DISTRICT OF COLUMBIA ~ DEPARTMENT OF HEALTH ~ ADAP

Ombitasvir, paritaprevir/ritonavir tablets; dasabuvir tablets (Viekira Pak™)

PRIOR AUTHORIZATION PROGRAM Request Form- Initial Request

CLIENT'S NAME: _____ ADAP ID:_____

CLIENT'S DATE OF BIRTH: _____ ADAP Pharmacy:_____

DC ADAP Policy:Viekira Pak™, (Ombitasvir, paritaprevir and ritonavir tablets co-packaged with dasabuvir tablets) include a fixed-dose co-formulated tablet of Ombitasvir (OBV), paritaprevir and ritonavir (PTV/r) which is a hepatitis C virus (HCV) NS5A inhibitor (ombitasvir), a HCV NS3/4 protease inhibitor (paritaprevir), and a CYP3A inhibitor (ritonavir) that inhibits metabolism of paritaprevir via CYP3A, thereby providing sustained paraprevir plasma concentrations. The second tablet in the co-package contains dasabuvir (DSV), a HCV non-nucleoside NS5B palm polymerase inhibitor. The OBV, PTV/r tablets are formulated for immediate release and contain ombitasvir 12.5mg, paritaprevir 75mg and ritonavir 50mg. The dasabuvir tablet is supplied as a separate tablet in the co-package and is also immediate release and contains 270.3mg dasabuvir sodium monohydrate equivalent to dasabuvir 250mg. Both tablets are for oral administration.
Viekira Pak™ requires prior approval for coverage. Allow up to 96 hours for completion of request.Please Fax (1) Supportive medical letter of necessity (2) Applicable diagnostic test results and (3) Patient signed acknowledgement and Commitment letter (4) Indicate Jurisdiction of ADAP Approval □DC □ MD □VA □WVA

Indication for Use:
Viekira Pak™, the fixed dose combination of OBV, PTV/r; DSV co-packaged tablets, with or without ribavirin, is indicated for the treatment of patients with genotype 1 chronic hepatitis C virus (HCV) infection including patients with compensated cirrhosis and HIV/HCV co-infection.

Viekira Treatment Regimen:

Drug	***Dose***	***Route***	***Frequency***

Criteria for use

Please complete and check all that apply:

1. Medical Provider is experienced in the care of HIV/hepatitis C infection, or in consultation with an infectious disease specialist or gastroenterologist.
   YES □ NO □
2. Client does have adherence issues with antiretroviral or other medications.
3. Client's has confirmed clinical diagnosis of Hepatitis C, genotype 1a or 1b
   YES □ NO □
4. Client is not being treated with medications not recommended for use with or contraindicated with ombitasvir, paritaprevir/ritonavir tablets; dasabuvir tablets (refer to product labeling)
   YES □ NO □
5. Client is not being treated with moderate or strong CYP3A inducers, e.g. efavirenz, phenytoin
   YES □ NO □
6. Client is not being treated with CYP2C8 inhibitors or inducers, e.g. rifampin, carbamazepine
   YES □ NO□
7. Client is not pregnant or attempting to become pregnant and/or female partner of a male patient is no pregnant.
   YES □ NO □

8. Client does have decompensated liver disease.
   YES □ NO □
9. Client has cirrhosis.
   YES □ NO □
10. Client has had a positive hepatitis C viral load taken within the last 6 months.
    YES □ NO □
11. Client has a FibroSure score of _____. Date of test_____ or biopsy proven fibrosis score of _____, Date _____.
12. Client has not been previously treated with Solvadi®
    YES □ NO □
13. Client's anticipated start date of Viekira Pak™ is_____.
14. Client's anticipated duration of CHC treatment is _____ weeks.

Recommended dosage and administration: The recommended dosage of Viekira Pak™ (OBV, PTV/r; DSV) is two OBV, PTV/r 12.5/75/50mg co-formulated tablets once daily in the morning and one DSV 250mg tablet twice daily in the morning and in the evening with a meal without regard to fat or calorie content. Co-administration with ribavirin (RBV) in 2 divided doses with food is recommended in select patient populations. Treatment regimen and duration is based on patient characteristics as described in the following table.

OBV, PTV/r; DSV Treatment Regimens and Durations based on Patient Characteristics (Reference Only)

Patient Population	Treatment Regimen	Treatment Duration
Genotype 1a without cirrhosis	OBV, PTV/r; DSV + RBV	12 weeks
Genotype 1a with cirrhosis	OBV, PTV/r; DSV + RBV	24 weeks**
Genotype 1b without cirrhosis	OBV, PTV/r; DSV	12 weeks
Genotype 1b with cirrhosis	OBV, PTV/r; DSV + RBV	12 weeks

*** For patients with an unknown or mixed genotype 1 subtype, follow genotype 1a dosing recommendations**
**** 12-week duration may be considered for some patients based on prior treatment history**
For patients with HCV/HIV-1 co-infection, use the dosage recommendations in the above table
For patients who are liver transplant recipients with normal hepatic function and mild fibrosis (Metavir fibrosis score ≤2), the recommended duration of OBV, PTV/r; DSV + RBV is 24 weeks

Physician's signature:_____ Date:_____

Physician's Name (Print):_____Phone#:_____Fax#:_____

Fax Completed Form to Clinical Pharmacy Associates:Fax: 1 (888) 971-7229

Phone: 1 (800) 745-0434 ext 150 Attention: Prior Approval Program

Approval: YES □ NO □ Date_____ Initials_____ Office use only

Reason for denial_____