

**Drug Utilization Review Board
Meeting Minutes
January 25, 2019
9:00 a.m.**

**John H. Winters Human Service Complex Public Hearing Room
701 West 51st
Austin, TX 78751**

Table 1: Drug Utilization Review Board member attendance at the Friday, January 25, 2019 meeting.

MEMBER NAME	YES	NO	MEMBER NAME	YES	NO
Dr. James Barnes	X		Dr. Alejandro Kudisch	X	
Dr. Scott Blaszczyk	X		Dr. Jill Lester	X	
Mr. Dennis Borel	X		Dr. Thanhhao Ngo		X
Dr. Deborah Briggs	X		Dr. Richard Noel	X	
Dr. Oscar Brown	X		Dr. Joseph Vazhappilly	X	
Dr. Deeatra Craddock	X		VACANT		
Dr. Salil Deshpande		X	VACANT		
Dr. Jennifer Fix	X		VACANT		
Dr. Robert Hogue		X	VACANT		
Dr. Summer Keener	X		VACANT		

Table 2: Drug Utilization Review Board state agency staff attendance at the Friday, January 25, 2019 meeting.

STATE AGENCY STAFF NAME	YES	NO	STATE AGENCY STAFF NAME	YES	NO
Dr. Mitchel Abramsky	X		Louisa Cervera	X	
Aaliya Ahmad, PharmD	X		Joshua Dominguez, PharmD	X	
Nahid Assadi, RPh	X		Gina Marie Muniz, CBCP	X	
Maribel O. Castoreno	X		Arshad Qureshi, PharmD	X	

Table 3: Drug Utilization Review Board contractor attendance at the Friday, January 25, 2019 meeting.

CONTRACTOR NAME	YES	NO	CONTRACTOR NAME	YES	NO
Chris Andrews, Pharm.D. (Magellan Medicaid Administration)	X		Matthew Lennertz, Pharm.D. (Magellan Medicaid Administration)	X	
Larry Dent Pharm.D., (Conduent)	X		Jennifer Seltzer, Pharm.D. (University of Texas College of Pharmacy)	X	
Christina Faulkner, Pharm.D. (Health Information Designs, LLC.)	X				

Agenda Item 1: Call to Order

Dr. Oscar Brown called the meeting to order at 9:00 a.m. Dr. Brown introduced and turned the floor over to Ms. Stephanie Gutierrez, HHSC, Advisory Committee Coordination Office. Ms. Gutierrez read meeting logistics and conducted roll call. Ms. Gutierrez noted there was a quorum.

Agenda Item 2: Approval of minutes from October 26, 2018

Ms. Gutierrez reminded members a copy of the DRAFT minutes were sent by email. Ms. Gutierrez opened the floor for discussion. Hearing none, Ms. Gutierrez requested a motion.

MOTION: Dr. Scott Blaszyck motioned to approve the October 26, 2018 minutes with Dr. Alejandro Kudisch seconding the motion. A roll call vote was taken and the minutes were approved unanimously with no objections nor abstentions. The motion carried.

Agenda Item 3: New Business

Dr. Brown opened the floor to public comment on the drug classes on the therapeutic and clinical drug review for the Medicaid Preferred Drug List. Ms. Gutierrez read Public Comment Announcements to members of the Board and members of the audience.

Dr. Brown reviewed the classes of drugs for public comment. The following individuals provided testimony to the Board and answered questions:

Speaker	Representing	Recommendations	PDL Class
John Hall	Pfizer	Embeda	Analgesics, narcotic long
Anthony Colavecchia	Pfizer	Embeda	Analgesics, narcotic long
Mai Duong	Novartis	Entresto	Angiotensin modulator combinations
Trey Gardner	Silvergate	Obrelis	Angiotensin modulators
Jennifer Ward	Eli Lilly	Emgality	Antimigraine agents, other
Scott Budsberg	Amgen	Aimovig	Antimigraine agents, other
Maggie Murphy	Teva	Ajovy	Antimigraine agents, other
Joseph Vaughan	Self	CGRP's	Antimigraine agents, other
Anthony Colavecchia	Pfizer	Eucrisa	Immunomodulators, atopic dermatitis
Kevin Duhrlcopf	Sanofi Genzyme	Dupixent	Immunomodulators, atopic dermatitis
Maggie Murphy	Teva	Austedo	Movement disorders
Monica Guillory	Neurocrine Bioscience	Ingrezza	Movement disorders
Greg Hensch	NAMI Texas	Open Access	Movement disorders
Mary Porter	Optinose US	Xhance	Intranasal rhinitis agents
Denna Jermain	Pfizer	Lyrica	Neuropathic pain
John Hall	Pfizer	Lyrica	Neuropathic pain
Maria Llanna-Posey	Pfizer	Chantix	Smoking cessation
Michael Peterson	Self	Chantix	Smoking cessation
Amy Everitt	Tris Pharma	Dyanavel XR, Quillivant XR, Quillichew ER	Stimulants and related agents
Joseph Gilhody	Tris Pharma	Dyanavel XR, Quillivant XR, Quillichew ER	Stimulants and related agents

