Effective Date **1/1/2024**
Next Review Date… **1/1/2025**
Coverage Policy Number **IP0186**

Ledipasvir/Sofosbuvir

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Related Coverage Resources

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. 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.

Overview

This policy supports medical necessity review for the following products:

- **Harvoni®** (ledipasvir/sofosbuvir tablets and oral pellets)
- ledipasvir/sofosbuvir tablets (generics to Harvoni 90 mg/400 mg tablets only)

Additional criteria that support the review for medical necessity exceptions of non-covered products are located in the Non-Covered Product Table by the respective plan type and drug list where applicable.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Initial Approval Criteria

Ledipasvir/sofosbuvir (Harvoni) is considered medically necessary for the treatment of chronic hepatitis C virus (HCV) genotype 1 in an adult, when the individual meets ALL of the following criteria:

1. Age 18 years or older
2. **ONE** of the following:
    a. Treatment-naïve, does NOT have cirrhosis, does NOT have human immunodeficiency virus (HIV), is NOT awaiting liver transplantation, and has a baseline hepatitis C virus (HCV) RNA less than 6 million IU/mL – [duration of 8 weeks]
    b. Treatment-naïve and **ONE** of the following – [duration of 12 weeks]:
        i. With or without HIV, with compensated cirrhosis (Child-Pugh A), regardless of baseline HCV RNA
        ii. With or without HIV, without cirrhosis, and has a baseline HCV RNA ≥ 6 million IU/mL
    c. Treatment-experienced* and does NOT have cirrhosis – [duration of 12 weeks]
    d. Treatment-experienced* with compensated cirrhosis (Child-Pugh A) and meets **BOTH** of the following – [duration of 12 weeks]:
        i. Is ribavirin eligible
        ii. The medication will be prescribed in combination with ribavirin
    e. Treatment-naïve or treatment-experienced*, with decompensated cirrhosis (Child-Pugh B or C), and meets **BOTH** of the following – [duration of 12 weeks]:
        i. Is ribavirin eligible
        ii. The medication will be prescribed in combination with ribavirin
    f. **ONE** of the following – [duration of 24 weeks]:
        i. Treatment-experienced*, with compensated cirrhosis (Child-Pugh A), and is ribavirin ineligible according to the prescriber
        ii. Treatment-naïve or treatment-experienced*, with decompensated cirrhosis (Child-Pugh B or C), and is ribavirin ineligible according to the prescriber
        iii. Prior sofosbuvir-containing treatment failure, with decompensated cirrhosis (Child-Pugh B or C), and medication will be prescribed in combination with ribavirin
3. Medication is prescribed by, or in consultation with, a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
4. Non-Covered Product Criteria is met, refer to below table:

Employer Group Non-Covered Products and Criteria:

Non-Covered Product	Criteria
ledipasvir/sofosbuvir tablets	Documentation of an inability to obtain Harvoni (the brand name product) due to market availability

*Treatment-experienced individuals are those who have failed treatment with either peginterferon alfa + ribavirin or a hepatitis C virus protease inhibitor (for example, boceprevir [Victrelis], simeprevir [Olysio], or telaprevir [Incivek/Incivo]) + peginterferon + ribavirin.

Ledipasvir/sofosbuvir (Harvoni) is considered medically necessary for the treatment of chronic hepatitis C virus (HCV) genotype 1 in a pediatric individual when ALL of the following criteria are met:

1. Age 3 to 17 years
2. **ONE** of the following:
    a. Treatment-naïve without cirrhosis or with compensated cirrhosis (Child-Pugh A) – [duration of 12 weeks]
    b. Treatment-experienced* without cirrhosis – [duration of 12 weeks]
    c. Treatment-experienced* and has compensated cirrhosis (Child-Pugh A) – [duration of 24 weeks]
3. Medication is prescribed by, or in consultation with, a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
4. Non-Covered Product Criteria is met, refer to below table:

Employer Group Non-Covered Products and Criteria:

Non-Covered Product	Criteria
ledipasvir/sofosbuvir tablets	Documentation of an inability to obtain Harvoni (the brand name product) due to market availability

*Treatment-experienced individuals are those who have failed treatment with either peginterferon alfa + ribavirin or a hepatitis C virus protease inhibitor (for example, boceprevir [Victrelis], simeprevir [Olysio], or telaprevir [Incivek/Incivo]) + peginterferon + ribavirin.

