

## FORMULARY EXCEPTION POLICY

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

**DATE REVISED:** 06/16/2021

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**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  $\geq 3$  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 ( $\geq 18$  Years of Age).** Approve for the specified duration if the patient meets the following criteria (A, B, and C):
- A. Patient is  $\geq 18$  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 ( $\geq 3$  Years of Age).** Approve for the specified duration if the patient meets the following criteria (A, B, and C):
- A. Patient is  $\geq 3$  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 ( $\geq 18$  Years of Age).** Approve for 12 weeks if the patient meets the following criteria (A, B, and C):
- A. Patient is  $\geq 18$  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 ( $\geq 3$  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  $\geq 3$  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  $\geq 3$  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 ( $\geq 18$  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  $\geq 18$  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 ( $\geq 3$  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  $\geq 3$  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  $\geq 3$  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  $\geq 3$  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 ( $\geq 18$  Years of Age):** Approve for 12 weeks in patients who meet the following criteria (A, B, C, and D):

- A. Patient is  $\geq 18$  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 ( $\geq 3$  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  $\geq 3$  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  $\geq 3$  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 Eplusa where applicable.   |
| DEU revision                  | Added criteria for pediatric patients $\geq 12$ years of age or $\geq 45$ 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<br>12/02/2020 | No criteria changes  |
| DEU revision                  | <p>Chronic Hepatitis C Virus (HCV) Genotype 1: Criteria for treatment-naïve patients were removed. Mavyret is not approved.</p> <p>Chronic Hepatitis C Virus (HCV) Genotype 2, Adults (<math>\geq 18</math> years of age). Criteria for treatment-naïve patients were removed. Mavyret is not approved.</p> <p>Chronic Hepatitis C Virus (HCV) Genotype 3, Adults (<math>\geq 18</math> years of age). Criteria for treatment-naïve patients were removed. Mavyret is not approved.</p> <p>Chronic Hepatitis C Virus (HCV) Genotype 4. Criteria for treatment-naïve patients were removed. Mavyret is not approved.</p> <p>Chronic Hepatitis C Virus (HCV) Genotype 5 or 6. Criteria for treatment-naïve patients were removed. Mavyret is not approved.</p> <p>Hepatitis C Virus (HCV) Genotype 1, Renal Impairment (estimated glomerular filtration rate [eGFR] <math>&lt; 30</math> mL/min or end-stage renal disease [ESRD]). Criteria for treatment-naïve patients were removed. Mavyret is not approved.</p> <p>Hepatitis C Genotype 4 with Renal Impairment (estimated glomerular filtration rate [eGFR] <math>&lt; 30</math> mL/min or end-stage renal disease [ESRD]). Criteria for treatment-naïve patients were removed. Mavyret is not approved.</p> <p>Hepatitis C Virus (HCV) Genotype 1, Kidney Transplant. Criteria for treatment-naïve patients were removed. Mavyret is not approved.</p> <p>Hepatitis C Virus (HCV) Genotype 4, Kidney Transplant. Criteria for treatment-naïve patients were removed. Mavyret is not approved.</p> |
| DEU Revision                  | <p>Mavyret oral pellets were added to the policy. Any reference to “up to” for the duration of approval was removed.</p> <p>Hepatitis C virus (HCV) any genotype: Age criteria were revised form <math>\geq 12</math> years of age or <math>&lt; 45</math> kg to <math>\geq 3</math> years of age.</p> <p>Chronic Hepatitis C Virus (HCV) Genotype 1: Age criteria were revised form <math>\geq 12</math> years of age or <math>&lt; 45</math> kg to <math>\geq 18</math> years of age.</p>  |

