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Chief Medical Officer

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
DIVISION OF PUBLIC AND BEHAVIORAL HEALTH
DISEASE PREVENTION AND INVESTIGATION**

Office of HIV/AIDS
4126 Technology Way, Suite 200
Carson City, Nevada 89706
Telephone: (775) 684-4190 · Fax: (775) 684-4185

HIV/AIDS MEDICAL ADVISORY COMMITTEE (MAC) MEETING MINUTES

November 3, 2018

1:00 PM

Hyatt Regency Hotel Lake Tahoe
111 Country Club Drive
Incline Village, NV 89451

-- DRAFT--

COMMITTEE MEMBERS PRESENT:

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
Rosanne Sugay, MD, UMC Wellness Center
Shawn Mapleton, MD, Family Medicine, Infectious Disease Specialist
Steven C. Zell, MD, AAHIVS, University
Todd R. Bleak, PharmD, Clinical Pharmacist, SNHD
Ivy Spadone, MS, PA-C, Northern NV HOPES
Jan Richardson, RN, UMC Wellness Center Manager

COMMITTEE MEMBERS ABSENT:

Alireza Farabi, MD, UMC Wellness Center
Charles G. Krasner, MD, Vice Chairperson, Northern NV HOPES
Dino J. Gonzalez, MD, AAHIVM, Community Physician, Southern Region
Paul M. McHugh, MD, UMC Wellness Center
Steven W. Parker, MD, Sierra Infectious Disease Specialist; Community Physician Northern/Rural Region
Trudy A. Larson, MD, UNR School of Medicine
Miguel Forero, Department of Corrections

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH STAFF PRESENT:

Tory Johnson, MMgt, Office of HIV/AIDS, Manager
Michael Thomas Blissett, HPS I, Aids Drug Assistance Program (ADAP) Coordinator
Vanessa Caceres, Program Officer I

1. **Roll Call and Introductions** – *Dr. Dennis Fuller, Chairperson*
Dr. Fuller confirmed that a quorum was met.

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

This was postponed until later in the meeting.

3. **Review and Approval of the March 6, 2018 draft minutes** – *Dr. Dennis Fuller, Chairperson*

Dr. Bleak motioned to approve the minutes; Dr. Sugay 2nd the motion. All members agreed.

4. **Ryan White Part B Program Update** – *Michael Thomas Blissett, ADAP Coordinator, Office of HIV/AIDS*

ADAP Update: The Office of HIV/AIDS (OHA) spoke about trying to get more consumers on insurance at our last MAC meeting. We are now looking at a start date of April 1st for all of our uninsured consumers to start receiving health insurance. The OHA wants to make sure all our providers are listed on the insurance provider list so that everyone can be seen by their current doctor. Currently listed are the providers in the Ramsell database and those who prescribe medications. If you know of a provider who is not on the list and needs to be, please email that information to Thomas Blissett or Dr. Fuller.

There are quite a few consumers that are enrolled in ADAP but are not utilizing ADAP services. The OHA wants to find out why that is, specifically if it is due to an adherence issue. The project will be rolled out in December starting with the Minority AIDS Initiative (MAI) population so that the OHA will be making use of MAI funds. Then at the beginning of the grant year, which is April 1st, the program will be expanded to all consumers.

Dr. Fuller: Will there be any major hurdles around insuring our current uninsured population besides making sure all providers are on the provider list?

Thomas Blissett: AHN is our current ADAP provider, and they are finding it difficult to work with insurance companies as they required a social security number which most of our uninsured population do not have. With that in mind, we had to come up with something more creative, so the decision was made to hire a broker who will form an association (set up like a group plan) for our uninsured population so we can individually enroll them into health insurance and establish our own rules for eligibility and enrollment. The plan is to have enrollment on a quarterly basis. This is not a done deal, this is just a preliminary overview, as we still do not know that doing this would be cost effective. The OHA will have more information about this roll-out, at the next MAC meeting in March.