Ledipasvir/sofosbuvir (Harvoni) is considered medically necessary for the treatment of chronic hepatitis C virus (HCV) genotype 4, 5, or 6 when the individual meets ALL of the following criteria:

1. Age 3 years or older
2. **ONE** of the following:
    a. Treatment-naïve or treatment-experienced* without cirrhosis or with compensated cirrhosis (Child-Pugh A) – [duration of 12 weeks]
    b. Treatment-naïve or treatment-experienced*, with decompensated cirrhosis (Child-Pugh B or C), and meets **BOTH** of the following – [duration of 12 weeks]:
        i. Is ribavirin eligible
        ii. The medication will be prescribed in combination with ribavirin
    c. Treatment-naïve or treatment-experienced*, with decompensated cirrhosis (Child-Pugh B or C), and is ribavirin ineligible according to the prescriber– [duration of 24 weeks]
    d. Prior sofosbuvir-containing treatment failure, with decompensated cirrhosis (Child-Pugh B or C), and medication will be prescribed in combination with ribavirin – [duration of 24 weeks]
3. Medication is prescribed by, or in consultation with, a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
4. Non-Covered Product Criteria is met, refer to below table:

Employer Group Non-Covered Products and Criteria:

Non-Covered Product	Criteria
ledipasvir/sofosbuvir tablets	Documentation of an inability to obtain Harvoni (the brand name product) due to market availability

*Treatment-experienced individuals are those who have failed treatment with either peginterferon alfa + ribavirin or a hepatitis C virus protease inhibitor (for example, boceprevir [Victrelis], simeprevir [Olysio], or telaprevir [Incivek/Incivo]) + peginterferon + ribavirin.

Ledipasvir/sofosbuvir (Harvoni) is considered medically necessary for the treatment of chronic hepatitis C virus (HCV) post-liver transplantation, genotypes 1 or 4 when the individual meets ALL of the following criteria:

1. Age 3 years or older
2. Has recurrent hepatitis C virus (HCV) after a liver transplantation and **ONE** of the following:
    a. Treatment-naïve or treatment-experienced* without cirrhosis or with compensated cirrhosis (Child-Pugh A) – [duration of 12 weeks]
    b. Treatment-naïve with decompensated cirrhosis (Child-Pugh B or C) and the medication will be prescribed in combination with ribavirin – [duration of 12 weeks]
    c. Treatment-experienced* individual with decompensated cirrhosis (Child-Pugh B or C) and the medication will be prescribed in combination with ribavirin – [duration of 24 weeks]
3. Medication is prescribed by, or in consultation with, a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
4. Non-Covered Product Criteria is met, refer to below table:

Employer Group Non-Covered Products and Criteria:

Non-Covered Product	Criteria
ledipasvir/sofosbuvir tablets	Documentation of an inability to obtain Harvoni (the brand name product) due to market availability

*Treatment-experienced individuals are those who have failed treatment with either peginterferon alfa + ribavirin or a hepatitis C virus protease inhibitor (for example, boceprevir [Victrelis], simeprevir [Olysio], or telaprevir [Incivek/Incivo]) + peginterferon + ribavirin.

Ledipasvir/sofosbuvir (Harvoni) is considered medically necessary for the treatment of chronic hepatitis C virus (HCV) post-liver transplantation, genotypes 5 or 6 when the individual meets ALL of the following criteria:

1. Age 18 years or older
2. Has recurrent hepatitis C virus (HCV) after a liver transplantation and **ONE** of the following:
    a. Treatment-naïve or treatment-experienced* without cirrhosis or with compensated cirrhosis (Child-Pugh A) – [duration of 12 weeks]
    b. Treatment-naïve with decompensated cirrhosis (Child-Pugh B or C) and the medication will be prescribed in combination with ribavirin – [duration of 12 weeks]
    c. Treatment-experienced* individual with decompensated cirrhosis (Child-Pugh B or C) and the medication will be prescribed in combination with ribavirin– [duration of 24 weeks]
3. Medication is prescribed by, or in consultation with, a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
4. Non-Covered Product Criteria is met, refer to below table:

Employer Group Non-Covered Products and Criteria:

Non-Covered Product	Criteria
ledipasvir/sofosbuvir tablets	Documentation of an inability to obtain Harvoni (the brand name product) due to market availability

*Treatment-experienced individuals are those who have failed treatment with either peginterferon alfa + ribavirin or a hepatitis C virus protease inhibitor (for example, boceprevir [Victrelis], simeprevir [Olysio], or telaprevir [Incivek/Incivo]) + peginterferon + ribavirin.

Ledipasvir/sofosbuvir (Harvoni) is considered medically necessary for the treatment of chronic hepatitis C virus (HCV) in kidney transplant recipients, genotypes 1, 4, 5 or 6 when the individual meets ALL of the following criteria:

1. Age 18 years or older
2. Treatment-naïve or treatment-experienced* without cirrhosis or with compensated cirrhosis (Child-Pugh A) – [duration of 12 weeks]
3. Has NOT been previously treated with another direct-acting-antiviral (DAA) regimen (for example, Daklinza [daclatasvir], Epclusa [sofosbuvir/velpatasvir], Harvoni [ledipasvir/sofosbuvir], Mavyret [glecaprevir/pibrentasvir], Viekira Pak [ombitasvir/paritaprevir/ritonavir; dasabuvir, co-packaged], Zepatier [elbasvir/grazoprevir])
4. Medication is prescribed by, or in consultation with, a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician
5. Non-Covered Product Criteria is met, refer to below table:

Employer Group Non-Covered Products and Criteria:

Non-Covered Product	Criteria
ledipasvir/sofosbuvir tablets	Documentation of an inability to obtain Harvoni (the brand name product) due to market availability

*Treatment-experienced individuals are those who have failed treatment with either peginterferon alfa + ribavirin or a hepatitis C virus protease inhibitor (for example, boceprevir [Victrelis], simeprevir [Olysio], or telaprevir [Incivek/Incivo]) + peginterferon + ribavirin.

Ledipasvir/sofosbuvir (Harvoni) is considered medically necessary for the treatment of chronic hepatitis C virus (HCV) when the individual has already been started on the medication and will be completing a course of therapy.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Continuation of Therapy

Not applicable for continuation beyond initial approval duration.

Authorization Duration

Initial approval duration:

Chronic HCV Genotype 1, Adult (age 18 or older):

1. **Treatment-naïve, without cirrhosis, HIV-uninfected, & pretreatment HCV RNA < 6 million IU/mL:** 8 weeks
2. **Treatment-naïve with or without compensated cirrhosis:** 12 weeks
3. **Treatment-experienced* without cirrhosis:** 12 weeks
4. **Treatment-experienced* with compensated cirrhosis (Child-Pugh A):** 12 weeks in combination with ribavirin or 24 weeks if ribavirin ineligible
5. **Treatment-naïve and treatment-experienced* with decompensated cirrhosis (Child-Pugh B or C):** 12 weeks in combination with ribavirin or 24 weeks if ribavirin ineligible
6. **Prior sofosbuvir-containing treatment failure, with decompensated cirrhosis (Child-Pugh B or C):** 24 weeks in combination with ribavirin

Chronic HCV Genotype 1, Pediatric (3 to 17 years of age):

1. **Treatment-naïve without cirrhosis or with compensated cirrhosis:** 12 weeks
2. **Treatment-experienced* without cirrhosis:** 12 weeks
3. **Treatment-experienced* with compensated cirrhosis (Child-Pugh A):** 24 weeks

Chronic Hepatitis C Virus (HCV) Genotype 4, 5, or 6:

1. **Treatment-naïve or treatment-experienced* without cirrhosis or with compensated cirrhosis:** 12 weeks
2. **Treatment- naïve or treatment-experienced* with decompensated cirrhosis (Child-Pugh B or C):** 12 weeks in combination with ribavirin or 24 weeks if ribavirin ineligible
3. **Prior sofosbuvir-containing treatment failure, with decompensated cirrhosis (Child-Pugh B or C):** 24 weeks in combination with ribavirin

