New Jersey Drug Utilization Review Board
Meeting Transcript
July 16, 2025

Board Members:
Eileen Moynihan M.D.
Steven Marcus M.D.
Kristine Olson M.S., R.N., A.P.N-C
Linda Gochfeld M.D.
David E. Swee M.D., Chairman
Jihad Slim, M.D.
Thomas Lind, M.D.

Panelists:
Teressa Barringer
Reut Ghodsi
Zankhana Desai
Elizabeth Bailey
Ruchi Banker
Pinali Agrawal
Ruchi Banker
Edward Vaccaro

Attendees:
Valerie Barnes
Jim Musick
Aharon Levi
Elena Fernandez
Mary Fox
Adam Denman
Jim McCarthy
Steven McRae
Mark Walther
Jim Pitt
Adam Ferguson
Doris Chen
Dana Roman
Jenna Doerr
Theresa Cortina

Noah Greenberg
Andy Berg
Marilyn Gutierrez
Fredrick Bennard
May Fratantoni
Sherri Giorgio
Karen Franks
Jay Patel
Niki Hwang
Sam Currie
Genevieve Goslin
Samantha Williams
Mona Kripalani
John Addelman
Ashraf Sunesara
Timothy Brembos

Dr. David E. Swee: I am Dr. Swee. I am calling to order this meeting with the following official statement. In compliance with Chapter 231 of the Public Laws of 1975. Notice of this meeting was given by way of filings in the Trenton Times, Star Ledger and Atlantic City Press, among others.

Roll call. I'm going to go across my screen. I'm David Swee. I'm a family physician with an appointment at Rutgers, Robert Wood Johnson Medical School.

Kristine.

Kristine Olson M.S., R.N., A.P.N-C: Kristine Olson, nurse practitioner with experience in adult primary care and oncology and hematology.

David E. Swee M.D.: Okay. Dr. Slim.

Jihad Slim M.D.: Jihad Slim, infectious disease and assistant professor at New York Medical College, in Valhalla, New York.

David E. Swee M.D.: Steve Marcus.

Steven Marcus M.D.: Hi Steve Marcus, I am a retired pediatrician and a medical toxicologist. I still keep my hand in doing consultations and assorted stuff.

David E. Swee M.D.: Tom Lind.

Thomas Lind M.D.: Tom Lind, Medical Director for New Jersey Division of Medical Assistance and Health Services (DMAHS).

Thomas Lind M.D.: Okay.

David E. Swee M.D.: Linda Gochfeld.

Linda Gochfeld M.D.: I'm a psychiatrist working with many Medicaid patients, recently retired.

David E. Swee M.D.: Judith Barberio.

Judith Barberio PH.D., A.P.N-C: Hi! I'm Judy Barberio, associate professor at Rutgers, and a nurse practitioner in pain management, palliative care and substance use disorder.

David E. Swee M.D.: Eileen Moynihan.

Eileen Moynihan M.D.: Hi Eileen Moynihan, rheumatologist and also working with the Medicare program in the northern and western parts of the country.

David E. Swee M.D.: Okay, thank you. That's the full board, as other people talk will ask them to identify themselves at that time.

A review of the meeting transcript was distributed in advance and some of us made minor suggestions. It was very well done. Are there any additions, deletions, or comments from the Board at this time?

Hearing none. Is there a motion to approve?

Steven Marcus M.D.: So moved.

Linda Gochfeld M.D.: Second.

Judith Barberio PH.D., A.P.N-C: Second.

David E. Swee M.D.: Okay. Any further discussion?

Hearing none. All those in favor say, aye.

Board Members: Aye.

David E. Swee M.D.: Anybody opposed or abstaining? No.

Similarly, there was a draft meeting summary in the packet which was distributed publicly. Are there any additions, deletions or corrections for that document?

Hearing none, is there a motion to approve?

Steven Marcus M.D.: So moved.

Judith Barberio PH.D., A.P.N-C: Second.

David E. Swee M.D.: Okay and then that brings us to the secretary's report. Dr. Agrawal.

Pinali Agrawal: Okay. So, the State fiscal year annual report…

David E. Swee M.D.: Can you please officially identify yourself please, Pinali.

Pinali Agrawal: Pinali Agrawal, I'm the secretary to the Board and I work for Gainwell Technologies.

David E. Swee M.D.: Thank you.

