

Local AIDS Pharmaceutical Assistance (LPAP) Service Standard

HRSA Definition: LPAP is operated by a RWHAP Part B recipient or subrecipient as a supplemental means of providing medication assistance when an ADAP has a restricted formulary, waiting list, and/or restricted financial eligibility criteria.

Limitations: State AIDS Drug Assistance Program (ADAP) funds may not be used for LPAP support. LPAP funds are not emergency financial assistance for medications.

- Local pharmacy assistance programs are not funded with ADAP earmark funding.
- LPAPs are not to take the place of the ADAP program.
- 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 Programs (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 Assistance service category funds should be used for the above situations)

Services: RWHAP recipients using the LPAP service category must establish the following:

- Uniform benefits for all enrolled clients throughout the service area;
- A recordkeeping system for distributed medications;
- An LPAP advisory board;
- A drug formulary approved by the local advisory committee/board;
- A drug distribution system;
- A client enrollment and eligibility determination process that includes screening for ADAP and LPAP eligibility with rescreening at a minimum of every six months;
- Coordination with the State's RWHAP Part B ADAP (a statement of need should specify restrictions of the state ADAP and the need for the LPAP); and
- Implementation in accordance with requirements of the 340B Drug Pricing Program and the Prime Vendor Program.

Program Guidance: 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. Only RWHAP Part B Base award or Part A grant funds may be used to support an LPAP. ADAP funds may not be used for LPAP support. LPAP funds are not to be used for Emergency Financial Assistance. Emergency Financial Assistance may assist with medications not covered by the LPAP.

Statement of Need: The Texas ADAP (TX ADAP) has a limited formulary and currently limits income eligibility to 200%¹ of the Federal Poverty Limit (FPL), with a spend-down adjustment to account for the cost of HIV medications. Providers must first use patient and/or pharmaceutical assistance programs (PAP) prior to the use of LPAP. However, these programs may not fully meet the needs of clients with HIV-related medication needs because the full spectrum of HIV and HIV-related medications that may be prescribed to improve health outcomes may not be affordable or available via a PAP. The LPAP is needed to assist clients that have incomes above 200% of FPL, after spend down adjustment. LPAP is further needed to assist clients requiring long-term HIV and HIV-related medications that cannot be obtained through the TX ADAP program or PAPs.

The TX ADAP must be accessed by eligible clients prior to using the LPAP.

- The LPAP may not duplicate services available through the TX ADAP program.
- Clients needing long-term assistance with prescription medications shall be assisted with completing a TX ADAP application and, when applicable, PAP applications.
- If the medication is not on the TX ADAP formulary and is not available through assistance programs, the client may be served with LPAP funds if the medication is on the LPAP formulary.
- If short-term medication assistance is required and a client is eligible, this need may be met with Emergency Financial Assistance funds.
- Clients with insurance and other third-party payer sources are not eligible for LPAP assistance unless there is documentation on file that the medication is not covered by their prescription benefits.

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 Texas HIV Medication Program (THMP) of which the TX ADAP is part of; and/or
- Implemented in accordance with requirements of the 340B Drug Pricing Program and the Prime Vendor Program².

LPAP shall, to the extent allocations permit, provide eligible clients with medications on the local area's LPAP formulary that have been prescribed by a qualified, prescribing medical provider. Patients denied enrollment into the THMP may access medications on the ADAP formulary via LPAP only if other payer sources have been exhausted and the medication is on the local area's LPAP formulary.

¹ In the event that TX ADAP income eligibility changes, this policy will comply with the revised TX ADAP income eligibility/percentage of FPL.

² For a list of 340B eligible entity types see: <https://www.hrsa.gov/opa/eligibilityandregistration/index.html>. Ryan White HIV/AIDS Program Recipients and Subrecipients are eligible entities.

LPAP medications must be purchased at the lowest possible cost, such as 340B Program pricing. Clients must obtain their medications through a 340B covered entity or pharmacy OR a comparable medication discount program. Contracts/Memorandums of Understanding (MOU) must be set up to purchase medications at wholesale or another below retail price.

All LPAP programs will use the statement of need and 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.

Prescribed Over-the-Counter (OTC) medications 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. All OTC medications purchased with LPAP funds must be FDA approved.

Medications not included in the LPAP formulary cannot be purchased. All medications purchased with LPAP funds must be FDA-approved. The provider wishing to prescribe a medication not on the formulary shall make a request to the LPAP Board for approval.

Service Standard and Performance Measure

The following Standards and Performance Measures are guides to improving healthcare outcomes for PLWH throughout the State of Texas within the Ryan White Part B and State Services Program.