Speaker	Representing	Recommendations	PDL Class
Matthew Brams	Self	Dyanavel XR	Stimulants and related agents
Daniel Tan	Self	Dyanavel XR	Stimulants and related agents
Craig Smith	Genentech	Xofluza	Antivirals, oral
Laura Smith	Takeda	Takhzyro	HAE treatments

Agenda Item 4: Therapeutic and clinical drug reviews and updates

Dr. Brown turned the floor over to Dr. Matt Lennertz, Magellan Medicaid Administration, MMA. Dr. Lennertz reviewed points of the classes that have not been brought up by public comment or previous meetings.

Agenda Item 5: Executive Work Session

Dr. Brown announced the Board will go into closed session at 10:45 a.m. Dr. Brown read the legislation granting the Board the ability to meet in executive session.

Agenda Item 6: Announcements of drugs recommended for the Medicaid PDL

Dr. Brown reconvened the meeting from executive session at 12:46 p.m. Dr. Brown turned the floor over to Dr. Lennertz. Dr. Lennertz reviewed, for the record, the proposed recommendations decided by the Board in executive session. Dr. Lennertz referenced the PowerPoint, *Texas Medicaid Drug Utilization Review Board January 25, 2019*.

Dr. Brown turned the floor over to Ms. Gutierrez for the process of a motion. Ms. Gutierrez requested a motion.

MOTION: Dr. James Barnes motioned to approve and accept the proposed recommended drug list. Mr. Dennis Borel seconded. A voice vote was taken and the motioned carried unanimously with no objections nor abstentions.

Agenda Item 7: Retrospective DUR

Dr. Brown introduced and turned the floor over to Dr. Larry Dent, Board Certified Pharmacotherapy Specialist, Conduent, LLC. Dr. Dent referenced the PowerPoint and handout, *Texas Medicaid Vendor Drug Program Drug Utilization Review Board Meeting- Retrospective Drug Use Proposals*.

Agenda Item 7a: Report on recent retrospective DUR interventions

Dr. Dent covered the report of recent interventions:

- Opioid Prescribing was mailed out on 10/30/2018 to 911 providers impacting 1,069 patients.
- Second Generation Antipsychotics in Youth was mailed out on 11/13/2018 to 614 providers impacting 1,482 children.

Agenda Item 7b: Report on recent retrospective DUR intervention outcomes

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

- ADHD High Dose was mailed out on 10/23/2018 with potential cost avoidance over \$29,000. Reported impact on the clinical indicators was overall about 28% total.

- Psychotropic Drugs in Adults was mailed on 12/18/2017 with potential cost avoidance over \$489,000. Reported impact on the clinical indicators was over 31%.
- Migraine Prevention and Treatment was mailed on 01/05/2018 with potential cost avoidance over \$109,000. Reported impact on the clinical indicators was over 27%.

Agenda Item 7c: Retrospective DUR Proposals

Dr. Dent proceeded with retrospective DUR proposals.

Agenda Item 7ci: Appropriate Use of Antibiotics

Dr. Dent highlighted the importance of this single-performance indicator intervention. High percentage of oral broad spectrum antibiotic use has historically generated about 2000 letters.

Dr. Brown expressed concerns about the wide spread use of 2nd and 3rd generation cephalosporins and suggested that it may be more useful to know about the appropriateness of antibiotic as compare to the reason it was given. Dr. Dent explained that the pharmacy claims data does not include the reasons for each antibiotic prescription so it is not possible to find out if an antibiotic was prescribed appropriately or not.

