

Prior Authorization for Peg-interferon and Oral Ribavirin

Dear Provider,

Please review the instructions on the attached Peg-interferon & ribavirin prior authorization forms to complete and return to MADAP with the required lab reports. Completed requests will be reviewed upon arrival to determine if the client is eligible for MADAP coverage of these drugs. The MADAP fax number is 410-333-2608.

- The Initial MADAP Request form is required to determine eligibility for the first 12-week period of Hepatitis C treatment.
- The Continued MADAP Request form is required to determine eligibility for subsequent 12 -week periods.
- ***MADAP will pay for a course of treatment, or portion thereof, for a maximum of 48 weeks pending approval of the continuation requests.***

When authorization for Peg-interferon & ribavirin is requested with an HCV protease inhibitor or polymerase inhibitor for a triple-drug Hepatitis C regimen, the Supplemental Request form must be completed and submitted with the Initial or Continued request. ***Please note that the MADAP formulary does not cover any of the HCV protease inhibitors or polymerase inhibitor.***

If a triple-drug regimen is prescribed, the following must be considered:

- The patient must be diagnosed with chronic HCV genotype 1 with confirmation of significant liver fibrosis.
- In the judgment of the clinician, it would be detrimental to the patient's prognosis to delay prescribing a triple-drug regimen for Hepatitis C.
- The patient must be on an ART regimen that is not projected to interact with the triple-drug regimen or on no ART with a CD4 count >500.

Please keep in mind that the client must have active and ongoing MADAP eligibility for a minimum period of 12 weeks. A client approved for TAP is not eligible for MADAP coverage of Hepatitis C treatment.

You may contact me at 410-767-5262 if you need further assistance, additional forms or have any questions about the status of the submitted request.

Sincerely,

Arlette M Lindsay, PA
MADAP Clinical Advisor

Dated: 14Jan2014

Return Completed Form to:
MADAP
500 N. Calvert Street, 5th Floor
Baltimore, MD 21202
Confidential Fax: (410) 333-2608
Phone: (410) 767-6535

MADAP OFFICE USE ONLY	
Date Rec'd: _____	Insurance coverage: <input type="checkbox"/> Yes <input type="checkbox"/> No
Date Rev'd: _____	Authorized: <input type="checkbox"/> Yes <input type="checkbox"/> No Initials: _____
MADAP Exp: _____	Date updated in database: _____
Coverage Dates: _____	

INITIAL REQUEST FOR MADAP COVERAGE OF PEGINTERFERON (ALFA 2A OR ALFA 2B) & RIBAVIRIN

CLIENT'S NAME: _____ **MADAP ID: 94** _____

Instructions: In order for a MADAP client to receive peginterferon alfa 2a or 2b and oral ribavirin:

- The client must have active and ongoing MADAP certification for a minimum period of 12 weeks. (A client approved for TAP is not eligible for MADAP coverage of these drugs.)
- The client's liver biopsy or *HCV Fibrosure* test results must describe the stage of fibrosis or give fibrosis score.
- The patient must be diagnosed with Hepatitis C infection that in the judgment of the clinician has the prognosis of being eradicated (treat to cure). Treatment for histological benefit alone (for maintenance) is not eligible for MADAP coverage.
- The prescribing clinician must complete and submit this form to MADAP with the required documentation and *Supplemental Request*, if indicated, for a review and determination of the client's eligibility.

MADAP will pay for a course of treatment, or portion thereof, not to exceed a 48-week period. The clinician must submit the *Continued MADAP Coverage of peginterferon alfa 2a or 2b & ribavirin* request at 90-day intervals and *Supplemental Request*, if indicated, to evaluate the client's eligibility for continued MADAP support.

1. Medical history and current status (Please ✓ all that apply)

The Clinician certifies the following:	<input type="checkbox"/> No evidence of: Carcinoma, Hemochromatosis, Hepatoma, Decompensated End Stage Liver Disease (no concurrent significant liver disease)
<input type="checkbox"/> Patient's ability to adhere to treatment	
<input type="checkbox"/> Patient is using Contraception	For Females Only:
<input type="checkbox"/> No severe depression or current suicidality	<input type="checkbox"/> Negative Pregnancy Test at initiation of therapy
<input type="checkbox"/> No current excessive alcohol use	

2. Clinical & Laboratory Results

- a) Current HCV/RNA Level: _____ Date reported: ___/___/___
- b) Does patient have acute HCV? No Yes (A liver biopsy is not needed if patient has acute HCV)
- c) HCV Genotype: _____ (A liver biopsy is not needed for Genotypes 2 & 3)
- d) Liver Biopsy or *HCV FibroSURE* test date: ___/___/___ (A copy of the results must be submitted.)

