

## PHARMACY POLICY STATEMENT

### Georgia Medicaid

|   |   |
|---|---|
| DRUG NAME   | Mavyret (glecaprevir and pibrentasvir)  |
| BILLING CODE  | Must use valid NDC code   |
| BENEFIT TYPE  | Pharmacy  |
| SITE OF SERVICE ALLOWED                                     | Home  |
| COVERAGE REQUIREMENTS                                       | Prior Authorization Required (Preferred Product)<br>Alternative preferred product includes Epclusa<br>QUANTITY LIMIT— 84 tabs per 28 days |
| LIST OF DIAGNOSES CONSIDERED <b>NOT</b> MEDICALLY NECESSARY | <a href="#">Click Here</a>  |

Mavyret (glecaprevir and pibrentasvir) is a **preferred** product and will only be considered for coverage under the **pharmacy** benefit when the following criteria are met:

Members must be clinically diagnosed with one of the following disease states and meet their individual criteria as stated.

### HEPATITIS C (without cirrhosis or with compensated cirrhosis (Child-Turcotte-Pugh Class A))

For **initial** authorization:

1. Member must be 12 years of age or older; AND
2. Member has ONE of the following statuses:
  - a) Treatment-naïve with genotype 1, 2, 3, 4, 5 or 6 (laboratory documentation required); OR
  - b) Treatment-experienced with one of the following:
    - i) genotype 1, who previously have been treated with a regimen containing an HCV NS5A inhibitor<sup>1</sup> or an NS3/4A protease inhibitor<sup>2</sup>, **but not both**; OR
    - ii) genotype 1, 2, 3, 4, 5 or 6 with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A protease inhibitor<sup>2</sup> or NS5A inhibitor<sup>1</sup>; AND
3. Medication must be prescribed by a board certified hepatologist, gastroenterologist, infectious disease specialist or a nurse practitioner working with the above specialists; AND
4. Member's documented viral load taken within 6 months of beginning therapy and submitted with chart notes; AND
5. Member has documented current monthly negative urine drug and alcohol screens for 3 consecutive months (laboratory documentation required); AND
6. Member does **not** have any of the following:
  - a) Moderate to severe hepatic impairment (Child-Turcotte-Pugh B and C);
  - b) Currently on atazanavir and rifampin.
7. **Dosage allowed:** Three tablets (total daily dose: glecaprevir 300 mg and pibrentasvir 120 mg) taken orally once daily with food.

*Note: Member's life expectancy must be no less than one year due to non-liver related comorbidities.*

<sup>1</sup> NS5A inhibitor regimens includes ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin.

<sup>2</sup> NS3/4A protease inhibitor regimens includes simeprevir and sofosbuvir, or simeprevir, boceprevir, or telaprevir with pegylated interferon and ribavirin.



***If member meets all the requirements listed above, the medication will be approved for 8 weeks for treatment-naïve members with no cirrhosis or for 12 weeks for treatment-naïve members with compensated cirrhosis. If request is for treatment-experienced member, the medication will be approved for 8-16 weeks, see Appendix below.***

For **reauthorization**:

1. Medication will not be reauthorized.

**CareSource considers Mavyret (glecaprevir and pibrentasvir) not medically necessary for the treatment of the diseases that are not listed in this document.**

| DATE       | ACTION/DESCRIPTION   |
|------------|--|
| 11/22/2017 | New policy for Mavyret created.  |
| 12/07/2017 | Criterion of “life expectancy not less than one year due to non-liver related comorbidities” removed from criteria and added in a form of the note. Hepatitis B testing is no longer required. |
| 12/21/2017 | Fibrosis score requirement was removed.  |
| 05/01/2019 | Coverage was adjusted for age; drug covered for members of 12 years of age and older.  |

References:

1. Mavyret [Package insert]. North Chicago, IL: AbbVie Inc.; August 2017.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America (AASLD) and Infectious Diseases Society of America (IDSA). HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C; 2017. Available at: <https://www.hcvguidelines.org/>.
3. Hepatitis C Information | Division of Viral Hepatitis | CDC. (2015, May 31). Retrieved from <https://www.cdc.gov/hepatitis/hcv/index.htm>.
4. Afdhal, N. (2012). Fibroscan (Transient Elastography) for the Measurement of Liver Fibrosis. *Gastroenterology & Hepatology*, 8(9), 605-607.

Effective date: 07/01/2019

Revised date: 05/01/2019

Appendix. Treatment Duration for Mavyret for Treatment-Experienced Members

| HCV Genotype    | Member Previously Treated with a Regimen Containing:  | Treatment Duration |                                      |
|-----------------|---|--------------------|--------------------------------------|
|                 |   | No Cirrhosis       | Compensated Cirrhosis (Child-Pugh A) |
| 1               | An NS5A inhibitor <sup>1</sup> without prior treatment with an NS3/4A protease inhibitor  | 16 weeks           | 16 weeks                             |
|                 | An NS3/4A PI <sup>2</sup> without prior treatment with an NS5A inhibitor  | 12 weeks           | 12 weeks                             |
| 1, 2, 4, 5 or 6 | Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor | 8 weeks            | 12 weeks                             |
| 3               | Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or sofosbuvir, but no prior treatment experience with an HCV NS3/4A PI or NS5A inhibitor | 16 weeks           | 16 weeks                             |

<sup>1</sup> NS5A inhibitor regimens included ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin.

<sup>2</sup> NS3/4A protease inhibitor regimens included simeprevir and sofosbuvir, or simeprevir, boceprevir, or telaprevir with pegylated interferon and ribavirin.