UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 2132-10
Program	Prior Authorization/Medical Necessity
Medication	Mavyret® (glecaprevir/pibrentasvir)
P&T Approval Date	9/2017, 11/2018, 6/2019, 11/2019, 11/2020, 5/2021, 8/2021, 8/2022, 7/2023, 7/2024
Effective Date	10/1/2024

1. Background:

Mavyret (glecaprevir/pibrentasvir) is a fixed-dose combination of glecaprevir, a hepatitis C virus (HCV) NS3/4A protease inhibitor, and pibrentasvir, an HCV NS5A inhibitor, and is indicated for the treatment of adult and pediatric patients 3 years and older with chronic HCV genotype (GT) 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, but not both.[1]

2. Coverage Criteria[a]:

A. For the treatment of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 infection in treatment-naïve patients without cirrhosis or with compensated cirrhosis, **Mavyret** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 infection

-AND-

2. Patient is treatment-naïve

-AND-

3. **One** of the following:

   a. Patient is without cirrhosis

   b. Patient has compensated cirrhosis (Child-Pugh A)

-AND-

4. Patient is not receiving Mavyret in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]

-AND-

5. Physician/provider asserts patient demonstrates treatment readiness, including the ability

to adhere to the treatment regimen

Authorization will be issued for 8 weeks.

B. For the treatment of chronic hepatitis C genotype 1, 2, 4, 5 or 6 infection in patients who are treatment-experienced with regimens containing interferon, pegylated interferon, ribavirin, and/or Sovaldi (sofosbuvir) without cirrhosis, **Mavyret** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1, 2, 4, 5 or 6 infection

-AND-

2. Patient has prior treatment experience with a regimen including at least **one** of the following:

   a. Interferon (e.g., Intron-A)
   b. Pegylated interferon (e.g., Pegasys, PegIntron)
   c. Ribavirin (e.g., Rebetol)
   d. Sofosbuvir (e.g., Sovaldi)

-AND-

3. Patient has **no** prior treatment experience with **any** of the following regimens:

   a. HCV NS3/4A protease inhibitor [e.g., Incivek (teleprevir), Victrelis (boceprevir), Viekira (dasabuvir/ombitasvir/paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir)]
   b. HCV NS5A inhibitor [e.g., Daklinza (daclatasvir), Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Viekira (dasabuvir/ombitasvir/ paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir)]

-AND-

4. Patient is without cirrhosis

-AND-

5. Patient is not receiving Mavyret in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]

-AND-

6. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

Authorization will be issued for 8 weeks.

C. For the treatment of chronic hepatitis C genotype 1, 2, 4, 5 or 6 infection in patients who are treatment-experienced with regimens containing interferon, pegylated interferon, ribavirin, and/or Sovaldi (sofosbuvir) with cirrhosis, **Mavyret** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1, 2, 4, 5 or 6 infection

-AND-

2. Patient has prior treatment experience with a regimen including at least **one** of the following:

   a. Interferon (e.g., Intron-A)
   b. Pegylated interferon (e.g., Pegasys, PegIntron)
   c. Ribavirin (e.g., Rebetol)
   d. Sofosbuvir (e.g., Sovaldi)

-AND-

3. Patient has **no** prior treatment experience with **any** of the following regimens:

   a. HCV NS3/4A protease inhibitor [e.g., Incivek (teleprevir), Olysio (simeprevir), Victrelis (boceprevir), Viekira (dasabuvir/ombitasvir/paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir)]
   b. HCV NS5A inhibitor [e.g., Daklinza (daclatasvir), Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Viekira (dasabuvir/ombitasvir/paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir)]

-AND-

4. Patient has compensated cirrhosis (Child-Pugh A)

-AND-

5. Patient is not receiving Mavyret in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]

-AND-

6. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

Authorization will be issued for 12 weeks.

D. For the treatment of chronic hepatitis C genotype 3 infection in patients who are treatment-

experienced with regimens containing interferon, pegylated interferon, ribavirin, and/or Sovaldi (sofosbuvir), who are without cirrhosis or have compensated cirrhosis, or is a liver or kidney transplant recipient, **Mavyret** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 3 infection

-AND-

2. Patient has prior treatment experience with a regimen including at least **one** of the following:

   a. Interferon (e.g., Intron-A)
   b. Pegylated interferon (e.g., Pegasys, PegIntron)
   c. Ribavirin (e.g., Rebetol)
   d. Sofosbuvir (e.g., Sovaldi)

-AND-

3. Patient has **no** prior treatment experience with **any** of the following regimens:

   a. HCV NS3/4A protease inhibitor [e.g., Incivek (teleprevir), Victrelis (boceprevir), Viekira (dasabuvir/ombitasvir/paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir)]
   b. HCV NS5A inhibitor [e.g., Daklinza (daclatasvir), Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Viekira (dasabuvir/ombitasvir/ paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir)]

-AND-

4. **One** of the following:

   a. Patient is without cirrhosis
   b. Patient has compensated cirrhosis (Child-Pugh A)
   c. Patient is a liver or kidney transplant recipient

-AND-

5. Patient is not receiving Mavyret in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]

-AND-

6. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

Authorization will be issued for 16 weeks.

