

PHARMACY POLICY STATEMENT

BILLING CODE	Must use valid NDC code
BENEFIT TYPE	Pharmacy
SITE OF SERVICE ALLOWED	Home
STATUS	Prior Authorization Required

Mavyret is a fixed-dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor. It was initially approved by the FDA in 2017 and is indicated for the treatment of adult and pediatric patients 3 years and older with chronic HCV genotype 1, 2, 3, 4, 5 or 6 infection without cirrhosis (i)-1 (mati)-11.1(houtyTD[(i-i)4.4 8[(tr)0pens07 0 Td[ptrtrr[(tr)0.7appoentasi(onlyas0.7a have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.

Mavyret (glecaprevir and pibrentasvir) will be considered for coverage when the following criteria are met:

For _____ authorization:

1. Member must be 3 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 inhibitor¹ or an NS3/4A protease inhibitor², 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 inhibitor² or NS5A inhibitor¹; 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. If Member is 12 years of age or older, OR weighing more than 45 kg, must have a clinical reason why the tablets cannot be taken.
- 7.

Adult dosing: Three tablets (total daily dose: glecaprevir 300 mg and pibrentasvir 120 mg) taken orally once daily with food (Quantity Limit: 84 tablets per 28 days).

Pediatric Patients Aged 12 Year or older, or Pediatric Patients Weighing at least 45 kg: Three tablets taken at the same time orally once daily (total daily dose: glecaprevir 300 mg and pibrentasvir 120 mg) with food (Quantity Limit 84 tablets per 28 days).

Pediatric Patients Aged 3 years or older:

Less than 20 kg	150mg/60mg per day	Three 50mg/20mg packets of oral pellets once daily
20 kg to less than 30 kg	200mg/80mg per day	Four 50mg/20m packers of oral pellets once daily
30 kg to less than 30 kg	250mg/100mg per day	Five 50mg/20mg packets of oral pellets once daily
45 kg and greater OR 12 years of age and older	300mg/120mg per day	Three 100mg/40mg once daily

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; 2021. Available at: <https://www.hcvguidelines.org/>.
3. Hepatitis C Information | Division of Viral Hepatitis | CDC. (July 2020). Retrieved from <https://www.cdc.gov/hepatitis/hcv/index.htm>.

Effective date: 07/01/2022

Revised date: 02/24/2022

Appendix: Treatment Duration for Mavyret for Treatment-Experienced Members Treatment Duration