviral [e.g., Sovaldi (sofosbuvir)]

-AND-

3. Patient has received a kidney transplant

-AND-

4. **One** of the following:

   a. Patient is without cirrhosis

-OR-

   b. Patient has compensated cirrhosis (Child-Pugh A)

-AND-

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

-AND-

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

-AND-

7. **One** of the following:

   a. History of intolerance or contraindication to Epclusa therapy

   -OR-

   b. Patient is currently on Harvoni therapy

Authorization will be issued for 12 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. Harvoni [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 April 9, 2025.

Program	Prior Authorization/Medical Necessity - Harvoni (ledipasvir/sofosbuvir)
Change Control	
4/2015	Coverage requirements for State of New Jersey effective 5/18/2015.
8/2015	Added criteria for genotype 4 infection
11/2015	Changed program title to include all lines of business, added genotypes 5 and 6, and updated language regarding documentation of liver fibrosis.
8/2016	Revised treatment-experienced with cirrhosis criteria to include ribavirin and Epclusa.
11/2016	Added California coverage information.
12/2016	Removed abstinence-based criteria and replaced with treatment readiness screening criteria. Added Maryland, Indiana and West Virginia coverage information.
5/2017	Administrative update to reorder criteria. State mandate reference language updated.
5/2017	Administrative update to correct formatting.
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.

11/2017	Update to language in Genotype 1 criteria for treatment naïve compensated cirrhotic patients.
6/2019	Annual review. Added kidney transplant recipient section based on AASLD guidelines to allow for 12 weeks of therapy. Updated references.
3/2020	Added requirement of Epclusa use for requests greater than 8 weeks. Clarified kidney transplant criteria to align with current AASLD guidelines. Updated background and references.
5/2021	Annual review. Removed prescriber requirement. Updated references.
5/2022	Reformatted criteria. Updated references.
5/2023	Annual review. 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. Updated references.