



## DRUG QUANTITY MANAGEMENT POLICY – PER DAYS

- POLICY:** Hepatitis C – Harvoni Drug Quantity Management Policy – Per Days
- Harvoni® (ledipasvir/sofosbuvir tablets and oral pellets – Gilead)
  - ledipasvir/sofosbuvir tablets (authorized generic to Harvoni 90mg/400 mg tablets – Gilead)

**REVIEW DATE:** 10/07/2025

### INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

## CIGNA NATIONAL FORMULARY COVERAGE:

### OVERVIEW

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.<sup>1</sup> It is indicated for the treatment of **chronic HCV** in patients  $\geq$  3 years of age in the following instances:

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

### Dosing

In adults, the recommended dosage of ledipasvir/sofosbuvir is one tablet (90 mg/400 mg) taken orally once daily with or without food.<sup>1</sup>

The recommended dose of ledipasvir/sofosbuvir tablets or pellets in pediatric patients ≥ 3 years of age is based on weight (Table 1).<sup>1</sup> The ledipasvir/sofosbuvir pellets can be taken in pediatric patients who cannot swallow the tablet formulation. Table 1 below provides the recommended duration of therapy with ledipasvir/sofosbuvir.

**Table 1. Ledipasvir/sofosbuvir\* Dosing in Pediatric Patients ≥ 3 Years of Age.<sup>1</sup>**

Body Weight (kg)	Dose of Pellets or Tablets	Daily Dose of ledipasvir/sofosbuvir
< 17 kg	1 x 33.75 mg/150 mg packet of pellets QD	33.75 mg/150 mg
17 kg to < 35 kg	1 x 45 mg/200 mg packet of pellets QD; OR 1 x 45 mg/200 mg tablet QD	45 mg/200 mg
≥ 35 kg	2 x 45 mg/200 mg packets of pellets QD; OR 2 x 45 mg/200 mg tablets QD; OR 1 x 90 mg/400 mg tablet QD	90 mg/400 mg

\* Only 90 mg/400 mg tablets are available as the authorized generic to Harvoni. All other dosage forms are available as Harvoni only (see *Availability* below); QD – Once daily

## Availability

Brand Harvoni is available as a tablet containing 90 mg of ledipasvir/400 mg sofosbuvir or 45 mg/ledipasvir/200 mg sofosbuvir.<sup>1</sup> It is also available as an oral pellet packet formulation containing 45 mg ledipasvir/200 mg sofosbuvir or 33.75 mg ledipasvir/150 mg sofosbuvir. The ledipasvir/sofosbuvir authorized generic is *only* available as the 90 mg/400 mg strength tablet. The table below provides the FDA recommended ledipasvir/sofosbuvir treatment durations for treatment-naïve and treatment-experienced patients and those with and without cirrhosis.

**Table 2. Recommended Treatment Duration for ledipasvir/sofosbuvir in Patients ≥ 3 Years of Age with Chronic HCV Genotype 1, 4, 5, or 6.<sup>1</sup>**

Patient Population	Duration of Treatment
Genotype 1 – Treatment-naïve with or without compensated (Child Pugh A) cirrhosis	ledipasvir/sofosbuvir 12 weeks*
Genotype 1 – Treatment-experienced** without cirrhosis	ledipasvir/sofosbuvir 12 weeks
Genotype 1 – Treatment-experienced** with compensated (Child Pugh A) cirrhosis	ledipasvir/sofosbuvir 24 weeks <sup>†</sup>
Genotype 1 – Treatment-naïve and treatment-experienced** with decompensated (Child-Pugh B or C) cirrhosis.	ledipasvir/sofosbuvir + ribavirin 12 weeks
Genotype 1 or 4 – Transplant recipients without cirrhosis, or with compensated (Child-Pugh A) cirrhosis	ledipasvir/sofosbuvir + ribavirin 12 weeks
Genotype 4, 5, or 6 – Treatment-naïve and treatment-experienced**, with or without compensated (Child-Pugh A) cirrhosis	ledipasvir/sofosbuvir 12 weeks

HCV – Hepatitis C virus; \* Ledipasvir/sofosbuvir for 8 weeks can be considered in treatment-naïve patients without cirrhosis who have pretreatment hepatitis C virus RNA < 6 million IU/mL; \*\* Treatment-experienced patients who have failed treatment with either peginterferon alfa + ribavirin or a hepatitis C virus protease inhibitor + peginterferon + ribavirin; <sup>†</sup> Ledipasvir/sofosbuvir for 12 weeks can be considered in treatment-experienced patients with cirrhosis who are eligible for ribavirin.

