

VIRGINIA Ryan White HIV/AIDS Part B (RWHAP B)

STANDARD OPERATING PROCEDURE

Accessing Long Acting Injectable Antiretroviral (LARV) For Active VA MAP Clients

Effective Date: August 24, 2021

Revised Date: Not Applicable

Background:

The first FDA-approved long acting injectable for HIV treatment is now available for providers of Direct VA MAP clients. The term long-acting ARV injectable refers to an antiretroviral drug that is delivered via an injection and persists in the body for an extended period. The Health Resources and Services Administration (HRSA) reports that in addition to the medication addressing sub-optimal adherence, other potential benefits include less-frequent dosing, avoidance of pill fatigue, relieving challenges associated with oral medications, and protecting health privacy.

Stakeholders:

Clients, Case Managers, Providers, Nursing Staff, VA MAP Staff, Health Care Services, Public Health Educators, Health Departments, Central Pharmacy, Pharmaceutical Manufacturers, HIV Specialty Pharmacies, Infusion Centers and other sites that can administer injectable medications.

Policy and Purpose:

As described in HRSA's operational manual for AIDS Drug Assistance Programs (ADAPs), ADAPs are a State- or Territory-administered program authorized under Part B of the Ryan White HIV/AIDS Program that provides FDA-approved medication to low income individuals with HIV diagnosis who have limited or no coverage from private insurance, Medicaid, or Medicare. In accordance with the provisions of Title XXVI of the Public Health Service Act, the purpose of all Ryan White HIV/AIDS Program ADAP funds is to ensure that eligible HIV-infected persons gain or maintains access to HIV-related medications. This policy, within the purview of the standards, will improve access to medications, decrease medication fatigue by reducing dosing requirements, and increase medication adherence through the utilization of LARV treatment.

LARV access-eligibility requirements for Direct MAP Client

- Documented proof of HIV infection (one time requirement).
- Client must be a resident of Virginia.
- Household Income must be \leq 500% of the Federal Poverty Level (FPL).
- Client must not be enrolled in Medicaid (VA MAP will not pay for this clients medication, see "*VDH DPS dispensing and billing for clients with Medicaid insurance*" section below)
- Client must be an active direct VA MAP client, which means enrolled in VA MAP and has up-to-date eligibility certification status with VA MAP.

- Requirements for clients to be a candidate for an FDA approved injectable regimen, should closely adhere to the treatment guidelines associated with that specific drug manufacturer.

Eligibility requirements for Provider, Dosing and Administration Education, Storage and Handling:

- It is the prescriber's responsibility to follow drug manufacturer's clinical guidelines for each approved specific long- acting antiretroviral medication on the VA MAP formulary.
- Administration site must demonstrate its ability to properly handle, store and inventory these medication accordingly to manufacturer guidelines. VA MAP may request documentation before the first shipment of these medications to assure the site establishes the appropriate protocols. VDH-contracted subrecipients or vendors may periodically assess these protocols during various programmatic compliance visits by VDH-contracted subrecipients or vendors as part of VDH's management of its federal award.

Procedure:

To order LARV for Direct MAP clients

- Cabenuva is currently the only LARV currently available on the ADAP Formulary. To access Cabenuva, follow this link [Cabenuva for Active VA MAP Clients](#)

Shipping

- DPS can ship the medication directly to the medication administration site. Note: DPS ships cold items on Mondays, Tuesdays and Wednesdays.
- The site needs a CSR for medication labeled for a specific client. Follow this link to the [Controlled Substance Registration \(CSR\) Application](#)

If there is a problem with medication shipment

- If the administration site receives a damaged product in its shipment, it should contact DPS and provide documentation of damage including a photo.

Invoicing VDH for Medication Administration Costs

- Providers who will serve Direct MAP clients by only administering this medication can collaborate with another VDH RWHAP B-contracted entity if they meet all of the above conditions including eligibility requirements for Providers.
- The collaborating entity will be responsible for assuring the client's VA MAP eligibility is up to date, for any VDH billing/administrative issues, and reimbursing the entity that administers the medication. This cost can be included in the routine monthly invoicing to VDH for allowable RWHAP B services.
- The VDH-contracted agency can bill the cost of the medication administration to ADAP funds. VDH-contracted agencies can also bill office visit and injection administration fees to Outpatient Ambulatory Health Services and transportation costs to Medical Transportation Services if these services are part of their award.

