VENTURA COUNTY
HEALTH CARE PLAN

FORMULARY EXCEPTION POLICY

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

DATE REVISED: 06/16/2021

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 20 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 < 3 years of age.

2. **Chronic Hepatitis C Virus (HCV) Genotype 1, Adults (≥ 18 Years of Age):** Approve for the duration specified below if the patient meets the following criteria (A, B, and C):
   - **A.** Patient is ≥ 18 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; AND
   - **C.** Patient meets ONE of the following conditions (i, ii, or iii)
     - **i.** Condition 1: Approve for 12 weeks if the patient meets the following criteria (a and b):
       - **a)** Patient has previously been treated with pegylated interferon/ribavirin, Incivek, Olysio, or Victrelis; AND
       - **b)** Patient has completed a course of therapy with ONE of Epclusa (brand or generic), Harvoni (brand or generic), or Zepatier and has documentation that they 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)** Patient has previously been treated with Daklinza, Epclusa (brand or generic), Harvoni (brand or generic), or Zepatier; AND
       - **b)** Patient has completed a course of therapy with Vosevi and has documentation that they did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required]**. OR
     - **iii.** Condition 3: Approve for 16 weeks if the patient meets ONE of the following criteria (a or b):
       - **a)** Patient has previously been treated with Sovaldi + ribavirin with or without pegylated interferon/interferon; OR
       - **b)** Patient has previously been treated with Sovaldi + Olysio.

3. **Chronic Hepatitis C Virus (HCV) Genotype 1, Pediatric Patient (≥ 3 Years of Age and < 18 Years of Age):** Approve for the duration specified below if the patient meets the following criteria (A, B, and C):
   - **A.** Patient is ≥ 3 years of age and < 18 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; AND

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

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

a) Patient has previously been treated with pegylated interferon/ribavirin, Incivek, Olysio, or Victrelis; AND

b) Patient has completed a course of therapy with ONE of Epclusa (brand or generic), Harvoni (brand or generic) and has documentation that they 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) Patient has previously been treated with Daklinza, Epclusa (brand or generic), Harvoni (brand or generic), or Zepatier. OR

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

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

b) Patient has previously been treated with Sovaldi + Olysio.

4. Chronic Hepatitis C Virus (HCV) Genotype 2. Approve for 12 weeks if the patient meets the following criteria (A, B, and C):

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; AND

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

i. Condition 1: Patient meets ONE of the following criteria (a and b):

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

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

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

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

5. Chronic Hepatitis C Virus (HCV) Genotype 3, Adults (≥ 18 Years of Age). Approve for the specified duration if the patient meets the following criteria (A, B, and C):

A. Patient is ≥ 18 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; AND

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

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

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

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

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

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

b) Patient has completed a course of therapy with Epclusa (brand or generic) and has documentation that they 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 (≥ 3 Years of Age).** Approve for the specified duration if the patient meets the following criteria (A, B, and C):
   - **A.** Patient is ≥ 3 years of age and < 18 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; AND
   - **C.** Patient meets ONE of the following (i, ii, or iii):
     - **i.** Condition 1: Approve for 12 weeks if the patient meets the following criteria (a):
       - **a)** Patient is treatment-naïve; OR
     - **ii.** Condition 2: Approve for 16 weeks if the patient meets the following criteria (a and b):
       - **a)** Patient has previously been treated with pegylated interferon/ribavirin; AND
       - **b)** Patient has completed a course of therapy with Epclusa (brand or generic) and has documentation that the patient did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required].** OR
     - **iii.** Condition 3: Approve for 16 weeks if the patient meets the following criteria (a):
       - **a)** Patient has previously been treated with Sovaldi + ribavirin with or without pegylated interferon/interferon.

