**California Office of AIDS, ADAP Supplemental Form for Hepatitis C Drug Use**
**TELEPHONE: 888-311-7632 FAX: 800-848-4241**

The ADAP Medical Advisory Committee has determined criteria for use of hepatitis C drugs on the ADAP formulary. Complete the appropriate questions listed below for determination of treatment authorization. HIV viral load and supporting lab documents are required.

**Patient Name:** _____ **Prescribing Physician:** _____
Last Name First Name
**ADAP ID Code:** _____ **Physician DEA #:** _____

**DOB:** _____**Height:** _____ **Weight:** _____ **Physician Phone #:** _____ **Fax#:** _____

**Latest CD4 count &Viral Load:** _____/_____ **Pharmacy Name:** _____

**Date of results:** _____ **NABP#:** _____ **Contact Person:** _____

_____ **Pharmacy Phone#:** _____ **Fax#:** _____
***Signature of pharmacist or physician*** ***Date***

**NOTE TO PHYSICIAN:** *Please be aware access to HCV treatment may be affected by the client's ADAP eligibility end date. You will be notified accordingly.*

**HCV genotype (circle): 1a 1b 2 3 4 5 6**

1. Prior HCV treatment (check): (Note: See Section 2.1 of simeprevir package insert for definition of prior relapse, partial and null responders)
   - ☐ None (treatment naïve)
   - ☐ Prior relapse to PEG/ribavirin
   - ☐ Prior partial responder to PEG/ribavirin
   - ☐ Prior null responder to PEG/ribavirin
   - ☐ Prior sofosbuvir-containing
   - ☐ Prior PEG-INF/RBV/HCV protease inhibitor regimen

2. Planned HCV treatment regimen and duration (check all that apply):
   - ☐ ombitasvir 12.5 mg/paritaprevir 75 mg/ritonavir 50 mg co-formulated tablets, 2 tablets once daily, co-packaged with dasabuvir 250 mg tablets (Viekira Pak™) twice daily for _____ weeks – ***Preferred regimen. If selected, indicate whether or not ribavirin will also be used and then go to #4.***
   - ☐ ledipasvir 90 mg/sofosbuvir 400 mg (Harvoni®) once daily for _____ weeks
   - ☐ sofosbuvir (Sovaldi™) 400 mg orally once daily for _____ weeks
   - ☐ simeprevir (Olysio®) 150 mg orally once daily with food for _____weeks (24 week therapy restricted to cirrhosis with genotype 1)
   - ☐ ombitasvir 12.5 mg/paritaprevir 75 mg/ritonavir 50 mg (Technivie™) two tablets once daily with food for _____ weeks (restricted to genotype 4 without cirrhosis)
   - ☐ peginterferon alfa-2a (PEGASYS®) 180 mcg subQ weekly for ____ weeks
   - ☐ peginterferon alfa-2b (PegIntron®) 1.5 mcg/kg subQ weekly for _____ weeks
   - ☐ weight-based ribavirin (< 75 kg: 500 mg po BID; > 75 kg: 600 mg po BID) for _____weeks

3. Clinical justification for not prescribing Viekera Pak™
   - ☐ Genotype 2, 3, 5, or 6 ☐ Child-Pugh B (*see page 2*) ☐ Child-Pugh C (*see page 2*)
   - ☐ Ribavirin required with Viekera Pak™ and ribavirin contraindicated – Specify: _____
   - ☐ Drug interaction – specify: _____ ☐ Other – specify: _____
   - ☐ ADAP is secondary payer and Primary Payer has approved the chosen medication

4. For all:
   - ☐ I agree to submit HCV RNA result from 12 weeks after treatment completion for program evaluation purposes (FAX to Ramsell).
   - ☐ I have reviewed the clinical information on the proposed prescription for possible drug-drug interactions with other medications currently prescribed to the patient.

Child-Pugh Scoring

| Component | Points Scored | | |
|---|---|---|---|
| | 1 | 2 | 3 |
| Encephalopathyŧ | None | Grade 1-2 | Grade 3-4 |
| Ascites | None | Mild or controlled with diuretics | Moderate or refractory despite diuretics |
| Albumin | > 3.5 g/dl | 2.8 - 3.5 g/dl | < 2.8 g/dl |
| Total bilirubin or Modified total bilirubin§ | < 2 mg/dl | 2 - 3 mg/dl | > 3mg/dl |
| | < 4 mg/dl | 4 - 7 mg/dl | > 7mg/dl |
| Prothrombin time (seconds prolonged) or International normalized ratio (INR) | < 4 | 4-6 | > 6 |
| | < 1.7 | 1.7-2.3 | > 2.3 |

ŧ Encephalopathy:

Grade 1: mild confusion, anxiety, restlessness, fine tremor, slowed coordination
Grade 2: drowsiness, disorientation, asterixis
Grade 3: somnolent but arousable, marked confusion, incomprehensible speech, incontinence, hyperventilation
Grade 4: coma, decerebrate posturing, flaccidity

§ Modified total bilirubin used to score patients who have Gilbert's syndrome or who are taking atazanavir or indinavir

Information on the prevention of hepatitis C re-infection:

Successful treatment of hepatitis C does not prevent hepatitis C re-infection. Clinicians should educate their patients on ways to avoid hepatitis C reinfection, including safer sex practices and not sharing needles or any equipment used in the preparation of illicit injection drugs.

For information related to hepatitis C reinfection, visit:
The U.S. Department of Veterans Affairs – Frequently Asked Questions page at: http://www.hepatitis.va.gov/patient/faqs/reinfection.asp, or
The Centers for Disease Control and Prevention Hepatitis C FAQs for the Public at: http://www.cdc.gov/hepatitis/hcv/cfaq.htm.

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Additional information:

If the planned hepatitis C treatment regimen includes **ribavirin** please note the following:
Due to the risk of fetal malformations and fetal death with ribavirin, all women being considered for treatment with ribavirin should have a negative pregnancy test before treatment. Women of childbearing potential should use effective contraception during treatment and for 6 months after treatment. Men with female partners who are pregnant or who may become pregnant should use barrier contraception during treatment and for 6 months after treatment.

For patients with cirrhosis, hepatocellular carcinoma screening by ultrasound is recommended every 6 months.

For the latest HCV treatment recommendations consult the American Association for the Study of Liver Diseases (AASLD)/Infectious Diseases Society of America (IDSA) Hepatitis C Treatment Guidelines at www.hcvguidelines.org.