## Guidelines

The American Association for the Study of Liver Diseases/Infectious Diseases Society of America have simplified recommendations for the management of chronic HCV in adults (December 19, 2023).<sup>2</sup> In treatment-naïve adults without cirrhosis, the recommended regimens are Mavyret® (glecaprevir/pibrentasvir tablets and oral pellets) for 8 weeks or Epclusa® (sofosbuvir/velpatasvir tablets [generic] and oral pellets) for 12 weeks. In treatment-naïve adults with compensated cirrhosis, the recommended regimens are Mavyret for 8 weeks (genotypes 1 through 6) or sofosbuvir/velpatasvir for 12 weeks (genotypes 1, 2, 4, 5, or 6; patients with genotype 3 require baseline NS5A resistance-associated substitution testing and those without Y93H can be treated with 12 weeks of Epclusa). Additional genotype-specific and/or special circumstance-specific recommendations are also provided for patients falling outside of these parameters.

Ledipasvir/sofosbuvir continues to be recommended in various situations as outlined below in Table 3.

**Table 2. AASLD Recommendations for Ledipasvir/Sofosbuvir.<sup>2</sup>**

DAA	Duration	FDA Approved (Y/N)	AASLD Level of Evidence
<b>Genotype 1, 4, 5, and 6 Chronic HCV Treatment-Naïve Adults – Recommended</b>			
ledipasvir/sofosbuvir	12 weeks (± compensated cirrhosis) Not recommended for genotype 6e if subtype is known.	Y	Class I, Level A Class IIa, Level B (Genotype 4 compensated cirrhosis, Genotype 5/6 ± compensated cirrhosis)
ledipasvir/sofosbuvir	8 weeks (HIV-uninfected, HCV RNA < 6 million IU/mL, no cirrhosis, absence of genotype 4r)	Y	Class I, Level B
<b>Genotype 1, 4, 5, or 6 Chronic HCV, Decompensated Cirrhosis Adults Ribavirin Eligible – Recommended</b>			
ledipasvir/sofosbuvir + ribavirin	12 weeks	Y	Class I, Level A
<b>Genotype 1, 4, 5, or 6 Chronic HCV, Decompensated Cirrhosis Adults Ribavirin Ineligible – Recommended</b>			
ledipasvir/sofosbuvir	24 weeks	N	Class I, Level A
<b>Genotype 1, 4, 5, or 6 Chronic HCV, Decompensated Cirrhosis Adults Prior Sovaldi or NSA Failure – Recommended</b>			
ledipasvir/sofosbuvir + ribavirin	24 weeks	N	Class II, Level C
<b>Genotype 1, 4, 5, or 6 Recurrent HCV Post-Liver Transplant, No Cirrhosis, Treatment-Naïve or Treatment-Experienced – Recommended</b>			
ledipasvir/sofosbuvir	12 weeks	Y	Class I, Level B
<b>Genotype 1, 4, 5, or 6 Recurrent HCV Post-Liver Transplant, Compensated Cirrhosis, Treatment-Naïve or Treatment-Experienced – Recommended</b>			
ledipasvir/sofosbuvir	12 weeks	Y	Class I, Level A
<b>Genotype 1, 4, 5, or 6 Recurrent HCV Post-Liver Transplant, Decompensated Cirrhosis, Treatment-Naïve or Treatment-Experienced – Recommended</b>			
ledipasvir/sofosbuvir + ribavirin	12 to 24 weeks	Y	Class I, Level B