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|  | <p>Chronic Hepatitis C Virus (HCV) Genotype 1, Pediatric Patient (<math>\geq 3</math> Years of Age and <math>&lt; 18</math> Years of age): New criteria were added.</p> <p>Chronic Hepatitis C Virus (HCV) Genotype 2, Adults (<math>\geq 18</math> Years of Age): Age criteria were revised from <math>\geq 18</math> years of age to <math>\geq 3</math> years of age.</p> <p>Chronic Hepatitis C Virus (HCV) Genotype 2, Pediatric Patient (<math>\geq 12</math> Years of Age or <math>&lt; 45</math> kg): Separate criteria were removed (see above).</p> <p>Chronic Hepatitis C Virus (HCV) Genotype 3, Pediatric Patient (<math>\geq 12</math> Years of Age or <math>&lt; 45</math> kg): Age criteria were revised from <math>\geq 12</math> years of age or <math>&lt; 45</math> kg to <math>\geq 3</math> 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.</p> <p>Chronic Hepatitis C Virus (HCV) Genotype 4, Pediatric Patient (<math>\geq</math> Years of Age and <math>&lt; 18</math> 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.</p> <p>Chronic Hepatitis C Virus (HCV) Genotype 5 or 6: Age criteria were revised form <math>\geq 12</math> years of age or <math>&lt; 45</math> kg to <math>\geq 3</math> years of age.</p> <p>Hepatitis C Virus (HCV) Genotype 1, Renal Impairment (estimated glomerular filtration rate [eGFR] <math>&lt; 30</math> mL/min or end-stage renal disease [ESRD]): Age criteria were revised form <math>\geq 12</math> years of age or <math>&lt; 45</math> kg to <math>\geq 18</math> years of age.</p> <p>Hepatitis C Virus (HCV) Genotype 1, Renal Impairment (estimated glomerular filtration rate [eGFR] <math>&lt; 30</math> mL/min or end-stage renal disease [ESRD]), Pediatric Patient (<math>\geq 3</math> Years of Age and <math>&lt; 18</math> Years of Age): New criteria were added.</p> <p>Hepatitis C Virus (HCV) Genotype 4, Renal Impairment (estimated glomerular filtration rate [eGFR] <math>&lt; 30</math> mL/min or end-stage renal disease [ESRD]): Age criteria were revised form <math>\geq 12</math> years of age or <math>&lt; 45</math> kg to <math>\geq 18</math> years of age.</p> <p>Hepatitis C Virus (HCV) Genotype 4, Renal Impairment (estimated glomerular filtration rate [eGFR] <math>&lt; 30</math> mL/min or end-stage renal disease [ESRD]), Pediatric Patient (<math>\geq 3</math> Years of Age and <math>&lt; 18</math> Years of Age): New criteria were added.</p> <p>Hepatitis C Genotype 2, 3, 5, or 6 with Renal Impairment (estimated glomerular filtration rate [eGFR] <math>&lt; 30</math> mL/min or end-stage renal disease [ESRD]): Age was updated to <math>\geq 3</math> years of age.</p> <p>Hepatitis C Virus (HCV) Genotype 1 or 4, Kidney Transplant: Age criteria were revised form <math>\geq 12</math> years of age or <math>&lt; 45</math> kg to <math>\geq 3</math> years of age. Treatment-naïve patients are included and approved for 12 weeks.</p> <p>Hepatitis C Virus (HCV) Genotype 1, 2, 3, 4, 5, or 6, Liver Transplant: Age criteria were revised form <math>\geq 12</math> years of age or <math>&lt; 45</math> kg to <math>\geq 3</math> years of age.</p> <p>Recurrent Hepatitis C Virus Post-Liver Transplantation, Genotype 1, 4, 5, or 6: Age criteria were revised form <math>\geq 12</math> years of age or <math>&lt; 45</math> kg to <math>\geq 18</math> years of age.</p> <p>Recurrent Hepatitis C Virus Post-Liver Transplantation, Genotype 1, 4, 5, or 6, Pediatric Patient (<math>\geq 3</math> Years of Age and <math>&lt; 18</math> Years of age): New criteria were added.</p> <p>Recurrent Hepatitis C Virus Post-Liver Transplantation, Genotype 2 or 3: Age criteria were revised form <math>\geq 12</math> years of age or <math>&lt; 45</math> kg to <math>\geq 3</math> years of age.</p> |
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