Ryan White Part B Update – *Tory Johnson, Office of HIV/AIDS, Manager*

The total grant award for this year of 2018, was a little over \$9.1 million; \$2.1 of that is allocated to Part B; \$6.8 of that is allocated toward ADAP, and a little over \$74,000 is ear-marked for MAI. MAI funds can only be used for ADAP, so that is roughly \$6.9 total for ADAP services. The lion's share of funds out in the community are based on the money we receive through Rebates. Gilead, who is our biggest pharmaceutical company and provides Rebates, has been very slow in giving Rebates back this year. Our rebates come in on a calendar year. Currently, we are still waiting for 1st and 2nd quarter dollars to come in. In the meantime, we have ample money in our accounts, plus we have our base dollars (grant dollars) and have not had to touch those yet. This is just something to be aware of, our biggest pot of money is coming in slower. We are still submitting for rebates and will be submitting for 3rd quarter rebates. Although we have no control over when they come in, we do submit for rebates at every opportunity.

The OHA just released the last year 3-year grant cycle for funding through RWPB and ADAP, submissions are in, and currently being reviewed. Funding for 2019 will be level with 2018 finding. We did have some supplemental funding last year, but the OHA did not apply for supplemental funding this year. Currently, we have about \$6.2 million in direct service dollars between ADAP and Part B on the ground. Funding will stay

level to make sure we get our rebates coming in and then in 2019 for our new RFP cycle we can allow for growth. Tory is currently working on getting the Nevada OHA grant cycle on the same timeline HRSA recommends. The OHA is currently on year 2 of our 5-year grant cycle from HRSA. The OHA is fully staffed at this time, all vacancies have been filled. Administrative changes are coming up; Tory is relocating to Las Vegas next year around March or April. Due to surgery Tory will be out of the office for a bit, but services will continue as usual with his staff. He will keep everyone updated as he learns more.

Dr. Fuller: Does the rebate amount look about the same year to year or is there more some years? Are we running behind? Do things look to be steady?

Thomas Blissett: Yes and no, Gilead had some changes in the way that they negotiated with the National Task Force, so that reduced the amount of rebates that we brought in this year because they would not allow for Medicare claims to be allocated starting July 1st, and if you paid by co-pay it is dollar for dollar versus the full rebate. So, we did see a decrease of \$2.3 million, but that is in line with what we were currently seeing based on what they were letting us invoice. But the good news is that come January 1st, 2019, we will enter into a new agreement. In the new agreement they will allow us to submit Medicare claims for those who have low-income subsidies, so we will see that increase. As far as overall rebates, we will be at about \$14-18 million in rebates, just to give an estimate.

5. **Ramsell presents Prior Authorization (PA) methodology for the ADAP program** – *Dr. Colleen Higgs, PharmD*
Dr. Higgs is a Pharmacist at Ramsell, and responsible for Clinical and Pharmacy Services. Dr. Higgs was invited here today to discuss the prior authorization process for Hepatitis C medications and will start by going over the various necessary forms.

Ramsell started working with the Nevada OHA in the fall of 2017. Ramsell manages Nevada's network of Pharmacies and works together with Thomas Blissett and his team on claims adjudication processes and data management. Ramsell was founded in 1964 by a Pharmacist, then incorporated in 1966. They got started in ADAP administration when San Francisco County reached out to them for a solution as they attempted to redistribute patients across the city. There was a situation where all patients were getting their meds at San Francisco General, and the County wanted to make access easier for them. From there, Ramsell has managed several programs, and currently manage 12 ADAPs of various sizes and all doing slightly different things, so they do have a lot of experience in managing ADAPs. Ramsell considers itself to be a "solutions" provider meaning that claims adjudication and PBM services are part of what they do, but they also provide support with premium payments. They also provide patient portal support and medication therapy management solutions in some states. They do more than just the typical Pharmacy Benefit Management service.

Our goal in having a prior authorization process is to determine the appropriateness of covering the medication, particularly those with high cost or those that you might have additional concerns about use, and we want to get in front of dispensing to do that. We will work together with the program and with the Medical Advisory Committee to ensure that the criteria that are set to meet your needs. If you have established criteria perhaps for another drug, we can help you apply that process to ensure that your criteria are being met, and the appropriate patients are receiving those medications.

