

**HIV/AIDS MEDICAL ADVISORY COMMITTEE
MINUTES
January 12, 2012
12:00 P.M.**

MEETING LOCATIONS

Nevada State Health Division

4150 Technology Way
Conference Room #301
Carson City, NV 89706
775-684-4285

Teleconference

Toll Free: 1-888-363-4735
Conference Code: 6540475

University Medical Center of Southern Nevada (UMC) - Wellness Center

Offices of Nevada AIDS Research and Education Society (NARES)
701 Shadow Lane, Suite 200
Las Vegas, NV 89106
702-383-2691 or 702-384-9101

CALL IN NUMBER: Toll Free: 1-888-363-4735 Conference Code: 6540475

NOTE: SOME COMMITTEE MEMBERS MAY ATTEND FROM ANY OF THE THREE LOCATIONS OR
FROM OTHER SITES VIA TELECONFERENCE

AGENDA ITEMS MAY BE TAKEN OUT OF ORDER, COMBINED FOR CONSIDERATION, AND/OR
REMOVED FROM THE AGENDA AT THE CHAIRPERSON'S DISCRETION

COMMITTEE MEMBERS PRESENT:

Dennis Fuller, PharmD, Committee Chair, HIV/AIDS Clinical Pharmacy Specialist, University Medical Center of Southern Nevada (UMC) Wellness Center and Nevada AIDS Research and Education Society (NARES)
Sue Trimmer, RPh, Committee Vice-Chair, Chief Pharmacist, Northern Nevada HIV Outpatient Program, Education and Services (HOPES)
Anthony Soto, BPharm, UMC Pharmacy
Charles Krasner, MD, HOPES
Dino Gonzales, MD, UMC Wellness Center
Ivy Spadone, PA-C, HOPES
Leslie Kellum-O'Brien, RN, Clinical Office Manager, UMC Wellness Center
Steven Zell, MD, HOPES
Steven Parker, MD, Sierra Infectious Disease Specialists
Trudy Larson, MD, University of Nevada-Reno (UNR), School of Medicine and HOPES

COMMITTEE MEMBERS NOT PRESENT:

Diana Bond, RPh, Director, UMC
Jerry Cade, MD, UMC and Southwest Medical Associates, Inc (SMA)

HEALTH DIVISION STAFF PRESENT:

Dan J. Olsen, MPH, Section Manager of Nevada Office of HIV/AIDS, Program Manager, Ryan White CARE Act Part B Program (RWPB), Bureau of Child, Family and Community Wellness (BCFCW)
Martha Fricano, AIDS Drug Assistance Program (ADAP) Coordinator, RWPB, BCFCW
Steve Dion, Data Management Coordinator, RWPB, BCFCW

Rob Langguth, Management Analyst, Quality Management Coordinator, RWPB, BCFCW
Rebecca Huddleston, Administrative Assistant, Recording Secretary, RWPB, BCFCW

OTHERS PRESENT:

Deborah Wafer, Gilead Sciences Pharmaceuticals
Kevin Miyasato, Assistant Executive Director, Community Counseling Center (CCC)
Leah Thompson-Mewes, Director of Quality Management and Resources, HOPES
Mike Gilbert, District Business Manager, Bristol-Meyers Squibb Pharmaceuticals

1. Roll Call, Welcome and Introductions

Dr. Dennis Fuller called to order the HIV/AIDS Medical Advisory Committee (MAC) meeting at **12:04 PM**, held via teleconference from Nevada State Health Division (NSHD) in Carson City and from the University Medical Center of Southern Nevada (UMC) Wellness Center, Nevada AIDS Research and Education Society (NARES) Office in Las Vegas. This was a public meeting where the public was invited to make comments. In accordance with the Nevada Open Meeting Law (OML), this meeting's agenda was posted at the following locations: NSHD, Elko County Library, Northern Nevada HOPES, UMC Wellness Center, Nevada State Library and Archives, and on the NSHD website at <http://health.nv.gov>.

2. Approval of September 22, 2011 Minutes

Dr. Fuller asked for any discussion on the minutes for approval from the previous meeting held on September 22, 2011. Dr. Fuller and Sue Trimmer noted one correction to Agenda Item 4 regarding the name of one medication listed there. No public comment.