LARV Access for Clients who have insurance coverage through VA MAP

Clients insured though VA MAP should first access medication through their insurance carriers. As long as the medication is a pharmaceutical benefit, Ramsell will pay cost-shares for eligible and active VA MAP clients through their usual claim adjudication process. Providers should charge ancillary costs for

office visits and medication administration with the client's insurance carrier. For active VA MAP clients who receive their health insurance coverage through their employers, VA MAP will pay medication cost shares only. If insurance carriers do not provide this medication **at all**, clinicians may access medications for these clients following the process for Direct MAP clients.

VDH DPS dispensing and billing for clients with Medicaid

- Per normal DPS procedures, clients with Medallion 4.0 Health Plans may have prescriptions filled at DPS. There is no requirement that clients with insurance have their medication dispensed by DPS.
- Medication will be ordered and dispensed following above procedures. The 14-day refill window may be shorter depending on plan requirements. As soon as the insurance plan allows, DPS will fill the order and ship the medication.
- DPS will request Prior Authorizations (PA) when necessary. DPS will notify the administration site contact of the need for a PA.
- As soon as DPS receives approval for the PA, it will fill order. Shipping is only on Mondays, Tuesdays, or Wednesdays.

HRSA Performance Measure: None

Guidance:

1. Ensure that the therapeutics included on the list of classes of core antiretroviral therapeutics established by the Secretary under subsection (e) of the legislation are, at a minimum, the treatments provided by the State pursuant to this section;
2. Provide assistance for the purchase of treatments determined to be eligible under paragraph (1), and the provision of such ancillary devices that are essential to administer such treatments;
3. Provide outreach to individuals with HIV/AIDS, and as appropriate to the families of such individuals;
4. Facilitate access to treatments for such individuals;
5. Document the progress made in making therapeutics described in subsection (a) available to individuals eligible for assistance under this section;
6. Encourage, support, and enhance adherence to and compliance with treatment regimens, including related medical monitoring;
7. The U.S. Department of Health and Human Services (HHS) develops federal guidelines on the appropriate administration of HIV/AIDS treatments, including antiretroviral therapies, and medications for the prevention and treatment of opportunistic infections. HHS regularly updates these guidelines using the latest scientific research findings by expert panels. ADAPs and other RWHAP recipients that provide HIV/AIDS medications must ensure that clients receive medication therapies consistent with current Federal HIV/AIDS treatment guidelines;
8. Ryan White recipients and their contractors "are expected to vigorously pursue enrollment into health care coverage for which their clients may be eligible (e.g., Medicaid, CHIP, Medicare, state-funded HIV/AIDS programs, employer-sponsored health insurance coverage, and/or other private health insurance) to extend finite RWHAP grant resources to new clients and/or needed services." (p. 35, HRSA ADAP Manual);
9. Implementing HRSA required guidelines and controls to providers to ensure compliance with legislative and programmatic requirements, encouraging continuity of client care; and improve client health outcome.

10. Ensuring client's eligibility for participation in VA MAP at initial enrollment, during 6-month recertification, and on an annual basis thereafter. The State/Territory must consistently apply the eligibility standards to all ADAP applicants. As per Policy Clarification Notice (PCN) #13-02 (and PCN# 16-02), VA MAP must document client eligibility, whether through paper client files or electronically. It is HRSA's expectation that ADAPs design enrollment, certification and recertification processes to allow clients access to medications in a timely manner.

Exceptions: None

References:

Health Resources and Services Administration (HRSA), HIV/AIDS Bureau (HAB), Division of State HIV/AIDS Programs, AIDS Drug Assistance Program (ADAP) Manual, 2016.

HRSA's Long-acting Antiretroviral (ARV) Medication Guidance and Ryan White HIV/AIDS Program, December 4, 20019 at <https://hab.hrsa.gov/program-grants-management/policy-notices-and-program-letters>.

HRSA Policy Clarification Notice # 13-02, "Clarifications on Ryan White Program Client Eligibility Determinations and Recertification Requirements" at <https://hab.hrsa.gov/program-grants-management/policy-notices-and-program-letters>.

HRSA Policy Clarification Notice # 16-02, "Ryan White HIV/AIDS Program Services: Eligible Individuals and Allowable Use of Funds" at <https://hab.hrsa.gov/program-grants-management/policy-notices-and-program-letters>.