The prior authorization is a perspective tool for utilization management, and it also helps you regarding budget flexibility. In the prior authorization process, you can even tell Ramsell you want to place a cap – perhaps based on your budget (i.e.: on the number of patients) because Ramsell is also tracking the number of patients that are receiving product at any given time or "X" number of patients over a fiscal year.

The Supplemental Form –The top of the form includes basic information, the name of the provider and the pharmacy to be used to fill the prescription. The following sections talk about your criteria, talk about what supporting labs or chart documentation will be expected and required for approval or consideration of a request. The intent is not to make this overly burdensome on prescribers, but we do want to make sure there is enough information to make an assessment for that patient. (Genotype, prior history, CBC, Viral load information, etc.)

Moving on to the section “Please Confirm the following Statements” asks the prescribers to acknowledge that the patient is on a stable ARV regimen and acknowledge their viral load, and to let us know if they are coming for treatment because the patient has failed multiple trials of ARV therapy due to advanced liver disease. This again helps in the appropriateness of the choice of therapy. At the end of the treatment period, we ask them to agree to submit results after treatment, so the program has access to information about whether their patients have been cured of their ailment. We also ask that providers acknowledge that they have reviewed their patients’ regimen for drug-drug interactions with the medications that are being prescribed. The last box indicates the documents that will need to be provided to Ramsell.

When asked how to go about getting help with treatment guidelines (for doctors who may not have a large number of HIV/AIDS patients in their practice), Dr. Higgs said that the Instruction Document gives a reference for treatment guidelines and that there is also a phone number listed on that document as well. The last section of the document is just a check sheet, so they can be sure they have completed everything before sending it all in.

Dr. Higgs talked briefly about the Clinician Notification form and how important it is to get all information filled in, so everyone will get notified once approval has been made. This goes to the prescriber, so it is important to get the phone numbers and the fax number for the prescriber and the pharmacy as well so that Ramsell can send the notification to both places at the same time, so everyone is aware. Based on the regimen Ramsell will be able to determine what the start date and end dates should be, and if eligibility requirements were met.

The Claims Authorization form is completed by the pharmacy. The pharmacy will give Ramsell information such as their identifier, MPI number, patient ID, more specifics about the drug, the prescription number, and if there is a co-pay amount. Ramsell will issue the pharmacy an approval to bill, and it will be a long-term approval based on the treatment regimen.

Ramsell will stay in contact with the provider via e-mail and provide updates on each prior authorization form. Often there is a 24 hour turn around period if Ramsell gets all the information needed. Prior authorizations for Hepatitis C medications will take longer, roughly 48 hours.

Dr. Fuller: Thomas, what does the committee need to do to move forward with this?

Thomas: The OHA will be moving forward with this prior authorization process. If there were any objections, we could make revisions based on the committee’s comments and expertise. Discussion ensued regarding the possibility of a wait list and transition from ADAP to Medicaid as secondary insurance coverage.

Dr. Higgs: Final versions of the documents in the presentation will be converted into writeable PDF forms so that it is just a matter of checking a box and typing in the information by the prescriber. The forms are made available on the Ramsell website for easy access. Fill in the form electronically, print it off, get the prescriber signature, and then faxed it to Ramsell. Electronic signatures are not allowable at this time.

When asked if the committee was setting the criteria or if they are using pre-existing criteria, Thomas said he and Tory are presenting what they want, but if MAC members see something in this proposal, they want to modify, those suggestions will be taken into consideration.

Hearing no objections, the committee will move forward with the prior authorization process presented by Ramsell.

6. Review and Update ADAP Formulary

Recommendations to add/delete medications to the formulary – *Dr. Dennis Fuller, Chairperson*

Hepatitis C medications: Dr. Fuller asked the committee if there was any objection to adding all currently available Hepatitis C medications to the formulary effective January 1, 2019. Dr. Fuller asked for a motion to add all currently available Hepatitis C medications to the formulary effective January 1, 2019; new Hepatitis C medications will be added to the formulary based on approval by the committee. Dr. Cade made the motion, Dr. Sugay 2nd. As there were no objections, the motion moved forward.

