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	N	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

Member name	Attended	Member name	Attended
Dr. Robert Hogue	N	Dr. Natalie Vanek	Y
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	Representing	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.

- 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

Drug Utilization Review Board (DURB)

Friday, October 13, 2023

9:00 a.m.
Approved
Virtual: Teams Meeting Platform
In-Person Meeting Site: Robert D. Bernstein Building, Building K, K-100,
1100 W. 49th Street, Austin, TX 78756

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 9:00 a.m.

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 a roll call and announced the presence of a quorum.

Table 1: Drug Utilization Review Board member attendance at the Friday, October 13, 2023, meeting.

Member name	Attended	Member name	Attended
Dr. Scott Blaszczyk	N	Dr. Sarah Kubes	Y
Mr. Dennis Borel	N	Dr. Alejandro Kudisch	Y
Dr. Marlo Brawner	N	Dr. Jill Lester	Y
Dr. Dominique Brewster	Y	Dr. Brigetta Martinez	Y
Dr. Deborah Briggs	N	Dr. Richard Noel	Y
Dr. Salil Deshpande	Y	Dr. Kim Pham	Y
Dr. Jennifer Fix	Y	Dr. Lisa Sprenger	Y
Dr. Robert Hogue	N	Dr. Natalie Vanek	N
Dr. Heather Holmes	Y	Dr. Kathryn Velasquez	Y
Dr. Joshua Tonche-Johns	N	Dr. Carlos Omar Viesca	N

Agenda Item 2: 88th Texas Legislature, Regular Session (2023), Legislative Update

Dr. Alejandro Kudisch, Chair, turned the floor to Dr. Justin Luong, Vendor Drug Program Drug Utilization Review and Formulary Management Director, to provide the 88th Texas Legislature, Regular Session (2023), Legislative Update related to House Bill (HB) 3286 and HB 1283.

- Member discussion included confirmation from Dr. Luong that:
    - a recipient who was discharged from an inpatient facility on a non-preferred drug, including long-acting injectables (LAIs), and is stable would be enough alone to continue that medication as an outpatient as described in HB 3286
    - a 24-hour turnaround time, including weekends, on manual prior authorization requests if not first automatically approved through claim data mining
    - a temporary non-preferred status for any new drugs available but not yet reviewed by DURB
    - HB 3286 was not the legislative bill that prohibited coverage of medications for weight loss
    - physician calls to obtain prior authorization (PA) will get a determination at the end of the call

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

Agenda Item 3: Retrospective drug use criteria for outpatient use in Vendor Drug Program: The University of Texas at Austin College of Pharmacy

Dr. Justin Pedigo, Pharm. D, The University of Texas at Austin College of Pharmacy referenced PowerPoint, *Texas Medicaid Vendor Drug Program Drug Utilization Review Board Meeting-Retrospective Drug Use Criteria Proposals October 13, 2023.*

- Oral Public comment – Kenneth Berry, Alkermes, yielded his time back to the DUR Board to make himself available to the DUR Board for questions.
- Dr. Pedigo stated he will add to Table 1 of the Antipsychotics (Oral) criteria set, the indication of agitation associated with dementia due to Alzheimer's disease the Rexulti (brexpiprazole).

- **Motion:** Dr. Richard Noel moved to approve revisions with the noted addition by Dr. Justin Pedigo. Dr. Jennifer Fix seconded the motion. Following roll call votes, the motion passed with a majority vote with 10 yeas (Brewster, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Noel, Pham, Velasquez), 0 nays, 0 abstentions.

Agenda Item 4: Prospective prior authorization proposal (clinical edits): KEPRO, LLC.

Dr. Christina Faulkner, Kepro, referenced the PowerPoint, *Texas HHSC DUR Board Meeting Prospective Prior Authorization Proposals October 13, 2023.*

a. Antipsychotics (ASY) Agents – Revisions

- Oral Public comment – Kenneth Berry, Alkermes, provided drug information
- Member discussion included:
  - use of check insomnia diagnosis
  - how antidepressant agents are identified in check for use of other antidepressants and used for the managed care required PMUR
  - age check for under 18 years
  - no impact on clinical PA criteria from HB 3286
- Member discussion resulted in recommendations for:
  - removing insomnia diagnosis check
  - updating the duplicate therapy check to 2 or more antipsychotics with unique active pharmaceutical agents
- **Motion:** Dr. Sarah Kubes moved to approve the revised criteria for clinical prior authorization (CPA) for Antipsychotics (ASY) Agents as amended above. Dr. Jennifer Fix seconded the motion. Following a roll call vote, the motion passed by a majority vote with 10 yeas (Brewster, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Noel, Pham, Velasquez), 0 nays, 0 abstentions.

