

ADAP Medical Advisory Committee

October 20, 2021 Meeting Notes

1) Welcome and Rollcall

- I. Welcome:
Meeting opened by Sharisse Kemp, ADAP Branch Chief
- II. Introductions:
MAC Members, CDPH and Magellan introduced themselves

MAC Members in Attendance

Stephen O'Brien, Michelle Sherman,
Danny Toub, Lucas Hill, David Grelotti,

Laveeza Bhatti, David Lewis, Wilbert
Jordan

MAC Members not in Attendance
Jennefer Yoon

Magellan Representatives in Attendance

Jason Eugenio, Carrie Holden

Magellan Representatives not in Attendance

Eric Brundige

CDPH/Office of AIDS staff in Attendance

Philip Peters, Sharisse Kemp, Marisa
Ramos, Becca Parks, Chris Unzueta,
James Vo

CDPH/Office of AIDS staff not in Attendance

Ann Nakamura

Update from MAC Members:

James Vo, ADAP Formulary Specialist, announced:

New MAC members were selected, and their terms will begin in 2022

Cliff Okada

Arlet Arratoonian

Glenn San Agustin

Joanna Eveland

David Lewis: Was there any effort made to reach out to the councils for community members?

Dr. Peters: The efforts for this recruitment primarily focused on professional members and we weren't sure what the interest would be or if we would receive high quality candidates. We were surprised with the amount of interest and with the high-quality candidates. We concluded that we would need to recruit community advocate through Part A planning councils and advertise to get high quality people to apply as community advocates.

Sharisse Kemp: We want to have more community members on board, mirror recruitments for our community planning groups, and make sure recruitment information is distributed at the Part A planning council meetings to folks who

may not know about the MAC and we will start a separate effort to recruit community members.

2) ADAP / MAC Updates

I. COVID-19 vaccines:

Dr. Peters announced:

We are currently following everything that's been happening with COVID vaccines. The Pfizer vaccine received FDA approval and although the cost is free of charge at this point, we were using FDA approval of the COVID vaccine as the indicator of when we will bring the vaccine on to the ADAP formulary. We have started a Director's Approval Request to add the vaccines to the ADAP formulary. At this point it is not expected to incur any cost, but we may assume at some point the cost for COVID vaccines will revert to health care charges. So, we wanted to have it on the formulary and have it ready before this happens. A Dear Colleague letter went out on October 13, 2021 on influenza along with an FAQ, trying to reemphasize the importance for people to also get their influenza vaccine this season and reviewing information that influenza and COVID vaccines may be provided at the same time.

Stephen O'Brien: Issue of COVID vaccines is the injection fee, which is the professional fee. Will you allow the pharmacy to charge this fee, or will this be an all-inclusive fee for the COVID vaccine?

Dr. Peters: Right now, the process is an all-inclusive fee at the pharmacy. ADAP, unlike Ryan White, does not allow for those professional fees and it's been limited to pharmacy benefits. With Cabenuva being approved, we have looked at different methods for reimbursing professional fees. Chris Unzueta will review some ideas on how those professional fees will be reimbursed similar to injectable ARVs but potentially could create a mechanism for other types of injection services.

II. Medications added to the ADAP formulary

Dr. Peters announced:

There were several medications added. We've added a few medications that are used and recommended for gender affirming hormone treatment regimen: 17B estradiol, dutasteride, finasteride and spironolactone all added to the formulary. These medications were added on August 6, 2021, and a Management Memo on August 18 was distributed. Anecdotally, we've received some positive feedback from people who notice the additions and we plan to advertise and promote to make sure people are aware of these medications added to the formulary.

In addition, there were a number of medications added for mental health including clonazepam (Klonopin®), duloxetine (Cymbalta®), escitalopram (Lexapro®), and hydroxyzine pamoate (Vistaril®); additional options to treat major depressive disorder and anxiety disorder. This came from a number of presentations from our former Magellan pharmacist, Kristen, who was reviewing mental health medications and where the gaps were in ADAP coverage. These medications were added on July 30, 2021 and a Management Memo went out on August 18.

Wanted to highlight two other categories discussed at MAC meetings that were still actively being worked on and still in process that are not forgotten. Working through the cost analysis and approvals, these include medications that were reviewed for hypertension treatment and diabetes treatment. Hopefully in the January 2022 meeting, we will have a more thorough update.

Stephen O'Brien: For the controlled substances, narcotics, and the opioids and the benzodiazepines that are on the formulary, what type of special monitoring does ADAP do, and Magellan do? Are you looking for high utilizers, are you giving any reports back to providers or looking for inequities or disparities in the distribution of those controlled substance medications?

