

State of Illinois Drugs and Therapeutics Advisory Board

Minutes for August 1, 2024, Meeting

- I. Dr. Patel opened the meeting at 8:33am.
- II. Roll Call was taken.
- III. No conflicts of interest.
- IV. The April 11, 2024, meeting minutes were unanimously approved.
- V. PDL Drug Appeals

A. Product: Rexulti

Presented by: Matt John, Medical Science Liaison, Otsuka

Presented Material Highlights:

- New indication for Alzheimer's associated agitation
- Only one approved Alzheimer's associated agitation
- No data to show superiority to other second-generation anti-psychotics.
- Showed decrease in Alzheimer's associated agitation in studies.
- Not indicated for any other dementia agitation

Discussion Highlights:

- Manufacturer is requesting preferred status for all 3 of its indications.
- No head-to-head studies with older anti-psychotics
- Alzheimer's agitation is very hard to treat.
- Board has had positive experience with this product.
- Patients have usually tried many other products before getting to Psychiatrist.
- Suicide and mortality are seen in this population inherently as well because of this medication.
- Indication is very specific.

Motion: Dr. Berkowitz moved to make Rexulti preferred with PA.

Second: Dr. Albers

Motion passed Dr. Patel abstained.

B. Product: Caplyta

Presented by: Chris Gallardo, PhD, IntraCellular

Presented Material Highlights:

- Schizophrenia and MDD indications

- Black box warning for suicidal ideation in pediatrics

Discussion Highlights:

- Also fills a gap in treatment.

Motion: Dr. Berkowitz moved to make Caplyta preferred with PA.

Second: Dr. Florence

Motion passed without dissent. Dr. Goyal abstained.

VI. New Drug Appeals

- a. None for this meeting.

VII. Class Reviews

- a. Topic: Glucagon Rescue Agents

Presented by: Jen Phillips, PharmD

Presented Material Highlights:

- Hypoglycemia must be treated emergently.
- Treat at glucose less than 70
- Guidelines recommend agents that don't require reconstitution.
- Ease of administration
- Guidelines recommend all patients that receive insulin be offered a prescription for a rescue product.
- No safety differences between products
- Baqsimi was shown to achieve a lower blood glucose level than the other newer products.
- Zealogue is indicated for 6 years and older, Baqsimi 4 years and older and GVOKE for 2 years and older.

Discussion Highlights:

- Having more agents than less is better.
- Older products have dosing related to weight.
- A prescription should be offered at the pharmacy for all insulin dependent patients.

Motion: Dr. Patel moved to make all products preferred

Second: Dr. Vergara-Rodriguez

Motion passed without dissent.

Motion: Dr. Goyal moved that because hypoglycemia is a life-threatening emergent condition, a prescription should be offered at the pharmacy for all insulin dependent patients for a glucagon emergency agent.

Second: Dr. Vergara-Rodriguez

Motion passed without dissent.

b. Topic: Anti-asthmatic Monoclonal Antibodies

Presented by: Jen Phillips, PharmD

Presented Material Highlights:

- Add on treatment for severe asthma.
- Discussion Highlights:
- Discussed that these are not emergent products.
- Indications require lab verification of levels.
- These are well tolerated.
- Dose to diagnosis verification also
- PA is currently not a barrier to access.

Motion: Dr. Patel moved to make all Preferred with PA

Second: Dr. Vergara-Rodriguez

Motion passed without dissent.

c. Topic: Overactive Bladder Medications

Presented by: Jen Phillips, PharmD and Dr. Teni Brown

Presented Material Highlights:

- Anti-muscarinic and Beta-3 agents are recommended.
- Guidelines recommend patient focused therapy.
- Evidence shows that increase risk of dementia is seen with anti-muscarinic agents.
- No pediatric evidence is available.
- Dr. Brown spoke to her research in this disease.
- Very debilitating
- Chronic treatment is necessary.
- Oxybutynin is the highest risk for dementia.
- African Americans are disproportionately affected.
- Mirabegron is contraindication in patients with uncontrolled hypertension.
- Mirabegron also carries the risk of many drug interactions.