Dr. Barnes asked when the outcome of this intervention would be presented to the Board. Dr. Dent responded in about a year.

Ms. Gutierrez read Public Comment Announcements to members of the Board and members of the afternoon audience.

Dr. Brown turned the floor over to Ms. Gutierrez for the process of a motion. Ms. Gutierrez requested a motion.

MOTION: Dr. James Barnes motioned to approve the appropriate use of antibiotics of the retrospective DUR proposals. Dr. Deborah Briggs seconded. A voice vote was taken and the motioned carried unanimously with no objections nor abstentions.

Agenda Item 7cii: Medication adherence

Dr. Dent focused on the following drug classes:

- Second generation Antipsychotics: oral medications
- Chronic obstructive pulmonary disease: inhaled medications
- Thyroid Replacement

Dr. Brown requested a motion.

MOTION: Dr. James Barnes motioned to approve medication adherence. Dr. Jennifer Fix seconded. A voice vote was taken and the motioned carried unanimously with no objections nor abstentions.

Agenda Item 7ciii: Respiratory Disease Management

Dr. Dent introduced this intervention as a new intervention for Texas Medicaid and reviewed the individual performance indicators:

- Overutilization of short-acting beta-agonists (SABA) inhalers in patients with asthma
- Underutilization of inhaled corticosteroids (ICS) in patients with asthma

- Use of long-acting beta-agonists (LABA) inhaler without SABA inhaler in patients with asthma
- Use of LABA inhaler without long-acting antimuscarinic antagonists (LAMA) inhaler in patients with COPD
- Use of SABA inhaler without short-acting antimuscarinic antagonist (SAMA) inhaler in patients with COPD
- Use of ICS without LABA inhaler in patients with COPD
- Overutilization of oral glucocorticoids in patients with asthma and or COPD
- Duplicative ingredient inhalers in patients with asthma and/or COPD
- History of smoking in patients with asthma and/or COPD

Members discussed:

- The definition of rescue inhaler in an effort to increase appropriate use
- Including the formulary inhalers by class and indications in the letter
- Looking at duplications of oral therapy for treatment of asthma
- Clarifying the qualifications for history of smoking

MOTION: Dr. Fix motioned to approve the respiratory disease management letter. Dr. Blazczyk seconded. A voice vote was taken and the motioned carried unanimously with no objections nor abstentions.

Agenda Item 8: Prospective prior authorization proposals (clinical edits)

Dr. Brown introduced and turned the floor over to Dr. Christina Faulkner, Pharm. D., Health Information Designs, LLC. Ms. Faulkner referenced the PowerPoint, *Texas HHSC DUR Board Meeting Prospective Prior Authorization Proposals*.

Agenda Item 8a. Cytokine and CAM antagonists- addition of Olumiant criteria

Dr. Faulkner presented these proposals:

Cytokine and CAM Antagonists- addition of Olumiant with the following PA approval criteria:

- Age \geq 18 years
- Diagnosis of rheumatoid arthritis found in the last 730 days
- Claim for a TNF-blocker found in the last 180 days
- No claim for a JAK inhibitor, biologic DMARD or potent immunosuppressant found in the last 30 days
- No claim for an OAT3 inhibitor found in the last 90 days
- No diagnosis that indicates increased risk of GI perforation, thrombosis or malignancy found in the last 180 days
- No diagnosis of severe renal impairment (eGFR less than 60) or severe hepatic impairment found in the last 365 days
- No diagnosis of serious active infection found in the last 180 days
- Daily dose is less than or equal to 1 tablets daily

MOTION: Dr. Barnes motioned to approve prior authorization proposals for Cytokine and CAM antagonists with the added prior authorization criteria for Olumiant. Dr. Fix seconded. A voice vote was taken and the motioned carried unanimously with no objections nor abstentions.

