Drug Coverage Policy

Effective Date……07/01/2025
Coverage Policy Number……IP0737
Policy Title……Mavyret Prior Authorization Policy

Hepatitis C – Mavyret Prior Authorization for Preferred Specialty Management Policy

- Mavyret® (glecaprevir/pibrentasvir tablets and oral pellets - AbbVie)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

Mavyret, a direct-acting antiviral, contains glecaprevir, a pangenotypic NS3/4A protease inhibitor and pibrentasvir, a pangenotypic NS5A inhibitor.[1] It is indicated for the treatment of **chronic hepatitis C virus** (HCV) in the following scenarios:

- Patients ≥ 3 years of age with genotype 1, 2, 3, 4, 5, or 6 infection without cirrhosis or with compensated cirrhosis (Child-Pugh A).
- Patients ≥ 3 years of age with genotype 1 infection who have previously been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both.

Dosing

The duration of therapy is based on prior treatment experience, genotype, and the presence or absence of cirrhosis (see Tables 1 and 2). In addition, Mavyret is recommended for 12 weeks in patients ≥ 3 years of age who are liver or kidney transplant recipients. Similar to non-transplant recipients, a 16-week treatment duration is recommended in genotype 1-infected patients who are NS5A inhibitor-experienced without prior treatment with an NS3/4A protease inhibitor or in genotype 3-infected patients who are treatment-experienced with regimens containing interferon, pegylated interferon, ribavirin, and/or Sovaldi® (sofosbuvir tablets/oral pellets).

Table 1. Recommended Duration for Treatment-Naïve Patients.[1]

HCV Genotype	Treatment Duration	
	No Cirrhosis	Compensated Cirrhosis (Child-Pugh A)
1, 2, 3, 4, 5, or 6	8 weeks	8 weeks

HCV – Hepatitis C virus.

Table 2. Recommended Duration for Treatment-Experienced Patients.[1]

HCV Genotype	Prior Treatment Experience	Duration	
		Without Cirrhosis	With Compensated Cirrhosis (Child-Pugh A)
1, 2, 4, 5, 6	PRS	8 weeks	12 weeks
3	PRS	16 weeks	16 weeks
1	NS3/4 PI[1] (NS5A-naïve)	12 weeks	12 weeks
	NS5A inhibitor[2] (NS3/4 PI-naïve)†	16 weeks	16 weeks

HCV – Hepatitis C virus; PRS – Prior treatment experience with regimens containing interferon, pegylated interferon, ribavirin, and/or Sovaldi® (sofosbuvir tablets), but no prior treatment experience with an HCV NS3/4A protease inhibitor (PI) or NS5A inhibitor; PI – Protease inhibitor; [1] Regimens containing Olysio® (simeprevir capsules) and Sovaldi, or Olysio, Victrelis® (boceprevir capsules), or Incivek® (telaprevir tablets) with interferon or pegylated interferon and ribavirin were studied; [2] Regimens containing ledipasvir/sofosbuvir or Daklinza® (daclatasvir tablets) + pegylated interferon + ribavirin [unapproved regimen] were studied.

Guidelines

The American Association for the Study of Liver Diseases/Infectious Diseases Society of America (AASLD/IDSA) provide recommendations for testing, monitoring, and treating HCV (December 19, 2023).[2] Instances in which the guidelines provide recommendations for Mavyret outside of the FDA-approved indications are outlined below.

With the availability of pangenotypic HCV treatment regimens, HCV genotyping is no longer required prior to treatment initiation for all individuals.[2] Pretreatment genotyping is still recommended in patients with cirrhosis and/or past unsuccessful HCV treatment, because treatment regimens may differ by genotype. However, for treatment-naïve patients without cirrhosis, although genotyping may impact the preferred treatment approach, it is not required if a pangenotypic regimen is used. In treatment-naïve adults without cirrhosis, the recommended regimens are Mavyret for 8 weeks or sofosbuvir/velpatasvir for 12 weeks. Additional genotype-specific and/or special circumstance-specific recommendations are also provided for patients falling outside of these parameters. Mavyret is recognized as a recommended regimen (12 weeks) for the treatment of patients with recurrent HCV post-liver transplantation (without cirrhosis or with compensated cirrhosis). Treatment-naïve adults with compensated cirrhosis are also eligible for simplified treatment. In patients with compensated cirrhosis, the recommended regimen in patients with genotype 1 through 6 is Mavyret for 8 weeks; sofosbuvir/velpatasvir for 12 weeks is recommended in patients with genotype 1, 2, 4, 5, or 6 (patients with genotype 3 require baseline NS5A resistance-associated substitution testing. Those without Y93H can be treated with sofosbuvir/velpatasvir for 12 weeks). Genotype testing is not required for Mavyret as part of the simplified algorithm in patients with compensated cirrhosis.

