

STATE OF NEVADA

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HIV/AIDS MEDICAL ADVISORY COMMITTEE (MAC) MEETING MINUTES

March 6, 2018

12:00 pm

DRAFT

Physical Locations of Meeting:

- Northern Nevada HOPES Board Room, 580 W. 5th Street, Reno, NV
- UMC Wellness Center Conference Room, 701 Shadow Lane, Suite 200, Las Vegas, NV
- Bureau of Health Wellness and Prevention, 4126 Technology Way, Suite 200, Carson City NV

COMMITTEE MEMBERS PRESENT:

Alireza Farabi, MD, UMC Wellness Center
Dennis K. Fuller, Chairperson, PharmD, Clinical Pharmacy Specialist, HIV/AIDS, AAHIVP, UMC Wellness
Jerry L. Cade, MD, UMC Wellness Center and Southwest Medical Associates, Inc.
Mark Crumby, Vice Chairperson, PharmD, BCPS, Director of Pharmacy Northern NV HOPES
Paul M. McHugh, MD, UMC Wellness Center
Rosanne Sugay, MD, UMC Wellness Center
Steven C. Zell, MD, AAHIVS, University
Steven W. Parker, MD, Sierra Infectious Disease Specialist; Community Physician Northern/Rural Region
Todd R. Bleak, PharmD, Clinical Pharmacist, SNHD
Trudy A. Larson, MD, UNR School of Medicine
Ivy Spadone, MS, PA-C, Northern NV HOPES
Jan Richardson, RN, UMC Wellness Center Manager

COMMITTEE MEMBERS ABSENT:

Charles G. Krasner, MD, Northern NV HOPES
Dino J. Gonzalez, MD, AAHIVM, Community Physician, Southern Region
Mary Staples, PharmD, Assistant Director, UMC Pharmacy Services
Miguel Forero, Department of Corrections
Shawn Mapleton, MD, Family Medicine, Infectious Disease Specialist

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH, OFFICE OF HIV/AIDS STAFF PRESENT:

Tory Johnson, MMgt, Section Manager
Michael Thomas Blissett, Health Program Specialist 1 (ADAP Coordinator)
William Rocheleau, Program Officer 1 (Health Insurance Specialist)
Darla Beers, Administrative Assistant II

Dr. Fuller called the meeting to order shortly after 12:00 pm. This meeting was properly posted in accordance with the Nevada Open Meeting Law (NOML).

1. **Roll Call and Introductions** – *Dr. Dennis Fuller, Chairperson*

A quorum was established.

2. **Public Comment** – *Dr. Dennis Fuller, Chairperson*

Dr. Fuller will ask for Public Comment later in the meeting.

3. **Ryan White Part B Program Update** – *Tory Johnson, MMgt. Section Manager, Office of HIV/AIDS*

The new Part B ADAP contract starts April 1, 2018 and goes through March 31, 2019. He said his staff are on track to have the new partially or fully executed Sub Awards coming out before April 1. Currently the Sub Awards are over with the Administrative Fiscal Dept for review and approval and if needed our HIV Fiscal person is prepared to make any needed edits. The only hiccup we see is that we can't possibly get our Sub Awards out until we get our Notice of Grant Award (NOGA) which doesn't normally come until late March. Perhaps supplementing with Rebates will allow us to get the Sub Awards out sooner.

Since last meeting last year, the HIV/AIDS staff has grown. There is now a Minority AIDS Initiative Coordinator on board working on AIDS and Minority Health and Co-Morbidities. There is a contracts Coordinator working directly with Supplemental Funding that came into effect last year in October. Tory said he filled Tim Taycher's old position and is anxious to get that person on board. In addition there is one other staff person who will handle social service situations like housing and case management.

4. **Review and Approval of the draft minutes from October 14, 2017.** Several errors were noted and the meeting secretary was asked to make the following corrections:

- Replace Jan Richardson's workplace and title to read Clinical Manager, UMC Wellness Center, not UNR School of Medicine
- Remove the extra letter e in Dr. Sugay's first name to read Rosanne vs Roseanne
- Fix the page numbering issue

Dr. Fuller asked about the membership status of Dr. Kevin Prince, and Michael Blissett said Dr. Prince's name had not yet been removed from the committee membership list yet because there had not been a vote to take that action. Dr. Fuller asked if we should go ahead and take that vote now. Meanwhile the meeting secretary noted that the Oct 14, 2017 minutes mentioned the need to look and discuss whether to keep or remove both Dr. Prince and Dr Mary Staples name from membership. As a side note, the October minutes also mention Dr Fuller asking about Dr. Stephen Zell and Dr. Steven Parker, at which Dr. Larson suggested a letter be sent to both Dr. Zell and Dr. Parker to see about their wish to continue as members or not.

Committee members voted to remove Dr. Princes name from the membership roster as he is retired. Dr. Larson made the motion to remove and Dr. Cade 2nd the motion, and it was agreed upon by all members. No opposing vote was heard.

Committee members voted to remove Dr. Mary Staples name from the membership roster. Dr. Cade made the motion to remove and Dr. Larson 2nd that motion, and it was agreed upon by all members. No opposing vote was heard.

