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EDMUND G. BROWN JR.
Governor

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

Management Memorandum
Memorandum Number: 2015-12

Date: July 1, 2015

TO: LOCAL ADAP COORDINATORS
ADAP ENROLLMENT WORKERS

SUBJECT: **REVISION OF ADAP HEPATITIS C TREATMENT POLICY**

Effective July 1, 2015, the Office of AIDS (OA) AIDS Drug Assistance Program (ADAP) has expanded access to hepatitis C virus (HCV) medications to include all HCV co-infected ADAP clients. This policy is in alignment with the federal Health and Human Services guidelines for treating HCV co-infection among HIV-infected persons. Previous ADAP clinical access criteria have been revised to be in line with national HCV treatment guidelines.

Due to the lower cost of ombitasvir/paritaprevir/ritonavir tablets (Viekira Pak™), ADAP will continue to prioritize the use of this regimen when it is equally effective and no medical contraindications for its use exist. Clinicians who wish to treat their ADAP clients with a HCV drug other than Viekira Pak™ must provide clinical justification. OA worked with the ADAP Medical Advisory Committee to identify multiple clinical situations which require the use of another HCV drug, and the use of another HCV drug will be quickly approved in these situations. The revised ADAP HCV Prior Authorization (PA) form (attached) reflects the new expanded access and options for use of other HCV drugs on the ADAP formulary.

ADAP requires its Pharmacy Benefits Manager (PBM) to track all HCV PA treatment requests and approve or deny these in accordance with the established MAC clinical criteria. HCV treatment requests denied through the PA process can be appealed to OA by the prescriber through the PBM. Appeals should be addressed to Eunice S.

Ndzerem (ndzerem@ramsellcorp.com), PharmD, Senior Managed Care Pharmacist. All related PA documents, client information and the prescriber's rationale for the appeal will be forwarded to OA for consideration. These appeals are clinically reviewed on a case-by-case basis. Cynthia Reed-Aguayo (Cynthia.Reed-Aguayo@cdph.ca.gov), ADAP Health Program Specialist, will assure timely OA review of the appeal, working with the PBM to acquire additional clinical information, as needed, for an accurate review of the appeal and final determination.

If you have any questions regarding the change to the HCV PA form, 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 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: _____
Last Name First Name

ADAP ID Code: _____

DOB: _____ **Height:** _____ **Weight:** _____

Latest CD4 count & Viral Load: _____/_____

Date of results: _____

Signature of pharmacist or physician _____ **Date** _____

Prescribing Physician: _____

Physician DEA #: _____

Physician Phone #: _____ **Fax#:** _____

Pharmacy Name: _____

NABP#: _____ **Contact Person:** _____

Pharmacy Phone#: _____ **Fax#:** _____

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

- 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
- 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)
 - 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
- 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
- ADAP requires one of the following:**
 - 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)
- For all:
 - I agree to submit HCV RNA result from 12 weeks after treatment completion for program evaluation purposes (FAX to Ramsell).

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.