b. Anxiolytics and Sedative-Hypnotics (ASH) Agents – Revisions

- Member discussion for Rozerem (ramelteon) included:
  - what drugs are included in the check for concurrent therapy agents
  - confirmation that check for substance abuse is going away
- Member discussion resulted in no recommended changes to CPA criteria for Rozerem (ramelteon) as presented.
- **Motion:** Dr. Richard Noel moved to approve the CPA criteria for Rozerem (ramelteon) of the ASH as presented. Dr. Sarah Kubes seconded the motion. Following a roll call vote the motion passed by a

majority vote with 10 yeas (Brewster, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Noel, Pham, Velasquez), 0 nays, 0 abstentions.

c. Cytokine and CAM Antagonists – New Criteria for Litfulo (Ritlecitinib)

- Member discussion included:
  - what diagnoses are used to identify severe hepatic impairment found in the last 365 days
  - confirmation of the list of diagnoses to identify severe hepatic impairment is listed in the criteria
  - typical duration of therapy of these agents
- Member discussion resulted in no recommended changes to CPA criteria for Litfulo (Ritlecitinib) as presented.
- **Motion:** Dr. Kim Pham moved to approve the proposed new CPA for Litfulo (Ritlecitinib) as presented. Dr. Richard Noel seconded the motion. Following a roll call vote the motion passed by a majority vote with 10 yeas (Brewster, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Noel, Pham, Velasquez), 0 nays, 0 abstentions.

d. Calcitonin Gene-Related Peptide Receptor (CGRP) - New criteria for Zavzpret (Zavegepant)

- Member discussion included:
  - the process to handle if a member reaches the eight-quantity max
  - ensure other chronic baseline management agents and stabilized monoclonal drugs are included in the check history use step
  - the need for longer approval for chronic use and shorter approval for acute use
- Member discussion resulted in recommendations for:
  - a check for routine prophylactic therapy and if found, approve for 365 days otherwise, if not found, approve for 90 days.
- **Motion:** Dr. Sarah Kubes moved to approve new CPA criteria for Zavzpret (Zavegepant) of CGRP guide as amended above. Dr. Jennifer Fix and Dr. Kim Pham seconded the motion. Following a roll call vote, the motion passed by a majority vote with 10 yeas (Brewster, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Noel, Pham, Velasquez), 0 nays, 0 abstentions.

e. Filspari (Sparsentan) – New Criteria

- Oral public comment:
  - John Omick, Trevere Therapeutics, discussed the use of Filspari (Sparsentan) and questioned the proposed lookback period

- Written public comment was received from the following organizations/associations:
    - South Texas Renal Care Group
    - IGA Nephropathy Foundation
- Member discussion included the possible limited distribution of Filspari (Sparsentan)
- Member discussion resulted in no recommended changes to the new CPA criteria for Filspari (Sparsentan)
- **Motion:** Dr. Jennifer Fix moved to approve the proposed new criteria for Filspari (Sparsentan) CPA as presented. Dr. Sarah Kubes seconded the motion. Following a roll call vote, the motion passed by a majority vote with 10 yeas (Brewster, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Noel, Pham, Velasquez), 0 nays, 0 abstentions.

f. Imcivree (Setmelanotide) – New Criteria

- Member discussion included:
    - the lookback period for the genetic testing
    - the weight check on renewal criteria for patients with continued growth potential
    - verification of the step numbering in the criteria document
    - impact of this criteria on the speaker from the DURB meeting the day before
    - reclassification of this drug to the drug class of melanocortin receptor agonist which allows for Medicaid coverage
    - no indication for Chung Jansen syndrome
- Oral public comment:
    - Jordan Smelley, self
    - Codey Gerber, Rhythm Pharmaceuticals, discussed the needed criteria step renumbering, requested the addition of ICD10 Code Q87.83, the reclassification of Imcivree (Setmelanotide) as to drug class of melanocortin receptor agonist, and responded to member question confirming no indication for Chung Jansen Syndrome and only the indications in Dr. Faulkner's presentation.
- Written public comment was received from the following organizations/associations:
    - Rhythm Pharmaceuticals
- Member discussion resulted in recommendations for:
    - updating step 4 to go to step 6 if the answer to step 4 is "yes"
    - adding ICD10 Code Q87.83 for Bardet-Biedl syndrome for Imcivree
- **Motion:** Dr. Sarah Kubes moved to approve new CPA criteria for Imcivree (Setmelanotide) as amended above. Dr. Jennifer Fix