After review by all members, and several corrections were noted, Dr. Cade motioned to accept the October 14, 2017 meeting minutes (once corrections were made). Dr. Larson 2nd that motion, and that action was also

agreed upon by all members, with no opposing vote heard.

5. **Review and Approval of changes in membership** (refer to handout) – *Dr. Dennis Fuller, Chairperson*
Refer to #4, just after the October 14, 2017 meeting minutes were reviewed and approved.
6. **Review and Approval of Dr. Mark Crumby for Vice-Chair** – *Dr. Dennis Fuller, Chairperson*
This was briefly discussed. Dr. Cade made the motion to approve Dr. Mark Crumby as Vice-Chair. Jan Richardson 2nd the motion. Dr. Dennis Fuller asked if anyone opposed, and when nothing was heard, Dr. Fuller declared the approval unanimous. Dr. Crumby expressed his thanks.
7. **Review and Update ADAP Formulary**
 - a. Recommendations to add medications to the Formulary (*refer to handout*) – *Dr. Dennis Fuller, Chairperson*
Members took a few moments to review the formulary. Dr. Fuller said he thought Erythropoietin had been removed but it was still showing up and asked that it be taken off the list. When Dr. Fuller asked if anything else that needed to be removed from the list, no suggestions were mentioned. Dr. Larson commended and thanked the group for putting the formulary together by class.

Dr. Fuller then asked members to look at and discuss what medications they would like to add. Dr. Fuller said he didn't see any Proton Pump Inhibitors on their list. When someone saw Omeprazole was on the list, Dr. Fuller asked if more than that one was needed, and one member answered no that one was enough, everyone agreed and the discussion continued.

Medications Associated with Treatment of DVTs –

- Lovenox – After brief discussion, committee members voted to add the medication Lovenox to the ADAP Formulary. The motion to add it was made by Dr. Farabi and several voices 2nd the motion. No opposing vote was heard.
- Warfarin – After brief discussion, committee member voted to add the medication Warfarin to the ADAP Formulary. The motion to add it was made by Dr. Larson, and several voices 2nd the motion. No opposing vote was heard.
- Eliquis – After brief discussion, committee members voted to add the medication Eliquis to the ADAP Formulary. The motion to add it was made by Dr. McHugh and Dr. Parker 2nd the motion. No opposing vote was heard.
- Savaysa – After discussing this medication, all members agreed to hold off on this until the clinical need or a pitfall for it comes up.
- H2 Blocker vs. Proton Pump Inhibitor – After brief discussion, committee members voted to add the medication Famotidine to the ADAP Formulary. The motion to add it was made by Dr. McHugh, and Dr. Cade 2nd the motion. No opposing vote was heard.

Diabetic Medications – Ramsell, who is helping with the formulary, provided a suggested list.

Dr. Fuller asked Michael Blissett what information he received from Ramsell about monitors and strips for monitors. Michael said Ramsell wanted to go with strips and lancets, but not the monitors. When asked by Dr. Fuller if this was something he was able to do, Dr. Crumby replied strips are much more expensive than monitors (which run \$10 - \$30 each). Dr. Fuller asked if there was a certain provider that NV Medicaid model uses for strips. Michael said that NV Medicaid has a list of strips that are allowed. He said it mainly depends on what the pharmacy may have in stock for strips and lancets and that Ramsell said to just go with what the pharmacy has on hand. Dr. Larson expressed concern about the client cost, and

asked how costly this would be to the ADAP formulary, will there be a cost shift and will they use ADAP funds first? Also, will there be funds if the committee goes ahead and approves Diabetic supplies. Tory Johnson answered her saying he would need to know how many clients there are potentially, and then do a cost analysis and go from there to see if it would be feasible to add those supplies to the formulary. Dr. Cade concurred, saying it is always a good idea to look at getting that kind of information. With that Dr. Fuller suggested tabling the entire discussion on Diabetic products for now since the monitoring is an issue, and asked to put the discussion on monitoring strips, insulin, and the oral hypoglycemics off until the next meeting. In the meantime he asked that Tory's office prepare a cost estimate as to what this might do to the budget. Dr. Fuller would like it broken down into 2 groups: 1.) of monitor strips and insulin – and then 2.) monitor strips and oral medications as well as insulin. He said oral medications will potentially impact more people, but might be less expensive. After a brief pause, Dr. Fuller took Chair's prerogative, and members agreed, to table further discussion on this topic until the next meeting in November.

Birth Control – Dr. Fuller asked members about favorite medications or any concerns to discuss in dealing with the birth control medications issue. When asked by Dr. Larson what they use in the clinic at HOPES, Ivy Spadone said mostly they use a wide variety of pills, IUD's and are currently pushing trying to get the long-acting implantables so they can start using those as well, however noting those are expensive. Dr. Crumby said it is usually the cheapest Monophasic birth control if they are uninsured, and after running a quick impromptu report on the retail side, said Tri-Sprintec is probably the least expensive and has the highest volume. It was also noted that this medication was not on the list handed out. Dr. Crumby said there is probably a generic for it, it's a estradiol/norgestimate combination and is Triphasic, so the concentrations of it vary throughout the cycle. Dr. Fuller would like to get a list of the top 5 (in each grouping of Monophasic, Biphasic and Triphasic) to go over at the next meeting. Dr. Larson said that was a good idea as she would like to know what people are using and finding effective and which ones are not causing problems with other medications. Dr. Fuller said if there were no other concerns, he would again like to take Chair's prerogative and table this discussion as well until November. In the meantime, in addition to the top 5, he would also like to see if they could find a couple of OB-GYNs to give us a hand with what is going on in that community.

