# State of Illinois Drugs and Therapeutics Advisory Board Minutes for April 11, 2024 Meeting

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

Presented by: Neelesh Nadkarni, PharmD, MSPH, Medical Outcomes & Science Liaison

# Presented Material Highlights:

- Once daily
- Four indications
- D3 preferring mechanism of action
- Longest half-life of 1 week
- Neutral metabolic profile
- Minimal sedation

### Discussion Highlights:

- Well tolerated with coverage of all 4 indications
- We need to expand access to these medications to decrease hospitalizations.
- By the time patients get to a psychiatrist they have likely already tried 1<sup>st</sup> line drugs
- Commercial insurance companies do make patients fail generics first
- Significant utilization
- Metabolic neutrality plays a role in patients adherence
- Side effect profile in general is a huge determinant in adherence
- Prevention of long-term metabolic issues is important
- Should have metabolic monitoring
- Due to psychiatrist shortages, primary care doctors need a larger tool box
- No studies show superiority to preferred agents

Motion: Dr. Berkowitz moved to make Vraylar preferred.

Second: Dr. Vergara-Rodriguez

Motion passed 7 yes, 1 no, zero abstention. Role Call: Albers yes

Goyal yes Moreland yes Patel no Shaw yes

Vergara-Rodriguez yes

Florence yes Sproat yes

Motion: Dr. Patel move Vraylar to preferred with PA. (monitoring needed)

Second: Garry Moreland

Motion passed 5 yes, 3 no, 1 abstention

Role /call: Goyal abstain

Moreland yes Albers no Patel Yes Shaw yes

Vergara-Rodriguez yes

Berkowitz no Florence no Sproat yes

B. Product: Siklos

Presented by: Chris Muollo, Executive Director, Clinical Programs Viking Healthcare

# Presented Material Highlights:

- This is a tablet vs a capsule
- Capsules have 26 dosing vs Siklos has 51
- More dosing options for children
- This is a weight based drug

# Discussion Highlights:

- Less concern of toxicity
- Manufacturer ask is for preferred in patients 2-17 years old

Motion: Garry Moreland make Siklos preferred with PA

Second: Dr. Berkowitz

Motion passed without dissent.

C. Product: Carbaglu

Presented by: Andrea Hawkinson, Sr. Medical Science Liaison

# Presented Material Highlights:

- Request to be at parity to generic product
- Approved for 3 indications vs one
- Recommended in guidelines as 1<sup>st</sup> line

# Discussion Highlights:

Very low utilization

Motion: Dr. Patel moved to leave Carbaglu as non-preferred

Second: Garry Moreland

Motion passed without dissent

# VI. New Drug Appeals

a. None for this meeting.

### VII. Class Reviews

a. Topic: Adenergic Combination Inhalers Presented by: Jen Phillips, PharmD

### Presented Material Highlights:

- Guidelines recommend formoterol for asthma
- Guidelines recommend formoterol for COPD
- Digihalers have shown better compliance
- Trellergy is only triple therapy

# Discussion Highlights:

- Discussion around different formulations
- Most patients can use any delivery device if properly trained
- Technique is key to success

Motion: Garry Moreland moved to make Symbicort non-preferred and Breyna preferred

Second: Dr. Patel

Motion passed without dissent.

Motion: Garry Moreland moved to make Advair Diskus non-preferred and Wixela preferred

Second: Dr. Albers

Motion passed without dissent.

