**Note**: Processing may be delayed if information submitted is illegible or incomplete.

# ENROLLEE INFORMATION

**Enrollee’s Last Name: Enrollee’s First Name:**

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**Date of Birth: Enrollee’s Medicaid ID (2 letters, 5 numbers, 1 letter):**

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**Gender:** MaleFemale

# PRESCRIBER INFORMATION

**Prescriber’s Last Name: Prescriber’s First Name:**

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**Contact Person:**

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**National Provider Identifier (NPI) Number:**

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**Office Phone Number: Office Fax Number:**

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**Enrollee’s Last Name: Enrollee’s First Name:**

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# REQUESTED DRUG(S) INFORMATION

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **PREFERRED TREATMENT REGIMENS – PLEASE SELECT ONE** | | | | | |
|  | **Treatment Regimen** | **HCV Genotype** | **Treatment Experience** | **Presence of Cirrhosis (if applicable)** | **Treatment Duration** |
|  | Mavyret® | 1,2,3,4,5,6 | Treatment-naïve | Without cirrhosis or with compensated cirrhosis (CTP A) | 8 weeks |
|  | Mavyret® | 1 | Previously treated with NS5A inhibitor without an NS3/4A PI | Without cirrhosis or with compensated cirrhosis (CTP A) | 16 weeks |
|  | Mavyret® | 1 | Previously treated with NS3/4A PI without an NS5A inhibitor | Without cirrhosis or with compensated cirrhosis (CTP A) | 12 weeks |
|  | Mavyret® | 1,2,4,5,6 | Previously treated with pegylated interferon, RBV, and/or sofosbuvir | Without cirrhosis | 8 weeks |
|  | Mavyret® | 1,2,4,5,6 | Previously treated with pegylated interferon, RBV, and/or sofosbuvir | With compensated cirrhosis (CTP A) | 12 weeks |
|  | Mavyret® | 3 | Previously treated with pegylated interferon, RBV, and/or sofosbuvir | Without cirrhosis or with compensated cirrhosis (CTP A) | 16 weeks |
|  | Vosevi® | 1,2,3,4,5,6 | Previously treated with an NS5A inhibitor | Without cirrhosis or with compensated cirrhosis (CTP A) | 12 weeks |
|  | Vosevi® | 1a, 3 | Previously treated with sofosbuvir without an NS5A inhibitor | Without cirrhosis or with compensated cirrhosis (CTP A) | 12 weeks |
|  | sofosbuvir /velpatasvir | 1,2,3,4,5,6 | Treatment-naïve and -experienced | Without cirrhosis or with compensated cirrhosis (CTP A) | 12 weeks |
|  | sofosbuvir /velpatasvir + RBV | 1,2,3,4,5,6 | Treatment-naïve and -experienced | With decompensated cirrhosis (CTP B and C) | 12 weeks |
| **NON-PREFERRED REGIMEN (REQUESTED TREATMENT DURATION MUST BE INDICATED BELOW)** | | | | | |
|  | **Treatment Regimen** | **HCV Genotype** | **Treatment Experience** | **Presence of Cirrhosis (if applicable)** | **Treatment Duration** |
|  |  |  |  |  |  |

NS5A= nonstructural protein 5A, NS3/4A= nonstructural protein 3/4A, PI= protease inhibitor, RBV= ribavirin

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**Enrollee’s Last Name: Enrollee’s First Name:**

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# REQUESTED DRUG(S) INFORMATION (*CONTINUED*)

**Drug #1:**

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Strength: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dosage form: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Directions: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Quantity: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Refills: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Total weeks of therapy: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Drug #2 (if applicable):**

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Strength: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Dosage form: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Quantity: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Refills: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Total weeks of therapy: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Please answer the following if requesting a non-preferred ribavirin product as part of treatment.

1. Has the patient experienced a treatment failure with a preferred ribavirin product?

Yes  No

1. Has the patient experienced an adverse drug reaction with a preferred ribavirin product?

Yes  No

1. Does the patient have a documented history of successful therapeutic control with a non-preferred ribavirin and transition to a preferred drug is medically contraindicated?

Yes  No

1. Other – Please specify the clinical reason the patient is unable to use a preferred ribavirin:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Enrollee’s Last Name: Enrollee’s First Name:**

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# Clinical Criteria

1. Does the patient have Chronic Hepatitis C (CHC) infection?

Yes  No

If no, specify diagnosis: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Provide clinical rationale for the off-label use and include clinical literature supporting use for this indication:

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1. What is the patient’s hepatitis C genotype?

1a  1b  2  3  4  5  6

1. Has the patient had a baseline quantitative HCV RNA level completed?

Yes  No

Baseline quantitative HCV RNA (IU/ML): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. What is the patient’s cirrhosis status?

No cirrhosis

Compensated cirrhosis (CTP A)

Decompensated cirrhosis (CTP B or C)

1. Was screening for evidence of current or prior hepatitis B virus (HBV) infection completed?

Yes  No

*(Form continued on next page.)*

**Enrollee’s Last Name: Enrollee’s First Name:**

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# CLINICAL CRITERIA (*CONTINUED*)

## For Sovaldi® requests ONLY:

1. Has the patient been diagnosed with hepatocellular carcinoma awaiting liver transplantation?

Yes  No

## Treatment history:

1. Was the current treatment regimen initiated at another healthcare facility or previously covered by another health plan?

Yes  No

1. If **YES**, how many weeks of previous therapy have been completed prior to the date of this request?

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Has the patient been treated previously for Hepatitis C?

Yes (treatment-experienced)  No (treatment-naïve)

1. If treatment-experienced, provide previous treatment regimen/outcome:

Regimen: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Outcome: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

## Treatment readiness:

1. 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: <https://www.drugabuse.gov/nidamed-medical-health-professionals/screening-tools-resources/chart-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: <https://prepc.org/>

Other assessment tool: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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**Enrollee’s Last Name: Enrollee’s First Name:**

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# CLINICAL CRITERIA (*CONTINUED*)

1. Has the patient demonstrated treatment readiness, including the ability to adhere to the prescribed treatment regimen?

Yes  No

**Retreatment/Reinfection**:

1. Did the patient achieve a sustained virological response (SVR)  at week 12 or longer following the completion of their last hepatitis C direct-acting antiviral regimen?

Yes  No

## Harvoni® (ledipasvir/sofosbuvir) and Zepatier® (elbasvir/ grazoprevir) requests for genotype 1a and Epclusa® (sofosbuvir/velpatasvir) requests for genotype 3 ONLY:

1. Has NS5A resistance-associated substitution (RAS) testing been completed?

Yes  No

If **No**, please provide rationale for not completing the test:

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

1. Did the RAS testing show resistance to the medication being requested?

Yes  No

If **Yes**, please consider an alternative regimen.

|  |  |  |
| --- | --- | --- |
| Prescriber Signature (Required) |  | Date |
| *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.* | | |

**Fax Number:** 1-800-268-2990

**Billing Questions:** 1-800-343-9000

For clinical concerns or Preferred Drug Program questions, please visit <http://newyork.fhsc.com> or call 1-877-309-9493.

**Direct Acting Antiviral (DAA) Agents for the Treatment of Chronic Hepatitis C Infection**

**Food and Drug Administration (FDA) Product Information**

**New York State Fee-for-Service Medicaid Preferred HCV DAA Agents**

* *Prior to the initiation of HCV treatment all patients should be tested for evidence of current or prior HBV infection by measuring hepatitis B surface antigen (HBsAg) and hepatitis B core antibody (anti-HBc)*

**Table 1: Preferred Agents Dosing Recommendations1-3**

|  |  |
| --- | --- |
| HCV DAA Agent | Dosing Recommendations |
| Mavyret®  (glecaprevir 100 mg/pibrentasvir 40 mg)  [GLE/PIB] | 3 tablets daily with food |
| sofosbuvir 400 mg/velpatasvir 100 mg  (authorized generic product for Epclusa®)  [SOF/VEL] | 1 tablet daily with or without food |
| Vosevi®  (sofosbuvir 400 mg/velpatasvir 100 mg/voxilaprevir 100 mg)  [SOF/VEL/VOX] | 1 tablet daily with food |

DAA= direct acting antiviral, HCV= hepatitis C virus

**Table 2: Preferred Agents Treatment Naïve Regimens1-2**

|  |  |  |  |
| --- | --- | --- | --- |
| TREATMENT-NAIVE | | | |
| HCV GENOTYPE 1, 2, 3, 4, 5, OR 6 | | | |
| Preferred HCV DAA | Duration | | |
| No Cirrhosis | Compensated Cirrhosis  (Child-Pugh A) | Moderate to Severe Hepatic Impairment (Child-Pugh B or C) |
| GLE/PIB | 8 weeks | 8 weeks | Contraindicated |
| SOF/VEL | 12 weeks | 12 weeks | 12 weeks with ribavirin [RBV] |

DAA= direct acting antiviral, GLE/PIB= glecaprevir/pibrentasvir [Mavyret®], HCV= hepatitis C virus, RBV= ribavirin, SOF/VEL= sofosbuvir/velpatasvir [Epclusa®]

