State of Illinois Drugs and Therapeutics Advisory Board

Minutes for October 20, 2022 Meeting

I. Dr. Albers opened the meeting at 8:37 am
II. Roll Call was taken. Drs. Albright Berkowitz were excused from attendance. A quorum was established.
III. No conflicts of Interest
IV. The July meeting minutes were unanimously approved.
V. Public Testimony was presented as below:

Speaker	Product	Organization
Brooke Wilkins, PharmD	Cosentyx	Novartis
Rick Melbye, MOL	Cimzia	UCB
Bobbi Bentz, Evidence & Outcomes Liaison	Taltz	Lilly
Nishil Patel, Medical Value and Access Liaison	Otezla	Amgen
Nishil Patel, Medical Value and Access Liaison	Enbrel	Amgen
Rick Szymialis, Director, Field HEOR	Sotyktu	BMS
Irina Smith, Medical Outcomes & Science Liaison	Rinvoq	AbbVie
Irina Smith, Medical Outcomes & Science Liaison	Skyrizi	AbbVie
Keith Powell, Medical Science Liaison	Quviviq	Idorsia

VI. There are no PDL Drug Appeals for this meeting.
VII. There are no New Drug Appeals for this meeting.

VIII. Ryan Rodriguez, PharmD. presented the Biologic Response Modifier class monograph.

Dr. R. Rodriguez explained the unique format for the Biologic Response Modifier class due the very large and very broad nature of the disease states, drugs and mechanisms of action within this class. The class was divided into 4 primary disease state sections and the drugs, MOAs and place in therapy were then discussed in context to those primary disease sections. A composite table of all the drugs and the guideline recommendations by disease state was also prepared for the Board's reference.

The first section covers Rheumatoid Arthritis (RA) and Juvenile Idiopathic Arthritis (JIA). For RA 1st line therapy is still Methotrexate for moderate to severe disease with biologic DMARDs or JAK agents following failure on Methotrexate. The guidelines do not recommend one DMARD or JAK over another in this space. There are some notable safety concerns with the JAK class in general. If a patient fails either a JAK or biologic, the guidelines do recommend switching the patient to a different class rather than a second agent with the same mechanism of action. In JIA, the guidelines also recommend methotrexate 1st line with the biologic DMARDs as second line therapy. They also do not recommend one agent over another. No comments or questions were expressed.

The second section covers Psoriasis and Psoriatic Arthritis. In plaque psoriasis there are multiple monotherapy options that come with a strong guideline recommendation for moderate to severe disease. These include TNF inhibitors, IL-17 and IL-23 inhibitors. No preference for one monotherapy over the other is expressed. In pediatric patients both Cosentyx and Stelara have strong recommendations. About one-third of patients with plaque psoriasis go on to develop psoriatic arthritis so it may make sense to choose a product that is approved for both conditions. First line therapy here is a TNF inhibitor, followed by an IL-17 or IL-23 inhibitor. Again, no questions or comments were expressed.

Section three covers Ankylosing Spondylitis and Non-Radiographic Axial Spondyloarthritis (NRAS). Guidelines here strongly recommend TNF inhibitors following failure on NSAID treatment. No particular TNF is preferred over the others. TNF inhibitors are strongly recommended in NRAS. Cosentyx and Remicade are conditionally recommended but not particular agents are recommended over others in the same class. Again, no questions or comments were expressed.

Section four covers Ulcerative Colitis (UC) and Chron's Disease (CD). The guidelines generally recommend TNF inhibitors for disease that is resistant to corticosteroids and methotrexate.

In a safety wrap-up, Dr. R. Rodriguez shares that generally all agents in this class carry either a warning or a boxed warning for infections. The TNF and JAK inhibitors have boxed warning s for malignancies. TNF Inhibitors carry a warning for risk of heart failure and JAK inhibitors have box warnings regarding all-cause mortality. The JAK inhibitors were recently updated for use after failure of a TNF due to these safety concerns. Cimzia has an indication for use during pregnancy. Humira has the most indications for the disease that were the focus of this review.

Discussion: Dr. Vergara-Rodriguez commented that based on prevalence those products that are effective in more disease states seem like they should be more utilized. A discussion around access issues and prevalence of use of those agents that have been on the market longer and have more safety and comfort levels for patients and physicians. Garry Moreland spoke to outpatient utilization tending towards Humira in his experience. Access issues are two-fold, both approvals and cost of stocking these agents in a retail pharmacy setting. Route of administration can also affect utilization with SQ and oral routes being much easier to get at home over infusion products. Cyndi VonSteenburg relayed that for Molina most of the infused drugs are run through a medical rather than a pharmacy claim. Cyndi also asked about how the biosimilars will be treated. Sheri Dolan responded that if the biosimilar is considered clinically equal the Department will look at the financial feasibility versus the brand product. Dr. Patel asked about making an IL-17 preferred as second line therapy as well as a JAK. Discussion around this issue ensued. Historically this was a cost concern but the longer they have been on the market the less cost is a concern. Dr. R. Rodriguez shared that in the absence of head to head studies, his meta-analysis review did not reveal any significant differences in the IL-17 agents. The difference here lays mostly in the number of indications they have been studied for. Cyndi VonSteenburg brought up the idea of stratifying the agents so that a step through a preferred agent is still possible prior to moving on to a more expensive agent. Discussion was then centered around making an agent or group of agents available without a PA and the risks and benefits of this idea. Cyndi shared her experience that in Michigan when they removed the PA, costs and utilization skyrocketed. It takes away the methotrexate mandate as 1st line. The suggestion was made by Dr. Patel to leave the class as is but add an IL-17 as PPA as a second choice like the JAK. The idea of one preferred TNF without a PA was brought up and discussion was had around the benefits versus the risks

