Ryan White Part A Quality Management

Emergency Financial Assistance-HIV Medications/Prior Authorization (EFA-PA) Service Delivery Model

Palm Beach County

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Palm Beach Care Council LPAP Committee Quality Management Committee

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Statement of Intent

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 to establish a LPAP Board that will develop a formulary that meets the needs of the jurisdiction and 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 and/or other means of accessing medications are not available (i.e., pharmaceutical company assistance programs)

Purchase of pharmaceuticals must be:

□ 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, Prime Vendor Program, and/or Alternative Methods Project

EFA-PA can be used to fund dispensing fees associated with ADAP/LPAP medications. It is required that EFA-PA medication be purchased at the lowest possible cost, preferably 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.

All EFA-PA 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.

The provider wishing to prescribe a medication not on the formulary shall make a request to the Grantee approved LPAP Clinical Review Committee. Approval or denial will be granted within 3 working days.

Service Definition

Emergency Anti Retroviral medications provided to clients on a limited or short-term basis when no other payer sources are available. Medications purchased under this program must be purchased at Public Health Service (PHS) prices or less.

Limitations

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

EFA-PAs 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).

Standards of Care

| Facility Standards | Indicator | Data Source |
|--|--|--|
| 1. 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 Florida. | 1.1 Active pharmacy license is on site. | 1.1 Documentation of licensure |
| 2. Program must have a Florida licensed pharmacist designated as pharmacist in charge. | 2.1 Documentation of Florida licensed pharmacist on file. | 2.1 Documentation of licensure |
| Confidentiality statement signed by pharmacy employees. | 3.1 Signed confidentiality statements of staff on file (HIPAA compliance). | 3.1 Documentation of confidentiality statement |
| 4. Storage of Medications | 4.1 Pharmacy shall maintain appropriate, locked storage of medications and supplies (including refrigeration) according to the State Board of Pharmacy regulations. | 4.1 Documentation of compliance by Pharmacy Supervisor |
| 5. Client Grievance Policy | 5.1 Pharmacy or medication or site providing medications will have a policy and procedure in place for clients to voice complaints or grievances with services. | 5.1 Documentation of policies |

| Staff Standards | Indicator | Data Source |
|---|--|---|
| Only authorized personnel may dispense/provide prescription medication. | 6.1 Licensed pharmacists authorized by Florida State Board of Pharmacy to dispense medications. 6.2 Pharmacy technicians and other personnel authorized to dispense medications are under the supervision of a licensed pharmacist. | 6.1 Documentation of licensure6.2 Documentation of licensure |

| Program Standards | Indicator | Data Source |
|---|---|--|
| 7. EFA-PA is payer of last resort | 7.1 Documentation that client is eligible for Ryan White Part A EFA-PA services (NOE) and that medications are not covered by any insurance client is covered by. 7.2 Written program procedure outlining steps to assure all feasible alternative revenue systems (pharmaceutical company patient assistance programs, PANF, and other funding) are pursued before requesting reimbursement through EFA-PA. 7.3 Documentation of attempts to access medications through other sources maintained in client file. | 7.1 Documentation of eligibility in Grantee database 7.2 Documentation of written procedures 7.3 Documentation in Grantee database |
| 8 Purchasing medications during ADAP application period. | 8.1 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. | 8.1 Documentation of time limits |

| Patient Standards | Indicator | Data Source |
|---|--|--|
| 9 Every prescription is filled correctly. | 9.1 Provider maintains quality assurance logs showing any irregularities, complaints regarding errors, etc. | 9.1 Documentation of logs |
| 10 Every prescription includes proper indications and dosing instructions. | 10.1 Packaging instructions available for review by monitors upon request. | 10.1 Documentation of instructions |
| 11 Patient receives education and counseling including a review of drug interactions specific to antiretroviral therapy and the HIV disease state. | 11.1 Provider procedures provide an outline for reviewing drug interactions and HIV education. | 11.1 Documentation of patient education on medications |

| 12 Patient receives counseling on how his/her medication should be taken and any possible side effects. At least 5 minute initial consultation when dispensing to a patient that is new to antiretroviral therapy. | 12.1 Provider procedures describe guidelines for counseling participants on medications and possible side effects. Providers can demonstrate how counseling is given. | 12.1 Documentation of policies |
|--|--|---|
| 13 New prescriptions and refills are available to participants in a reasonable amount of time. | 13.1 Client files document causes of any delays in the availability of medications and steps taken to reduce delays. | 13.1 Documentation in client file |
| 14 Prescription label directions in Spanish, whenever appropriate. | 14.1 Provider demonstrates labeling in Spanish as requested. | 14.1 Documentation of Spanish language instructions |

*Standards of Care are guidelines or flexible directions to be used in the treatment of HIV/AIDS. Departures from these standards may arise due to a client's unique situation and/or based on an experienced professional's judgment.