New York State Medicaid Preferred Drug Program Fax Number: (800) 268-2990

Harvoni® Prior Authorization Worksheet

| Enrollee Information | | |
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| enrollee Name: | | |
| enrollee medicaid Id number (2 letters, 5 numbers, 1 letter): | enrollee date of birth: | gender:  Female  Male |

| Prescriber Information | | |
| --- | --- | --- |
| prescriber Name: | | |
| Contact person: | | |
| 10-digit Npi number: | office Phone Number:  (     )      - | office Fax number:  (     )     - |
| Are you a gastroenterologist, hepatologist, transplant physician or infectious disease specialist?  Yes  No | | |
| If no, are you working in collaboration with a specialist listed above?  Yes  No | | |
| If no, do you have clinical experience with the management and treatment of hepatitis c virus (HCV) infection?  Yes  No  *Clinical experience is defined as the management AND treatment of at least 10 patients with HCV infection within the past 12 months and at least 10 HCV-related CME credits in the last 12 months.* | | |

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| Clinical Criteria |
| MEDICAL STATUS |
| Diagnosis  Chronic Hepatitis C Infection  HCV Genotype:  1A  1B  4  5  6  Has documentation confirming genotype been submitted?  Yes  No  Has the patient had a baseline quantitative HCV RNA level completed?  Yes  No  Baseline quantitative HCV RNA:       IU/ml Date completed:  Does the member have cirrhosis?  Yes No  If yes, please indicate Child- -Pugh class  A  B  C  **OR**  METAVIR fibrosis score  1  2  3  4  (evaluation of liver fibrosis is recommended for all patients with HCV to assist in determining the HCV treatment strategy.)  Does the patient have severe renal impairment (estimated glomerular filtration rate  [eGFR] <30 mL/min/1.73 m2) or end stage renal disease (ESRD)?  Yes  No  *(sofosbuvir is not recommended in patients with severe renal impairment or ESRD)*  Was screening for evidence of current or prior Hepatitis B virus (HBV) infection completed?  Yes  No  *Health care professionals should screen all patients for evidence of current or prior HBV infection before starting treatment with DAAs, and monitor patients using blood tests for HBV flare-ups or reactivation during treatment and post-treatment follow-up*   |  | | --- | | PREGNANCY |   For female patients of child bearing potential: Has a negative pregnancy test been collected  within 30 days prior to initiation of therapy OR medical record submitted documenting pregnancy status? Yes  No |
| TREATMENT HISTORY |
| |  |  | | --- | --- | | Was the current Harvoni regimen initiated at another healthcare facility or previously  covered by another health plan?  Yes  No  IF YES, how many weeks of previous therapy have been completed prior to the date of this request?  Please check the box that best describes the patient’s HCV treatment status: | | | Treatment-naïve  Yes  No  Treatment-experienced  Yes  No  If treatment experienced, is the patient non-responder to:  pegylated interferon + ribavirin  Yes  No  sofosbuvir + ribavirin  Yes  No  pegylated interferon + ribavirin + HCV protease inhibitor (telaprevir, boceprevir or simeprevir)  Yes  No  Other: | |

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| **TREATMENT READINESS** | | | |
| Please indicate which of the following scales/assessment tools was used to evaluate the readiness of the patient (only one is required):  SAMHSA-HRSA Center for Integrated Health Solutions – Drug & Alcohol Screening Tools – Available at: <http://www.integration.samhsa.gov/clinical-practice/screening-tools>  If checked, please provide the name of SAMSHA-HRSA drug and alcohol screening tool used (required):  Psychosocial Readiness Evaluation and Preparation for Hepatitis C Treatment (PREP-C) – Available at: [www.prepc.org](http://www.prepc.org)  Has the patient demonstrated treatment readiness, including the ability to adhere to the  prescribed treatment regimen?  Yes  No | | | |
| **CONTINUATION OF THERAPY REQUESTS *\*\*This portion is not required for initial therapy requests*** | | | |
| Week 4 ( ±2 weeks) HCV RNA Level: |  | Date Taken: |  |
| Week 12 ( ±2 weeks) HCV RNA Level: |  | Date Taken: |  |
| Has documentation confirming HCV RNA levels at the appropriate week been submitted?  Yes  No | | | |
| Has the patient completed all HCV evaluation appointments and procedures and demonstrated compliance to their treatment regimen?  Yes  No | | | |

