Clinical Policy: Non-Formulary Hepatitis C Treatments

Reference Number: AZ.CP.PHAR.400
Effective Date: 08/2018
Last Review Date: 08/2018 Revision Log
Line of Business:Arizona Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
The intent of the criteria is to ensure that patients follow selection elements established by The Arizona Health Care Cost Containment System (AHCCCS) and Arizona Complete Health clinical policy for the treatment of chronic Hepatitis C (HCV).

- Copegus® (ribavirin tablet)
- Daklinza® (daclatasvir)
- Epclusa® (sofosbuvir/velpatasvir)
- Harvoni® (ledipasvir/sofosbuvir)
- Mavyret® (glecaprevir/pibrentasvir)
- Moderiba® (ribavirin tablet)
- Olysio® (simeprevir)
- Rebetol® (ribavirin capsule and oral solution)
- Ribasphere® (ribavirin capsule/tablet)
- Ribatab® (ribavirin tablet)
- Ribapak® (ribavirin tablet)
- Sovaldi® (sofosbuvir)
- Technivie® (paritaprevir/ritonavir, ombitasvir)
- Viekira XR®, Viekira Pak® (paritaprevir/ritonavir, dasabuvir, ombitasvir)
- Vosevi® (sofosbuvir/velpatasvir/voxilaprevir)
- Zepatier® (elbasvir/grazoprevir)

Policy/Criteria
It is the policy of Arizona Complete Health that Hepatitis C virus infection (HCV) therapy is **medically necessary** when the following criteria are met:

I. Approval Criteria
A. HCV genotype 1, 2, 3, 4, 5, or 6
1. Inclusion criteria: Refer to Appendix A: AHCCCS Medical Policy Manual (AMPM) Policy 320-N, Hepatitis C (HCV) Prior Authorization Requirements for Direct Acting Antiviral Medication Treatment. Available at https://www.azahcccs.gov/Shared/MedicalPolicyManual/?ID=contractormanuals
2. Mavyret® is the preferred medication for patients with no cirrhosis or with compensated cirrhosis (Child-Pugh A), and no documented contraindication or intolerance to Mavyret®. Prior authorization criteria for Mavyret are maintained as Clinical Policy CP.AHCS.44.
3. Alternative medications may be considered if the member has documented contraindications or intolerance to the preferred medication. Approval of alternative medications will be based on the level of evidence available to inform the best regimen for each patient and the strength of the recommendation from the Food and Drug Administration (FDA) and the American Association for the Study of Liver

Diseases (AASLD) guidelines (HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C, www.hcvguidelines.org)

Approval duration:

Please refer to the current FDA and AASLD guidelines (HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C, www.hcvguidelines.org) for recommended treatment durations.

Appendices

Appendix A: Inclusion criteria

The guidelines for identification of HCV treatment candidates and other considerations for approval are based on AHCCCS Medical Policy Manual (AMPM) Policy 320-N, Hepatitis C (HCV) Prior Authorization Requirements for Direct Acting Antiviral Medication Treatment, located at https://www.azahcccs.gov/Shared/MedicalPolicyManual/?ID=contractormanuals. The AHCCCS policy specifies inclusion criteria, documentation requirements, monitoring parameters and limitations of HCV treatment coverage.

Reviews, Revisions, and Approvals	Date	Approval Date
New policy	08/18	08/18

References

1. American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA). HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C. Available at: http://www.hcvguidelines.org/ and at: http://www.hcvguidelines.org/full-report-view. Accessed: June 2018.
2. Mavyret [package insert]. North Chicago, IL: AbbVie Inc.; Accessed August 2018.
3. AHCCCS Medical Policy Manual Policy 320-N available at https://www.azahcccs.gov/Shared/MedicalPolicyManual/?ID=contractormanuals
4. AHCCCS Drug List – Acute/Long Term Care. Available at https://www.azahcccs.gov/Resources/GuidesManualsPolicies/pharmacyupdates.html

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or

administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.

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