PREFERRED SPECIALTY MANAGEMENT POLICY

POLICY: Hepatitis C Virus Direct-Acting Antivirals Preferred Specialty Management Policy for National Preferred Formulary

- Epclusa® (sofosbuvir/velpatasvir tablets – Gilead)
- sofosbuvir/velpatasvir tablets (authorized generic to Epclusa – Gilead)
- Harvoni® (ledipasvir/sofosbuvir tablets and oral pellets – Gilead)
- ledipasvir/sofosbuvir tablets (authorized generic to Harvoni – Gilead)
- Mavyret™ (glecaprevir/pibrentasvir tablets – AbbVie)
- Sovaldi® (sofosbuvir tablets and oral pellets – Gilead)
- Vosevi™ (sofosbuvir/velpatasvir/voxilaprevir tablets – Gilead)
- Zepatier™ (grazoprevir/elbasvir tablets – Merck)

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OVERVIEW

The standard of care for all Hepatitis C genotypes is all-oral therapy with direct-acting antivirals. For more information on criteria within a Prior Authorization program by specific condition refer to the respective standard *Hepatitis C Prior Authorization Policy*.

Several direct-acting antivirals are available; indications vary among the products. Epclusa is indicated for the treatment of chronic hepatitis C virus (HCV) genotypes 1 through 6 in patients ≥ 6 years of age or ≥ 17 kg with or without compensated cirrhosis or with decompensated cirrhosis in combination with ribavirin.[1-3,10-11] Harvoni is indicated for the treatment of adults and pediatric patients ≥ 3 years of age: 1) with genotypes 1, 4, 5, and 6 chronic HCV with or without compensated cirrhosis; 2) with genotype 1 chronic HCV with decompensated cirrhosis; and 3) with genotype 1 or 4 infection in liver transplant recipients without cirrhosis or with compensated cirrhosis, in combination with ribavirin. Mavyret is indicated for the treatment of adult and pediatric patients ≥ 12 years of age or ≥ 45 kg with chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection with or without compensated cirrhosis and for the treatment of adult and pediatric patients ≥ 12 years of age or ≥ 45 kg with HCV genotype 1 infection who have previously been treated with a regimen containing an HCV NS5A inhibitor or an NS3/4A protease inhibitor, but not both. Mavyret is additionally indicated in kidney and liver transplant patients with specific dosing for these patient populations. Sovaldi is indicated for the treatment of adults with genotypes 1, 2, 3, and 4 chronic HCV in combination with ribavirin or pegylated interferon + ribavirin. Sovaldi is also indicated in pediatric patients ≥ 3 years of age with genotypes 2 or 3 chronic HCV in combination with ribavirin. Vosevi is indicated for the treatment of adult patients with chronic HCV infection without cirrhosis or with compensated cirrhosis (Child-Pugh A): Who have genotype 1, 2, 3, 4, 5, or 6 infection and have previously been treated with an HCV regimen containing an NS5A inhibitor; and for patients with genotype 1a or 3 infection and who have previously been treated with an HCV regimen containing Sovaldi without an NS5A inhibitor. Zepatier is indicated for the treatment of adults with genotypes 1 and 4 chronic HCV.

Epclusa and Harvoni are the available products indicated in decompensated liver disease. Harvoni (in adults) is indicated in post-transplant recurrent HCV.

POLICY STATEMENT

This Preferred Specialty Management program has been developed to encourage the use of Preferred Products. For all medications (Preferred and Non-Preferred), the patient is required to meet the respective standard *Hepatitis C Prior Authorization Policy* criteria. The program also directs the patient to try one Preferred Product prior to the approval of a Non-Preferred Product. Requests for Non-Preferred Products will also be reviewed using the exception criteria (below). If the patient meets the standard *Hepatitis C Prior Authorization Policy* criteria, but has not tried a Preferred Product, a review will be offered for the Preferred Product using the respective standard *Hepatitis C Prior Authorization Policy* criteria. All approvals are provided for the duration documented in the respective standard *Hepatitis C Prior Authorization Policy*.

Documentation: Documentation is required for use of a non-preferred product as noted in the criteria as **[documentation required]**. Documentation may include, but is not limited to, chart notes, prescription claims records, prescription receipts, and/or other information.

Automation: None.

Preferred and Non-Preferred Products for Chronic Hepatitis C Virus.

	Genotype 1	Genotype 2	Genotype 3	Genotype 4	Genotype 5 or 6
Preferred	•Epclusa (brand) •Harvoni (brand) •Vosevi •Zepatier	•Epclusa (brand) •Vosevi	•Epclusa (brand) •Vosevi	•Epclusa (brand) •Harvoni (brand) •Vosevi •Zepatier	•Epclusa (brand) •Harvoni (brand) •Vosevi
Non-Preferred	•Mavyret •sofosbuvir/ velpatasvir (generic) •ledipasvir/ sofosbuvir (generic)	•Mavyret •Sovaldi •sofosbuvir/ velpatasvir (generic)	•Mavyret •Sovaldi •Sofosbuvir/velpatasvir (generic)	•Mavyret •sofosbuvir/velpatasvir (generic) •ledipasvir/sofosbuvir (generic)	•Mavyret •sofosbuvir/velpatasvir (generic) •ledipasvir/sofosbuvir (generic)

RECOMMENDED EXCEPTION CRITERIA

Non-Preferred Product	Exception Criteria
Epclusa (brand only)	**1.** Approve for the duration specified in the standard *Hepatitis C – Epclusa PA Policy* if the patient has met the standard *Hepatitis C – Epclusa PA Policy* criteria.
sofosbuvir/ velpatasvir (generic only)	**1.** Sofosbuvir/velpatasvir (generic only) is not approved; offer to review for Epclusa (brand only) using the standard *Hepatitis C – Epclusa PA Policy* criteria.
Harvoni (brand only)	**1.** Approve for the duration specified in the standard *Hepatitis C – Harvoni PA Policy* criteria.
ledipasvir/ sofosbuvir (generic only)	**1.** Ledipasvir/sofosbuvir (generic only) is not approved; offer to review for Harvoni (brand only) using the standard *Hepatitis C – Harvoni PA Policy* criteria.

Sovaldi	**1. Genotype 2 Chronic Hepatitis C Virus, Pediatric Patients (≥ 3 Years of Age and < 18 Years of Age) – New Start.** Approve for the duration specified in the standard *Hepatitis C – Sovaldi PA Policy* criteria. **2. Genotype 3 Chronic Hepatitis C Virus, Pediatric Patients (≥ 3 Years of Age and < 18 Years of Age) – New Start.** Approve for the duration specified in the standard *Hepatitis C – Sovaldi PA Policy* criteria. **3. Patient Continuing Therapy with Sovaldi.** Refer to the standard *Hepatitis C – Sovaldi PA Policy* criteria.

Mavyret	**1. Genotype 1 Chronic Hepatitis C Virus – New Start.** **A)** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* if the patient meets BOTH of the following criteria (i and ii): **i.** Patient has met the *Hepatitis C* – Mavyret PA for PSM Policy criteria; AND **ii.** Patient meets ONE of the following criteria (a, b or c): **a)** Patient is treatment-naïve or has previously been treated with pegylated interferon/ribavirin, Incivek, Olysio, or Victrelis AND meets the following criteria (1): **(1)** Patient has completed a course of therapy with ONE of Epclusa (brand or generic), Harvoni (brand or generic), or Zepatier and has documentation that the patient did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) with the respective therapy **[documentation required]**; OR **b)** Patient has previously been treated with Daklinza, Epclusa (brand or generic), Harvoni (brand or generic), or Zepatier and meets the following criteria (1): **(1)** Patient has completed a course of therapy with Vosevi and has documentation that the patient did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) with the respective therapy **[documentation required]**; OR **c)** Patient has previously been treated with Sovaldi + ribavirin ± pegylated interferon/interferon OR Sovaldi + Olysio. **B)** Patient meets criteria 1Ai and 1Aiia but NOT 1Aiia(1): offer to review for sofosbuvir/velpatasvir (generic only), ledipasvir/sofosbuvir (generic only), Vosevi, or Zepatier using the respective standard *Hepatitis C PA Policy* criteria. **C)** Patient meets criteria 1Ai and 1Aiib but NOT 1Aiib(1): offer to review for Vosevi using standard *Hepatitis C – Vosevi PA Policy* criteria. **2. Genotype 2 Chronic Hepatitis C Virus, Adults (≥ 18 Years of Age) – New Start.** **A)** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* if the patient meets BOTH of the following criteria (i and ii): **i.** Patient has met the *Hepatitis C – Mavyret PA for PSM Policy* criteria; AND **ii.** Patient meets ONE of the following criteria (a or b): **a)** Patient is treatment-naïve or has previously been treated with pegylated interferon/ribavirin AND meets the following criteria (1): **(1)** 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) with the respective therapy **[documentation required]**; OR **b)** Patient has previously been treated with Sovaldi + ribavirin ± pegylated interferon/interferon. **B)** Patient meets criteria 2Ai and 2Aiia but NOT 2Aiia(1); offer to review for sofosbuvir/velpatasvir (generic only) using the standard *Hepatitis C – Epclusa PA Policy* criteria.

