CareSource

PHARMACY POLICY STATEMENT **Ohio 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) QUANTITY LIMIT— 84 tabs per 28 days
LIST OF DIAGNOSES CONSIDERED **NOT** MEDICALLY NECESSARY	Click Here

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:
Member must meet all criteria below Step 1 and Step 2 and Step 3.

Step 1 (evaluation of member's readiness):

1. Member must be 18 years of age or older; AND
2. Member must be free for 6 months from alcohol use, controlled drug abuse, and illicit drug use before consideration of therapy (laboratory documentation required for month 1 and for month 6 and for one additional month between month 2-5); AND
3. Member must meet kidney function as indicated in package labeling for product (No dosage adjustment of Mavyret is required in members with mild, moderate or severe renal impairment, including those on dialysis); AND
4. Member must not be concomitantly taking drugs that have significant clinical interaction as described in the prescribing information (Mavyret is contraindicated with atazanavir or rifampin); AND
5. Member must agree to be adherent with office visits, lab testing, imaging, procedures and, if deemed a candidate, the HCV medication regimen. Prescribers must submit documentation demonstrating the member attests to meet these requirements (Office notes documenting this are sufficient to meet this criteria); AND

Step 2 (clinical assessment of disease):

6. Member has confirmation of chronic hepatitis C (CHC):
   a) Hepatitis C Virus (HCV) antibody test reactive; AND
   b) Provide HCV RNA load measured within 90 days prior to starting DAA therapy; AND
   c) Specify the Genotype (choose one of the following statuses):
      i) Treatment-naïve with Genotype 1, 2, 3, 4, 5 or 6 (laboratory documentation required); OR
      ii) Treatment-experienced with one of the following:
         (1) Genotype 1, who previously have been treated with a regimen containing an HCV NS5A inhibitor[1] or an NS3/4A protease inhibitor[2], **but not both**; OR
         (2) 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[2] or NS5A inhibitor[1]; AND

7. Member has documented progression of disease:
   a) Document the degree of liver fibrosis:
      i) Liver biopsy; OR
      ii) One radiological and one serological test; AND
   b) If cirrhosis is present, indicate whether cirrhosis is compensated or decompensated and provide the Child-Turcotte-Pugh (CTP) score (Mavyret is not recommended in members with moderate hepatic impairment (Child-Pugh B) and is contraindicated in members with severe hepatic impairment (Child-Pugh C)); AND
8. Document that member does not have limited life expectancy (less than 12 months) due to non-liver-related comorbid conditions; AND
9. Document any previously tried Hepatitis C treatments, dates treated, and response/outcome (member will not be approved if any other HCV treatments have been used in the last 6 months); AND

Step 3 (Direct Acting Antivirals (DAA) conditions for coverage):

10. Medication must be prescribed by, or in consultation with, a hepatologist, gastroenterologist, or infectious disease specialist; AND
11. Member's documented HCV RNA testing is required every 4 weeks and submitted with chart notes; AND
12. Providers of HIV/HCV-coinfected persons should recognize and manage interactions with other antiretroviral medications (e.g. DAAs); AND
13. Only regimens listed as recommended or alternative in the current AASLD guidance (http://hcvguidelines.org) will be approved with duration of approval based upon guidelines. Regimens listed as not recommended will not be approved.
14. **Dosage allowed:** Three tablets (total daily dose: glecaprevir 300 mg and pibrentasvir 120 mg) taken orally once daily with food.

[1] NS5A inhibitor regimens includes ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin.
[2] 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.
12/17/2018	Criteria changed per Ohio Department of Medicaid requirement. Minimum of 3 months of "drug/alcohol free period" criterion changed to 6 months; no fibrosis score required, but documentation of degree liver fibrosis changed; kidney function and clinical interactions addressed; HCV RNA load measurement prior to starting DAA therapy changed from

	“within 6 months” to “within 90 days”; cirrhosis score required; prescribers specialty changed; HCV RNA testing is now required every 4 weeks.

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: 01/01/2019
Revised date: 12/17/2018

Appendix. Treatment Duration for Mavyret for Treatment-Experienced Members

		Treatment Duration	
HCV Genotype	**Member Previously Treated with a Regimen Containing:**	**No Cirrhosis**	**Compensated Cirrhosis (Child-Pugh A)**
1	An NS5A inhibitor[1] without prior treatment with an NS3/4A protease inhibitor	16 weeks	16 weeks
	An NS3/4A PI[2] 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

[1] NS5A inhibitor regimens included ledipasvir and sofosbuvir or daclatasvir with pegylated interferon and ribavirin.

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