both clinically and in the interest of keeping cost in check. Dr. Goyal asked about utilization in MI going up with or without outcomes. Dr. Goyal advocated for one product being preferred with guidance to providers and monitoring. Then others would be PPA or PA only and then review again in a year. Dr. Patel asked for pharmacy input. Garry Moreland says that always making something preferred is best for the patient as long as it is financially feasible. Discussion around possible system edits was then entertained. A diagnosis edit would lag behind an actual first fill. Dr. Patel recommends making a TNF preferred and then reassessing in 6-12 months. The MCOs would not support this as a first option. Dr. Goyal expressed the need for a clinical consideration first. He also would like to see a preferred and then reassess in 1-2 years. He feels strongly that PA does not show outcomes. Outcomes will require a separate study. Dr. Shaw recommends reviewing methotrexate in a year and making Humira preferred. Dr. Vergara-Rodriguez moved to make Humira preferred without a PA and Cosentyx the IL-17 that we move to preferred leaving the rest of the class as is. Dr. Albers seconded the motion with the addendum that we come back and review the data in 1 year and the class in 18-24 months. Garry Moreland speaks in support of the motion. He also questioned getting outcomes data. He asked how we handle going back to the manufacturers for additional rebate. We will look at the products that still offer best clinical and financial outcome. The motion unanimously passed.

IX. New Drug Initial Reviews-Dr. Ryan Rodriguez presents with discussion and vote:

a. Quiviviq-Dr. R. Rodriguez is presenting a brief summary of this drug. The drug manufacturer spoke during Public Testimony and also shared some drug information. This is the third drug in this class of sleep aids to be approved. It is shown to improve sleep latency by about 30 minutes and sleep duration by about 20 to 30 minutes. Studies have shown that this product is equal in efficacy to others in the class and other sleep treatments with the exception of benzodiazepines and are potentially less efficacious here. Contraindicated with narcolepsy. Guidelines recommend changes in sleep hygiene as first line and really do not recommend any one agent over another in the group and all recommendation are weak. Trazadone was recommended in the guidelines with moderate efficacy.

   Dr. Patel expressed that this category of agents would be more for people who could not stay asleep and the evidence only shows an increase of 20-30 minutes over placebo at best. He requested a look at what is currently preferred in this category. He also requested that others on the board weigh in especially if they prescribe these. We have both controlled and non-controlled agents. We don't know how many are using some agents off label for sleep. Dr. Vergara-Rodriguez talked about the use of doxepin and rozarem without PA or melatonin. Sleep studies show much different outcomes then what people self-report. Dr. Patel asked about head to head studies against any other agents. He expressed hesitancy to move a drug like this when the evidence of efficacy is not great. There are lots of options here and Dr. Vergara-Rodriguez would like to see something with more data for efficacy. Dr. Patel moved to have the drug remain non-preferred. Garry Moreland seconded. Motion passed unanimously. Dr. Vergara-Rodriguez moved to have the sleep agents reviewed at a meeting in 2023. Dr. Goyal seconded. The motion passed unanimously.

X. Future Agenda Preview-Sheri Dolan shared the proposed calendar for 2023 meetings as below:

Jan. 19, 2023-Tardive Dykinesia and Hereditary Angioedema

April 13, 2023-CGRP and a Class Clean-up
July 13, 2023-Sickle Cell Disease
October 12, 2023-TBA

Sheri thanked all for the extra hard work that went into this class review.

XI. Department Update-no report.

XII. Adjournment-Dr. Patel adjured the meeting at 10:39 am

Attendees

The names of board members and speakers are bolded.

Panelist List

1. Alyssa Stephenson
2. Sheri Dolan
3. **Cynthia VanSteenburg**
4. Donna Clay
5. **Arvind Goyal**
6. Claudia Colombo
7. **Garry Moreland**
8. Ryan Rodriguez
9. **Maurice Shaw**
10. **Janet Albers**
11. Lori Uildriks
12. Jose Jimenez
13. Melissa Davis
14. **Nicole Florence**
15. Mary Moody
16. Jennifer Dewitt
17. **Mahesh Patel**
18. **Pamela Vergara-Rodriguez**

Attendee List

1. Akesha Coleman
2. Beth Kingeter
3. **Bobbi Bentz**
4. Brent Fushimi
5. **Brooke Wilkins**
6. Call in User 3
7. Dan Murphy
8. Daniel Turelli

9. Daphne Ni
10. Doug Johnson
11. Eddie Carver
12. Elizabeth Plouff
13. Hani Said
14. Huzefa Master
15. **Irina Smith**
16. James Sharp
17. Jenny Carrell
18. Judy Jakuszewski
19. **Keith Powell**
20. Kelly Hamilton
21. Ken Ring
22. Linda Krueger
23. Lisa Tracz
24. Mary Kaneaster
25. Matt Bradley
26. **Nishil Patel**
27. O'HaraKeith
28. Patrick Murphy
29. Patty Monear
30. Robin Selsor
31. **Rick Melbye**
32. **Rick Szymialis**
33. Sabine Puglia
34. Sakib Hassan
35. Sara Gao
36. Scott Bischoff
37. Sunny Hirpara
38. Thomas Erickson
39. Thomas Vayalil
40. Tiawana Parker
41. Vicki Mee
42. Yvonne Collins
43. Zhen Ou