Drug Utilization Review Board
Approved Meeting Minutes -V.3
July 21, 2023
9:00 a.m.

Hybrid Meeting:
TEAMS Virtual Meeting – John H. Winters Building, Public Hearing Room 125

Table 1: Drug Utilization Review Board member attendance at the Friday, July 21, 2023, meeting.

MEMBER NAME	YES	NO	MEMBER NAME	YES	NO
Dr. Scott Blaszczyk		X	Dr. Sarah Kubes	X	
Mr. Dennis Borel	X		Dr. Alejandro Kudisch	X	
Dr. Marlo Brawner		X	Dr. Jill Lester	X	
Dr. Dominique Brewster	X		Dr. Brigetta Martinez	X	
Dr. Deborah Briggs		X	Dr. Richard Noel	X	
Dr. Salil Deshpande	X		Dr. Kim Pham		X
Dr. Jennifer Fix	X		Dr. Lisa Sprenger	X	
Dr. Robert Hogue	X		Dr. Natalie Vanek	X	
Dr. Heather Holmes		X	Dr. Kathryn Velasquez		X
Dr. Joshua Tonche-Johns		X	Dr. Carlos Omar Viesca	X	

Table 2: Drug Utilization Review Board state agency staff attendance at the Friday, July 21, 2023, meeting.

STATE AGENCY STAFF NAME	YES	NO	STATE AGENCY STAFF NAME	YES	NO
Priscilla Parilla	X		Maribel O. Castoreno	X	
Julie Nieto		X	Audrey Walper	X	
Nahid Assadi, RPh	X		Renee Goertz	X	
Diantha Gonzales, Pharm D	X		Dr. Ryan Van Ramshorst		X
Justin Luong, PharmD	X		Mitchell Abramsky	X	

Table 3: Drug Utilization Review Board contractor attendance at the Friday, July 21, 2023, meeting.

CONTRACTOR NAME	YES	NO	CONTRACTOR NAME	YES	NO
Amy Cully, Pharm.D.(Conduent)	X		Kathryn Novak, RPh (Magellan Medicaid Administration)	X	
Christina Faulkner, Pharm.D. (Kepro, LLC.)	X		Kristen Haloski, PharmD (Magellan Medicaid Administration)	X	
Justin Pedigo, Pharm.D.(University of Texas College of Pharmacy)	X				

Agenda Item 1: Call to Order
Dr. Alejandro Kudisch, Drug Utilization Review Board (DURB) Chair, called the meeting to order at 9:00 a.m. Dr. Kudisch turned the floor over to Ms. Jacqueline Thompson, facilitator with the Health and Human Services Commission (HHSC), Advisory Committee Coordination Office (ACCO), who announced that the meeting was being conducted in accordance with the Texas Open Meetings Act, and conducted the member roll call. Ms. Thompson announced the presence of a quorum.

Agenda Item 2: Consideration of April 28, 2023, draft meeting minutes
Dr. Alejandro Kudisch, Chair, turned the floor to Ms. Thompson to facilitate the vote for approval of the April 28, 2023 meeting minutes as presented. The floor was open for discussion. Hearing none, Dr. Kudisch requested a motion.

MOTION: Dr. Robert Hogue moved to approve the April 28, 2023 minutes as presented. The motion was seconded by Dr. Richard Noel. Ms. Jacqueline Thompson, ACCO Facilitator conducted a roll call vote. Ms. Thompson advised the chair, Dr. Alex Kudisch, the motion passed by a vote of ten approvals, no disapprovals, one abstention, and seven absents (Dr. Scott Blaszczyk, Dr. Marlo Brawner, Dr. Deborah Briggs, Dr. Heather Holmes, Dr. Joshua Tonche-Johns, Dr. Kim Pham, and Dr. Kathryn Velasquez).

Dr. Alejandro Kudisch, Chair, announced the April preferred drug list (PDL) recommendations were approved by HHS Executive Commissioner and are available on Vendor Drug Program (VDP) website.

Ms. Thompson made the open meeting public comments announcement.

