



IEHP UM Subcommittee Approved Authorization Guideline			
<b>Guideline</b>	Hepatitis C Center of Excellence (COE) Admission Criteria	<b>Guideline #</b>	UM_OTH 14
		<b>Original Effective Date</b>	07/12/2018
<b>Section</b>	Other	<b>Revision Date</b>	05/13/2020

## COVERAGE POLICY

### I. Identifying Treatment Candidates:

- A. This policy applies to all IEHP Medi-Cal Members.
- B. Criteria for Admission: (AASLD-IDSA, 2017)
  - 1. Documentation of HCV infection.
    - a. Positive Hepatitis C antibody test (anti-HCV test). This is available as a laboratory-based assay or as a Point-of-Care assay.
    - b. Confirmatory HCV nucleic acid testing (NAT) to determine if positive anti-HCV test is an active infection, past infection that has resolved, or a false-positive result.
      - i. HCV NAT can confirm an active HCV infection using a qualitative assay.
      - ii. If the NAT is positive, secondary testing with a quantitative assay will provide a baseline level of viremia (i.e. viral load).
      - iii. HCV NAT is also recommended in persons with a negative anti-HCV test who are either immunocompromised or who may have been exposed to HCV within the previous 6 months since these individuals have been known to test negative.
    - c. Testing for HCV viral load should be done prior to initiation of antiviral therapy to document baseline level of viremia.
    - d. HCV genotype testing may be considered for those in whom it may alter treatment recommendations.

### II. Patient Readiness and Adherence: (DHCS 2018)

- A. Members being referred to the Hepatitis C COE should first be evaluated for readiness to initiate treatment.
- B. Members should be able and willing to strictly adhere to treatment protocols prescribed by the Hepatitis C COE provider.
- C. Caution should be exercised with patients who have a history of treatment failure with prior Hepatitis C treatment due to non-adherence with treatment regimen and appointments. Patients should be educated regarding potential risks and benefits of hepatitis C virus therapy as well as the potential for resistance and failed therapy if medication is not taken as prescribed.
- D. Treatment candidates must be at least the minimum ages approved by the FDA for use of the medication.

### III. Treatment Criteria

Please refer to Pharmacy and Therapeutic Subcommittee Drug Class Prior Authorization Criteria: Hepatitis C for formulary HCV treatment regimens.

### IV. Reauthorization/continuation of therapy

- A. Continuation of HCV treatment may be authorized if initial authorization criteria have been met.
- B. However, evidence of lack of adherence may result in denial of treatment reauthorization, including missed medical appointments related to HCV.

## COVERAGE LIMITATIONS AND EXCLUSIONS

Member's treatment for Hepatitis C with drugs outlined in IEHP Pharmacy and Therapeutic Subcommittee's Hepatitis C Prior Authorization Policy will be covered.

Populations unlikely to benefit from HCV treatment include those with a limited life expectancy (less than 12 months) who cannot be remediated by HCV therapy, liver transplant or another directed therapy. Patients with a short life expectancy owing to liver disease should be managed in consultation with an expert (DHCS 2020).

## ADDITIONAL INFORMATION

Hepatitis C is a liver infection caused by the Hepatitis C virus (HCV). Transmission of HCV is primarily through exposure to infected blood, such as via injection drug use, blood transfusion, needlestick injuries in the healthcare setting or birth to an HCV-infected mother. Although historically 75-85% of people infected with HCV were believed to develop chronic infection, the proportion may be as low as 64% depending on age at the time of infection (CDC 2020).

While the infection may make some individuals clinically ill, the majority of infected persons might not be aware that they have HCV (CDC 2015). Although there are no vaccines for HCV, there are curative treatments. The Centers for Disease Control and Prevention recommends a one-time HCV test in all adults  $\geq 18$  years, screening of all pregnant women (regardless of age) during each pregnancy and testing of individuals with history of exposures, behaviors and conditions that increase risk for HCV infection (e.g. end stage renal disease on hemodialysis, a history of intravenous drug use and healthcare personnel after needle sticks involving HCV-positive blood) (CMS 2020). The United States Preventative Services Task Force recommends that all adult ages 18-79 years be screened for Hepatitis C (USPSTF 2020).

