State of California—Health and Human Services Agency
California Department of Public Health

RON CHAPMAN, MD, MPH
Director & State Health Officer

EDMUND G. BROWN JR.
Governor

OFFICE OF AIDS AIDS Drug Assistance Program (ADAP)	Management Memorandum Memorandum Number: 2014-07

Date: July 23, 2014

TO: LOCAL ADAP COORDINATORS
ADAP ENROLLMENT WORKERS

SUBJECT: **ADDITION OF TWO NEW HEPATITIS C DRUGS (SIMEPREVIR AND SOFOSBUVIR) TO THE ADAP FORMULARY**

Effective July 18, 2014, simeprevir (Olysio™) 150mg tablets and sofosbuvir (Sovaldi®) 400mg tablets have been added to the ADAP formulary. Simeprevir and sofosbuvir are for the treatment of patients with hepatitis C virus (HCV). The federal Food and Drug Administration (FDA) approved simeprevir on November 22, 2013 and sofosbuvir on December 6, 2013. Both new drugs are prescribed as a single tablet to be taken once per day (simeprevir with food and sofosbuvir with or without food) in combination with peginterferon alfa and/or ribavirin.

Due to the high cost of simeprevir and sofosbuvir, OA worked with ADAP's Medical Advisory Committee (MAC) to ensure those most in need and most likely to benefit can receive HCV treatment. Prior to dispensing these drugs, the client's ADAP pharmacy will be required to submit a Prior Authorization (PA) form, completed by the prescribing clinician, to ADAP's Pharmacy Benefits Manager. The qualifying clinical access criteria outlined in the PA form have been developed under the guidance of the ADAP MAC, in consultation with other HCV treatment experts. ADAP's PA criteria are similar to the criteria used by Medi-Cal to approve these same HCV medications in the Medi-Cal population. ADAP clients will be assessed to see if they qualify for access to the new HCV drugs based on the clinical information provided by their treating physician via the PA process. The PA is attached for your reference.

ADAP clients who do not meet the ADAP PA criteria may be able to obtain treatment with the new drugs through the Patient Assistance Programs (PAPs) operated by Gilead Sciences Inc. (sofosbuvir) and Janssen Pharmaceuticals (simeprevir). For your reference and to learn more about each manufacturer's PAP, please follow the links provided below.

Sofosbuvir – http://www.mysupportpath.com/

Simeprevir – http://www.olysio.com/support/financial-assistance

With the addition of simeprevir and sofosbuvir, ADAP has 187 drugs on the formulary.

If you have any questions regarding the addition of these medications to the ADAP formulary, please contact me or Cynthia Reed-Aguayo, ADAP Specialist, at (916) 449-5791.

Celia Banda-Brown, Chief
ADAP Section
Office of AIDS

Attachment

California Office of AIDS, ADAP Supplemental Form for Sofosbuvir (Sovaldi™) or Simeprevir (Olysio®) Use
TELEPHONE: 888-311-7632 FAX: 800-848-4241

The ADAP Medical Advisory Committee has determined the criteria for use of Sofosbuvir or Simeprevir. Complete the appropriate section listed below for determination of treatment authorization. CD4, 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 HCV treatment approval requires that the client's ADAP eligibility end date is on or after the end date of HCV treatment. You will be advised accordingly.

Section 1 – Medical Justification - Completion of all questions 1-5 with documentation are REQUIRED for approval

Coverage for these medications is limited to advanced liver disease (stage 3 & 4).

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
2. Planned HCV treatment regimen and duration (check all that apply):
   - ☐ sofosbuvir (Sovaldi™) 400mg orally once daily for _____ weeks
   - ☐ simeprevir (Olysio®) 150mg orally once daily with food for 12 weeks
   - ☐ peginterferon alfa-2a (PEGASYS®) 180mcg subQ weekly for ____ weeks
   - ☐ peginterferon alfa-2b (PegIntron®) 1.5mcg/kg subQ weekly for _____ weeks
   - ☐ weight-based ribavirin (< 75kg: 500mg po BID; > 75kg: 600mg po BID) for _____weeks
3. **ADAP would require all of the following except where indicated (check all that apply)**:
   - ☐ On a stable antiretroviral regimen for HIV with HIV viral load < 200 copies/mL for at least 8 weeks (submit copy of viral load result to Ramsell) **OR**
   - ☐ HIV Elite Controller with HIV viral load < 200 copies/mL or long term non-progressor without antiretroviral medication (submit copy of viral load result or medical documentation to Ramsell) **OR**
   - ☐ Failed multiple trials of antiretroviral therapy due to advanced liver disease precluding antiretroviral treatment prior to HCV treatment (submit medical documentation to Ramsell)
   - ☐ **AND** Patient with advanced liver disease as indicated by any of the following (**check all that apply & submit documentation**):
     - ☐ Clinical (e.g. palpable left lobe, splenomegaly, palmar erythema), laboratory, AND abdominal imaging findings consistent with cirrhosis. Submit documentation of platelet count and abdominal imaging:
       - Platelet count < 100,000/µL **and**
       - Abdominal imaging (e.g. ultrasound, CT, MRI) showing surface abnormalities (e.g. nodularity, left lobe/caudate lobe hypertrophy), features of portal hypertension (e.g. splenomegaly, recanalization of umbilical vein, collaterals), and/or ascites.
     - ☐ Liver Fibrosis Imaging (e.g. Vibration Controlled Transient Elastography [Fibroscan®], or Acoustic Radiation Force Impulse Imaging [ARFI])
       - ☐ Fibroscan value > 9.5 kiloPascals (associated with METAVIR F3-F4)
       - ☐ ARFI value of > 1.75 meters/second
     - ☐ Serum Markers of Fibrosis (e.g. APRI, FIB-4, or FibroTest/FibroSure)
       - ☐ APRI > 1.5 (associated with advanced fibrosis i.e. METAVIR F3-F4)
       - ☐ FIB-4 > 3.25 (associated with advanced fibrosis i.e. METAVIR F3-F4)
       - ☐ Fibrotest/Fibrosure > 0.58 (associated with advanced fibrosis i.e. METAVIR F3-F4)
     - ☐ Liver Biopsy
       - METAVIR or Batts-Ludwig stage 3 or 4 fibrosis (on a scale from 0 to 4)
       - Modified Ishak stage 4, 5, or 6 fibrosis (on a scale from 0 to 6)
   - ☐ **OR** Extrahepatic manifestations of HCV (leukocytoclastic vasculitis, symptomatic cryglobulinemia, or membranoproliferative glomerulonephritis despite mild liver disease) (submit medical documentation to Ramsell)
4. For simeprevir (Olysio®) only:
   - ☐ HCV genotype 1
5. For all:
   - ☐ I agree to submit HCV RNA result from 12 weeks after treatment completion for program evaluation purposes (FAX to Ramsell).