E. For the treatment of chronic hepatitis C genotype 1 infection in patients who are treatment-experienced with an NS5A inhibitor without prior treatment with an NS3/4A protease inhibitor, who are without cirrhosis or have compensated cirrhosis, or is a liver or kidney transplant recipient, **Mavyret** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1 infection

-AND-

2. Patient has prior treatment experience with an HCV NS5A inhibitor [e.g., Daklinza (daclatasvir), Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir)]. This does not include combination products also containing an NS3/4A inhibitor [e.g., Viekira (dasabuvir/ombitasvir/paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir)].

-AND-

3. Patient has **no** prior treatment experience with an NS3/4A protease inhibitor [e.g., Incivek (teleprevir), Olysio (simeprevir), Victrelis (boceprevir), Viekira (dasabuvir/ombitasvir/ paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir)]

-AND-

4. **One** of the following:

   a. Patient is without cirrhosis
   b. Patient has compensated cirrhosis (Child-Pugh A)
   c. Patient is a liver or kidney transplant recipient

-AND-

5. Patient is not receiving Mavyret in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]

-AND-

6. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

Authorization will be issued for 16 weeks.

F. For the treatment of chronic hepatitis C genotype 1 infection in patients who are treatment-experienced with an NS3/4A protease inhibitor without prior treatment with an NS5A inhibitor, who are without cirrhosis or have compensated cirrhosis, **Mavyret** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1 infection

-AND-

2. Patient has prior treatment experience with an NS3/4A protease inhibitor [e.g., Incivek (teleprevir), Olysio (simeprevir), Victrelis (boceprevir)]. This does not include combination products also containing an NS5A inhibitor [e.g., Viekira (dasabuvir/ombitasvir/ paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir)].

-AND-

3. Patient has **no** prior treatment experience with an HCV NS5A inhibitor [e.g., Daklinza (daclatasvir), Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Viekira (dasabuvir/ombitasvir/paritaprevir/ritonavir), Zepatier (elbasvir/grazoprevir)]

-AND-

4. **One** of the following:

   a. Patient is without cirrhosis

   -OR-

   b. Patient has compensated cirrhosis (Child-Pugh A)

-AND-

5. Patient is not receiving Mavyret in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]

-AND-

6. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

Authorization will be issued for 12 weeks.

G. For the treatment of hepatitis C genotype 1, 2, 3, 4, 5 or 6 infection in kidney or liver transplant recipients who are without cirrhosis or have compensated cirrhosis, **Mavyret** will be approved based on **all** of the following criteria:

1. Diagnosis of hepatitis C genotype 1, 2, 3, 4, 5 or 6 infection

-AND-

2. **One** of the following:

a. Patient is a liver transplant recipient

b. Patient is a kidney transplant recipient

-AND-

3. **One** of the following:

   a. Patient is without cirrhosis

   -OR-

   b. Patient has compensated cirrhosis (Child-Pugh A)

-AND-

4. Patient is not receiving Mavyret in combination with another HCV direct acting antiviral agent [e.g., Epclusa (sofosbuvir/velpatasvir), Harvoni (ledipasvir/sofosbuvir), Sovaldi (sofosbuvir), Zepatier (elbasvir/grazoprevir)]

-AND-

5. Physician/provider asserts patient demonstrates treatment readiness, including the ability to adhere to the treatment regimen

Authorization will be issued for 12 weeks.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place

4. References:

1. Mavyret [package insert]. North Chicago, IL: AbbVie Inc.; October 2023.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. https://www.hcvguidelines.org/. Accessed June 5, 2024.

Program	Prior Authorization/Medical Necessity – Mavyret (glecaprevir/pibrentasvir)
Change Control	
Date	Change
9/2017	New program.
11/2018	Annual review with no changes to clinical criteria. Updated references.
6/2019	Updated indication based on label update. Added section on kidney transplant patients to allow for 12 week approval based on AASLD guidelines.
11/2019	Updated treatment duration for treatment naïve patients with compensated cirrhosis to 8 weeks, based on updated prescribing information.
11/2020	Annual review. Added liver transplant to clinical criteria. Updated references.
5/2021	Removed prescriber requirement. Updated references.
8/2021	Updated background with no changes to clinical criteria. Updated references.
8/2022	Annual review. Revised clinical criteria for treatment-experienced liver or kidney transplant recipients per prescribing information. Updated references.
7/2023	Annual review. No changes to coverage criteria. Updated references.
7/2024	Annual review. Removed liver disease staging criteria that was included for quality purposes rather than part of coverage decision. Updated references.