Trogarzo: Monthly medication cost is right at \$5,000 per month, this is not including other costs incurred to administer the drug in an outpatient setting. Thomas said this medication will go on the formulary, as HRSA requires it because it is a new class of medication, and ADAP formularies are required to have one drug from each medication class, and since this is the only drug in its new class it must go on the formulary. Thomas said he will get the final recommendation from HRSA, but he will wait so the committee can iron things out. Thomas will talk to Ramsell about putting in a prior authorization, and then Ramsell will need to speak with the Medical Advisory Committee. Dr. Fuller suggested tabling this conversation until the committee can investigate it further.

Next was Egrifta, which had previously been tabled. Dr. Fuller directed everyone to their handout packets for information regarding this medication. At this point, Dr. Fuller introduced Duane Hadley, Director of National Accounts for Thera Technologies whose company makes both Egrifta and Trogarzo, who spoke under public comment (see Item #7). After the presentation by Thera Technologies, Dr. Fuller asked the committee for their thoughts. Discussion ensued. Someone suggested tabling this until more criteria could be factored in, i.e., Cardio-Vascular risk, age, regimens involved. Everyone agreed to table it for now for more medical review.

Diabetic Medications After review and discussion, Ivy Spadone made a motion to add the Lantus Solostar pen, Novolog Flexpen, lancets, needles, glucose level testing machines, and test strips for insulin-using patients to the formulary as of January 1, 2019. Dr. Zell 2nd the motion. There were no objections, and the motion moved forward. Ivy Spadone motioned to add all oral anti-diabetic medications to the formulary upon approval. Dr. Crumby 2nd the motion. There were no objections, and that motion moved forward.

Prednisone had been on the formulary and then taken off. After a brief discussion, Dr. Mapleton made the motion to add it to the formulary upon approval, and Dr. Cade 2nd. There were no objections, and the motion moved forward.

Medications for Deep Vein Thrombosis

Dr. Fuller asked if we should consider these in the future (rather than today) due to the cost. Discussion ensued. Dr. Fuller took Chair privilege and decided to table this discussion until next the meeting due to time and budgetary impact.

Birth Control

Dr. Bleak said that the Southern Nevada Health District Family Planning Clinic uses all forms of birth control, but is switching over from an Ortho product to a branded generic equivalent for oral birth control. He said the formulary would be fine with just a handful of the drugs on the proposed list, (one of each type of oral birth control: monophasic, triphasic, biphasic, and progestin-only), which should be based on cost.

Dr. Fuller asked members if they could go forward based on cost only. Discussion ensued.

Tory Johnson said the committee could go forward based on cost.

Dr. Fuller started to call for a motion and 2nd when Thomas spoke up to say that cost fluctuates each month according to market value. With that in mind, Dr. Fuller suggested the cost could then be based as of January 1, 2019, with the contract length being one year. After further discussion, Dr. Zell made the motion to add one medication of each oral birth control category (Monophasic, Triphasic, Biphasic, and Progestin-only) based on cost as of January 1, 2019, with a contract length of 1 year. Dr. Crumby 2nd the motion. There were no objections, and the motion moved forward.

7. Public Comment – Dr. Dennis Fuller, Chairperson

Duane Hadley said he is more involved in the commercial sales side of things but did want to introduce himself in the events that the committee had questions for him. He went on to introduce the medical liaison for Thera Technologies with him. The medical science liaison then spoke about the concern of cancer risk for in-patients using Egrifta specifically because of the increase of IGF1. She explained Egrifta does stimulate growth hormone production and everything that entails and went on to say malignancy risk is unknown. However, the manufacturer suggests hormone levels should be monitored closely during Egrifta therapy. She stated that at week 52, human growth hormone production percentage rates dropped as the body acclimates to the therapy and in the cyclical studies the incidence of cancer was not significantly different between the Egrifta group and the placebo group. She went on to say in April of 2018 studies were halted as the FDA said labeling was sufficient to address safety concerns.

8. Adjournment

Motion to adjourn the meeting was made by Ivy Spadone. Dr. Crumby 2nd the motion and the meeting adjourned.