MARYLAND
Department of Health and Mental Hygiene

MADAP
500 N. Calvert Street, 5th Floor
Baltimore, MD 21202
Phone: (410) 767-6535
Fax: (410) 333-2608 or (410) 244-8696

MADAP Prior Authorization Requirements for Hepatitis C Treatment

Purpose: Prior authorization is required for MADAP coverage of Hepatitis C medications to ensure that the patient is eligible for MADAP services and meets the clinical criteria for treatment in accordance with the AASLD/IDSA *HCV Guidance: Recommendations for Testing, Managing, and Treating Hepatitis C*. **Website: www.hcvguidelines.org**

Patient eligibility criteria

- The prescribing clinician must complete the MADAP Prior Authorization Request Form for Hepatitis C Therapy and submit it to MADAP with the applicable documentation to determine the patient's eligibility for MADAP coverage.
- The completed prior authorization request must be faxed to: (410) 333-2608 or (410) 244-8696.
- MADAP must verify that the patient has at least 3 to 6 months of remaining eligibility or is eligible for recertification, depending upon the patient's HCV genotype.
- A patient enrolled in the **Transitional Assistance Program (TAP)**, while awaiting Medicaid coverage, **is not eligible for MADAP coverage of HCV drugs**.
- MADAP must review the client's insurance coverage, *if applicable*, to determine if the insurance plan is expected to cover some portion of the HCV drug regimen ***or*** if MADAP is primary.
- 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.
- If the patient's Hepatitis C therapy has been approved by MADAP 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.)

Clinical and treatment criteria

- The patient must have evidence of chronic hepatitis C infection, with a:
  - Specified genotype and 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.
- The results of the client'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.
- 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.
  1. 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 having a prior authorization request submitted.
  2. The patient should be assessed for potential drug-drug interactions with concomitant medications prior to starting HCV therapy.
  3. 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.
- 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).
- The prescribing clinician must certify that an adherence assessment has been performed with the patient and will be conducted throughout the course of treatment to ensure successful completion of the HCV treatment regimen.
- MADAP will pay for one course of treatment, for a current FDA-approved or AASLD recommended drug regimen, not to exceed a 12 to 24-week period, as determined by the patient's HCV genotype, subject to a review of the client's treatment response and/or re-authorization at 6-week intervals.

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

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Client Services Use Only

Date Rec'd: _____ **Insurance Review:** _____

Date Rev'd: _____ ☐ **Approved:** _____ ☐ **Denied:** _____

Elig. Date: _____ **PA Dates:** _____

PA entered: _____/_____/_____ **PA#:** _____ **Int:** _____

Fax completed form to: (410) 333-2608 or (410) 244-8696

MADAP PRIOR AUTHORIZATION REQUEST FORM FOR HEPATITIS C THERAPY

Part 1: Patient Information

Name: _____ MADAP Client ID #: **9 4** __ __ __ __ __ __ __ __ __

DOB: _____/_____/_____ Body Weight: _____ kg Pt's Daytime Phone #: _____

What is the expected or actual start date of the patient's Hepatitis C treatment regimen? _____/_____/_____

Part 2: Hepatitis C Treatment Plan

Check the requested treatment regimen from the following selections.

☐ **Daklinza®** (daclatasvir) _____ mg:
Take once daily for _____ weeks

☐ **Olysio®** (simeprevir) 150 mg:
Take once daily for _____ weeks

☐ **Technivie ®** (ombitasvir/paritaprevir/ritonavir) 25 mg/150 mg/ 100 mg:
Take _____ tablet(s) once daily for _____ weeks

☐ **Zepatier®** (elbasvir/grazoprevir) 50 mg/100 mg:
Take once daily for _____ weeks

☐ **Ribavirin** _____ mg: Take _____ in the morning and _____ in the afternoon for _____ weeks

☐ _____:
Take _____ as directed for _____ weeks

☐ **Harvoni®** (ledipasvir-sofosbuvir) 90 mg/400 mg:
Take _____ tablet(s) once daily for _____ weeks

☐ **Sovaldi®** (sofosbuvir) 400 mg:
Take once daily for _____ weeks

☐ **Viekira Pak®** (dasabuvir) 250 mg + (ombitasvir/paritaprevir/ritonavir) 25 mg/150 mg/100 mg:
Take as directed for _____ weeks

☐ **Peginterferon alfa** _____ mcg:
Inject once weekly for _____ weeks

☐ _____:
Take _____ as directed for _____ weeks

☐ _____:
Take _____ as directed for _____ weeks

Part 3: Hepatitis C Diagnostic Information

Complete <u>all</u> of the diagnostic information that follows as it applies to this patient.

