PREFERRED SPECIALTY MANAGEMENT POLICY

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

- Epclusa® (sofosbuvir/velpatasvir tablets and oral pellets – Gilead)
- sofosbuvir/velpatasvir tablets (authorized generic to Epclusa 400 mg/100 mg tablets – Asegua Therapeutics)
- Harvoni® (ledipasvir/sofosbuvir tablets and oral pellets – Gilead)
- ledipasvir/sofosbuvir tablets (authorized generic to Harvoni – Asegua Therapeutics)
- Mavyret® (glecaprevir/pibrentasvir tablets and oral pellets – AbbVie)
- Sovaldi® (sofosbuvir tablets and oral pellets – Gilead)
- Vosevi® (sofosbuvir/velpatasvir/voxilaprevir tablets – Gilead)
- Zepatier® (grazoprevir/elbasvir tablets – Merck)

REVIEW DATE: 04/01/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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.*

All of the direct-acting antivirals (DAAs) are indicated for the treatment of **chronic hepatitis C virus** (HCV). Mavyret is the only agent indicated for **acute HCV**.[6] Epclusa is indicated for the treatment of HCV genotypes 1 through 6 in patients ≥ 3 years of age with or without compensated cirrhosis, or with decompensated cirrhosis in combination with ribavirin.[4] Harvoni is indicated for the treatment of 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.[1] Mavyret is indicated for the treatment of patients ≥ 3 years of age with acute or chronic HCV genotype 1, 2, 3, 4, 5, or 6 infection with or without compensated cirrhosis and for the treatment of patients ≥ 3 years of age 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.[6] 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.[2] 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 adults with chronic HCV infection with or without compensated cirrhosis in the following types of patients: Patients with genotype 1, 2, 3, 4, 5, or 6 infection who 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.[5] Zepatier is indicated for the treatment of patients ≥ 12 years (or ≥ 30 kg) with genotypes 1 and 4 chronic HCV.[3]

Epclusa and Harvoni are the products indicated in decompensated liver disease.

The Kidney Disease Improving Global Outcomes clinical practice guideline for the prevention, diagnosis, evaluation, and treatment of HCV in chronic kidney disease (CKD) [2022] recommend that all patients with CKD (stages 1 through 5), on dialysis (stage 5), and kidney transplant recipients with HCV be evaluated for DAA therapy.[7] The choice of the specific regimen should be based on prior treatment history, drug-drug interactions, kidney function, stage of hepatic fibrosis, transplant candidacy, and comorbid conditions. If pangenotypic regimens are not available, HCV genotype should guide the choice of treatment. In patients with an estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m^2, any genotype-appropriate DAA may be used. In patients with an eGFR < 30 mL/min/1.73 m^2 the quality of evidence is generally higher with Mavyret and Zepatier vs. Epclusa and Harvoni.

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. 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.

National Preferred Formulary and Basic Formulary – 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)

*Note: Epclusa oral pellets and Harvoni oral pellets are only available as a brand product. The authorized generics are not available as oral pellets.

***Hepatitis C Virus Direct-Acting Antivirals Preferred Specialty Management Policy* non-preferred product(s) is(are) covered as medically necessary when the following non-preferred product exception criteria is(are) met. Any other exception is considered not medically necessary.**

NON-PREFERRED PRODUCT 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.

Non-Preferred Product	Exception 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* if the patient has met 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 or 3 Chronic Hepatitis C Virus, Pediatric Patient (≥ 3 Years of Age and < 18 Years of Age) – New Start.** Sovaldi is not approved. Offer to review for Epclusa (brand only) using the standard *Hepatitis C – Epclusa PA Policy* criteria. **2. Patient Continuing Therapy with Sovaldi.** Refer to the standard *Hepatitis C – Sovaldi PA Policy* criteria.
Mavyret	**1. Genotype 1, 2, 3, 4, 5, or 6, Acute Hepatitis C Virus.** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* criteria if the patient has met the *Hepatitis C – Mavyret PA for PSM Policy* criteria. **2. Genotype 1 Chronic Hepatitis C Virus Adults (≥ 18 years of age) – New Start.** **A)** Patient is treatment-naïve: Mavyret is not approved. Offer to review for Epclusa (brand only), Harvoni (brand only), or Zepatier using the respective *Hepatitis C PA Policy* criteria; OR **B)** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* if the patient meets BOTH of the following (i and ii): **i.** Patient has met the *Hepatitis C* – Mavyret PA for PSM Policy criteria; AND **ii.** Patient meets ONE of the following (a, b, or c): **a)** Patient has previously been treated with pegylated interferon/ribavirin, Incivek, Olysio, or Victrelis AND meets the following (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 (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. **C)** Patient meets criteria 2Bi and 2Biia but NOT 2Biia(1): offer to review for Epclusa (brand only), Harvoni (brand only),

