

AIDS Drug Assistance Program Treatments

Description from the Health Resources and Services Administration (HRSA) Policy Clarification Notice 16-02:

The AIDS Drug Assistance Program (ADAP) is a state-administered program authorized under RWHAP Part B to provide U.S. Food and Drug Administration (FDA)-approved medications to low-income clients living with HIV who have no coverage or limited health care coverage. HRSA RWHAP ADAP formularies must include at least one FDA-approved medicine in each drug class of core antiretroviral medicines from the U.S. Department of Health and Human Services' Clinical Guidelines for the Treatment of HIV HRSA RWHAP ADAPs can also provide access to medications by using program funds to purchase health care coverage and through medication cost sharing for eligible clients. HRSA RWHAP ADAPs must assess and compare the aggregate cost of paying for the health care coverage versus paying for the full cost of medications to ensure that purchasing health care coverage is cost effective in the aggregate. HRSA RWHAP ADAPs may use a limited amount of program funds for activities that enhance access to, adherence to, and monitoring of antiretroviral therapy with prior approval.

Program Guidance:

HRSA RWHAP Parts A, C and D recipients may contribute RWHAP funds to the RWHAP Part B ADAP for the purchase of medication and/or health care coverage and medication cost sharing for ADAP-eligible clients.

Virginia Ryan White Part B Service Unit Definition:

One ADAP medication pick-up with one or more ADAP medications (e.g., five medications picked up at one time = one unit).

All service provision will comply with the Department of Health and Human Services (HHS) Guidelines and the Commonwealth of Virginia Department of Health (VDH) Service Standards for people with HIV, including the following:

1.0 Intake and Eligibility

As outlined in HRSA HAB Policy Clarification Notice 21-02 Clarifications (PCN) on Ryan White Program Client Eligibility Determinations and Recertification Requirements, people are eligible to receive RWHAP services when they meet each of the following factors:

- 1. HIV Status:** A documented diagnosis of HIV. (Note: People who do not have an HIV diagnosis are eligible to receive certain services as outlined in HRSA HAB PCN 16-02)

2. Low- Income: The RWHAP recipient defines low-income. Low-income may be determined based on percent of Federal Poverty Level (FPL), which can be measured in several ways (e.g., Modified Adjusted Gross Income, Adjusted Gross Income, Individual Annual Gross Income, and Household Annual Gross Income).

3. Residency: The RWHAP recipient defines its residency criteria, within its service area. Note: Immigration status is irrelevant for the purposes of eligibility for RWHAP services. RWHAP recipients or subrecipients should not share immigration status with immigration enforcement agencies.

Standard	Measure
Eligibility	
1.1) The client’s eligibility for Ryan White Part B services is determined.	1.1) Documentation of the client’s eligibility is present in the client’s record.
<p>1.2) The client’s eligibility for Ryan White Part B services is determined. To be eligible for this service applicants must:</p> <ul style="list-style-type: none"> a) Be diagnosed with HIV (one time only) b) Live in Virginia c) Have an individual or family income at or below 500% of the Federal Poverty Level (FPL) d) Be ineligible for other payer sources covered by Federal or State programs such as Medicare, Medicaid, all other forms of insurance or third-party payers such as private and commercial insurance plans, and other payers that provide the service they are seeking. <ul style="list-style-type: none"> • Client Access Reviews (CARs) - refer to periodic checks of enrolled RWHAP B clients to identify any potential changes that may affect eligibility. • Provide continuation of eligibility every 24 months with proof of income, changes in insurance coverage, or any changes in residency • Client eligibility ensures Part B services are used as the payer of last resort and other funding sources must be vigorously pursued. Client must agree to participate in the insurance option that 	<p>1.2) Documentation of the client’s eligibility is present in the client’s record that verifies:</p> <ul style="list-style-type: none"> a) Client is diagnosed with HIV b) Client lives in Virginia c) Client meets income guidelines d) Client Medicaid status verified (gap of services) <ul style="list-style-type: none"> • Ongoing CARS and complete Continuation Eligibility Determination every 24 months • Client agrees to participate in insurance option that best meets their medical needs and for which the client is eligible.