Discussion Highlights:

- It is necessary for primary care physicians to be comfortable with anti-muscarinic and prescribe.
- Oxybutynin is the longest approved product.
- Oxybutynin can increase risk for dementia by 2-fold in a little as 3 months.
- This is a disease state that is particularly hard to have a fail-first method in place.
- Many patients see success with these where failure was seen with anti-cholinergic.
- No reason to choose one anti-muscarinic over the other.

Motion: Vergara-Rodriguez moved to make Mirabegron and Vibegron preferred

Second: Garry Moreland

Motion passed Dr. Goyal abstained.

VIII. New Drug Initial Reviews

- A. Product: Ogsiveo
Presented by: Jen Phillips, PharmD

Presented Material Highlights:

- Indicated for desmoid tumors.
- Usually cause death but cause many complications.
- Oral dosing
- Long-term data shows durability
- Does have drug interactions.
- Only product to receive FDA approval for the indication.

Discussion Highlights:

- Very rare disease

Motion: Dr. Patel moved to leave non-preferred

Second: Dr. Vergara-Rodriguez

Motion passed without dissent.

- B. Product: Rezdiffra
Presented by: Jen Phillips, PharmD/Tara McKinley, Health Systems Scientific Director-Madrigal

Presented Material Highlights:

- Indicated for NASH
- Only medications for this indication for the with fibrosis scores of F2-F3
- NASH renamed as Metabolic dysfunction-associated steatohepatitis (MASH)
- Only drug approved for this indication.
- No contraindications but requires liver enzyme tests.

Discussion Highlights:

- Bariatric surgery is a treatment for NASH.
- Shows improvement in fibrosis scores.

Motion: Dr. Vergara-Rodriguez moved to make preferred with PA

Second: Dr. Florence

Motion passed with no dissent.

- C. Product: Simlandi

Presented by: Jen Phillips, PharmD/Jasmine Inman, PharmD, Director, Field Medical Lead-Teva

Presented Material Highlights:

- Adilimumab-ryvk that is interchangeable with high concentration Humira.
- Approved for most indications that are covered by Humira.
- No differences were seen in switching trials with Humira.

Discussion Highlights:

- Discussion of interchangeable definition
- Value in recognizing biosimilar use and should be encouraged.
- Maybe should allow the Department to choose the most cost-effective options preferred.
- Discussed review process by the Department.
- Discussed need to have more than one preferred adalimumab.
- Interchangeable is like a generic for the novel drug.
- Others are not.
- No benefit in switch from Humira to another adalimumab product
- Humira is the Kleenex of adalimumab.

Motion: Dr. Patel moved to leave non-preferred

Second: Dr. Goyal

Motion passed. Dr. Shaw abstained.

Motion: Garry Moreland moved to allow the Department to choose the most cost-effective option of a clinically interchangeable product preferred with PA.

Second: Dr. Vergara-Rodriguez

Motion passed.

Motion: Dr. Patel moved to retract his initial motion

Second: Dr. Vergara-Rodriguez

Motion passed.

D. Product: Zurzuvae

Presented by: Jen Phillips, PharmD/Daphne Ni, Medical Account Director-Biogen

Presented Material Highlights:

- This is the only oral product indicated for post-partum depression.
- More targeted mechanism of action for this population
- Quick onset of action-as soon as 3 days
- 14-day course of treatment
- Patients advised not to drive for 12 hours after administration.
- Request preferred status.

Discussion Highlights:

- No evidence on breastfeeding
- Can be switched from another antidepressant if not stable.
- Durability data out to 45 days
- Can be started on another antidepressant after Zurzuvae therapy or can be used adjunctively.
- No transition data
- No drug interactions within the class
- Concerns about significant impairment and abuse potential

- Box warning for driving impairment for the duration of therapy.
- No long-term data
- Alternatives available
- Very little available in this space
- Post-partum depression is an emergency.
- No longer term follow-up for moms.
- Other Medicaid programs have as preferred

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

Second: Dr. Florence

Secondary motion: Dr. Goyal moved to table until further data is available reconsider in 6 months

Second: Dr. Berkowitz

Motion passed.

