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**Treatment Policy for the Management of Chronic Hepatitis C
Updated and Effective December 9, 2021**

This policy was developed by the California Department of Health Care Services (DHCS) based upon 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). This policy may be revised as new information becomes available.

1. Treatment considerations and choice of regimen for hepatitis C virus (HCV)-infected patients:
 - a. Please refer to AASLD guidelines (hcvguidelines.org) for recommended treatment regimens and durations.
2. Identifying treatment candidates:
 - a. Treatment is recommended for all patients with chronic HCV infection, except those with a short life expectancy who cannot be remediated by HCV therapy, liver transplantation, or another directed therapy.
 - 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 HCV treatment due to non-adherence with treatment regimen and appointments.
 - iv. Patients shall be educated regarding the potential risks and benefits of HCV therapy, as well as the potential for resistance and failed therapy if medication is not taken as prescribed.
3. Other considerations
 - a. Quantity limits:
 - i. Prescription of HCV 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.
 - ii. Evidence of lack of adherence may result in denial of treatment reauthorization.
 - iii. Missed medical appointments related to HCV may result in the denial of treatment authorization.

- c. Laboratory testing:
 - i. Documentation of baseline HCV-RNA level.
 - ii. Laboratory testing and monitoring should be consistent with current AASLD/IDSA guidelines.

- d. Populations unlikely to benefit from HCV treatment:

According to AASLD/IDSA HCV guidelines, "Patients with a limited life expectancy that cannot be remediated by HCV treatment, liver transplantation or another directed therapy do not require antiviral treatment. Patients with a short life expectancy owing to liver disease should be managed in consultation with an expert." Please refer to AASLD guidelines for more information on populations unlikely to benefit from HCV treatment (hcvguidelines.org).

- 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:

Any unlabeled use of medication requires prior authorization.

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 upon:

- i. Reference to current medical literature.
- ii. Consultation with provider organizations and academic and professional specialists.

When specifically considering treatment authorization requests (TARs) related to direct-acting antiviral (DAA) medications for HCV-uninfected transplant recipients receiving organs from HCV-viremic donors, upon approval of the organ transplant, the separate TAR for DAA medications will be deemed medically necessary and automatically approved as consistent with reasonable and current prescribing practices