Agenda Item 3: Retrospective drug utilization review (DUR): Conduent, LLC: Presenter Dr. Amy Cully, Conduent, LLC
Dr. Cully referenced the PowerPoint, *Texas DUR Board Proposed Retrospective – DUR Interventions July 21, 2023.*

Dr. Cully presented the following:

a: Report on recent retrospective DURB interventions:
Dr. Cully covered the report of recent interventions:

i. Appropriate Use of Antibiotics letters mailed 03/27/23 to 1,299 providers, impacting no patients
ii. Combined Use of Opioids and Central Nervous System Depressants Management letters were mailed 03/28/23 to 27 providers, impacting 20 patients
iii. Single Maintenance and Reliever Therapy (SMART) Alternative for Patients with Asthma letters were mailed 05/17/23 to 201 providers, impacting no patients

b: Report on recent retrospective DURB intervention outcomes

Dr. Cully reported on the cost savings and the clinical outcomes associated with the following interventions:

i. Combined Use of Opioids and Central Nervous System Depressants: mailed 03/28/2023, the extrapolated 12-month state savings of $2,433.60 with a total baseline of 26, post-intervention change extrapolated through May 2023 with an overall -3.8%
ii. Heart Failure Management mailed 05/23/2022 with 12-month state savings of -$9,893.54. A total baseline of 158, 6 months (December 2022) post-intervention of 113, with an overall -28.5% change in the clinical indicators
iii. Hypertension Disease Management mailed 03/17/2023 with the extrapolated 12-month state savings of -$8,284.44 with a total baseline of 224 through May 2023 post-intervention of 991, post-intervention change extrapolated through May 2023 with an overall -3.2% change in the clinical indicators
iv. Influenza Prevention: Vaccination and Education (2022-2023) mailed 10/17/2022 with 12-month state savings of -$311.60. A total baseline of 228, 6 months (May 2023) post-intervention of 334, with an overall -36.4% change in the clinical indicators
v. Management of Psychotropic Drugs in Adults mailed 03/22/2023 with extrapolated 12-month state savings of -$234,660.57. A total baseline of 454, 6 months (November 2022) post-intervention of 334, post-intervention change extrapolated through May 2023 with an overall -2.9% change in the clinical indicators
vi. Migraine of Psychotropic in Adults mailed 06/30/2022 with 12-month state savings of $4,110.50. A total baseline of 454, 6 months (November 2022) post-intervention of 334, with an overall -37.5% change in the clinical indicators
vii. Naloxone in High-Risk Patients mailed 02/17/2023 with extrapolated 12-month state savings of -$8,860.44. A total baseline of 454, 6 months (November 2022) post-intervention of 334, post-intervention change extrapolated through May 2023 with an overall -6.7% change in the clinical indicators

Member Discussion:
Mr. Borel asked what the negative dollar amount meant in the Management of Psychotropic Drugs in Adults outcome report. Dr. Cully explained the negative dollar amount represents a decrease and no negative would represent an increase. Dr. Cully added this particular intervention did have the amount extrapolated due to the end of the contract and with a full six months post-intervention period for providers to implement some of the suggestions from intervention more of a change would be expected. Mr. Borel stated he understood the outcome report is not final and asked if the contract end was due to the legislative change of extending DURB. Dr. Cully responded she was not aware of an extension past July 31st contract end.

Dr. Kudisch asked about the zero amount of members found in the Combined Use of Opioids and Central Nervous System Depressants Management intervention

outcome report. Dr. Cully explained zero patients were found to meet the baseline clinical indicator six months prior to the mailing and also after the mailing. This could signify the pharmacy point of sale (POS) system and provider awareness is doing a great job preventing this drug combination. Dr. Kudisch stated despite that finding he still believes this is an issue and wishes to revisit this topic moving forward.