Motion: Garry Moreland moved to make Airsupra preferred

Second: Dr. Albers

Motion passed without dissent.

b. Topic: Anticholinergic Inhalers
Presented by: Jen Phillips, PharmD

# Presented Material Highlights:

- All approved for COPD
- Spiriva also approved for asthma
- No preference in products in the guidelines

### All well tolerated

# Discussion Highlights:

- Nebulized solutions are rarely used
- Spiriva only for pediatrics

Motion: Dr. Vegara-Rodriguez moved to leave class as is

Second: Dr. Albers

Motion passed without dissent.

c. Topic: Beta Adrenergic Inhalers
Presented by: Jen Phillips, PharmD

# Presented Material Highlights:

- Albuterol inhalers are available for 2 years and older
- Make terbutaline tablets non-preferred
- Digihalers are sometimes better for some patients

# Discussion Highlights:

Powders are sometimes needed

Motion: Dr. Vegara-Rodriguez moved to make ProAir Digihaler preferred

Second: Dr. Albers

Motion passed without dissent

Motion: Garry Moreland moved to make terbutaline tablets non-preferred

Second: Dr. Patel

Motion passed without dissent

d. Topic: Steroid Inhalers

Presented by: Jen Phillips, PharmD

# Presented Material Highlights:

- Consider age range for devices
- Differing delivery methods are also available
- Fluticasone Aerosol and Asmanex HFA are once daily all others are twice daily
- Arnuity adds a second fluticasone option and is once daily
- Lots of utilization of QVAR

# Discussion Highlights:

- Make Arnuity preferred
- Generic fluticasone powder preferred

Motion: Garry Moreland moved to make Arnuity preferred

Second: Dr. Vergara-Rodriguez Motion passed without dissent.

Motion: Garry Moreland moved to make Fluticasone powder preferred

Second: Dr. Albers

Motion passed without dissent

Motion: Dr. Vergara-Rodriguez moved to make Pulmicort preferred

Second: Dr. Albers

Motion passed without dissent

# VIII. New Drug Initial Reviews

# A. Product: Daybue

Presented by: Jen Phillips, PharmD
 Presented Material Highlights:

- For Rett's Syndrome
- Severe and rare neurodevelopment syndrome
- Loss of hand and fine motor symptoms
- Approved for 2 years and above
- Diarrhea in 80.6% was main side effect
- Guidelines do not mention since this was recently approved
- Only drug for core symptoms of Rett's

# Discussion Highlights:

- Very low evidence of efficacy with high incidence of side effects
- 60% in study had no response
- Reviewing on a case by case basis
- Not enough clinical evidence at this time to fully back this as preferred

Motion: Dr. Patel moved to leave non-preferred

Second: Dr. Vergara-Rodriguez Motion passed without dissent.

# B. Product: Skyclarys

Presented by: Jen Phillips, PharmD/Daphne Ni, Medical Account Director Presented Material Highlights:

- For Friedrich's Ataxia
- Symptoms range from mild to severe
- Hallmark symptom is loss of motor function
- Most require wheelchair 15 years after diagnosis
- Oral
- Some baseline labs should be run
- 2 point increase in MFARS score was seen
- No published US guidelines

# Discussion Highlights:

- Increase of 2 points out of 93 does not seem hugely significant
- Only product for this disease
- Decrease in falls was seen
- Continue to watch long-term results
- Substantial metabolic side effects

Motion: Dr. Vergara-Rodriguez moved to leave non-preferred

Second: Dr. Patel

Motion passed with no dissent.

# C. Product: Xdemvy

Presented by: Jen Phillips, PharmD Presented Material Highlights:

- For demodex blephoritis
- Mites on the eyelashes
- Eye drops
- Side effects were burning on administration
- Resistance to other treatments is beginning to be seen
- Highly effective

# Discussion Highlights:

- Most patients are mild to moderate and respond to other treatments
- Only ophthalmic administration
- PA criteria is not stringent

Motion: Garry Moreland moved to leave non-preferred

Second: Dr. Berkowitz

Motion passed with no dissent.

