MEDICATION POLICY

Generic Name: Glecaprevir/Pibrentasvir

Therapeutic Class or Brand Name: Mavyret™

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

Date of Origin: 10/16/17 **Date Last Reviewed/Revised**: 4/6/2018

GPI Code: 1235990235

Prior Authorization Criteria (may be considered medically necessary when criteria I through VI are met):

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

II. 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.

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

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

V. Minimum age requirement: 18 years old.

VI. 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).
- Moderate or severe hepatic impairment (Child-Pugh B or C).
- Coadministration of Mavyret™ with any of the drugs listed in the table below:

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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
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 table directly below.

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^

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 judgment in providing the most appropriate care for their patients.

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Drug Therapy	Cirrhosis	G1a		G1b		G2	
		TN	TE	TN	TE	TN	TE

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.

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

Appendix:

N/A

References:

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

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Historical Tracking Of Changes Made To Policy	
4/6/2018	No changes