Agenda Item 4: Prospective prior authorization proposal (clinical edits): KEPRO, LLC. Presenter Dr. Christina Faulkner, Kepro.
Dr. Faulkner referenced the PowerPoint, *Texas HHSC DUR Board Meeting Prospective Prior Authorization Proposals July 21, 2023.*

a. Amyotrophic Lateral Sclerosis (ALS) Agents – New criteria for Relyvrio (sodium phenylbutyrate and taurursodiol)

Dr. Faulkner presented an overview of the Amyotrophic Lateral Sclerosis (ALS) Agents – New clinical prior authorization (CPA) criteria for Relyvrio (sodium phenylbutyrate and taurursodiol) including indications, dosing, and pricing. Dr. Faulkner continued with presenting the proposed clinical prior authorization (CPA) approval criteria including checks for ALS in the last 730 days, client age greater than or equal to 18 years of age, client not currently having a tracheostomy or permanent assisted ventilation, client not having concurrent therapy with a contraindicated drug, client not having a diagnosis of moderate to severe renal impairment or moderate to severe hepatic impairment in the last 365 days, and requested dose is less than or equal to two packets daily.

Member Discussion: None

Hearing no further questions, Dr. Kudisch announced there was written testimony submitted by Texas Children's Health Plan and asked for a motion to approve with no changes.

Motion: Dr. Noel moved to approve the new criteria for Relyvrio from Amyotrophic Lateral Sclerosis (ALS) Agents as presented. The motion was seconded by Dr. Brigetta Martinez. Ms. Jacqueline Thompson, ACCO Facilitator conducted a roll call vote. Ms. Thompson advised Dr. Alex Kudisch, chair the motion passed by a vote of eleven approvals, no disapprovals, no abstention, and seven absent.

b. Daybue (trofinetide) – new criteria

Dr. Faulkner presented an overview of the proposed new CPA for Daybue (trofinetide) including, indication, dosing, dosing directions, and pricing. Dr. Faulkner continued with presenting the proposed clinical prior authorization (CPA) approval criteria including checks of diagnosis of Rett syndrome in the last 730 days, client age greater than or equal to two years of age, client not having concurrent therapy with a contraindicated drug, client does not have a diagnosis of moderate to severe renal impairment in the last 365 days, and requested quantity less than or equal to 24 grams daily.

Dr. Kudisch, Chair, opened the floor to comments and questions.

Speaker	Representing	Drug
"*" denotes written testimony provided to Board members prior to the meeting and name announced at the public meeting "" denotes both oral and written public testimony**		
** Benjamin Skoog	Acadia Pharmaceuticals	Daybue
** Kimberly Goodspeed	Self - Physician practitioner	Daybue
Vaness Peace	International Rett Syndrome Foundation	Daybue
**Benjamin Skoog	Acadia Pharmaceuticals	Daybue
Bernhard Suter	Baylor College of Medicine/ TX Children's Hospital	Daybue
** Kimberly Goodspeed	Self - Physician practitioner	Daybue

Member Discussion:
Dr. Kudisch asked if the speaker, Dr. Kimberly Goodspeed, has any experience with the Daybue and if so describe her clinical experience. Dr. Goodspeed responded drug is new, her clinic has prescribed it but has not seen it in clinical practice yet, it helps with overall symptoms of Rett syndrome over time, and counsel is provided on side effects. Dr. Kubes asked Dr. Goodspeed if she anticipates the early use of the Daybue to help with some of developmental issues. Dr. Goodspeed responded it's too early to tell, seems like a reasonable hypothesis, but data is not available to say that just yet. Dr. Fix asked about the comparison of 1 to 15,000 cases and what is the number in Texas. Dr. Goodspeed responded she did not know and would have to look that up.

Dr. Borel asked the speaker, Vanessa Peace, about the trials in Canada that have been using Dayvue that she has been tracking and asked if she is using attentive care. Ms. Peace replied attentive care is hard to get and challenging. Dr. Kudisch asked how Ms. Peace is accessing the drug. Ms. Peace replied she could access the drug through private insurance. Dr. Kudisch asked if Ms. Peace understand how members with Medicaid could access the drug. Ms. Peace replied she does not know about Medicaid access and would like to learn. Dr. Kubes thanked Ms. Peace for bringing her story to the group and expressed her sympathies, and willingness to help with anything people in this situation as Dr. Kubes has a personal experience in a related situation and understands.

