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 and or followed.

Guidance for hepatitis C treatment in adults is changing frequently with the advent of new therapies and maturing studies. A static version of this guidance, such as website material, booklets, slides, and other materials, may be outdated by the time you read this. UHA will base coverage determination for treatment of Hepatitis C on the latest available scientifically valid recommendation. At this time, UHA recognizes the clinical criteria for treatment of the American Association for the Study of Liver Diseases (AASLD) and the Infectious Diseases Society of America (IDSA) and limits coverage to those patients who will realize the highest benefit of pharmacologic therapy. These recommendations can be found at:

http://www.hcvguidelines.org/full-report/hcv-testing-and-linkage-care

We urge you to review the clinical criteria and recommendations found on this website prior to requesting authorization for treatment coverage.

II. Background

When and in whom to initiate HCV Therapy:

In August 2014, the Infectious Diseases Society of America and the American Associations for the Study of Liver Diseases, in collaboration with the International Antiviral Society-USA, released a new section to their online guidelines (hcvguidelines.org) to cover information on when and in whom to begin therapy for chronic hepatitis C virus (HCV) infection. The new section is intended to aid clinicians in prioritizing treatment to patients who will benefit most.

The guidelines propose that because all patients cannot receive treatment immediately upon the approval of new agents, priority should be given to those with the most urgent need. The recommendations include the following:

- Patients with advanced fibrosis, those with compensated cirrhosis, liver transplant recipients, and those with severe extrahepatic manifestations of hepatitis are to be given the highest priority for treatment
- Based on available resources, patients at high risk for liver-related complications and severe extrahepatic hepatitis C complications should be given high priority for treatment

As referenced by the AASLD, the most immediate and high-impact benefits of SVR will be realized by populations that are at the highest risk for liver-related complications due to progressive liver disease (Metavir F3 or F4) and transplant recipients or those with clinically severe extrahepatic manifestations. We urge you to review this guidance on the website prior to requesting authorization for treatment coverage. UHA limits coverage to those patients who will benefit most from pharmacologic 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. Successful hepatitis C treatment results in sustained virologic response (SVR), as referenced by the AASLD, the most immediate and high-impact benefits of SVR will be realized by populations that are at the highest risk for liver-related complications due to progressive liver disease (Metavir F3 or F4) and transplant recipients or those with clinically severe extrahepatic manifestations. UHA coverage for Hepatitis C pharmacologic treatment is limited to patients who have ONE of the following:
   a. Liver biopsy with a METAVIR score of F3 or F4
   b. Transient elastography (Fibroscan) score greater than or equal to 9.5 kPa
   c. FibroTest (e.g., FibroSure) score of greater than or equal to 0.58
   d. Radiological imaging consistent with cirrhosis (e.g., evidence of portal hypertension)
   e. Ascites
   f. Esophageal varices
   g. Serious extrahepatic manifestations of hepatitis C, such as cryoglobulinemia

2. The medication is being prescribed by, or in consultation with, ONE of the following specialists:
   a. Hepatologist
   b. Gastroenterologist
   c. Infectious Disease Specialist

3. 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 whatsoever
   d. Drug testing, when recommended by the treating provider or required by UHA
   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 members’ 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.
A. Coverage for treatment of HCV is limited by the following criteria. Other limitations may apply.

1. The criteria for treatment specified above are not met.
2. Coverage will generally be limited to one treatment per lifetime. Repeat treatments for any of the following will not be covered:
   a. Inadequate compliance resulting in failure to achieve sustained viral response (SVR)
   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
3. The plan will not cover replacement medication for pills that are lost or stolen.
4. Coverage is limited by any additional ineligibility criteria as specified by the AASLD.
5. 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 www.uhahealth.com.
6. 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:

   http://www.hcvguidelines.org/full-report/hcv-testing-and-linkage-care

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. These PA forms can be found at the UHA website https://uhahealth.com/page/prior-authorization-forms

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

Policy Number: M.MIS.21.150317
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