MINUTES

HIV/AIDS MEDICAL ADVISORY COMMITTEE
November 7th, 2006

The meeting was initiated at 12:18 pm via teleconference with six voting members and four guests present. Minimum voting quorum is met.

Attending from Clark County:

Jerry Cade, M.D.	UMC-LV Wellness Center
Gary Schroeder, M.D.	UMC-LV Wellness Center
Dennis Fuller, PharmD	UMC-LV Wellness Center
Leslie Kellum-O'Brien, Director	UMC-LV Wellness Center

Attending from Reno:

Steven Zell, M.D.	Northern Nevada HOPES
Sue Trimmer, RPh	Northern Nevada HOPES

Attending from Carson City:

Bill Hale, MBA	Program Manager, HIV / STD / TB
Nikki Isaacs, PhD	Program Coordinator, Ryan White CARE Act Title II
Steve Dion	HIV Prevention / Ryan White CARE Act Title II
April Romo (Minutes)	HIV Prevention / Ryan White CARE Act Title II

Agenda Item #1: * Approval of Minutes from August 8th, 2006.

DISCUSSION: None.

ACTION on Item #1: Minutes accepted as written. Motion passed unanimously.

Agenda Item #2: * Discussion of Testim and clarification of whether prior approval of Androgel included Testim and/or other forms of testosterone:

DISCUSSION: Testim, a topical testosterone, is not currently listed as a line item on the ADAP Formulary. At $55.50 per dispensed unit, compared to $84.00 for an equal unit of Androgel, the less expensive Testim represents a considerable cost savings for ADAP and is considered an effective alternative for the patient. 'Androgel' is currently listed as a separate line item under the "Miscellaneous" category on the Formulary and Eligibility Requirements as posted 08/15/06 on the State of Nevada, AIDS Drug Assistance Program. The same category lists 'Testosterone patches or injectable only'. (See Attachment 2 of 2.)

Consideration was given to possibly listing Testim or other such topical testosterone products on the Formulary individually and to the need to list on the Formulary the generic names of products separately. While testosterone pills are available, it is recommended that our patients steer away from their use. While the patches are not as effective for all patients, these are preferred for certain cases and applications. If the Formulary were changed to include 'topical' testosterone treatments, both Androgel and Testim could be prescribed by the attending physician as appropriate for the patient's care.

The Committee recognizes the need for physicians to be able to prescribe certain non-generic medications when it is best for the particular patient's care. In order to allow the pharmacy to optimize its buying power, generic names are currently listed on the Formulary. Maybe a disclaimer can be added to the Formulary that use of a generic drug is always an alternative to the branded counterpart. In the event that certain branded drugs become generic, the Formulary may need to be changed to reflect those options.

> ACTION on Item #2: The Committee recommends that Androgel, as it is currently listed, be removed from the formulary and the entry for Testosterone be changed as follows: "Testosterone topical or injectable only". Motion carried unanimously.

Agenda Item #3: * Discussion and possible approval for process of drug approval by generic drug classification:

DISCUSSION: Concern was expressed that since the Committee meets quarterly, the process of drug approval be systematic and in place to handle possible situations that may arise between meetings, with its goal to ensure smooth processing among the physicians, practitioners and billing services with regards to the Formulary. The Committee recognized the need to allow for smart buying in regards to various competitors offering the drugs, being certain to allow the attending physician to make the call on using generic or name brand drugs as best suited for the needs of the patient. A disclaimer was suggested to be included on the Formulary giving physicians & practitioners the option to use generics as they become available.

> ACTION on Item #3: No action was taken, no motion made.

Agenda Item #4: * Discussion and possible recommendation of coming medications – TMC 125 (Tibotec), MK-0518 (Merck) and Maravararoc (Pfizer):

DISCUSSION: It has been the practice of the Committee to allow new drugs to be added to the Formulary given they are not fiscally irresponsible, especially as these pertain to HIV therapy. Some concern was expressed regarding the proper and most effective use of the new drugs available now and those upcoming, especially where the use of these necessitate additional costs such as lab work for proper administration. Given that all participating physicians and practitioners in the Nevada ADAP keep abreast of all the research, new drugs

in development and coming available, latitude is prudent in allowing these professionals to continue their present level of care without intervention.

