

MINUTES

HIV/AIDS MEDICAL ADVISORY COMMITTEE

Meeting Held on FEBRUARY 28th, 2008 via Teleconference. Called to Order at 12:06 PM.

MAC VOTING MEMBERS	Regional Participation	Attended	Absent
PHYSICIANS - 5			
1. Jerry Cade, MD	South - UMC		X
2. Brian Onbirbak, MD	South - UMC	YES	
3. Gary Schroeder, MD	South - UMC	YES	
4. Dino Gonzales, MD	South – UMC / Community		X
5. Steven Zell, MD	Northern NV	YES	
6. Trudy Larson, MD	Northern NV	YES	
7. Steven Parker, MD	Community		X
NURSES - 2		1	1
8. Leslie Kellum-O'Brien, RN	South - UMC	YES	
9. Karen Redding, RN	North - HOPES		X
PHARMACISTS - 2		3	1
10. Anthony Soto, RPh	South - UMC	YES	
11. Diana Bond, Director	South - UMC		X
12. Dennis Fuller, PharmD, Chairperson	South - UMC	YES	
13. Sue Trimmer, RPh	North - HOPES	YES	
CORRECTIONS DEPT - 1		0	1
Miguel Forero (for Dr. Bannister)	North - Corrections		
14. Robert Bannister, MD	North - Corrections		X
(8) Simple Majority for Quorum – MET/YES	Voting Members Present	8	
(14) Voting Members from Categories	Voting Members Absent		6

NON-VOTING ATTENDANCE	Participation	Attended
Mary Pennington, Program Manager	Communicable Disease Program	YES-CC
Steve Dion, RWCA & HIV-Prevention	Communicable Disease Program	YES-CC
Rebecca Huddleston, Recording Secretary	Communicable Disease Program	YES-CC
Bill Fullenbach, Interim Exec Director	Northern Nevada HOPES	YES-Reno
Dana Pierce-Hedge, Manager, National Accts	Gilead Sciences, Inc.	YES-Phone
Total # Guests Present =		5

Nikki Isaacs, Ryan White Part B Program Coordinator, scheduled to present at this meeting, was absent. Some of the items listed for her presentation were covered by Steve Dion. Others items were tabled for future consideration or presentation.

Agenda Item #1: * Approval of Minutes for the October 17th, 2007 Meeting.

ACTION on Agenda Item #1: NONE.
Motion to accept Minutes for the October 17th, 2007 meeting was tabled until certain items can be clarified, changes and/or corrections made, and the amended Minutes presented to the members for review and approval.

DISCUSSION:

The numbered items list the challenges, concerns, or corrections requested in review of the Minutes from the meeting held October 17th, 2007. See Addendum #1 for the response or action resulting from each numbered item listed below.

1. Attendance record shows Dr. Cade as absent, however, he was recorded as having made a motion on Agenda Item #6. He arrived later in the meeting, after roll call.
2. A request was made that the draft of the Minutes from the meeting be made available to the voting members as soon as it is available. This will allow the members to plan future action for the next meeting.
3. Referencing the second paragraph under the discussion of Agenda Item #6, page four of the Minutes as submitted, "Current procedure for adding medications to the ADAP formulary", concern was expressed that members were unaware of this as required procedure, requesting that the Minutes be amended to reflect what that member thought was the procedure from past experience where antiretroviral drugs were automatically and immediately added to the formulary upon FDA approval and then finalized at the next meeting of the Committee. Discussion included the suggestion that the issue of this procedure be included as a future agenda item.
4. Also referencing Agenda Item #6, "* Report on drugs approved for addition to the ADAP formulary. Discussion and possible recommendation regarding interim care for EAP (Early Access Program) patients." concern was expressed that this action did not cover the full intention of the Committee, in that members of the Committee had intended this be a blanket policy for all medications to be added to the formulary once gaining FDA approval.
5. One member noted that one item of discussion from the meeting of October 17th, 2007 was missing from the Minutes: Dr. Larson's request to know the name of who signs for or approves the recommendations made by the Committee.
6. Referencing Agenda Item #7 * "Report from the ad-hoc subcommittee to examine and revamp the miscellaneous list on the formulary into a category of HIV-associated conditions requiring treatment and for medications to be removed, to include discussion and possible recommendations," on page 5 of the proposed Minutes, some members thought this item had been approved or it was to have been included on the agenda for the next meeting.
7. Referencing Agenda Item #10, Public Comment, on page 7 of the proposed Minutes, one member asked that the list on non-voting attendees be moved into position just after the member attendance and before Agenda Item #1, leaving off the names from that list of persons who did not attend.

Agenda Item #2: Report on current caseloads/number of clients enrolled in ADAP (AIDS Drugs Assistance Program).

ACTION on Item #2: None. Report only, not an action item.

DISCUSSION:

- Catalyst provides an executive summary which ADAP will include at future meetings.
- Utilization for January 2007 jumped from an average of 61% to 70%, this being attributed to the cessation of the Medicare Part D Enhanced Plan effective 12/31/2007 and subsequent changes in billing.
- Prior to January 1, 2008, ADAP paid premiums for the Medicare Part D enhanced plans.
- Effective January 1st, 2008, the enhanced plans were dropped and the State Pharmacy Assistance Program (SPAP) went into effect. SPAP is funded through State general funds for ADAP and covers co-pays, deductibles, and the coverage gap.
- After the coverage gap, Medicare Part D catastrophic coverage goes into effect - 95% is covered by Medicare Part D with only 5% being covered by State ADAP.
- All members/participants receiving medications through ADAP were mailed eligibility cards: white for standard eligibility and silver for those members whose eligibility includes additional services. All members are to present their card when requesting prescriptions to be filled or any other applicable service. Whatever is paid for using this card counts toward true out-of-pocket expenditures for the member.
- Pharmacy managers will meet with ADAP staff to address the differences in Pharmacy reconciliation and that of the Catalyst reports; the reporting billing codes; procedures; and guidance on administering the various plans like Sierra Rx and Disability Rx.

Agenda Item #3: Report on Pharmacy Benefit Manager (PBM) / Medicare Part D / SPAP (State Pharmacy Assistance Program). Back-up for Catalyst.

ACTION on Item #3: None. Report only, not an action item.

DISCUSSION:

- The information regarding Agenda Item #3 were covered in the discussion under Agenda Item #2 above, so the Committee will move on to Agenda Item #4.

Agenda Item #4: Report on dispensing fees and Rx co-pay reimbursements.

ACTION on Item #4: None. Report only, not an action item.

DISCUSSION:

- Nikki Isaacs is not present to give this report; she will address these topics at a later meeting.
- Concern was expressed by pharmacy personnel over the possible reduction in dispensing fees from the current \$28 fee to \$20 planned for April 2008. In addition to the personnel expense incurred in filling the prescriptions, purchasing at the Public Health Service (PHS) pricing schedule rather than using regular inventory was at great expense to the pharmacies. Otherwise, the State would have to recoup rebates from the drug companies.

- It was also noted that the ADAP would not run on volunteer pharmacy services, that the pharmacies would have to be compensated for the services provided.
- Ryan White Program guidelines are specific in that direct support to clients for drugs always takes priority over all services.
- Given the possibility of rescission of Ryan White funding, several cost containment measures are being considered, bringing Nevada's fees more in line with common practice. In comparison to other state's ADAP dispensing fee schedules, Nevada ranks very high.
- One member noted that the closest state to Nevada to compare would be California where their pharmacies fill ADAP prescriptions at AWP rates less 13%, plus a dispensing fee; a much more generous plan than what Nevada currently uses.
- It was suggested that other cost containment measures to consider before cutting the dispensing fees would be to [1] stop giving meds to the jails and [2] stop giving gate meds to the prisons.

Agenda Item #5: Report on protocol for future changes to the formulary where the drugs in question are cost-neutral to ADAP.