| **CURRENT TREATMENT REGIMEN** |
| --- |
| **Please indicate the Harvoni treatment regimen that is being prescribed:**   |  |  |  |  |  | | --- | --- | --- | --- | --- | |  | **Genotype(s)** | **Patient Population** | **Treatment Regimen** | **Length of Authorization** | |  | 1 | Treatment-naïve **without** cirrhosis with baseline HCV RNA level  < 6 million IU/mL | Harvoni | 8 weeks\* | |  | Treatment-naïve **without** cirrhosis or with compensated cirrhosis (Child-Pugh A) | Harvoni | 12 weeks^ | |  | Treatment-experienced\*\* **without** cirrhosis | Harvoni | 12 weeks^ | |  | Treatment-experienced\*\* **with compensated** cirrhosis (Child-Pugh A) | Harvoni | 24 weeks†^ | |  | Treatment-naive and treatment-experienced\*\* with decompensated cirrhosis (Child-Pugh B or C) | Harvoni + ribavirin (RBV)± | 12 weeks | |  | 1, 4 | Treatment-naïve and treatment-experienced\*\* liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A) | Harvoni + RBV# | 12 weeks | |  | 4, 5, 6 | Treatment**-**naïve and treatment-experienced\*\* **without** cirrhosis or with compensated cirrhosis (Child-Pugh A) | Harvoni | 12 weeks^ |   \*Harvoni for 8 weeks can be considered in treatment-naïve patients with genotype 1 infection without cirrhosis with baseline HCV RNA < 6 million IU/mL  ^ Recommended treatment regimen and duration for pediatric patients who are ≥ 12 years of age or weigh ≥ 35 kg.  \*\* Treatment-experienced includes patients who have failed a peginterferon alfa + ribavirin regimen with or without an HCV protease inhibitor.  †Harvoni + RBV regimen for 12 weeks may be considered in treatment-experienced patients with genotype 1 infection with cirrhosis who are eligible to receive RBV.  ± In patients with decompensated cirrhosis, the starting dose for RBV is 600 mg which can be titrated up to 1000 mg for patients <75 kg and 1200 mg for those ≥ 75 kg in 2 divided doses with food.  # The daily RBV dose is 1000 mg for patients < 75 kg and 1200 mg for patients ≥ 75 kg, administered in 2 divided doses with food.  Patients with HCV/HIV-1 co-infection should follow the recommendations in the table above.  Please provide dosing information for the treatment regimen selected above:  Harvoni DIRECTIONS: 1 TABLET DAILY WITH OR WITHOUT FOOD QUANTITY:       REFILLS:  Ribavirin  Other Ribavirin Product STRENGTH:       DIRECTIONS:       QUANTITY:       REFILLS: |

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| **Please answer the following questions if requesting a non-preferred ribavirin product as part of treatment:** | | |
| Patient has experienced a treatment failure with a preferred drug. | | Yes  No |
| Patient has experienced an adverse drug reaction with a preferred drug. | | Yes  No |
| There is a documented history of successful therapeutic control with a non-preferred drug and transition to a preferred drug is medically contraindicated. | | Yes  No |
|  | Other (Please specify the clinical reason the patient is unable to use a preferred agent in the same drug class. If necessary, fax additional pages): | |
|  |  | |
| **Please provide any additional information that should be considered in the space below:** | | | |

I attest that this is medically necessary for this patient and that all of the information on this form is accurate to the best of my knowledge. I attest that documentation of the above diagnosis and medical necessity is available for review if requested by New York Medicaid.

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| Prescriber’s signature |  | date |

**Ledipasvir/Sofosbuvir (Harvoni™)**

Ledipasvir/sofosbuvir was the first combination pill approved for treatment of chronic hepatitis C virus (HCV) genotype (GT) 1, 4, 5, and 6 infection, in patients who are treatment naïve or experienced.1 For adult patients with GT1 infection the product is indicated for patients without cirrhosis or with compensated (Child-Pugh A) or decompensated (Child-Pugh B or C) cirrhosis and for GT 4, 5, and 6 infections it is indicated for patients without cirrhosis or with compensated cirrhosis (Child-Pugh A). Ledipasvir/sofosbuvir was approved by the Food and Drug Administration (FDA) in October 2014 for adult patients. In April 2017, the product received FDA approval for pediatric patients aged ≥12 years or weighing ≥35 kg, with genotype 1, 4, 5, and 6, without cirrhosis or with compensated cirrhosis (Child-Pugh A). Specific criteria are outlined below (see Advantages).