3. HCV Treatment Status and Information

- a) Is patient currently on peginterferon alfa 2a or 2b & ribavirin? No Yes, start date: ___/___/___
- b) Prior treatment with peginterferon & ribavirin? No Yes, start date: ___/___/___ end date: ___/___/___
- c) Was HCV/RNA level suppressed on prior treatment? N/A No Yes *If yes, submit copy of report.*

Comments: _____

4. Patient will be prescribed oral ribavirin and peginterferon: *alfa 2a* or *alfa 2b*

5. Patient is expected to take telaprevir: No Yes *If yes, complete Supplemental Request, section A.*

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

Prescribing Clinician: _____ **License No. & State:** _____

Street Address: _____ **Phone #:** _____

City, State & Zip: _____ **Fax #:** _____

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

SUPPLEMENTAL REQUEST FOR MADAP COVERAGE OF PEGINTERFERON AND RIBAVIRIN

CLIENT'S NAME: _____ MADAP ID: 94 _____

Please select (✓) and complete section A or B and prescribing clinician's information below.

A. Initial use of Peginterferon and Oral Ribavirin with Telaprevir (INCIVEK)

NOTE: The prescribing clinician must complete this section and submit the signed form to MADAP for initial prior authorization of peg-interferon and oral ribavirin when a patient is being prescribed triple drug therapy with telaprevir (INCIVEK). MADAP does not cover telaprevir, but recommends the use of the appropriate patient assistance program for treatment coverage.

The patient must be diagnosed with chronic HCV genotype 1 with confirmation of significant liver fibrosis. In the judgment of the clinician, a delay in triple drug therapy would be detrimental to the patient's prognosis. The patient must be on an ART regimen that is not projected to interact with telaprevir or on no ART with a CD4 count >500.

1. Patient is expected to take/is currently on telaprevir (Incivek): No Yes, start date: ____/____/____
2. If patient is not on antiretroviral therapy, please report the patient's current CD4 count: _____/mm³
3. If patient is on antiretroviral therapy, please list the drugs being prescribed:

B. Continuing use of Peginterferon and Oral Ribavirin with Telaprevir (INCIVEK)

NOTE: The prescribing clinician must complete this section and submit the signed form to MADAP for prior authorization of peg-interferon and oral ribavirin when a patient's treatment with telaprevir and the requested drugs has been ongoing for 90 days, regardless of payer. The results of the HCV/RNA levels at 90 days/12 weeks on the triple drug therapy will determine if MADAP will pay for treatment after 12 weeks. MADAP coverage ends at 24 weeks (depending on RNA levels) or 48 weeks from the initiation of treatment.

1. Intend to continue telaprevir treatment? No Yes

If the answer to question 1 is "No", then treatment discontinuation is due to: (Please ✓ all that apply)

- | | |
|---|---|
| <input type="checkbox"/> Telaprevir treatment course has been completed | <input type="checkbox"/> Patient non-compliance or request |
| <input type="checkbox"/> Positive or detectable HCV RNA at 12 weeks of therapy | <input type="checkbox"/> Other/Not listed, please describe: |
| <input type="checkbox"/> Side effect(s) associated with telaprevir:
rash, anemia, fatigue, pruritus, nausea/vomiting | |

If the answer to question 1 is "Yes", please continue with questions 2 – 4.

2. Date telaprevir treatment began: ____/____/____
3. If treatment has been ongoing for 90 Days/12 weeks, are HCV RNA levels at 12 weeks:
 Detectable? or Undetectable? (*Supporting laboratory report must be submitted*)
4. Is patient continuing/resuming HIV treatment? No Yes *If yes, list the ART being prescribed:*

Prescribing Clinician: _____ License No. & State: _____

Street Address: _____ Phone #: _____

City, State & Zip: _____ Fax #: _____

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