Generic Name: Glecaprevir/Pibrentasvir

Therapeutic Class or Brand Name: Mavyret™

Applicable Drugs (if Therapeutic Class): N/A.

GPI Code: 1235990235

Preferred: N/A.

Non-preferred: N/A.

Date of Origin: 10/16/2017

Date Last Reviewed / Revised: 7/22/2020

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met)

I. Documented diagnosis of chronic hepatitis C (CHC) genotypes 1, 2, 3, 4, 5, or 6 infection.

II. Documentation of patient's Hepatitis C treatment history and baseline viral load.

III. Documentation that patient's hepatitis C drug therapy is prescribed as outlined in the table under Authorization in the Approval Length section.

IV. Patient is at least 12 years old or weighs at least 45 kilograms.

V. Prescriber is a Gastroenterologist, Infectious Disease Specialist, or Hepatologist.

EXCLUSION CRITERIA

- As retreatment when there has been relapse after, or no response to, a prior treatment course with Mavyret™ (glecaprevir/pibrentasvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir), Vosevi® (sofosbuvir/velpatasvir/ voxilaprevir), or Zepatier™ (elbasvir/grazoprevir).
- Mavyret is not indicated for the treatment of patients with chronic HCV genotype 1 infection who have failed BOTH a regimen containing an HCV NS5A inhibitor and a regimen containing an NS3/4A protease inhibitor.
- Moderate or severe hepatic impairment (Child-Pugh B or C).
- Coadministration of Mavyret™ with any of the drugs listed in the table below:

• **Drug Class**	• **Drugs within class**
• Anticonvulsants	• Carbamazepine
• Antimycobacterials	• Rifampin
• Ethinyl Estradiol-Containing Products	• Ethinyl estradiol containing medications such as combined oral contraceptives
• Herbal Products	• St. John's Wort (*Hypericum perforatum*)
• HIV-Antiviral Agents	• Atazanavir, darunavir, efavirenz, lopinavir, ritonavir

• Drug Class	• Drugs within class
• HMG-CoA Reductase Inhibitors	• Atorvastatin, lovastatin, rosuvastatin (if > 10 mg/day), simvastatin
• Immunosuppressants	• Cyclosporine (if > 100 mg/day)
• Other NS5A inhibitors, protease inhibitors, or polymerase inhibitors used to treat chronic hepatitis C virus infection	• Daklinza™ (daclatasvir), Epclusa® (sofosbuvir/velpatasvir), Harvoni® (ledipasvir/ sofosbuvir), Olysio® (simeprevir), Sovaldi® (sofosbuvir), Technivie™ (ombitasvir, paritaprevir, and ritonavir), Viekira Pak™/XR™ (dasabuvir, ombitasvir, paritaprevir, ritonavir), Vosevi® (sofosbuvir/velpatasvir/voxilaprevir), Zepatier™ (elbasvir/grazoprevir)

OTHER CRITERIA

- N/A.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 84 tablets per 28 days.

APPROVAL LENGTH

- **Authorization:** See tables directly below:

Drug Therapy	Cirrhosis	G1a		G1b		G2	
		TN	TE	TN	TE	TN	TE
Mavyret™	No	8w	8w[12], 12w[14], 16w[13]	8w	8w[12], 12w[14], 16w[13]	8w	8w[12]
	No & Post Transplant^	12w	16w[13]	12w	16w[13]	12w	12w
	Comp	8w	12w[14], 16w[13]	8w	12w[14], 16w[13]	8w	12w[12]
	Comp & Post Transplant^	12w	16w[13]	12w	16w[13]	12w	12w

Drug Therapy	Cirrhosis	G3		G4		G5		G6	
		TN	TE	TN	TE	TN	TE	TN	TE
Mavyret™	No	8w	16w[12]	8w	8w[12]	8w	8w[12]	8w	8w[12]
	No & Post Transplant^	12w	16w[12]	12w	12w[13]	12w	12w	12w	12w
	Comp	8w	16w[12]	8w	12w[12]	8w	12w[12]	8w	12w[12]
	Comp & Post Transplant^	12w	16w[12]	12w	12w	12w	12w	12w	12w

TN = treatment naïve; TE = treatment experienced; Comp = compensated; RBV = ribavirin; w = weeks

[12]For patients who have failed PRS therapy (combination of pegIFN, RBV, and/or sofosbuvir) but no prior treatment experience with a NS3/4A protease inhibitor or NS5A inhibitor.

[13]For patients who have failed a regimen containing an NS5A inhibitor without prior treatment with a NS3/4A protease inhibitor.

[14]For patients who have failed a regiment containing a NS3/4A protease inhibitor without prior treatment with an NS5A inhibitor.

- **Re-Authorization:** N/A

APPENDIX

N/A

REFERENCES

1. http://www.rxabbvie.com/pdf/mavyret_pi.pdf .
2. http://hcvguidelines.org/full-report-vie .
3. Medi-Span®.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
7/22/2020	1. **Changed** treatment duration of treatment-naïve patients with compensated cirrhosis from 12 weeks to 8 weeks **under Approval Length.**
5/20/2019	1. **Changed** " Minimum age requirement: 18 years old." To "Patient is at least 12 years old or weighs at least 45 kilograms." To address new pediatric indication **under Prior Authorization Criteria.** 2. **Added** "Mavyret is not indicated for the treatment of patients with chronic HCV genotype 1 infection who have failed BOTH a regimen containing an HCV NS5A inhibitor and a regimen containing an NS3/4A protease inhibitor." **Under Exclusion Criteria.**

3. **Changed** table **under Approval Length** to reflect addition of footnotes 12-14 per updates to sections 2.2 and 2.3 of package insert (reference #1).

