Medications for Treatment of Hepatitis C

Pre-Authorization Guidelines

Effective Date: November 15, 2016

Introduction:

Hepatitis C has been identified as a significant etiology of chronic liver disease, associated co-morbidities, need for liver transplant and death. These guidelines are specific for the use of medications on the Rhode Island Medicaid preferred Drug List. Additional medications or drug classes subsequently receiving FDA approval will require separate review. On October 4, 2016 the U.S. Food and Drug Administration (FDA) began requiring a *Boxed Warning* about the risk of Hepatitis B Virus (HBV) reactivation to be added to the labels of direct acting antiviral (DAA) agents. Detailed information is available at http://www.fda.gov/Drugs/DrugSafety/ucm522932.htm.

Modifications to these guidelines will be issued as needed.

General Approval Criteria:

1. Prescribers
    a. Requesting physician must be a gastroenterologist, Hepatologist or Infectious Disease trained clinician. Interested physicians must submit the Preferred Provider Application available on the EOHHS website and await approval before submitting medication pre-authorization requests.
    b. Physician Assistants and Nurse Practitioners employed by and co-located with a Physician on the Preferred Provider List may request preferred Provider status.
2. Documentation

    The following information must be included in the pre-authorization request:

    a. Summary of current clinical status including hepatic function data and as appropriate determination of compensated/non-compensated cirrhosis. Patients with decompensated cirrhosis must be referred to a physician with experience in managing such disease – ideally at a center with liver transplant capabilities.
    b. History of prior Hepatitis C therapy if relevant.
    c. Hepatitis C Genotype, quantitative viral load and date of testing. Testing must be within 90 days of request.
    d. Treatment plan including:
        i. Medication name, dose and duration
        ii. Method and frequency of patient monitoring
        iii. Planned post treatment follow up
        iv. Agreement to submit post treatment viral load data
    e. Documentation of stage 3 or 4 hepatic fibrosis or Cirrhosis. Documentation may be by any of the following:
        i. AST to Platelet Ratio (APRI) greater than or equal to 1.0
        ii. Current liver biopsy is not required, however prior biopsy indicating METAVIR score of 3 or 4 may be used.
        iii. Fibroscan score greater than or equal to 9.5kPa
        iv. Fibrotest score greater than or equal to 0.58
        v. Imaging study consistent with Cirrhosis.

f. Patients with HIV co-infection are eligible for treatment with stage 2 disease as documented by any one of the tests listed below:
    i. APRI greater than or equal to 0.5 to 1.0
    ii. Current liver biopsy is not required, however prior biopsy indicating METAVIR score of 2 disease
    iii. Fibroscan score greater than or equal to 7.0kPa
    iv. Fibrotest score greater than or equal to 0.32
    v. Imaging study consistent with Cirrhosis.

3. Monitoring Program

   For patients with current or past significant alcohol or intravenous drug abuse, patient must be actively participating in a clinician monitored treatment program or abuse free for a minimum of 6 months. Treatment and monitoring may be maintained in the treating clinician's office and may be documented by attestation.

4. Patient Responsibility
    a. Patient must indicate a willingness to comply with treatment and monitoring plans as documented by having a signed "Patient Contract" (sample is available on EOHHS website).
    b. Contract does not have to be submitted with pre-authorization request but must be maintained as part of the provider's clinical documentation.
5. Approval
    a. Medication approval will be for a full course of treatment with medication being dispensed in 28 day increments. Evidence of non-compliance may cause cancellation of approved medication refills.
    b. Approval will be valid for 56 days from date of approval.
    c. EOHHS and the Medicaid Managed Care Organizations (MCO) will periodically review randomly selected, de-identified prior authorizations to ensure consistent application of this policy for all Medicaid enrollees.
    d. The health plan Medical Director will be accountable to ensure that all utilization criteria adhere to the prior-authorization criteria.
    e. Any request for a non FDA approved treatment regimen will be denied.
6. Treatment recommendations as of November 15, 2016:
    a. Genotype 1a – treatment naïve with or without compensated Cirrhosis:
        i. Harvoni x 12 weeks with option for 8 weeks if viral load 6 million units or less.
        ii. Zepatier x 12 weeks treatment naïve or IFN/RBV experienced without NS5A polymorphisms. 16 weeks with NS5A polymorphisms.
        iii. Daklinza x 12 weeks with sofosbuvir or ribavirin
    b. Genotype 1a – prior treatment with or without compensated Cirrhosis
        i. Harvoni x 12 weeks
        ii. Zepatier x 12 weeks
        iii. Viekira x 24 weeks with ribavirin
    c. Genotype 1b – treatment naïve with or without compensated Cirrhosis
        i. Harvoni x 12 weeks
        ii. Zepatier x 12 weeks
    d. Genotype 1b – prior treatment with or without compensated Cirrhosis
        i. Harvoni x 12 weeks
        ii. Zepatier x 12 weeks
        iii. Viekira x 12 weeks with ribavirin
    e. Genotype 2 – will be evaluated on a case by case basis
    f. Genotype 3 – treatment naïve with or without compensated Cirrhosis

        i. Daklinza x 12 weeks with sofosbuvir or ribavirin
    g. Genotype 4 – treatment naïve without Cirrhosis
        i. Zepatier x 12 weeks
        ii. Technivie x 12 weeks
    h. Genotype 4 – prior treatment with compensated Cirrhosis
        i. Zepatier x 16 weeks with ribavirin
        ii. Technivie x 12 weeks
    i. Genotype 5 or 6 – treatment naïve with or without Cirrhosis
        i. Harvoni x 12 weeks

Any alternative treatment requests will require detailed clinical documentation of need for alternative treatment and will be considered on a case by case basis.

7. Continuity of Treatment

When transitioning between publicly funded delivery systems (e.g. between Fee for Service Medicaid and Managed Care Medicaid, between Managed Care Medicaid and Fee for Service Medicaid or between the department of Corrections and the Medicaid program), any authorization granted by the prior delivery system will be honored for the portion of the treatment that remains after the transition.