<u>ACTION on Item #5:</u>	None. Report only, not an action item.
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DISCUSSION:

- Notice has been received by ADAP staff from Health Division Administration that if a drug is cost-neutral, it can be added to the formulary. Where a significant cost increase would impact ADAP, this would be reviewed on a case-by-case basis, with recommendation to Health Division Administration from the Committee.
- Defining 'cost-neutral' is basically applied in considering Drug A for the formulary, where Drug A would replace Drug B within a maximum 5-10% cost increase window.
- It was noted that this would be more simply applied to medications treating side effects or for re-formulations such as changing from tablets to capsules or to generic formulations, than to antiretrovirals which do not typically 'replace' one another where there are different drug classes and resistance issues to consider.
- Prior to Medicare Part D, the average cost of drugs was about \$935 per month per active client. Even with all the changes since that time and the cost of new drugs, current ADAP drug costs stand at about \$1,100 per month per active client (an increase of only about 15% over approximately two years time), with the average drug claims at 2/month/active client.
- Typically, new formulations are presented for better client treatment or to improve adherence and compliance. The cost for these reformulations may or may not exceed the cost-neutral \leq 10% guideline. The Committee requests and recommends that if the cost were greater than the cost-neutral \leq 10% guideline, that use of and proposed inclusion on the Formulary be brought back before the Committee for consideration and recommendation.
- The question was asked if these protocols for adding medications to the ADAP formulary are in written format other than in the Minutes of the Committee's meetings. While this information had been presented and archived in the Minutes, ADAP staff is currently developing a Policies and Procedures Manual which would address this issue.
- The Committee has requested that the ADAP Policies and Procedures Manual be included on the agenda for the next meeting.

Agenda Item #6: Report on utilization/cost for the new drugs that were added to the ADAP Formulary from July 1st, 2007.

ACTION on Item #6: None. Report only, not an action item.

DISCUSSION:

- Referencing a report generated from Catalyst (PBM) for December 2007, it was noted that the non-antiretrovirals represent a small percentage of the overall expenditures for ADAP medications. About 30% of all prescriptions filled at HOPES were for these non-retroviral medications, with about 18% of the total filled at UMC. The cost for dispensing these non-antiretrovirals is relatively high. (See attachment #3.)
- The question was raised as to the impact of the three antiretrovirals most recently added to the formulary: TMC 125 (Tibotec), MK-0518 (Merck) and Maraviroc (Pfizer). As the Catalyst reporting system is relatively new, no specific impact is readily evident at this time.
- A full report from Catalyst of all medications from October 1st, 2007 forward will be presented at the next Committee meeting.

Agenda Item #7: Discussion regarding protocols for all medications listed on the ADAP formulary as related to PBM.

ACTION on Item #7: None. Report only, not an action item.

DISCUSSION:

- The protocols intended for discussion here, originally placed as a cost containment measure on the first line and second line medications, have now outlived their usefulness.
- The new Catalyst system requires an override to these outdated cost containment protocols by the State's ADAP staff, causing a delay in getting medications to the patients.
- These medications in question do not require protocols for medical reasons or practice.
- The Committee's chairperson will submit a list to ADAP staff and the recording secretary of the medications with these cost containment protocols as an action item on the agenda for the next Committee meeting.

Agenda Item #8: * Old Business: Report on Statewide Quality Management Team – MAC Representation. Discussion and possible recommendations. Postponed from 10-17-2007.

ACTION on Item #8: None. Item tabled to the next meeting.

DISCUSSION:

- Nikki Isaacs, absent from this meeting, was scheduled to have presented this item.

- General consensus was that it would be important to have a member from the Committee on the Quality Management Team other than Dr. Larson, who currently represents Ryan White Part B on that Team.
- Sue Trimmer will discuss Dr. Larson her own possible membership, representing the Medical Advisory Committee, on the Quality Management Team (Subcommittee of the State AIDS Task Force) with and get back to the Committee on her recommendations.

Agenda Item #9: * Schedule next meeting and determine deadline for submitting agenda items.

ACTION on Item #9: None.

DISCUSSION:

- The Committee’s By-Laws require either quarterly or semi-annual meetings, at the discretion and direction of the Chairperson.
- Chairperson will send out to members a list of possible dates in June 2008 for the next meeting.

