Clinical Policy: Hepatitis C Treatments

Reference Number: CA.CP.PMN.03
Effective Date: 08/16
Last Review Date: 01/20 Revision Log
Line of Business: 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 California Health & Wellness and Health Net 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 California Health & Wellness and Health Net 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: California Department of Health Care Services (DHCS) Treatment Policy for the Management of Chronic Hepatitis
2. Sofosbuvir/velpatasvir (generic Epclusa®) is the preferred medication for all patients with no documented contraindication or intolerance to sofosbuvir/velpatasvir.
3. Either Sofosbuvir/velpatasvir (generic Epclusa®) or Mavyret® are approvable for the following:
   a. Genotypes 5 and 6: treatment-naïve with no cirrhosis or compensated cirrhosis (Child-Pugh A)
   b. Genotypes 5 and 6: PEG-INF/RBV-experienced with compensated cirrhosis (Child-Pugh A)

4. For decompensated cirrhosis (Child-Pugh B and C), sofosbuvir/velpatasvir (generic Epclusa®) plus ribavirin for 12 weeks is the preferred regimen.
5. 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.

II. Off-label use of medications

Per the California Department of Health Care Services Treatment Policy for the Management of Chronic Hepatitis, authorization for unlabeled use of drugs shall not be granted unless the requested unlabeled use represents reasonable and current prescribing practices. The determination of reasonable and current prescribing practices shall be based on:

- Reference to current medical literature
- Consultation with provider organizations, academic and professional specialists

Appendices

Appendix A: Inclusion criteria

The guidelines for identification of HCV treatment candidates and other considerations for approval are based on the California Department of Health Care Services (DHCS) Treatment Policy for the Management of Chronic Hepatitis. The California DHCS policy is available at: http://www.dhcs.ca.gov/Documents/DHCS_Hep_C_Policy_7_1_18.pdf

CLINICAL POLICY
Hepatitis C Treatments

Reviews, Revisions, and Approvals	Date	Approval Date
New policy	08/16	08/16
Zepatier requests: Added NS5A resistance testing for genotype 1a Reformatted criteria based on genotypes Updated references	09/16	09/16
Updated references	06/17	07/17
Removed INF-based regimens as these are not recommended by the AASLD guidelines For approval criteria and duration, added reference to FDA guidelines for alternate recommended regimens Added Mavyret preferencing for all genotypes Updated references	09/17	09/17
Added Viekira® XR to list of Hep C medications in Description Attached current CA DHCS Treatment Policy for Hep C Effective July 1, 2018 References updated	07/18	07/18
Renamed Policy from CA.PPA.03 to CA.CP.PMN.03	02/19	02/19
Redirected to preferred medication generic Epclusa® except in select patients where Mavyret® is still preferred.	06/19	07/19
Added either generic Epclusa® or Mavyret® can be approved for select patients with genotypes 5 and 6.	11/19	01/20

References

1. State of California-Health and Human Services Agency, Department of Health Care Services. All Pan Letter 15-016. June 29, 2015. Hepatitis C Virus Treatment Policy Update. Available at: http://www.dhcs.ca.gov/formsandpubs/Documents/MMCDAPLsandPolicyLetters/APL2015/APL15-016.pdf. Accessed: November 2019
2. State of California-Health and Human Services Agency, Department of Health Care Services. California Department of Health Care Services Treatment Policy for the Management of Chronic Hepatitis C Effective July 1, 2018. Available at: http://www.dhcs.ca.gov/Documents/DHCS_Hep_C_Policy_7_1_18.pdf. Accessed: November 2019.
3. 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: November 2019.
4. Mavyret [package insert]. North Chicago, IL: AbbVie Inc.; Accessed November2019.

5. Ecplusa [package insert]. Foster City, CA: Gilead Inc.; Accessed November 2019.

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.

terms and conditions by providing services to members and/or submitting claims for payment for such services.

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.