HIV/AIDS MEDICAL ADVISORY COMMITTEE (MAC) MEETING MINUTES

December 17, 2021
1:11 PM

-- DRAFT—

Microsoft Teams Teleconference

COMMITTEE MEMBERS PRESENT:

Alireza Farabi, MD, UMC Wellness Center
Dennis K. Fuller, Chairperson, PharmD, Clinical Pharmacy Specialist, HIV/AIDS, AAHIVP, UMC Wellness
Mark Crumby, Vice Chairperson, PharmD, BCPS, Director of Pharmacy Northern NV HOPES
Paul M. McHugh, MD, UMC Wellness Center
Steven C. Zell, MD, AAHIVS, University
Jan Richardson, RN, UMC Wellness Center Manager
Tory Johnson, MMgt Section Manager
Dino J. Gonzalez, MD, AAHIVM, Community Physician, Southern Region
Jerry L. Cade, MD, UMC Wellness Center and Southwest Medical Associates, Inc.

COMMITTEE MEMBERS ABSENT:

Charles G. Krasner, MD, Vice Chairperson, Northern NV HOPES
Rosanne Sugay, MD, UMC Wellness Center
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
Miguel Forero, Department of Corrections
Ivy Spadone, MS, PA-C, Northern NV HOPES

DIVISION OF PUBLIC AND BEHAVIORAL HEALTH STAFF PRESENT:

Tory Johnson, MMgt, Office of HIV, Manager
Michael Thomas Blissett, HPS I, Aids Drug Assistance Program (ADAP) Coordinator
Vanessa Caceres, Program Officer I
Xhosha Millington, Health Resource Analyst I
Sarah Cohen, Office of HIV, NMAP Coordinator
Pierron Tackes, Deputy Attorney General

1. Call to Order, Roll Call, Quorum was met – *Section manager*

2. Public Comment – *Dr. Dennis Fuller, Chairperson*
Dr Fuller suggested skipping public comment until the end in order to approve draft minutes from March 9, 2021. Pierron Tackes, deputy attorney general, stated that public comment can only be skipped if included on each action item. She thought this was the only action item on the agenda. Suggested public comment period be held at the end of each item. Dr Fuller agreed. Stated that they wanted to move to corrective actions first.

3. For Possible Corrective Action**:** Due to technical difficulties, march 9th meeting has been inadvertently lost. As a result, action taken during the March 9, 2021 meeting is deemed void. Pursuant to NRS 241.0365, corrective action must be taken by the committee to reconsider the two action items present at March 9, 2021 meeting.

   a. For Possible Corrective Action: Review and Approval of the March 9, 2021 draft minutes – *Dr. Dennis Fuller, Chairperson (For possible action)*
   Motion to Approve: Dr. Steven C. Zell Motion 2nd: Dr. Jerry L Cade All members agreed.

   b. For Possible Corrective Action: Discussion and possible action to recommend the addition of Cabenuva to the AIDS Drug Assistance Program (ADAP) Formulary – *Dr. Dennis Fuller, Chairperson*
   Deputy Attorney General Tackes reminded of need for public comment. Dr Dino Gonzalez stated his concern over the cost of administering the new treatment. Suggested that a mechanism be put in place that not everyone be switched to Cabenuva in order to keep costs down. He was informed that decision had been made to not restrict providers on deciding what is appropriate. Was suggested to start with no restrictions before moving to add restrictions as needed in the face of potential pricing issues. Also pointed out that Cabenuva was only $40 difference with many current treatments so price difference is not an issue. Dr Gonzalez retracted his concerns at that.

   Tory Johnson, brought up that bylaws state there is a stipulation that any drugs approved by the FDA are to be automatically added to formularies unless the price of the drug is 15% more or less than the top drug in use. Two other drugs used as comparison, does not violate this. Only reason it has not been added to the formulary is due to try to making sure that a safe administration policy is put in place. Will probably borrow from California model and roll out in phases.

   Dr Fuller stated he felt this was an important enough drug to push it to get added to the formulary and work with distributors to get it into circulation.

   Sarah Cowan stated that it is not hard to add to the formulary. Difficulty is that not everyone has it on their own formulary or even know that Cabenuva exists. Also, Cabenuva requires specific environmental situations in order to be safely stored. Working to find the best place to use as administration site for new drug.

   Tory stated that there are two known clients using Cabenuva, being administrated through UMC. Able to get due to having reached their out of pocket maxes. Working with Patient Access Program in order to ensure continued access to the drug. Currently having discussion with using Walgreens due to it being an injectable site, though previous opinion of the committee was not positive. At least for the South. North currently using HOPES who has started to administer Cabenuva.

   Sarah continued that current PBM, Ramsell, not a lot of states have added Cabenuva due to administrative issues. Currently working towards new PBM, so hoping to get it on formulary time new PBM added. July was stated goal as long term addition.

   Steve Zell stated that the drug is used for people who are suppressed, already on treatment plans that are working. No reason to rush approval and best to ensure safe administrative site before opening up.

Dr Cade added that first patient he had treated with Cabenuva had difficulties with oral treatment. Due to necessity of high viral load and low T Cell count he waived 28 Day oral lead in so client could get needed treatment. Stated that viral load now undectable.

Sarah pointed out that to be added to formulary as form of treatment, treatment plan must be FDA approved. Only FDA approved plan for Cabenuva requires 28 day oral lead-in. Moving straight to injections is not FDA approved at this time.Dr Cade clarified that it was done due to being only way to treat client. Also stated that need for oral lead-in will be waived by FDA in the next year. Sarah asked for further clarification as FDA testing stated that oral lead-in was necessary. She expressed concern regarding violation of by-laws on what and how to add drugs to the formulary.

