

Nevada Office of HIV/AIDS Nevada Ryan White Part B Program HIV/AIDS Medical Advisory Committee

DATE

10/5/2017~~12/2/2016~~10/11/2016

PURPOSE OF UPDATE

Purpose

BACKGROUND

The Nevada Ryan White Part B Program uses an advisory body to guide decision making and to provide a connection to the community serving PLWHA.

The HIV/AIDS MAC works in an advisory capacity to maintain the formulary with the most successful medication regimes, the Nevada Division of Public and Behavioral Health (DPBH) which maintains the federal HRSA grant has final responsibility and authority of formulary management.

The MAC shall be convened: to consider and recommend drugs that are not HIV-specific, such as those for opportunistic infections; at their Chairperson's request; and/or at the request of the DPBH or the RWPB Program.

Per federal guidelines, no medications are added to the Nevada ADAP Formulary without Federal Drug Administration (FDA) approval and the price is negotiated and approved on a national level by NASTAD. Experimental drug therapies are not available through ADAP.

The Nevada Division of Public and Behavioral Health reserves the right to conduct a cost analysis before expanding the formulary to avoid a budget shortfall for HIV/AIDS medications and a possible waiting list for clients.

Should an ADAP budget short fall exist due to rising costs or increased client participation, the MAC will be required to review the formulary and recommend cost containment strategies (such as eliminating non-HIV/AIDS medications, or limiting HIV/AIDS medications, etc.) to avoid a waiting list.

NEVADA OHPC RESPONSIBILITY

[Text]

CLIENT RESPONSIBILITY

It is the responsibility of the client to provide the eligibility provider the requested government issued documentation that has the client's legal name affixed to it.

HIV/AIDS MEDICAL ADVISORY COMMITTEE BYLAWS

Section I – Name

The name of this body shall be the HIV/AIDS Medical Advisory Committee.

Section II – Authority

The HIV/AIDS Medical Advisory Committee (Committee) is an appointive committee under the auspices of the Division of Public and Behavioral Health (Division) through the Ryan White HIV/AIDS Part B (RWPB) Program and the Bureau of Child, Family and Community Wellness (BCFCW). The duty of the Committee is to evaluate benefits and costs associated with HIV/AIDS drugs and other medications needed to treat HIV and related conditions, and their additions to/deletions from the AIDS Drug Assistance Program (ADAP) formulary. Recommendations of the Committee are reported to and submitted by the RWPB Program, routed through the BCFCW, for approval by the Division. The Division Administrator, in cooperation with the Chief Medical Officer, has final approval of any recommendations or actions of the Committee.

Section III – Mission

The mission of the Committee is to assist the ADAP by providing an important link in an overall continuum of care for people in Nevada with HIV by recommending which antiretroviral and other medications are needed to treat HIV and related conditions for patients covered by ADAP.

Section IV – Members

- A. A minimum of twelve (12) voting members will be selected by agencies or practices within a respective identified group from medical professionals involved in HIV treatment and care, working with and knowledgeable about antiretroviral medications and ADAP, approved by a vote of the Committee, including:
 - 1. Physicians, nurses, and physician’s assistants from the University Medical Center of Southern Nevada (UMC) Wellness Center, Northern Nevada HIV Outpatient Program Education Services (HOPES), and from the community at large; and
 - 2. Pharmacists from designated ADAP pharmacies.
- B. Ex-Officio members include Nevada Department of Corrections staff, both administrative and medical personnel involved with the care and treatment of inmates who are HIV+, RWPB Program/ADAP staff and other Division staff.
- C. Voting members from the above identified groups shall consist of the following:
 - 1. Any two physicians from the UMC Medical Center (Wellness Center);
 - 2. Any two physicians from Northern Nevada HOPES;
 - 3. A minimum of one physician from the southern communities and a minimum of one physician from the northern and rural communities;
 - 4. One nurse or physician’s assistant from the UMC Wellness Center;

5. One nurse or physician's assistant from Northern Nevada HOPES;
 6. A minimum of one nurse or physician's assistant from the southern communities and a minimum of one from the northern and rural communities; and
 7. One pharmacist from each designated ADAP Pharmacy.
- D. Nominations for Committee membership will be forwarded to the Chairperson with a completed Member Nomination Form; the Chairperson will confirm the nominee's intent, then, submit the completed form and notes to the RWPB Manager. The nominations will be included on the agenda for the next MAC meeting.