MOTION: Sue Trimmer moved to accept the minutes as presented with the one correction.
SECOND: Leslie Kellum O'Brien
PASSED: Unanimously

3. Reports (Informational)

Introduction of the new HIV/AIDS Section Manager/Ryan White Part B Program (RWPB) Manager with updates on RWPB and the AIDS Drug Assistance Program (ADAP).

Ryan White Part B (RWPB) Program Manager and the Office of HIV/AIDS Section Manager; Martha Fricano, RWPB Eligibility and ADAP Coordinator; and Steve Dion, RWPB Research, Development, and Data Coordinator.

Rob Langguth reported the AIDS Education and Training Center (AETC) staff at University of Nevada-Reno (UNR), under the direction of Dr. Patty Charles, is making great progress in updating the Statewide Coordinated Statement of Need (SCSN) and Comprehensive Care Plan (CCP) for Nevada. Both reports are due to the Health Resources and Services Administration (HRSA) by mid June, 2012. AETC staff held meetings in Carson City, Reno, and Las Vegas. They are now asking members of this Committee for their input and expertise as practitioners on a survey which was sent out to the Committee in preparation for this meeting, per Dr. Trudy Larson's request; she will have more to say on this survey. There is also a survey for the Ryan White Part B clients.

Steve Dion referenced the Catalyst summaries included in the meeting packet, noting about \$7,073,000 expended to date for AIDS Drug Assistance Program (ADAP), about \$447,844 for Continuation of Benefits Program (COB), and \$491,492 for State Pharmacy Assistance Program (SPAP). Mr. Dion stated the costs for these three programs is about \$500,000 less than this time last year; due to better pricing negotiated for ADAP; having more clients on insurance; and referring any clients at 150% FPL to the Low Income Subsidy (LIS) program. He expects more price cuts as and the National Alliance of State and Territorial AIDS Directors (NASTAD) continue negotiations for ADAP. There is no anticipated

wait list required for the next two years, barring any drastic changes. RWPB staff is continues working to identify options for any surplus rebate monies across fiscal years.

Program	Enrolled	Active	Utilization	Est. \$ to Date
ADAP- AIDS Drug Assistance Program	786	598	76.3%	\$7,072,671
COB – Continuation of Benefits	167	112	67.6%	\$447,844
SPAP- State Pharmacy Assistance Program	315	127	51.1%	\$491,492

Martha Fricano introduced Dan Olsen, the new Ryan White Part B Manager and Section Manager for the Office of HIV/AIDS. Mr. Olsen greeted the Committee, stating that he looks forward to meeting and working with them.

Dr. Larson gave her public comment to express appreciation for the help she and the work group have received in the process of updating the SCSN and CCP. Two very brief surveys are being distributed, one for the clients and one for the treating professionals and service providers. She asked for assistance in getting the client surveys out, whether by electronic copy or paper, as their voice needs to be heard; to identify their needs and concerns of the RWPB recipients. These surveys will give a quantitative measure of that need. Return the paper copies of the survey to Jennifer Bennett.

4. Discussion and possible recommendations to add the following medications to the ADAP formulary: Cobicistat; Scopalamine Patch; Moxifloxacin; and Posaconazole; given the standing requirements that each is approved by the United States Food and Drug Administration (FDA) and NASTAD has negotiated and published approved ADAP pricing prior to being added to the ADAP formulary.

Mr. Dion clarified that the standing requirements regarding the approval process by FDA and NASTAD pricing applies to HIV-specific drugs, like Cobicistat, not to those medications used to treat opportunistic infections (OIs).

Cobicistat was addressed first; it's still in clinical trials and not yet available. Concern was expressed about its efficacy as a stand-alone medication and about the pricing. Cobicistat as part of the 'Quad' performs as a booster; it is unknown how it would perform on its own. Since this drug is not yet available or through the approval process, the overall feeling of the Committee is to await further clinical data; without any overwhelming compulsion to vote to add this to the formulary, the issue is tabled.

Mike Gilbert offered public comment to announce the 'Quad' is scheduled for FDA approval August 27th this year, launching it in the marketplace in September.