Dr. Fix asked what was the expected average dosing for Daybue. Are all patients expected to be at maximum dose? Dr. Goodspeed responded dosing is weight-based and hard to get a percentage. Dr. Vanek thanked the presenter and asked about the number of the registry group which was mentioned as an estimated 300 patients in Texas. Ms. Peace responded it is an intranational foundation list and voluntary and not accurate.

Motion: Dr. Kubes moved to approve CPA criteria for Daybue as presented. Dr. Fix seconded the motion. Ms. Jacqueline Thompson, ACCO Facilitator conducted a roll call vote. Ms. Thompson advised Dr. Alex Kudisch, chair the motion passed by a vote of eleven approvals, no disapprovals, no abstention, and seven absent.

c. Fecal Microbiota Transplantation (FMT) Agents – new criteria for Vowst

Dr. Faulkner presented an overview of the proposed new CPA for Vowst (fecal microbiota spores, live-brpk) including indication, dosing, guidelines, and pricing. Dr. Faulkner continued with presenting the proposed clinical prior authorization (CPA) approval criteria including checks of client age greater than or equal to 18 years, client having had 3 or more episodes of Clostridioides difficile infection (CDI) in the last 365 days, client having had at least 10 days of antibiotic treatment for CDI in the last 60 days, and the request is for less than or equal to 12 capsules.

Dr. Kudisch, Chair, opened the floor to comments and questions.

Member Discussion:

Dr. Vanek stated many times this is done in the hospital and asked if this is a request for this drug to be done as an outpatient procedure. Dr. Faulkner replied, this is a new agent, oral, and can be done at home. Dr. Kubes asked if the check for the 10-day use of antibiotics care included metronidazole which is no longer recommended based on CDI guidelines. Dr. Faulkner confirmed it is included but that can be removed. Dr. Kubes added for greater than 18 years old, we should probably remove metronidazole as one of the drugs because there's been a lot of treatment failure with that just due to resistance in general and keep vancomycin and Zinplava. Dr. Dominique Brewster asked how a check for documented episodes of CDI was acquired. Dr. Faulkner responded we are looking for a diagnosis CDI in an outpatient setting, hospitals anywhere in which a claim is submitted. Dr. Vanek asked if antibiotic use in the hospital or rehabs can be captured. Dr. Faulner responded if use is not in the claim information, the physician or provider can send chart notes or give us a call and let us know. Dr. Vanek asked if there’s any way to expedite this because client are so sick so fast.

Dr. Faulkner said she could add a phone number and a website to document inpatient antibiotic treatment for fee-for-service (FFS). Dr. Brewster asked if all patients need 10 days of therapy for treating CDI. Dr. Vancik added if the client is on the third episode, it is definatly a 10-day duration. Dr. Kubes added if a third or higher episode would be treated inpatient and some clients be better after 5 days of therapy. Dr. Faulkner responded we can amend the antibiotic use to one claim for antibiotic treatment of CDI.

Public comment followed.

Speaker	Representing	Drug
Allyson T. Fonte	Axsome Therapeutics	Vowst

Dr. Kubes asked the speaker, Ms. Allyson T. Fonte, if a patient undergoes this treatment and then has a reoccurrence of CDI again, if the patient can have another round of therapy or if this was looked at in trial. Ms. Fonte responded this was included in the trials, out of 89 patients who received Vowst, only 11 recurred, and all of these patients opted to roll into a trial for a second dose at week 8. All were recurrent-free at week 8.

Hearing no further questions from members, Dr. Kudisch asked for a repeat of recommended changes and a motion.