7. **Chronic Hepatitis C Virus (HCV) Genotype 4, Adult (≥ 18 Years of Age).** Approve for 12 weeks if the patient meets the following criteria (A, B, and C):
   - **A.** Patient is ≥ 18 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; AND
   - **C.** Patient meets ONE of the following conditions (i or ii)
     - **i.** Condition 1: Patient meets ONE of (a and b):
       - **a)** Patient has previously been treated with pegylated interferon/ribavirin; AND
       - **b)** Patient has completed a course of therapy with Epclusa (brand or generic), Harvoni (brand or generic), or Zepatier and has documentation that they did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required].** OR
     - **ii.** Condition 2: Patient meets the following criteria (a):
       - **a)** Patient has previously been treated with Sovaldi + ribavirin with or without pegylated interferon/interferon.

8. **Chronic Hepatitis C Virus (HCV) Genotype 4, Pediatric Patient (≥ 3 Years of Age and < 18 Years of Age).** Approve for 12 weeks if the patient meets the following criteria (A, B, and C):
   - **A.** Patient is ≥ 3 years of age and < 18 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; AND
   - **C.** Patient meets ONE of the following conditions (i or ii)
     - **i.** Condition 1: Patient meets ONE of (a and b):
       - **a)** Patient has previously been treated with pegylated interferon/ribavirin; AND
       - **b)** Patient has completed a course of therapy with Epclusa (brand or generic) or Harvoni (brand or generic) and has documentation that they did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required].** OR
     - **ii.** Condition 2: Patient meets the following criteria (a):

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

9. **Chronic Hepatitis C Virus (HCV) Genotype 5 or 6.** Approve for 12 weeks if the patient meets the following criteria (A, B, and C):
   - **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; AND
   - **C.** Patient meets ONE of the following conditions (i or ii)
     - **i.** Condition 1: Patient meets ONE of the following criteria (a and b):
       - **a)** Patient has previously been treated with pegylated interferon/ribavirin; AND
       - **b)** Patient has completed a course of therapy with Epclusa (brand or generic) or Harvoni (brand or generic) and has documentation that they did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required].** OR
     - **ii.** Condition 2: Patient meets the following criteria (a):
       - **a)** Patient has previously been treated with Sovaldi + ribavirin with or without pegylated interferon/interferon.

10. **Hepatitis C Virus (HCV) Genotype 1, Renal Impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min or end-stage renal disease [ESRD]), Adults (≥ 18 Years of Age):** Approve for the duration specified below if the patient meets all of the following criteria (A, B, and C):
   - **A.** Patient is ≥ 18 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; AND
   - **C.** Patient meets ONE of the following conditions (i or ii)
     - **i.** Condition 1: Approve for 12 weeks if the patient meets the following (a and b):
       - **a)** Patient has previously been treated with pegylated interferon/ribavirin, Incivek, Olysio, or Victrelis; AND
       - **b)** Patient has completed a course of therapy with Zepatier and has documentation that they 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)** Patient has previously been treated with Daklinza, Epclusa (brand or generic), Harvoni (brand or generic), or Zepatier; OR
       - **b)** Patient has previously been treated with Sovaldi + ribavirin with or without pegylated interferon/interferon; OR
       - **c)** Patient has previously been treated with Sovaldi + Olysio.

11. **Hepatitis C Virus (HCV) Genotype 1, Renal Impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min or end-stage renal disease [ESRD]), Pediatric Patient (≥ 3 Years of Age and < 18 Years of Age):** Approve for the duration specified below if the patient meets all of the following criteria (A, B, and C):
   - **A.** Patient is ≥ 3 years of age and < 18 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; AND
   - **C.** 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):

a) Patient has previously been treated with pegylated interferon/ribavirin, Incivek, Olysio, or Victrelis. OR

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

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

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

c) Patient has previously been treated with Sovaldi + Olysio.