Recurrent Hepatitis C Virus (HCV) Post-Liver Transplantation, Genotypes 1 or 4 (age 3 or older):

1. **Treatment-naïve or treatment-experienced* without cirrhosis or with compensated cirrhosis (Child-Pugh A):** 12 weeks
2. **Treatment-naïve with decompensated cirrhosis (Child-Pugh B or C):** 12 weeks in combination with ribavirin
3. **Treatment-experienced* with decompensated cirrhosis (Child-Pugh B or C):** 24 weeks in combination with ribavirin

Recurrent Hepatitis C Virus (HCV) Post-Liver Transplantation, Genotypes 5 or 6 (age 18 or older):

1. **Treatment-naïve or treatment-experienced* without cirrhosis or with compensated cirrhosis (Child-Pugh A):** 12 weeks
2. **Treatment-naïve with decompensated cirrhosis (Child-Pugh B or C):** 12 weeks in combination with ribavirin
3. **Treatment-experienced* with decompensated cirrhosis (Child-Pugh B or C):** 24 weeks in combination with ribavirin

Hepatitis C Virus (HCV) Kidney Transplant Recipients, Genotype 1, 4, 5, or 6: 12 weeks

*Treatment-experienced individuals are those who have failed treatment with either peginterferon alfa + ribavirin or a hepatitis C virus protease inhibitor [for example, boceprevir (Victrelis), simeprevir (Olysio), or telaprevir (Incivek/Incivo)] + peginterferon + ribavirin.

Reauthorization approval duration: not applicable

Conditions Not Covered

Any other use is considered experimental, investigational or unproven including the following (this list may not be all inclusive):

1. **Hepatitis C Virus (HCV) [any genotype], Combination with Any Other Direct-Acting Antivirals (DAAs) Not Including Ribavirin.** Ledipasvir/sofosbuvir (Harvoni) provides a complete antiviral regimen for individuals with genotype 1 HCV. Ledipasvir/sofosbuvir (Harvoni) is not recommended to be used with other products containing sofosbuvir.

2. **Life Expectancy Less Than 12 Months Due to Non-Liver Related Comorbidities.** Individuals with limited life expectancy for whom HCV therapy would not improve symptoms or prognosis do not require treatment.[2] According to AASLD guidance, the panel recommends treatment for all individuals with chronic HCV infection, except those with short life expectancies that cannot be remediated by treating HCV, by transplantation, or by other directed therapy. For these individuals, the benefits of HCV treatment are unlikely to be realized, and palliative care strategies should take precedence.

3. **Pediatric Individuals (Age less than 3 years).** The safety and efficacy of ledipasvir/sofosbuvir (Harvoni) have not been established in pediatric individuals less than 3 years of age.[1]

4. **Retreatment with Ledipasvir/Sofosbuvir (Harvoni) in Individuals Who Have Previously Received Ledipasvir/Sofosbuvir (e.g., retreatment in prior null responders, prior partial responders, prior relapse individuals, individuals who have not completed a course of therapy due to an adverse reaction or for other reasons).** There are other direct-acting antivirals indicated for individuals who have previously been treated with ledipasvir/sofosbuvir (Harvoni).

Background

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. It is indicated for the treatment of **chronic HCV** in patients ≥ 3 years of age in the following instances:[1]

- 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 taken orally once daily with or without food.[1] The recommended dose of ledipasvir/sofosbuvir tablets or pellets in pediatric patients ≥ 3 years of age is based on weight. 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. The ledipasvir/sofosbuvir authorized generic is only available as the 90 mg/400 mg strength tablet; ledipasvir/sofosbuvir is additionally available as a lower strength tablet (45 mg/200 mg) as well as oral pellets (45 mg/200 mg and 33.75 mg/150 mg).