Pinali Agrawal: So, the first item that I have is that the State fiscal year 2024 annual report is still being worked on and it's with the Commissioner's office. The second item is the April 2025 DURB recommended protocols were signed off by the Commissioners. These include the Protocol for Attention Deficit Hyperactivity Disorder for Children Less than 6 Years of Age, Protocol for Spravato and Protocol for Zepbound for Obstructive Sleep Apnea.

The next item is a follow-up on tianeptine that Dr. Marcus brought up during the last meeting. We confirmed there is no utilization within the Medicaid program for it. It's currently not an FDA-approved product in the United States. There is no national drug code that they could use to bill Medicaid.

Last item, we don't have any updates on the Board's vacant positions. That's all I have for the secretary's report today.

David E. Swee M.D.: Thank you. Any further questions for the secretary from the Board?

Hearing none, let's move on to the old business and that reminds me this was the other issue I wanted to talk about in advance. Is there another way of distributing or displaying some of these issues, because the bar graphs tend to be confusing as to what's going on, really. If anybody has suggestions for a better way of displaying these, maybe line graphs or other formats might be better? The bar graph doesn't really work very well. As you can see, the percentages are very different, even though the bars look the same and they are not. I think we need a different format, but I'll take suggestions from the Board or from anybody else who wants to make suggestions as to how we should see them.

Pinali Agrawal: Dr. Swee, we talked about this internally, and we agree with you as well. We're going to try to present it in a different way. We just have to brainstorm and think of a good way to present this information and provide the trends.

David E. Swee M.D.: Okay, very good. Linear trend is my guess, but we'll get to that. Alright hearing no other issues on those pages, we will just keep an eye on it. I don't think we need this one anymore, the Calcitonin Gene-Related Peptide Inhibitors. It's too stable for it to be significant.

Okay, and then these are the protocols that we just talked about. They were updated at our last meeting. So, that should not be a problem for us, changing the age to less than 6. Page 15 is also good, the criteria is updated with the use of the word appropriately and that's fine.

Linda Gochfeld M.D.: That brings us to new business.

David E. Swee M.D.: Who's going to talk about this first one?

Pinali Agrawal: I'll give a summary.

David E. Swee M.D.: Okay.

Pinali Agrawal: We're bringing this protocol back because Amvuttra was approved for an additional indication and the FDA approved a new drug, Attruby. We wanted to update the protocol with all of this information. In addition to Amvuttra's original indication for polyneuropathy of hereditary transthyretin-mediated amyloidosis, it is also now indicated for the cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis in adults. We also updated the background. If you scroll down to criteria 9 and 10 these were updated as well. We added Tegsedi to criteria 9, another drug that's indicated for polyneuropathy of hereditary transthyretin-mediated amyloidosis. We added Amvuttra and Attruby to criteria 10 for cardiomyopathy of wild type or hereditary transthyretin-mediated amyloidosis.

David E. Swee M.D.: Okay. Are there additional questions from the Board about these changes to the previous protocol?

Hearing none. Is there a motion to approve?

Eileen Moynihan M.D.: So moved.

David E. Swee M.D.: Thank you, Eileen. Is there a second?

Kristine Olson M.S., R.N., A.P.N-C: Second.

David E. Swee M.D.: Okay Kristine, thank you.

David E. Swee M.D.: Any further discussion before going onto the next one.
No. Okay, all those in favor say aye.

Board Members: Aye.

David E. Swee M.D.: Anybody opposed or abstaining?
No. Okay, very good. Next is the addendum to the protocol for setmelanotide.

Pinali Agrawal: Dr. Swee, I'll just do the same for this one. Just give an overview, and then the Board can discuss. We are bringing this protocol back because Imcivree recently had a labeling change where it's now indicated for patients 2 years of age and older. Prior to the update, it was indicated for patients 6 years and older. We also updated the obesity criteria based on the CDC and its definition of obesity in patients that are 20 years and older and in patients less than 20 years of age to keep it consistent.
The other major change is in the continuation of therapy criteria. We deleted the following, after 16 weeks of treatment, reduction in weight compared with baseline, as this is no longer in the prescribing information. In order to continue assessing a patient's treatment response, in patients 6 years of age and older with POMC, PCKS1, and LEPR deficiency at least a 10% reduction in BMI at one year must be seen and for patients with Bardet-Biedl Syndrome at least a 5% reduction in BMI at one year must be seen, based on studies. For patients 2 to less than 6 years of age with obesity due to POMC, PCSK1, or LEPR deficiency, or Bardet-Biedl Syndrome we updated the criteria to state a documented positive response to therapy as evidenced by a reduction in BMI at one year from baseline. Those were the changes that we made to this protocol.

