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 12 weeks. HCV RNA should be monitored at Weeks 4 and Weeks 12 to determine duration and treatment futility. Duration of therapy for treatment naive patients and prior relapse patients: If HCV RNA is undetectable at Weeks 4 and Weeks 12, treat with peginterferon and ribavirin for an additional 12 weeks. If HCV RNA is detectable, (1000 IU per mL or less) at Weeks 4 and/or Weeks 12, treat with peginterferon and ribavirin for an additional 36 weeks. Duration of therapy for prior partial and null responder patients: All patients should receive triple therapy for 12 weeks, followed by an additional 36 weeks of dual therapy (total duration 48 weeks). Discontinuation rules for all patients: if HIV RNA levels measure greater than 1000 IU per mL at Weeks 4 or Weeks 12, discontinuation of telaprevir, peginterferon and ribavirin (telaprevir complete at Week 12) is recommended. If there is detectable virus at week 24, 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

[ ] Yes [ ] No Date ____________ Initials ____________ Office use only

Reason for denial: ____________________________________________________________________

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* A partial responder is defined as patient who had a HCV RNA level drop by at least 2 log IU/mL at treatment Week 12, yet had detectable HCV RNA levels at Week 24. 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 Week 12.