However, a process needs to be in place to have these drugs added to the Formulary as they become available on the open market to satisfy the needs of all patients, those on EAP and those who are not. It was noted that where EAP (Expanded Access Program) patients have had access to the drugs in their experimental, pre-approval phase, once FDA approval is secure and the drugs are available on the open market, these same patients will no longer have the same access to the drugs unless these drugs are listed on the ADAP Formulary. There is a certain ethical obligation to maintain the continuity of a patient's level of care that may be affected by this situation. Perhaps recommending carte blanche approval of these drugs as FDA approval comes forward would be necessary.

Protocol has been to immediately add to the formulary any drugs that interfere with viral replication. For the patients' sake, the committee feels that having these drugs listed on the formulary can't wait for some extended approval process. If a particular drug is not on the formulary at the time a prescription is dispensed, the pharmacy cannot be paid for it. All were in agreement that we must be able to provide the patient with the care needed, when it is needed, with no delay of treatment to any of our patients.

Procedure requires that once the Committee makes a recommendation regarding the addition of drugs to the formulary, these must be submitted by ADAP to the Nevada Health Administration for approval. This process requires considerable research together with impact studies, therapeutic statistical input, cost and benefits projections, clinical assessments, etc. to be formatted into a report and then submitted to Administration for consideration and approval. This process could take weeks or months.

In a cooperative effort to expedite the inclusion of these particular drugs and to expedite the process for others to come, Dr. Dennis Fuller will act as therapeutic point person/clinical liaison in collecting the required data, submitting this to Nikki Isaacs of ADAP for processing and submission to Administration. As these and other drugs are announced with several months notice, it is hoped that this process will allow for smooth transition from open market access to immediate inclusion on the formulary.

> ACTION on Item #4: The Committee recommends that (1) TMC 125 (Tibotec), MK-0518 (Merck) and Maravararoc (Pfizer) be included on the formulary; (2) some future criteria may be required for the use of Maravararoc; (3) cost-neutral drugs be added automatically on the formulary; and (4) viral inhibitors be added to the formulary without delay. Motion carried unanimously.

Agenda Item #10: * Removing Hydroxyurea and Ganciclovir (Cytovene): **This agenda item being addressed out of order:**

DISCUSSION: Of all patients on the program, only one still uses Hydroxyurea. Funds from Title III can be used to accommodate this patient's needs. Otherwise, it is used so little that it would be prudent to remove it from the formulary. Ganciclovir has been replaced by much better and more effective drugs.

ACTION on Item #10: The Committee recommends that Hydroxyurea and Ganciclovir be removed from the formulary, specifically the Cytovene capsules. Motion carried unanimously.

Agenda Item #5: * Discussion and possible recommendation of formulary HMG co A reductase inhibitors:

DISCUSSION: Some question as to the utility and need of this medication being added to the formulary since Lipitor is already listed. So far everyone seems happy with it, no real problems or concerns now.

ACTION on Item #5: None.

Agenda Item #6: * Discussion and possible recommendation of flouroquinolone and/or cephalosporin for bronchitis:

DISCUSSION: Generally, there is a high incidence of sinusitis and respiratory infection in the HIV population, especially in the fall. For those patients on ADAP with no other coverage, this can be a severe need. The Committee recognizes the need for such drugs to be added to the formulary. A list of several options could be provided, allowing for the pharmacies to buy at the best cost possible. For example, augmentin is available to ADAP for $.95 per bottle.

ACTION on Item #6: The Committee recommends that flouroquinolone and cephalosporin drugs such as augmentin, cefaclor, levaquin and avelox be added to the formulary, for treatment of sinusitis, bronchitis and other respiratory infections, selection based on best use for the patient and economic viability. Motion carried unanimously.

