UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1231-8
Program	Prior Authorization/Notification
Medication	Mavyret® (glecaprevir/pibrentasvir)
P&T Approval Date	9/2017, 11/2018, 11/2019, 3/2020, 3/2021, 8/2021, 8/2022, 8/2023
Effective Date	11/1/2023

1. Background:
Mavyret 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 and 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)]

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)]

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)]

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), 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. **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)]

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)]

Authorization will be issued for 16 weeks.

F. For the treatment of chronic hepatitis C genotype 1 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.
   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)]

Authorization will be issued for 12 weeks.

G. For treatment of hepatitis C genotype 1, 2, 3, 4, 5, and 6 in liver or kidney 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)]

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
- Medical necessity may be in place.

4. References:

1. Mavyret [package insert]. North Chicago, IL: AbbVie Inc.; June 2021.
2. American Association for the Study of Liver Diseases and the Infectious Diseases Society of America. Recommendations for Testing, Managing, and Treating Hepatitis C. Accessed July 12, 2022.

Program	Prior Authorization/Notification – Mavyret (glecaprevir/pibrentasvir)
Change Control	
Date	Change
9/2017	New program.
11/2018	Annual review with no changes to clinical criteria. Updated references.
11/2019	Annual review. Updated treatment duration for treatment naïve patients with cirrhosis based on updated labeling. Updated background and references.
3/2020	Updated criteria to include treatment for liver and kidney transplant recipients. Updated background and references.
3/2021	Annual review with no changes to clinical criteria. Updated references.
8/2021	Updated background with no changes to clinical criteria. Updated references.
8/2022	Annual review. Updated coverage criteria for liver or kidney transplant recipients per prescribing information. Updated references.
8/2023	Annual review with no changes to coverage criteria.