seconded the motion. Following a roll call vote the motion passed by a majority vote with 10 yeas (Brewster, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Noel, Pham, Velasquez), 0 nays, 0 abstentions.

10 Minute Break
The Drug Utilization Review Board took a short break from 11:00 a.m. until 11:10 a.m. Dr. Alex Kudisch, chair called the meeting to order. Ms. Jacqueline Thompson, ACCO Facilitator, HHSC called roll and confirmed a quorum was present.

Agenda 4g continued:

g. Rezurock (Belumosudil) – New Criteria
- Member discussion included:
  - appropriate PA approval duration to address effectiveness
  - safety parameters
- Members discussion resulted in recommendations for:
  - not requiring a prior systemic therapy for renewal requests
  - initial requests, approval for 90 days, and renewal requests approval for 365 days
- **Motion:** Dr. Sarah Kubes moved to approve new CPA criteria for Rezurock (Belumosudil) as amended above. Dr. Jennifer Fix seconded the motion. Following a roll call vote the motion passed by a majority vote with 10 yeas (Brewster, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Noel, Pham, Velasquez), 0 nays, 0 abstentions.

h. Skyclarys (Omaveloxolone) – New Criteria
- Member discussed lab limits in the last 90 days which resulted in no recommended changes.
- **Motion**: Dr. Bridgetta Martinez moved to approve new CPA criteria for Skyclarys (Omaveloxolone) as presented. Dr. Heather Holmes seconded the motion. Following a roll call vote the motion passed by a majority vote with 10 yeas (Brewster, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Noel, Pham, Velasquez), 0 nays, 0 abstentions.

i. Vesicular Monoamine Transporter 2 (VMAT2) Inhibitors – Revision of current criteria
- Member discussion included:
  - adding dopamine-blocking agents to check for prior antipsychotic therapy
  - processes to use these agents for rare diseases as last-line therapy for those under 18 years of age
  - educating DURB members of the PA processes with timeframes

- Member discussion resulted in recommendations for:
    - changing the check for prior antipsychotic therapy to a check for prior dopamine-blocking therapy
    - adding Generic Code Numbers (GCNs) for metoclopramide to the table
- **Motion:** Dr. Sarah Kubes moved to approve new CPA criteria for VMAT2 with amended above. Dr. Jennifer Fix seconded the motion. Following a roll call vote the motion passed by a majority vote with 10 yeas (Brewster, Fix, Holmes, Kubes, Kudisch, Lester, Martinez, Noel, Pham, Velasquez), 0 nays, 0 abstentions.

j. Hormonal Therapy Agents – New Criteria

- Member discussion included:
    - changing lookback period for diagnosis of gender dysphoria
    - understanding the rationale behind the proposed criteria
    - providing members with more information, any relevant legislation, or historical information related to any expected action of the DURB on an agenda item
- Members' discussion resulted in the recommendation to change look back period from 365 to one day.
- **Motion:** Dr. Sarah Kubes moved to approve new CPA criteria for Hormonal Therapy Agents as amended above. Dr. Jennifer Fix seconded the motion. Following a roll call vote the motion did not pass by a majority vote with 2 yeas (Kubes, Pham), 0 nays, and 8 abstentions (Brewster, Fix, Holmes, Kudisch, Lester, Martinez, Noel, Velasquez).

Agenda Item 5: Review of action items for the next meeting

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

Agenda Item 6: Adjournment and Thank You

- Dr. Alejandro Kudisch, Chair, thanked board members and members of the public for their attendance and adjourned the meeting at 12:09 p.m.

Below is the link to the archived video of the October 13, 2023, Drug Utilization Review Board meeting to view and listen for approximately, two years from the date of the meeting is posted in accordance with the HHS records retention schedule.

Drug Utilization Review Board