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PHARMACY POLICY STATEMENT
Kentucky 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) Alternative preferred product includes Epclusa 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:

1. Member must be 18 years of age or older; AND
2. Member is treatment-naïve with genotype 1, 2, 3, 4, 5 or 6 (laboratory documentation required); 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 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.
6. **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. Please submit fibrosis score and drug screening with prior authorization.

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, see Appendix A below.

For **reauthorization** or for **retreatment**:

1. Member must be in compliance with **ALL** other initial criteria and be treatment-experienced with one of the following:
   a) 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
   b) 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
2. Prescriber **must** submit completed "Supplemental Form Hepatitis C for KY Medicaid" with reauthorization request (see Appendix B below); AND
3. Member is compliant with drug therapy regimen by paid pharmacy claims; AND
4. Member has documented current monthly negative urine drug and alcohol screens for 3 consecutive months (laboratory documentation required); AND
5. If the member has a recent history (within the past 6 months) of alcohol or substance abuse, the following is required:
   a) Documentation that the member has completed or is participating in a recovery program, receiving alcohol or substance abuse counseling services, or seeing an addiction specialist as part of HCV treatment; AND
   b) Documentation that the member is not actively participating in illicit substance use or alcohol abuse with confirmatory laboratory testing (e.g., urine drug screen); AND
6. Member has evidence of liver fibrosis stage 3 or 4 confirmed by liver biopsy, or elastography only (lab chart notes required) unless **one** of the following (fibrosis stage F0-4 covered):
   a) Hepatocellular carcinoma meeting Milan criteria (awaiting liver transplantation);
   b) Post liver transplantation;
   c) Extrahepatic disease (i.e., kidney disease: proteinuria, nephrotic syndrome or membranoproliferative glomerulonephritis; cryoglobulinemia with end- organ manifestations (e.g., vasculitis));
   d) HIV or HBV coinfection.
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.

[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 8-16 weeks, see Appendix A below.

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" removed from criteria and added in a form of the note. Hepatitis B testing is no longer required.

03/07/2018	Criteria revised based on new requirements from Kentucky Department of Medicaid Services. Documentation of fibrosis level and current monthly negative urine drug and alcohol screens for 3 consecutive months are no longer required for initial authorization for treatment-naïve members. Reauthorization criteria added for treatment-experienced members. New Appendix added (Supplemental Form Hepatitis C for KY Medicaid).
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

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Appendix A. 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.

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Appendix B. Supplemental Form Hepatitis C for KY Medicaid

1. Prescriber **must answer ALL** of the following questions with prior authorization submission:
   a) Is retreatment necessary due to treatment failure or reinfection?

   b) Was the member compliant (e.g., few to no missed doses) with previous Direct-Acting Antiviral (DAA) therapy? If not, why?

   c) Were there any additional factors that led to DAA treatment failure? If so, describe these factors and how they have been addressed or are no longer relevant.

2. Member **has been evaluated** for potential clinically significant drug interactions. Please see package insert for details: https://www.rxabbvie.com/pdf/mavyret_pi.pdf.

3. Provider **attests** that:
   a) Member is willing and able to comply with the requirements of the proposed retreatment plan; AND
   b) Any factors that may have led to noncompliance with previous treatment(s) have been addressed; AND
   c) Member has received education regarding risk behaviors (e.g., IV drug use) associated with HCV infection.

Prescriber's name: Signature: Date: