DISTRICT OF COLUMBIA ~ DEPARTMENT OF HEALTH ~ ADAP

Daclatasvir tablet (Daklinza™)

PRIOR AUTHORIZATION PROGRAM Request Form – Initial Request (12 weeks maximum)

CLIENT'S NAME: _____ ADAP ID:_____

CLIENT'S DATE OF BIRTH_____ ADAP Pharmacy_____

DC ADAP Policy: Daklinza™ (Daclatasvir) is an inhibitor of hepatitis C virus (HCV) nonstructural protein 5A (NS5A). Daclatasvir is available as 60 mg and 30 mg tablets for oral administration.

Daklinza™ requires prior approval for coverage. Allow up to 96 hours for completion of request.

Please fax (1) supportive medical letter of necessity of necessity (2) applicable diagnostic tests and (3) patient signed acknowledgement and commitment letter (4) Indicate Jurisdiction of Client ADAP Approval □DC □ MD □VA □WVA

Indication for Use:

Daclatasvir is indicated for use with sofosbuvir, with or without ribavirin, for the treatment of chronic hepatitis C (CHC) genotype 1 or 3 infection as a component of a combination antiviral treatment regimen.

The sustained virologic response (SVR) rates are reduced in genotype 3 patients with cirrhosis receiving daclatasvir in combination with sofosbuvir for 12 weeks.

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 sofosbuvir or daclatasvir (refer to product labeling).
   YES □ NO □
4. Client is currently receiving strong CYP3A inhibitors, e.g. clarithromycin, ritonavir
   YES □ NO □
5. Client is currently receiving moderate CYP3A inducers, e.g. efavirenz, etravirine
   YES □ NO □
6. Client is currently receiving strong CYP3A inducers, e.g. phenytoin, carbamazepine
   YES □ NO □
7. Client's has confirmed clinical diagnosis of Hepatitis C, genotype 1 or 3.
   YES □ NO□ Other genotype _____ (specify)
8. Has resistance testing been done if client has genotype 1a?
   YES □ NO □
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 □
    Child-Pugh Class ____
12. Client has not previously been treated with sofosbuvir?
    YES □ NO □
13. Client has a FibroSure score of _____.
    Date of test_____ or biopsy proven score of _____ Date:_____
14. Client has had a positive hepatitis C viral load taken within the last 6 months.
    YES □ NO □
15. Client's anticipated start date of Daklinza™ is_____.
16. Client's anticipated duration of CHC treatment is _____ weeks.
17. Client's dose of Daklinza™ is _____ mg.

Recommended dosage and administration: The recommended dose is one 60 mg tablet orally once a day with or without food. Daclatasvir should be administered in combination with sofosbuvir to treat chronic hepatitis C in adults.

Treatment Regimen andDose modification due to Drug-Drug Interactions *(Reference Only)*

Genotype	Patient Population	Treatment Regimen	Treatment Duration
1	Without cirrhosis or Compensated cirrhosis (Child-Pugh A)	Daclatasvir + Sofosbuvir	12 weeks
	Decompensated cirrhosis (Child-Pugh B or C) or Post -transplant	Daclatasvir + Sofosbuvir + Ribavirin	12 weeks
3	Without cirrhosis	Daclatasvir + Sofosbuvir	12 weeks
	Compensated or decompensated cirrhosis or post-transplant	Daclatasvir + Sofosbuvir + Ribavirin	12 weeks

Concomitant Strong CYP3A Inhibitors	Concomitant Moderate CYP3A Inducers	Concomitant Strong CYP3A Inducers
Daclatasvir 30 mg daily	Daclatasvir 90 mg daily	**Contraindicated**

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_____