Agenda Item #7: * Discussion and possible recommendation of doxycycline for syphilis tx:

DISCUSSION: Many of ADAP patients are referred to Washoe County Health for treatment and follow-up as there is no cost to our program. Treatment for recurrence may require up to 14 days of IV penicillin.

A bottle of 50 count, 100 mg tablets of doxycycline is available for $1.42. At such a low cost, total treatment of the patient is cost effective and viable. As a secondary benefit, doxycycline is also used effectively in the treatment of bronchitis.

ACTION on Item #7: The Committee recommends that doxycycline be added to the formulary for treatment of syphilis tx, bronchitis or as needed by the patient. Motion carried unanimously.

Agenda Item #8: * Discussion and possible recommendation of an addition of topical steroid:

DISCUSSION: There is certainly a problem with the patients having exemplary dermatitis, desert psoriasis and the like. It would be to the patients' benefit to add this. Cost for one such topical treatment is priced at as little as $3.83.

ACTION on Item #8: The Committee will gather a list of typically used topical treatments, verify the pricing and make a therapeutic recommendation for addition to the formulary.

Agenda Item #9: * Discussion and possible recommendation of addition of formulary PPI or H2 antagonist:

DISCUSSION: Though concern was expressed that we may be moving into primary care issues in considering treatment of GERD or acid reflux disease for our HIV patients, it was pointed out that many of the drugs currently used in treatment are, in and of themselves, cause to these two conditions. An example was given for the cost of Prevacid (non-generic) for 100 count, 30 mg at $173. However, for an equal amount and strength of a comparable generic, such as omeprazole, the cost is $9.88 from one source or $3.22 from another.

Given this cost comparison and other cost comparisons given in this meeting, it was noted that ADAP has access to medications at a really low cost as compared to the relatively huge cost to our patients without the program. Given our current surplus due to the number of our patients on Medicare Part D, maybe we should look at possibly making available to physicians and practitioners treating our population other medications used for major medical problems such as diabetes, hypertension, etc. The cost to the program would be minimal, the benefit to the patient, great.

The Committee will compile a 'wish list' of targeted medications to submit for inclusion on the formulary which would be periodically reviewed for cost effectiveness and patient benefit. A separate proposal will be drafted and submitted by Nikki Isaacs to Administration where a cap of maybe $20.00 per month for a particular medication per patient, based on the recommendation of the Committee, be added to the formulary.

For the next meeting, consideration will be given to opening the formulary; the logistics of billing and reimbursement from ADAP funds; and would it be advisable and cost effective to extend the formulary to include pain medication.

ACTION on Item #9: (1) The Committee recommends that addition to the formulary PPI and H2 antagonist. Motion carried unanimously.

Agenda Item #11: Report on current caseloads / number of clients enrolled in ADAP:

DISCUSSION: ADAP has on record 691 recipients with the distribution as outlined in the following chart:

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RECIPIENTS	ADAP ONLY	MEDICARE PART D	TOTAL RECIPIENTS
Northern Region	163	27	190
Southern Region	363	138	501
TOTALS	526	165	691

DISCUSSION: A question was raised as to why those patients on Medicare Part D were also on the ADAP rolls. Patients must be ADAP eligible for ADAP to pay their premiums. There may be some of these participants whose Medicare Part D premiums are fully funded elsewhere. Should these names be removed from ADAP if they are not getting ADAP funds?

ACTION on Item #11: Further discussion was tabled until more information can be provided to the Committee as to the justification of these patients being left on the ADAP patient roster.

Agenda Item #12: * Scheduling of next meeting.

DISCUSSION: Though we would ordinarily meet in December or January, the meeting is to be postponed due to the upcoming move of Health Division to its new location. April Romo has been custodian of the ADAP calendar. She will verify that we are within our guidelines as to scheduling of these meetings. She will email the Committee if there is a problem.

ACTION on Item #12: Next meeting scheduled for February 6th, 2006, the first Tuesday in February. Motion carried unanimously.

Agenda Item #13: Public Comment (no action may be taken). None present.