Dr. Faulkner stated the recommended changes are adding a check for antibiotic treatment to '1 claim for antibiotic treatment for CDI', adding the following information to step 3: 'To provide information about inpatient antibiotic treatment for FFS clients, prescribers may call the FFS PA call center at 877-728-3927. For MCO clients, prescribers can access MCO PA call center information at: www.txvendordrug.com/resources/mco-search, and removing metronidazole from Table 3, antibiotics for the treatment of CDI

Motion: Dr. Kubes moved to approve the proposed new CPA for Vowst with changes as recommended (listed above). The motion was seconded by Dr. Vanek. Ms. Jacqueline Thompson, ACCO Facilitator conducted a roll call vote. Ms. Thompson advised Dr. Alex Kudisch, chair the motion passed by a vote of eleven approvals, no disapprovals, no abstention, and seven absent.

d. Growth Hormone Agents New criteria – new criteria for Sogroya (somapacita-beco)

Dr. Faulkner presented an overview of the new CPA criteria for Sogroya of the Growth Hormone Agents criteria guide. An overview was presented regarding the indication treatment, dosing, and pricing. Dr. Faulkner also presented the additional proposed initial approval criteria including checks for client age greater than or equal to 2.5 years of age, for the diagnosis of growth hormone deficiency in the last 3 years, for documentation to support the requested diagnosis is included with the request to support the initial or renewal request, check for no diagnosis of Prader-Willi syndrome (PWS) in the last 730 days or, if PWS is found, client does not have a diagnosis of severe obesity or severe respiratory impairment in the last 365 days, check for no diagnosis of active malignancy or history of chemotherapy/radiation in the last 180 days, check for no diagnosis of active proliferative or severe non-proliferative diabetic retinopathy in the last 365 days, check for no diagnosis of papilledema in the

last 180 days, and check for requested dose less than or equal to 8 mg weekly. Dr. Faulkner asked the DURB, if a check for cute critical illness after open heart surgery or abdominal surgery, multiple accidental traumas, or acute respiratory failure due to the increased risk of mortality, as per package insert.

Member Discussion:
Dr. Kubes stated acute critical illness is hard to assess and for the pediatric population with growth hormone deficiency and anytime they are admitted to hospital, we usually withhold growth hormone. Dr. Kubes asked what would be the time window for this concern to address the package insert question. Dr. Faulkner agreed it is difficult and that is why it was not included in proposal. Dr. Kubes recommended not adding prior authorization criteria but more of a warning for prescribers.

Motion: Dr. Jennifer Fix moved to approve new clinical prior authorization criteria for Sogroya for the Growth Hormone Agents guide as presented by Dr. Christina Faulkner. The motion was seconded by Dr. Kubes. Ms. Jacqueline Thompson, ACCO Facilitator conducted a roll call vote. Ms. Thompson advised Dr. Alex Kudisch, chair the motion passed by a vote of eleven approvals, no disapprovals, no abstention, and seven absent.

e. Opioid/Benzodiazepine/Muscle Relaxants Combinations - revision

Dr. Faulkner presented an overview of Opioid/Benzodiazepine/Muscle Relaxants Combinations guide. An overview was presented of current CPA criteria using a 10-day overlap and the proposed approval criteria revision to check for a 7-day overlap combination of Opioid/Benzodiazepine/Muscle Relaxants in the last 35 days.

Member Discussion:
Dr. Kubes asked to be reminded which specific benzodiazepine and muscle relaxants are included. Dr. Faulkner stated benzodiazepines don't include the rectal diazepam, for muscle relaxants [criteria] do not include any that treat spasticity like tizanidine and Baclofan, Flexeril and cyclobenzaprine are included, along with Robaxom, carisoprodol, and methocarbamol. Dr. Kubes asked if for benzodiazepines internasals are excluded, if there are any way to identify meds prescribed as needed (PRN) vs a scheduled med, and if meds used for seizure disorders are excluded. Dr. Faulkner responded no intranasal meds are included, except for the ODT's, and there is no way to distinguish between PRN vs scheduled. Ms. Nahid Assadi, VDP pharmacist, suggested sharing the diagnosis list with Dr. Kubes to review.
Dr. Kudisch asked for a repeat of recommended changes and a motion.

Dr. Faulkner stated the recommended change is adding a check for seizure disorder in criteria where benzodiazepines are included.

