



## Commercial/Healthcare Exchange PA Criteria

*Effective: January 31, 2018*

**Prior Authorization:** Mavyret

**Products Affected:** Mavyret (glecaprevir/pibrentasvir) tablet, Mavyret oral pellets (glecaprevir/pibrentasvir)

**Medication Description:**

Mavyret, a direct-acting antiviral (DAA), is indicated for the treatment of adult and pediatric patients 3 years and older or with chronic hepatitis C virus (HCV) genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A). Mavyret is also indicated for the treatment of adult and pediatric patients 3 years and older with HCV genotype 1 infection, who previously have been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor (PI), but not both.

**Covered Uses:** Chronic Hepatitis C Virus (HCV)

**Exclusion Criteria:**

Mavyret has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval in the following circumstances:

1. Previous treatment with Mavyret
2. Genotypes 1 infection and previous treatment with both an NS5A inhibitor and NS3/4A inhibitor
3. Moderate to severe hepatic impairment (Child-Pugh B or C) or those with any history of prior hepatic decompensation
4. Coadministration with rifampin or atazanavir
5. Concomittant treatment with other direct acting antiviral (DAA) medications

**Required Medical Information:**

1. Current HCV viral load (documentation required)
2. HCV genotype (documentation required)
3. Previous treatment regimens
4. For patients with cirrhosis, cirrhosis is documented by FibroScan, FibroTest Actitest, liver biopsy, or radiological imaging
5. Child-Pugh score

**Age Restrictions:** 3 years of age or older

**Prescriber Restrictions:** Must be prescribed by, or in consultation with, a hepatologist, gastroenterologist, infectious disease specialist, liver transplant physician, healthcare practitioner experienced and trained in the treatment of Hepatitis C Virus, or healthcare practitioner under the direct supervision of one of the above listed specialists.

**Coverage Duration:** Coverage duration will be in accordance with FDA-approved prescribing information.

Last Res. July 2022



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**Other Criteria:**

**Initial Criteria:**

**1. Chronic Hepatitis C Virus**

- A. The patient has a diagnosis of Chronic Hepatitis C Virus (HCV); **AND**
- B. The patient has a current viral load; **AND**
- C. The viral load is post-treatment in previously treated patients; **AND**
- D. Patient has genotype 1, 2, 3, 4, 5, or 6 infection, **AND**
- E. Patient is treatment naïve **OR** patient is treatment experienced and hasn't been previously treated with both an NS5A inhibitor and NS3/4A inhibitor; **AND**
- F. Mavyret is prescribed by, or in consultation with, a hepatologist, gastroenterologist, infectious disease specialist, liver transplant physician, healthcare practitioner experienced and trained in the treatment of Hepatitis C Virus, or healthcare practitioner under the direct supervision of one of the above listed specialists; **AND**
- G. Patient is 3 years of age or older; **AND**
- H. Patient does not have cirrhosis **OR** patient has compensated cirrhosis, documented by FibroScan, FibroTest Actitest, liver biopsy, or radiological imaging; **AND**
- I. Patient has a Child Pugh score A

**References:**

- 1. Mavyret™ tablets [prescribing information]. North Chicago, IL: AbbVie; August 3, 2017.
- 2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Testing, managing, and treating hepatitis C. Available at: <http://www.hcvguidelines.org>. Updated September 21, 2017. Accessed on November 1, 2017.
- 3. Product Information: MAVYRET(R) oral tablets, oral pellets, glecaprevir pibrentasvir oral tablets, oral pellets. AbbVie Inc (per manufacturer), North Chicago, IL, 2021.

**Policy Revision history**

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	1/18/2018
2	Update	Updated indication, age range, contraindications	Medication Description, Coverage Exclusions, Age Restrictions	10/1/2019

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3	Update	CCI to adopt EH Policy & Template CCI P&T Review History: 2/16, 5/16, 11/16, 2/17, 11/17, 1/18 CCI Revision Record: 2/16, 5/16,	All	12/31/2019
4	Update	Added Mavyret Oral Pellets to Products Affected; Updated Age Restrictions and Initial Criteria from 12 years and older to 3 years and older, updated Medication	Products Affected, Age Restrictions, updated Medication Description, Initial Criteria	7/8/2022