

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 (Enfuvirtide)

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? <input type="checkbox"/> Yes <input type="checkbox"/> No
- If yes, what medications? <input type="text"/>
- Describe the reaction: <input type="text"/>

<input type="checkbox"/> Trogarzo (Ibalizumab-uiyk)
1) Current antiretroviral regimen: <input type="text"/>
2) Please attach copies of the most recent viral load, CD4 count and all available resistance testing.
3) Proposed optimized regimen: <input type="text"/>
4) Does the client have a history of moderate to severe adverse events/intolerances/allergies to medications? <input type="checkbox"/> Yes <input type="checkbox"/> No
- If yes, what medications? <input type="text"/>
- Describe the reaction: <input type="text"/>
5) Please attach the most recent prescribers note and a list of all current non-HIV medications to asses if there are potential drug interactions thatsupport requiring salvage therapy.
<i>If a client's regimen includes Trogarzo, the Georgia ADAP recommends contacting Thera Patient Support at https://www.therapatientssupport.com.</i>

<input type="checkbox"/> Rukobia (Fostemsavir)
1) Current antiretroviral regimen: <input type="text"/>
2) Please attach copies of the most recent viral load, CD4 count and all available resistance testing.
3) Proposed optimized regimen: <input type="text"/>
4) Does the client have a history of moderate to severe adverse events/intolerances/allergies to medications? <input type="checkbox"/> Yes <input type="checkbox"/> No
- If yes, what medications? <input type="text"/>
- Describe the reaction: <input type="text"/>
5) Please attach the most recent prescribers note and a list of all current non-HIV medications to asses if there are potential drug interactions thatsupport requiring salvage therapy.

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***The following section is specific to GA ADAP Hepatitis C Program.
Hepatitis C Medications are unavailable until further notice.***

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

- | | | |
|--|--|--|
| <input type="checkbox"/> Harvoni (Ledipasvir-sofosbuvir) | <input type="checkbox"/> with Ribavirin or | <input type="checkbox"/> without Ribavirin |
| <input type="checkbox"/> Epclusa (Velpatasvir-Sofosbuvir) | <input type="checkbox"/> with Ribavirin or | <input type="checkbox"/> without Ribavirin |
| <input type="checkbox"/> Zepatier (Elbasvir-Grazoprevir) | <input type="checkbox"/> with Ribavirin or | <input type="checkbox"/> without Ribavirin |
| <input type="checkbox"/> Mavyret (Glecaprevir-Pibrentasvir) | | |
| <input type="checkbox"/> 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)		<input type="checkbox"/> Yes <input type="checkbox"/> No
2) Client Weight: <input style="width: 100px;" type="text"/>	3) Client Age: <input style="width: 100px;" type="text"/>	4) Client Sex: <input style="width: 100px;" type="text"/>
5) Current antiretroviral regimen: <input style="width: 100%; height: 30px;" type="text"/>		
6) List of current non-HIV medications: <input style="width: 100%; height: 30px;" type="text"/>		
7) Does the client have a history of moderate to severe adverse events/intolerances/allergies to medications?		<input type="checkbox"/> Yes <input type="checkbox"/> No
- If yes, what medications? <input style="width: 100%; height: 30px;" type="text"/>		
- Describe the reaction: <input style="width: 100%; height: 30px;" type="text"/>		
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: <input type="checkbox"/> 0 <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> 3 <input type="checkbox"/> 4 <input type="checkbox"/> compensated cirrhosis <input type="checkbox"/> decompensated cirrhosis		
- Please check the lab performed within the last 12 months and include a copy:		
<input type="checkbox"/> Liver Biopsy	<input type="checkbox"/> FIB-4 Calculation	<input style="width: 100px;" type="text"/>
<input type="checkbox"/> MELD or Child-Pugh Score	<input type="checkbox"/> Non-Invasive Biomarker Testing	
10) Does the client have a history of Hepatitis C treatment?		<input type="checkbox"/> Yes <input type="checkbox"/> No
- If yes, what treatment? <input style="width: 100%; height: 30px;" type="text"/>		
- Length of treatment? <input style="width: 100%; height: 30px;" type="text"/>		
- Outcome of treatment? <input style="width: 100%; height: 30px;" type="text"/>		

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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):	<input type="text"/>	Phone:	<input type="text"/>
Email:	<input type="text"/>	Signature:	<input type="text"/>

Request Determination:

Date Received:	<input type="text"/>	Date of Decision:	<input type="text"/>
<input type="checkbox"/> Request approved <input type="checkbox"/> Request Denied			
Medical Advisor (Last, First, M):	<input type="text"/>		
Phone:	<input type="text"/>	Email:	<input type="text"/>
Medical Advisor/ Prescriber Signature:	<input type="text"/>		

Comments/Additional Information or Instructions:

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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