The Committee Chairperson and Vice-Chairperson will have the authority to contact agencies or medical practices in the communities regarding representation on the Committee, where these are directly involved in the care and treatment of HIV+ patients, both currently and potentially RWPB eligible. Any such contact and results will be reported on a completed Member Nomination Form, and then emailed to the RWPB Manager.

Section V – Alternate Member

Should a member be unable to attend a meeting, he/she may designate an alternate to serve in his/her absence. The alternate shall have all the rights and privileges of the member while acting on his/her behalf. The member will designate the alternate, in writing, prior to, or at the time of the meeting.

Section VI – Officers

Composition: The Committee shall have a Chairperson and a Vice-Chairperson.

Duties of Officers:

- A. Chairperson: The Chairperson shall direct the meeting and report the activities of and recommendations of the Committee to the Division. The Chairperson shall have powers and duties as the Division may assign. In the event of a tie vote, the Chairperson or Acting-Chairperson shall cast the deciding vote.
- B. Vice-Chairperson: The Vice-Chairperson shall act for, and on behalf of the, Chairperson in all cases of his/her absences and shall perform other duties as assigned by the Committee.
- C. Chairperson and Vice-Chairperson shall be elected by vote of the members, and serve a six-year term or until they resign their duties, whichever comes first.
- D. The officer may, at his/her discretion, nominate themselves for additional terms of office.
- E. Officers must maintain his/per practice in HIV care and treatment to include working with and being knowledgeable about antiretroviral medications and ADAP and the RWPB Program in order to continue membership and his/her office.
- F. Within two months of the officer's termination date, nominations for new officers shall be presented to the RWPB Manager and the ADAP/RWPB Eligibility Coordinator who will confirm the nominations to be presented for vote at the next MAC meeting.

Section VII – Terms of Appointment

Committee members shall serve a five-year term which shall renew for additional five-year terms at the pleasure of the member, provided their practice continues to be in HIV care and treatment, and their membership is confirmed by a vote of the Committee. In the event a member vacated a position in one identified group, he/she may continue membership on the Committee if his/her practice continues to be in HIV care and treatment and if his/her new position is in one of the identified groups; this continued membership must be confirmed by a vote of the Committee.

Section VIII – Voting

Each member of the Committee identified in Section IV shall be entitled to one vote on all business requiring action by the Committee.

Section IX – Meetings

Meetings of the Committee will be held a minimum of twice per year, at the request of the Division, or as the Chairperson determines the need for specific action of the Committee. Meetings will be conducted in any of three manners:

- A. By videoconference with Las Vegas and Carson City at conferencing sites pre-selected as available.
- B. by telephone conference calling, provided that at least one location in Las Vegas, Reno and Carson City, has sufficient room for attendance by the general public, or
- C. By face-to-face meeting if the Chairperson and membership feel it will better accomplish the goals and responsibilities of the Committee.

Section X – Quorum

A simple majority vote of the total members identified in Section IV, Part C shall suffice for passage of business items requiring a vote.

Section XI – Notices

Meetings shall be conducted in accordance with NRS 241, “Nevada’s Open Meeting Law,” and conducted following a published agenda. Agendas will be mailed to members and pharmaceutical representatives approximately 14 days prior to the scheduled meeting date. Notice of meetings will be posted in accordance with NRS 241 at designated locations and on the Division website.

Section XII – Special Meetings

The Chairperson, or a majority of the voting body, may request and hold special meetings when the need is determined.

Section XIII – Service Area

The Committee is a body of agencies and medical professionals addressing the needs of persons living with HIV in Nevada.