Dr. Peters: We conducted an initial review of utilization of benzodiazepines and opioids. Other than that initial review, there's no monitoring process that's currently in place but there is a drug utilization review process that can be done. It's been focused more on utilization of antiretrovirals and gaps in people's antiretrovirals therapy, but there may be a possibility to look at benzodiazepines and opioids, and in situations where there is high utilization to outreach to physicians.

Dr. Peters: Would the MAC members be supportive of figuring out a process for high utilization of controlled substances? We may pursue a little bit more vigorously. Magellan has a good handle on the data which may be possible to leverage.

Stephen O'Brien: Glad that the medications are on the formulary so people may access them, but we have a responsibility for monitoring utilization. Nervous that the monitoring of these controlled substances is taking a big step back in the middle of an opioid epidemic. So, there is a concern but also understand that there is limited staffing ability.

Jordan Wilber: If there are limited staff, it's fair to hope they are monitoring opioid use more than antiretroviral use.

Michelle Sherman: When prescribing control substances, are they checking the CURES data base before writing the prescriptions? The pharmacies that are dispensing these should be checking CURES.

Dr. Peters: It is certainly best practice, but we don't monitor in that level of detail what people are doing in their individual practices. If people are identified and there was a threshold in place and utilization above that threshold then at a minimum there would be outreach to review that the best practices are occurring, and efforts being made to look for alternatives. Maybe these are the only regimen that are going to treat this person's particular chronic pain or mental health condition or a combination, but the provider should be doing everything to look at the alternatives as well. It's possible to see multiple prescriptions within ADAP but it is also possible there could be multiple prescribers outside of ADAP. So, this is something people must monitor for best practices especially when prescribing higher doses.

Lucas Hill: If there is a way, kind of like a nudge but if you have coverage limits for amounts of control substances that are above what people might think of as best practice, maybe require a prior authorization to flag that prescription and not necessarily cover it but have folks going through a thought process in justifying why prescribing above best practices is warranted in this case?

Dr. Peters: Propose we will circle back with Magellan and look at this process called Drug Utilization Review that's currently looking at inappropriate ARVs and see if that can be refocus on opioids and benzodiazepines use. This has definitely been an interest of ours and at our January meeting we could present initially on what we are seeing and what we might be able to do, and we could explore this idea of some kind of flag or nudge or prior authorization that gets triggered at a high level of use as a check for providers to indicate that everything is being done at this high level of

use and if there's not then we will think of some resources we could steer people towards. Peer to peer consultations that may encourage people, trying to think of alternative strategies for the treatment they are providing.

III. Medications removed from the ADAP formulary

Dr. Peters announced:

There were no medications removed from the formulary since the last ADAP MAC meeting.

Update on the Medications Discussed During the April 2021 MAC Meeting

Dr. Peters announced:

Chris Unzueta will provide an update on Cabenuva and where we stand with adding the medication to the ADAP formulary:

Chris Unzueta announced:

Cabenuva was added to the formulary on October 8, 2021. The enrollment workers were informed through a Management Memo. One thing to note, we are working on rolling out Cabenuva in phases. So, phase one was rolled out and we are only covering the cost of the medication, only copay. We are not covering the cost of the administration just yet. We are working on covering the cost of the administration, with our contractors Pool Administrators Inc. (PAI) and Magellan Rx, which would be phases two and three. For Magellan Rx, when Cabenuva billed as a pharmacy benefit, we're working with Magellan to have that covered and billed to Magellan, that way we would have no cost to the administrative portion. When Cabenuva is billed as a medical benefit and the client has insurance, our contractor PAI will be covering the reimbursement when claims are submitted.

Phase one, the administration portion is covered if the client is enrolled in one of our insurance assistance programs, OA-HIPP, EB-HIPP or Medi-Cal Part D premium payment program, the client submits a claim for Cabenuva when it's billed as an outpatient expense, then they may submit that claim over to PAI and PAI will work with the provider for reimbursement.

Dr. Peters: We are really pushing for people who are ADAP-only to really consider moving into a comprehensive healthcare plan, a lot of the limitations relate to people who are concerned because of their immigration status. Although there are mechanisms where people can go through a non-covered California plan mirroring the benefit of an ACA

plan and enroll despite their immigration status with ADAP copay but there are a lot of fear and trauma related to public charge. It's not a simple process but we are trying to increase the number of people who are using their ADAP benefit to get comprehensive healthcare rather than just the medication coverage for ADAP only.

Lucas Hill: Related to patients who have a commercial insurance plan, and the plan rejects at the pharmacy saying it's not a pharmacy benefit that it's a medical benefit. For those patients who have secondary ADAP, is it ok to bill Cabenuva as a pharmacy benefit directly to ADAP at that point because the primary insurance does not cover it as a pharmacy benefit?