<p>the client is eligible for and that best meets the client’s medical needs regardless of preference.</p> <p>Submission of eligibility assessments should be through the Provide Enterprise® data system.</p>	
Intake	
1.3) Complete eligibility screening and intake within 15 days of initial contact with client.	1.3) Documentation of intake and eligibility screening in record signed and dated.
<u>Client Access Reviews/Continuation of Eligibility</u>	
1.4) Client Access Reviews (CARs) refer to periodic checks of enrolled RWHAP B clients to identify any potential changes that may affect eligibility and continuation of eligibility conducted every 24 months to continue to receive Ryan White services. There is no grace period.	1.4) Documentation of CARS and continuation of eligibility is present in the client’s record.
<u>2.0 Key Services Components and Activities</u>	
Standard	Measure
Documentation	
2.1) Document provision of ADAP services by: <ul style="list-style-type: none"> a) Client eligibility b) Number of individuals served c) Medications provided. 	2.1) Documentation of ADAP services provided.
Provision of Services	
2.2) Provide a formulary of medications to people with HIV for the treatment of HIV disease and the prevention of opportunistic infections. The formulary must include pharmaceutical agents: <ul style="list-style-type: none"> a) From all the approved classes of antiretroviral medications in the PHS Clinical Practice Guidelines for use of Antiretroviral Agents in HIV-1 infected Adults and Adolescents b) Be FDA approved. 	2.2) Documentation of medication formulary.

<p><i>Note:</i> A process must be used to secure the best price available for all products on the formulary including 340B pricing or better.</p>	
<p>2.3) Provide outreach (awareness) to individuals with HIV, and as appropriate the families of such individuals regarding ADAP and its programs to facilitate access to treatments for such individuals and to document progress in making therapeutics available.</p>	<p>2.3) Documentation of state’s efforts and methods used to raise awareness.</p>
<p>2.4) Encourage, support, and enhance adherence to and compliance with treatment regimens including medical monitoring. Activities include:</p> <ul style="list-style-type: none"> • Enabling individuals to gain access to medications • Supporting adherence to the individual’s prescribed drug regimen to receive the full health benefits afforded by the medications. • Providing services to monitor the client’s progress in taking HIV-related medications. 	<p>2.4) Documentation of activities undertaken to improve access to medications and increase and support adherence to medication regimens.</p>
<p>2.5) Data sharing agreement in place with the Centers for Medicare and Medicaid (CMS) for the purpose of tracking True Out of Pocket Costs (TrOOP) for ADAP clients with Medicare Part D for whom ADAP is paying Medicare Part D Premiums, co-pays and deductibles.</p> <p><i>Note:</i> A data system necessary to track and account for ADAP payments for TrOOP costs must be established. These systems may be located at the ADAP’s PBM.</p>	<p>2.5) Documentation of amount of ADAP funds used to pay TrOOP for clients with Medicare Part D and a signed data sharing agreement between ADAP and CMS.</p>
<p>2.6) Facilitate client access to ADAP medication programs via:</p> <ul style="list-style-type: none"> • Direct purchase medication program for clients not eligible for other programs or awaiting open enrollment 	<p>2.6) Documentation of:</p> <ul style="list-style-type: none"> • Medication distribution system for directly dispensing physician prescribed medications to eligible clients

