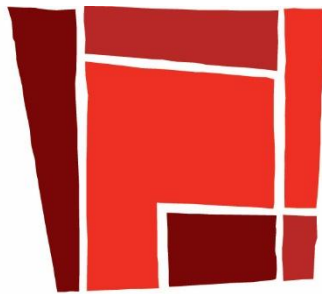# GUIDANCE FOR GRANT AWARD MANAGEMENT

ARIZONA DEPARTMENT OF HEALTH SERVICES

PREPAREDNESS

Office of HIV & Hepatitis C Services
AIDS Drug Assistance Program

LONG ACTING ANTI-RETROVIRAL THERAPY
POLICY & PROCEDURES

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Cabenuva Background

Cabenuva (cabotegravir extended-release injectable suspension and rilpivirine extended-release injectable suspension co-packaged for intramuscular use) is the first long-acting injectable antiretroviral (ARV) medication approved by the U.S. Food and Drug Administration (FDA). Cabenuva is a complete regimen for the treatment of HIV-1 infection in adults who have achieved viral suppression on a stable oral antiretroviral regimen but want to switch to an injectable regimen.

Coverage Exemptions

- To ensure continuity of the Cabenuva injections and the subsequent medical administration office visit(s) and to limit the risk of integrase resistance due to delayed or missed doses, any Ryan White/ADAP client in a pre-approved eligibility status is **NOT** authorized to receive Cabenuva through the ADAP 340B Contract Pharmacy. The client will only be permitted to receive Cabenuva after the pre-approved eligibility status has been reviewed and the client is made active. Please note: If an exception is needed due to extenuating clinical circumstances, please contact the ADAP Medication Access Manager.
- Arizona ADAP is unable to support any clinic driven "buy and bill" ordering and/or provide copay support through a non-ADAP contract pharmacy.
- Arizona ADAP is unable to support in-office Medical Administration/Copay Support claims only. Arizona ADAP must arrange for AND pay the applicable medical or pharmacy copay for Cabenuva.
- Per HRSA HAB regulations, Arizona ADAP cannot reimburse clients directly for any costs paid out of their pocket.

Medication Coverage Criteria

Both ADAP 340B and ADAP Assist clients **must obtain** the Cabenuva medication regimen through the applicable delivery mechanism below.

When/if there becomes a disproportionate volume of un/under-insured clients receiving Cabenuva through ADAP 340B, ADAP coverage and/or support may be discontinued until ADHS/ADAP can ensure continued coverage will be programmatically cost-effective and therefore sustainable. Proportionate volume of covered clients receiving Cabenuva must be insured so to ensure rebate generation is occurring; this, in turn, allows financial stability for ongoing programmatic coverage of Cabenuva for un/under-insured clients.

Mechanisms for Eligibility, Medication and/or Admin-Copay support

For ADAP 340B (uninsured) clients and/or ADAP clients that have a documented denial of Cabenuva through their payer of last resort (POLR):

- Medical Provider or an applicable designee must contact the ADAP Medication Access Manager and/or the ADAP Retention Coordinator prior to prescribing of Cabenuva to check and verify the client's eligibility status. This outreach is to ensure continuity of the Cabenuva injections and the subsequent medical administration office visit(s) and to limit the risk of integrase resistance due to delayed or missed doses. Any Ryan White/ADAP client in a pre-approved eligibility status is **NOT** authorized to receive Cabenuva through the ADAP 340B Contract Pharmacy. The ADAP Medication Access Manager can be reached by secure email at jimmy.borders@azdhs.gov or at 480-258-1069 and the ADAP Retention Coordinator can be reached by secure email at laura.kroger@azdhs.gov or at 480-254-7417.
- Medical Provider must contact the ADAP contracted pharmacy directly. Contracted pharmacy will obtain a written prescription (Rx) for Cabenuva and a frequency of administration calendar for the client from the Medical Provider. Cabenuva will be ordered by the ADAP contracted pharmacy using the ViiV-specific Cabenuva ordering process and arrange for the initial and all subsequent deliveries to Medical Provider for administration on a date/time agreed to by all parties involved.
- Medical Admin/Copay Support: Medical Provider must contact the Arizona ADAP Medical Benefits Manager (MBM) team at 520-628-7223 directly. The Medical Provider will be reimbursed an all-inclusive administrative copay only after confirmation of medication administration and treatment is documented.
- For ADAP clients that have a documented denial of Cabenuva through their POLR, prior to outreach to the ADAP contracted pharmacy, the requesting Medical Provider must have obtained a prior authorization or coverage denial and a subsequent prior authorization or coverage appeal denial before coverage of Cabenuva can be considered. *Please note: the denial must be for a medical indication and not just Cabenuva is non-formulary/non-preferred.*