	Vosevi, or Zepatier using the respective standard *Hepatitis C PA Policy* criteria. **D)** Patient meets criteria 2Bi and 2Biib but NOT 12iib(1): offer to review for Vosevi using standard *Hepatitis C – Vosevi PA Policy* criteria. **3. Genotype 1 Chronic Hepatitis C Virus, Pediatric Patient (≥ 3 Years of Age and < 18 Years of Age) – New Start.** **A)** Patient is treatment-naïve: Mavyret is not approved. Offer to review for Epclusa (brand only) or Harvoni (brand only) using the respective *Hepatitis C PA Policy* criteria; OR **B)** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* if the patient meets BOTH of the following (i and ii): **i.** Patient has met the *Hepatitis C – Mavyret PA for PSM Policy* criteria; AND **ii.** Patient meets ONE of the following (a, b, or c): **a)** Patient has previously been treated with pegylated interferon/ribavirin, Incivek, Olysio, or Victrelis AND meets the following (1): **(1)** Patient has completed a course of therapy with ONE of 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 Daklinza, Epclusa (brand or generic), Harvoni (brand or generic), or Zepatier; OR **c)** Patient has previously been treated with Sovaldi + ribavirin ± pegylated interferon/interferon OR Sovaldi + Olysio. **C)** Patient meets criteria 3Bi and 3Biia but NOT 3Biia(1): offer to review for Epclusa (brand only) or Harvoni (brand only) using the respective standard *Hepatitis C PA Policy* criteria. **4. Genotype 2 Chronic Hepatitis C Virus – New Start.** **A)** Patient is treatment-naïve: Mavyret is not approved. Offer to review for Epclusa (brand only) using the standard *Hepatitis C – Epclusa PA Policy* criteria; OR **B)** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* if the patient meets BOTH of the following (i and ii): **i.** Patient has met the *Hepatitis C – Mavyret PA for PSM Policy* criteria; AND **ii.** Patient meets ONE of the following (a or b): **a)** Patient has previously been treated with pegylated interferon/ribavirin AND meets the following (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. **C)** Patient meets criteria 4Bi and 4Biia but NOT 4Biia(1); offer to review for Epclusa (brand only) using the standard *Hepatitis C – Epclusa PA Policy* criteria. **5. Genotype 3 Chronic Hepatitis C Virus Pediatric Patient (≥ 3 Years of Age and < 18 Years of Agee) – New Start.** **A)** Patient is treatment-naïve: Mavyret is not approved. Offer to review for Epclusa (brand only) using the standard *Hepatitis C – Epclusa PA Policy* criteria; OR **B)** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* if the patient meets BOTH of the following (i and ii): **i.** Patient has met the *Hepatitis C – Mavyret PA for PSM* criteria; AND **ii.** Patient meets ONE of the following (a or b): **a)** Patient has previously been treated with pegylated interferon/ribavirin AND meets the following (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. **C)** Patient meets criteria 5Bi and 5Biia but NOT 5Biia(1): offer to review for Epclusa (brand only) using the standard *Hepatitis C – Epclusa PA Policy* criteria. **6. Genotype 3 Chronic Hepatitis C Virus, Adult (≥ 18 Years of Age) – New Start.** **A)** Patient is treatment-naïve: Mavyret is not approved. Offer to review for Epclusa (brand only) using the standard *Hepatitis C – Epclusa PA Policy* criteria; OR **B)** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* if the patient meets BOTH of the following (i and ii): **i.** Patient has met the *Hepatitis C – Mavyret PA for PSM* criteria; AND **ii.** Patient meets ONE of the following (a or b):

a) Patient has previously been treated with pegylated interferon/ribavirin AND meets the following (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 (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].**

C) Patient meets criteria 6Bi and 6Biia but NOT 6Biia(1): offer to review for Epclusa (brand only) using the standard *Hepatitis C – Epclusa PA Policy* criteria.