David E. Swee M.D.: So, I have a couple of questions. Obviously, this is ultra rare as it's labeled. Do we know if we have any patients in the State who have this?

Pinali Agrawal: I don't have the utilization unfortunately for Imcivree but, you're right it is very rare. I can follow up after the meeting and then definitely provide that information.

Reut Ghodsi: Yes, we have about seven members utilizing this drug in 2025.

David E. Swee M.D.: Okay. I'm just curious about using a specific percentage for continuation of therapy. I mean, if they got to 9% reduction in BMI, we would say you can't have the drug. I don't understand that.

Pinali Agrawal: Yes, if we saw that at one year, based on this protocol, we would deny the request unless the prescriber had other information that they could provide that would warrant an approval but the 10% reduction is what was seen in the trials and that is what we went with to base the criteria on.

David E. Swee M.D.: Of course, it is a trial but these are so rare that it could easily be where maybe they only need a 5% reduction. It makes me very nervous when we cut off a drug because it didn't make a percentage. I'm not sure we can do anything about it if that's the protocol out there. But I'd like to know if we're actually stopping anybody from getting the medication because they didn't lose enough weight, for example, they only lost 9% or 8%.

Pinali Agrawal: Even in the updated prescribing information, the FDA did remove or have the manufacturer remove that specific statement that at 16 weeks they would have to see a 10% reduction in BMI. We could suggest the criteria be updated to the following, any evidence of a positive response and like you said because it's ultra rare having a predefined 10% or 5% just based on the clinical studies may not make clinical sense. So, we could state, any positive response for these individuals if that makes more clinical sense.

David E. Swee M.D.: It does, and I would just take out the rest of the sentence and update that there is a documented positive response to therapy.

Pinali Agrawal: Okay.

David E. Swee M.D.: We don't need to say what it is.

Pinali Agrawal: Dr. Swee, can we state a positive response to therapy as evidenced by a reduction in BMI so can we specify the parameter we're looking for?

David E. Swee M.D.: If you want to say it that way, it's fine. I would assume that's what a positive response would mean but that's defining positive response as a reduction in BMI. Yes.

Pinali Agrawal: Okay.

David E. Swee M.D.: Any other comments from the Board, or any other suggestions for changes.

Hearing none. Is there a motion to approve with the suggested changes I made.

Linda Gochfeld M.D.: So moved.

David E. Swee M.D.: Thank you, Linda. Is there a second?

Kristine Olson M.S., R.N., A.P.N-C: Second.

Steven Marcus M.D.: Second.

David E. Swee M.D.: Thank you. Okay. Any further discussion?

Hearing none. All those in favor say, aye.

Board Members: Aye.

David E. Swee M.D.: Anybody opposing or abstaining?

No. Okay, keep going. Next.

Pinali Agrawal: So next, we're bringing back an addendum to a protocol that was previously approved for paroxysmal nocturnal hemoglobinuria (PNH) products. We updated the continuation of therapy criteria. We didn't have any major changes to the initial therapy criteria. For the continuation of therapy criteria, we are removing criteria E, absence of unacceptable toxicity from the drug. It didn't align with the other parameters referencing treatment response. Also**,** I wanted to clarify what we are updating for criteria D, instead of an increase in reticulocyte count, the criteria is updated to state, a decrease or a normalization in

reticulocyte count, as that's what you would expect to see in these patients with treatment for PNH.

Ruchi, if you could just scroll back up one. So, the other thing that we're adding to the protocols is the statement, the protocol applies to FDA approved biosimilars and related indications and dosages. This just helps us from not having to bring back a protocol to only add a biosimilar. This will account for any new biosimilars that are FDA approved for their respective counterparts.

David E. Swee M.D.: Okay. The people at the Board understand that actually was a typo there. It should be decrease not increase in reticulocyte count.

Pinali Agrawal: So, we would say decrease or normalization in reticulocyte count.

David E. Swee M.D.: I'm assuming that prior to this it was at a higher level so I'm not sure why you have to say normalization. It's by definition normalization would be a decrease. They're not having a lower reticulocyte in advance, right?

