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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) 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 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[1] or an NS3/4A protease inhibitor[2], **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[2] or NS5A inhibitor[1]; 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 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; AND
7. 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.

8. **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 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.

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: 12/13/2017
Revised date: 12/07/2017

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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.