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Magellan Rx MANAGEMENT

NYRx the Medicaid Pharmacy Program

Hepatitis C Agents – Direct Acting Antivirals

Prior Authorization Worksheet

Fax Number: 1-800-268-2990

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

ENROLLEE INFORMATION

Enrollee's Last Name:

Enrollee's First Name:

Date of Birth:

Enrollee's Medicaid ID (2 letters, 5 numbers, 1 letter):

PRESCRIBER INFORMATION

Prescriber's Last Name:

Prescriber's First Name:

National Provider Identifier (NPI) Number:

Board Certified Specialty:

Prescriber's Street Address:

City:

State:

Zip Code

Prescriber's Phone Number:

Prescriber's Fax Number:

Enrollee's Last Name: **Enrollee's First Name:**

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

Enrollee's Last Name: **Enrollee's First Name:**

REQUESTED DRUG(S) INFORMATION *(CONTINUED)*

Drug #1:

Drug Name: _____ Drug Strength: _____

Dosage Form: _____ Quantity: _____ Refills: _____

Directions: _____

Total Weeks of Therapy: _____

Drug #2 (if applicable):

Drug Name: _____ Drug Strength: _____

Dosage Form: _____ Quantity: _____ Refills: _____

Directions: _____

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
2. Has the patient experienced an adverse drug reaction with a preferred ribavirin product?
   ☐ Yes ☐ No
3. 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
4. Other – Please specify the clinical reason the patient is unable to use a preferred ribavirin:

CLINICAL CRITERIA

5. 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:

6. What is the patient's hepatitis C genotype?
   ☐ 1a ☐ 1b ☐ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

Enrollee's Last Name: **Enrollee's First Name:**

CLINICAL CRITERIA *(CONTINUED)*

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

   ☐ Yes ☐ No Baseline quantitative HCV RNA (IU/ML): _____

8. What is the patient's cirrhosis status?

   ☐ No cirrhosis ☐ Compensated cirrhosis (CTP A) ☐ Decompensated cirrhosis (CTP B or C)

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

   ☐ Yes ☐ No

For Sovaldi® Requests ONLY:

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

    ☐ Yes ☐ No

Treatment History:

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

    ☐ Yes ☐ No

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

    _____

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

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

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

    Regimen: _____

    Outcome: _____

Treatment Readiness:

15. 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: _____

Enrollee's Last Name: **Enrollee's First Name:**

CLINICAL CRITERIA *(CONTINUED)*

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

☐ Yes ☐ No

Retreatment/Reinfection:

17. 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:

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

☐ Yes ☐ No

If **NO**, provide rationale for not completing test:

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

☐ Yes ☐ No If **YES**, please consider an alternative regimen.

Submission of this form confirms the information is accurate and true, and that the supporting documentation is available for review upon request of said plan, the NYSDOH or CMS. The submitter understands that any person who knowingly makes or causes to be made a false record to statement that is material to a Medicaid claim may be subject to civil penalties and treble damages under both federal and NYS False Claims Acts.

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 Recommendations[1–3]

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 Regimens[1–2]

Treatment-Naïve 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 Regimens[1–3]

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 =s ofosbuvir/ velpatasvir [Epclusa®], SOF/VEL/VOX = sofosbuvir/velpatasvir/voxilaprevir [Vosevi®]

Table 3: Special Populations Recommendations[1–3]

Preferred Agents			
Agent	**Decompensated Cirrhosis**	**Liver Transplant Recipients or Kidney Transplant Recipients**	**Renal Disease (mild, moderate, severe)**
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 m^2) 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 m^2) 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.