DISTRICT OF COLUMBIA ~ DEPARTMENT OF HEALTH~ ADAP

Telaprevir (Incivek™) for Chronic Hepatitis C Virus (HCV) infection

PRIOR AUTHORIZATION PROGRAM ~ Initial Request

CLIENT'S NAME:_____ ADAP ID:_____

ADAP Policy: Telaprevir is an oral, direct-acting antiviral available through ADAP under this Prior Authorization Program for use in combination therapy for the treatment of patients chronically infected with hepatitis C virus (HCV) genotype 1.

1. Is there confirmation of the patient's infection with HCV genotype 1? ☐ Yes ☐ No
2. Will the patient receive pegylated interferon and ribavirin therapy? ☐ Yes ☐ No

3. Is the patient pregnant or trying to become pregnant? ☐ Yes ☐ No
   Is the female partner of the patient (male) pregnant? ☐ Yes ☐ No

4. Is the patient currently taking any of the following medications? alfuzosin, rifampin, ergot derivatives, St. John's Wort, lovastatin, simvastatin, sildenafil or tadalafil, oral midazolam, triazolam, darunavir/ritonavir, fosamprenavir/ritonavir or lopinavir/ritonavir? ☐ Yes ☐ No

5. Has the patient received prior interferon and ribavirin therapy? ☐ Yes ☐ No
   If yes, please characterize the response*: ☐ partial responder, ☐ relapser or ☐ null responder

6. Has the patient received prior therapy with telaprevir? ☐ Yes ☐ No
7. Does the patient have moderate to severe liver impairment or decompensated liver disease? ☐ Yes ☐ No

Recommended dosage and administration: The recommended dose for telaprevir is 750mg orally three times a day given with food (not low fat). Telaprevir must be administered with pegylated interferon and ribavirin (see prescribing information). The recommended duration of therapy for telaprevir combined with peginterferon and ribavirin is 12weeks. HCV RNA should be monitored at Weeks4 and Weeks12 to determine duration and treatment futility. **Duration of therapy for treatment naïve patients and prior relapse patients:** If HCV RNA is undetectable at Weeks4 and Weeks12, treat with peginterferon and ribavirin for an additional 12Weeks. If HCV RNA is detectable, (1000 IU per mL or less) at Weeks4 and/or Weeks12), treat with peginterferon and ribavirin for an additional 36weeks. **Duration of treatment for prior partial and null responder patients:** All patients should receive triple therapy for 12weeks, followed by an additional 36weeks of dual therapy (total duration 48weeks). **Discontinuation rules for all patients:** if HIV RNA levels measure greater than 1000 IU per mL at Weeks4 or Weeks12, discontinuation of telaprevir, peginterferon and ribavirin (telaprevir complete at Week12) is recommended. If there is detectable virus at week24, discontinue peginterferon and ribavirin. **Telaprevir is not intended for use as monotherapy.** Telaprevir is a pregnancy category B medication.

Physician's signature:_____**Date:**_____

Physician's Name:_____**Phone:**_____**Fax:**_____
Fax to Clinical Pharmacy Associates: (301) 617-9882 Phone: (301) 617- 0555 ext. 30
Attention: Prior Approval Program

Approval: ☐ Yes ☐ No Date_____ Initials_____ Office use only

Reason for denial_____

Only employees/agents of the HIV/AIDS Hepatitis, STD and Tuberculosis Administration or Clinical Pharmacy Associates are intended recipients of this document. Any disclosure, dissemination or copying of information by unintended individuals is strictly prohibited. If you have received this form in error, please notify us by telephone and fax original to the number listed above. Thank you.

*A **partial responder** is defined as patient who had a HCV RNA level drop by at least 2 log IU/mL at treatment Week12, yet had detectable HCV RNA levels at Week24. A **relapser** is defined as a patient who had HCV RNA levels become undetectable during treatment, and then become detectable after the cessation of treatment. The **null responder** occurs in patients with HCV RNA levels that did not decrease by at least 2 log IU/mL at treatment Week12.

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