

State of Illinois Drugs and Therapeutics Advisory Board

Minutes for April 14, 2022

Minutes

- I. **Dr. Florence opened the meeting at 8:35am**
- II. **Roll Call was taken. Dr. Albright was excused from attendance.**
- III. **Dr. Florence welcomed everyone**
- IV. **No conflicts of Interest**
- V. **January meeting minutes are unanimously approved (Dr. Goyal motion, Dr. Berkowitz 2nd)**
- VI. **Public Testimony**

Speaker	Product	Organization
Tate Winter, Director of Medical Affairs	Carglumic Acid	Eton Pharmaceuticals
Maitrey Patel, Medical Science Liaison	Azstarys	Corium, Inc.
Mohammed Homsy, Pediatric Neurologist	Qelbree	Amita Health
Opeoluwa Fagbemi, Pharmacist	Qelbree	Supernus
Paul Amato, Medical Science Liaison	Apretude	ViiV

- VII. **PDL Appeals**-None for this meeting.
- VIII. **New Drug Appeals**-None for this meeting.
- IX. **Drug Class Reviews**-Ryan Rodriguez, PharmD. presented each class monograph.
 - a. **Inhaled Aminoglycosides**- Guidelines recommend tobramycin for CF, treatment of chronic pseudomonas disease. Tobramycin is the most used product. TOBI podhaler is the only inhaler option. MCOs ask that the generic be made preferred and Kitabis moved to non-preferred (recommendation presented by Cynthia VonSteenburg). Dr. Rodriguez moved to make the generic preferred. Dr. Patel second. Garry Moreland voiced concern that brand costs more for pharmacies. Realizing decision is cost based. Motion is passed
 - b. **ADHD Agents**-Stimulants are first line therapy. Individual patient will determine the best product as far as long-acting, etc. Long-Acting is recommended for adults. Complex ADHD-non-stimulant use if drug use disorder is present. Misuse is a safety concern. All agents are efficacious. In children methylphenidates may work better and in adults amphetamines work better. Long-Acting products are generally preferred by patients.

Dr. Rodriguez and Dr. Florence would like to see long-acting products for privacy and convenience. Dr. Berkowitz added that the long-acting agents generally are better tolerated. Dr. Rodriguez commented on the complexity of this review and would like to take a deeper dive. Garry Moreland commented on the difficulty for patients moving between insurance plans. He also emphasized the effects for the patients on this therapy. Dr. Berkowitz recommended having a non-stimulant be preferred. MCOs support this suggestion. Dr. Rodriguez recommends going through this class line by line because it is so complex. Also, this class affects so many lives. Dr. Goyal points out that in many cases the brand products are sometimes less expensive. He also suggested to table the drug class. Dr. Goyal moved to table this class and then coming back at the next meeting with recommendations. Mary Moody suggested an ad hoc group to dive deep and then come back to the board with a recommendation. Dr. Goyal amended his motion to include the ad hoc committee. Dr. Rodriguez second. Motion passed.

Committee will meet June 7th with the following on the committee:

