



KAREN L. SMITH, MD, MPH
Director & State Health Officer

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



EDMUND G. BROWN JR.
Governor

OFFICE OF AIDS (OA)
AIDS Drug Assistance Program (ADAP)

Management Memorandum
Memorandum Number: 2015-10

Date: May 14, 2015

TO: LOCAL ADAP COORDINATORS
ADAP ENROLLMENT WORKERS

SUBJECT: ADDITION OF TWO HEPATITIS C DRUGS [(ledipasvir/sofosbuvir (Harvoni®) and ombitasvir, paritaprevir, and ritonavir tablets; dasabuvir tablets (Viekira Pak™)] TO THE ADAP FORMULARY

Effective May 13, 2015, the following Food and Drug Administration (FDA) approved drugs for the treatment of patients with hepatitis C virus (HCV) have been added to the ADAP formulary:

1. Ledipasvir 90 mg/sofosbuvir 400 mg tablets (Harvoni®) – This drug was approved by the FDA as the first combination pill to treat chronic HCV. Ledipasvir/sofosbuvir received FDA approval on October 10, 2014. This new HCV drug is a single tablet to be taken once per day (with or without food) for patients with genotype 1 infection.
2. Ombitasvir 12.5 mg/paritaprevir 75 mg/ritonavir 50 mg co-formulated tablets co-packaged with dasabuvir 250 mg tablets (Viekira Pak™) – This drug received FDA approval on December 19, 2014 to treat patients with chronic HCV genotype 1 infection. The tablets are to be taken with food. Three of the drugs, ombitasvir, paritaprevir, and dasabuvir, work together to inhibit the growth of HCV while ritonavir increases blood levels of paritaprevir. These tablets are to be taken with food.

These two HCV drugs do not require that they be co-administered with interferon which is known to cause side effects that include but are not limited to: flu like symptoms, fatigue, anxiety, and depression.

OA, in collaboration with ADAP's Medical Advisory Committee (MAC), updated the previously approved prior authorization form for HCV treatment (for simeprevir and sofosbuvir) to include these additional HCV drugs. The attached prior authorization form continues to prioritize treatment for HCV co-infected ADAP clients with more advanced liver disease and clients with earlier stages of liver disease with extra-hepatic manifestations. In addition, the prior authorization form prioritizes the use of ombitasvir/paritaprevir/ritonavir tablets with dasavuvir tablets, due to lower cost, among eligible patients when the regimen is equally effective and no medical contraindications to its use exists. Clinicians who wish to treat their ADAP client with a hepatitis C drug other than ombitasvir/paritaprevir/ritonavir tablets with dasavuvir tablets must provide clinical justification (see question 3).

With the addition of these two hepatitis C drugs, ADAP has 193 drugs on its formulary.

If you have any questions regarding the addition of these two new 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 Hepatitis C Drug Use

TELEPHONE: 888-311-7632 FAX: 800-848-4241

The ADAP Medical Advisory Committee has determined the criteria for use of hepatitis C drugs on the ADAP formulary. Complete the appropriate section listed below for determination of treatment authorization. CD4, HIV viral load and supporting lab documents are required.

Patient Name: Last Name First Name

Prescribing Physician:

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.

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

Coverage for these medications is limited to advanced liver disease (stage 3 & 4) or specified extrahepatic manifestations of hepatitis C.

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)
2. Planned HCV treatment regimen and duration (check all that apply):
3. Clinical justification for not prescribing Viekera Pak
4. ADAP would require all of the following except where indicated (check all that apply):
5. For all:

Child-Pugh Scoring

Component	Points Scored		
	1	2	3
Encephalopathy†	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

† 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

Additional information:

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.

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.