Georgia ADAP Application for Prior Approval Medications

DATE OF REQUEST:

CLIENT INFORMATION:

Client Name (Last, First, M):

District/Clinic where the client is seen:

Client/Caregiver:

1) Patient is willing to take (or caregiver to administer) medications as directed. ☐ Yes ☐ No

2) Patient has prior evidence of adherence to therapy and medical care; and prescriber has reasonable expectation that adherent behavior will continue. ☐ Yes ☐ No

3) Patient's home has sufficient storage at the proper temperature. ☐ Yes ☐ No

DRUGS REQUESTED & REQUIRED INFORMATION:

Please complete the corresponding section for the specific drugs requested and check the appropriate boxes, or supply the response/supporting documentation.

☐ Fuzeon (Enfuviritide)

1) Current antiretroviral regimen:

2) Please attach copies of the most recent viral load, CD4 count and all available resistance testing.

3) Proposed optimized regimen:

4) Does the client have a history of moderate to severe adverse events/intolerances/ allergies to medications? ☐ Yes ☐ No

- **If yes**, what medications?

- Describe the reaction:

5) Does the client have a history of enrollment in a recent study or Expanded Access Program? ***(If yes**, please provide documentation.)* ☐ Yes ☐ No

If a client's regimen includes Fuzeon, the Georgia ADAP recommends *completing a "Fuzeon Nurse Connections" enrollment form to arrange for a home visit from a Fuzeon Nurse Educator to help the client to become confident in their ability to reconstitute and inject Fuzeon. The form is available at* ***www.fuzeon.com*** *or via phone at 877-4FUZEON (877-438-9366).*

☐ Selzentry (Maraviroc)

1) Current antiretroviral regimen:

2) Please attach copies of the most recent viral load, CD4 count, tropism assay test, and all available resistance testing.

3) Proposed optimized regimen:

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4) Does the client have a history of moderate to severe adverse events/intolerances/ allergies to medications? ☐ Yes ☐ No

- **If yes**, what medications?

- Describe the reaction:

☐ **Videx (Didanosine)**

1) Current antiretroviral regimen:

2) Length of time on current regimen:

3) Reason for continuing or adding Videx to the regimen:

4) Please attach copies of the most recent viral load, CD4 count and all available resistance testing.

☐ **Zerit (Stavudine)**

1) Current antiretroviral regimen:

2) Length of time on current regimen:

3) Reason for continuing or adding Zerit to the regimen:

4) Please attach copies of the most recent viral load, CD4 count and all available resistance testing.

Please select requested regimen from the options listed below. (Ribavirin will be weight based.):

☐ **Harvoni (Ledipasvir-sofosbuvir)**	☐ **with Ribavirin or**	☐ **without Ribavirin**
☐ **Daklinza (Daclatasvir) plus Sovaldi (Sofosbuvir)**	☐ **with Ribavirin or**	☐ **without Ribavirin**
☐ **Epclusa (Velpatasvir-Sofosbuvir)**	☐ **with Ribavirin or**	☐ **without Ribavirin**
☐ **Zepatier (Elbasvir-Grazoprevir)**	☐ **with Ribavirin or**	☐ **without Ribavirin**
☐ **Technivie**	☐ **with Ribavirin or**	☐ **without Ribavirin**
☐ **VIEKIRA PAK**	☐ **with Ribavirin or**	☐ **without Ribavirin**
☐ **Mavyret (Glecaprevir-Pibrentasvir)**		
☐ **Sovaldi (Sofosbuvir) plus Ribavirin**		

Requested Course of Therapy: ☐ **8 weeks** ***(only Mavyret)*****,** ☐ **12 weeks,** ☐ **16 weeks, or** ☐ **24 weeks**

1) Client is an active and stable ADAP client. (***Requirement***) ☐ Yes ☐ No

2) Client Weight:	3) Client Age:	4) Client Sex:

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5) Current antiretroviral regimen:

6) List of current non-HIV medications:

7) Does the client have a history of moderate to severe adverse events/intolerances/ allergies to medications? ☐ Yes ☐ No

- **If yes**, what medications?

- Describe the reaction:

8) Please attach copies of the most recent lab work: HIV viral load, CD4 count, CMP, CBC, PT/INR, pregnancy test (if woman of child bearing age), Hepatitis A (HAV) total antibody, Hepatitis C (HCV) antibody, HCV viral load, resistance-associated polymorphism test (if indicated per guidelines), HCV genotype/subtype, i.e. 1a, 1b, etc. In addition, all clients initiating HCV therapy should be assessed for HBV coinfection with HBsAg, anti-HBs, and anti-HBc, as per current AALSD guidelines and FDA Safety Announcement.

9) Hepatitis C Stage: ☐ 0 ☐ 1 ☐ 2 ☐ 3 ☐ 4 ☐ compensated cirrhosis ☐ decompensated cirrhosis

- Please check the lab performed within the last 12 months and include a copy:

☐ Liver Biopsy ☐ FIB-4 Calculation

☐ MELD or Child-Pugh Score ☐ Non-Invasive Biomarker Testing

10) Does the client have a history of Hepatitis C treatment? ☐ Yes ☐ No

- If yes, what treatment?

- Length of treatment?

- Outcome of treatment?

11) The requesting provider is asking the State Medical Advisor to make the treatment recommendation. ☐ Yes ☐ No

NOTE: Providers must submit results of the test of cure Hepatitis C Viral Load (12-weeks following treatment).

Prescriber Information:

Provider Name (Last, First, M): Phone:

Email: Signature:

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Request Determination:			
Date Received:		Date of Decision:	
☐ Request approved	☐ Request Denied		
Medical Advisor (Last, First, M):			
Phone:		Email:	
Medical Advisor/ Prescriber Signature:			

Comments/Additional Information or Instructions:

Provider/Prescriber Guidelines:
Patient must have a repeat HIV viral load and CD4 count performed 12 and 24 weeks after initiation of the regimen to assess effectiveness.
If CD4 and/or viral load have not improved, clinical improvement (or clinically stable if condition was worsening before) must be documented for continuation of the new regimen.
The prescriber must review the state guidelines and/or restrictions concerning the use of these medications to determine that the patient qualifies.
The prescriber should be an experienced HIV/AIDS provider or should consult with a specialist and must have sufficient office/clinic capability to provide patient education and monitoring.
Guidelines: http://aidsinfo.nih.gov/guidelines / https://dph.georgia.gov/nurse-protocols
Hepatitis C Guidelines: http://www.hcvguidelines.org/
Georgia Department of Public Health Hepatitis C Testing Toolkit
FDA Drug Safety Communication: FDA warns about the risk of Hepatitis B reactivating in some patients treated with direct-acting antiretrovirals for Hepatitis C: http://www.fda.gov/Drugs/DrugSafety/ucm522932.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery