Georgia ADAP Prior Approval Form

Please complete and attach this ADAP Prior Approval Form along with the requested supporting documentation and send them in an encrypted email to: ADAPConsult@dph.ga.gov.

DATE OF REQUEST:	

CLIENT INFORMATION:		
Client Name (Last, First, MI):		
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

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.

◯ **Cabenuva™ (cabotegravir/rilpivirine)**

Requested Course of Therapy: ◯ 1-month (400mg/600mg kit) ◯ 2-month (600mg/900mg kit)

◯ **Rukobia™ (fostemsavir)**

◯ **Selzentry™ (maraviroc)**

◯ **Sunlenca™ (lenacapavir)**

◯ **Symtuza™ (darunavir/cobicistat/emtricitabine/TAF)**

◯ * **Trogarzo™ (ibalizumab)**

*If a patient's regimen includes Trogarzo™, access will be coordinated through Thera Patient Support

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 and why an alternative regimen is not feasible:

4) If Cabenuva™ is proposed regimen:

◯ HIV viral load < 200 copies/mL

◯ HIV viral load ≥ 200 to <100,000 copies/mL with virus sensitive to the components cabotegravir + rilpivirine in patients with adherence issues not responding to adherence interventions

◯ Has the patient demonstrated immunity to Hepatitis B, in the process of receiving Hepatitis B vaccine, or has not responded to Hepatitis B vaccine in the past?

Note: Patients that are chronically infected with Hepatitis B who are on an oral tenofovir + emtricitabine or lamivudine-based regimen for their hepatitis B, need to have their Hep B treatment continued if being transitioned to Cabenuva™.

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5) Does the client have a history of moderate to severe adverse events/intolerances/ allergies to medications **(including any components of requested medication)**? ◯ Yes ◯ No

◯ **If yes**, what medications?

◯ Describe the reaction:

6) Please attach the most recent prescriber's notes and a list of all current non-HIV medications to assess if there are potential drug interactions that support requiring the requested medication.

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

8) Please attach copies of signed ADAP Cabenuva™ Storage Attestation, and ADAP Cabenuva™ Inventory Management Attestation forms.

Prescriber Information:			
Provider Name (Last, First, M):		Phone:	
Email:		Signature:	

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

Fiscal Request Determination*:			
Date Received:		Date of Decision:	
◯ Request approved	◯ Request Denied		
Approver (Last, First, M):			
Approver Signature:			
Phone:		Email:	

***Note:** *Fiscal determination confirms the program budget has been reviewed by Ryan White Part B management based on current medication cost estimates provided by the Office of HIV/AIDS, and a decision rendered according to current funding parameters to support medication initiation.*

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Comments/Additional Information or Instructions:

Provider/Prescriber Guidelines:
Patients must have a repeat HIV viral load within 2-8 weeks from medication initiation and if the HIV RNA is detectable at 2-8 weeks, repeat testing every 4-8 weeks until viral load is suppressed to <200 copies/mL.
If the viral load has not improved, this must be documented, a genotype should be performed, and the case discussed with the HIV Medical Advisor for continuation of the new regimen,
The prescriber must review the state guidelines and/or restrictions concerning the use of these medications to determine if 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

Handling and Storage Requirements:
Cabenuva™
Medical Prescriber must be able to meet cold chain storage requirements with the ability to store medication refrigerated at 2℃ - 8℃ (36℉ - 46℉) **AND** have a procedure for receiving and storing cold chain medications in a timely manner.
Medical Prescriber must have an appropriate clinical environment and supplies to safely administer injectable medications.

Inventory Management Requirements:
Cabenuva™
Clinic must agree to create and implement an internal administration and inventory management log to provide oversight and management of Cabenuva™ inventory received from GA ADAP.
Copy of Cabenuva™ inventory log must be emailed electronically by the first day of the month, each month, to designated ADAP Contract Pharmacy and GA ADAP.