Clinical Criteria for Medication Management of Hepatitis C Virus (HCV)

All HCV medications **require Prior Authorization** and will be considered for coverage when all the criteria below are met, confirmed with supporting medical documentation. A multidisciplinary approach involving specialists, such as hepatologists, gastroenterologists, infectious disease specialists, and potentially others like nephrologists, cardiologists, and mental health professionals, can optimize treatment and management for individuals with HCV and comorbid conditions.

Acute Hepatitis C Treatment:

I. Criteria for Approval

- Direct-acting antiviral (DAA) Medication(s) are FDA-approved for age range,
- Baseline lab values should include an HCV RNA quantitative and the absence of HCV antibodies within 6 months of initial diagnosis,
- Confirmation that the patient has not been exposed to DAA therapy previously,
- HBV status and, if active HBV disease, current antiretroviral regimen and degree of viral suppression within 6 months of application for therapy,
- HIV status and, if HIV positive, current antiretroviral regimen and degree of viral suppression within 6 months of application for therapy,

II. Dosing/Administration/Duration

All DAA medication must be administered according to the current FDA labeling guidelines for dosage and timing

Maryland
DEPARTMENT OF HEALTH

Chronic Hepatitis C Treatment

I. Criteria for Approval

- Direct-acting antivirals (DAA) medications are FDA-approved for age ranges,
- Chronic hepatitis C and HCV genotype and sub-genotype documented*,
- Patients who have prior exposure to DAA therapy must have a pre-DAA genotype and post-DAA genotype documented (Appendix A), including previous HCV treatment history and outcome,
- HCV RNA quantitative within 180 days of application for therapy, unless the patient is cirrhotic, then the baseline lab values must be within 90 days of the prior authorization request and should include a total bilirubin, albumin, and INR,
- Accepted fibrosis test (ex. fibrosure, hepascore/fibroscore, liver-biopsy, fibroscan, point shear wave elastography (PSWE), acoustic radiation force impulse imaging (AFRI)*^,
- HBV status and, if active HBV disease, current antiretroviral regimen and degree of viral suppression within 6 months of application for therapy,
- HIV status and, if HIV positive, current antiretroviral regimen and degree of viral suppression within 6 months of application for therapy,
- Drug resistance testing as indicated,
- If the patient or their partner is of childbearing age, recommend at least two (2) forms of contraception (by the patient or their partner) if an RBV-containing regimen is prescribed throughout therapy and for six (6) months after the regimen is completed.

II. Dosing/Administration/Duration

All DAA medications must be administered according to the current FDA labeling guidelines for dosage and timing

*Not required in the treatment of HCV-Uninfected Recipients of organs from HCV-Viremic Donors

^Fibrosis evaluation for pediatric patients should be done in accordance with the recommendations from the AASLD/IDSA HCV Guidelines

Appendix A:

HCV Treatment Definitions

Retreatment: Previous exposure to an HCV treatment direct-acting antiviral (DAA) regimen, which does NOT result in achievement of SVR, and current need for an additional course of therapy to treat chronic HCV infection.

Conditions required:

- Detectable HCV RNA at 12 weeks post-treatment.
- HCV genotype is the SAME before and after the INITIAL HCV treatment regimen.

Reinfection: Exposure to an HCV treatment regimen, which results in the achievement of SVR.

Conditions required:

- Detectable HCV RNA > 12 weeks post-treatment
- HCV genotype is DIFFERENT after the INITIAL HCV treatment regimen.
- The current infection has been present for ≥ 6 months.