	3. Genotype 2 or 3 Chronic Hepatitis C Virus Pediatric Patients (≥ 12 Years of Age or ≥ 45 kg) – New Start. Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* criteria. **4. Genotype 3 Chronic Hepatitis C Virus, Adults (≥ 18 Years of Age) – New Start.** **A)** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* if the patient meets BOTH of the following criteria (i and ii): **i.** Patient has met the standard *Hepatitis C – Mavyret PA for PSM* criteria; AND **ii.** Patient meets ONE of the following criteria (a or b): **a)** Patient is treatment-naïve or has previously been treated with pegylated interferon/ribavirin AND meets the following criteria (1): **(1)** 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) with the respective therapy **[documentation required]**; OR **b)** Patient has previously been treated with Sovaldi + ribavirin ± pegylated interferon/interferon and meets the following criteria (1): **(1)** The patient has completed a course of therapy with Vosevi and has documentation that the patient did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) with the respective therapy **[documentation required].** **B)** Patient meets criteria 4Ai and 4aiia but NOT 4Aiia(1): offer to review for Epclusa (brand only) using the standard *Hepatitis C – Epclusa PA Policy* criteria. **C)** Patient meets criteria 4Ai and 4Aiib but NOT 4Aiib(1): offer to review for Vosevi, using the standard *Hepatitis C – Vosevi PA Policy* criteria. **5. Genotype 4 Chronic Hepatitis C Virus – New Start.** **A)** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* if the patient meets BOTH of the following criteria (i and ii): **i.** Patient has met the *Hepatitis C – Mavyret PA for PSM Policy* criteria; AND **ii.** Patient meets ONE of the following criteria (a or b): **a)** Patient is treatment-naïve or has previously been treated with pegylated interferon/ribavirin AND meets the following criteria (1): **(1)** Patient has completed a course of therapy with Epclusa (brand or generic), Harvoni (brand or generic), or Zepatier, and has documentation that the patient did not achieve a sustained viral response (SVR; virus undetectable 12 weeks following completion of therapy) with the respective therapy **[documentation required]**; OR **b)** Patient has previously been treated with Sovaldi + ribavirin ± pegylated interferon/interferon. **B)** Patient meets criteria 5Ai and 5Aiia but NOT 5Aiia(1); offer to review for Epclusa (brand only), Harvoni (brand only), or Zepatier using the respective standard *Hepatitis C PA Policy* criteria. **6. Genotype 5 or 6 Chronic Hepatitis C Virus – New Start.** **A)** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* if the patient meets BOTH of the following criteria (i and ii):

i. Patient has met the *Hepatitis C – Mavyret PA for PSM Policy* criteria; AND

ii. Patient meets ONE of the following criteria (a or b):

a) Patient is treatment-naïve or has previously been treated with pegylated interferon/ribavirin AND meets the following criteria (1):

(1) Patient has completed a course of therapy with Epclusa (brand or generic) or Harvoni (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) with the respective therapy **[documentation required]**; OR

b) Patient has previously been treated with Sovaldi + ribavirin ± pegylated interferon/interferon.

B) Patient meets criteria 6Ai and 6Aiia but NOT 6Aiia(1): offer to review for Epclusa (brand only) or Harvoni (brand only) using the respective standard *Hepatitis C PA Policy* criteria.

7. Genotype 1 Hepatitis C Virus with Renal Impairment (Estimated Glomerular Filtration Rate [eGFR] < 30 mL/min or End-Stage Renal Disease [ESRD]) – New Start.

A) Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* if the patient meets BOTH of the following criteria (i and ii):

i. Patient has met the *Hepatitis C – Mavyret PA for PSM Policy* criteria; AND

ii. Patient meets ONE of the following criteria (a or b):

a) Patient is treatment-naïve or has previously been treated with pegylated interferon/ribavirin, Incivek, Olysio, or Victrelis and meets the following criteria (1):

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

b) Patient has previously been treated with Sovaldi + ribavirin ± pegylated interferon/interferon, or Sovaldi + Olysio, or Daklinza, or Epclusa (brand or generic), or Harvoni (brand or generic), or Zepatier.