**Table 3: Preferred Agents Treatment-Experienced Regimens1-3**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **TREATMENT-EXPERIENCED**  **Preferred Agents** | | | | | |
| GT | Previous Treatment Regimen | DAA AGENT | DURATION | | |
| Preferred Options | No Cirrhosis | Compensated Cirrhosis (Child-Pugh A) | Moderate to Severe Hepatic Impairment (Child-Pugh B or C) |
| 1 | NS5A inhibitor without prior treatment with an NS3/4A PI | GLE/PIB | 16 weeks | 16 weeks | Contraindicated |
| NS3/4A PI without prior treatment with an NS5A inhibitor | 12 weeks | 12 weeks |
| PEG+RBV and/ or SOF but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor | 8 weeks | 12 weeks |
| PEG+RBV with or without an HCV NS3/4A PI | SOF/VEL | 12 weeks | 12 weeks | 12 weeks with RBV |
| NS5A inhibitor | SOF/VEL/VOX | 12 weeks | 12 weeks | Not recommended |
| 1a ONLY: SOF without an NS5A inhibitor | 12 weeks | 12 weeks |
| 2, 4, 5, or 6 | PEG+RBV and/ or SOF but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor | GLE/PIB | 8 weeks | 12 weeks | Contraindicated |
| PEG+RBV with or without an HCV NS3/4A PI | SOF/VEL | 12 weeks | 12 weeks | 12 weeks with RBV |
| NS5A inhibitor | SOF/VEL/VOX | 12 weeks | 12 weeks | Not recommended |
| 3 | PEG+RBV and/ or SOF but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor | GLE/PIB | 16 weeks | 16 weeks | Contraindicated |
| PEG+RBV with or without an HCV NS3/4A PI | SOF/VEL | 12 weeks | 12 weeks | 12 weeks with RBV |
| An NS5A inhibitor | SOF/VEL/VOX | 12 weeks | 12 weeks | Not recommended |
| SOF without an NS5A inhibitor | 12 weeks | 12 weeks | Not recommended |

DAA= direct acting antiviral, GLE/PIB (glecaprevir/ pibrentasvir [Mavyret™], GT= genotype, HCV= hepatitis C virus, NS5A= nonstructural protein 5A, NS3/4A= nonstructural protein 3/4A, PEG= pegylated interferon, PI= protease inhibitor, RBV= ribavirin, SOF= sofosbuvir [Sovaldi®], SOF/VEL=sofosbuvir/ velpatasvir [Epclusa®], SOF/VEL/VOX=sofosbuvir/velpatasvir/voxilaprevir [Vosevi®]

**Table 3: Special Populations Recommendations1-3**

|  |  |  |  |
| --- | --- | --- | --- |
| Agent | Decompensated Cirrhosis | Liver Transplant Recipients or Kidney Transplant Recipients | Renal Disease  (mild, moderate, severe) |
| **Preferred Agents** | | | |
| GLE/PIB | Contraindicated | 12-weeks:  Treatment-naïve patients, ≥12 years of age or weighing ≥45 kg  16-weeks:  GT1 and previously treated with NS5A inhibitor without prior treatment with a NS3/4A PI  OR  GT3 and previously treated with PRS | No dosage adjustment is needed for mild moderate or severe renal impairment including those on dialysis |
| SOF/VEL | FDA-Approved | Safety not established | Not recommended in patients with severe (estimated glomerular filtration rate [eGFR] < 30 mL/min/1.73 m2) or end-stage renal disease |
| SOF/VEL/VOX ¥ | Not recommended | Safety not established | Not recommended in patients with severe (estimated glomerular filtration rate [eGFR] < 30 mL/min/1.73 m2) or end-stage renal disease |
| ¥Indicted for genotype 1-6 infections and previously treated with an HCV regimen containing an NS5A; Genotype 1a or 3 infection previously treated with an HCV regimen containing SOF without NS5A inhibitor | | | |

DAA= direct acting antiviral, HCV= hepatitis C virus, GLE/PIB= glecaprevir/pibrentasvir [Mavyret®], GT= genotype, HCV= hepatitis C virus, NS5A= nonstructural protein 5A, NS3/4A= nonstructural protein 3/4A, PI= protease inhibitor, PRS= prior treatment experience with (peg) interferon, ribavirin and/or sofosbuvir but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor, SOF/VEL= sofosbuvir/velpatasvir [Epclusa®], SOF/VEL/VOX=sofosbuvir/velpatasvir/voxilaprevir [Vosevi®]

**References:**

1. Mavyret® [product insert]. AbbVie, Inc.; 2019.
2. Epclusa® [product insert]. Gilead Sciences, Inc.; 2017.
3. Vosevi® [product insert]. Gilead Sciences, Inc.; 2017.