Both ledipasvir and sofosbuvir are direct-acting antiviral (DAA) agents against HCV, and they are supplied in a fixed-dose combination which may be taken with or without ribavirin (RBV).1 Sofosbuvir is a nucleotide analog that interferes with the HCV life cycle by inhibiting HCV NS5B ribonucleic acid (RNA)-dependent RNA polymerase to prevent replication of the HCV virus. In contrast, ledipasvir inhibits NS5A and interferes with viral replication.

**Advantages of ledipasvir/sofosbuvir**

Ledipasvir/sofosbuvir should be administered orally once daily, with or without RBV, in adult patients.1 For pediatric patients aged ≥12 years or weighing ≥35 kg, ledipasvir/sofosbuvir should be administered orally once daily, without RBV. The treatment duration depends on prior treatment experience and the presence or absence of cirrhosis. FDA-approved uses of ledipasvir/sofosbuvir are outlined in the table below. Treatment experienced for adult patients is defined as history of failed treatment with either pegylated interferon plus RBV or pegylated interferon plus RBV plus an HCV protease inhibitor. Treatment experienced for pediatric patients is defined as history of failed treatment on an interferon-based regimen with or without RBV. Clinical trials have demonstrated the efficacy of ledipasvir/sofosbuvir in both adult and pediatric patients with HCV genotype 1, 4, 5, or 6 infection. The primary endpoint for the clinical trials was defined as HCV RNA less than the lower level of quantification (<25 IU/mL) at 12-weeks post-treatment (SVR12).

**FDA-approved uses of ledipasvir/sofosbuvir:**

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| --- | --- | --- | --- | --- |
| **Patient Group** | **HCV Genotype** | **Presence of Cirrhosis** | **Co-infection** | **HCV Treatment Status** |
| Adult (≥18 years) | 1 | Without cirrhosis or with compensated cirrhosis (Child-Pugh A) or decompensated cirrhosis (Child-Pugh B or C) | With or without HIV-1 | Naïve or experienced |
| 1 or 4 | Post-liver transplant, without cirrhosis, or with compensated cirrhosis (Child-Pugh A) |
| 4, 5, or 6 | Without cirrhosis or with compensated cirrhosis (Child-Pugh A) |
| Pediatric (12-17 years or weight ≥35 kg) | 1 | Without cirrhosis or with compensated cirrhosis (Child-Pugh A) | With or without HIV-1 | Naïve or experienced |
| 4, 5, or 6 | Without cirrhosis or with compensated cirrhosis (Child-Pugh A) |

HIV= human immunodeficiency virus

**Cautions1**

* Prior to initiating therapy with any HCV DAA agent, all patients should be tested for evidence of current or prior hepatitis B virus (HBV) infection by measuring hepatitis B surface antigen (HBsAg), hepatitis B surface antibody (anti-HBs) and hepatitis B core antibody (anti-HBc). In patients with serologic evidence of HBV infection, monitor for clinical and laboratory signs of hepatitis flare or HBV reactivation during treatment with a DAA agent and during post-treatment follow-up.
* Coadministration of ledipasvir/sofosbuvir with amiodarone is not recommended due to risk of serious symptomatic bradycardia.
* Ledipasvir/sofosbuvir should not be used with other products that contain sofosbuvir.
* Ledipasvir is an inducer of P-glycoprotein (P-gp) and breast cancer resistance protein (BCRP). In addition, ledipasvir and sofosbuvir are substrates of P-gp and BCRP. Do not coadminister ledipasvir/sofosbuvir with potent P-gp inducers due to risk of reduced ledipasvir/sofosbuvir concentrations and therapeutic effect.
* For patients with severe renal impairment (estimated glomerular filtration rate [eGFR] <30 mL/min/1.73m2), or end stage renal disease, no dose recommendations are available.
* No adequate human data are available to establish whether or not ledipasvir/sofosbuvir poses a risk to pregnancy outcomes. When given in combination with RBV, the combination is contraindicated in pregnant women due to teratogenicity of RBV.

**Where does ledipasvir/sofosbuvir fit into therapy and how should it be used?**

In January 2014, the American Association for the Study of Liver Diseases and Infectious Diseases Society of America, in collaboration with the International Antiviral Society – USA, launched [www.hcvguidelines.org](http://www.hcvguidelines.org) for the purpose of disseminating expert opinion on management of chronic HCV. The guidelines have continued to evolve as new clinical information and agents have become available. Patient-specific factors, such as treatment experience, presence of cirrhosis, and other comorbid conditions, must be taken into consideration when deciding to initiate DAA therapy. Ledipasvir/sofosbuvir is dosed once daily and is indicated for both adult and pediatric patients. Specific ledipasvir/sofosbuvir dosing information is available in the below table. The goal of treatment is to achieve a HCV RNA less than the lower level of quantification (<25 IU/mL) at 12-weeks post-treatment (SVR12).