Dr. Rodriguez
Dr. Berkowitz
Garry Moreland
Dr. Florence
Dr. Goyal

- X. New Drug Initial Review-Ryan Rodriguez, PharmD. (with discussion and vote)**
- a. Livetency-CMV post-transplant infection refractive to 1st line treatment. Less SE than ganciclovir and vancyclovir. Many transplant patients do experience refractory infection. Guidelines recommend ganciclovir and vancyclovir 1st line then Livtency 2nd line. Dr. Patel expressed concern about the SE of first line therapy. Dr. Patel moves to make it Preferred with PA. Dr. Rodriguez second. Motion passed.
 - b. Kerendia-oral and approved to reduce the risk of sustained eGFR decline, end-stage kidney disease, cardiovascular death, non-fatal myocardial infarction, and hospitalization for heart failure in adult patients with chronic kidney disease (CKD) associated with type 2 diabetes (T2D). Decreases CVD death in End Stage Kidney Disease and Chronic Kidney Disease patients. Guidelines recommend SGLT-2 agents as first line and Kerendia as second line as add-on therapy. This is adjunct therapy. Dr. Florence added that she does see more allergies to SGLT-2's as the class is used more. Dr. Ryan Rodriguez believes there could be many patients eligible for this therapy and sees this as Preferred with PA as it is add-on therapy. Garry Moreland moved for Preferred with PA. Dr. Rodriguez second. Motion passed.
 - c. Aprelude- IM every 2 months. PI emphasizes careful selection of the proper patient. Must be HIV negative and must be tested prior to each dose. Dr. Ryan Rodriguez noted that standard PrEP is available now. Dr. Rodriguez noted high interest in this drug. She says her patients are not compliant with oral PrEP. Resistance is a concern when doses are missed. Can be used with or without oral lead-in. Dr. Rodriguez noted that oral lead-in would be preferable in a perfect world and noted that the LBGTQ community has already too many barriers to care. Dr. Patel notes the non-adherence to PrEP and

believes this is necessary. Dr. Patel moved the Apretude be preferred without a PA. Dr. Rodriguez second. Motion passed. Dr. Goyal abstained.

- d. Carglumic Acid-Can be stored at room temperature for 90 days. This is longer than the brand. Brand is also indicated for a second disease. It is recommended as 1st line treatment for hyperammonemia, a urea cycle disorder caused by lack of a certain liver enzyme. Garry Moreland moved to make this preferred with PA and Dr. Patel seconded. Motion passed.

- XI. **Aduhelm Review**-Dr. Ryan Rodriguez presents the clinical information. This was approved via accelerated approval. A further RCT is required but is not due until 2030. Original trials were terminated for not meeting the primary endpoint. ENGAGE and EMERGE studies contradicted each other. Goal was to decrease amyloid plaques by 0.5 points and ultimately reached a 0.39 point decrease. This provided the approval under accelerated approval. Major side effect is ARIA. This is 1st in class therapy. There has been a lot of controversy around the approval and many are concerned about how it was approved by the FDA. Clinical improvement was 0.39 on an 18 point scale. Clinical statements regard this as mild improvement only. Jodi Jensen from Biogen spoke to the indication of Aduhelm and dosing. She spoke to the study differences and stated that the EMERGE patients did not get the maximum dose during the trial period. MRIs must be done to look for ARIA. They ask that the Department approve the product to label. Dr. Rodriguez questioned the clinical benefit. Ms. Jensen explained that the patients in the EMERGE trial did show a statistical improvement and were able to perform daily activities. Dr. Rodriguez asked how we know that the clearance of plaques is beneficial? Ms. Jensen noted that the ARIA is the inflammatory response to the plaque clearance. Medicare has determined to cover Aduhelm only in the context of an investigational trial. Dr. Patel notes a possible small benefit. Nothing else is available. The cost to ancillary treatment is extremely high. Dr. Patel notes that the findings are relatively inconsistent and it is an area where we desperately need treatment options. He notes that the CMS decision and the controversy around the approval makes him believe the department should follow the lead from CMS. Dr. Goyal notes that CMS indicated the evidence did not support treatment of Alzheimer's but did possibly support treatment of mild cognitive impairment. He noted the cost and the cost reduction by Biogen after the product was on the market as well as the change in the label. He further notes the department's meetings with Biogen. He notes that many healthcare entities are refusing to prescribe. He noted the need for a recommendation from the Board because it is difficult to review this drug as we would normally review a new drug. Sheri Dolan noted that the department is required to cover the drug, but the department is looking for a recommendation on how to construct the criteria. The department has concerns around the safety and efficacy of the drug. Ms. Jensen noted that 19 states are structuring criteria around the label. Illinois is the first state to meet after the CMS guidelines were made final. Dr. Rodriguez expressed approval for following the CMS guidance. She would like to see the most rigorous criteria possible. Dr. Goyal notes the difficulty of determining where mild disease ends and moderate begins. He offers that we can table and wait for clarification of CMS guidance. Ms. Jensen noted how the mild versus moderate was determined in the trial. Dr. Goyal questions the use of the secondary endpoint and the surrogate endpoint for approval. The drug is non-preferred now. Dr. Patel asked how many trials are based in Illinois. Based on the controversy he believes we should leave prescribing of this drug to the experts and it should be done at centers where trials are taking place. He notes Aduhelm is a step in the right direction. He would like to table the recommendation until further information can be obtained. Dr. Patel notes that we are having to make these recommendations and criteria because the FDA did not approve this drug