Agenda Item 8b. Epidiolex - new criteria

Dr. Faulkner presented the Epidiolex clinical prior authorization criteria as follow:

- Age \geq 2 years

- Diagnosis of Lennox-Gastaut syndrome or Dravet syndrome found in the last 730 days

Members discussed:

- Limiting Epidiolex to Dravet Syndrome diagnosis and Lennox-Gastaut Syndrome in an effort to target the correct patient population
- Determining Dravet Syndrome versus Lennox-Gastaut Syndrome
- Criteria for qualifying for Epidiolex
- Dose restrictions per age range not being an issue
- Follow-up testing not being a requirement
- Product being open access to physicians
- Disseminating information to pharmacies
- Showing positive on a generalized drug screen and negative on a blood test
- Patients meeting the clinical versus the genetic requirement to confirm a diagnosis
- Prior authorization for continuity of care if a patient has been on Epidiolex previously
- Six months for a retrospective review
- State monitoring utilization
- Dr. Briggs recommended to remove the ICD-10 diagnosis codes for generalized epilepsy and epileptic syndromes and instead allow a manual PA review for diagnosis of Dravet Syndrome.
- Mr. Boral asked what it would take to allow an easy access for patients who do not meet the above diagnosis criteria but are currently on this drug and are doing better.
- Dr. Joshua Dominquez, Vendor Drug Program, and Dr. Faulkner responded by saying that following the initial claim reject, there would be an appeal process for which either HID or a VDP clinical staff would review the case and approve or reject the PA request.
- Dr Kudisch asked if this is available for prescribing by all physicians and specialties.

In response to pregnancy category question, the manufacturer's representative gave a testimony.

Public Testimony: Kendra Davies, Pharm D, Health Outcome Liaison for Greenwich Biosciences, responded to the pregnancy question. She said that they do not have any data currently, and if pregnancy occurs, it should be dealt with on a case-by-case basis when benefit outweighs the risk. She also reiterated that this drug is only marketed to prescribers for the aforementioned diagnosis.

Nahid Assadi, RPh., VDP, asked if there should be a standard requirement for a generic testing to help with diagnosis of Dravet syndrome.

The Board responded, a genetic test would be helpful for diagnosis but it must not be required.

Dr. Kudisch asked when we can conduct a retro-DUR review on this drug. Dr. Larry Dent, Conduent, responded usually when there is enough claims data available to review.

Dr. Faulkner stated the proposed changes:

- Remove all ICD codes for generalized seizures
- Approve based on the medical necessity for those with Dravet syndrome.

MOTION: Dr. Briggs motioned to approve prior authorization proposals for Epidiolex as per the changes stated by Dr. Faulkner. Dr. Barnes seconded. A voice vote was taken and the motioned carried unanimously with no objections nor abstentions.

Agenda Item 8c. Orilissa - new criteria

Dr. Faulkner presented the following approval criteria:

- Age \geq 18 years
- Diagnosis of endometriosis found in the last 730 days
- 1 claim for an NSAID and 1 claim for an oral contraceptive found in the last 180 days.
- No diagnosis of osteoporosis found in the last 365 days
- No claims for strong OAT-1B1 inhibitor found in the last 90 days
- Dosing does not exceed maximum recommended

Dr. Roxanne Dominguez introduced herself as the Abbvii medical Science liaison, available for any questions.

The Board approved these approval criteria without changes.

MOTION: Dr. Fix motioned to approve prior authorization proposals for Orilissa. Dr. Alejandro Kudisch seconded. A voice vote was taken and the motioned carried unanimously with no objections nor abstentions.

Agenda Item 9: Retrospective drug use, criteria for outpatient use in Vendor Drug Program

Dr. Brown introduced and turned the floor over to Dr. Jennifer Seltzer, Pharm. D., University of Texas at Austin, College of Pharmacy. Dr. Seltzer the PowerPoint, *Texas Medicaid Vendor Drug Program Drug Utilization Review Board Meeting - Retrospective Drug Use Proposals*.

Dr. Seltzer presented on updates on the indications, adult and pediatric dosages, drug-drug interactions, duration of therapy and other information for the following drugs/drug classes:

- 5-HT3 Receptor Antagonists
- Angiotensin II Receptor Blockers
- Angiotensin-Converting Enzyme Inhibitors
- ADHD Medications
- GLP-1 Receptor Agonists
- Oral Antidiabetic Agents
- Pramlintide
- Serotonin 5-HT1B/1D Receptor Agonists
- Substance P/Neurokinin 1 Receptor Antagonists

MOTION: Dr. Fix motioned to approve prior authorization proposals for Orilissa. Dr. Alejandro Kudisch seconded. A voice vote was taken and the motioned carried unanimously with no objections nor abstentions.

Agenda Item 10: Adjournment

Dr. Brown adjourned the meeting at 2:57 p.m.

The webcasting link is: <https://texashsc.swagit.com/play/01252019-656>