VENTURA COUNTY
HEALTH CARE PLAN

FORMULARY EXCEPTION POLICY

POLICY: Mavyret® (glecaprevir/pibrentasvir tablets – AbbVie)

DATE REVISED: 10/02/2019

Documentation: Documentation will be required for patients requesting Mavyret where noted in the criteria as [documentation required]. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts and/or laboratory data.

CRITERIA

1. **Hepatitis C virus (HCV) any genotype.** Patients who meet any of the following criteria do not qualify for treatment with Mavyret (A, B, C, or D): [Note: for patients who do not meet one of the following criteria A through D, review using the appropriate criteria 2 through 8 below]:
   - **A.** Combination use with direct-acting antivirals (DAAs); OR
   - **B.** Life expectancy < 12 months due to non-liver related comorbidities; OR
   - **C.** Child-Pugh Class B or C liver disease (severe hepatic impairment); OR
   - **D.** Pediatric patients < 12 years of age or < 45 kg.

2. **Chronic Hepatitis C Virus (HCV) Genotype 1:** Approve Mavyret for the duration specified below if the patient meets the following criteria (A, B, and C):
   - **A.** The patient is ≥ 12 years of age or ≥ 45 kg; AND
   - **B.** Mavyret is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
   - **C.** The patient meets ONE of the following conditions (i, ii, or iii)
     - **i.** Condition 1: Approve for up to 12 weeks if the patient meets ONE of a or b and c:
       - **a)** The patient is treatment-naïve; OR
       - **b)** The patient has previously been treated with pegylated interferon/ribavirin, Incivek, Olysio, or Victrelis; AND
       - **c)** The patient has completed a course of therapy with ONE of Epclusa (brand or generic), Harvoni (brand or generic), or Zepatier and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required].** OR
     - **ii.** Condition 2: Approve for 16 weeks if the patient meets the following criteria (a and b):
       - **a)** The patient has previously been treated with Daklinza, Epclusa (brand or generic), Harvoni (brand or generic), or Zepatier; AND
       - **b)** The patient has completed a course of therapy with Vosevi and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required]**. OR
     - **iii.** Condition 3: Approve for up to 16 weeks if the patient meets the following criteria (a or b):
       - **a)** The patient has previously been treated with Sovaldi + ribavirin with or without pegylated interferon/interferon; OR
       - **b)** The patient has previously been treated with Sovaldi + Olysio.

3. **Chronic Hepatitis C Virus (HCV) Genotype 2, Adults (≥ 18 years of age).** Approve Mavyret for up to 12 weeks if the patient meets the following criteria (A, B, and C):
   - **A.** The patient is ≥ 18 years of age; AND

B. Mavyret is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND

C. The patient meets ONE of the following conditions (i or ii):

i. Condition 1: The patient meets ONE of a or b and c:

a) The patient is treatment-naïve; OR

b) The patient has previously been treated with pegylated interferon/ribavirin; AND

c) The patient has completed a course of therapy with Epclusa (brand or generic) and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required].** OR

ii. Condition 2: The patient meets the following criteria (a):

a) The patient has previously been treated with Sovaldi + ribavirin with or without pegylated interferon/interferon.

4. Chronic Hepatitis C Virus (HCV) Genotype 2, Pediatrics (≥ 12 years of age or ≥ 45 kg). Approve Mavyret for 12 weeks if the patient meets the following criteria (A and B):

A. The patient is ≥ 12 years of age OR ≥ 45 kg; AND

B. Mavyret 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 3, Adults (≥ 18 years of age). Approve Mavyret for the specified duration if the patient meets the following criteria (A, B, and C):

A. The patient is ≥ 18 years of age; AND

B. Mavyret is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND

C. The patient meets ONE of the following conditions (i, ii or iii)

i. Condition 1: Approve for up to 12 weeks if the patient meets the following criteria (a and b):

a) The patient is treatment-naïve; AND

b) The patient has completed a course of therapy with Epclusa (brand or generic) and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required].** OR

ii. Condition 2: Approve for 16 weeks if the patient meets the following criteria (a and b):

a) The patient has previously been treated with Sovaldi + ribavirin with or without pegylated interferon/interferon; AND

b) The patient has completed a course of therapy with Vosevi and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required].** OR

iii. Condition 3: Approve for up to 16 weeks if the patient meets the following criteria (a and b):

a) The patient has previously been treated with pegylated interferon/ribavirin; AND

b) The patient has completed a course of therapy with Epclusa (brand or generic) and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required].**

6. Chronic Hepatitis C Virus (HCV) Genotype 3, Pediatric (≥ 12 years of age OR ≥ 45 kg). Approve Mavyret for the specified duration if the patient meets the following criteria (A, B, and C):

A. The patient is ≥ 12 years of age OR ≥ 45 kg; AND

B. Mavyret is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND

C. The patient meets ONE of the following (i or ii):

i. Condition 1: Approve for up to 12 weeks if the patient meets the following criteria (a):

a) The patient is treatment-naïve; OR

ii. Condition 2: Approve for up to 16 weeks if the patient meets the following criteria (a or b):

a) The patient has previously been treated with Sovaldi + ribavirin with or without pegylated interferon/interferon; OR

b) The patient has previously been treated with pegylated interferon/ribavirin.