D) Patient meets criteria 6Bi and 6Biib but NOT 6Biib(1): offer to review for Vosevi, using the standard *Hepatitis C – Vosevi PA Policy* criteria.

7. Genotype 4 Chronic Hepatitis C Virus, Adult (≥ 18 Years of Age) – New Start.

A) Patient is treatment-naïve: Mavyret is not approved. Offer to review for Epclusa (brand only), Harvoni (brand only), or Zepatier using the respective standard *Hepatitis C PA Policy* criteria; OR

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

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

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

a) Patient has previously been treated with pegylated interferon/ribavirin AND meets the following (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.

	C) Patient meets criteria 7Bi and 7Biia but NOT 7Biia(1); offer to review for Epclusa (brand only), Harvoni (brand only), or Zepatier using the respective standard *Hepatitis C PA Policy* criteria. **8. Genotype 4 Chronic Hepatitis C Virus, Pediatric Patient (≥ 3 Years of Age and < 18 Years of Age) – New Start.** **A)** Patient is treatment-naïve: Mavyret is not approved. Offer to review for Epclusa (brand only) or Harvoni (brand only) using the respective standard *Hepatitis C PA Policy* criteria; OR **B)** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* if the patient meets BOTH of the following (i and ii): **i.** Patient has met the *Hepatitis C – Mavyret PA for PSM Policy* criteria; AND **ii.** Patient meets ONE of the following (a or b): **a)** Patient has previously been treated with pegylated interferon/ribavirin AND meets the following (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. **C)** Patient meets criteria 8Bi and 8Biia but NOT 8Biia(1); offer to review for Epclusa (brand only) or Harvoni (brand only) using the respective standard *Hepatitis C PA Policy* criteria. **9. Genotype 5 or 6 Chronic Hepatitis C Virus – New Start.** **A)** Patient is treatment-naïve: Mavyret is not approved: Offer to review for Epclusa (brand only) or Harvoni (brand only) using the respective standard *Hepatitis C PA Policy* criteria; OR **B)** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* if the patient meets BOTH of the following (i and ii): **i.** Patient has met the *Hepatitis C – Mavyret PA for PSM Policy* criteria; AND **ii.** Patient meets ONE of the following (a or b): **a)** Patient has previously been treated with pegylated interferon/ribavirin AND meets the following (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.

C) Patient meets criteria 9Bi and 9Biia but NOT 9Biia(1): offer to review for Epclusa (brand only) or Harvoni (brand only) using the respective standard *Hepatitis C PA Policy* criteria.

10. Genotype 1 Hepatitis C Virus with Renal Impairment (Estimated Glomerular Filtration Rate [eGFR] < 30 mL/min or End-Stage Renal Disease [ESRD]), Adult (≥ 18 Years of Age) – New Start.

A) Patient is treatment-naïve: Mavyret is not approved. Offer to review for Zepatier using the standard *Hepatitis C – Zepatier PA Policy* criteria; OR

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

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

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

a) Patient has previously been treated with pegylated interferon/ribavirin, Incivek, Olysio, or Victrelis and meets the following (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.

C) Patient meets criteria 10Bi and 10Biia but NOT 10Biia(1): offer to review for Zepatier using the standard *Hepatitis C – Zepatier PA Policy* criteria.

11. Genotype 4 Hepatitis C Virus with Renal Impairment (Estimated Glomerular Filtration Rate [eGFR] < 30 mL/min or End-Stage Renal Disease [ESRD]), Adult (≥ 18 Years of Age) – New Start.

A) Patient is treatment-naïve: Mavyret is not approved. Offer to review for Zepatier using the standard *Hepatitis C – Zepatier PA Policy* criteria; OR