12. Hepatitis C Genotype 4 with Renal Impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min or end-stage renal disease [ESRD]), Adult (≥ 18 Years of Age): Approve for 12 weeks if the patient meets all of the following criteria (A, B, and C):

A. Patient is ≥ 18 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; AND

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

i. Condition 1: Patient meets both of the following criteria (a and b):

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

b) Patient has completed a course of therapy with Zepatier and has documentation that they did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required].** OR

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

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

13. Hepatitis C Genotype 4 with Renal Impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min or end-stage renal disease [ESRD]), Pediatric Patient (≥ 3 Years of Age and < 18 Years of Age): Approve for 12 weeks if the patient meets all of the following criteria (A, B, and C):

A. Patient is ≥ 3 years of age and < 18 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; AND

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

i. Condition 1: Patient meets the following criteria (a):

a) Patient has previously been treated with pegylated interferon/ribavirin; OR

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

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

14. 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 for the duration specified below if the patient meets all of the following criteria (A, B, and C):

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; 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: Approve for 16 weeks.

15. **Hepatitis C Virus (HCV) Genotype 2, 3, 5, or 6, Kidney Transplant:** Approve for the duration specified below if the patient meets all of the following criteria (A, B, C, and D):
    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.
    D. Patient meets ONE of the following conditions (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.

16. **Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6, Liver Transplant:** Approve for the duration specified below if the patient meets all of the following criteria (A, B, C, and D):
    A. Patient is ≥ 3 years of age; AND
    B. Patient is a liver 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: a gastroenterologist, hepatologist, infectious diseases physician, or a liver transplant physician; AND
    D. Patient meets ONE of the following (i or ii):
        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.

17. **Recurrent Hepatitis C Virus Post-Liver Transplantation, Genotype 1, 4, 5, or 6, Adult (≥ 18 Years of Age):** Approve for 12 weeks in patients who meet the following criteria (A, B, C, and D):
    A. Patient is ≥ 18 years of age; AND
    B. Patient is a liver 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, or liver transplant physician; AND
    D. Patient has completed a course of therapy with Harvoni (brand or generic) and has documentation that they did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) **[documentation required].**

18. **Recurrent Hepatitis C Virus Post-Liver Transplantation, Genotype 1, 4, 5, or 6, Pediatric Patient (≥ 3 Years of Age and < 18 Years of Age):** Approve for 12 weeks in patients who meet the following criteria (A, B, C, and D):
    A. Patient is ≥ 3 years of age and < 18 years of age; AND
    B. Patient is a liver 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, or liver transplant physician; AND

19. **Recurrent Hepatitis C Virus Post-Liver Transplantation, Genotype 2 or 3:** Approve for 12 weeks in patients who meet the following criteria (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.

20. 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
Annual revision 12/02/2020	No criteria changes
DEU revision	Chronic Hepatitis C Virus (HCV) Genotype 1: Criteria for treatment-naïve patients were removed. Mavyret is not approved. Chronic Hepatitis C Virus (HCV) Genotype 2, Adults (≥ 18 years of age). Criteria for treatment-naïve patients were removed. Mavyret is not approved. Chronic Hepatitis C Virus (HCV) Genotype 3, Adults (≥ 18 years of age). Criteria for treatment-naïve patients were removed. Mavyret is not approved. Chronic Hepatitis C Virus (HCV) Genotype 4. Criteria for treatment-naïve patients were removed. Mavyret is not approved. Chronic Hepatitis C Virus (HCV) Genotype 5 or 6. Criteria for treatment-naïve patients were removed. Mavyret is not approved. Hepatitis C Virus (HCV) Genotype 1, Renal Impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min or end-stage renal disease [ESRD]). Criteria for treatment-naïve patients were removed. Mavyret is not approved. Hepatitis C Genotype 4 with Renal Impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min or end-stage renal disease [ESRD]). Criteria for treatment-naïve patients were removed. Mavyret is not approved. Hepatitis C Virus (HCV) Genotype 1, Kidney Transplant. Criteria for treatment-naïve patients were removed. Mavyret is not approved. Hepatitis C Virus (HCV) Genotype 4, Kidney Transplant. Criteria for treatment-naïve patients were removed. Mavyret is not approved.
DEU Revision	Mavyret oral pellets were added to the policy. Any reference to "up to" for the duration of approval was removed. Hepatitis C virus (HCV) any genotype: Age criteria were revised form ≥ 12 years of age or < 45 kg to ≥ 3 years of age. Chronic Hepatitis C Virus (HCV) Genotype 1: Age criteria were revised form ≥ 12 years of age or < 45 kg to ≥ 18 years of age.

