# **Drug Utilization Review Board (DURB)**

Thursday, October 12, 2023

9:00 a.m. Approved Virtual: Teams Meeting Platform In-Person Meeting Site: John H. Winters Building, Public Hearing Room 125, Austin, Texas

# Agenda Item 1: Call to order, roll call, and welcoming remarks

Dr. Alejandro Kudisch, Chair, called the Drug Utilization Review Board (DURB) meeting to order at 9:01 a.m.

Dr. Alejandro Kudisch, Chair, welcomed committee members, the public in attendance

Ms. Jacqueline Thompson, Advisory Committee Coordination Office (ACCO), Health and Human Services Commission (HHSC) read the logistical announcements and stated the meeting was being conducted in accordance with the Texas Open Meetings Act. Ms. Thompson conducted roll call and announced no presence of a quorum. Due to no quorum, the Board continued to the non-actionable agenda item (agenda item #3).

# Table 1: Drug Utilization Review Board member attendance at the Thursday,October 12, 2023, meeting.

Member name	Attended	Member name	Attended
Dr. Scott Blaszczyk	Ν	Dr. Sarah Kubes	Y
Mr. Dennis Borel	Y	Dr. Alejandro Kudisch	Y
Dr. Marlo Brawner	N	Dr. Jill Lester	Y
Dr. Dominique Brewster	N	Dr. Brigetta Martinez	Y
Dr. Deborah Briggs	N	Dr. Richard Noel	N
Dr. Salil Deshpande	N	Dr. Kim Pham	Y
Dr. Jennifer Fix	Y	Dr. Lisa Sprenger	Y
Dr. Robert Hogue	N	Dr. Natalie Vanek	Y

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Member name	Attended	Member name	Attended
Dr. Heather Holmes	Y	Dr. Kathryn Velasquez	Y
Dr. Joshua Tonche-Johns	N	Dr. Carlos Omar Viesca	N

# Agenda Item 3: Public comment and discussion on the July drug classes to be reviewed for the Medicaid Preferred Drug List (PDL)

Ms. Thompson, Advisory Committee Coordination Office (ACCO), Health and Human Services Commission (HHSC) read the logistical announcements for providing public comments.

#### **10 Minute Break**

The Drug Utilization Review Board took a short break from 9:11 a.m. until 9:16 a.m. Dr. Alex Kudisch, chair called the meeting to order.

#### Agenda 3 continued:

Speaker name	Representing	Drug	PDL Class
* also written comment			
*Marcus StanPaland	PTC Therapeutics	Benlysta	Immunomodulators, Lupus
Eku Oben, PharmD	Alcon	Eysuvis	Ophthalmics, anti- inflammatory/immunomodulator
Chase Janak	Pfizer	Myfembree	Uterine Disorder Treatments
Written Comment			
Jonathan Blaize, PhD	PTC Therapeutics	Emflaza	Glucocorticoids, oral
Marcus Stanaland	PTC Therapeutics	Benlysta	Immunomodulators, Lupus

## Agenda Item 4: Public comment and discussion on the July drug classes to be reviewed for the Medicaid Preferred Drug List (PDL)

Speaker name *also written comment	Representing	Drug	PDL Class Madeline
Andrea Scherschel	Nestle Health Sciences	Vowst	Antibiotics, gastrointestinal
Brian Kim, MD, MPH	Organon Pharmaceutical	Xaciato Vaginal Gel 2%	Antibiotics, vaginal
Herbert Peeples	UCB Inc.	Fintepla, Briviact, Nayzilam	Anticonvulsants
Karen Keough	Practitioner	Epidiolex (cannabidiol)	Anticonvulsants
Sindi Rosales	Epilepsy Foundation Central & South Texas	All Anticonvulsants	Anticonvulsants
Michael Faithe	Jazz Pharmaceuticals	Epidiolex (cannabidiol)	Anticonvulsants
Mathew Baker	Aurinia	Lupkynis	3g. Immunomodulators, Lupus
Anita Thomas	North Pointe Psychiatry	Abilify Asimtufii (Intramusc)	Antipsychotics
David Miley	Teva	Uzedy	Antipsychotics
Emanga Ekinde	Indivior	Perseris	Antipsychotics
Tanushree Thote	Intra-Cellular Therapeutics, Inc	Caplyta	Antipsychotics
James Rush, MD	Top of Texas Psychiatry	Abilify Asimtufii (Intramuscular)	Antipsychotics
James Rush, MD	Top of Texas Psychiatry	Abilify Maintena (Intramuscular)	Antipsychotics
Kenneth Berry	Alkermes	Aristada/Lybalvi	Antipsychotics
Nathan Blake	AbbVie	Vraylar (cariprazine)	Antipsychotics
Lissette Galvan	NAMI Texas	All drugs in class	Antipsychotics

Speaker name *also written comment	Representing	Drug	PDL Class Madeline
Nishil Patel	Amgen	Prolia and Evenity	Bone Resorption Suppression and Related Agents
Madeline Shurtleff	Otsuka	Abilify Maintena, Rexulti	Antipsychotics
*Frank Chen	PTC Therapeutics	Abilify Asimtufii	Antipsychotics
*Susanne Yaws	Tope of Texas Psychiatry	Rexulti	Antipsychotics
*Madeline Shurtleff	Otsuka	Rexulti	Antipsychotics

#### **10 Minute Break**

The Drug Utilization Review Board took a short break from 10:38 a.m. until 10:50 a.m. Dr. Alex Kudisch, chair called the meeting to order.

Ms. Jacqueline Thompson, Advisory Committee Coordination Office (ACCO), Health and Human Services Commission (HHSC) conducted roll call and announced a quorum was present.

#### **Continued to Agenda Item 2:**

# Agenda Item 2: Consideration of July 21, 2023, draft meeting minutes

Ms. Jacqueline Thompson, ACCO, referred members to the draft minutes provided by the program liaison and called for any edits. Dr. Kudisch commented the time of the meeting conclusion needed to be corrected and called for additional edits. Hearing none, Dr. Kudisch called for a motion to approve the meeting minutes of July 21, 2023.

**Motion**: Mr. Dennis Borel moved to approve the July 21, 2023 minutes with the as amended. Dr. Kubes seconded the motion. Following a roll call vote, the motion passed by a majority vote of 7 yeas (Borel, Fix, Kubes, Kudisch, Lester, Martinez, Vanek) 0 nays, 3 abstentions (Holmes, Pham, Velasquez).

Speaker name \*also written comment Drug

PDL Class Madeline

Continued with Agenda Item 4: Public comment and discussion on the July drug classes to be reviewed for the Medicaid Preferred Drug List (PDL)

Carla M. Davis, MD	Practitioner	Auvi-Q	Epinephrine, self-injected
Daysi Fardales	Pfizer Biopharma	Ngenla	Growth Hormone
Sophie Hoang	Novo Nordisk Inc	Sogroya and Norditropin	Growth Hormone
Tracey Maravilla, PharmD	Ascendis Pharma, Inc	Skytrofa (lonapegsomatropin- tcgd)	Growth Hormone
Porscha Showers	Gilead Sciences, Inc	Biktarvy	HIV/AIDS
Jordan Smelley	self	All GPL-1 Antagonist	Hypoglycemics, incretin mimetics/enhancers
Jamyia Clark	Boehringer Ingelheim Pharmaceuticals, Inc	Empagliflozins (Jardiance, Synjardy and Synjardy XR)	Hypoglycemics, sodium- glucose cotransprot-2 (SGLT2) inhibitors
Emanga Ekinde	Indivior	Sublocade	Opiate dependence treatments
JayDee Frederickson	Paratek Pharma	Nuzyra	Tetracyclines
Written Comments			
Anita McDonnell	Kaleo	Auvi-Q	Epinephrine
Jignesh Patel	Novo Nordisk	Sogroya and Norditropin	Growth Hormone
Gail Berman, MD	Paratek Pharma	Nuzyra	Tetracyclines

- Public oral comment consisted of drug information or new drug information or requests for the preferred status of drugs or open access to drugs or prior authorization criteria recommendations or spoke on personal experience with drugs.
- Member questions asked of speakers:
  - Discuss off-label use of Epidiolex of Anticonvulsants class.
  - Differentiate Uzedy and Risperdal Consta of Anticonvulsants class.

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- Differentiate between the risperidone preferred products and Perseris and Uzedy of the Anticonvulsant class.
- Explain how to use different aripiprazole (Aristada products) in patients populations.
- Financial benefits versus disadvantages of having open access to all antipsychotic drugs.
- Confirm Rexuliti's new indication is for Alzheimer's disease.
- What conditions in adults can growth hormones address?
- How many Texans have Bardet-Biedl Syndrome or Chung Jansen Syndrome, what challenges does the speaker have with these two conditions?
- Explain further on requiring a diagnosis of type 2 diabetes to access some medications that could benefit you even through you don't have diabetes.
- Provide more information and challenges about having both Bardet-Biedl Syndrome or Chung Jansen Syndrome.
- Are either Bardet-Biedl Syndrome or Chung Jansen Syndrome genetic predisposition, and is one of the primary symptoms obesity?
- How was speaker able to access Wygovi a few months ago?