Dr Cade stated that was in order to prevent potential side effects. That oral lead-in was not necessary for Cabenuva to be effective, just to prevent potential issues which was why the FDA was going to waive requirement in the future.

Tory asked if client is on Cabenuva. Dr. Cade clarified that he worked with another program to pay for it due to medical necessity. Tory expressed the hope that a drop date of July 1st, but if possible planning to add it to formulary sooner due to cost factor associated with administration.

Dr Cade asked Dr Fuller if a vote was now needed. Dr Fuller expressed his concern regarding the further delay in adding Cabenuva to the formulary. That despite extenuating circumstances, it has not been more speedily added. Wanted something put on paper to stress that providers want this drug added.

Dr Gonzalez then asked if it was possible to add Cabenuva to the formulary now while deferring to individual sites to work out delivery method. With additional acknowledgement, that work would be done to figure out best practices to help clients.

Tory stated that if it is added to formulary then PBM requires immediately assisting clients in helping to pay for drugs. So delay is to help deal with associated costs before adding. Sarah further clarified that they are working on it, and that UMC wellness does administer it and is able to store it. They are currently the only one with the capabilities, and are striving to get additional injection sites created.

Dr Fuller asked about potential for sites and providers being added in waves rather than all at once. Tory stated that the MAC can advise and put it in writing, but would then go to the state Medical Director for approval and logistics. Advantage of July 1st date is to either create independent injection site, or to work with providers to help create multiple sites including clients that are not necessarily their clients.

Addendumt to motion: Cabenuva added to formulary no later than July 1st, 2022.
Dr. Jerry L Cade (For Possible action)
Dr. Dennis K Fuller extened time for public comment. No comment made.
Motion to approve: Dr Jerry L Cade Motion 2nd: Dr Steven C Zell. All members agreed

4. For Discussion Only**:** HIV/AIDS Medical Advisory Committee (MAC) Updates: retirement of Dr Paul McHugh and departure of Dr Shawn Mapleton – *Dr Dennis Fuller, Chairperson*

   Dr McHugh has retired from UMC. Dr Mapleton has expressed concerns about being able to continue as a member of the MAC Committee. He has tendered his resignation. Tory mentioned Jan Richardson, nurse from UMC stepping away. No established replacement at the meeting. Dr Crumby no longer with HOPES, so has been removed from the committee and is no longer co-chair.

5. For Discussion Only: Select Health Insurance company decision to cover Biktarvy no longer on their formulary as of January 1, 2022 – *Dr. Dennis Fuller, Chairperson* – Dr Rosanne Sugay and Tory brought up that Select Health is dropping Biktarvy from their formulary. Attempted to have meeting

with Select Health regarding prior authorization but that never happened. Then heard it was dropped from SHI formulary, reached out to Nevada Division Insurance, SHI stated they were still offering similar drugs that were in the same class, but have chosen not to cary Biktarvy specifically. Tory suggested that they work with those clients on Biktarvy to switch coverage in order to make sure they get to keep their doctors and medication.

Silver State Equity Director reached out to Tory to see if there was anything that could be done. Because everything was working in real time, Tory was working with clients to get them on new insurance for ease for clients. Dr Fuller asked why this was happening as early as September, Tory did not have an answer because SHI was not providing any answers.

6. For Discussion Only: - Ryan White Part B Program Update – Tory Johnson, Section manager, Office of HIV/AIDS

   Tory clarified that Part B grant is around $2m, but that costs are $4m to $6m thanks to rebates. Recently multiple 340b entities were dispensing their medications to NMAP clients have caused a reduction in rebate income for RWPB, grant year started with $5m deficit. Covid money was provided in order to keep additional programs moving. Supplemental funding has been applied for. If any programs need to be cut, Tory said it would be done in a way to maintain medical access for clients. Possible that cuts will have to happen if changes to funding are not made. This also impacts ability to fund Cabenuva. There was no additional questions or comments from the committee

7. For Discussion Only: Speaker from Nevada Medicaid to discuss about Silver State Scripts Board (SSSB).

   Tory introduced David Olson, Pharmacy Services with Healthcare Financing and Policy. RWPB did not Pharmacy Benefit Manager, Magellan, with a go live date of July 2022. Departments wanted to streamline processes including advisory committee. Working towards SSSB, and working with Medicaid for advisory committee. Goal is to dissolve MAC and adapt SSSB where MAC members can join.

   Plan is to have SSSB work as the advisory committee for Medicaid and WRPB. Made up of physicians and pharmacists, and additional people can be added. David gave his e-mail for those interested to be able to apply to join the board: rxinfo@dhcfp.nv.gov
   David clarified that details are still being made regarding scope of SSSB. Intended to be advisory level influence. Tory asked if there was an application. David clarified that there is a flyer, but no actual application beyond CV or resume.

   John Phoenix asked about advisory committee limitations on positions allowed to apply. David said that he was unaware of any, such as they need to be a physician or pharmacist. John stated he was an advanced practitioner, Physician's Assistant, which was provided a great deal of the care for patients.

   Tory stated that the goal was to make Medicaid's formulary NMAPs since it covers more medications. It ties into the goal of getting even more people on insurance to help provide needed medications.

8. Public Comment – *Dr Dennis Fuller, Chair Person*
   John Phoenix wanted to provide some context regarding SHI and Biktarvy. Trying to talk to them about access and stigma and wanting to prevent this as setting a prescedence in order to prevent future dropping of medications.

9. **Adjournment**
   Dr. Fuller called for a motion to adjourn. Dr Cade provided motion and a 2nd provided. All agreed and the meeting adjourned. – Meeting concluded approximately 1:55 pm.