Mavyret is recognized as a recommended regimen (12 weeks) for the treatment of patients with recurrent HCV post-liver transplantation (without cirrhosis or with compensated cirrhosis).

The European Society for Pediatric Gastroenterology, Hepatology and Nutrition recommendations on the treatment of hepatitis C (2024) describe the optimal therapeutic management of adolescents and children with HCV infection.[3] Direct-acting antiviral regimens are recommended for all treatment-naïve and treatment-experienced children ≥ 3 years of age with chronic HCV. When available, the regimen of choice should be one that has the shortest treatment duration and does not require concomitant ribavirin. In addition, to simplify treatment and avoid the need of genotyping and/or baseline resistance-associated substitutions assessment, pangenotypic regimens are preferred. In children and adolescents without cirrhosis, or with compensated cirrhosis, recommended regimens are Mavyret, sofosbuvir/velpatasvir, or ledipasvir/sofosbuvir. In children and adolescents with decompensated cirrhosis, treatment should follow adult guidelines.

Coverage Policy

POLICY STATEMENT

Prior Authorization is required for prescription benefit coverage of Mavyret. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Mavyret as well as the monitoring required for adverse events and efficacy, approval requires Mavyret to be prescribed by or in consultation with a physician who specializes in the condition being treated.

NOTE: This product also requires the use of preferred products before approval of the requested product. Refer to the respective *Hepatitis C Virus Direct-Acting Antivirals Preferred Specialty Management Policy for Employer Plans (PSM025) or Hepatitis C Virus Direct-Acting Antivirals Preferred Specialty Management Policy for Individual and Family Plans (PSM026)* for additional preferred product criteria requirements and exceptions.

Mavyret is considered medically necessary when ONE of the following is met (1, 2, 3, 4, 5, 6, 7, 8, 9, 10, 11, 12, 13, 14, or 15):

FDA-Approved Indications

1. **Chronic Hepatitis C Virus (HCV) Genotype 1.** Approve for the duration noted if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 3 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Approve for 12 weeks if the patient meets ONE of the following (a or b):
       - **a)** Patient is treatment-naïve; OR
       - **b)** Patient has previously been treated with pegylated interferon/ribavirin, Incivek (telaprevir tablets), Olysio (simeprevir capsules), or Victrelis (boceprevir capsules); OR
     - **ii.** Approve for 16 weeks if the patient meets ONE of the following (a, b, or c):
       - **a)** Patient has previously been treated with Daklinza (daclatasvir tablets), sofosbuvir/velpatasvir, ledipasvir/sofosbuvir, or Zepatier (elbasvir/grazoprevir tablets); OR
       - **b)** Patient has previously been treated with Sovaldi (sofosbuvir tablets/oral pellets) + ribavirin with or without pegylated interferon/interferon; OR
       - **c)** Patient has previously been treated with Sovaldi + Olysio; AND
   - **C)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

2. **Chronic Hepatitis C Virus (HCV) Genotype 2.** Approve for 12 weeks if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 3 years of age; AND
   - **B)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

3. **Chronic Hepatitis C Virus (HCV) Genotype 3.** Approve for the duration noted if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 3 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Approve for 12 weeks if the patient is treatment-naïve; OR
     - **ii.** Approve for 16 weeks if the patient meets BOTH of the following (a or b):
       - **a)** Patient has previously been treated with Sovaldi (sofosbuvir tablets/oral pellets) + ribavirin with or without pegylated interferon/interferon; OR
       - **b)** Patient has previously been treated with pegylated interferon/ribavirin; AND
   - **C)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