7. Chronic Hepatitis C Virus (HCV) Genotype 4. Approve Mavyret for 12 weeks if the patient meets the following criteria (A, B, and C):

A. The patient is ≥ 18 years of age; AND

B. Mavyret is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND

C. The patient meets ONE of the following conditions (i or ii)

i. Condition 1: The patient meets ONE of a or b and c:

a) The patient is treatment-naïve; OR

b) The patient has previously been treated with pegylated interferon/ribavirin; AND

c) The patient has completed a course of therapy with Epclusa (brand or generic), Harvoni (brand or generic), or Zepatier and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required].** OR

ii. Condition 2: The patient meets the following criteria (a):

a) The patient has previously been treated with Sovaldi + ribavirin with or without pegylated interferon/interferon.

8. Chronic Hepatitis C Virus (HCV) Genotype 5 or 6. Approve Mavyret for 12 weeks if the patient meets the following criteria (A, B, and C):

A. The patient is ≥ 12 years of age or ≥ 45 kg; AND

B. Mavyret is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND

C. The patient meets ONE of the following conditions (i or ii)

i. Condition 1: The patient meets ONE of a or b and c:

a) The patient is treatment-naïve; OR

b) The patient has previously been treated with pegylated interferon/ribavirin; AND

c) The patient has completed a course of therapy with Epclusa (brand or generic) or Harvoni (brand or generic) and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required].** OR

ii. Condition 2: The patient meets the following criteria (a):

a) The patient has previously been treated with Sovaldi + ribavirin with or without pegylated interferon/interferon.

9. Hepatitis C Virus (HCV) Genotype 1, Renal Impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min or end-stage renal disease [ESRD]): Approve Mavyret for the duration specified below if the patient meets all of the following criteria (A, B, and C):

A. The patient is ≥ 12 years of age or ≥ 45 kg; AND

B. Mavyret is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, nephrologist, kidney transplant physician, or a liver transplant physician; AND

C. The patient meets ONE of the following conditions (i or ii)

i. Condition 1: Approve for up to 12 weeks if the patient meets ONE of a or b and c:

a) The patient is treatment-naïve; OR

b) The patient has previously been treated with pegylated interferon/ribavirin, Incivek, Olysio, or Victrelis; AND

c) The patient has completed a course of therapy with Zepatier and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required].** OR

ii. Condition 2: Approve for 16 weeks if the patient meets ONE of the following criteria (a, b, or c):

a) The patient has previously been treated with Daklinza, Epclusa (brand or generic), Harvoni (brand or generic), or Zepatier; OR

b) The patient has previously been treated with Sovaldi + ribavirin with or without pegylated interferon/interferon; OR

c) The patient has previously been treated with Sovaldi + Olysio.

10. Hepatitis C Genotype 4 with Renal Impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min or end-stage renal disease [ESRD]): Approve Mavyret for up to 12 weeks if the patient meets all of the following criteria (A, B, and C):

A. The patient is ≥ 12 years of age or ≥ 45 kg; AND

B. Mavyret is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, nephrologist, kidney transplant physician, or a liver transplant physician; AND

C. The patient meets ONE of the following conditions (i or ii)

i. Condition 1: The patient meets ONE of a or b and c:

a) The patient is treatment-naïve; OR

b) The patient has previously been treated with pegylated interferon/ribavirin; AND

c) The patient has completed a course of therapy with Zepatier and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required].** OR

ii. Condition 2: The patient meets the following criteria (a):

a) The patient has previously been treated with Sovaldi + ribavirin with or without pegylated interferon/interferon.

11. Hepatitis C Genotype 2, 3, 5, or 6 with Renal Impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min or end-stage renal disease [ESRD]): Approve Mavyret for the duration specified below if the patient meets all of the following criteria (A, B, and C):

A. The patient is ≥ 12 years of age or ≥ 45 kg; AND

B. Mavyret is prescribed by or in consultation with a gastroenterologist, hepatologist, infectious diseases physician, nephrologist, kidney transplant physician, or a liver transplant physician; AND

C. The patient meets ONE of the following (i, ii, or iii):

i. The patient has genotype 2, 5, or 6: Approve for 12 weeks.

ii. The patient has genotype 3 and is treatment-naïve: Approve for 12 weeks.

iii. The patient has genotype 3 and has previously been treated: Approve for 16 weeks.

