

ADAP Medical Advisory Committee

April 21, 2021 Meeting Notes

Welcome and Rollcall

I. Welcome

Meeting opened by Marisa Ramos, OA Division Chief

Introductions:

- Sharisse Kemp, ADAP Branch Chief
- Ann Nakamura, ADAP Fiscal Forecasting, Evaluation, and Monitoring Section Chief

II. Rollcall

Dr. Peters rollcall:

MAC Members in Attendance

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

MAC Members not in Attendance

Jennefer Yoon, Laveeza Bhatti, David Lewis

Magellan Representatives in Attendance

Kristen Haloski

Magellan Representatives not in Attendance

Jason Eugenio, Nicole Quackenbush

CDPH/Office of AIDS staff in Attendance

Philip Peters, Sharisse Kemp, Marisa Ramos, Becca Parks, Ann Nakamura, James Vo

CDPH/Office of AIDS staff not in Attendance

N/A

1) ADAP / MAC Updates

I. Medications Added to the ADAP Formulary

Dr. Peters announced:

- COVID-19 vaccines
 - As discussed in the last MAC meeting, CDPH is following the status of the COVID-19 vaccines closely. At this time, these vaccines are approved for use under an emergency use authorization and the cost of these vaccines is being completely covered by the federal government through the Provider Relief Fund from HRSA. We expect at some point these vaccines will receive full FDA-approval and we will move to add the COVID-19 vaccines to the ADAP formulary at that time.
 - Question, Stephen O'Brien: Currently insurance companies are not being charged for the vaccine, but are paying for the administration fees to the clinics and other places that are billing for the vaccine, will ADAP be assuming this role at any point?
 - Dr. Peters response: A good topic to put on the agenda to discuss for the next MAC meeting. For people who have ADAP only coverage with no other comprehensive insurance, ADAP has been covering vaccinations but not a separate administration fee for the pharmacist or provider. It was interpreted that it may not be an allowable expense for ADAP, but we are currently looking at this again. This is something that would impact all vaccines and we

don't have the reimbursement mechanisms built in for the ADAP-only coverage.

Dr. Peters announced:

- There were a number of medications added since the last MAC meeting. We've added medications to treat substance use disorder as well as some symptoms of withdrawal to the ADAP formulary. The formulary now includes:
 - buprenorphine/naloxone (Bunavail[®], Suboxone[®], Zubsolv[®]) and buprenorphine (Subutex[®])
 - naltrexone (ReVia, Vivitrol[®]) – both oral and long-acting injectable versions
 - disulfiram (Antabuse[®]) and Acamprosate (Campral[®])
 - baclofen (Lioresal[®]), clonidine (Catapres[®]), ondansetron (Zofran[®]), topiramate (Topamax[®], Qudexy[®]XR).
 - In addition, we have also added Amoxicillin/clavulanic acid (Augmentin[™]) to the ADAP formulary as another antibiotic option to treat community-acquired pneumonia.
 - Finally, Capsaicin (Qutenza[®]), tramadol (Ultram[®], Ultram[®] ER, Ryzolt[®]) and pregabalin (Lyrica[®]) were added to the ADAP formulary to treat people with HIV who are experiencing chronic pain.
- All of these medications were added to the ADAP formulary as of February 22, 2021.

II. Medications Removed from the Formulary

Dr. Peters announced:

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

III. Update on the Medications Discussed During the January 2021 MAC Meeting

Dr. Peters provided the following updates:

- As you know, on January 21, 2021 the U.S. Food and Drug Administration approved long-acting, injectable cabotegravir and rilpivirine (brand name: Cabenuva) and the oral lead in medications as a complete regimen for the treatment of (HIV-1) infection in adults and the MAC voted to add this medication to the ADAP formulary. In April 2021, the AIDS Crisis Taskforce finalized an agreement of the pricing for this medication on behalf of the ADAPs nationally. Now that the price has been finalized, we have requested approval to formally add long-acting, injectable cabotegravir and rilpivirine to the ADAP formulary and expect that will happen soon.
- This medication will not have a prior authorization requirement.
- As you know administering this medication involves clinical costs including the fee to administer the injection and the fee for the monthly clinic visit. HRSA has allowed the use of ADAP funding to cover these clinical costs which is a new process for CDPH. CDPH is working with Magellan Rx on a process to cover these clinical costs and we are close to finalizing that plan which will be communicated to Office of AIDS stakeholders including members of the MAC.