4. **Chronic Hepatitis C Virus (HCV) Genotype 4.** Approve for 12 weeks if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 3 years of age; AND
   - **B)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

5. **Chronic Hepatitis C Virus (HCV) Genotype 5 or 6.** Approve for 12 weeks if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 3 years of age; AND
   - **B)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

6. **Hepatitis C Virus (HCV) Genotype 1, Renal Impairment (Estimated Glomerular Filtration Rate [eGFR] < 30 mL/min or End-Stage Renal Disease [ESRD]).** Approve for the duration noted if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 3 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** Approve for 12 weeks if the patient meets ONE of the following (a or b):
       - **a)** Patient is treatment-naïve; OR
       - **b)** Patient has previously been treated with pegylated interferon/ribavirin, Incivek (telaprevir tablets), Olysio (simeprevir capsules), or Victrelis (boceprevir capsules); OR
     - **ii.** Approve for 16 weeks if the patient meets ONE of the following (a, b, or c):
       - **a)** Patient has previously been treated with Daklinza (daclatasvir tablets), sofosbuvir/velpatasvir, ledipasvir/sofosbuvir, or Zepatier (elbasvir/grazoprevir tablets); OR
       - **b)** Patient has previously been treated with Sovaldi (sofosbuvir tablets/oral pellets) + ribavirin with or without pegylated interferon/interferon; OR
       - **c)** Patient has previously been treated with Sovaldi + Olysio; AND
   - **C)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, nephrologist, kidney transplant physician, or a liver transplant physician.

7. **Hepatitis C Virus (HCV) Genotype 4 with Renal Impairment (Estimated Glomerular Filtration Rate [eGFR] < 30 mL/min or End-Stage Renal Disease [ESRD]).** Approve for 12 weeks if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 3 years of age; AND
   - **B)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, nephrologist, kidney transplant physician, or a liver transplant physician.

8. **Hepatitis C Virus (HCV) Genotype 2, 3, 5, or 6 with Renal Impairment (Estimated Glomerular Filtration Rate [eGFR] < 30 mL/min or End-Stage Renal Disease [ESRD]).** Approve for the duration noted if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 3 years of age; AND
   - **B)** Patient meets ONE of the following (i, ii, or iii):
     - **i.** Patient has genotype 2, 5, or 6: Approve for 12 weeks; OR
     - **ii.** Patient has genotype 3 and is treatment-naïve: Approve for 12 weeks; OR
     - **iii.** Patient has genotype 3 and has previously been treated: Approve for 16 weeks; AND
   - **C)** The medication is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, nephrologist, kidney transplant physician, or a liver transplant physician.

9. **Hepatitis C Virus (HCV) Genotype 1, Kidney Transplant.** Approve for the duration noted if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 3 years of age; AND
   - **B)** Patient is a kidney transplant recipient; AND
   - **C)** Patient meets ONE of the following (i or ii):
     - **i.** Patient is treatment-naïve: Approve for 12 weeks; OR
     - **ii.** Patient has previously been treated for HCV: Approve for 16 weeks; AND
   - **D)** The medication is prescribed by or in consultation with one of the following prescribers who is affiliated with a transplant center: gastroenterologist, hepatologist, infectious diseases physician, nephrologist, renal transplant physician, or liver transplant physician.

10. Hepatitis C Virus (HCV) Genotype 2, 3, 5, or 6, Kidney Transplant. Approve for the duration noted if the patient meets ALL of the following (A, B, C, and D):
- **A)** Patient is ≥ 3 years of age; AND
- **B)** Patient is a kidney transplant recipient; AND
- **C)** Patient meets ONE of the following (i, ii, or iii):
  - **i.** Patient has genotype 2, 5, or 6: Approve for 12 weeks.
  - **ii.** Patient has genotype 3 and is treatment-naïve: Approve for 12 weeks.
  - **iii.** Patient has genotype 3 and has previously been treated for HCV: Approve for 16 weeks; AND
- **D)** The medication is prescribed by or in consultation with one of the following prescribers who is affiliated with a transplant center: gastroenterologist, hepatologist, infectious diseases physician, nephrologist, renal transplant physician, or liver transplant physician.

