

State of Illinois Drugs and Therapeutics Advisory Board

Minutes for July 13, 2023 Meeting

- I. Dr. Albers opened the meeting at 8:34 am
- II. Roll Call was taken.
- III. No conflicts of Interest
- IV. The April 6, 2023 meeting minutes were unanimously approved.
- V. Public Testimony was presented as below:

Speaker	Product	Organization
Ifeanyi Beverly Chukwudozie	All	Patient Advocate
Paige Reilly, MD	All	Sick Cells
TaLana Hill-Hughes	All	Executive Director, Caregiver and member of the Illinois Rare Disease Commission
Austin Wesevich, Hematology/Oncology Fellow	All	University of Chicago
Maggie Jalowsky, Director of Advocacy	All	Sick Cells
Terrace Hill	All	Sickle Cell Disease Association of IL., Sick Cells, Global Healthy Living Foundation
Lewis L. Hsu, MD, PhD pediatric hematologist	All	Sickle Cell Disease Association of Illinois
Gail Telber, NP	Oxbryta	Loyola Medical Center
Charles Stark, Sr. VP of Clinical Development & Medical Affairs (Joe Viscera)	Endari	Emmaus Medical, Inc.
Amanda Haikalis, Medical Advisor	Siklos	Medunik, USA
Barima Opong-Owusu, PharmD., BCPS	Oxbryta	Pfizer Pharmaceuticals
Eric Kruep, PharmD, MS	Orserdu	Stemline Therapeutics
Jennifer S. Kim, MD	AUVI-Q	Kaleo, Inc.
Anita McDonnell	AUVI-Q	Kaleo, Inc.
Sylvia Poulos, Medical Science Liaison	Carbaglu	Recordati Rare Diseases

- 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: Sickle Cell Disease
Presented by: Jen Phillips, PharmD

Presented Material Highlights:

- Discussed the multifaceted disease presentation in individuals.
- Need for a variety of medications to individualize treatment for each patient.
- Guidelines recommend Hydroxyurea due to better data available.
- Last update for guidelines was in 2014.
- Discussed differences between the medications indicated.
- L-glutamine has data for children down to 5.

Discussion Highlights:

- ~1,400 patients on Sickle Cell medication.
- Hydroxyurea has the most utilization.
- Adakveo decreases vaso-occlusive crisis.
- Voxelator approved through accelerated approval.
- Discussed the need for PA here.
- Discussed need to be able to live a productive life. Hospitalization should not be the criteria.
- Preventative drugs so there is time to request a PA.
- Discussed PA criteria in general.
- PA staff is looking at the whole patient but there is no evidence of combination use.
- Looking for efficacy to determine renewals.

Motion: Dr. Albers moved to make Endari preferred

Second: Dr. Vergara-Rodriguez

Motion passed without dissent.

IX. New Drug Initial Reviews

a. Product: AUVI-Q

Presented by: Jen Phillips, PharmD

Presented Material Highlights:

- Several formulations are available.
- Audio recording and visual instructions.
- 0.1mg dosage form with shorter needle for infants/toddler.
- Data supports ease of use.

Discussion Highlights:

- Audio has value in the training process.
- Discussion around the infant/toddler dosing.
- Less chance of injury with shorter needle.
- Auto-injector is preferred to prefilled syringe.

Motion: Dr. Vergara-Rodriguez moved to make AUVI-Q infant toddler dose preferred

Second: Dr. Albright

Motion passed without dissent.

- b. Product: Carbaglu
Presented by: Jen Phillips, PharmD

Presented Material Highlights:

- One of 3 carglumic acid available.
- Approved for 3 indications rather than the 1 indication of the generics.
- 30-day stability after opening.
- 2-4 times daily dosing.

Discussion Highlights:

- Only one approved for NAGS.
- Urea cycle diseases are very rare.
- Eleven patients using these products.
- Other products can be used for urea cycle disorders.

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

Second: Dr. Vergara-Rodriguez

Motion passed with no dissent.

- c. Product: Orserdu
Presented by: Jen Phillips, PharmD

Presented Material Highlights:

- Discussed safety, efficacy, and place in therapy.
- Not first line therapy.
- Not noted yet in the guidelines.

Discussion Highlights:

- Mutation specific.
- Standard of care was fulvestrant in the trial.
- Must have tried and failed at least 1 or 2 other therapies.
- Seven requests for approval/6 approved.
- PA based on indication and NCCN guidelines.
- 34% vs 20% survival data at 6 months/21% vs 9% at 12 months.
- Oral vs injection dosage form.
- Adherence was not assessed during the clinical trial.

Motion: Dr. Vergara-Rodriguez moved Orserdu be preferred

Second: Dr. Florence

Motion passed with no dissent. Dr. Goyal abstained.

- X. Provider Review Request

- None at this meeting.

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

October 12, 2023-Blood Glucose Products

XII. Department Update-

- Dr. Goyal shared the intent to review weight loss products at the October meeting.
- Dr. Vergara-Rodriguez suggested a knowledge session before the actual meeting.

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

Attendees

The names of board members and speakers are bolded.

Panelist List

1. Sheri Dolan
2. **Deborah Albright**
3. Donna Clay
4. **Arvind Goyal**
5. Claudia Colombo
6. Jen Phillips
7. **Maurice Shaw**
8. **Janet Albers**
9. Heather Freeman
10. **Pamela Vergara-Rodriguez**
11. Jennifer Dewitt
12. Mary Moody
13. **Mahesh Patel**
14. **Paul Berkowitz**
15. **Nicole Florence**

Attendee List

1. Call-in User 10- 438227****
2. Call-in User 12- 301787****
3. Call-in User 13- 248938****
4. Call-in User 14- 317435****
5. Call-in User 16- 480620****
6. Call-in User 17- 630334****
7. Call-in User 2- 765505****
8. Call-in User 21- 773536****
9. Call-in User 22- 312351****
10. Call-in User 24- 312864****
11. Call-in User 25- 218396****
12. Call-in User 26- 310214****
13. Call-in User 28- 713962****
14. Call-in User 3- 404820****
15. Call-in User 30- 217558****

16. Call-in User 31- 708843****
17. Call-in User 32- 312864****
18. Call-in User 35- 847846****
19. Call-in User 37- 815543****
20. Call-in User 38- 317441****
21. Call-in User 39- 630596****
22. Call-in User 4- 479721****
23. Call-in User 40- 610944****
24. Call-in User 41- 724417****
25. Call-in User 42- 773544****
26. Call-in User 43- 217402****
27. Call-in User 45- 513594****
28. Call-in User 46- 773805****
29. Call-in User 47- 630385****
30. Call-in User 5- 317556****
31. Call-in User 6- 850901****
32. Call-in User 7- 708365****
33. Call-in User 8- 215896****
34. Call-in User 48- 404820****
35. Call-in User 49- 724417****
36. Call-in User 50- 805707****
37. Chintan Patel
38. Patrick Hostert
39. Joe Vicera (sp?)
40. Gale Talbers, NP