DISTRICT OF COLUMBIA ~ DEPARTMENT OF HEALTH ~ ADAP

Elbasvir and Grazoprevir tablet (Zepatier™)

PRIOR AUTHORIZATION PROGRAM Request Form – Initial Request (16 weeks maximum)

CLIENT'S NAME: ___________________________ ADAP ID:____________________________________

CLIENT'S DATE OF BIRTH____________________ ADAP Pharmacy______________________________

DC ADAP Policy: Zepatier™ (Elbasvir and Grazoprevir) is a fixed dose combination of elbasvir, an inhibitor of hepatitis C virus (HCV) nonstructural protein 5A (NS5A) and grazoprevir, an inhibitor of HCV NS3/4A protease. Each tablet contains elbasvir 50 mg and grazoprevir 100 mg.

Zepatier™ 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 tests (3) patient signed acknowledgement and commitment letter (4) Indicate Jurisdiction of ADAP Approval □DC □ MD □VA □WVA

Indication for Use:

Elbasvir/Grazoprevir is indicated, with or without ribavirin, for the treatment of adult patients with genotype 1 or 4 chronic hepatitis C virus (HCV) infection.

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. Does client have adherence issues with antiretroviral or other medications?
   YES □ NO □
3. Client is not being treated with medications that are not recommended for use with or contraindicated with Elbasvir/Grazoprevir (refer to product labeling).
   YES □ NO □
4. Client is currently receiving OATP1B1/3 inhibitor, e.g. lopinavir, ritonavir, rifampin
   YES □ NO □
5. Client is currently receiving strong CYP3A inhibitors, e.g. clarithromycin, ritonavir
   YES □ NO □
6. Client is currently receiving moderate CYP3A inducers, e.g.efavirenz, etravirine
   YES □ NO □
7. Client is currently receiving strong CYP3A inducers, e.g. phenytoin, carbamazepine
   YES □ NO □
8. Client's has confirmed clinical diagnosis of chronic Hepatitis C infection, genotype 1 or 4.
   YES □ NO□ Other genotype ____________________ (specify)
9. Client is not pregnant or attempting to become pregnant and/or female partner of a male patient is not pregnant.
   YES □ NO □
10. Does client have decompensated liver disease?
    YES □ NO □

11. Client has cirrhosis?
    YES □ NO □
12. Client has baseline NS5A polymorphism?
    YES □ NO □
13. Client has previously been treated with Peginteferon and ribavirin?
    YES □ NO □
14. Client has a FibroSure score of ___________.
    Date of test________ or biopsy proven score of _______ Date:________
15. Client has had a positive hepatitis C viral load taken within the last 6 months.
    YES □ NO □
16. Client's anticipated start date of Zepatier™ is_________________.
17. Client's anticipated duration of chronic HCV treatment is _______ weeks.

Recommended dosage and administration: The recommended dose of Zepatier (Elbasvir/Grazoprevir, EBR/GZR) is one tablet orally once a day with or without food. The dosage regimens and duration should be based on the patient's clinical data as described in the following table.

Patient Population	Treatment	Duration
Genotype 1a: Treatment-naïve or PegIFN/RBV-experienced€ without baseline NS5A polymorphism*	EBR/GZR	12 weeks
Genotype 1a: Treatment-naïve or PegIFN/RBV-experienced **with** baseline NS5A polymorphism	EBR/GZR + RBV	16 weeks
Genotype 1b: Treatment-naïve or PegIFN/RBV-experienced€	EBR/GZR	12 weeks
Genotype 1a or 1b: PegIFN/RBV/PI-experienced◊	EBR/GZR + RBV	12 weeks
Genotype 4: Treatment-naïve	EBR/GZR	12 weeks
Genotype 4: PegIFN/RBV-experienced€	EBR/GZR + RBV	16 weeks

€Peginterferonalfa + ribavirin

*Polymorphisms at amino acid positions 28, 30, 31, or 93

◊Peginterferonalfa + ribavirin + HCV NS3/4A protease inhibitor

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____

Only employees/agents of the HIV/AIDS Hepatitis, STD and Tuberculosis Administration or Clinical Pharmacy Associates are intended recipients of this document. Any disclosure, dissemination or copying of information by unintended individuals is strictly prohibited. If you have received this form in error, please notify us by telephone and fax original to the number listed above.