For ADAP Assist (insured/copay support only) clients:

- Medical Provider must contact the Arizona ADAP Medical Benefits Manager (MBM) team at 520-628-7223 directly prior to prescribing. The MBM team will obtain information on the client's primary insurance name and benefits offered so to research and best advise all parties on how Cabenuva can be obtained and how the admin/copay cost(s) can be reimbursed.
- The MBM team will follow up with the primary insurance benefit department and then coordinate medication ordering and copay wrap around via the ADAP Assist Prescription Benefits Manager (PBM), if Cabenuva is covered as a prescription benefit, **or** internally, if Cabenuva is covered as a medical benefit.
    - o **Pharmacy Benefit**: If Cabenuva is covered as a Pharmacy benefit under the client's primary insurance, the ADAP MBM team will advise the Medical Provider as to what pharmacy to call the Cabenuva prescription into. The ADAP MBM team will ensure the pharmacy is in the ADAP PBM pharmacy network and will also advise the pharmacy as to how they will bill the remaining Rx copay to the ADAP PBM. If the pharmacy is not in the ADAP PBM pharmacy network, the MBM team will contact the ADAP Medication

Access Manager who will work with the ADAP PBM to have the pharmacy quickly added to the pharmacy network. ADAP pharmacy preference will be all prescriptions are filled through the ADAP 340B contract Pharmacy as this streamlined approach greatly improves ordering, delivery and billing coordination.

- Once the Medical Provider has administered Cabenuva to the client, the Medical Provider must contact the Arizona ADAP Medical Benefits Manager (MBM) team at 520-628-7223 directly. The Medical Provider will be asked to provide both their invoice and the client Explanation of Benefits (EOB) that clearly shows the remaining amount owed to the Medical Provider for the service(s) rendered on the date of service. Only the amount identified on the EOB as the client owed to the Medical Provider will be reimbursed to the Medical Provider. Any reimbursement amount(s) identified by the insurer for the Medical Provider to cease payment pursuit of will not be paid on behalf of the client and will be disregarded.

- **Medical Benefit:** If Cabenuva is covered as a Medical benefit under the client's primary insurance, the ADAP MBM team will advise the Medical Provider on how to obtain Cabenuva. The ADAP MBM team will also follow up accordingly so the remaining Cabenuva copay can be billed to the ADAP MBM directly. The expectation will be the medication is to be released to the client/Medical Provider and the distributor will receive the remaining Cabenuva copay after billing the ADAP MBM for the primary insurance approved amount(s) owed

  - Once the Medical Provider has administered Cabenuva to the client, the Medical Provider must contact the Arizona ADAP Medical Benefits Manager (MBM) team at 520-628-7223 directly. The Medical Provider will be asked to provide both their invoice and the client Explanation of Benefits (EOB) that clearly shows the remaining amount owed to the Medical Provider for the service(s) rendered on the date of service. Only the amount identified on the EOB as client owed to the Medical Provider will be reimbursed to the Medical Provider. Any reimbursement amount(s) identified by the insurer for the Medical Provider to cease payment pursuit of will not be paid on behalf of the client and will be disregarded.

Questions?

Please direct any questions to the ADAP Medication Access Manager.