<b>Genotype 1, 4, 5, or 6 Kidney Transplant Treatment-Naïve or DAA-Experienced ± Compensated Cirrhosis, Adults – Recommended</b>			
ledipasvir/sofosbuvir	12 weeks	N	Class I, Level A
<b>Genotype 1, 4, 5, or 6 Treatment-Naïve Adolescents ≥ 3 years, ± Compensated Cirrhosis – Recommended</b>			
ledipasvir/sofosbuvir	12 weeks	Y	Class I, Level B
<b>Genotype 1, 4, 5, or 6 Treatment-Experienced (Interferon + Protease Inhibitor) Adolescents ≥ 3 years, ± Compensated Cirrhosis – Recommended</b>			
ledipasvir/sofosbuvir	12 weeks (genotype 1 no cirrhosis)	Y	Class I, Level C
ledipasvir/sofosbuvir	24 weeks (genotype 1 compensated cirrhosis)	Y	Class I, Level C
ledipasvir/sofosbuvir	12 weeks (genotypes 4, 5, or 6 ± compensated cirrhosis)	Y	Class I, Level C

AASLD – American Association for the Study of Liver Diseases; DAA – Direct-acting antiviral; Y – Yes; N – No; HCV – Hepatitis C virus; HIV – Human immunodeficiency virus.

A quantity sufficient to allow for 8 weeks of therapy per 365 days will be covered without prior authorization. For coverage of additional quantities (for example, a 12-week or 24-week regimen), a coverage review is required.

## **POLICY STATEMENT**

This Drug Quantity Management program has been developed to prevent stockpiling, misuse and/or overuse of ledipasvir/sofosbuvir (Harvoni, generic). If the Drug Quantity Management rule is not met for the requested medication at the point of service, coverage will be determined by the Criteria below. All approvals are provided for 1 year in duration unless otherwise noted below.

## **Drug Quantity Limits**

<b>Product</b>	<b>Strength and Form</b>	<b>Retail or Home Delivery Maximum Quantity per 365 days</b>
Harvoni® (ledipasvir/sofosbuvir)	90/400 mg tablets	56 tablets (28 tablets per dispensing)
	45/200 mg tablets	112 tablets (56 tablets per dispensing)
	45/200 mg pellet packets	112 packets (56 packets per dispensing)
	33.75/150 mg pellet packets	56 packets (28 packets per dispensing)
Ledipasvir/sofosbuvir (authorized generic)	90/400 mg tablets	56 tablets (28 tablets/28 days)

**EXCEPTIONS TO THE QUANTITY LIMITS LISTED ABOVE ARE COVERED AS MEDICALLY NECESSARY WHEN THE FOLLOWING CRITERIA ARE MET. ANY OTHER EXCEPTION IS CONSIDERED NOT MEDICALLY NECESSARY.**

## CRITERIA

Ledipasvir/sofosbuvir 90 mg/400 mg tablets (Harvoni, generic)

### 1. Chronic Hepatitis C Virus, Genotype 1.

- A)** Approve 84 tablets per 365 days at retail or home delivery if the patient meets ONE of the following (i, ii, or iii):
- i.** Patient is treatment-naïve AND meets at least ONE of the following (a, b, or c):
    - a)** Patient has compensated cirrhosis (Child-Pugh A) [includes patients awaiting liver transplant]; OR
    - b)** Patient does not have cirrhosis and baseline HCV RNA  $\geq$  6 million IU/mL (includes patients awaiting liver transplant); OR
    - c)** Patient has human immunodeficiency virus; OR
  - ii.** Patient has previously been treated for HCV and does not have cirrhosis; OR
  - iii.** Patient is treatment-naïve OR has previously been treated for HCV AND meets BOTH of the following (a and b):
    - a)** Patient has decompensated cirrhosis (Child-Pugh B or C); AND
    - b)** The medication will be prescribed in combination with ribavirin.  
Note: This is a quantity sufficient to treat with one tablet per day for 12 weeks.
- B)** Approve 168 tablets per 365 days at retail or home delivery if the patient meets ONE of the following (i or ii):
- i.** Patient has previously been treated for HCV AND has compensated cirrhosis (Child-Pugh A); OR
  - ii.** Patient is treatment-naïve OR has previously been treated for HCV AND meets BOTH of the following (a and b):
    - a)** Patient has decompensated cirrhosis (Child-Pugh B or C); AND
    - b)** Patient is ribavirin ineligible, according to the prescriber.  
Note: This is a quantity sufficient to treat with one tablet per day for 24 weeks.

### 2. Chronic Hepatitis C Virus, Genotype 4, 5, or 6. Approve 84 tablets per 365 days at retail or home delivery.

Note: This is a quantity sufficient to treat with one tablet per day for 12 weeks.

### 3. Recurrent Hepatitis C Virus Post-Liver Transplantation, Genotype 1, 4, 5, OR 6. Approve 84 tablets per 365 days at retail or home delivery.

Note: This is a quantity sufficient to treat with one tablet per day for 12 weeks.

### 4. Hepatitis C Virus Kidney Transplant Recipient, Genotype 1 or 4. Approve 84 tablets per 365 days at retail or home delivery.

Note: This is a quantity sufficient to treat with one tablet per day for 12 weeks.

### 5. For an indication or condition addressed as an approval in the above criteria section, approve the quantity requested, not to exceed 168 tablets per 365 days at retail or home delivery, to complete a course therapy.

Note: For example, if the patient has received 4 weeks of therapy (28 tablets) and is eligible for 12 weeks of treatment, approve 56 tablets to complete 12

weeks of therapy. If a patient has received 4 weeks (28 tablets) of therapy and is eligible for 24 weeks of treatment, approve 140 tablets to complete 24 weeks of therapy.

Harvoni 45 mg/200 mg tablets, Harvoni 45 mg/200 mg pellet packets

**1. Chronic Hepatitis C Virus (HCV) Genotype 1.**

**A)** Approve 168 tablets or pellet packets per 365 days at retail or home delivery if the patient meets criterion (i) AND meets ONE of the following (ii or iii or iv):

**i.** Patient is < 12 years of age; AND

**ii.** Patient is treatment-naïve AND meets at least ONE of the following (a, b, or c):

**a)** Patient has compensated cirrhosis (Child-Pugh A) [includes patients awaiting liver transplant]; OR

**b)** Patient does not have cirrhosis and baseline HCV RNA  $\geq$  6 million IU/mL (includes patients awaiting liver transplant); OR

**c)** Patient has human immunodeficiency virus; OR

**iii.** Patient has previously been treated for HCV and does not have cirrhosis; OR

**iv.** Patient is treatment-naïve OR has previously been treated for HCV AND meets BOTH of the following (a and b):

**a)** Patient has decompensated cirrhosis (Child-Pugh B or C); AND

**b)** The medication will be prescribed in combination with ribavirin.

Note: This is a quantity sufficient for two tablets or two pellet packets per day for 12 weeks.

**B)** Approve 336 tablets or pellet packets per 365 days at retail or home delivery if the patient meets BOTH of the following (i and ii):

**i.** Patient is < 12 years of age; AND

**ii.** Patient meets ONE of the following (a or b):

**a)** Patient has previously been treated for HCV AND has compensated cirrhosis (Child-Pugh A); OR

**b)** Patient is treatment-naïve OR has previously been treated for HCV AND meets BOTH of the following (1 and 2):

**(1)** Patient has decompensated cirrhosis (Child-Pugh B or C);

**(2)** Patient is ribavirin ineligible, according to the prescriber.

Note: This is a quantity sufficient for two tablets or two pellet packets per day for 24 weeks.

**2. Chronic Hepatitis C Virus Genotype, 4, 5, or 6.** If the patient is < 12 years of age, approve 168 tablets or pellet packets per 365 days at retail or home delivery.

Note: This is a quantity sufficient to treat with two tablets or pellet packets per day for 12 weeks.

**3. Recurrent Hepatitis C Virus Post-Liver Transplantation, Genotype 1 OR**

**4.** If the patient is < 12 years of age, approve 168 tablets or pellet packets per 365 days at retail or home delivery.

Note: This is a quantity sufficient to treat with two tablets or pellet packets per day for 12 weeks.

4. For an indication or condition addressed as an approval in the above criteria section, approve the quantity requested, not to exceed 336 tablets or pellet packets per 365 days at retail or home delivery, to complete a course therapy. Note: For example, if the patient has received 4 weeks of therapy (56 tablets or pellet packets) and is eligible for 12 weeks of treatment, approve 112 tablets to complete 12 weeks of therapy. If a patient has received 4 weeks (56 tablets or pellet packets) of therapy and is eligible for 24 weeks of treatment, approve 280 tablets or pellet packets to complete 24 weeks of therapy.

Harvoni 33.75 mg/150 mg pellet packets

**1. Chronic Hepatitis C Virus Genotype 1.**

- A)** Approve 84 pellet packets per 365 days at retail or home delivery if the patient meets BOTH of the following (i and ii):
- i. Patient is < 12 years of age; AND
  - ii. Patient meets ONE of the following (a, b, or c):
    - a) Patient is treatment-naïve AND meets at least ONE of the following (1, 2, or 3):
      - (1) Patient has compensated cirrhosis (Child-Pugh A) [includes patients awaiting liver transplant]; OR
      - (2) Patient does not have cirrhosis and baseline HCV RNA  $\geq$  6 million IU/mL (includes patients awaiting liver transplant); OR
      - (3) Patient has human immunodeficiency virus; OR
    - b) Patient has previously been treated for HCV and does not have cirrhosis; OR
    - c) Patient is treatment-naïve OR has previously been treated for HCV AND meets BOTH of the following (1 and 2):
      - (1) Patient has decompensated cirrhosis (Child-Pugh B or C); AND
      - (2) The medication will be prescribed in combination with ribavirin.  
Note: This is a quantity sufficient to treat with one pellet packet per day for 12 weeks.
- B)** Approve 168 tablets per 365 days at retail or home delivery if the patient meets BOTH of the following (i and ii):
- i. Patient is < 12 years of age; AND
  - ii. Patient meets ONE of the following (a or b):
    - a) Patient has previously been treated for HCV AND has compensated cirrhosis (Child-Pugh A); OR
    - b) Patient is treatment-naïve OR has previously been treated for HCV AND meets BOTH of the following (1 and 2):
      - (1) Patient has decompensated cirrhosis (Child-Pugh B or C);
      - (2) Patient is ribavirin ineligible, according to the prescriber.  
Note: This is a quantity sufficient to treat with one pellet packet per day for 24 weeks.

- 2. Chronic Hepatitis C Virus Genotype 4, 5, or 6.** If the patient is < 12 years of age, approve 84 pellet packets per 365 days at retail or home delivery.

Note: This is a quantity sufficient to treat with one pellet packet per day for 12 weeks.

**3. Recurrent Hepatitis C Virus Post-Liver Transplantation, Genotype 1 OR**

**4.** If the patient is < 12 years of age, approve 84 pellet packets per 365 days at retail or home delivery.

Note: This is a quantity sufficient to treat with one pellet packet per day for 12 weeks.

**4.** For an indication or condition addressed as an approval in the above criteria section, approve the quantity requested, not to exceed 168 pellet packets per 365 days at retail or home delivery, to complete a course therapy.

Note: For example, if the patient has received 4 weeks of therapy (28 pellet packets) and is eligible for 12 weeks of treatment, approve 56 tablets to complete 12 weeks of therapy. If a patient has received 4 weeks (28 pellet packets) of therapy and is eligible for 24 weeks of treatment, approve 140 tablets to complete 24 weeks of therapy.

**REFERENCES**

1. Harvoni® tablets and oral pellets [prescribing information]. Foster City, CA: Gilead; December 2024.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Testing, managing, and treating hepatitis C. Available at: <http://www.hcvguidelines.org>. Updated December 19, 2023. Accessed on September 12, 2025

**HISTORY**

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/28/2023
Annual Revision	No criteria changes.	10/07/2024
Annual Revision	No criteria changes.	10/07/2025

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