What is the patient's HCV genotype and subtype? _____

Baseline quantitative HCV RNA (within 90 days of request date): _____ IU/mL; Test date: ____/____/____

Has a fibrosis test been performed? ☐ No ☐ Yes; Test date: ____/____/____; Test used: _____

If Yes, Metavir Grade: _____; Metavir Stage: _____ APRI/FIB4 Score: _____, if applicable

Has a liver biopsy been performed? ☐ No ☐ Yes; Test date: ____/____/____

If Yes, Metavir Grade: _____; Metavir Stage: _____

✧ A copy of the HCV genotype, RNA, fibrosis and/or biopsy test results must be provided with this request. ✧
(If performed, please include a copy of the patient's test results for the presence of resistance-associated variants.)

The patient is diagnosed with Hepatitis C infection that in the judgment of the prescribing clinician has a prognosis of virologic cure with treatment. ☐ No ☐ Yes, select one of the following:

☐ Acute Hepatitis C infection
(HCV seroconversion or discrete exposure less than 6 months prior to request date)

☐ Chronic Hepatitis C

☐ Hepatocellular Carcinoma

☐ Liver transplant recipient:
HCV genotype and subtype of pre-transplant liver: _____
HCV genotype and subtype of post-transplant liver: _____

☐ Other: _____

Part 4: Hepatitis C Treatment History

Has this patient been treated for Hepatitis C in the past? ☐ Treatment Naïve ☐ Treatment Experienced

If Treatment Experienced, what was the outcome of the previous treatments:

☐ Relapsed ☐ Partial Responder ☐ Non-Responder ☐ Toxicities

Please indicate what prior regimen(s) the patient has taken, if treatment experienced:

HCV regimen	Treatment duration/ dates	Treatment Outcome
		□ Relapsed □ Partial Responder □ Non-Responder □ Toxicities □ Other: _____
		□ Relapsed □ Partial Responder □ Non-Responder □ Toxicities □ Other: _____

Part 5: HIV Treatment Status

HIV RNA viral load (within 90 days of request date): _____ copies/ml Date: ___/__/__

Has the patient been on HIV anti-retroviral therapy ≥ 6 months? ☐ No ☐ Yes

Patient is expected to take HIV medications during HCV treatment: ☐ No ☐ Yes

If No, state reason: _____

If Yes, list the ART being prescribed: _____

Part 6: Precautions Review and Adherence Assessment

Has a pre-treatment precautions review and adherence assessment been performed? ☐ No ☐ Yes, ***please specify:***

Patient has an active diagnosis of a substance use disorder. ☐ No ☐ Yes

Patient is engaged in or has been referred to substance abuse treatment. ☐ No ☐ Yes ☐ NA

Pregnancy-related precautions were reviewed with the patient. ☐ No ☐ Yes ☐ NA

Will precautions and adherence monitoring continue during the course of HCV treatment? ☐ No ☐ Yes

Please describe any other precautions and/or adherence issues that were reviewed with the patient:

_____

_____

Part 7: Patient Assistance Affidavit

Is the prescribing clinician prepared to have the patient enrolled in other patient assistant drug programs to complete the Hepatitis C therapy, if MADAP has approved the HCV regimen, but the patient subsequently becomes ineligible for MADAP coverage? ☐ No ☐ Yes

I certify that the information provided is accurate. Supporting documentation is available for State audits.

Prescribing Clinician: _____ License No. & State: _____

Clinic/Hospital Name: _____ NPI #: _____

Street Address: _____ Phone #: _____

City, State & Zip: _____ Fax #: _____

Clinician's Signature: _____ Date: _____/_____/_____