# Agenda Item 5: Public comment and discussion on single new drugs to be reviewed for the Medicaid PDL:

Speaker name *also written comment	Representing	Drug	PDL Class
Tyler Gums	Pfizer	Zavzpret	Antimigraine Agents, other
Jamyia Clark	Boehringer Ingelheim Pharmaceuticals , Inc	Cyltezo	Cytokine and CAM Antagonists
Eory Madera Miranda	Organon Pharmaceutical	Hadlima (injection) (CF) 100 mg/ml,50 mg/ml, pen kit 100 mg/ml,50 mg/ml	Cytokine and CAM Antagonists
*Erik Schindler	Sanofi	Altuviiio	Hemophilia Treatment
*Ingrid Ma	BioMarin Pharmaceuticals	Roctavian	Hemophilia Treatment

Speaker name *also written comment	Representing	Drug	PDL Class	
David Miley	Teva	Austedo XR (oral)	Movement Disorders	
David Miley	Teva	Austedo XR Titr Pk (oral)	Movement Disorders	
*Dustin Farr	Rigel Pharmaceuticals , Inc.	Rezlidhia (oral)	Oncology, oral – Hematologic	
Alisa Nguyen	Azurity Pharmaceuticals	Konvomep Oral Susp.	Proton Pump Inhibitors	
Written Comment				
Peter Barrio	United Therapeutics Corporation	Orenitram Titration Kit (oral	PAH Agents, oral and inhaled	

- Speakers provided existing drug information, and new drug information, and requested the preferred status of drugs or open access to drugs.
- Agenda 5v Roctavian was included on the agenda in error, testimony was heard but no action was taken because the drug is not eligible for coverage on the Texas Medicaid Formulary
- Member questions to speakers:
  - Define the most bothersome symptom.
  - How does return time to normal function in 30 minutes rate?
  - Any drug interaction and can the patient take naproxen along with Zavzpret?
  - What is the time of onset of action compared to total resolve?
  - What was the placebo group, double-blinded?
  - Any crossover in the study for those that need treatment for migraines?
  - Were any patients using monoclonal for prevention excluded from study Zavzpret study?
  - Are agenda 5b,c,d,and e, biosimilars?
  - Any potential studies for Austedo XR that address pediatric patients?

## Agenda Item 6: Therapeutic and clinical drug reviews and updates: Magellan Medicaid Administration

Dr. Honesty Peltier, PharmD, Magellan Medicaid Administration, reviewed clinical drug points of the classes that have not been brought up by Public Comment or previous meetings.

## Agenda Item 7: Executive work session

Dr. Kudisch announced the Board would go into closed session at 12:52 p.m. Dr. Kudisch read the legislation granting the Board the ability to meet in executive session.

## Agenda Item 8: Announcements of drugs recommended for the Medicaid PDL: Magellan Medicaid Administration

Dr. Honesty Peltier, PharmD, Magellan Medicaid Administration referenced PowerPoint, *Texas Medicaid Drug Utilization Review Board October 12, 2023.* 

- Dr. Kudisch, Chair, reconvened the meeting from the executive session at 1:30 p.m.
- Ms. Thompson, ACCO, conducted a roll call and announced that there was a quorum present.
- Dr. Peltier, Magellan Medicaid Administration (MMA) reviewed, for the record, the proposed recommendations of the Board in the executive session. Ms. Novak referenced the PowerPoint, *Texas Medicaid Drug Utilization Review Board October 12, 2023*.
- Dr. Peltier noted that Roctavian [from the single drug review] was included on the agenda [in error] has been removed from the recommendations [presentation] as that is a non-reviewed product as it is a strictly physician administered.
- Following a roll call vote, the motion passed by a majority vote of 10 yeas (Borel, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Pham, Vanek. Velasquez), 0 nays, 0 abstentions

# Agenda Item 9: Review of action items for the next meeting: January 26, 2024, 9:00 a.m.

• Dr. Alejandro Kudisch, Chair, announced the next meeting DURB meeting scheduled for January 26, 2024, at 9:00 a.m. a site to be determined.

# Agenda Item 10: Adjourn

Dr. Alejandro Kudisch, Chair, adjourned the meeting at 4:13 p.m.

Below is the link to the archived video of the October 12, 2023, Drug Utilization Review Board meeting that will be available for viewing approximately two years from the date of the meeting posted on the website and in accordance with the HHS records retention schedule.

Drug Utilization Review Board