<ul style="list-style-type: none"> • Insurance program • Medication co-pay, co-insurance, and deductible assistance • Insurance continuation assistance. 	<ul style="list-style-type: none"> • Insurance purchasing program for eligible clients <ul style="list-style-type: none"> ▪ Health Insurance Marketplace Program (HIMAP) • Medication co-pays, co-insurance, and deductible assistance for eligible clients <ul style="list-style-type: none"> ▪ Insurance Continuation Assistance Program (ICAP) ▪ Medicare Part D Assistance Program (MPAP)
Transition and Discharge	
<p>2.7) Client discharged when ADAP services are no longer needed, goals have been met, upon death or due to safety issues. (see 2.8)</p> <p><u>Prior to discharge:</u> Conduct discussion with client over reasons for discharge and options for other service provisions. Whenever possible, discussion should occur face-to-face. If not possible, provider should attempt to talk with client via phone. If verbal contact is not possible, a certified letter* must be sent to client’s last known address. If client is not present to sign for the letter, return to the provider.</p> <p><i>*Exception: If the client has noted during the intake or at any other time to the VA MAP staff that sending mail is not permitted, no letter will be sent. If this is the case, VDH will document this in progress notes and discharge summary.</i></p> <p><u>Documentation:</u> Client’s record must include:</p> <ol style="list-style-type: none"> a) Date services start b) Special client needs c) Services needed/actions taken, if applicable d) Date of discharge e) Reason(s) for discharge f) Referrals made at time of discharge, if applicable. 	<p>2.7) Documentation of discharge plan and summary in client’s record with clear rationale for discharge within 30 days of discharge, including certified letter*, if applicable.</p> <p><i>*Exception: If the client has noted during the intake or at any other time to the subrecipient staff, that sending mail is not permitted, no letter will be sent. If this is the case, case managers will document this in progress notes and discharge summary.</i></p>

<p><u>Transfer:</u> If client transfers to another location (state), agency or service provider, transferring agency will provide discharge summary and other requested records within 5 business days of request. If client moves to another area, transferring agency will make referral for needed services in the new location.</p> <p><u>Unable to Locate:</u> If client cannot be located, agency will make and document a minimum of three follow-up attempts on three separate dates (by phone or in person) over a three-month period after first attempt. The three attempts should start no later than three months prior to the due date. A certified letter* must be mailed to the client’s last known mailing address within five business days after the last attempt to notify the client. The letter will state case closure within 30 days from the date on the letter if no appointment is schedule with the provider.</p> <p><i>*Exception: If the client has noted during the intake or at any other time to the subrecipient staff that sending mail is not permitted, no letter will be sent. If this is the case, case managers will document this in progress notes and discharge summary.</i></p> <p><u>Withdrawal from Service:</u> If client reports no longer needing services or decides to no longer participate in the Service Plan, client may withdraw from services. Because clients may withdraw for a variety of reasons it may be helpful to conduct an exit interview to ensure understanding reasons for withdrawal, or if client still needs services identify factors interfering with the client’s ability to fully participate. If other issues are identified that cannot be managed by the agency clients should be referred to appropriate agencies.</p> <p><u>Administrative Discharge:</u> Discharge clients who engage in behavior that abuses the safety or violates the confidentiality of others. Prior to discharging a client for this reason, agency</p>	<p>Discharge summary and other records send with the patient</p> <p>Document attempts made</p>
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<p>leadership according to that agency’s policies must review the case. Provide clients discharged for administrative reasons written notification of and reason for the discharge and notify of possible alternative resources. A certified letter* that notes the reason for discharge and includes alternative resources must be mailed to the client’s last known mailing address within five business days after the date of discharge, and a copy must be filed in the client’s chart.</p> <p><i>*Exception: If the client has noted during the intake or at any other time to the subrecipient staff that sending mail is not permitted, no letter will be sent. If this is the case, case managers will document this in progress notes and discharge summary.</i></p>	
<p>Case Closure</p>	
<p>2.8) Case will be closed if client:</p> <ul style="list-style-type: none"> a) Obtains other resources for medication treatment; b) No longer meets eligibility criteria; c) Decides to transfer to another agency; d) Needs are more appropriately addressed in other programs; e) Moves out of state; f) Fails to provide updated documentation of eligibility status thus, no longer eligible for services; g) Fails to maintain contact with the ADAP staff for a period of three months despite three (3) documented attempts to contact client; h) Can no longer be located; i) Withdraws from or refuses funded services, reports that services are no longer needed, or no longer participates in the individual service plan; j) Exhibits pattern of abuse as defined by agency’s policy. 	<p>2.8) Documentation of case closure in patient’s record with clear rationale for closure.</p>