Table 1. Recommended Treatment Duration for ledipasvir/sofosbuvir in Patients ≥ 3 Years of Age with Chronic HCV Genotype 1, 4, 5, or 6.[1]

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†
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/sofosbuvir12 weeks

Hepatitis C virus – Hepatitis C virus; * Harvoni for 8 weeks can be considered in treatment-naïve patients without cirrhosis who have pretreatment HCV 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; † Harvoni for 12 weeks can be considered in treatment-experienced patients with cirrhosis who are eligible for ribavirin. The daily dose of ribavirin is weight-based (1,000 mg for patients < 75 kg and 1,200 mg for those ≥ 75 kg) administered in two divided doses. ‡ In patients with decompensated cirrhosis, the starting dosage of ribavirin is 600 mg and can be titrated up to 1,000 mg for patients <75 kg and 1,200 mg for those ≥75 kg in two divided doses with food. If the starting dosage of ribavirin is not well tolerated, the dosage should be reduced as clinically indicated based on hemoglobin levels. § The daily dosage of ribavirin is weight-based (1,000 mg for patients < 75 kg and 1,200 mg for those ≥ 75 kg) administered orally in two divided doses with food.

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 (October 2022).[2] 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 [generics] 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. For the most up-to-date information always refer to the guidelines.

Ledipasvir/sofosbuvir continues to be recommended in various situations as outlined below in Table 2.

Table 2. AASLD Recommendations for Harvoni.[2]

DAA	Duration	FDA Approved (Y/N)	AASLD Level of Evidence
Genotype 1, 4, 5, and 6 Chronic HCV Treatment-Naïve Adults – Recommended			
ledipasvir/sofosbuvir	12 weeks (± compensated cirrhosis)	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)	Y	Class I, Level B
Genotype 1, 4, 5, or 6 Chronic HCV, Decompensated Cirrhosis Adults Ribavirin Eligible – Recommended			
ledipasvir/sofosbuvir + ribavirin	12 weeks	Y	Class I, Level A
Genotype 1, 4, 5, or 6 Chronic HCV, Decompensated Cirrhosis Adults Ribavirin Ineligible – Recommended			
ledipasvir/sofosbuvir	24 weeks	N	Class I, Level A
Genotype 1, 4, 5, or 6 Chronic HCV, Decompensated Cirrhosis Adults Prior Sovaldi-Based Failure Only – Recommended			
ledipasvir/sofosbuvir + ribavirin	24 weeks	N	Class II, Level C
Genotype 1, 4, 5, or 6 Recurrent HCV Post-Liver Transplant, No Cirrhosis, Treatment-Naïve or Treatment-Experienced – Recommended			
ledipasvir/sofosbuvir	12 weeks	Y	Class I, Level B
Genotype 1, 4, 5, or 6 Recurrent HCV Post-Liver Transplant, Compensated Cirrhosis, Treatment-Naïve or Treatment-Experienced – Recommended			
ledipasvir/sofosbuvir	12 weeks	Y	Class I, Level A
Genotype 1, 4, 5, or 6 Recurrent HCV Post-Liver Transplant, Decompensated Cirrhosis, Treatment-Naïve or Treatment-Experienced – Recommended			
ledipasvir/sofosbuvir + ribavirin	12 to 24 weeks	Y	Class I, Level B
Genotype 1, 4, 5, or 6 Kidney Transplant Treatment-Naïve or DAA-Experienced ± Compensated Cirrhosis, Adults – Recommended			
ledipasvir/sofosbuvir	12 weeks	N	Class I, Level A
Genotype 1, 4, 5, or 6 Treatment-Naïve Adolescents ≥ 3 years, ± Compensated Cirrhosis – Recommended			
ledipasvir/sofosbuvir	12 weeks	Y	Class I, Level C

Table 2 (continued). AASLD Recommendations for Harvoni.[2]

DAA	Duration	FDA Approved (Y/N)	AASLD Level of Evidence
Genotype 1, 4, 5, or 6 Treatment-Experienced Adolescents ≥ 3 years, ± Compensated Cirrhosis – Recommended			
ledipasvir/sofosbuvir	24 weeks (GT1 compensated cirrhosis)	Y	Class I, Level C
ledipasvir/sofosbuvir	12 weeks (GT 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.

References

1. Harvoni® tablets and oral pellets [prescribing information]. Foster City, CA: Gilead; March 2020.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Testing, managing, and treating hepatitis C. Updated October 24, 2022. Available at: http://www.hcvguidelines.org. Accessed on November 2, 2022.