



MARYLAND
Department of Health

MADAP

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MADAP Requirements for Hepatitis C Treatment Preauthorization

Purpose: MADAP requires preauthorization for Hepatitis C medications to ensure that eligible clients receive these drugs within program guidelines. Furthermore, MADAP advises adherence to the established Hepatitis C clinical and treatment guidelines to optimize the therapeutic benefits to each patient.

A. Program Requirements:

1. The preauthorization request process to obtain MADAP coverage for an HCV treatment regimen is **initiated by having the pharmacy submit the prescription claim(s) for payment**. MADAP will make every effort to process the preauthorization for submitted claims within **1-3 business days**.
2. MADAP will provide coverage for an FDA-approved Hepatitis C drug regimen recommended by the current **AASLD HCV guidelines for patients with HIV/HCV co-infection**. The standard treatment period may not exceed a 16-week course, as determined by the patient's HCV genotype, treatment regimen and prior treatment history, subject to a review of the patient's treatment response.
3. MADAP must verify that the patient has a sufficient period of eligibility to cover the date range of the prescribed HCV drug regimen. A patient enrolled in the **Temporary Assistance Program (TAP)**, while awaiting Medicaid coverage, **is not eligible for MADAP coverage of HCV medications**.
4. MADAP must review the patient's insurance status. As **payer of last resort**, MADAP will provide coverage for the prescription plan deductibles, co-pays and co-insurance for insured clients and the full drug costs for clients who are uninsured or denied coverage by their primary insurance plans, within program limits.
5. If the Hepatitis C therapy has been approved by MADAP, initially, and the patient becomes ineligible for MADAP coverage during therapy, the prescribing clinician must be prepared to enroll the patient in other patient assistance drug programs to complete therapy. (MADAP will make every reasonable effort to maintain coverage until other resources are identified and put into place.)

B. Clinical and Treatment Guidelines:

1. The patient must have evidence of chronic hepatitis C infection, with a:
 - Specified genotype, subtype and baseline HCV RNA to determine the course of therapy;
 - Liver biopsy, *FibroSure*™, *FibroScan*® or other comparable HCV test for fibrosis;
 - Prognosis of achieving virologic cure, with treatment, in the judgment of the prescribing clinician.
2. The results of the patient's liver biopsy, *FibroSure*™, *FibroScan*® or other comparable test must describe the stage of fibrosis and/or report a Metavir or APRI/FIB4 fibrosis score.
3. It is recommended that the patient have an HIV and HCV treatment plan developed and/or medication(s) prescribed in collaboration with a provider who is trained or experienced in treating Hepatitis C or related infectious disease co-morbidities, gastroenterology, or hepatology.
 - a. The patient must be on HIV anti-retroviral therapy \geq 6 months and/or have an HIV viral load <200 copies/mL within 90 days of starting HCV therapy.
 - b. The patient should be assessed for potential drug-drug interactions with concomitant medications prior to starting HCV therapy.
 - c. The HCV RNA viral load should be monitored after 4 weeks of therapy and at 12 weeks following the completion of therapy, per HCV guidelines, to assess the patient's response to the treatment regimen.
4. If a ribavirin-containing HCV regimen is prescribed, the patient must utilize 2 forms of contraception while on the regimen and for up to 6 months after stopping, if the patient is:
 - a woman of child-bearing age (at risk for pregnancy), or
 - the male partner of a woman of child-bearing age (at risk for pregnancy).
5. It is expected that the prescribing clinician will do an adherence assessment with the patient prior to starting treatment and throughout the course of therapy to ensure successful completion of the HCV treatment regimen.

Please consult the *HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C*

Unique Patient Populations: Patients with HIV/HCV Coinfection

<http://www.hcvguidelines.org/full-report/unique-patient-populations-patients-hivhcv-coinfection>