



## Hepatitis C Treatment

### **I. Policy**

University Health Alliance (UHA) will reimburse for treatment of Hepatitis C when determined to be medically necessary and when the medical criteria guidelines (subject to limitations and exclusions) indicated below are met.

### **II. Background**

The combined American Association for the Study of Liver Diseases (AASLD) and Infectious Diseases Society of America (IDSA) guidelines for the treatment of chronic Hepatitis C are available at [www.hcvguidelines.org/](http://www.hcvguidelines.org/). These guidelines are updated frequently, so providers should check them periodically for the most up to date recommendations on patient care. The recommendations in these guidelines are a valuable resource for this policy but do not alone form a basis for approval of a particular course of treatment.

To ensure that patients with the greatest need receive treatment, patients must be prioritized so that those with at least portal fibrosis, liver-related complications or severe extrahepatic Hepatitis C complications are given the highest priority for treatment.

### **III. Criteria/Guidelines**

Guidance for Hepatitis C treatment in adults is frequently changing with the advent of new therapies and other developments. UHA will base coverage determination for treatment of Hepatitis C on the latest available scientifically valid recommendations.

- A. Treatment of HCV infection (subject to Limitations/Exclusions and Administrative Guidelines) is covered when all of the following criteria are met:
1. The patient is of approved age as indicated by current FDA approvals;
  2. The prescribing physician attests that the patient is at low risk for noncompliance with the treatment regimen;
  3. The patient has an HCV RNA positive diagnosis documented by a quantitative titer;
  4. The patient has no history of alcohol or substance abuse within three months prior to treatment initiation;
  5. The patient has ONE of the following indications:
    - a. Liver biopsy with a METVAIR score of F1, F2, F3, or F4;
    - b. Score from another blood test that detects serological markers of hepatic fibrosis that is equivalent to a METAVIR stage of F1, F2, F3, or F4;
    - c. Transient elastography (Fibroscan) score greater than or equal to 5.3 kPa;
    - d. FibroTest (e.g., FibroSure) score greater than or equal to 0.27;
    - e. Radiological imaging consistent with cirrhosis (e.g., evidence of portal hypertension);
    - f. Clinical findings consistent with cirrhosis (e.g., radiologic evidence of portal hypertension, ascites or esophageal varices, serious extrahepatic manifestations of

Hepatitis C such as cryoglobulinemia with end organ manifestations, proteinuria, nephrotic syndrome, or MPG);

- g. Organ transplant; or
  - h. HIV co-infection.
6. The medication is being prescribed by, or in consultation with, ONE of the following specialists:
- a. Hepatologist;
  - b. Gastroenterologist;
  - c. Infectious Disease Specialist; or
  - d. HIV Specialist.
7. The patient agrees to the following:
- a. 100% medication compliance;
  - b. Regular follow-up with specialty pharmacist or treating provider;
  - c. No alcohol or illicit drug use during the course of treatment;
  - d. Drug testing, when recommended by the treating provider or when required by UHA; and
  - e. Blood draws to measure HCV RNA, when ordered.

**NOTE:**

*This UHA payment policy is a guide to coverage, the need for prior authorization and other administrative directives. It is not meant to provide instruction in the practice of medicine and it should not deter a provider from expressing his/her judgment.*

*Even though this payment policy may indicate that a particular service or supply is considered covered, specific provider contract terms and/or member individual benefit plans may apply, and this policy is not a guarantee of payment. UHA reserves the right to apply this payment policy to all UHA companies and subsidiaries.*

*UHA understands that opinions about and approaches to clinical problems may vary. Questions concerning medical necessity (see Hawaii Revised Statutes §432E-1.4) are welcome. A provider may request that UHA reconsider the application of the medical necessity criteria in light of any supporting documentation.*

#### **IV. Limitations and Exclusions**

- A. Coverage for treatment of HCV is limited by the following criteria (other limitations may apply):
- 1. The criteria for treatment specified above are met.
  - 2. Treatment of HCV with DAA medication may not be covered for patients with short life expectancies due to comorbid conditions.
  - 3. Coverage will generally be limited to one treatment per lifetime. Repeat treatments for any of the following will not be covered:
    - a. Inadequate compliance
    - b. Reinfection
    - c. Discontinuation of treatment secondary to harmful alcohol and/or drug abuse
    - d. A prior treatment failure when there is no recognized, effective retreatment regimen

4. The plan will not cover replacement medication for pills that are lost or stolen.
5. Coverage is limited by any additional ineligibility criteria as specified by the AASLD.
6. Medication selection and coverage is limited by any additional criteria specified by UHA's Pharmacy Benefits Manager. These criteria can be found on the drug prior authorization forms on the UHA website.
7. In making coverage determination, UHA also will reference the dosage and duration of Hepatitis C pharmacologic therapy found in the prescribing information compiled by the Federal Food and Drug Administration. FDA prescribing guidelines can be found on the FDA website or by contacting UHA's Pharmacy Benefit Manager (PBM).

## V. Administrative Guidelines

- A. Prior authorization is required. We urge you to review the AASLD criteria for treatment prior to requesting authorization for treatment coverage. These recommendations can be found at: [www.hcvguidelines.org/evaluate/testing-and-linkage](http://www.hcvguidelines.org/evaluate/testing-and-linkage).
- B. For initial Treatment of Hepatitis C:
  1. Refer to the UHA Pharmacy Benefit Manager (PBM) prior authorization (PA) forms for authorization of specific Hepatitis C drugs. To request prior authorization, please submit via UHA's online portal. If a login has not been established, you may contact UHA at 808-532-4000 to establish one.
  2. UHA may require clinical documentation in addition to the requirements of the PBM. If additional documentation is needed, a written request will be sent in compliance with UHA policy. Requested documentation may include:
    - a. Written treatment plan from the requesting provider.
    - b. Documentation that the member has been assessed for potential non-adherence to treatment regimen and/or documentation of adherence after initiation of treatment.
    - c. Documentation of response to therapy.
- C. Continued treatment of HCV beyond the initial course approved by UHA may require additional prior authorization.

## VI. Policy History

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