State of Illinois Drugs and Therapeutics Advisory Board Minutes for October 5, 2023 Meeting

- I. Dr. Patel opened the meeting at 8:33 am.
- II. Roll Call was taken.
- III. No conflicts of interest.
- IV. The July 13, 2023, meeting minutes were unanimously approved.
- V. Board Elections
 - Dr. Goyal moved that the current Officers retain their positions.
 - Dr. Berkowitz 2nd the motion
 - Motion passed unanimously.
 - Dr. Patel will remain Chair and Dr. Albers will remain Vice Chair
- VI. Public Testimony was presented as below:

Speaker	Product	Organization
Justin Ryder, Ph.D	All Weight Loss	Northwestern University, Lurie Children's
		Hospital
Arden Arslanyan, Managed	Abilify Asimtufii	Otsuka
Markets Liaison		
Erin Petrusic	Abilify Asimtufii	Otsuka/Thresholds
Jasmin Inman	AustedoXR/Ulzedy	Teva
Lindsay Bebout, MOVL	Perseris	Indivior
David Shin, Health	Dificid/Prevymis	Merck
Systems Medical Affairs		
Director		
Brian Denger, Community	Elevidys	Parent Project Muscular Dystrophy
Engagement Coordinator		
Mariam Alboustani,	Elevidys	Sarepta
Pharm/D		
Marit Sivertson	Elevidys	Parent
Nathan Plasman	Elevidys	Sarepta
Laura A. Niewiadomski,	Vyjuvek	Krystal Biotech
Senior National Director,		
Field Medical Affairs		

- VII. There are no PDL Drug Appeals for this meeting.
- VIII. New Drug Appeals
 - Perseris (Reviewed below with Uzedy and Abilify Asimtufi)

- Rinvoq Presented by Neelesh Nadkarni
 - JAK Inhibitor
 - 7 indications
 - Atopic Dermatitis indication where current JAK is not.
- Skyrizi Presented by Neelesh Nadkarni
 - IL-23 Antagonist
 - 3 indications

Motion: Garry Moreland motions to leave both Rinvoq and Skyrizi non-preferred.

Second: Dr. Vergara-Rodriguez seconded the motion.

Motion passed without dissent.

IX. Class Reviews

a. Topic: Anti-Obesity GLP-1 Inhibitors Presented by: Jen Phillips, PharmD

Presented Material Highlights:

- Medication is indicated in patients with a BMI >27 with a comorbidity and 30 without.
- Success is achieved if a 5% weight loss is achieved in 3 months. If not achieved, other forms of treatment should be investigated.
- ADA guidelines recommend Semaglutide.
- APA guidelines recommend medication treatment for children in > the 95th percentile in children 12 years and older.
- Tirzepatide not yet approved was seen to be the most effective and is dual acting.
- GLPs are seen to be more effective than other weight loss products.
- SE may affect adherence.

Discussion Highlights:

- The Board believes that they should be closely monitored and written by those with experience in using them for weight loss.
- They would like to see wide access to these products.
- They feel this is very useful in overweight diabetic and pre-diabetic patients.
- The feeling is that general criteria for these should be developed.
- They have found them to be more effective for weight loss than orals.
- The Department is working towards making these drugs available for obesity.
- Federal government consent is necessary for the Department to cover.
- MCOs seeing 10% off-label use of GLP-1 drugs.
- Concern over long-term utilization.
- Maintenance doses may be indicated.
- Should be prescribed under the FDA indications.

- Commercial insurers are also hesitant to cover now.
- This is a class where coverage continues to evolve.
- Shortages are a huge issue to dose maintenance.
- Department acts as a safety net to monitor utilization so make preferred with PA.
- Will need to come back to look at new products as they enter this space.
- Harm could result from lack of monitoring and the start and stop of the medication.
- Opening the class may help with the supply issue for diabetics as these are not indicated for diabetes.

Motion: Garry Moreland motions to include the Anti-Obesity class on the PDL subject to federal approval for the Department to cover the class.

Second: Dr. Albers seconded the motion.

Motion passed without dissent.

X. New Drug Initial Reviews

• Product: Dificid

Presented by: Jen Phillips, PharmD

Presented Material Highlights:

- Tablets and oral suspension.
- Data shows it to be superior to vancomycin.
- Dificid has been moved to the preferred option in the guidelines.

Discussion Highlights:

• Cost difference is huge so concern over when we begin to save money in medical bills.

Motion: Garry Moreland moved to make Dificid preferred.

Second: Dr. Vergara-Rodriguez seconded

Motion passed without dissent.

Dr. Goyal abstained.

• Product: Austedo XR

Presented by: Jen Phillips, PharmD

Presented Material Highlights:

• Once daily formulation.

Discussion Highlights:

- Will be used for many psychiatric patients with TD.
- There are some side effects.
- TD is a consequence of long-term antipsychotic use in many.

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

Second: Dr. Berkowitz seconded the motion. Motion passed with no dissent.