Section XIV – Bylaw Amendments

These bylaws may be amended by majority vote of the members of the Committee, when it serves the purposes of the Committee.

Section XV – Policies and Procedures

- A. These By-Laws and the policies and procedures established herein are a part of the RWPB Program and ADAP Policies and Procedures within the BCFCW. The HIV/AIDS Medical Advisory Committee serves the Division and the RWPB Program in much the same capacity as any Pharmacy and Therapeutics Committee or Formulary Committee in its execution of reviewing new and existing medications, making recommendations for medications to be included on or deleted from the ADAP formulary, based on research, on safety and how well the drugs work, on which HIV antiretroviral (ARV) drugs are the most effective in treatment, selecting the most cost-effective drugs in each therapeutic class, and the like.
- B. The ADAP Services: The RWPB Program guidelines are specific in that direct support to clients for drugs always takes priority over all other services. It is the responsibility of this Committee, in cooperation with RWPB 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 the ADAP and RWPB eligible clients.
- C. The ADAP Formulary and RWPB Eligibility Criteria: The ADAP formulary contains the antiretroviral (ARV) therapeutics and other medications, listed by therapeutic category, authorized by the State for use by medical practitioners to treat HIV/AIDS or prevent the serious deterioration of health arising from HIV/AIDS, including measures for the prevention and treatment of opportunistic infections in the care and treatment of HIV disease for RWPB eligible clients in Nevada.

Nevada’s ADAP formulary also lists the RWPB eligibility criteria. As such, the formulary may be updated by the RWPB Eligibility Coordinator, or his/her designee, to reflect these changes. In the event of such changes and/or updates, the formulary shall be distributed to MAC members, the ADAP pharmacies, and posted on the Division website in the HIV/AIDS Section webpage. RWPB Program staff will maintain records of all formularies, past & present.

At the recommendation of the Committee and upon approval of the Division, medication updates and amendments to the formulary shall be made immediately and the formulary distributed as listed above.

- D. 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 ADAP formulary must be submitted to the Committee Chairperson who notifies the RWPB Manager and the appropriate ADAP staff of the medication to be considered, identifying the therapeutic classification for placement on the ADAP formulary

2. The RWPB Manager forwards this to Program staff to initiate the 'Request for Addition/Deletion to the ADAP Formulary' Form, providing the full therapeutic name with the pricing and dosing information on the form
3. The secretary logs the information for the next MAC meeting, then forwards the form via email to the sponsoring Committee member and the Chairperson
4. The sponsoring Committee member completes the rest of the 'Request' form, returning it to the Secretary to be included in the meeting packet for the next Committee meeting
 5. 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
6. Final recommendations of the Committee are submitted by RWPB staff within two business days of the meeting via email to Division Administration and the State Medical Officer for final approval; the email will include the recommendation of the Committee; with a cc to the Section Manager, the RWPB Eligibility Coordinator, the Bureau Office Manager, and the Bureau Chief. The email will attach a copy of the formulary listing the approved medications in their respective therapeutic classification and the completed 'Request' form for each medication noted in the Committee's recommendation.
7. Upon receipt of a return email granting the Administrator's approval, the formulary will be updated accordingly and distributed to MAC members, the ADAP pharmacies, and posted on the Division website in the HIV/AIDS Section webpage.

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

New HIV-specific medications, whether in single medication entities or co-formulated medications will be immediately added to the ADAP formulary once RWPB staff has received a 'Request for Addition/Deletion to the ADAP Formulary' Form from the Committee Chair, notice of FDA approval, NASTAD negotiated ADAP pricing, and approval from the Division Administration via email 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.

The Chairperson requests the medication be brought to Committee for discussion Request by the Division or the RWBP Program for medication review by the Committee

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

[DRAFT 15-26 HIV/AIDS Medical Advisory Committee Current](#)~~15-26 HIV/AIDS Medical Advisory Committee~~

F. 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. In the event that 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 RWPB Manager 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.

