

Local AIDS Pharmaceutical Assistance (LPAP) Standards of Care

Definition:

The purpose of a Local AIDS Pharmaceutical Assistance Program (LPAP) is to provide therapeutics to treat HIV/AIDS or to prevent the serious deterioration of health arising from HIV/AIDS in eligible individuals, including measures for prevention and treatment of opportunistic infections. An LPAP is a program to ensure that clients receive medications when other means to procure medications are unavailable or insufficient. As such, LPAPs are meant to serve as an ongoing means of providing medications for a period of time.

Limitations:

Local pharmacy assistance programs are not funded with AIDS Drug Assistance Program (ADAP) earmark funding.

LPAPs are not to take the place of the ADAP program.

LPAPs are not emergency financial assistance for medications

Clients cannot be enrolled in another medication assistance program for the same medication, excluding co-payment discounts.

Funds may not be used to make direct payments of cash/vouchers to a client.

No charges may be imposed on clients with incomes below 100% of the Federal Poverty Level (FPL).

Local AIDS Pharmacy Assistance Program (LPAP) do not dispense medications as:

- A result or component of a primary medical visit
- A single occurrence of short duration (an emergency)
- Vouchers to clients on an emergency basis

(Emergency Financial Aid service category should be used for the above situations)

Services:

The purpose of a Local Pharmaceutical Assistance Program (LPAP) is to provide therapeutics to treat HIV/AIDS or to prevent the serious deterioration of health arising from HIV/AIDS in eligible individuals including measures for prevention and treatment of opportunistic infections. Each LPAP is required to establish a LPAP Board that will develop a formulary that meets the needs of the jurisdiction. There is no definitive list of medications that are to be included or excluded from a formulary as each jurisdiction needs to determine what these are based on client need. Each LPAP Board must have a process in place to add or delete medications in a timely manner as the need changes.

Local AIDS Pharmaceutical Programs provide:

- HIV medications that are not included in the ADAP formulary
- Medications when the ADAP financial eligibility is restrictive
- Medications if there is a protracted State ADAP eligibility process (such as a wait list) and/or other means of accessing medications are not available (i.e., pharmaceutical company assistance programs)

Purchase of pharmaceuticals must be directly linked to the management of HIV disease that is:

- Consistent with the most current HIV/AIDS Treatment Guidelines
- Coordinated with the State's Part B AIDS Drug Assistance Program (ADAP)
- Implemented in accordance with requirements of the 340B Drug Pricing Vendor Program and/or Alternative Methods Project

~~LPAP can fund prescribed medications deemed medically necessary by a provider for that are NOT on TMHP formulary TMHP-enrolled patients.~~

LPAP can be used to fund dispensing fees associated with ADAP/LPAP medications.

It is preferable that LPAP medication be purchased at the lowest possible cost, ~~preferably such as~~ 340B Program pricing. Where possible clients need to obtain their medications through a 340B covered entity or pharmacy that is under contract with the 340B Program. Another alternative for purchasing medication is to establish a cost reimbursement system with pharmacies licensed to distribute medications in Texas. Contracts/Memorandums of Understanding (MOU) must be set up to purchase medications at wholesale or another below retail price.

~~Agencies may purchase medication through the HIV/STD Medication Program (Medication Plus Program).~~ All LPAP programs will use available standards of care to inform their services and will operate in accordance with legal and ethical standards. The importance of maintaining confidentiality is critical and all programs must comply with the Health Insurance Portability and Accountability Act (HIPAA) standards for information disclosure.

Over-the-Counter medications to include vitamins may be purchased with LPAP funds if the medication is listed on the LPAP formulary and the provider has deemed that the medication is needed for prevention and treatment of opportunistic infections or to prevent the serious deterioration of health.

Medications not included in the LPAP formulary cannot be purchased. The provider wishing to prescribe a medication not on the formulary shall make a request to the LPAP Board for approval.

Personnel and Facility Standards

Pharmacies and pharmacy staff will adhere to the Texas State Board of Pharmacy rules and regulations.

Facility Standards	Expected Practice
Agencies dispensing medications shall adhere to all local, state and federal regulations and maintain current facility licenses required to operate as a pharmacy in the State of Texas.	Active pharmacy license is on site and is renewed every two years.
If the owner of the pharmacy is not a Texas licensed pharmacist, the owner is consulting with a pharmacist in charge (PIC) or with another licensed pharmacist.	Documentation on file that a licensed pharmacist is consulting with the owner.
Confidentiality statement signed by pharmacy employees.	Signed confidentiality statements of staff on file (HIPPA compliance)
Storage of Medications	Pharmacy shall maintain appropriate, locked storage of medications and supplies (including refrigeration) according to the State Board of Pharmacy regulations.
Client Grievance Policy	Pharmacy or medication or site providing medications will have a policy and procedure in place for clients to voice complaints or grievances with services

Staff Qualification	Expected Practice
Only authorized personnel may dispense/provide prescription medication.	<p>Licensed pharmacists authorized by the Texas State Board of Pharmacy to dispense medications.</p> <p>Pharmacy technicians and other personnel authorized to dispense medications are under the supervision of a licensed pharmacist.</p> <p>A licensed nurse or practitioner designated by the pharmacist-in-charge (PIC) as supportive personnel may provide unit of use packaged medications.</p>

