



## Florida AIDS Drug Assistance Program (ADAP) Application For Hepatitis C (HCV) ADAP Medication Assistance Pilot Program



***This form must be completed and signed by the clinician prescribing and supervising the treatment for the patient.***

Criteria for enrollment in this program are:

- Provider compliance with the American Association for the Study of Liver Disease (AASLD) guidelines for use of Harvoni or Viekira pak or ribavirin in the treatment of HIV/HCV coinfecting patient <http://www.hcvguidelines.org/full-report-view> and <http://www.hcvguidelines.org/>
- *As additional therapeutic uses of the HCV medications are approved in guidelines, the procedure for treatment will be the same*
- ADAP Program requirements to obtain the therapy being prescribed (see below)

Pilot Program Medications:

- Viekira Pak® (paritaprevir 150 mg/ritonavir 100 mg/ombitasvir 25 mg once daily; dasabuvir 250 mg twice daily, plus/minus weight-based ribavirin)
- Harvoni® (ledipasvir 90 mg/sofosbuvir 400 mg once daily)

For general questions, call the HIV/AIDS Section Medical Team (850)-245-4334, ext. 2514.

Patient Name: \_\_\_\_\_

Medical Record/ID# \_\_\_\_\_

Date of Birth: \_\_\_\_/\_\_\_\_/\_\_\_\_

Clinician Name: \_\_\_\_\_ County: \_\_\_\_\_

Clinician Phone number: \_\_\_\_\_

Clinician Email: \_\_\_\_\_

ADAP County Contact Name: \_\_\_\_\_ Phone number: \_\_\_\_\_

FDOH Email: \_\_\_\_\_

Treatment Naïve     Prior Failure with: \_\_\_\_\_

HCV genotype: \_\_\_\_  without cirrhosis  compensated cirrhosis    Body Wt: \_\_\_\_ lbs. or kg.

Date \_\_\_\_\_ HCV RNA level \_\_\_\_\_ (Within 90 days of treatment start date)

Date \_\_\_\_\_ HCV Fibrosis Score \_\_\_\_\_

This Hepatitis C online resource can be used for calculating the patient's fibrosis score:  
<http://www.hepatitisc.uw.edu/page/clinical-calculators/fib-4>

We recommend preferentially using the Fibrosis score calculator.

Type of Fibrosis Test \_\_\_\_\_

\_\_\_\_\_

**Please select regimen:**

Daily fixed-dose combination of paritaprevir (150 mg)/ritonavir (100 mg)/ombitasvir (25 mg) plus twice-daily dasabuvir (250 mg) (Viekira pak<sup>®</sup>).

12 weeks OR

24 weeks (compensated cirrhosis genotype 1a)

OR

Daily fixed-dose combination of ledipasvir (90 mg)/sofosbuvir (400 mg) (Harvoni<sup>®</sup>) for 12 weeks

Weight-based ribavirin:

1000 mg if < 75 kg for 12 weeks

1000 mg if < 75 kg for 24 weeks

1200 mg if > 75 kg for 12 weeks

1200 mg if > 75 kg for 24 weeks

I have attached to this application the patient's prescription for 28 days of medication(s) with two to five (2-5) refills for the ADAP staff.

Note to Clinician: You may call the HIV/AIDS Section Medical Team at (850)-245-4334, ext. 2514 to request an exception to use these medications to treat compensated cirrhosis and/or other genotype.

**Clinician assurance:**

I have assessed the patient's existing medications, both HIV and non-HIV, and will implement any changes needed to avoid concomitant drug-drug interactions per [www.hep-druginteractions.org/](http://www.hep-druginteractions.org/) and package insert/AASLD Guidelines. The patient's combination ARV regimen is one that can be combined with the prescribed HCV therapy (see attached table).

I consent to providing additional follow-up medical information as a part of this pilot related to the treatment outcome.

Clinician Signature: \_\_\_\_\_

Print Clinician Name: \_\_\_\_\_ Date: \_\_\_\_\_

**▶▶ ATTENTION CLINICIAN: Instruct the patient they MUST RETURN (1) THIS FORM, AND (2) THE PRESCRIPTION(S) TO ADAP-MIAMI STAFF TO PROCESS ENROLLMENT INTO THIS PILOT PROGRAM.**

Note: For updated/other AASLD guideline approved uses with Harvoni and Viekira Pak +/- ribavirin medications, clinician may contact the HIV/AIDS medical team.

---

Viekira Pak<sup>®</sup> prescribing information is available at [http://www.rxabbvie.com/pdf/viekirapak\\_pi.pdf](http://www.rxabbvie.com/pdf/viekirapak_pi.pdf)

Viekira Pak<sup>®</sup> treatment support resources are available through the manufacturer at

<http://www.viekirahcp.com/proceed/how-can-proceed-help/>

Harvoni<sup>®</sup> prescribing information is available at

[http://www.accessdata.fda.gov/drugsatfda\\_docs/label/2014/205834s000lbl.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/label/2014/205834s000lbl.pdf)

**▶▶ ATTENTION ADAP STAFF:**

Enrollment in this pilot program will be approved upon submission of this completed form to the Florida ADAP Central Office in Tallahassee with a photocopy of the prescription(s) via scan or fax # 850-414-6719 to your ADAP Consultant. Follow your standard routine for sending original prescription(s) to your local pharmacy and/or Central Pharmacy for processing.