	Chronic Hepatitis C Virus (HCV) Genotype 1, Pediatric Patient (≥ 3 Years of Age and < 18 Years of age): New criteria were added. Chronic Hepatitis C Virus (HCV) Genotype 2, Adults (≥ 18 Years of Age): Age criteria were revised from ≥ 18 years of age to ≥ 3 years of age. Chronic Hepatitis C Virus (HCV) Genotype 2, Pediatric Patient (≥ 12 Years of Age or < 45 kg): Separate criteria were removed (see above). Chronic Hepatitis C Virus (HCV) Genotype 3, Pediatric Patient (≥ 12 Years of Age or < 45 kg): Age criteria were revised from ≥ 12 years of age or < 45 kg to ≥ 3 years of age. Patients previously treated with pegylated interferon/ribavirin are required to try Epclusa (brand or generic) and have documentation that the patient did not achieve a sustained viral response. Documentation is required. Chronic Hepatitis C Virus (HCV) Genotype 4, Pediatric Patient (≥ Years of Age and < 18 Years of Age): New criteria were added. Patients previously treated with pegylated interferon/ribavirin are required to try Epclusa (brand or generic) and have documentation that the patient did not achieve a sustained viral response. Documentation is required. Chronic Hepatitis C Virus (HCV) Genotype 5 or 6: Age criteria were revised form ≥ 12 years of age or < 45 kg to ≥ 3 years of age. Hepatitis C Virus (HCV) Genotype 1, Renal Impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min or end-stage renal disease [ESRD]): Age criteria were revised form ≥ 12 years of age or < 45 kg to ≥ 18 years of age. Hepatitis C Virus (HCV) Genotype 1, Renal Impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min or end-stage renal disease [ESRD]), Pediatric Patient (≥ 3 Years of Age and < 18 Years of Age): New criteria were added. Hepatitis C Virus (HCV) Genotype 4, Renal Impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min or end-stage renal disease [ESRD]): Age criteria were revised form ≥ 12 years of age or < 45 kg to ≥ 18 years of age. Hepatitis C Virus (HCV) Genotype 4, Renal Impairment (estimated glomerular filtration rate [eGFR] < 30 mL/min or end-stage renal disease [ESRD]), Pediatric Patient (≥ 3 Years of Age and < 18 Years of Age): New criteria were added. 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]): Age was updated to ≥ 3 years of age. Hepatitis C Virus (HCV) Genotype 1 or 4, Kidney Transplant: Age criteria were revised form ≥ 12 years of age or < 45 kg to ≥ 3 years of age. Treatment-naïve patients are included and approved for 12 weeks. Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6, Liver Transplant: Age criteria were revised form ≥ 12 years of age or < 45 kg to ≥ 3 years of age. Recurrent Hepatitis C Virus Post-Liver Transplantation, Genotype 1, 4, 5, or 6: Age criteria were revised form ≥ 12 years of age or < 45 kg to ≥ 18 years of age. Recurrent Hepatitis C Virus Post-Liver Transplantation, Genotype 1, 4, 5, or 6, Pediatric Patient (≥ 3 Years of Age and < 18 Years of age): New criteria were added. Recurrent Hepatitis C Virus Post-Liver Transplantation, Genotype 2 or 3: Age criteria were revised form ≥ 12 years of age or < 45 kg to ≥ 3 years of age.