| | |
|---|--|
| <p>LPAP Prescriptions: Providers may use funding to assist eligible clients with purchasing medications that are over the Medicaid monthly allotment or that the THMP program does not cover.</p> <p>A copy of the client’s prescription from the prescribing provider is on file with the agency. The prescription must include:</p> <ul style="list-style-type: none"> • Name of the client • Date of Birth • Medication • Dose • Signature of prescribing medical provider | <p>Percentage of client charts that have the documented prescriptions funded through LPAP assistance with: name of client; date of birth; medication; dose; and signature of prescribing medical provider.</p> |
| <p>Timeliness of Service: Agencies must have a system for clients to access prescriptions. Prescriptions should be available and approved for LPAP assistance within two (2) business days.</p> <p>Otherwise eligible clients shall have ongoing access to medications prescribed by a qualified prescribing medical provider through the local area’s LPAP program so long as the medication is on the LPAP formulary and allocations permit.</p> | <p>Percentage of clients accessing services under LPAP have access to their prescribed medication(s) that are not on the State Formulary within two (2) business days of approved LPAP-funding.</p> |
| <p>Prescribed Over the Counter (OTC) medications: LPAP can assist clients with their OTC medications if the provider has prescribed the medication and has</p> | <p>Percentage of client files with prescribed OTC medications paid through LPAP funding have documented evidence from prescribing provider of medical necessity.</p> |

| | |
|--|---|
| <p>deemed the medication is needed for prevention and treatment of opportunistic infections (OI) or to prevent the serious deterioration of the client's health AND the medication is on the LPAP formulary.</p> | |
| <p>Medication Adherence Counseling: Clients are offered counseling on medication adherence when assistance is requested.</p> | <p>Percentage of clients who have documented evidence of adherence counseling offered at the time of assistance request.</p> |
| <p>Viral Suppression: Clients who access HIV medications for long-term assistance (more than 60 days) have documentation in their files of viral suppression.</p> | <p>Percentage of clients accessing HIV medication assistance for long-term (more than 60 days) have documented evidence of viral suppression within the measurement year.</p> |

References

HRSA/HAB Division of Service Systems Program Monitoring Standards – Part A April, 2013, 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. Payer of Last Resort (Policy 590.001). Located at <http://www.dshs.texas.gov/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 Payer. (Policy 220.101). Located at <http://www.dshs.texas.gov/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.texas.gov.tx.us/hivstd/policy/policies.shtm>.

HRSA/HAB Ryan White & Global HIV/AIDS Programs, Program & Grants Management, Policy Notices and Program Letters, Policy Change Notice 16-02, <https://hab.hrsa.gov/program-grants-management/policy-notices-and-program-letters>.

***Sample Letter of Agreement
Local Pharmacy Assistance Program (LPAP)***

The [“Requesting Administrative Agency”] and the [“Administrative Agency with an LPAP”] agree to the following with regard to the implementation of a Local Pharmacy Assistance Program for the [Name of HIV Service Delivery Area(s) (HSDAs)]:

Purpose of Agreement:

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. Texas Department of State Health Services (DSHS) LPAP Standards of Care require an Administrative Agency (AA) allocating funds to the local pharmacy assistance service category in an HSDA under their jurisdiction to, among other requirements, establish a formal LPAP Advisory Board and publish an approved Formulary of medications allowable to be provided through the LPAP.

This agreement stipulates that the [“Requesting Administrative Agency”] shall rely on the already established LPAP Advisory Board and published LPAP formulary of the [“Administrative Agency with an LPAP”] which is supported to function as the LPAP advisory board for the [Name of HSDA(s)].

[“Requesting Administrative Agency”] and the [“Administrative Agency with an LPAP”] agree to the following conditions and stipulations regarding the agreement:

- This agreement is expressly limited to the reliance by [“Requesting Administrative Agency”] on the already established LPAP advisory board and formulary in order for [“Requesting Administrative Agency”] to meet Health Resources Services Administration (HRSA) Ryan White HIV/AIDS Program LPAP requirements;
- [“Administrative Agency with an LPAP”] shall not incur cost or liability with respect to [“Requesting Administrative Agency”] meeting its contractual obligations to DSHS;
- [“Requesting Administrative Agency”] shall not provide funding towards the support of the already established LPAP advisory board;
- [“Administrative Agency with an LPAP”] agrees to share the most current list of medications approved by the LPAP Advisory Board with the [“Requesting Administrative Agency”];
- [“Administrative Agency with an LPAP”] will include [“Requesting Administrative Agency”] to the extent feasible when convening LPAP advisory board meetings. [“Administrative Agency with an LPAP”] will promptly notify [“Requesting Administrative Agency”] of changes made to the formulary by the LPAP advisory board;
- [“Requesting Administrative Agency”] may participate in the [“Administrative Agency with an LPAP”] LPAP advisory board to the extent feasible;

- [“Requesting Administrative Agency”] shall follow the same procedure as other stakeholders with respect to requesting the LPAP advisory board to add medications to the formulary. The decisions of the LPAP advisory board with respect to adding or removing medications from the formulary shall be binding upon [“Requesting Administrative Agency”] except as noted below;
- [“Requesting Administrative Agency”] may, when clinically indicated, supplement the published LPAP formulary by adding otherwise allowable medications to the LPAP formulary for the HSDA(s) administered by [“Requesting Administrative Agency”]. Such additions shall not be binding on the [“Administrative Agency with an LPAP”] LPAP formulary;
- [“Name of Requesting Administrative Agency”] may, when appropriate, further restrict medications on the approved LPAP formulary for the HSDA(s) administered by [“Name of Requesting Administrative Agency”]. Such restrictions shall not be binding on [“Administrative Agency with an LPAP”] LPAP formulary;
- This agreement shall be reviewed annually by all parties and updated as needed;
- Any party to this agreement may terminate the agreement by giving thirty (30) day written notice to the other parties.

Agreed to this date by:

[“Requesting Administrative Agency”]

Name & Title

Date

[“Administrative Agency with an LPAP”]

Name & Title

Date