<p>k) Becomes housed in an “institutional” program anticipated to last for a minimum of 30 days, such as a nursing home, prison or inpatient program; or</p> <p>l) Is deceased.</p>	
<u>3.0 Client Rights and Responsibilities</u>	
Standard	Measure
<p>3.1) Services are available and accessible to any individual who meets program eligibility requirements.</p> <p>Each provider shall assist clients with conducting Ryan White Part B eligibility, regardless of whether they receive other Part B services at your agency.</p> <p>All providers shall comply with all applicable federal, state, and local anti-discrimination laws and regulations, including but not limited to the Americans with Disabilities Act. All providers shall adopt a non-discrimination policy prohibiting the refusal of rendering any service on the basis of fact or perception of race, color, creed, religion, national origin, ancestry, age, sex, sexual orientation, gender identity, domestic partner status, marital status, height, weight, disability, or HIV/AIDS diagnosis.</p> <p>Each provider shall make available to clients a process for requesting interpretation services, including American Sign Language.</p>	<p>3.1) Written eligibility requirements and non-discrimination policy on file.</p>
<p>3.2) Each agency should have a Client’s Rights and Responsibilities policy, which requires each client to sign & date a form indicating they have been offered:</p> <p>a) explanation of the policy, and</p> <p>b) copy of <i>Client’s Rights and Responsibilities</i> and to communicate client’s understanding of the policy.</p>	<p>3.2) Written policy on file.</p>

<p>3.3) Provide explanation of <i>Client's Rights and Responsibilities</i> to each client.</p> <p>Client rights include:</p> <ul style="list-style-type: none"> • Be treated with respect, dignity, consideration, and compassion; • Receive services free of discrimination; • Be informed about services and options available. • Participate in creating a plan of services; • Reach an agreement about the frequency of contact the client will have either in person or over the phone. • File a grievance about services received or denied; • Not be subjected to physical, sexual, verbal and/or emotional abuse or threats; • Voluntary withdraw from the program; • Have all records be treated confidentially; <p>Have information released only when:</p> <ul style="list-style-type: none"> • A written release of information is signed; • A medical emergency exists; • There is an immediate danger to the client or others; • There is possible child or elder abuse; or • Ordered by a court of law. <p>Client responsibilities include:</p> <ul style="list-style-type: none"> • Treat other clients and staff with respect and courtesy; • Protect the confidentiality of other clients; • Participate in creating a plan of service; • Let the agency know any concerns or changes in needs; • Make and keep appointments, or when possible, phone to cancel or change an appointment time; • Stay in contact with the agency by informing the agency of change in address and phone number; respond to phone calls and mail and 	<p>3.3) Current <i>Client's Rights and Responsibilities</i> form signed and dated by client and located in client's record. If client unable to sign, progress note should include documentation the client has received a copy of the rights and responsibilities.</p>
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<ul style="list-style-type: none"> Avoid subjecting the agency’s staff to physical, sexual, verbal and/or emotional abuse or threats. 	
<u>4.0 Grievance Process</u>	
Standard	Measure
<p>4.1) Grievance policy requires each client to sign & date indicating they have been offered:</p> <p style="padding-left: 40px;">a) explanation of the policy, b) copy of <i>Grievance Procedure</i> and c) communication of client’s understanding of the policy.</p> <p>Policy shall describe the process for resolving client grievances, including identification of whom to contact and applicable timelines.</p> <p>Policy shall be available in languages and formats (e.g., for persons with disabilities) appropriate to populations served.</p>	<p>4.1) Written grievance procedure on file, available in languages and formats appropriate to populations served.</p>
<p>4.2) Provide explanation of <i>Grievance Procedure</i> to each client.</p> <p>Clients may file a grievance if denied their request for services, if they have any complaint, or concern about the services received.</p>	<p>4.2) Current <i>Grievance Procedure</i> form signed and dated by client and located in client’s record. If client unable to sign, progress note should include documentation the client has received a copy of the grievance procedure.</p>
<p>4.3) Grievance process shall be fair and expeditious for resolution of client grievances.</p>	<p>4.3) Documentation of client grievances, status, and resolution.</p>
<p>4.4) Review of grievance policy yearly with client signature.</p>	<p>4.4) Current <i>Grievance Procedure</i> form signed and dated by client and located in client’s record. If client unable to sign, progress note should include documentation the client has received a copy of the client’s grievance procedure.</p>
<u>5.0 Personnel Qualifications (including licensure)</u>	
Standard	Measure