Agenda Item #14: Adjournment

ACTION on Item #14: Meeting adjourned at 1:20 PM. Motion carried unanimously.

Attachment 1 of 2: Formulary of 08/15/06, current at the time of this meeting and referenced several times during this meeting:

STATE OF NEVADA
AIDS DRUG ASSISTANCE PROGRAM
FORMULARY AND ELIGIBILITY REQUIREMENTS

HIV ANTIRETROVIRALS:

NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS

AZT, zidovudine (Retrovir™) Glaxo
3TC, lamivudine (Epivir™) Glaxo
ddI, didanosine (Videx™) Bristol-Myers Squibb
ddC, zalcitabine (Hivid™) Roche
d4T,stavudine (Zerit™) Bristol-Myers Squibb
lamivudine/ zidovudine (Combivir™) Glaxo
Abacavir (Ziagen™) Glaxo
Abacavir sulfate/Lamivudine/Zidovudine (Trizivir™) Glaxo
Emtricitabine (Emtriva™) Gilead Sciences
Epivir/Ziagen (Epzicom™) Glaxo
Emtricitabine/Tenofovir (Truvada™) Gilead

NUCLEOTIDE ANALOG

Tenofovir (Viread™) Gilead Sciences

NON-NUCLEOSIDE REVERSE TRANSCRIPTASE INHIBITORS

Nevirapine (Viramune™) Boehringer Ingelheim
Delavirdine (Rescriptor™) Agouron
Efavirenz (Sustiva™) DuPont
Atripla™ Gilead

PROTEASE INHIBITORS

Saquinavir (Invirase™ & Fortovase™) Roche
Ritonavir (Norvir™) Abbott
Indinavir (Crixivan™) Merck
Nelfinavir (Viracept™) Agouron
Amprenavir (Agenerase™) Glaxo
Lopinavir/Ritonavir (Kaletra™) Abbott
Atazanavir sulfate (Reyataz™) Bristol-Myers Squibb
Fosamprenavir calcium (Lexiva™) Glaxo
Tipranavir (Aptivus™) Boehringer Ingelheim
Darunavir, TMC-14 (Prezista™) Tibotec Therapeutics

FUSION INHIBITOR

Enfuvirtide/T-20 (Fuzeon™) Roche

MISCELLANEOUS

Androgel
Acyclovir
Amitriptyline (Elavil™)
Atorvastatin Calcium (Lipitor™)
Atovaquone (Mepron™)
Azithromycin (Zithromax™)
Ciprofloxacin (Cipro™)
Clarithromycin (Biaxin™)
Clindamycin (Cleocin™)
Clotrimazole (Mycelex™)
Dapsone
Diphenoxylate/Atropine (Lomotil™)
Divalproex Sodium (Depakote™) *HIV seizures only*
Dronabinol (Marinol™)
Darbopoeiten
Erythropoetin
Ethambutol (Myambutol™)
Fenofibrate (Tricor ™) *second line treatment*
Fluconazole (Diflucan™) *for treatment only*
Gabapentin (Neurontin™)
Ganciclovir (Cytovene)
GCSF (Neupogen™)
Gemfibrozil (Lopid ™) *first line treatment*
Hydroxyurea (Droxia™, Hydrea™)
Itraconazole (Sporanox™)
Leucovorin
Loperamide (Imodium™)
Megestrol (Megace™)
Nystatin (Nilstat™)
Niaspan *first line treatment*
Ondansetron-only after Compazine™ (Zofran™)
Paromomycin (Humatin™)
Phenytoin (Dilantin™) *HIV seizures only*
Prochlorperazine (Compazine™)
Pyramethamine
Rifabutin *for treatment of MAC*
Sulfadiazine
Testosterone *patches or injectable only*
Trazodone (Desyrel™)
Trimethoprim/Sulfa (Septra™ Bactrim™)
Ultrase MT-20™ -Pancreatic Enzymes
Valganciclovir (Valcyte™)

ELIGIBILITY REQUIREMENTS:

- **The client income must not exceed 400% of Federal Poverty Guidelines-approximately $39,200/year for one person**
- **The client may own a home and a car.**
- **Additional assets of the client may not exceed $4,000.**
- **Lab tests for T-Cell and Viral Load must be done every six months.**
- **For more information, please call Nevada State Health Division, ADAP staff at 775-684-5952**

ADAPFM.18.doc
8/15/06

Attachment 2 of 2: Agenda for this meeting:

NEVADA STATE HEALTH DIVISION
HIV/AIDS MEDICAL ADVISORY COMMITTEE
(An advisory group to the Health Division)
Tuesday, November 7, 2006 at 12:00 PM
AGENDA

The meeting will be held via telephone conference from the following:
Northern Nevada HOPES, 467 Ralston Street, Dining Room area, Reno, NV
Kinkead Building, 505 E King Street, 2nd Floor Small Conference Room, Carson City, NV
UMC Wellness Center, 2300 S Rancho Drive, Las Vegas, NV
Teleconference: **1-866-302-8881, Pass Code: 7756844121**

Welcome and Introductions

1. *Approval of August 8, 2006 Minutes.....Dennis Fuller, PharmD
2. *Discussion of Testim and clarification of whether prior approval of Androgel included Testim and/or other forms of testosterone .....Dennis Fuller, PharmD
3. *Discussion and possible approval for process of drug approval by generic/drug class.....Dennis Fuller, PharmD
4. *Discussion and possible recommendation of coming medications-TMC 125 (Tibotec), MK-0518(Merck) and maravaroc (Pfizer).....Dennis Fuller, PharmD
5. *Discussion and possible recommendation of formulary HMG co A reductase inhibitors.....Dennis Fuller, PharmD
6. *Discussion and possible recommendation of fluoroquinolone and /or cephalosporin for bronchitis.....Dennis Fuller, PharmD
7. *Discussion and possible recommendation of doxycycline for syphilis tx (long term).....Dennis Fuller, PharmD
8. *Discussion and possible recommendation of an addition of topical steroid.....Dennis Fuller, PharmD
9. *Discussion and possible recommendation of addition of formulary PPI or H2 antagonist.....Dennis Fuller, PharmD
10. *Removing Hydroxyurea and ganciclovir (cytovene).....Dennis Fuller, PharmD
11. Report on current caseloads/number of clients enrolled in ADAP.....Nikki Isaacs, PhD
12. *Scheduling of next meeting.....Dennis Fuller, PharmD
13. Public Comment (no action may be taken)
14. Adjournment.....Dennis Fuller, PharmD

***ITEMS WHICH MAY REQUIRE ACTION**

NOTE: Agenda items may be taken out of order and public comment may be allowed as part of each agenda item in order to accomplish business in the most efficient manner.

Members of the public who are disabled or require special accommodations or assistance at the meeting are requested to notify the Secretary of the HIV/AIDS Medical Advisory Committee (775) 684-4121 at least 72 hours in advance of the meeting.

This is a public meeting being held in conformance with the Nevada Open Meeting Law. Notice of this meeting has been posted at the following locations:
KINKEAD BUILDING LOBBY-505 E King Street, Carson City;
WASHOE COUNTY DISTRICT HEALTH DEPARTMENT- 9TH and Wells, Reno;
NORTHERN NEVADA H.O.P.E.S.- 467 Ralston Street, Reno;
UMC WELLNESS CENTER- 2300 S Rancho Drive #205, Las Vegas;
SOUTHERN NEVADA HEALTH DISTRICT- 625 Shadow Lane, Las Vegas
NEVADA STATE LIBRARY AND ARCHIVES- 100 N Stewart Street, Carson City
STATE HEALTH DIVISION –WEBSITE- health2k.state.nv.us

Note: Persons who wish to be placed on a mailing list to receive copies of meting notices must submit a written request to: Secretary, HIV/AIDS Medical Advisory Committee, Nevada State Health Division, 505 E King Street, Room 103, Carson City, NV 89701