

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2021 P 2132-7
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
Effective Date	11/1/2021; Oxford only: 11/1/2021

**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.<sup>1</sup>

**2. Coverage Criteria<sup>a</sup>:**

<p>A. For the treatment of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 infection in treatment-naïve patients without cirrhosis or have compensated cirrhosis, <b>Mavyret</b> will be approved based on <b>all</b> of the following criteria:</p> <p>1. Diagnosis of chronic hepatitis C genotype 1, 2, 3, 4, 5 or 6 infection</p> <p style="text-align: center;"><b>-AND-</b></p> <p>2. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision</p> <p style="text-align: center;"><b>-AND-</b></p> <p>3. Patient is treatment-naïve</p> <p style="text-align: center;"><b>-AND-</b></p> <p>4. <b>One</b> of the following:</p> <p style="padding-left: 20px;">a. Patient is without cirrhosis</p> <p style="padding-left: 20px;">b. Patient has compensated cirrhosis (Child-Pugh A)</p> <p style="text-align: center;"><b>-AND-</b></p>
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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.**

- 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. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

3. 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., Copegus, Rebetol)
- d. Sofosbuvir (e.g., Sovaldi)

-AND-

4. 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-

5. Patient is without cirrhosis

-AND-

6. 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-

7. 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. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

3. 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., Copegus, Rebetol)
- d. Sofosbuvir (e.g., Sovaldi)

-AND-

4. 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-

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

-AND-

6. 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-

7. 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, **Mavyret** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 3 infection

-AND-

2. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

-AND-

3. 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., Copegus, Rebetol)
- d. Sofosbuvir (e.g., Sovaldi)

-AND-

4. 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-**

5. **One** of the following:

- a. Patient is without cirrhosis

**-OR-**

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

**-AND-**

6. 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-**

7. 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, **Mavyret** will be approved based on **all** of the following criteria:

1. Diagnosis of chronic hepatitis C genotype 1 infection

**-AND-**

2. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

**-AND-**

3. 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-**

4. 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-**

5. **One** of the following:

- a. Patient is without cirrhosis

**-OR-**

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

**-AND-**

6. 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-**

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

**Authorization will be issued for 16 weeks.**

- G. 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. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

**-AND-**

3. 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-**

4. 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-**

5. **One** of the following:

- a. Patient is without cirrhosis

**-OR-**

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

**-AND-**

6. 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-**

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

**Authorization will be issued for 12 weeks.**

- H. 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. For quality purposes only, please provide stage of liver disease (e.g., APRI score, FibroSure score, Fibroscan score, or other methods) – this information will not be considered as part of the coverage decision

**-AND-**

3. Patient has received a kidney or liver transplant

-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.**

<sup>a</sup> 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.; 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. <http://www.hcvguidelines.org/full-report-view> Accessed March 24, 2021.



Program	Prior Authorization/Medical Necessity – Mavyret (glecaprevir/pibrentasvir)
<b>Change Control</b>	
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.