11. Hepatitis C Virus (HCV) Genotype 4, Kidney Transplant. Approve for 12 weeks if the patient meets ALL of the following (A, B, and C):
- **A)** Patient is ≥ 3 years of age; AND
- **B)** Patient is a kidney transplant recipient; AND
- **C)** The medication is prescribed by or in consultation with one of the following prescribers who is affiliated with a transplant center: gastroenterologist, hepatologist, infectious diseases physician, nephrologist, renal transplant physician, or liver transplant physician.

12. Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6, Liver Transplant. Approve for the duration noted below if the patient meets ALL of the following (A, B, C, and D):
- **A)** Patient is ≥ 3 years of age; AND
- **B)** Patient is a liver transplant recipient; AND
- **C)** Patient meets ONE of the following (i, ii, or iii):
  - **i.** Patient has genotype 2, 4, 5, or 6: Approve for 12 weeks.
  - **ii.** Patient has genotype 1 or 3 and is treatment-naïve: Approve for 12 weeks.
  - **iii.** Patient has genotype 1 or 3 and has previously been treated for HCV: Approve for 16 weeks; AND
- **D)** The medication is prescribed by or in consultation with one of the following prescribers who is affiliated with a transplant center: a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

Other Uses with Supportive Evidence

13. Chronic Hepatitis C Virus (HCV), Genotype Unknown/Undetermined. Approve for 8 weeks if the patient meets ALL of the following (A, B, C, D, E, F, G, and H):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient meets ONE of the following (i or ii):
  - **i.** Patient does not have cirrhosis; OR
  - **ii.** Patient has compensated cirrhosis; AND
- **C)** Patient has not previously been treated for hepatitis C virus; AND
- **D)** Patient does not have hepatitis B virus; AND
- **E)** Patient is not pregnant; AND
- **F)** Patient does not have hepatocellular carcinoma; AND
- **G)** Patient has not had a liver transplantation; AND
- **H)** The medication will be prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician.

14. Recurrent Hepatitis C Virus (HCV) Post-Liver Transplantation, Genotype 1, 2, 3, 4, 5, or 6. Approve for 12 weeks if the patient meets ALL of the following (A, B, and C):
- **A)** Patient is ≥ 3 years of age; AND

B) Patient has recurrent HCV after a liver transplantation; AND
C) The medication is prescribed by or in consultation with one of the following prescribers who is affiliated with a transplant center: gastroenterologist, hepatologist, infectious diseases physician, or liver transplant physician.

15. Patient Has Been Started on Mavyret. Approve for an indication or condition above. Approve the duration described above to complete a course therapy (e.g., a patient who should receive 12 weeks, and has received 3 weeks should be approved for 9 weeks to complete their 12-week course).

Mavyret for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Hepatitis C Virus (HCV) Child-Pugh Class B or C Liver Disease (Moderate or Severe Hepatic Impairment).** Mavyret is contraindicated in patients with moderate or severe hepatic impairment (Child-Pugh Class B or C).

2. **Hepatitis C Virus (HCV) [any genotype], Combination with Any Other Direct-Acting Antivirals (DAAs).** Mavyret provides a complete antiviral regimen.

3. **Pediatric Patients (Age < 3 Years of Age).** The safety and efficacy of Mavyret have not been established in pediatric patients < 3 years of age.[1]

References

1. Mavyret® tablets and oral pellets [prescribing information]. North Chicago, IL: AbbVie; October 2023.
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 December 19, 2023. Accessed on March 25, 2025.
3. Indolfi G, Gonzalez-Peralta RP, Jona MM, et al. ESPGHAN recommendations on treatment of chronic hepatitis C virus infection in adolescents and children including those living in resource limited settings. *J Pediatr Gastroenterol Nutr.* 2024;78:957-972.

Revision Details

Type of Revision	Summary of Changes	Date
New	New policy	07/01/2025

The policy effective date is in force until updated or retired.