Chris Unzueta response: For those claims it will go through our contractor PAI, but it will be billed as a medical benefit, that's when ADAP will assist with any copays they may have with the administration of Cabenuva.

We are hoping to have a holistic approach with covering both as a pharmacy benefit and medical benefit, that way clients aren't left stranded, and we are able to absorb the cost.

3) Medication Discussion

I. New ARVs that have received FDA approval:

Dr. Peters announced:

There were no new FDA approved antiretroviral medications in the last six months since we've met so we don't have anything to vote on.

Lucas Hill: We may potentially see the approval of Lenacapavir prior to the next January meeting, will it likely be reviewed during the January meeting?

Dr. Peters: If it's approved before the January meeting then it will definitely be on the agenda and discussed. We could tentatively put Lenacapavir on the agenda pending approval. In some situations, if there is an urgency to get a medication on to the formulary, we've had an ad hoc reach out to MAC members to vote on something in between meetings.

Danny Toub: Would this apply for Cabotegravir for PrEP?

Dr. Peters response: Fortunately for PrEP, because we've added Cabenuva to the ADAP formulary we already have approval from our agency to bring the medication on to the PrEP formulary. This is something that could be discussed but fortunately it could be done quicker, and it wouldn't have to go through the same

approval process, cost analysis and approval through agency that often takes a little more time.

4) Opportunistic Infection Treatments

Public Comment:

There was no public comment recorded

Dr. Peters announced:

Thank you to Lucas Hill for reviewing the formulary and bringing two medications to our attention: Primaquine and Rifapentine.

Lucas Hill: Primaquine, there was a patient that could not use the alternative and was on ADAP but realize Primaquine was not on the ADAP formulary. Seems like something that should obviously be there for opportunistic infection treatment. Rifapentine was another alternative option for Latent TB treatment.

Dr. Peters: Magellan reviewed the data from the past few quarters for the request of use on these two medications. Not a high volume but there were a few instances where people have requested use and bill the medication but rejected. These medications will have no impact on the ADAP budget if we were to add.

The MAC members agreed that it would be a good idea to add Primaquine and Rifapentine on to the ADAP formulary.

David Grelotti had interest in reviewing beyond oral contraceptive options, there is an update related to this but our pharmacist from Magellan, Kristen Haloski, has been promoted to a higher position within Magellan. She started to put together the information, but the new person has just joined the team and we thought it would be a little early to ask for a presentation at this meeting but at our meeting in January, we will be putting this on the agenda for non-oral contraceptive options and how those might work with the ADAP formulary.

Danny Toub: What about the other COVID-19 treatments?

Dr. Peters: We will add this to our January meeting as well as, a review of what is currently FDA approved, what has an authorization, and what might get approved in the future. All of these treatments are being covered right now but similar to the vaccines, we may anticipate eventually that federal coverage will revert back to the regular billing system.

Lucas Hill: Is it in the scope of this meeting to recommend additions to the PrEP-AP formulary as well because meningococcal vaccines were not on the PrEP-AP formulary?

Dr. Peters: Before we moved to these formal meetings, there was an agenda item for PrEP-AP but the committee's work was getting a little

conflated with keeping track of what is on the PrEP-AP formulary and ADAP formulary. The last few meetings were focused on the ADAP formulary. This is an agenda item that we will bring back to provide an opportunity for any to make recommendations of medications to be added to the PrEP-AP formulary.

Marisa Ramos: Another reason the PrEP-AP formulary is not discussed at this meeting is because by statute, this committee is only for ADAP formulary voting on ARVs however, we could discuss the PrEP Assistance Program but there will be other mechanism to go through to add medications and it will also depend on cost. A little different process but there is no reason we can't discuss or bring up what you think would benefit our clients in the community.

James Vo: meningococcal vaccines were added to the PrEP-AP formulary on October 8, 2021. The management memo is circulating internally for approval and anticipate distribution sometime in early November.

David Grelotti: Premature, but later today, the AEIC will be voting on PCB15 and PCB20 so this may be something we keep an eye on depending on what the AEIC recommends.

Dr. Peters: In our interpretation, if we have a class of vaccines that's approved, or a new version of the vaccine gets approved then we would be allowed to bring it on to the formulary presuming there would be an indication for people with HIV to receive some of those new vaccines. Relatively straight forward process.

5) Magellan Rx Presentation

Jason Eugenio announced:

Kristen Haloski was promoted to a new position and the new pharmacy representative from Magellan that will be taking over Kristen's duties will be Carrie Holden.

6) Close of Meeting

Sharisse Kemp announced:

Next ADAP MAC meeting is scheduled for January 19, 2022 from 7:30 a.m. to 9:00 a.m.