## CLINICAL/REGULATORY RESOURCE

### **Centers for Medicare and Medicaid Services (CMS):**

Decision Memo CAG-00436N advises primary care providers to perform HCV screening on adults who were born between 1945 through 1965 and on those who are at high risk for HCV infection. It defines "high risk" as those with a current or past history of illicit drug use, and those who have a history of receiving a blood transfusion prior to 1992.

### **California Department of Health Care Services (DHCS):**

DHCS Treatment policy for the Management of Chronic Hepatitis C advises practitioners on baseline laboratory testing required for diagnosis, guidelines regarding treatment and choice of drug regimen, the criteria utilized to identify appropriate treatment candidates, and other considerations (e.g. screening patients for their readiness for adherence to therapy).

### **MCG Informed Care Strategies:**

Criteria for referral of a patient from a primary care provider to a specialist is given for instances such as suspected Hepatitis C infection and a need for assistance with diagnosis and management of complications of chronic hepatitis C infection including cirrhosis or coagulopathy, or a patient identified as a member of a high-risk group (e.g. coinfection with Hepatitis B/HIV, diabetes, or immunosuppression).

### **Apollo Managed Care Guidelines:**

Recommendations are given for when and how to test for Hepatitis C Virus in persons identified as being at risk for infection, including individuals who have a confirmed diagnosis of HIV, a history of illegal intravenous drug use and/or evidence of liver disease (e.g., persistently elevated liver function tests). Treatment is also discussed with various antiviral drug regimens listed in accordance with the latest guidelines endorsed by the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA).

### **DEFINITION OF TERMS**

**Viral Genotype:** The genetic makeup or variation of genes that make up a virus. HCV has 7 genotypes (Smith et al 2014).

**Viral Subtype:** Variation within a viral genotype. HCV has 67 subtypes (Smith et al 2014).

**Viral Load:** The measurement of the amount of a virus present. (United States Department of Veterans Affairs, 2018).

### **REFERENCES**

1. American Association for the Study of Liver Diseases (AASLD)- Infectious Disease Society of America (IDSA). 2017. Recommendation for Testing, Managing and Treating Hepatitis C. <https://www.hcvguidelines.org/>.
2. Apollo Medical Review Criteria Guidelines for Managing Care, 19<sup>th</sup> Edition, 7<sup>th</sup> Online Edition. 2020. INF 050 Hepatitis C.
3. California Department of Health Care Services (DHCS). 2020. Treatment Policy for the Management of Chronic Hepatitis C, Updated and Effective March 30, 2020. <http://www.dhcs.ca.gov/Pages/HepatitisC.aspx>.
4. Centers for Disease Control and Prevention (CDC). CDC Recommendations for Hepatitis C Screening Among Adults-United States, 2020. Morbidity and Mortality Weekly Report (MMWR) 69(2): 1-17, Recommendations and Reports/April 10,2020. <https://www.cdc.gov/hepatitis/hcv/index.htm>
5. Centers for Medicare & Medicaid Services (CMS) 2014. Decision Memo for Screening for Hepatitis C Virus (HCV) in Adults (CAG-00436N). <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=272>
6. Chopra, Sanjiv et. al. 2017. "Overview of the Management of Chronic Hepatitis C Virus Infection." Last modified August 07, 2017. <https://www.uptodate.com/contents/overview-of-the-management-of-chronic-hepatitis-c-virus-infection>
7. MCG Informed Care Strategies, Ambulatory Care, 23<sup>rd</sup> edition, 2019. Hepatitis C Infection Referral Management R-0043 (AC).
8. Smith, Donald B, Jens Bulch, Carla Kuiken, A Scott Muerhoff, Charles M Rice, Jack T Stapleton and Peter Simmonds. 2014. Expanded Classification of Hepatitis C Virus Into 7

- Genotypes and 67 Subtypes: Updated Criteria and Genotype Assignment Web Resource. *Hepatology* 59(1): 318-327. <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4063340/>
9. United States Department of Veterans Affairs 2018. Hepatitis C RNA quantitative testing. Last updated February 14, 2018. <https://www.hepatitis.va.gov/patient/hcv/diagnosis/labtests-RNA-quantitative-testing.asp>
  10. US Preventive Services Task Force (USPSTF). 2020. Screening for Hepatitis C Virus Infection in Adolescents and Adults-US Preventative Services Task Force Recommendation Statement. *JAMA* 2020; 323(10): 970-975. Doi: 10.1001/jam

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