**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 (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 and Dose modification due to Drug-Drug Interactions (Reference Only)

<table>
<thead>
<tr>
<th>Genotype</th>
<th>Patient Population</th>
<th>Treatment Regimen</th>
<th>Treatment Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Without cirrhosis or Compensated cirrhosis (Child-Pugh A)</td>
<td>Daclatasvir + Sofosbuvir</td>
<td>12 weeks</td>
</tr>
<tr>
<td></td>
<td>Decompensated cirrhosis (Child-Pugh B or C) or Post -transplant</td>
<td>Daclatasvir + Sofosbuvir + Ribavir</td>
<td>12 weeks</td>
</tr>
<tr>
<td>3</td>
<td>Without cirrhosis</td>
<td>Daclatasvir + Sofosbuvir</td>
<td>12 weeks</td>
</tr>
<tr>
<td></td>
<td>Compensated or decompensated cirrhosis or post-transplant</td>
<td>Daclatasvir + Sofosbuvir + Ribavir</td>
<td>12 weeks</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Concomitant Strong CYP3A Inhibitors</th>
<th>Concomitant Moderate CYP3A Inducers</th>
<th>Concomitant Strong CYP3A Inducers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daclatasvir 30 mg daily</td>
<td>Daclatasvir 90 mg daily</td>
<td>Contraindicated</td>
</tr>
</tbody>
</table>

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.

Revised April 2016