Pinali Agrawal: Right? Yeah, correct. I was trying to look that up to confirm if patients could present with lower reticulocyte counts. So intuitively what it seems like with patients with PNH, because they have that hemoglobin issue the bone marrow is supposed to technically increase the reticulocyte count to try to make up for that decrease in the hemoglobin.

So, ideally if they are responding to therapy, you would see that the bone marrow would kind of go back to that decreased production or trend towards normalization. I couldn't find information on if there are any patients presenting with a decreased reticulocyte count. However, the only case that I could think of where they would have a decrease in reticulocyte count at the start of therapy is if the bone marrow itself is not functioning and able to produce reticulocytes.

David E. Swee M.D.: Okay. So, decrease or normalization we will live with that. Alright.

Kristine Olson M.S., R.N., A.P.N-C: It wouldn't, you know, normalize immediately, but over time, of course.

David E. Swee M.D.: Yeah. Okay, anything else from the Board?

Hearing none. Is there a motion to approve?

Kristine Olson M.S., R.N., A.P.N-C: So moved.

Judith Barberio PH.D., A.P.N-C: Second.

David E. Swee M.D.: Okay, any further discussion?
Hearing none. All those in favor of the new protocol say, aye.

Board Members: Aye.

David E. Swee M.D.: Anybody opposed or abstaining?
No. Alright, last addendum. No, two more. There's the CAR T Cell products.

Pinali Agrawal: So, we added the statement about biosimilars to make sure that any new ones that are coming onto the market would be included without having to bring the protocol back to the Board unless we have major changes or updates to present. We removed the reference to the REMS program for these drugs. In addition, we updated the criteria for approval to include FDA-labeled or compendial approved age and contraindications to therapy, to align standard criteria within protocols. We removed criteria pertaining to the black box warning from the criteria for approval section and then for criteria number 12, I updated it to align with the indication as it is stated in the prescribing information.

Teressa Barringer: Pinali?

Pinali Agrawal: Yes.

Teressa Barringer: I have an attendee who wants to speak.

Pinali Agrawal: Oh, sure.

Teressa Barringer: Okay.

David E. Swee M.D.: Wait. Not yet. Finish the discussion of the protocol and then we'll ask the attendee to speak.

Teressa Barringer: Okay, no worries.

Pinali Agrawal: And then for criteria number 13, Breyanzi, we went ahead and included additional FDA approved indications for the drug. Also, similar change for criteria number 14, I just aligned it with the prescribing information and all the way at the end of the protocol, I included the boxed warnings. There's a little bit of a difference in the way that the black box warnings appear on the prescribing information for the different products. The black box warning for Abecma states prolonged cytopenia versus Carvykti, the black box warning states recurrent cytopenia. So that's why the statements look very similar. And then for Yescarta, Tecartus, Breyanzi and Kymriah the black box warnings are all the same, and that's included here.

David E. Swee M.D.: Alright, Teressa! Now let's see.

Teressa Barringer: Okay, I'm going to let allow the attendee to speak. The attendee is Jay Patel. Go ahead, Jay.

Jay Patel: Hi Committee, can you hear me?

David E. Swee M.D.: Yes.

Jay Patel: Alright. Thank you for the time to speak, I just want to bring to the attention of the committee that…

David E. Swee M.D.: Jay, you have to identify who you are first, please.

Jay Patel: Hi! My name is Jay Patel. I am a field HEOR pharmacist here at Bristol Myers Squibb.

David E. Swee M.D.: Okay.

Jay Patel: I just wanted to point out to the Committee that in April of 2024, the Abecma label was updated in accordance with the KarMMa-3 Trial for therapy after 2 or more lines of therapy and I noticed in the criteria it says four. So, I just wanted to bring that to your attention based on an update to our prescribing information last year.

David E. Swee M.D.: So, you're saying that should say two?

Jay Patel: Correct.

Pinali Agrawal: I'm just checking on fda.gov because I looked up the most recent labeling, let me just check.

David E. Swee M.D.: It was year and a half ago it should be there by now. You're saying it was April of 24, Jay?

Jay Patel: Correct. That's when the prescribing information was updated.

David E. Swee M.D.: Yeah. Go ahead Pinali.

Pinali Agrawal: It is two or more. We can update that to two or more. So, I will go ahead and update that.

David E. Swee M.D.: To make the change from four to two?

Pinali Agrawal: Yes.

David E. Swee M.D.: Okay, good. Thank you. Thank you, Dr. Patel.

Jay Patel: Thank you for your time.