Agenda Item #10: Public comment (no action may be taken).

ACTION on Item #10: None, not an action item.

DISCUSSION:

- It was noted that about two weeks previous to this meeting, the pharmacies were being charged a drastic increase of \$90.00 in the price paid for Truvada from Gilead.
- The expected cost impact of this increase is considerable: HOPES at about \$70,000 per year and about \$200,000 per year for UMC.
- Truvada currently ranks second on the list of Nevada’s total ADAP drug expense per month.
- As requested by HOPES Pharmacy, Cardinal checked on the increase to find that the pharmacies had been previously charged at the special rate under ADAP contract, in effect for the past five to six years, a rate significantly lower than PHS pricing.
- Purchases made from the point of the increase are being charged at the higher PHS pricing although each pharmacy has its own ADAP registration.
- A call had been made to Gilead to research the reason for this increase.
- Dana Pierce-Hedge, Manager, National Accounts for Gilead Sciences, Inc., in attendance at this meeting, agreed to follow-up with Gilead on the situation. She was previously unaware of any price increase for Nevada’s ADAP billing.

Agenda Item #11: * Adjournment.

ACTION on Item #11: Motion was made to adjourn the meeting by Dr. Onbirbak and seconded by Sue Trimmer.

Motion carried unanimously.

DISCUSSION: Meeting is adjourned at 1:04 P.M.

ADDENDUM 1 of 1: Response to requested changes, clarification, and corrections regarding Agenda Item #1: * Approval of Minutes for the October 17th, 2007 Meeting.

The numbered items list the challenges, concerns, or corrections requested in review of the Minutes from the meeting held October 17th, 2007. The response or action resulting from each numbered item is indicated below that respective item.

1. Attendance record shows Dr. Cade as absent, however, he was recorded as having made a motion on Agenda Item #6. He arrived later in the meeting, after roll call.
✓ *This correction has been made to the amended Minutes on page 1.*
2. A request was made that the draft of the Minutes from the meeting be made available to the voting members as soon as it is available. This will allow the members to plan future action for the next meeting.
✓ *Agreed. The draft will generally be made available to the voting members within six weeks of the meeting, or sooner as possible.*
3. Referencing the second paragraph under the discussion of Agenda Item #6, page four of the Minutes as submitted, “Current procedure for adding medications to the ADAP formulary”, concern was expressed that members were unaware of this as required procedure, requesting that the Minutes be amended to reflect what that member thought was the procedure from past experience where antiretroviral drugs were automatically and immediately added to the formulary upon FDA approval and then finalized at the next meeting of the Committee. Discussion included the suggestion that the issue of this procedure be included as a future agenda item.
✓ *No change will be made to the Minutes of this section.*
 - Whether committee members were aware of the procedure or not, this internal procedure for approval to add drugs to or remove drugs from the ADAP formulary has been in effect in its current form for several years. While it may have appeared to be automatic to members of the Medical Advisory Committee, there has always been a required internal procedure in place. As administrators of the federal grant monies that funds ADAP and other Ryan White programs and services, such procedures must be in place to ensure fiscal responsibility and accountability.
 - As part of this internal procedure, Ryan White staff must, often with the assistance of various Committee members, prepare and attach statements and projections of fiscal impact to the program for review by Health Administration in consideration of a request to add any medication(s) to the ADAP formulary.
 - The required internal procedures of the State Health Division or any one of its various programs is beyond the scope of purpose and mission of the Medical Advisory Committee and, therefore, will not be an item for recommendation on an Agenda for meetings of the Committee.
 - “The duty of the Committee is to evaluate benefits and costs associated with HIV/AIDS drugs, and their additions/deletions from the AIDS Drug Assistance Program (ADAP) Formulary. Recommendations are reported to the Bureau of Community Health of Nevada State Health Division.