**Ledipasvir/Sofosbuvir Treatment Regimen and Duration Recommendations**

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| --- | --- | --- | --- |
| **Genotype** | **Population** | **Adult Regimen and Duration** | **Pediatric Regimen and Duration\*** |
| Genotype 1 | Treatment-naïve without cirrhosis or compensated cirrhosis (Child-Pugh A)\*\* | 12 weeks | 12 weeks |
| Treatment- experienced without cirrhosis | 12 weeks | 12 weeks |
| Treatment-experienced with compensated cirrhosis (Child-Pugh A) | 24 weeks | 24 weeks |
| Treatment-naïve and treatment-experienced with decompensated cirrhosis (Child- Pugh B or C) | 12 weeks + RBV | Not indicated |
| Genotype 1 or 4 | Treatment-naïve and treatment-experienced liver transplant recipients without cirrhosis, or with compensated cirrhosis (Child-Pugh A) | 12 weeks + RBV | Not indicated |
| Genotype 4, 5, or 6 | Treatment-naïve and treatment-experienced without cirrhosis or with compensated cirrhosis (Child-Pugh A) | 12 weeks | 12 weeks |

RBV= ribavirin

\*Recommended treatment regimen and duration for pediatric patients who are aged ≥12 years or weigh ≥35 kg.

\*\* Treatment experienced for adult patients is defined as history of failed treatment with either pegylated interferon plus RBV or pegylated interferon plus RBV plus an HCV protease inhibitor. Treatment experienced for pediatric patients is defined as history of failed treatment with an interferon-based regimen with or without RBV.

**Notes:**

* Ledipasvir/sofosbuvir for 8 weeks can be considered in treatment-naïve GT 1 adult patients without cirrhosis who have pre-treatment HCV RNA < 6 million IU/ml
* For CHC/HIV co-infected adult or pediatric patients who are aged ≥12 years or weigh ≥35 kg follow the above dosing recommendations

**References:** **1.** Harvoni™ prescribing information. Gilead Sciences, 2017. **2.** Afdhal N, et al. N Engl J Med. 2014;370:1889-98. **3.** Afdhal N, et al. N Engl J Med. 2014;370:1483-93. **4.** Kowdley, K, et al. N Engl J Med. 2014; 370:1879-88. **5**. Naggie S, et al. N Engl J Med. 2015; 373: 705-13.

**Ledipasvir/Sofosbuvir Initiation and Monitoring**

Once patient readiness for chronic hepatitis C virus (HCV) treatment has been determined, the algorithm below outlines key decision points for initiating and monitoring combination therapy including sofosbuvir. Prior to initiating HCV DAA therapy, test for evidence of HBV infection by measuring HBsAg, anti-HBs, and anti-HBc.

*Note: Ribavirin is contraindicated in pregnancy therefore all female patients of childbearing age (or female partners of male patients) should be sure they are not pregnant prior to beginning treatment and should use 2 methods of non-hormonal birth control throughout treatment. Also note, HCV RNA testing should be conducted using a sensitive assay.*

LVD/SOF for 12 weeks

Yes

Genotype 4, 5 or 6

No

Has the patient been diagnosed with HCV genotype 1 and received quantitative HCV RNA testing?

Yes

No

No

Yes

Is the patient treatment-naïve?

Begin treatment with LVD/SOF for **12 weeks**

Is the patient treatment-naïve?

Does the patient have cirrhosis?

Can consider treatment with LVD/SOF for **8 weeks for adults only**

Yes

Does the patient have pre-treatment HCV RNA <6 million IU/mL?

Yes

Compensated Cirrhosis (Child-Pugh A): LVD/SOF for 24 weeks

Decompensated cirrhosis (Child-Pugh B or C): LVD/ SOF with RBV for 12 weeks

\*LVD/SOF = ledipasvir/sofosbuvir; RBV = ribavirin

For genotype 1 or 4, adult patient who are treatment-naïve or treatment-experienced liver transplant recipients without cirrhosis or with compensated cirrhosis (Child-Pugh A) give LVD/ SOF with RBV for 12 weeks.

Yes

No

Obtain HCV RNA level 12 weeks after the end of treatment to determine sustained virological response (SVR 12)

No