Standards of Care

<p>Implement a Local AIDS Pharmaceutical Assistance Program (LPAP) for the provision of HIV/AIDS medication using a drug distribution system that is consistent with the most current HIV/AIDS Treatment Guidelines</p>	<p>Elements of the Program must include:</p> <ul style="list-style-type: none"> • A client enrollment and eligibility determination process for Ryan White/state services funding that includes screening/applying for ADAP • Additional LPAP eligibility (i.e. financial criteria) if applicable • A LPAP advisory board • Uniform benefits for all enrolled clients throughout the region • Compliance with Ryan White requirement of payer of last resort • A recordkeeping system for distributed medications • A drug distribution system that includes a drug formulary approved by the LPAP Board or a subcommittee of a Planning Council/ADAP Advisory Board <ul style="list-style-type: none"> ◦ All medications have to be FDA approved • A system for drug therapy management
<p>Payer <u>Payer</u> of Last Resort</p>	<p>Clients must have successfully completed ADAP application and requisite re-certifications to be eligible for LPAP. Eligibility for LPAP will be determined by eligibility staff and documentation will be kept on file in the primary client record system.</p> <p>Ryan White Part B funds can be used to supplement approved state-operated pharmaceutical payment programs, like Medication Plus Program, only if adhering to the state AIDS Pharmaceutical Assistance (APA) <u>ADAP</u> co-pay sliding scale guidelines.</p> <p>Before assistance is provided there should be written documentation in the client's file that Ryan White funding is being used as the payer <u>payer</u> of last resort.</p> <p>As such, P programs providing LPAP medications must develop procedures to pursue all feasible alternative revenues systems (e.g., pharmaceutical</p>

	<p>company patient assistance programs) before requesting reimbursement through LPAP.</p> <p>Documentation should include attempts made to access client assistance programs with pharmaceutical companies, private or public insurance programs the client may have and other community resources.</p>
Medication Deductibles and/or Co-payments	<p>Providers may use funding to assist eligible clients with purchasing medications that are over the Medicaid monthly allotment or that the TMHP program does not cover. Clients who are having trouble paying medication deductibles or co-payments should be referred to the Medication Reimbursement Initiative. (This program pays the medication deductibles and co-payments for approved applicants, who then receive medications at home from a mail order pharmacy.)</p> <p>Agencies may charge clients <u>with a FPL above 100%</u> co-payment for medication based on an established sliding fee scale.</p>
Timeliness of Service	<p>Agencies will develop policies/procedures to:</p> <ul style="list-style-type: none"> -Provide access to its system of drug reimbursement for clients with HIV/AIDS through Memorandums of Understanding (MOUs) or Memorandums of Agreement (MOAs) with local pharmacies -Implement a system for clients to access prescriptions twenty-four (24) hours/day <u>if feasible</u> -Provide mechanisms for urgent and/or emergency care. -Determine amount of time between ordering of the medication by the provider and prescription availability to the client.
Purchasing Medications during ADAP application period	<p>No more than a 30-day supply of medication on the ADAP formulary can be purchased at a time for each client. If more than 30 days is needed, the medication can be refilled for another 30 days.</p> <p>If the ADAP denied the client coverage, the client's case manager should work with the client and the client's attending physician to find alternate funding sources which may include: manufacturers compassionate programs, religious groups, or other community resources prior to</p>

	using LPAP.
Over the Counter (OTC) medications	<p>LPAP can pay for over-the-counter medications if the provider has deemed that the medication is needed for prevention and treatment of opportunistic infections or to prevent the serious deterioration of health <u>and the medication is on the formulary.</u></p> <ul style="list-style-type: none"> • Provider must issue a prescription for the over-the-counter medication or a signed document approving use by the patient.
Cost efficient form of medication	Prescriptions filled are the most cost-efficient medications provided by the dispensing pharmacy as evidenced by receipts.
Dispensing Fee	Agency may reimburse the pharmacy a minimal dispensing fee per prescription as outlined in the MOU.
Record Keeping	Agency shall provide and maintain accurate program record keeping, including medication inventory control.
Documentation	<p>Eligibility determination will be kept on file in the primary client record system.</p> <p>Copies of receipt(s) for payment will be kept on file.</p>

References

HRSA/HAB Division of Service Systems Program Monitoring Standards – Part A April, 2011, page 6-7.

HRSA/HAB Division of State HIV/AIDS Programs National Monitoring Standards – Program Part B April, 2013, page 6-7.

HRSA HAB Local Pharmaceutical Assistance Programs(LPAPs): Update and clarifications. December 2013.

HRSA HAB Local Pharmaceutical Assistance Program(LPAP) FAQs · LPAP Policy Clarification Memo (8/29/13)

Texas Administrative Code: TAC 22, Chapter 15, 291.6

Texas Department of State Health Services HIV/STD Program Policies. Payor of Last Resort (Policy 590.001). Located at <http://www.dshs.state.tx.us/hivstd/policy/policies.shtm>

Texas Department of State Health Services HIV/STD Program Policies Purchasing Emergency Medications for Clients Awaiting an Eligibility Decision from the Texas HIV Medication (Policy 220.100). Located at <http://www.dshs.state.tx.us/hivstd/policy/policies.shtm>

Texas Department of State Health Services HIV/STD Program Policies Purchasing Prescription or Over-The-Counter Medications and Vitamins not Covered by a Third-Party Payor. (Policy 220.101). Located at <http://www.dshs.state.tx.us/hivstd/policy/policies.shtm>

Texas Department of State Health Services HIV/STD Program Policies HIV/STD Medication Program Pharmacy Eligibility Criteria. (Policy 700.003) Located at <http://www.dshs.state.tx.us/hivstd/policy/policies.shtm>