- The mission of the Committee is to assist the ADAP in providing an important link in an overall continuum of care and treatment for people in Nevada with HIV disease by recommending which antiretrovirals and other medications are needed to treat HIV and related conditions for patients covered by ADAP.” (From page 1 of the HIV/AIDS Medical Advisory Committee By-Laws as approved 12/05/2005.)
4. Also referencing Agenda Item #6, “* Report on drugs approved for addition to the ADAP formulary. Discussion and possible recommendation regarding interim care for EAP (Early Access Program) patients.” concern was expressed that this action did not cover the full intention of the Committee, in that members of the Committee had intended this be a blanket policy for all medications to be added to the formulary once gaining FDA approval.
- ✓ *No change will be made to the Minutes of this section to change the motion and its recorded approval in order to include such a ‘blanket’ policy change.*
- Given the requirements of the Open Meeting Laws, action can only be taken on the specific item as written on the approved and posted agenda.
 - The motion printed from that meeting reads: [Motion was made by Dr. Cade and seconded by Dr. Onbirbak that once a drug from an early access program has FDA approval, it be immediately added to the formulary, using PHS pricing if necessary prior to the drug’s approval by NASTAD.]
 - Prior to the meeting of February 28th, 2008, members did receive the Notice of Determination regarding the approval by Health Division Administration of: [1] the motion made by the Committee on this item as stated above and [2] the motion made to discontinue altogether the use of the Health Division Administration requirement to submit the forms “Nevada ADAP Fuzeon® (Enfuvirtide/T-20) Guidelines with its attached Patient Worksheet and Patient Approval Form” in order to prescribe Fuzeon® for HIV/AIDS patients. (See attachment # 5.)
 - However, please NOTE: Per HRSA’s specific requirements of the Ryan White Part B Grant, certain medications can be added to ADAP formularies only after the Program has received written notice from both FDA and NASTAD: of FDA approval *and* the Program has also received written notice of approval by NASTAD, once the pricing negotiations are complete. As a result, the approved motion as stated above may have to be addressed and possibly amended at a future date.
 - Once the Medical Advisory Committee recommends a particular medication to be added to the formulary, all protocols must be followed before a medication can be added to the ADAP formulary, satisfying both State and Federal requirements.

5. One member noted that one item of discussion from the meeting of October 17th, 2007 was missing from the Minutes: Dr. Larson's request to know the name of who signs for or approves the recommendations made by the Committee.
 - ✓ *Upon reviewing the recording of the meeting, this request was added to the Minutes of the October 17th, 2007 meeting on page five of the Amended Minutes under the discussion items of Agenda Item #6 "*Report on drugs approved for addition to the ADAP formulary. Discussion and possible recommendation regarding interim care for EAP (Early Access Program) patients" where Dr. Larson said the Committee requested that it be clearly stated so they know who is responsible for disapproving any of the Committee's recommendations, not just referring to 'Health Administration' in general, but to know a specific name of that person or persons who says no.*

6. Referencing Agenda Item #7 * "Report from the ad-hoc subcommittee to examine and revamp the miscellaneous list on the formulary into a category of HIV-associated conditions requiring treatment and for medications to be removed, to include discussion and possible recommendations," on page 5 of the proposed Minutes, some members thought this item had been approved or it was to have been included on the agenda for the next meeting.
 - ✓ *The corrections stated below have been added to the Amended Minutes of the October 17th, 2007 meeting on page 5.*
 - The Committee's Chairperson had requested input from the voting members be sent to him before the next meeting, noting any corrections, additions, a different view on the placement of a particular drug, etc., stating that he would forward the changes on this proposed tier system to the recording secretary, moving it forward for consideration at the next meeting.
 - While this item was not noted as missing from the proposed agenda for the February 2008 meeting as submitted to the Committee's Chair and Vice-Chair, the recording secretary apologizes for not including this item on that proposed agenda. (See attachment #4.)

7. Referencing Agenda Item #10, Public Comment, on page 7 of the proposed Minutes, one member asked that the list on non-voting attendees be moved into position just after the member attendance and before Agenda Item #1, leaving off the names from that list of persons who did not attend.
 - ✓ *The changes as requested have been made on page 1 to the Amended Minutes of the October 17th, 2007 meeting.*