The Scopalamine Patch is currently not in use in northern Nevada; southern Nevada has 5-10 patients using this at any one time; being consistently used for chemo patients. Concern was expressed about the quantity given out at any one time; consensuses held to letting the prescribing physician/practitioner decide on the need.

MOTION: Dr. Dino Gonzalez moved to add the Scopalamine Patch to the formulary.

SECOND: Anthony Soto

PASSED: By a counted vote of eight (8) yays and one (1) nay.

Moxifloxacin (Avelox), a member of the Quinolone family of antibiotics, used in treating *Mycobacterium avium complex* (MAC), allows the patient to take fewer pills a day. Susceptibility testing is available. Interaction issues may be of concern. Other antibiotic treatments may be preferred first; however, Avelox is generally effective in treating MAC as it is resistant to most ordinary antibiotics.

It was questioned whether treatment with Avelox would be more costly than more standard regimens; Mr. Soto stated this would not be the case. Dr. Charles Krasner stated he would approve this addition with restrictions, asking who would monitor this, who would be the gatekeeper. Mr. Soto agreed to contact Catalyst as to how this could be set up and managed.

MOTION: Dr. Larson moved to add the Moxifloxacin (Avelox), to the formulary for treatment of MAC with a 30 day restriction through Catalyst.

SECOND: Dr. Steven Zell

PASSED: Unanimous

Posaconazole is not a driver in treatment, but a fall back for the very unusual and resistant fungus, for example. It is very difficult for the patient to take as it must be refrigerated and taken with a high fat meal. If this were on the formulary, there would have to be a primary payer for use by SPAP and COB clients. It was noted Pfizer would give the drug at no cost to patients without any other mechanism to receive its treatment. Ms. Fricano agreed to check with Catalyst. Mr. Dion stated the ADAP could afford to have this on the formulary at this time. The Committee could recommend use of a Prior Authorization Request Form (PAR) be submitted to Catalyst Rx now, analyzing its use and cost in early 2013, giving a full year of data to be considered in the analysis.

MOTION: Dr. Larson moved to add the Posaconazole to the formulary, recommending low usage.

SECOND: Ms. Trimmer

PASSED: Unanimous

No other public comment.

5. Discussion and possible recommendations to accept the Nevada State Health Division's (NSHD) Administration streamlined procedure for HIV-specific medications to be added to the ADAP formulary:

New HIV-specific medications, whether in combination, stand alone, or an alternative/replacement to an existing medication on the formulary will be immediately added to the ADAP formulary once RWPB staff has received notice of FDA approval, NASTAD negotiated ADAP pricing, and approval from NSHD Administration.

The HIV/AIDS Medical Advisory Committee (MAC) shall be convened:

- to consider and recommend HIV drugs that are expected to have greater than a +10% cost impact to the ADAP;
- 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 NSHD or the RWPB Program.

Discussion regarding the +10% cost impact to the ADAP included concern as to its measure of 'cost neutral', as compared to the most expensive drug on the formulary? Or as comparable to the family of drugs? Considering the costs fuzeon or maraviroc, this could open the ADAP to unreasonable costs. Dr. Fuller provided the appropriate wording to be presented to NSHD Administration, as follows:

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 notice of FDA approval, NASTAD negotiated ADAP pricing, and approval from the NSHD administration UNLESS:

- The cost of the medication is +15% that of the most expensive medication in the same medication class
- 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
- 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.
- 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 Formulary committee.
- The committee chairman requests medication be brought to Formulary committee for discussion
- Request by NSHD or the RWBP Program for medication review by the Formulary committee.

MOTION: Dr. Larson moved to accept this policy and procedure, given the modification to be sent by Dr. Fuller.

SECOND: Dr. Parker

PASSED: Unanimous

No public comment.

6. Schedule next meeting and recommendations for agenda items.

It was agreed to move the next meeting out about six months, even out to August. Dr. Fuller will contact the Recording Secretary with possible dates closer to that time.

No public comment.

7. Public Comment

Ms. Kellum O'Brien announced the upcoming addition of a new physician to the UMC staffing; they are also looking at adding staff at the PA level.

Dr. Gonzalez noted he will be moving to a private practice in Las Vegas to help fill the huge void in HIV Primary care in the community after having several HIV-care doctors move or retire.

No other public comment.

8. Adjournment at 1:05 PM.