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

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

	ii. Patient meets ONE of the following (a or b): **a)** Patient has previously been treated with pegylated interferon/ribavirin and meets the following (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. **C)** Patient meets criteria 11Bi and 11Biia but NOT 11Biia(1): offer to review for Zepatier using the standard *Hepatitis C – Zepatier PA Policy* criteria. **12. Genotype 1 or 4 Hepatitis C Virus in a Patient 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) – New Start.** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* criteria if the patient has met the *Hepatitis C – Mavyret PA for PSM Policy* criteria. **13. 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]) – New Start.** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* criteria if the patient has met the *Hepatitis C – Mavyret PA for PSM Policy* criteria. **14. Genotype 1, 2, 3, 4, 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 if the patient has met the *Hepatitis C – Mavyret PA for PSM Policy* criteria. **15. 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 if the patient has met the *Hepatitis C – Mavyret PA for PSM Policy* criteria. **16. Genotype 1, 4, 5, or 6 Recurrent Hepatitis C Virus Post-Liver Transplantation – New Start, Adult (≥ 18 Years of Age).** **A)** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* if the patient meets the following (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 16Ai but NOT 16Aii: offer to review for Harvoni (brand only) using the standard *Hepatitis C – Harvoni PA Policy* criteria. **17. Genotype 1, 4, 5, or 6 Recurrent Hepatitis C Virus Post-Liver Transplantation – New Start, Pediatric (≥ 3 Years of Age and < 18 Years of Age).** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* criteria if the patient has met the *Hepatitis C – Mavyret PA for PSM Policy* criteria. **18. 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 if the patient has met the *Hepatitis C – Mavyret PA for PSM Policy* criteria. **19. Chronic Hepatitis C Virus (HCV), Genotype Unknown/Undetermined, No Cirrhosis.** Mavyret is not approved. Offer to review for Epclusa (brand only) using the *Hepatitis C – Epclusa PA Policy* criteria. **20. Chronic Hepatitis C Virus (HCV), Genotype Unknown/Undetermined, Compensated Cirrhosis.** Approve for the duration specified in the *Hepatitis C – Mavyret PA for PSM Policy* criteria if the patient has met the *Hepatitis C – Mavyret PA for PSM Policy* criteria. **21. 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 if the patient has met the standard *Hepatitis C – Vosevi PA Policy* criteria. **2. 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 if the patient has met the standard *Hepatitis C – Zepatier PA Policy* criteria. **2. Patient Continuing Therapy with Zepatier.** Refer to the standard *Hepatitis C – Zepatier PA Policy* criteria.

REFERENCES

1. Harvoni® tablets and oral pellets [prescribing information]. Foster City, CA: Gilead; December 2024.

2. Sovaldi® tablets and oral pellets [prescribing information]. Foster City, CA: Gilead; December 2024.
3. Zepatier® tablets [prescribing information]. Whitehouse Station, NJ: Merck; December 2021.
4. Epclusa® tablets and oral pellets [prescribing information]. Foster City, CA: Gilead; April 2022.
5. Vosevi® tablets [prescribing information]. Foster City, CA: Gilead; November 2019.
6. Mavyret® tablets and oral pellets [prescribing information]. North Chicago, IL: AbbVie; June 2025.
7. Kidney Disease Improving Global Outcomes. KDIGO 2022 clinical practice guideline for the prevention, diagnosis, evaluation, and treatment of hepatitis C in chronic kidney disease. *Kidney Int.* 2022;102 (Suppl 65);S129-S205.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	Mavyret **Chronic Hepatitis C Virus (HCV), Genotype Unknown/Undetermined, No Cirrhosis.** Criteria were modified to add "No Cirrhosis" to the indication (previously "Chronic Hepatitis C Virus (HCV), Genotype Unknown/Undetermined"). A patient continued to be offered a review for Epclusa (brand only) using the standard Epclusa PA Policy. **Chronic Hepatitis C Virus (HCV), Genotype Unknown/Undetermined, Compensated Cirrhosis.** Criteria were created for a patient with unknown or undetermined genotype with compensated cirrhosis. A patient is approved for the duration specified in the Hepatitis C – Mavyret PA for PSM Policy criteria if the patient has met the Hepatitis C – Mavyret PA for PSM Policy criteria. Previously, a patient would have been reviewed under criteria for "Chronic Hepatitis C Virus (HCV), Genotype Unknown/Undetermined" and would have been offered a review for Epclusa (brand only) using the standard Epclusa PA policy.	04/03/2024
Annual Revision	No criteria changes.	04/02/2025
Selected Revision	Mavyret **Acute Hepatitis C Virus (HCV), Genotype 1, 2, 3, 4, 5, or 6.** A condition of approval was added. Mavyret is approved for the duration specified in the Hepatitis C – Mavyret PA for PSM Policy criteria if the patient has met the Hepatitis C – Mavyret PA for PSM Policy criteria.	06/25/2025
Annual Revision	No criteria changes.	04/01/2026