

## Office of Pharmacy Service Prior Authorization Criteria

## Incivek (Telaprevir)

## Requests for Incivek will be prior authorized if the following criteria are met:

- 1. A documented diagnosis of Hepatitis C Genotype 1 with no HIV co-infection **AND** concurrent therapy with ribavirin and pegylated interferon.
- 2. The patient is eighteen (18) years or older.
- 3. The patient's previous treatment history and weight are presented at the time of initial request
- 4. The patient has been screened and counseled about the importance of refraining from drug and/or alcohol abuse.
- 5. The patient's Child-Pugh score is <6 (compensated cirrhotic liver disease).
- 6. The patient has not previously tried/failed therapy with a hepatitis C protease inhibitor (e.g. telaprevir or boceprevir).
- 7. The patient is not a pregnant female or a male with a pregnant female partner (ribavirin contraindication).
- 8. Telaprevir is prescribed in conjunction with an infectious disease specialist, gastroenterologist, or hepatologist.
- 9. A sensitive RT-PCR assay HCV-RNA test with a lower limit of quantification of ≤25 IU/ml and a limit of detection of approximately 10 to 15 IU/ml is required to be submitted before the start of therapy. Further testing must be scheduled for the end of weeks four (4), twelve (12) and twenty-four (24). Initial test results and the scheduled testing dates for the indicated weeks must be submitted before prior authorization will be issued.
- 10. The dispensing pharmacy agrees to dispense an initial six-week supply and work with the prescriber to ensure that viral levels are done at weeks four (4), twelve (12) and twenty-four (24) of therapy. (Initial approval of telaprevir will be for six (6) weeks, providing 4 weeks for initial treatment and 2 weeks for administrative review)
- 11. Viral levels are to be submitted at the end of weeks four (4), twelve (12) and twenty-four (24) of the treatment course. (Further prior approvals will not be issued without submission of viral levels performed with the sensitive RT-PCR assay HCV-RNA test with a lower limit of quantification of ≤25 IU/ml and a limit of detection of approximately 10-15 IU/ml.)

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