## HCV Direct Acting Antivirals Interactions with Antiretrovirals (ARVs) Table

Information adapted from DHHS Adult/Adolescent Antiretroviral Guidelines, package inserts and [www.hep-druginteractions.org](http://www.hep-druginteractions.org). Review references for any drug interactions not listed.

### HCV Direct-Acting Antiviral Agents

Select ARVs by Drug Classes	Sofosbuvir (SOF)	Ledipasvir/sofosbuvir (LDV/SOF)	Simeprevir (SMV)	Paritaprevir/Ritonavir/ Ombitasvir plus Dasabuvir (PTV/RTV/OBV plus DSV)	Paritaprevir/ Ritonavir/ Ombitasvir (PTV/RTV/OBV)	Daclatasvir (DCV)	Elbasvir/ Grazoprevir (EBR/GZR)
<b>Nucleoside Reverse Transcriptase Inhibitors</b>							
Abacavir (ABC)	✓	✓	✓	✓	✓	✓	✓
Emtricitabine (FTC)	✓	✓	✓	✓	✓	✓	✓
Lamivudine (3TC)	✓	✓	✓	✓	✓	✓	✓
Tenofovir Disoproxil Fumarate (TDF)	✓	✓	✓	✓	✓	✓	✓
Zidovudine (ZDV)	✓	✓	✓	✓	✓	✓	✓
<b>HIV Protease Inhibitors (PIs)</b>							
Atazanavir (ATV) (Unboosted)	✓	✓	✗	✓ <sup>3</sup>	✗	✓	✗
ATV/r, ATV/cobi		✓ <sup>1</sup>	✗	✓ <sup>4</sup>	✗	✓ <sup>6</sup>	✗
Darunavir (DRV)/r or RV/cobi	✓	✓ <sup>1</sup>	✗	✗	✓ <sup>5</sup>	✓	✗
Fosamprenavir (FPV) or FPV/r	✓	✓ <sup>1</sup>	✗	✗	✗	✓	✗
Lopinavir/r (LPV/r)	✓	✓ <sup>1</sup>	✗	✗	✗	✓	✗
Saquinavir/r (SQV/r)	✓	✓ <sup>1</sup>	✗	✗	✗	✓ <sup>6</sup>	✗
Tipranavir/r (TPV/r)	✗	✗	✗	✗	✗	✓ <sup>6</sup>	✗
<b>Non-nucleoside Reverse Transcriptase Inhibitors</b>							
Efavirenz (EFV)	✓	✓ <sup>2</sup>	✗	✗	✗	✓ <sup>7</sup>	✗
Etravirine (ETR)	✓	✓	✗	✗	✗	✓ <sup>7</sup>	✗
Nevirapine (NVP)	✓	✓	✗	✗	✗	✓ <sup>7</sup>	✗
Rilpivirine (RPV)	✓	✓	✓	✗	✗	✓	✓
<b>Integrase Strand Transfer Inhibitors</b>							
Dolutegravir (DTG)	✓	✓	✓	✓	✓	✓	✓
Elvitegravir (EVG)/cobi/TDF/FTC	✓	✗	✗	✗	✗	✓ <sup>6</sup>	✗
EVG/cobi/tenofovir alafenamide (TAF)/FTC	✓	✓	✗	✗	✗	✓ <sup>6</sup>	✗
EVG + PI/r (without coBI)	Refer to recommendation for specific ritonavir-boosted PI						
Raltegravir (RAL)	✓	✓	✓	✓	✓	✓	✓
<b>CCR5 Antagonist</b>							
Maraviroc	✓	✓	✓	✗	?	✓	✓

**Key to Symbols:**

✓= ARV agent and HCV drug can be used concomitantly

✗= Concomitant use of ARV agent and HCV drug **is not recommended**

? = Data on PK interactions with the ARV drug are unavailable or insufficient to make a recommendation

**Footnotes:**

1. Concomitant use of LDV/SOF with TDF and a ritonavir (/r)-boosted HIV PI or cobicistat (cobi)-boosted ATV or DRV may ↑ TDF exposure. Consider alternative HCV or ARV therapy, especially in patients with ↑ risk for renal insufficiency. If concomitant use necessary, monitor for TDF-associated adverse reactions by assessing measurements of renal function (i.e., estimated creatinine clearance, serum phosphorous, urine glucose, and urine protein) before HCV treatment and periodically during treatment.
2. Monitor for TDF-associated toxicity if EFV used with TDF/FTC due to ↑ TDF level
3. Reduce ATV dose to 300 mg and take in AM at same time as PTV/RTV/OBV plus DSV. If ritonavir cannot be used, choose an alternative HCV regimen.
4. Take ATV 300 mg in AM at same time as PTV/RTV/OBV plus DSV; discontinue RTV or COBI in HIV regimen until HCV therapy completed
5. When co-administered with PTV/RTV/OBV, darunavir 800 mg (without ritonavir) should be taken at the same time as PTV/RTV/OBV
6. Decrease DCV dose to 30 mg once daily
7. Increase DCV dose to 90 mg once daily

**Authors:**

Elizabeth Sherman, PharmD, AAHIVP, South Florida - Southeast AIDS Education and Training Center

Joanne Orrick, PharmD, AAHIVP, North Florida - Southeast AIDS Education and Training Center