David E. Swee M.D.: Alright anything else on this, on these very complicated protocols? I mean, obviously having drugs for multiple myeloma is important, to say the least. So, they're welcomed additions to the armamentariums.

Okay. With these changes that we've discussed, including the most recent change from four to two. Are there additional comments or proposals from the Board? If not, is there a motion to approve?

Linda Gochfeld M.D.: So moved.

David E. Swee M.D.: Thank you Dr. Gochfeld. Second?

Judith Barberio PH.D., A.P.N-C: Second.

David E. Swee M.D.: Okay.

David E. Swee M.D.: Any further discussion?

Hearing none. All those in favor say, aye.

Board Members: Aye.

David E. Swee M.D.: Anybody opposed or abstaining?

No. Okay, very good. Last, but not least, in terms of the new business is the always ongoing GLP-1 category that seems to be a forever product.

Steven Marcus M.D.: Yeah.

David E. Swee M.D.: Changing the indications at one time or another. This time we're dropping the product. It no longer exist which is hard to find.

David E. Swee M.D.: Anything else about the product?

Pinali Agrawal: Oh, sorry, Dr. Swee.

David E. Swee M.D.: No, go ahead.

Pinali Agrawal: I was going to go through this protocol like the other protocols, if you would like?

David E. Swee M.D.: That's fine.

Pinali Agrawal: All right. So, for this protocol we're adding the statement, protocol applies to the FDA approved biosimilars and we are bringing this back to include additional indications for the GLP receptor agonists. Most of the criteria for approval such as the age and contraindications, is unchanged and based on what was previously approved. So, going down to criteria number 5 we added the following indications, reduce the risk of major adverse

cardiovascular events and reduce the risk of sustained eGFR decline, end-stage kidney disease and cardiovascular death. In order for a request to meet criteria for approval for the indication to reduce the risk of major adverse cardiovascular events the patient must have a diagnosis of type 2 diabetes and established cardiovascular disease. And in order for a request to meet criteria for approval for the indication to reduce the risk of sustained eGFR decline, end-stage kidney disease and cardiovascular death the patient must have a diagnosis of type 2 diabetes and documentation of chronic kidney disease. Criteria B and C are aligned with the updated Diabetes Guidelines that were approved earlier this year. And for continuation of therapy criteria, we removed the statement regarding the contraindication, since they would already be on the treatment. Again, the update was based on the Diabetes Guidelines that were recently approved.

David E. Swee M.D.: So just as more of an operational issue for us as a Board and for you guys looking at drugs as they come across, I'm assuming that for every single drug we should have a biosimilar statement and no contraindication to therapy statement. Why do we have to put these in every protocol? Why don't we just say that's a standing order? Basically, I mean, for obvious reasons, we always want biosimilars to be approved and we want no contraindications to therapy by definition, otherwise we wouldn't give it to them. Why do we have to have it on every protocol? I don't know. I don't understand that.

Pinali Agrawal: So once these protocols are approved by the Board and signed off on by the Commissioners, they get sent to MCOs. The MCOs use these protocols to mirror their policies. It’s just ease of including it in there. That's my guess on why we would want to keep it on all of them. And the biosimilars, you're right. It could be assumed, but I think, having it in writing just helps for documentation purposes.

David E. Swee M.D.: I wasn't so much saying assume it, I was saying to make it a standing order and part of our operations, which is that all of our drugs are going to have biosimilars, and all of our drugs are going to prohibit contraindications and not have to have it stated every time. If you think you have to have it stated every time we'll live with it, but it just makes things more complicated. I'm always asking the same question, I know. When are we asking for requests to reduce the risk of sustained eGRF and kidney disease, I assume that we're just asking for an attestation from the physician who requests it or do they just assume that they know. My nurses get the approval for my Medicaid patients. I almost never see this kind of stuff. So, what kind of paperwork is being asked for here?

Pinali Agrawal: So, I think it would be labs to show that the patient has chronic kidney disease. We'd be looking for just that documentation.

David E. Swee M.D.: How often?

Pinali Agrawal: I believe this protocol will probably be approved 6 months to a year. And then, if they get the drug approved we're not asking for anything for continuation. The only thing we're going to check for continuation requests is that the drug is used for an FDA-approved indication or medically appropriate off-label indication. So, for continuation of therapy, if they just say that they have type 2 diabetes and they have chronic kidney disease, we would continue that therapy for them.