E. Product: Opsynvi

Presented by: Jen Phillips, PharmD

Presented Material Highlights:

- Combination product
- Benefits are related to compliance.
- Indicated for pulmonary hypertension.

Discussion Highlights:

- None

Motion: Dr. Patel moved to leave non-preferred

Second: Dr. Vergara-Rodriguez

Motion passed.

IX. Public Testimony

Speaker	Product	Organization
Speaking to Product		
Matt John, Managed Market Liaison	Rexulti	Otsuka
Christopher Gallardo, PhD	Caplyta	Intra-Cellular Therapies, Inc.
Tara McKinley, Health Systems Scientific Director	Rezdiffra	Madrigal Pharma
Jasmine Inman, PharmD, Field Value, Evidence & Outcomes	Simlandi	Teva Pharmaceuticals
Daphne Ni, Medical Account Director	Zurzuvae	Biogen
Public Comment		
Mark Heyrman, Facilitator	Rexulti/Caplyta	Mental Health Summit

Roueen Rafeyan, MD	Caplyta	Gateway Foundation
Tony Ohlhausen, Director of Research & Policy, NAMI	Caplyta/Rexulti	NAMI
Marcella Lindstrom, APRN	Rezdiffra	Madrigal Pharma
Judy Kelloway, PharmD, Director, Field Medical Lead	Nucala	GSK
Emily Rodman, Senior Medical Science Liaison	Tezspire	Amgen
Juanita Mora, MD	Tezspire	Chicago Allergy Center
Amea Patel, MD	Tezspire	Hines VA Medical Center & Loyola Univ. Medical Center
Vruti Patel	Gvoke	Xeris Medical Affairs Director

- X. Provider Review Request
 - None at this meeting.
- XI. Future Agenda Preview
 - October 10, 2024
 - Topic TBD
- XII. HFS Update
- XIII. Department Update-Jose Jimenez, BPAS Bureau Chief
 - New leadership across the board
 - New process for getting decisions.
 - Will get back as soon as possible.
- XIV. Adjournment-Dr. Patel adjured the meeting at 11:27 am.

Attendees

The names of board members are bolded.

Panelist List

1. Alyssa Stephenson
2. Sheri Dolan
3. **Arvind Goyal**
4. Heather Freeman
5. Brianna Hudak

6. **Paul Berkowitz**
7. **Janet Albers**
8. Jennifer Dewitt
9. Jose Jimenez
10. **Garry Moreland**
11. Claudia Colombo
12. **Maurice Shaw**
13. **Nicole Florence**
14. **Pamela Vergara-Rodriguez**
15. Mary Moody
16. **Mahesh Patel**
17. Melissa Davis
18. **Steve Sproat**
19. Thomas Dorn
20. Jen Phillips

Attendee List

1. A Meizlik
2. Amy Breen
3. Chris Dube
4. Chris Gallardo
5. Dan Calloway
6. Daphne Ni
7. Doug Johnson
8. Emily Rodman
9. Gary Dougherty
10. Gary Parenteau
11. Huzefa Master
12. Ian Sutker
13. Janie Huff

14. Jarret Helstern
15. Jasmin Inman
16. Jeff Knappen
17. Jenish Patel
18. Jim Sharp
19. Judy Kelloway
20. Kai Tao
21. Kara Naydyhor
22. Keith O'Hara
23. Kenneth Ring
24. Krupa Patel
25. Madison Zeltwanger
26. Marcella Lindstrom
27. Mark Baldrige
28. Mary Kaneaster
29. Matt John
30. M Heyrman
31. Michael Welton
32. Michele Shirley – Indivior
33. Michelle Brown – IL ACOG
34. Neelesh Nadkarni
35. Nichole Palusinski
36. Olivia Capperella
37. Roueen Rafeyan MD
38. Ryan Segroves
39. Steve Patterson
40. Jennifer Tamburo
41. Tara McKinley
42. Teni Brown

43. Thomas Vayalil

44. Tony Ohlhausen

45. Vruti Patel