- In other updates, ADAP received approval to add 17B estradiol, dutasteride, finasteride, leuprolide, and spironolactone to the ADAP formulary. These medications are the most commonly used and recommended gender affirming hormone-treatment regimens for transgender women. ADAP is moving swiftly to add the medications to the ADAP formulary.
- ADAP received approval to add the following medications to the ADAP formulary to treat major depressive disorders and anxiety disorders: clonazepam (Klonopin[®]) as a safe benzodiazepine option, duloxetine (Cymbalta[®]) as another serotonin-norepinephrine reuptake inhibitor option escitalopram (Lexapro[®]) as another selective serotonin reuptake inhibitor option, and hydroxyzine pamoate (Vistaril[®]). ADAP is moving swiftly to add the medications to the ADAP formulary.
- Hypertension and diabetes treatments have also been discussed at a prior MAC meeting and are being reviewed currently.
 - Question, Stephen O'Brien: for drugs to be added to the ADAP formulary does it need to be tied to HIV somehow and what is the bar or standard?
 - Dr. Peters response: The general guidance is that there are 3 tiers of medications and as the ADAP program runs with a fixed budget that each tier needs to be met in full before moving on to the next tier. The principle being that you try to cover all 3 tiers as fully as possible.
 - First tier: the medications for the direct treatment of HIV, antiretroviral are in tier 1. There are regulations that if a medication is in a new class that we need to bring onto the ADAP formulary. We have every antiretroviral that are clinically useful on the formulary.
 - Second tier: treatment for opportunistic infections, generally interpret this as using the Department of Health and Human Services opportunistic infection treatment guidelines. 17 different categories for opportunistic infections, CDPH continues to look for updates, although not as frequently as we would like, some of the treatments are not optimal for opportunistic infections.
 - Third tier: medications for comorbid conditions that are common among people living with HIV, so this is a very broad category. It is not necessarily having to be more common among people living with HIV than the general population but that might be a criteria to consider when considering an inclusion.

Looking at utilization for all the different categories of medications, the HIV medications specifically antiretroviral are driving the vast majority of the cost of the program. Tier three medications are vastly inexpensive and generic and when we review utilization we are seeing under utilization for comorbid conditions.

2) Medication Discussion

There were no new FDA approved antiretroviral medications listed for discussion during this meeting.

3) Opportunistic Infection Treatments

There were no opportunistic infection medications listed for discussion during this meeting.

4) Public Comment:

There was no public comment recorded.

5) Magellan Rx Presentation

I. Presentation/Discussion

o Oral Contraception

- MAC Members made a comment regarding:
 - clarification on no oral contraceptive medications currently on the ADAP formulary.
 - future presentations on exploring other contraceptive options (contraceptive patches, rings, IUD and emergency contraception)
 - bringing expert opinion to identify which types of contraceptive options would be optimal to bring on to the ADAP formulary.
 - having full support to bringing on contraceptive options as this has been an issue with women who are on ADAP.
 - getting feedback from patients on what their preference is, oral vs IUD. Maybe some types of research that would explore this and narrow down options.
 - being mindful of other options as Family Planning Program of CA has been generous and will cover contraceptive medications when enrolled in program.

- Dr. Peters response: we will explore both approaches, moving forward with adding medications to the formulary as many are generic and relatively cheap and bringing on expert opinion.

o Medications to treat Asthma

- MAC Members made comments regarding:
 - not having COPD medications currently on the ADAP formulary.
 - support of adding COPD medications to the ADAP formulary but wanted to point out that these are higher cost medications.

6) Close of Meeting

I. Announcement of July Meeting Date and Time

Next ADAP MAC meeting is scheduled for July 21, 2021 from 7:30 a.m. to 9:00 a.m..

Sharisse Kemp made a comment regarding the timeframe of next MAC meeting and to see if we have the optimal time set for these MAC meetings moving forward. MAC members will be sent a survey with different time options to see what works best for the majority.