David E. Swee M.D.: Yeah, but we're asking for a copy of a CMP, really, or a basic metabolic panel (BMP) every time you want to review one of these drugs. Okay. I mean, you know, it's fine we do those automatically for these patients. You have to do them because you have to take care of them but seems sort of silly. We're not going to say, oh, he has kidney disease but we actually made that up , he doesn't really have it, I mean, you know. Have you ever had the patients who ended up without the information? I'm just confused here a little bit. Our request that a confirmed diagnosis be provided? Obviously, documentation of Parkinson's disease is provided. Alright, once it's provided, once is what you're saying initially?

Pinali Agrawal: Yes.

David E. Swee M.D.: This is what? What page is this?

Pinali Agrawal: This is on page 32.

Thomas Lind M.D.: 32.

David E. Swee M.D.: Alright, hold on. Let me go back here in my material. So again, let's go back to all the documentation issues. We're obviously assuming this is all initially because you wanted them to have an A1c greater than 7 measured within the last 6 months, makes no sense to me. If you put a patient on this medication and they go below 7 you have to stop it? No, I would.

Pinali Agrawal: No, sorry the criteria for approval number 4, it's just for the initial to show that they have diabetes, so their hemoglobin A1c has to be greater than or equal to 7. But then, you know, once we approve it, and they've been on it for 3 months, 6 months, or a year we're not going to ask for the A1c. Again, because we already know that they have documented diabetes.

David E. Swee M.D.: Alright, but can you make sure that's clear for initial requests?

Pinali Agrawal: So the criteria for approval section is referring to initial requests. The continuation of therapy criteria has only the one statement, the medication requested is prescribed in accordance with.

David E. Swee M.D.: Yeah, okay, alright. And we're still going with metformin?

Pinali Agrawal: Yeah.

David E. Swee M.D.: Start with metformin?

Pinali Agrawal: Yes.

David E. Swee M.D.: Even though ADA is now saying you don't have to. Right?

Pinali Agrawal: Yes, we are still recommending that they use metformin first.

Judith Barberio PH.D., A.P.N-C: Pinali, I have a question for you. This addendum is only related to people with type 2 diabetes correct? Because some of these drugs are approved for people without diabetes who have sleep apnea, for instance. And we're not talking about those people in this addendum correct? This is only talking about the patients with diabetes that we prescribe this to.

Pinali Agrawal: Correct.

Judith Barberio PH.D., A.P.N-C: Okay. And we have another protocol that talks about prescribing it for obesity when diabetes is not a factor in their care.

Pinali Agrawal: So, Medicaid does not cover it just for obesity. But Zepbound, which is indicated for OSA, for people who are obese, is covered, and we have a separate protocol for that.

Judith Barberio PH.D., A.P.N-C: Okay, because Zepbound is approved for sleep apnea also. Right? So, you could start that on people without diabetes for the weight loss or the sleep apnea.

Pinali Agrawal: Yes, we would check if they have a diagnosis of sleep apnea. If they don't, then they wouldn't meet criteria for Zepbound.

Judith Barberio PH.D., A.P.N-C: But even if they were obese, I could use it until I made sure that they had sleep apnea, so I sent them in for testing.

David E. Swee M.D.: Protocol right now is moderate to severe sleep apnea, in fact.

Judith Barberio PH.D., A.P.N-C: Okay, moderate to severe. Okay, so not just for obesity by Medicaid, for approval, correct? Although it is for other insurance types.

Pinali Agrawal: Yes.

Judith Barberio PH.D., A.P.N-C: Thank you.

David E. Swee M.D.: Any other questions about this protocol?

My guess is as things change with these drugs, they're going to change again. This whole thing about kidney and cardiovascular disease are fairly recent and has been mentioned already. We're now looking at other data about dimensions and other things. Who knows? Next week it'll be a different thing, but certainly by October. Yes, Linda, you had your hand up.

Linda Gochfeld M.D.: I have a question about these. Have there been behavioral issues with any of them? Because I know someone who had severe behavioral problems on Ozempic. I just wanted to know while we're discussing all of these drugs.

David E. Swee M.D.: I'm not aware of it but that doesn't mean it doesn't exist. It's like everything else.

Linda Gochfeld M.D.: It is not listed. Oh, okay.

David E. Swee M.D.: Any other comments from the Board?

Hearing none. Is there a motion to approve as submitted?

Judith Barberio PH.D., A.P.N-C: I approve as submitted.