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

RWPB 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. In order to maintain the patient's care, ADAP pharmacies can dispense the medication using the Public Health Service (PHS) 340B Drug Pricing Program pricing prior to NASTAD having announced the negotiated price. The pharmacy would be able to bill the pharmaceutical company to recover the costs where the PHS pricing was higher than that negotiated with them by NASTAD.

H. Cost Containment Measures

1. ADAP Wait List

Policies and procedures are in place per HRSA requirements. If a waiting list became necessary for Nevada, all 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 could 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.

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 dropped off the formulary could be replaced as the funding allowed.

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.

The Committee would address any medications being considered for removal on a case-by-case basis. If a wait list were imminent or required, the Committee shall convene to discuss options and make recommendations for removing any specific medication or group of medications as a cost-saving measure.

I. Committee Representation

MAC assists the RWPB Program by having its members serve on a number of workgroups such as for the HRSA-required bi-annual Statewide Coordinated Statement of Need and Comprehensive Care Plan; the Quality Improvement and Management; the ADAP Wait List Protocols and Procedures; etc. where their expertise and perspective can significantly benefit and serve the RWPB eligible clients.

J. Sub-Committees of MAC

Any MAC sub-committee must be held to the same regulations and procedures as for any other Meeting to be held under Nevada's Open Meeting Law.

Approved as Revised: 07/29/2013

HIV/AIDS MEDICAL ADVISORY COMMITTEE – VOTING MEMBERS

Name	Credentials	Affiliation	Appointment Dates
Cade, Jerry L.	Medical Doctor (MD)	UMC Wellness Center, Physician	06/07/01 – 06/06/16
Eaton, Pamela	Registered Pharmacist (RPh)	Northern Nevada HOPES, Pharmacy	01/08/13 – 10/07/18
Farabi, Alireza	Medical Doctor (MD)	UMC Wellness Center Physician	07/29/13 – 07/28/18
Fuller, Dennis K.	PharmD, AAHIVP	Pharmacy Services	06/07/01 – 06/06/19
Gonzales, Dino J.	Medical Doctor, AAHIVS	Community Physician, Southern Nevada	08/22/07 – 08/21/17
Koceja, Vicki A.	RN-BC, OCN, MBA, FAAMA, PhD	UMC Wellness Center Nurse or PA	07/29/13 – 07/28/18
Krasner, Charles G.	Medical Doctor	Northern Nevada HOPES, Physician	10/13/10 – 10/12/15
Larson, Trudy A.	Medical Doctor	Northern Nevada HOPES, Physician	06/07/01 – 06/06/16
Parker, Steven W.	Medical Doctor	Community Physician, Northern/Rural NV	06/07/01 – 06/06/16
Soto, Anthony M.	BPharm	UMC ADAP Pharmacist	06/27/07 – 06/25/17
Spadone, Ivy	MS, PA-C	Northern Nevada HOPES, Nurse or PA	10/13/10 – 10/12/15
Staples, Mary	PharmD	UMC ADAP Pharmacist	02/13/12 – 02/12/15
Zell, Steven C.	MD, AAHIVS	Community Physician, Northern/Rural NV	06/07/01 – 06/06/16
		Nurse or PA from Southern Nevada	
		Nurse or PA from Northern/Rural NV	

1.

- E. *Ex-Officio members include Nevada Department of Corrections staff, both administrative and medical personnel involved with the care and treatment of inmates who are HIV+, RWPB Program/ADAP staff and other Division staff.*
- F. *Voting members from the above identified groups shall consist of the following:*
1. *Any two physicians from the UMC Medical Center (Wellness Center);*
 2. *Any two physicians from Northern Nevada HOPES;*
 3. *A minimum of one physician from the southern communities and a minimum of one physician from the northern and rural communities;*
 4. *One nurse or physician's assistant from the UMC Wellness Center;*
 5. *One nurse or physician's assistant from Northern Nevada HOPES;*
 6. *A minimum of one nurse or physician's assistant from the southern communities and a minimum of one from the northern and rural communities; and*
 7. *One pharmacist from each designated ADAP Pharmacy.*