FROM:

Drug Therapy	Cirrhosis	G1a		G1b		G2	
		TN	TE	TN	TE	TN	TE
Mavyret™	No	8w	8w[1], 12w[4,9], 16w[8z]	8w	8w[1], 12w[4,9], 16w[8z]	8w	8w[1], 12w[2]
	No & Post Transplant^	12w^	12w^	12w^	12w^	12w^	12w^
	Comp	12w	12w[1,4,9], 16w[8z]	12w	12w[1,4,9], 16w[8z]	12w	12w[1,2]
	Comp & Post Transplant^	12w^	12w^	12w^	12w^	12w^	12w^

TN = treatment naïve; TE = treatment experienced; Comp = compensated; RBV = ribavirin; w = weeks
[z]Except in patients who have failed NS3/4 protease inhibitor inclusive direct-acting antiviral combination regimens.
^For patients who develop HCV infection post-liver transplantation.
[1]For patients who have failed pegIFN/RBV.
[2]For patients who have failed sofosbuvir + RBV.
[4]For patients who have failed a NS3 protease inhibitor + pegIFN/RBV.
[8]For patients who have failed a NS5A inhibitor.
[9]For patients who have failed a non-NS5A inhibitor, sofosbuvir-containing regimen.

Drug Therapy	Cirrhosis	G3		G4		G5		G6	
		TN	TE	TN	TE	TN	TE	TN	TE
Mavyret™	No	8w	16w[1]	8w	8w[1]	8w	8w[1]	8w	8w[1]
	No & Post Transplant^	12w^	12w^	12w^	12w^	12w^	12w^	12w^	12w^
	Comp	12w	16w[1]	12w	12w[1]	12w	12w[1]	12w	12w[1]
	Comp & Post Transplant^	12w^	12w^	12w^	12w^	12w^	12w^	12w^	12w^

TN = treatment naïve; TE = treatment experienced; Comp = compensated; RBV = ribavirin; w = weeks
[z]Except in patients who have failed NS3/4 protease inhibitor inclusive DAA combination regimens.
^For patients who develop HCV infection post-liver transplantation.
[1]For patients who have failed pegIFN/RBV.

TO:

Drug Therapy	Cirrhosis	G1a		G1b		G2	
		TN	TE	TN	TE	TN	TE
Mavyret™	No	8w	8w[12], 12w[14],	8w	8w[12], 12w[14],	8w	8w[12]

			16w[13]		16w[13]		
	No & Post Transplant^	12w	16w[13]	12w	16w[13]	12w	12w
	Comp	12w	12w[14], 16w[13]	12w	12w[14], 16w[13]	12w	12w[12]
	Comp & Post Transplant^	12w	16w[13]	12w	16w[13]	12w	12w

TN = treatment naïve; TE = treatment experienced; Comp = compensated; RBV = ribavirin; w = weeks
[12]For patients who have failed therapy with combination of pegIFN, RBV, and/or sofosbuvir (PRS) but no prior treatment experience with a NS3/4A protease inhibitor or NS5A inhibitor.
[13]For patients who have failed a regimen containing an NS5A inhibitor without prior treatment with a NS3/4A protease inhibitor.
[14]For patients who have failed a regiment containing a NS3/4A protease inhibitor without prior treatment with an NS5A inhibitor.

Drug Therapy	**Cirrhosis**	**G3**		**G4**		**G5**		**G6**	
		TN	**TE**	**TN**	**TE**	**TN**	**TE**	**TN**	**TE**
Mavyret™	No	8w	16w[12]	8w	8w[12]	8w	8w[12]	8w	8w[12]
	No & Post Transplant^	12w	16w[12]	12w	12w[13]	12w	12w	12w	12w
	Comp	12w	16w[12]	12w	12w[12]	12w	12w[12]	12w	12w[12]
	Comp & Post Transplant^	12w	16w[12]	12w	12w	12w	12w	12w	12w

TN = treatment naïve; TE = treatment experienced; Comp = compensated; RBV = ribavirin; w = weeks
12For patients who have failed therapy with combination of pegIFN, RBV, and/or sofosbuvir (PRS) but no prior treatment experience with a NS3/4A protease inhibitor or NS5A inhibitor.
13For patients who have failed a regimen containing an NS5A inhibitor without prior treatment with a NS3/4A protease inhibitor.
14For patients who have failed a regiment containing a NS3/4A protease inhibitor without prior treatment with an NS5A inhibitor.

12/9/2018	1. **Deleted** under Prior Authorization Criteria: 1. Documentation that patient meets ONE of the following criteria A, B, or C: A. Has a Metavir score of F3 (advanced fibrosis) or F4 (compensated cirrhosis). B. Is post-liver transplant. C. Has clinically severe extrahepatic manifestations of hepatitis C infection as evidenced by one of the following 1 or 2: **1.** Type 2 or 3 essential mixed cryoglobulinemia with end-organ manifestations (i.e. vasculitis). **2.** Proteinuria, nephrotic syndrome, or membranoproliferative glomerulonephritis.

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.