Steven Marcus M.D.: Good.

David E. Swee M.D.: Second?

Steven Marcus M.D.: Second.

David E. Swee M.D.: Any further discussion?

Okay. That takes us into the prior authorization report and you can see here why I focused on Fidelis in the non-formulary area. They were way out of line compared to the other HMOs. So, we're going to wait for them to look into this further. They think that it was more of a timing and drug issue, right? But they're going to see if they can get themselves back into the same area, still high, but they were certainly off kilter. So, we'll see in the next report if they do any better. Other comments on this page?

Okay. Yeah, I continue to worry about anything where we see clinical criteria not met because again, Fidelis is in a different place than the other ones. Whereas I don't worry about excluded benefit so much that's just their choice of formulary. You know the clinical criteria not met, maybe because people didn't respond appropriately to our request for clinical information. So, I always worry about that.

Pinali Agrawal: So, Dr. Swee, we did reach out to the MCOs and for a lot of these for the clinical criteria not met, I'm sure the Board has seen these, but it can be missing information and or missing diagnosis. It can be a not approved indication. The off-label use is not supported by compendia. It could be duplicate therapy. There was one where they had specifically stated they had no trial of metformin, A1c is less than 7% for GLP-1. So those are

just some examples and also drug-drug interactions. So those could all fall under the clinical criteria not met.

David E. Swee M.D.: Okay, well, we'll keep an eye on it. Yeah, okay, all right. Next page.

Okay. I just wanted to make the statement, I always appreciate this now that we're getting a much more rapid turnaround from the Department. It's really important to keep ourselves updated these. So that's very useful. Thank you.

We should have our informational highlights.

Pinali Agrawal: Yes, and then we have the top drugs report, too, if any of the Board members wanted to talk about them.

David E. Swee M.D.: Okay. Dr. Marcus?

Pinali Agrawal: Ruchi. Sorry we're going back to the top drugs. Thank you.

Steven Marcus M.D.: No nothing astounding.

David E. Swee M.D.: Okay, as always, back up a second to the top drugs report. I'm always surprised by how high some drugs like insulin, which is, should be mother's milk kind of thing is up there.

Linda Gochfeld M.D.: Yeah.

David E. Swee M.D.: It's in the top 10 and obviously, it's a lot because we are just using a lot of it. But still, wasn't that much? I mean, it's 4,500. 4,300. Excuse me. But less than 400 claims. It's still in the top 10. So, what's the total for the month? Is it the quarter or a month?

Pinali Agrawal: It's a month. It's April. So it's comparing April 2025 and January 2025, that's just the ranking. Sorry, so in April 2025, it was ranked 9 versus in January 2025, it was ranked 14 in terms of the top drugs.

David E. Swee M.D.: So, it's being used even more often or cost more. And I thought it was going to get reduced in price I just don't understand why it's so high**,** but you know. Okay.

What was the total amount of money that the State spent on drugs this month? Close to 3 million.

Pinali Agrawal: Yes, just for the fee for service.

David E. Swee M.D.: Yeah, and the HMOs are doing their share, too. We're paying for their top drugs as well, though right? So, 3 million per month. That's a real number at the end of the year. Okay.

Judith Barberio PH.D., A.P.N-C: Well, one of them, like the buprenorphine-naloxone that is required. If you have a patient on an opiate, or it's actually an opiate or a benzodiazepine, so I could see that that's going to be up there all the time right there, because it's something that you only have to renew it every year, but you have to renew it because of a State law.

Linda Gochfeld M.D.: Hmm.

Judith Barberio PH.D., A.P.N-C: But that's going to be up there.

David E. Swee M.D.: Yep.

Steven Marcus M.D.: It's not a benzodiazepine.

David E. Swee M.D.: No, it's not.

Judith Barberio PH.D., A.P.N-C: No. I said, when you use an opiate with a benzodiazepine.

Steven Marcus M.D.: Oh, okay.

Judith Barberio PH.D., A.P.N-C: State law says, you must prescribe this.

Steven Marcus M.D.: Yeah, that's interesting. I didn't realize you had to prescribe buprenorphine whenever you prescribe a benzodiazepine and/or an opioid.

Judith Barberio PH.D., A.P.N-C: Well, the naloxone.

Steven Marcus M.D.: The naloxone. Okay.

Judith Barberio PH.D., A.P.N-C: Right, yeah, not just buprenorphine, but the naloxone, the Narcan.

