

State of Illinois Drugs and Therapeutics Advisory Board

Minutes for January 12, 2023 Meeting

- I. Dr. Patel opened the meeting at 8:30 am
- II. Roll Call was taken. Drs. Vergara-Rodriguez and Berkowitz were excused from attendance. A quorum was established.
- III. No conflicts of Interest
- IV. The October 20, 2022 meeting minutes were unanimously approved.
- V. Public Testimony was presented as below:

Speaker	Product	Organization
Michael Pham, Director of Medical Information	Hyftor	Nobelpharma America
Dr. John Flatt, Medical Science Liaison	Ztalmy	Marinus Pharmaceuti
Mariola Vazquez, Medical Outcomes Liaison	Adbry	Leo Pharma
Martha McGraw, Co-Director for Movement Disorders and Neurodegenerative Disease	Austedo	Northwestern Medicin DuPage Hospital
Jasmine Inman, Field, Value Evidence & Outcomes	Austedo	Teva Neuroscience
John Deason, Managed Care Liaison	Ingrezza	Neurocrine Bioscienc

- VI. There are no PDL Drug Appeals for this meeting.
- VII. There are no New Drug Appeals for this meeting.
- VIII. Class Reviews

- a. Topic: Tardive Dyskinesia Disorder
Presented by: Ryan Rodriguez, PharmD

Presented Material Highlights:

- FDA approved products for Tardive Dyskinesia (TD) in 2017
- Prior to this tetrabenazine was used off label
- Austedo and tetrabenazine have a boxed warning for depression and suicidality in patients with Huntington's Disease
- Most supporting evidence is for Austedo and Ingrezza
- No direct trials or comparisons have been performed
- 2020 APA guidelines for schizophrenia support the use of Austedo and Ingrezza because of the greater body of supporting evidence
- Austedo is twice daily with food and is also approved for chorea associated with Huntington's Disease
- Ingrezza is once daily with or without food

Discussion Highlights:

- The Board discussed whether was a need for a change from having all agents non-preferred
- Current basic criteria were shared

Motion: Dr. Patel-All drugs should stay non-preferred and show no change on the PDL
Second: Garry Moreland
Motion passed without dissent

- b. Topic: Hereditary Angioedema Agents
Presenter: Ryan Rodriguez, PharmD.

Presented Material Highlights:

- HAE is characterized by acute recurrent attacks of angioedema which are painful and can be disfiguring
- Frequency of attacks are variable
- Most are self-limiting and accompanied by a prodrome
- Can be fatal if they affect an airway and should be treated as early as possible
- Three management strategies include
 - a. On-demand treatment
 - b. Short-term prophylaxis
 - c. Long-term prophylaxis
- Short-term prophylaxis is usually used before a triggering life event such as a dental procedure or other stressful event
- Treatment options for all 3 were outlined
- No head to head trials or comparisons
- Many trials were open label, so it is hard to compare agents for laryngeal attacks
- C1 inhibitors have the most data but require reconstitution and IV administration apart from one agent
- Kalbitor is subcutaneous but has a boxed warning for anaphylaxis and must be administered by an HCP
- Icatibant is available in a pre-filled syringe and is the only on-demand treatment available generically

Discussion Highlights:

- Abuse potential and off-label use was discussed
- Kalbitor is the only IV and HCP administer
- Others are IV and appropriate for at home use
- Products that are easier to administer and more broadly indicated based on age group was discussed
- Not available through a retail pharmacy and must be mailed out from specialty pharmacy
- MCO's prefer all remain non-preferred
- All products will be on the PDL

Motion: Dr. Albers moved to make Berinert available preferred with a prior approval for on-demand treatment when prescribed by a specialist
Second: Dr. Goyal
Motion passed without dissent

IX. New Drug Initial Reviews

a. Product: Adbry

Presented by: Ryan Rodriguez, PharmD

Presented Material Highlights:

- Trial data found Adbry superior to placebo both in monotherapy and in therapy with topical corticosteroids-no active control trials
- A meta-analysis found it slightly less effective at 8-16 weeks
- Conjunctivitis is the side effect of special interest with Adbry
- 2020 European guidelines recommend Adbry at the same level as Dupixent

Discussion Highlights:

- Dupixent and Consentyx are currently preferred with PA on the PDL
- All are for moderate to severe disease

Motion: Dr. Patel moved to leave Adbry non-preferred as we already have preferred first line agents

Second: Dr. Albright

Motion passed without dissent.

b. Product: Hyftor

Presented by: Ryan Rodriguez, PharmD

Presented Material Highlights:

- Dermatologic features are frequent in patients with tubular sclerosis complex
- Other options can be invasive such as surgery or laser treatment
- The International Tubular Sclerosis Complex Consensus Group recognizes that some patients taking oral mtor inhibitors for other conditions have also seen improvements in facial angiofibromas but, systemic treatments are not recommended for facial angiofibromas alone
- This group does strongly recommend topical sirolimus for facial angiofibromas. Hyftor is the first product approved for this indication

Discussion Highlights:

- Incidence is 1:6,000 live births
- Wait for more information before making a decision
- Revisit in 6-12 months
- No invasive therapy would be required prior to approval

Motion: Garry Moreland, RPh moved to leave non-preferred

Second: Dr. Albers

Motion passed with no dissent.

c. Product: Ztalmy

Presented by: Ryan Rodriguez, PharmD

Presented Material Highlights:

- Rare disease, very hard to treat with supportive therapy as the current standard
- First drug indicated for cyclin-dependent kinase-like 5 deficiencies
- Illinois Law requires that no prior approval be necessary if a seizure disorder diagnosis is in the patient's medical records

Discussion Highlights:

- No guidelines were found for this disease
- No number of patients is available as it is so rare
- Discussion around the seizure disorder waiver and its function

Motion: Dr. Patel moved to leave Ztalmy non-preferred

Second: Garry Moreland, RPh

Motion passed with no dissent and one abstention

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

April 13, 2023-CGRP and a Class Clean-up

July 13, 2023-Sickle Cell Disease

October 12, 2023-TBA

- XI. Department Update-no report.

- XII. Adjournment-Dr. Patel adjured the meeting at 10:27 am

Attendees

The names of board members and speakers are bolded.

Panelist List

1. Alyssa Stephenson
2. Sheri Dolan
3. Deborah Albright
4. Cynthia VanSteenburg
5. Donna Clay
6. Arvind Goyal
7. Claudia Colombo
8. Garry Moreland
9. Ryan Rodriguez
10. Maurice Shaw
11. Janet Albers
12. Heather Freeman
13. Lori Uildriks
14. Jose Jimenez

15. Jennifer Dewitt
16. Mahesh Patel
17. Nicole Florence

Attendee List

1. Aa
2. Call in User 3
3. Call in User 4
4. Call in User 5
5. Call in User 6
6. Call in User 7
7. Call in User 8
8. Chase Williams
9. Cindy Pennington
10. Cyndi Anderson
11. Doug Johnson
12. Gary Parenteau
13. Heather Pezewski
14. Huzefa Master
- 15. Jasmine Inman**
16. Jen Tamburo
17. John Bullard
18. John Davis
- 19. John Deason**
- 20. John Flatt**
21. Ketih O'Hara
22. Kelly
23. Kenneth Berry
24. Kevin Gallagher
25. Kim White
- 26. Mariola Vazquez**
- 27. Martha McGraw**
28. Mary Kaneaster
29. Matt Grewe
- 30. Michael Pham**
31. Michele Shirley
32. Rob Kilo
33. Robert Pearce
34. Rob Abraham
35. Shauna Williams
36. Shelly Nickerson
37. Tiawana Parker
38. Tom Erickson

39. Zhen Ou