5.1) All ADAP personnel will have experience and education commensurate with their duties and tasks.	5.1) Copy of qualifications in employee personnel file.
5.2) Newly employed ADAP personnel, must complete orientation within 2 weeks of hire and the following training within 180 days of hire: <ul style="list-style-type: none"> • HIV 101 • HIV Care Continuum • Affordable Care Act/Insurance Marketplace • Medicare Part D • Cultural competency • Legal ramifications, including confidentiality • HIV Prevention 	5.2) Documentation of training completed in personnel file.

6.0 Cultural and Linguistic Competency

Standard	Measure
6.1) ADAP services are culturally and linguistically competent, client-guided and community based. At a minimum, documentation should include: <ul style="list-style-type: none"> a) Experience with providing services to the diverse ethnic, linguistic, sexual, or cultural populations targeted; b) Capacity of staff, including volunteers and Board, to design, provide and evaluate culturally and linguistically appropriate services; c) List of cultural competency trainings completed by staff 	6.1) Documentation of cultural and linguistic competence as reported in annual Cultural and Linguistic Competency Report.
6.2) Easy-to-understand print and multimedia materials and signage in the languages commonly used by the populations in the service area shall be available.	6.2) Culturally and linguistically appropriate materials and signage accessible.

7.0 Privacy and Confidentiality (including securing records)

Standard	Measure
7.1) Client confidentiality policy exists which include:	7.1) Written client confidentiality policy on file at provider agency.

<p>a) Release of information requirements, and b) Health Insurance Portability and Accountability Act.</p>	
<p>7.2) Client’s consent for release of information is determined.</p>	<p>7.2) Current <i>Release of Information Form</i> signed and dated by client and provider representative and located in client’s record. Each release form indicates who may receive the client’s information and has an expiration of not more than 12 months from date of signature.</p>
<p>7.3) Store each client’s file in a secure location with electronic client records protected from unauthorized use.</p>	<p>7.3) Files stored in locked file or cabinet with access limited to appropriate personnel. Electronic files are secure with password protection and access limited to appropriate personnel.</p>
<p>7.4) Annual submission of <i>Verification of Receipt of Assurance of Key Requirements</i> document by all staff that handle client identifying information.</p>	<p>7.4) Documentation of signed <i>Verification of Receipt of Assurance of Key Requirement</i> forms.</p>

8.0 Quality Management

Standard	Measure
<p>8.1) Measure and report client health outcomes using ADAP measures approved.</p>	<p>8.1) Performance measurement data on the following indicators:</p> <ul style="list-style-type: none"> • ADAP clients receiving medications or medication co-payments and/or deductibles, regardless of age, will have an HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement year. • Percentage of ADAP applications that were approved or denied for new ADAP enrollment within two weeks of ADAP receiving a complete application during the measurement period.

	<ul style="list-style-type: none">• Percentage of people enrolled in RW Part B-funded Program living with HIV and receiving ADAP services, regardless of age, who will have an HIV viral load less than 200 copies/mL at last HIV viral load test during the measurement.
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References

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