Motion: Dr. Sarah Kubes moved to approve the revision to the Opioid/Benzodiazepine/Muscle Relaxants Combinations CPA criteria with recommendations stated by Dr. Christina Faulkner. The motion was seconded by Dr. Vanek. Ms. Jacqueline Thompson, ACCO Facilitator conducted a roll call vote. Ms. Thompson advised Dr. Alex Kudisch, chair, the motion passed by a vote of eleven approvals, no disapprovals, no abstention, and seven absent.

f. Veozah (fezolinetant) – new criteria

Dr. Faulkner presented an overview of the new clinical prior authorization (CPA) criteria for Veozah. An overview was presented regarding the indication treatment, dosing, and pricing. Dr. Faulkner also presented the proposed approval criteria including checks for diagnosis of menopause found in the last 730 days, age greater than or equal to 12 years of age, no diagnosis of cirrhosis, severe renal impairment, or end-stage renal disease found in the last 365 days, client not having concurrent therapy with a contraindicated drug, and requested quantity being less than or equal to 1 tablet daily.

Member Discussion:
Dr. Kubes asked a check for diagnosis of cirrhosis be included and recommended having the liver function test (LFT) levels based on the manufacturer's recommendations and per the package insert, an evaluation of the liver before starting, and stated it is recommended to be assessed at three, six, and nine months. Dr. Vanek suggested specific LFT levels and an ongoing hepatic function test after six months should be included. Ms. Assadi suggested checking for a CPT code for a LFT instead of a specific level.
Dr. Faulkner stated a check for cirrhosis is already included, suggested it could be checked at an initial PA request and given a three-month PA duration, and after three months include a check for an ongoing hepatic function test. Dr. Desphande recommended not using CPA as a warning for prescribers and not using a three-month PA duration approval because it is burdensome and recommended at least 6 months of PA approval. Dr. Fix supported a 6 month PA duration.

Dr. Fix asked about the greater than 12 years of age check for menopause. Dr. Kubes stated in her review of trials there was no test for those under 18 years of age. Dr. Faulkner responded an age check wanted to be included but didn't want to exclude anyone that might need it but the age can be changed to 18 years.

Dr. Kudisch asked for a repeat of recommended changes and a motion.

Dr. Faulkner stated the recommended changes are increasing minimum age to 18 and older; adding a check for see if either hepatic function panel or CMP panel has been run; and changing PA approval duration for six months.

Motion: Dr. Sarah Kubes moved to approve new CPA criteria for Veozah with recommended changes as stated above by Dr. Christina Faulkner. The motion was

seconded by Dr. Noel. Ms. Jacqueline Thompson, ACCO Facilitator conducted a roll call vote. Ms. Thompson advised Dr. Alex Kudisch, chair the motion passed by a vote of eleven approvals, no disapprovals, no abstention, and seven absent.

Agenda Item 5: 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. Dr. Pedigo referred to the PowerPoint, *Texas Medicaid Vendor Drug Program Drug Utilization Review Board Meeting-Retrospective Drug Use Criteria Proposals July 21, 2023.*

Dr. Pedigo presented:

a. Acetylcholinesterase Inhibitors
b. Cyclooxygenase-2 Inhibitors
c. Histamine H2- Receptor Antagonists
d. Ketorolac (oral)
e. Leukotriene Receptor Antagonists
f. Mecasermin
g. Memantine

Dr. Kudisch, Chair, opened the floor to comments and questions. Hearing none, Dr. Kudisch asked for a motion.

Motion: Dr. Kubes made the motion to approve revisions as presented by Dr. Justin Pedigo. The motion was seconded by Dr. Viesca. Ms. Jacqueline Thompson, ACCO Facilitator, conducted a roll call vote. Ms. Thompson advised Dr. Alex Kudisch, chair the motion passed by a vote of eleven approvals, no disapprovals, no abstention, and seven absent.

Agenda Item 6: Review of action items for the next meeting:
The next meeting is set tentatively for October 12 and October 13, 2023, at 9:00 a.m. following COVID-19 guidelines that will dictate the platform and/or venue. Dr. Justin Luong, VDP Drug Utilization Review and Formulary Director, confirmed October's meetings will include the PDL review for July's and October's PDL classes.

Agenda Item 7: Dr. Alejandro Kudisch, Chair, adjourned the meeting at 11:03 a.m.

Below is the link to the archived video of the July 21, 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