like they have in past with other drugs. He believes that most states will re-evaluate and decide to follow CMS guidance. Ms. Jensen notes that the amyloid plaques must be present due to label. Sheri Dolan noted that Medicaid would only be responsible for straight Medicaid patients and not dual eligible patients. Garry Moreland asked if a recommendation was needed now. Dr. Goyal stated he would be comfortable if the Board recommended following the CMS guidance until further information was obtained. Mary Moody noted this would be helpful for the department. Dr. Goyal recommends that the Board not make a decision today but follow CMS guidance until we do. Garry Moreland moved for the Department to follow CMS guidance until a final recommendation on coverage criteria is made pending further information and clarity. Dr. Albers seconded. Motion passed. Dr. Goyal abstained.

- XII. Future Agenda Preview-**Sheri Dolan noted that our next Board meeting is July 14, 2022 and we will review the Hematopoietic Agents and revisit the ADHD as discussed earlier in the meeting. The Board will need to elect or reelect a Chair and Vice Chair in July. She asked for anyone interested to email her. She also noted that the Board will need to complete the required training for this year. A link will be sent out to the Board for the training site. Sheri requested that any of the ADHD manufacturers that wanted to have further information reviewed by the Board that it be sent by May 7. She also shared that the Department is currently reviewing all the recent legislation and planning implementation of the legislation.
- XIII. Provider Requested Reviews-** None for this meeting
- XIV. Department Update-**Included in Sheri Dolan's remarks above
- XV. Adjournment-**Dr. Florence adjured the meeting at 11:06 am.

Attendees

The names of the Board members and speakers are bolded.

Panelist List

1. Alyssa Stephenson
2. Sheri Dolan
3. **Cynthia VanSteenburg**
4. **Nicole Florence**
5. Donna Clay
6. **Arvind Goyal**
7. **Garry Moreland**
8. **Ryan Rodriguez**
9. **Maurice Shaw**
10. **Janet Albers**
11. Jennifer DeWitt
12. Heather Freeman
13. **Pamela Vergara-Rodriquez**
14. Mary Moody
15. **Mahesh Patel**

Attendee List

1. Anik Dharia
2. Ankit Patel
3. Bharathwaj Lakshminarayanan
4. Casey Johnson
5. Chad Morris
6. Chase Williams
7. Chris Williams
8. Chris Stanfield
9. Chris VanWynen
10. Christopher Voyiatt
11. Dan Murphy
12. Danfeng Ni
13. David Krempa
14. David Large
15. Elizabeth Plouff
16. George Vass
17. Holly Walpole
18. Huzefa Master
19. Jason Vandervest
20. Jerry Lubben
- 21. Jodi Jensen**
22. John Bullard
23. John Hogge
24. Justin Barnes
25. Kelly Hamilton
26. Ken Ring
27. Kunal Parekh
28. Leslie Zanetti
29. Lisa Tracz
- 30. Maitry Patel**
31. Mary Kaneaster
32. Michael Hawks
- 33. Mohammed Homs**
34. Nadeen Israel
35. Neelesh Nadkarni
36. Omar Martinez Gonzalez
- 37. Opeoluwa Fagbemi**
- 38. Paul Amato**
- 39. Robert Kilo**
40. Ron Abraham
41. Sakib Hassan

42. Samantha Paustian
43. Shauna Williams
44. Wunhye Moon
- 45. Tate Winter**
46. Thomas Erickson
47. Thomas Vayalil
48. Tiawana Parker
49. 3 unidentified call-in users