Steven Marcus M.D.: Yes.

Judith Barberio PH.D., A.P.N-C: Yeah, you have to prescribe.

Linda Gochfeld M.D.: But for how long?

David E. Swee M.D.: Every time.

Judith Barberio PH.D., A.P.N-C: As long as they're on the drug every year it has to be renewed Linda.

Linda Gochfeld M.D.: Wow!

David E. Swee M.D.: All right. Let's go into the medical information last thing. I'm not sure why this got posted now. I mean, we all know that if you stop the meds you gain your weight back, it's like, yeah, I use it as my major argument for patients not to start them. They'll say, well, I just want to lose 20 pounds and that doesn't work that way. These are not like that. Once you're on it, you're on it for life. Which you can do! There are other medications you are on for life, like your blood pressure medications and your diabetes medications, but people are just learning that you have to do that.

Thomas Lind M.D.: But I don't think we have enough data to say that definitively. It doesn't stretch out long enough to say that it's a lifetime commitment. It seems to be trending in that direction but I don't know that you could say that, like with blood pressure, medication.

David E. Swee M.D.: No, no! What I'm saying is that if you need it for weight loss it's a lifetime commitment. That's my point.

Thomas Lind M.D.: Right.

David E. Swee M.D.: Yeah, okay, you may not need it for diabetes control.

Pinali Agrawal: What I saw with this study is that when they discontinue the GLP-1, even if they stick to their diet and exercise, they're going to regain their weight.

David E. Swee M.D.: Which is at least 80%.

Pinali Agrawal: Which I don't know If that means people were not, you know, using these drugs along with diet and exercise to begin with. And so maybe that's why they didn't capture that.

David E. Swee M.D.: Well, always less than they should right?

Pinali Agrawal: Yeah.

David E. Swee M.D.: That's real life. Alright. Next one is the postexposure prophylaxis (PrEP) medications. HIV recommendations those are really not that new.

Steven Marcus M.D.: What's new is the controversy in providing drugs, particularly in what used to be USAID. I guess we don't want to get political here.

David E. Swee M.D.: Not today. And then the other informational highlight was in genitourinary problems around menopause. The guidelines have been updated but they're basically still, you know, another one of these undertreated areas that we probably need more.

The last one is some complications starting to be seen, although I haven't seen it yet in other areas and whether semaglutide is going to help there but you know another place where it could maybe help Steve, just start taking it like fluoride in the water, right?

Steven Marcus M.D.: They're trying to take fluoride out of the water now. So that's really a very funny comment but I mean, I know a couple of people that had, not alcoholic, but fatty hepatitis. I mean, this is an exciting possibility, but there are so many things that are so exciting. I have friends living with dementia, I mean I don't know why it's so difficult to get physicians to prescribe it for patients with early dementia. You know. What can I say?

David E. Swee M.D.: Well, these are all off-label uses right now, so we'll have to see, anyway, anything else to come before the Board. It's 6 min early, but there's nothing wrong with stopping early in the summertime. If not, you want to go over the upcoming dates for the next year.

Pinali Agrawal: The proposed dates. Yes, sorry. One second.

David E. Swee M.D.: Do you want me to find them?

Pinali Agrawal: Let's see who gets to them first.

David E. Swee M.D.: So, I'm going to read you the dates. January 28th, April 22nd, July 15th, and October 21st of next year.

Pinali Agrawal: So those are still proposed. In the October meeting we'll confirm them for sure, and then we will publish them in the papers, as we normally do.

David E. Swee M.D.: Yeah, no. I just wanted to make other people aware of them, so the other Board members can go back and check if any of those are major problems and we can always make changes before October. So, any of those are major problems, let me know, because we will try to move the meetings. Alright.

Linda Gochfeld M.D.: This is assuming that we're still the Board, and they haven't gotten anyone new.

David E. Swee M.D.: Of course.

Linda Gochfeld M.D.: It's important for us all to be here, of course.

David E. Swee M.D.: Okay. Is there a motion to adjourn? It's 11:57.

Judith Barberio PH.D., A.P.N-C: I make that motion to adjourn.

David E. Swee M.D.: Thank you. Anyone else?

Eileen Moynihan M.D.: Second, in favor of adjourning.

David E. Swee M.D.: All those in favor of adjourning say, aye.

Board Members: Aye.

David E. Swee M.D.: See you in October, have a good rest of the summer.