B) Patient meets criteria 7Ai and 7Aiia but NOT 7Aiia(1): offer to review for Zepatier using the standard *Hepatitis C – Zepatier PA Policy* criteria.

8. Genotype 4 Hepatitis C Virus with Renal Impairment (Estimated Glomerular Filtration Rate [eGFR] < 30 mL/min or End-Stage Renal Disease [ESRD]) – New Start.

A) Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* if the patient meets BOTH of the following criteria (i and ii):

i. Patient has met the *Hepatitis C – Mavyret PA for PSM Policy* criteria; AND

ii. Patient meets ONE of the following criteria (a or b):

a) Patient is treatment-naïve or has previously been treated with pegylated interferon/ribavirin and meets the following criteria (1):

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

	b) Patient has previously been treated with Sovaldi + ribavirin ± pegylated interferon/interferon. **B)** Patient meets criteria 8Ai and 8Aiia but NOT 8Aiia(1): offer to review for Zepatier using the standard *Hepatitis C – Zepatier PA Policy* criteria. **9. Genotype 2, 3, 5, or 6 Hepatitis C Virus with Renal Impairment (Estimated Glomerular Filtration Rate [eGFR] < 30 mL/min or End-Stage Renal Disease [ESRD]) Treatment-Naïve or Experienced – New Start.** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* criteria. **10. Genotype 1 or 4 Hepatitis C Virus, Kidney Transplant – New Start.** **A)** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* if the patient meets BOTH of the following criteria (i and ii): **i.** Patient has met *Hepatitis C – Mavyret PA for PSM Policy* criteria; AND **ii.** Patient meets ONE of the following criteria (a or b): **a)** Patient is treatment-naïve and meets the following criteria (1): **(1)** Patient has completed a course of therapy with Harvoni (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) with Harvoni (brand or generic) **[documentation required]**; OR **b)** Patient has previously been treated for HCV. **B)** Patient meets criteria 10Ai and 10Aiia but NOT 10Aiia(1): offer to review for Harvoni (brand only) using the standard *Hepatitis C – Harvoni PA Policy* criteria. **11. Genotype 2, 3, 5, or 6 Hepatitis C Virus, Kidney Transplant – New Start.** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* criteria. **12. Genotype 2, or 3 Recurrent Hepatitis C Virus post-liver transplantation – New Start.** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* criteria. **13. Genotype 1, 4, 5, or 6 Recurrent Hepatitis C Virus post-liver transplantation – New Start.** **A)** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* if the patient meets the following criteria (i and ii): **i.** Patient has met the *Hepatitis C – Mavyret PA for PSM Policy* criteria; AND **ii.** Patient has completed a course of therapy with Harvoni (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) with Harvoni (brand or generic) **[documentation required]**. **B)** Patient meets criteria 13Ai but NOT 13Aii: offer to review for Harvoni (brand only) using the standard *Hepatitis C – Harvoni PA Policy* criteria. **14. Genotype 1, 2, 3, 4, 5, or 6 Hepatitis C Virus Liver Transplant Recipient – New Start.** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* criteria. **15. Patient Continuing Therapy with Mavyret.** Refer to the *Hepatitis C – Mavyret PA for PSM Policy* criteria.
Vosevi	**1. Genotype 1, 2, 3, 4, 5, or 6 chronic Hepatitis C Virus.** Approve for the duration specified in the standard *Hepatitis C – Vosevi PA Policy* criteria. **A) Patient Continuing Therapy with Vosevi.** Refer to the standard *Hepatitis C – Vosevi PA Policy* criteria.

Zepatier	**1. Genotype 1 or 4 Chronic Hepatitis C Virus – New Start.** Approve for the duration specified in the standard *Hepatitis C – Zepatier PA Policy* criteria. **A) Patient Continuing Therapy with Zepatier.** Refer to the standard *Hepatitis C – Zepatier PA Policy* criteria criteria.

REFERENCES

1. Harvoni® tablets and oral pellets [prescribing information]. Foster City, CA: Gilead; March 2020.
2. Sovaldi® tablets and oral pellets [prescribing information]. Foster City, CA: Gilead; March 2020.
3. Zepatier™ tablets [prescribing information]. Whitehouse Station, NJ: Merck; December 2019.
4. Epclusa tablets [prescribing information]. Foster City, CA: Gilead; March 2020.
5. Vosevi™ tablets [prescribing information]. Foster City, CA: Gilead; November 2019.
6. Mavyret™ tablets [prescribing information]. North Chicago, IL: AbbVie; April 2019.