12. Hepatitis C Virus (HCV) Genotype 1, Kidney Transplant: Approve Mavyret for the duration specified below if the patient meets all of the following criteria (A, B, C, and D):

A. The patient is ≥ 12 years of age or ≥ 45 kg; AND

B. The patient is a kidney transplant recipient; AND
C. Mavyret 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.
D. The patient meets ONE of the following conditions (i or ii)
- **i.** Condition 1: Approve for 12 weeks if the patient meets the following criteria (a and b):
  - **a)** The patient is treatment-naïve; AND
  - **b)** The patient has completed a course of therapy with Harvoni (brand or generic) and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required].** OR
- **ii.** Condition 2: Approve for 16 weeks if the patient meets the following criteria (a):
  - **a)** The patient has previously been treated for HCV.

13. **Hepatitis C Virus (HCV) Genotype 2, 3, 5, or 6, Kidney Transplant:** Approve Mavyret for the duration specified below if the patient meets all of the following criteria (A, B, C, and D):
A. The patient is ≥ 12 years of age or ≥ 45 kg; AND
B. The patient is a kidney transplant recipient; AND
C. Mavyret 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.
D. The patient meets ONE of the following conditions (i, ii, or iii):
- **i.** The patient has genotype 2, 5, or 6: Approve for 12 weeks.
- **ii.** The patient has genotype 3 and is treatment-naïve: Approve for 12 weeks.
- **iii.** The patient has genotype 3 and has previously been treated for HCV: Approve for 16 weeks.

14. **Hepatitis C Virus (HCV) Genotype 4, Kidney Transplant:** Approve Mavyret 12 weeks if the patient meets all of the following criteria (A, B, C, and D):
A. The patient is ≥ 12 years of age or ≥ 45 kg; AND
B. The patient is a kidney transplant recipient; AND
C. Mavyret 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.
D. The patient meets ONE of the following conditions (i or ii)
- **i.** Condition 1: The patient meets the following criteria (a and b):
  - **a)** The patient is treatment-naïve; AND
  - **b)** The patient has completed a course of therapy with Harvoni (brand or generic) and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required].** OR
- **ii.** Condition 2: The patient meets the following criteria (a):
  - **a)** The patient has previously been treated for HCV.

15. **Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6, Liver Transplant:** Approve Mavyret for the duration specified below if the patient meets all of the following criteria (A, B, C, and D):
A. The patient is ≥ 12 years of age or ≥ 45 kg; AND
B. The patient is a liver transplant recipient; AND

C. Mavyret 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; AND

D. The patient meets ONE of the following (i or ii):

- **i.** The patient has genotype 2, 4, 5, or 6: Approve for 12 weeks.
- **ii.** The patient has genotype 1 or 3 and is treatment-naïve: Approve for 12 weeks.
- **iii.** The patient has genotype 1 or 3 and has previously been treated for HCV: Approve for 16 weeks.

16. **Recurrent Hepatitis C Virus Post-Liver Transplantation, Genotype 1, 4, 5, or 6:** Approve Mavyret for **12 weeks** in patients who meet the following criteria (A, B, C, and D):
    - **A.** The patient is ≥ 12 years of age or ≥ 45 kg; AND
    - **B.** The patient is a liver transplant recipient; AND
    - **C.** Mavyret 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; AND
    - **D.** The patient has completed a course of therapy with Harvoni (brand or generic) and has documentation that he/she did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required].**

17. **Recurrent Hepatitis C Virus Post-Liver Transplantation, Genotype 2 or 3:** Approve Mavyret for **12 weeks** in patients who meet the following criteria (A, B, and C):
    - **A.** The patient is ≥ 12 years of age or ≥ 45 kg; AND
    - **B.** The patient has recurrent HCV after a liver transplantation; AND
    - **C.** Mavyret 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.

18. **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).

HISTORY

Type of Revision	Summary of Changes*
New Policy	--
DEU revision	Added generics to Harvoni and Epclusa where applicable.
DEU revision	Added criteria for pediatric patients ≥ 12 years of age or ≥ 45 kg to all approval conditions. The exclusion criterion for pediatric patients (age < 18 years) was updated to < 12 years of age or < 45 kg.
DEU revision	Child Pugh Class B added to exclusions