Product: Perseris/Uzedy/Abilify Asimtufi
 Presented by: Jen Phillips, PharmD

Presented Material Highlights:

- Perseris and Uzedy indicated for schizophrenia.
- Abilify Asimtufi is indicated for both schizophrenia and Bipolar I.
- All require an oral trial before initiation.
- Uzedy is indicated for higher risperidone oral dosages and can be given monthly or bi-monthly.
- Perseris is monthly.
- Abilify Asimtufi is bi-monthly and is an IM rather than SQ.
- Guidelines advocate for long-acting agents but not a specific agent.

Discussion Highlights:

- Patient preference plays a big rule in product choice.
- SQ dosing can be painful due to volume.
- Aristada can also be used bi-monthly.
- Risperidone formulation is needed as preferred.
- Key is to get adherence.

Motion: Dr. Patel moved to make Uzedy, Perseris and Abilify Asimtufi preferred with PA. Second: Dr. Florence seconded the motion.

Motion passed with no dissent.

Product: Prevymis

Presented by: Jen Phillips, PharmD

Presented Material Highlights:

- Anti-viral for CMV in specific situations.
- Indicated for kidney transplant.
- Guidelines recommend as sole preferred agent.
- Not active against other herpes infection.
- Significant side effects are seen with drug interaction.

Discussion Highlights:

- Vangancyclovir is still used as primary in practice.
- Concern that Prevymis would be used as treatment rather than prophylaxis.

Motion: Dr. Patel moved to make Prevymis preferred with PA.

Second: Dr. Vergara-Rodriguez seconded the motion.

Motion passed with no dissent.

Product: Elevidys

Presented by: Jen Phillips, PharmD

Presented Material Highlights:

- Baseline and weekly liver function tests should be run initially.
- Accelerated approval using a surrogate endpoint.
- Approved only for boys between 4-5 years old.

Discussion Highlights:

- Clinical evidence is lacking but this is the only treatment.
- Is very different than the currently available treatment.
- Not a lot of other options.
- Could change the course of disease for children.
- Department reviews all of these on a case-by-case basis.
- Lack of long-term data.

Motion: Dr. Vergara-Rodriguez moved to come back to this drug when short and long-term clinical outcome data is available when the confirmatory trial reads out.

Second: Dr. Garry Moreland seconded the motion.

Motion passed with no dissent.

Product: Vyjuvek

Presented by: Jen Phillips, PharmD

Presented Material Highlights:

- Chronic use is required.
- Improved in wound healing and pain score.
- First in case.

Discussion Highlights:

- Three requests for this in the past year.
- Very rare.

Motion: Dr. Patel moved to leave in non-preferred and revisited when long-term data is available. *Amended to bring back for further review in January.

Second: Dr. Florence seconded the motion.

Motion passed with no dissent.

Product: Tadliq

Presented by: Jen Phillips, PharmD

Presented Material Highlights:

- Oral suspension of tadalifil.
- No approved for pediatric patients.

Discussion Highlights:

- Revatio suspension is available.
- Need would be based on need to absolutely have tadalafil.

- Difference in dosage frequency.
- Rare disease so most likely not abused.

Motion: Garry Moreland moved to leave non-preferred.

Second: Dr. Vergara-Rodriguez seconded the motion.

Motion passed with no dissent.

- XI. Provider Review Request
 - None at this meeting.
- XII. Future Agenda Preview-Sheri Dolan shared the proposed dates for 2024.
 - January 11, 2024
 - April 11, 2024
 - August 1, 2024
 - October 10, 2024
- XIII. Department Update-
 - Dr. Goyal shared that the Department has opened the RSV season effective October 1 and through February unless further review sees a need to extend it.
- XIV. Adjournment-Dr. Patel adjured the meeting at 11:23 am.

Attendees

The names of board members and speakers are bolded.

Panelist List

- 1. Alyssa Stephenson
- 2. Sheri Dolan
- 3. Donna Clay
- 4. Arvind Goyal
- 5. Nicole Florence
- 6. Garry Moreland
- 7. Maurice Shaw
- 8. Janet Albers
- 9. Pamela Vergara-Rodriguez
- 10. Jennifer Dewitt
- 11. Mary Moody
- 12. Mahesh Patel
- 13. Paul Berkowitz
- 14. Steve Sproat
- 15. Thomas Dorn
- 16. Jen Phillips

Attendee List

- 1. Arden Arslanyan Otsuka
- 2. Bryan Dillon Otsuka
- 3. Catie Ament Otsuka
- 4. Neelesh Nadkarni Abbvie
- 5. Justin Ryder Northwestern University, Lurie Children's Hospital
- 6. Jerry Lubben Merck
- 7. Keith O'Hara Otsuka
- 8. Christie Dention-UIC
- 9. Huzefa Master
- 10. Brittan Bolin American Diabetes Association
- 11. Mark Baldridge Alkermes
- 12. Jenny Veronica Carrell Janssen
- 13. Jasmine Inman Teva
- 14. Laura Niewiadomski Krystal Biotech
- 15. Heather Pezewski Neurocrine Biosciences
- 16. Stefanie Baran Paratek
- 17. Ali Anwar Psychiatrist
- 18. Gary Parenteau Dexcom
- 19. Erin Petrusic
- 20. Lindsay Bebout Perseris
- 21. David Shin Dificid/Prevymis
- 22. Mariam Alboustani Serepta
- 23. Marit Sivertson Parent
- 24. Nathan Plasman Parent