Nevada Office of HIV/AIDS
AIDS Drug Assistance Program (ADAP)
Medical Advisory Committee Policy and Procedures

SCOPE OF COVERAGE

These policies and procedures established herein are a part of the State of Nevada, Division of Public and Behavioral Health (DPBH), Office of HIV/AIDS (OHA), Ryan White Part B (RWPB) and the AIDS Drug Assistance Program (ADAP) Policies and Procedures. The HIV/AIDS Medical Advisory Committee (MAC) serves DPBH-OHA in much the same capacity as any Pharmacy and Therapeutics Committee or Formulary Committee in its execution of reviewing new and existing medications. MAC will make recommendations for medications to be included on or deleted from the ADAP formulary based on research, safety and how well the medications work, on which HIV antiretroviral (ARV) medications are the most effective in treatment, selecting the most cost-effective medications in each therapeutic class, and the like.

BACKGROUND

Health Resources Service Administration (HRSA) HIV/AIDS Bureau (HAB) strongly encourages RWPB/ADAP programs to have advisory bodies to provide recommendations on the use of Ryan White funds; on at least an annual basis. Committees focus on areas such as modifications to the ADAP formulary and eligibility criteria, assessments of potential ADAP cost effectiveness strategies, and feedback and guidance on the ADAPs quality management plan(s).

INSTRUCTIONS

A. The ADAP Services

HAB/RWPB Program guidelines are specific in that direct support to clients for medications always takes priority over all other services. It is the responsibility of this Committee, in cooperation with DPBH-OHA ADAP staff, to offer assistance and recommendations pertaining to cost containment measures, policies, procedures, or protocols being considered and/or implemented to meet this mandate in service to ADAP and RWPB eligible clients.

B. The ADAP Formulary and RWPB Eligibility Criteria

The ADAP formulary contains the antiretroviral (ARV) therapeutics and other medications, listed by therapeutic category, to treat HIV/AIDS or prevent the serious deterioration of health arising from HIV/AIDS for ADAP-eligible clients in Nevada.

Nevada's ADAP formulary may be updated by the ADAP Coordinator, or his/her designee, to reflect approved changes and/or updates. In the event of such changes and/or updates, the formulary shall be distributed to MAC members, the ADAP pharmacies, and posted on DPBH-OHA website, http://EndHIVNevada.org. DPBH-OHA RWPB Program staff will maintain records of all formularies, past & present.

At the recommendation of the Committee and upon approval of DPBH-OHA, medication updates and amendments to the formulary shall be made timely and the formulary distributed as listed above.

C. Process for Formulary Recommendations: Additions to and/or Deletions from the Medications/Therapeutics Listed on Nevada's ADAP Formulary

1. Any medication to be considered for either addition to or deletion from the Nevada ADAP formulary must be submitted to NVADAP@health.nv.gov; which will notify the MAC Chair, Co-Chair, and the appropriate DPBH-OHA ADAP staff of the medication to be considered for placement on the ADAP formulary.

2. ADAP staff to initiate the 'Request for Addition/Deletion to the ADAP Formulary' Form, providing the full therapeutic name with the pricing and dosing information.
3. Once the form is completed ADAP staff will logs the information for the next MAC meeting.
4. At the next meeting, the sponsoring Committee member presents the data from the 'Request' form, fielding questions and comments as the Committee considers the medication for recommendation to the formulary
5. Final recommendations of the Committee are submitted by ADAP staff to Division Administration and the State Medical Officer for final approval.
6. Upon the Division Administrator's and the State Medical Officer's approval, the formulary will be updated accordingly and distributed to MAC members and posted on the OHA webpage.

C.1. Antiretroviral (ARV) Medications and the Process for Formulary Recommendation

New HIV/HCV-specific medications, whether in single medication entities or co-formulated medications will be immediately added to the ADAP formulary once ADAP staff has received a notice of FDA approval and NASTAD negotiated ADAP pricing UNLESS:

1. The cost of the medication is +15% that of the most expensive medication in the same medication class
2. A co-formulated medication is +15% that of the most expensive co-formulated combination in the same medication class or is +10% that of the cost of the individual medications combined
3. The cost of the medication for a new medication class is +10% of the most expensive HIV-specific medication on the most up to date ADAP formulary
4. A member of the committee voices concerns related to the side effects of the medication which are significant enough to bring the medication to the Committee.
5. The Chairperson requests the medication be brought to Committee for discussion
6. Request by the Division or ADAP for medication review by the Committee

For any such condition as listed above regarding ARV medications, the MAC shall be convened.

C.2. Non-Antiretroviral Medications and the Process for Formulary Recommendation

The MAC shall be convened to consider and recommend adding drugs that are not HIV-specific, such as those for opportunistic infections or treating side effects.

New formulations are presented for better client treatment or to improve adherence and compliance. If medications on the formulary change for re-formulations such as changing from tablets to capsules or to generic formulations, these may be added to the formulary provided the drug is cost-neutral. Cost-neutral is defined as a maximum of 10% cost increase incurred in replacing one drug for another on the formulary or adding the generic formulation. The Committee Chairperson will complete, sign, and submit to the ADAP Coordinator a 'Request for Addition/Deletion to the ADAP Formulary' form for each. The formulary will then be updated and distributed as outlined above.

Any medication outside the cost-neutral parameters will be reviewed by the Committee on a case-by-case basis at a regularly scheduled or special meeting of the Committee.

D. Interim Care for Early Access Program (EAP) Patients

ADAP clients, who are on an Early Access Program (EAP) for ARVs with any pharmaceutical company, must have no interruption in patient care. Once the FDA approval is announced for the ARV, there is a 30-day window of continued coverage by the pharmaceutical company for EAP patients on the medication.

However, even with the procedure regarding HIV-specific drugs being added to the formulary in the most expeditious manner possible, that 30-day window could close before the medication is added to the formulary.

To maintain the patient's care, ADAP pharmacies will continue to dispense the medication to EAP Patients only until the formulary is updated.

E. Cost Containment Measures

E.1. ADAP Wait List

Policies and procedures are in place per HRSA requirements (see page 42 of the ADAP Manual). If a waiting list became necessary for Nevada ADAP, all Core and Supportive services will be curtailed except drugs and medical case management; the co-pay reimbursements come under the drug costs and would be continued.

If a waiting list was imminent or required, the Committee will call a meeting to discuss options at that point in time for removing any specific medication or group of medications as a cost-saving measure.

E.2. Alternate ADAP Formulary Plan, a 3-Tier System

The Committee has developed a 3-Tier System for organizing medications on the formulary for possible use in times of fiscal need:

- Tier 1 are HIV specific;
- Tier 2 as standard of care and for treating side effects to those in Tier 1; and
- Tier 3 for helping the patients in other areas.

In times of fiscal need, the tiered system could provide an alternate structure for the possible need to trim certain medications from the formulary, starting from Tier 3, working up through the tiers. Medications removed from the formulary could be replaced as funding is restored to sufficient levels.

The implementation of the tiered system has been tabled as it is believed the drugs that might be removed with the tiered system would have only a modest fiscal impact. The current formulary is structured in such a way as to obtain the same cost-saving results.