



Direct Acting Antiviral (DAA) Medications for Treatment of Hepatitis C

Pre-Authorization Guidelines

INTRODUCTION:

Hepatitis C has been identified as a significant etiology of chronic liver disease, associated co-morbidities, need for liver transplant and death. Newly approved direct acting antiviral (DAA) medications have changed recommendations and therapeutic guidelines. This document is designed as an interim policy with anticipated reviews at six month intervals until stable guidelines are in place.

GENERAL APPROVAL CRITERIA FOR DIRECT ACTING ANTIVIRAL MEDICATION:

1. Requesting provider must be a Gastroenterologist, Hepatologist or Infectious Disease practitioner. Medicaid recognizes that other clinicians (ex: Internists, Family Practitioners) may have interest, knowledge and patient support resources in place that allow for comprehensive Hepatitis C care. These practitioners may request designation as an approved prescriber upon submission of written request supporting this capability. Review and approval will be on a case by case basis. Interested providers should submit the Preferred Provider Application available on the EOHHS website. Once approved providers will not be required to submit detailed resource summaries with each preauthorization request.
2. The following documentation must accompany the preauthorization request:
 - a. Summary of current clinical status including hepatic function (compensated/decompensated). Patients with decompensated cirrhosis (moderate or severe hepatic impairment class B or C, must be referred to a physician with experience in that condition – ideally in a liver transplant center.
 - b. History of prior Hepatitis C therapy, if relevant.
 - c. Hepatitis C genotype, quantitative viral load and test date.
 - d. Treatment plan including:
 - i. Medication name, dose and duration
 - ii. Method and frequency of patient monitoring
 - iii. Planned post treatment follow up
 - e. Documentation of stage 3 or 4 hepatic fibrosis or documentation of stage 3 or 4 cirrhosis.
 - i. Documentation may be by any of the following:
 1. AST to Platelet Ratio Index (APRI) greater than or equal to 1.0
 2. Current liver biopsy is not required, however previous liver biopsy indicating METAVIR score of 3 or 4 may be used.
 3. Fibroscan score greater than or equal to 9.5kPa

4. Fibrotest score greater than or equal to 0.58
5. Imaging study consistent with Cirrhosis
3. For patients with current or past significant alcohol or intravenous drug use disorder, patient must be abuse free for a minimum of 6 months or actively participating in a substance abuse treatment program.
4. Approval:
 - a. Medication approval will be for a full course of treatment with medication being dispensed in 28 day supply increments. Evidence of non-compliance may cause cancellation of refill approval.
 - b. Approval will be valid for 56 days from date of approval.
 - c. EOHHS and Medicaid Managed Care Organizations will periodically jointly review randomly selected, de-identified prior authorizations to ensure consistent application of this policy.
 - d. The health plan Medical Director will be accountable to ensure that all utilization management decisions adhere to the prior authorization criteria.
5. Patient Responsibility:
 - a. Patient must indicate willingness to comply with treatment and monitoring plans as documented by having signed a "Patient Contract" (sample is available on EOHHS website).
 - b. Contract does not have to be submitted with preauthorization request but must be maintained as part of the provider's clinical documentation.

6. Post Treatment:

If requested, provider agrees to cooperate with EOHHS data collection efforts related to Sustained Viral Response, compliance, and relapse data. Information will be used for research purpose only and in a de-identified manner.

7. Treatment recommendations as of July, 2014:

Solvadi® (sofosbuvir) = S, Interferon = I, Ribavirin = R, Olysio® (simeprevir) = O

- a. Genotype 1 – Interferon eligible: S+I+R for 12 weeks
 - b. Genotype 1 – Interferon ineligible: review on a case by case basis
 - c. Genotype 2 – S+R for 12 weeks
 - d. Genotype 3 – Interferon eligible: S+I+R for 12 weeks
 - e. Genotype 3 – Interferon ineligible: S+R for 24 weeks
 - f. Genotype 4 – Interferon eligible: S+I+R for 12 weeks
 - g. Genotype 4 – Interferon ineligible: S+R for 24 weeks
 - h. Patients awaiting transplant - S+R for up to 48 weeks
 - i. All requests for non FDA approved regimens will be reviewed on a case by case basis.
8. Interferon ineligible is defined as one or more of the following clinically documented findings:
- a. Severe psychiatric disease, particularly depression with or without suicidal risk.
 - b. History of solid organ transplant
 - c. Autoimmune Hepatitis or similar disorders
 - d. Uncontrolled endocrine disorders

- e. Platelet count less than 75,000 or neutrophil count below 1,500 or Hemoglobin below 10.
- f. Hypersensitivity to Interferon
- g. Presence of Inflammatory Bowel Disease, Rheumatoid Arthritis, Sarcoidosis or Systemic Lupus
- h. Uncontrolled seizures
- i. Hepatitis C induced cryoglobulemia
- j. Other: please specify

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

FOR STATE USE:	
POLICY APPROVED BY: <u>Deirdre S. Ford, MD</u>	DATE APPROVED: <u>9-9-14</u>
1 ST REVISION APPROVED BY: _____	REVISION DATE: _____
2 ND REVISION APPROVED BY: _____	REVISION DATE: _____
3 RD REVISION APPROVED BY: _____	REVISION DATE: _____