Reference number(s)
5820-D

This document applies to the following:

Formulary	Applies
Standard Control (SF)	☑
Standard Control – Choice (SCCF)	☑
Preferred Drug Plan Design (PDPD)	☑
Advanced Control Specialty (ACSF)	☑
Advanced Control Specialty – Choice (ACSCF)	☑
Managed Medicaid Template (MMT)	☐
Marketplace (MF)	☐
Aetna Small Group Affordable Care Act (SG ACA) Aetna Health Exchange (AHE)	☐
Aetna Individual Lives (IVL)	☐
Value (VF)	☐

Formulary	Applies
New to Market (NTM)	☐
Standard Formulary Chart (SFC)	☑
Basic Control Chart Preferred Drug Plan Design (BCC PDPD)	☑
Advanced Control Specialty Formulary Chart (ACSFC)	☑
Value Formulary Chart (VFC)	☐
Medical Benefit	☐
Medical Benefit: Advanced Biosimilars First	☐
Medical Benefit: Managed Medicaid (MMMB)	☐
Medicare Part B	☐
Medicare Part B: Advanced Biosimilars First	☐

Exceptions Criteria
Hepatitis C Direct-Acting Antivirals (DAAs)

This document informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

These criteria were developed to align with the following: Standard Control Formulary (SF), Standard Control Choice Formulary (SCCF), Preferred Drug Plan Design (PDPD), Advanced Control Specialty Formulary (ACSF), Advanced Control Specialty – Choice Formulary (ACSCF), Standard Formulary Chart (SFC), Basic Control Chart Preferred Drug Plan Design (BCC PDPD), and Advanced Control Specialty Formulary Chart (ACSFC).

Plan Design Summary

This program applies to the hepatitis C virus (HCV) direct-acting antiviral (DAA) agents specified in this document. Coverage for targeted products is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to members who are initiating a new treatment regimen with a targeted product and to all members requesting treatment with a targeted generic product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Hepatitis C Virus Direct-Acting Antivirals

Medications considered formulary or preferred on your plan may still require a clinical prior authorization review.

Targeted products apply if applicable to specific genotype.

Vosevi is specifically preferred for those who failed prior treatment with an HCV NS5A inhibitor-containing regimen.

Genotype	Preferred Products	Targeted Products
1, 4, 5, 6	• Epclusa (sofosbuvir/velpatasvir) • Harvoni (ledipasvir/sofosbuvir) • Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	• ledipasvir/sofosbuvir (generic) • Mavyret (glecaprevir/pibrentasvir) • sofosbuvir/velpatasvir (generic) • Zepatier (elbasvir/grazoprevir)
2, 3	• Epclusa (sofosbuvir/velpatasvir) • Vosevi (sofosbuvir/velpatasvir/voxilaprevir)	• ledipasvir/sofosbuvir (generic) • Mavyret (glecaprevir/pibrentasvir) • sofosbuvir/velpatasvir (generic) • Zepatier (elbasvir/grazoprevir)

Exception Criteria

This program applies to members requesting treatment for an indication that is FDA-approved for the preferred products.

Coverage for a targeted product is provided when any of the following criteria is met:

- The request is for generic sofosbuvir/velpatasvir and the member has a documented clinical reason that the generic medication must be used over brand name Epclusa.
- The request is for generic ledipasvir/sofosbuvir and the member has a documented clinical reason that the generic medication must be used over brand name Harvoni.
- Member is currently receiving treatment with Mavyret or Zepatier.
- The request is for Mavyret and the member meets either of the following criteria:[1-6,8]
    - Member is 3 years of age to less than 18 years of age and meets one of the following criteria:
        - Member has genotype 1, 2, 3, 4, 5, or 6 and failed prior treatment with a regimen containing an NS5A inhibitor (e.g., Epclusa, Harvoni) without prior treatment with an NS3/4A protease inhibitor (PI) (e.g., Mavyret, Olysio, Zepatier).
        - Member has genotype 1, 2, 3, 4, 5, or 6 and failed prior treatment with a regimen containing an NS3/4A PI (e.g., Olysio) without prior treatment with an NS5A inhibitor (e.g., Epclusa, Harvoni).
    - Member is 18 years of age or older, has genotype 1, 2, 3, 4, 5, or 6, and has failed prior treatment with Epclusa or Harvoni, and Vosevi.

References

1. Epclusa [package insert]. Foster City, CA: Gilead Sciences, Inc.; April 2022.
2. Harvoni [package insert]. Foster City, CA: Gilead Sciences, Inc.; March 2020.
3. Ledipasvir and sofosbuvir [package insert]. Foster City, CA: Asegua Therapeutics LLC; March 2020.
4. Mavyret [package insert]. North Chicago, IL: AbbVie Inc.; October 2023.
5. Sofosbuvir and velpatasvir [package insert]. Foster City, CA: Asegua Therapeutics LLC; April 2022.
6. Vosevi [package insert]. Foster City, CA: Gilead Sciences, Inc.; November 2019.

7. Zepatier [package insert]. Rahway, NJ: Merck & Co., Inc.; May 2022.
8. AASLD/IDSA/IAS–USA. Recommendations for testing, managing, and treating hepatitis C. https://www.hcvguidelines.org. Last changes made December 19, 2023. Accessed September 23, 2024.

Document History

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