# IX. Public Testimony

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Speaker	Product	Organization
Neelesh Nadkarni, PharmD, MSPH, Medical	Vraylar	AbbVie
Outcomes & Science Liaison		
Chris Muollo, Executive Director, Clinical	Siklos	Viking Healthcare on behalf of
Programs		Medunik USA
Andrea Hawkinson, Sr. Medical Science	Carbaglu	Recordati Rare Diseases, Inc.
Liaison		
Stacey Repotski, PharmD, HEOR Director	Daybue	Acadia Pharmaceuticals
Daphne Ni, Medical Account Director	Skyclarys	Biogen
Judy Kelloway, Pharm D Dir, Field Medical	Trellegy	GSK
Lead	Ellipta	
Jalal Damani, DO	Trelegy	Swedish Hospital-Endeavor
	Ellipta	Health/Northshore
Rajive Tandon, MD	Trellegy	GSK
	Ellipta	
Amy Kreher, Caregiver	Daybue	

Robin Ryther, MD, PhD Director, Rett	Daybue	Rett Spectrum Clinic, Associate Prof of
Spectrum Clinic, Associate Prof of Neurology,		Neurology, Washington University of
Washington University of Medicine		Medicine
Becky Young, Parent Advocate	Skyclarys	
Emily Young, MSW	Skyclarys	

- X. Provider Review Request
  - None at this meeting.
- XI. Future Agenda Preview
  - August 1, 2024
  - October 10, 2024
- XII. HFS Update
  - None due to time constraint
- XIII. Department Update-Jose Jimenez
- XIV. Adjournment-Dr. Patel adjured the meeting at 11:27 am.

# **Attendees**

The names of board members and speakers are bolded.

### **Panelist List**

- 1. Alyssa Stephenson
- 2. Sheri Dolan
- 3. Arvind Goyal
- **4.** Heather Freeman
- 5. Paul Berkowitz
- 6. Janet Albers
- **7.** Jennifer Dewitt
- **8.** Jose Jimenez
- 9. Garry Moreland
- 10. Claudia Colombo
- 11. Maurice Shaw
- 12. Nicole Florence

- 13. Pamela Vergara-Rodriguez
- **14.** Mary Moody
- 15. Mahesh Patel
- **16.** Melissa Davis
- 17. Steve Sproat
- **18.** Thomas Dorn
- **19.** Jen Phillips

# **Attendee List**

- 1. A Meizlik
- 2. Amy Breen
- 3. Amy Kreher
- 4. Andrea Hawkinson
- 5. Becky Young
- 6. Bethany Howell
- 7. Brianna Hudak
- 8. Brittany Jacoby
- 9. Oliva Capperella
- 10. Chase Williams
- 11. Chris Muollo
- 12. Clemice Hurst
- 13. Dami Adeyemi
- 14. Dami HCSC
- 15. Daphne Ni
- 16. Emily Young
- 17. Doug Johnson
- 18. Gary Parenteau
- 19. Gregg Stein
- 20. Huzefa Master Meridian

- 21. Jamie Dean
- 22. Janie Huff
- 23. Jim Sharp
- 24. Judy Kelloway
- 25. Keith O'Hara
- 26. Kelly Hamilton
- 27. Kelly Petrowski
- 28. Kellyn Madden
- 29. Kenneth Ring
- 30. Kevin Hall Sanofi
- 31. Kimberly Canfield
- 32. Madison Zeltwanger-Artia Solutions
- 33. Mariah J Scott
- 34. Marissa
- 35. Mark Baldridge
- 36. Mary Kaneaster
- 37. Matt J
- 38. Melissa Davis
- 39. Michele Shirley Indivior
- 40. Neelesh Nadkarni
- 41. Nichole Palusinski
- 42. Ravi Patel
- 43. Renetta Mosley
- 44. Robin Ryther
- 45. Rod Scott
- 46. Ron Abraham
- 47. Ryan Segroves
- 48. Samantha
- 49. Shankari Sureshbabu

# 50. Stacey Repotski

- 51. Steve Patterson
- 52. Sunny Hirpara
- 53. Tamburo Jennifer
- 54. Thomas Vayalil
- 55. Tyler Craddock Bluebid Bio