California Department of Health Care Services

Treatment Policy for the Management of Chronic Hepatitis C

Effective July 1, 2015

This policy was developed by the California Department of Health Care Services (DHCS) based on a review of the medical literature, the most recent guidelines and reports published by the American Association for the Study of Liver Diseases (AASLD), Infectious Diseases Society of America (IDSA), European Association for the Study of the Liver (EASL), California Technology Assessment Forum (CTAF), Institute for Clinical and Economic Review (ICER), World Health Organization (WHO), federal Department of Veterans Affairs (VA), and recommendations from experts in the management of hepatitis C virus. The treatment of hepatitis C virus is rapidly evolving. Accordingly, this policy may be revised as new information becomes available.

1. Treatment considerations and choice of regimen for hepatitis C virus infected patients:
    A. Please refer to AASLD guidelines (hcvguidelines.org) for recommended treatment regimens and durations.
2. Identifying treatment candidates:
    A. Disease Prognosis and Severity—Any of the following clinical states identify candidates for treatment:
        i. Evidence of Stage 2 or greater hepatic fibrosis/cirrhosis including one of the following: Liver biopsy confirming a METAVIR score F2 or greater; OR Transient elastography (Fibroscan®) score greater than or equal to 7.5 kPa; OR FibroSure® score of greater than or equal to 0.48; OR APRI score greater than 0.7 OR FIB-4 greater than 3.25.
        ii. Evidence of extra-hepatic manifestation of hepatitis C virus, such as type 2 or 3 essential mixed cryoglobulinemia with end- organ

manifestations (e.g. vasculitis), or kidney disease (e.g. proteinuria, nephrotic syndrome or membranoproliferative glomerulonephritis).

iii. Persons with hepatocellular carcinoma with a life expectancy of greater than 12 months
iv. Pre- and post-liver transplant, or other solid organ transplant
v. HIV-1 co-infection
vi. Hepatitis B co-infection
vii. Other coexistent liver disease (e.g. nonalcoholic steatohepatitis)
viii. Type 2 diabetes mellitus (insulin resistant)
ix. Porphyria cutanea tarda
x. Debilitating fatigue impacting quality of life (e.g., secondary to extra-hepatic manifestations and/or liver disease)
xi. Men who have sex with men with high-risk sexual practices
xii. Active injection drug users
xiii. Persons on long-term hemodialysis
xiv. Women of childbearing age who wish to get pregnant.
xv. HCV-infected health care workers who perform exposure-prone procedures

B. Patient Readiness and Adherence:
   i. Patients shall be evaluated for readiness to initiate treatment.
   ii. Patients selected for treatment shall be able and willing to strictly adhere to treatment protocols prescribed by their provider.
   iii. Caution shall 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 shall 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.

C. Age requirements: Treatment candidate must be 18 years of age or older.

3. Other considerations
   A. Quantity Limits:
      i. Prescription of hepatitis C therapy will be dispensed in quantities up to 28 days at a time.
   B. Criteria for Reauthorization/Continuation of Therapy:
      i. Initial authorization criteria have been met, and
      ii. Evidence of lack of adherence may result in denial of treatment reauthorization.
      iii. Missed medical appointments related to the hepatitis C virus may result in denial of treatment authorization.

C. Laboratory Testing:
    i. Documentation of baseline hepatitis C virus-RNA level
    ii. Documentation of hepatitis C virus Genotype
    iii. Laboratory testing should be consistent with current AASLD/IDSA guidelines
D. Populations Unlikely to Benefit from Hepatitis C Virus Treatment: According to AASLD/IDSA hepatitis C virus Guidelines, “patients with limited life expectancy for whom hepatitis C virus therapy would not improve symptoms or prognosis do not require treatment. Chronic hepatitis C is associated with a wide range of comorbid conditions. Little evidence exists to support initiation of hepatitis C virus treatment in patients with limited life expectancy (less than 12 months) due to non–liver-related comorbid conditions. For these patients, the benefits of hepatitis C virus treatment are unlikely to be realized, and palliative care strategies should take precedence.” In patients with a life expectancy less than 12 months, treatment is not recommended.
E. Retreatment: Retreatment will be considered where there is evidence that such retreatment will improve patient outcomes. Please refer to AASLD guidelines for recommended retreatment regimens (hcvguidelines.org).
F. Criteria for coverage of Investigational Services (Title 22 § 51303)
    i. Investigational services are not covered except when it is clearly documented that all of the following apply:
    ii. Conventional therapy will not adequately treat the intended patient's condition;
    iii. Conventional therapy will not prevent progressive disability or premature death;
    iv. The provider of the proposed service has a record of safety and success with it equivalent or superior to that of other providers of the investigational service;
    v. The investigational service is the lowest cost item or service that meets the patient's medical needs and is less costly than all conventional alternatives;
    vi. The service is not being performed as a part of a research study protocol;
    vii. There is a reasonable expectation that the investigational service will significantly prolong the intended patient's life or will maintain or restore a range of physical and social function suited to activities of daily living;
    viii. All investigational services require prior authorization. Payment will not be authorized for investigational services that do not meet the

above criteria or for associated inpatient care when a beneficiary needs to be in the hospital primarily because she/he is receiving such non-approved investigational services.

G. Unlabeled use of medication: 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:
    i. Reference to current medical literature.
    ii. Consultation with provider organizations, academic and professional specialists.