Medications Associated with the Treatment of the Transgender Population –

Dr. Fuller said Spironolactone was supposed to have made the list, but didn't see it. Dr. Larson asked if they could just approve it today since it was discussed at the last meeting, however, Michael suggested they should err on the side of caution and put this on the agenda for the next meeting so the public will have an opportunity to comment. Dr. Fuller noted however that Spironolactone was mentioned in the October 14, 2017 minutes for it to be voted on at the next meeting (today), however didn't get on the list. After brief discussion members voted to add Spironolactone to the ADAP Formulary list. The motion to add it was made by Dr. Larson, and Dr. Cade 2nd that motion. No opposing vote was heard.

Dr. Parker brought up the topic of Egrifta, saying a couple of his patients have asked for it, then elected not to use it just because of the difficulty in using it. He asked if it should be made available for people who may become aware of it and would like to use it. He was not sure of the cost. Michael said the national average cost is \$70 per unit –is about \$5,000 per client-, but Rebates would bring that price down significantly, to say \$1100 per client. It would not end up being costly to the ADAP program. Dr. Parker added that it wouldn't be something they would advertise, but might want to have on hand in the case of a client wanting it. There was concern expressed about the long-term use of Egrifta and the increased risk of cancer, hypertension, even Diabetes. Dr. Fuller ask for any further comments, and as there were none asked to table further discussion until the November.

8. Public Comment – Dr. Dennis Fuller, Chairperson

Matt Sheffield introduced himself, Bridget Tygh, and Brandon Cash, PharmD, all representing Theratechnologies (the manufacturer of Egrifta) and clarified that the actual list price for Egrifta is \$4600, and then would be significantly discounted from there. He then gave way to Dr. Cash. Dr. Cash thanked everyone for the opportunity, as a company, to comment about this therapy. He said for those with product experience and the patient population that we are talking about that are disproportionately affected with metabolic issues, these are patients that have principally (most of them) been HIV positive for a long period of time and have been on First-generation protease inhibitors, and as Dr. Larson alluded to earlier in the call, talking about the aging population, we are seeing this metabolic phenomenon almost reoccur as the population has aged even after they went off the First-generation protease inhibitors. He said he understands and wants to address a few comments that were made by the prescribers on the call. First, as related to Cancer, I heard Dr. Farabi express his concern in the group as a whole, and certainly that is something we as a company have always gotten. That was one of the scientific reasons that Egrifta was developed as opposed to Exogenous GH. This therapy was designed specifically to minimize any Cancer risk. We have no evidence of increased Cancer risk, either in our Phase 3 trials (which is different than placebo) as well as in terms of long-term data.

He went on to explain about their ongoing, long-term observational study over the last 6 years. He said there has been a controlled group as well as a patient-on-drug group and in the past 6 years there have been no differences in those two groups. In terms of mortality, you are right that there is no outcome data on Egrifta as a therapy. It is notoriously difficult to create an outcome study on a population such as this, although we would certainly like to be able have that. He went on to say that 70% of patients do respond to Egrifta. Some will try it then don't want to stay on because they don't want to self-inject. He said he believes there are patients in your practices that would benefit from it, and offered to share more data with the committee as needed.

Dr. Fuller asked members if they had any questions. When no questions were presented, he again asked to table further discussion until the next meeting. He then asked Dr. Cash to stay on the line after the meeting ends so they can exchange contact information, and so Dr. Cash can send him additional information. Dr. Fuller will review the data and make a presentation to the MAC at the next meeting.

Changing subjects, Dr. Fuller said as part of the ByLaws, as new HIV-specific medications come onto the market, they are automatically reviewed for 340B pricing, and as long as the pricing is not out of control, they are put onto the formulary. He just wants to make sure that process is followed as the newer drugs Biktarvy and Juluca come out on the market. Michael said Juluca was added to the formulary as of January 1st, and as for Biktarvy, we are still waiting on the sub-ceiling with NASTAD and once that is done it will also be added to the formulary. Dr. Fuller said if anyone has any other HIV medications that need to be added to the formulary to just send him an email.

There was 1 more public comment from a lady on behalf of Juluca who said if anyone needed more information, have any questions, or needed a summary on it she would be happy to provide that.

Dr. Cash added that another HIV medication Trogarzo, was approved by the FDA today, and that if anyone needed more information feel free to contact him and he can provide clinical data on the basis for review at next committee meeting.

9. Adjournment

Hearing no other comments, Dr. Fuller thanked the committee for their time and effort and asked for a motion to adjourn. Dr. Cade motioned and Dr. Crumby provided the 2nd.