Drug Utilization Review Board
APPROVED Meeting Minutes
May 22, 2020
9:00 a.m.

Virtual Meeting

Table 1: Drug Utilization Review Board member attendance at the Friday, May 22, 2020 meeting.

<table>
<thead>
<tr>
<th>MEMBER NAME</th>
<th>YES</th>
<th>NO</th>
<th>MEMBER NAME</th>
<th>YES</th>
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<tbody>
<tr>
<td>Dr. James Barnes</td>
<td>X</td>
<td></td>
<td>Dr. Summer Keener</td>
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<tr>
<td>Dr. Scott Blaszczyk</td>
<td>X</td>
<td></td>
<td>Dr. Alejandro Kudisch</td>
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<td>Mr. Dennis Borel</td>
<td>X</td>
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<td>Dr. Jill Lester</td>
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<tr>
<td>Dr. Deborah Briggs</td>
<td>X</td>
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<td>Dr. Thanhiao Ngo</td>
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<tr>
<td>Dr. Mario Brawnner</td>
<td>X</td>
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<td>Dr. Richard Noel</td>
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<tr>
<td>Dr. Deeatra Craddock</td>
<td>X</td>
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<td>Dr. Kim Pham</td>
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<td>Dr. Salil Deshpande</td>
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<td>Dr. Joseph Vazhappilly</td>
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<td>Dr. Jennifer Fix</td>
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<td>Dr. Robert Hogue</td>
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<td>Dr. Heather Holmes</td>
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<td>VACANT</td>
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Table 2: Drug Utilization Review Board state agency staff attendance at the Friday, May 22, 2020 meeting.

<table>
<thead>
<tr>
<th>STATE AGENCY STAFF NAME</th>
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<th>STATE AGENCY STAFF NAME</th>
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<tbody>
<tr>
<td>Dr. Mitchel Abramsky</td>
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<td>Dr. Larry Lewellyn</td>
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<tr>
<td>Dr. Ryan Van Ramshorst</td>
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<td>Jasmine Singh, PharmD</td>
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<tr>
<td>Nahid Assadi, RPh</td>
<td>X</td>
<td></td>
<td>Alish Valdez</td>
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<tr>
<td>Maribel O. Castoreno</td>
<td>X</td>
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<td>Gina Marie Muniz, CBCP</td>
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<tr>
<td>Justin Luong, PharmD</td>
<td>X</td>
<td></td>
<td>Ruth Guajardo, PharmD</td>
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Table 3: Drug Utilization Review Board contractor attendance at the Friday, May 22, 2020 meeting.

<table>
<thead>
<tr>
<th>CONTRACTOR NAME</th>
<th>YES</th>
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<tbody>
<tr>
<td>Mariya Baranova Pharm.D., (Conduent)</td>
<td>X</td>
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<tr>
<td>Christina Faulkner, Pharm.D. (Health Information Designs, LLC.)</td>
<td>X</td>
<td></td>
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<tr>
<td>Matthew Lennertz, Pharm.D. (Magellan Medicaid Administration)</td>
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<td>X</td>
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<tr>
<td>Jennifer Seltzer, Pharm.D. (University of Texas College of Pharmacy)</td>
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**Agenda Item 1: Call to Order**

Dr. Robert Hogue called the meeting to order at 9:01 a.m. Dr. Hogue turned the floor over to Mr. John Chacón, HHSC, Facilitator, Advisory Committee Coordination Office (ACCO). Mr. Chacón read meeting logistics and conducted roll call. Mr. Chacón noted there was a quorum.
Agenda Item 2: Approval of minutes from January 24, 2020
Mr. Chacón reminded members a copy of the DRAFT minutes was sent by email as well as can be found in their electronic meeting packet. Mr. Chacón opened the floor for discussion. Hearing none, Mr. Chacón requested a motion.

MOTION: Mr. Dennis Borel motioned to approve the January 24, 2020 minutes as presented with Dr. Richard Noel seconding the motion. Mr. Chacón conducted a roll call vote and announced that the motion carried unanimously with no objections and abstentions.

Agenda Item 3: Announcement: Drug Utilization Review Board Conflict of Interest Policy Review
Ms. Maribel Castoreno stated that the DUR Board conflict of interest policy was being reviewed by HHSC for potential updates.

Ms. Castoreno stated:
- Under the Social Security Act section 1927d, Texas government code section 531.0735 and 0737 as well as Texas Administration Code section 354.1941 and 1942.
- Persons appointed to the board must be free of personal, financial interests and other relationships that may conflict with their duties as a DURB member.
- As part of the TAC rule amendment process, proposed changes will be posted on the Secretary of State registry for public comments and will result in the modification to the DURB bylaws by July 2021.

Agenda Item 4: New Business
Dr. Hogue opened the floor to public comment on the drug classes on the therapeutic and clinical drug review for the Medicaid Preferred Drug List from an online reference provided to members. Mr. Chacón read Public Comment Announcements to members of the Board and members of the audience.

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

- Dr. Brawner asked if there was a head to head study between Oxbryta and hydroxyurea?
- Ms. Jennifer Nelson commented the HOPE study included 63% of patients on stable hydroxyurea dose but not in comparison to Oxbryta.
- Dr. Frei-Jones asked the board 2 questions regarding initial approval criteria for Oxbryta and confirmation of drug requirements regarding clinical practice.
- Dr. Brawner asked Dr. Frei-Jones would you consider Oxbryta a first line or second line therapy after starting hydroxyurea?
• Dr. Frei-Jones commented Oxbryta is indicated for patients 12 years and older whereas hydroxyurea can be started in patients 9 to 24 months of age, therefore patients have already tried, failed or had poor response to hydroxyurea before starting Oxbryta.

• Dr. Brawner asked Mr. Charles Stark if he can explain how Endari (L-glutamine) is different than taking a glutamine supplement.

• Mr. Stark commented Endari has been regulated and approved through a FDA drug approval process, Code 21 CFR Part 2-11 as a finished pharmaceutical product regulatory pathway to approval rather than, glutamine, in the food category Code 21 CFR Part 1-11. Endari, regulated as a drug, is supplied as a prescription grade product to physicians to treat sickle cell disease over a lifetime to provide a consistent pharmaceutical product as opposed to a food.

Agenda Item 5: Public comment and therapeutic and clinical drug to be reviewed for the Medicaid preferred drug list:
Dr. Hogue continued the open floor to public comment on the new drugs from an online reference provided to members. The following individuals provided testimony to the Board and answered questions:

<table>
<thead>
<tr>
<th>Speaker</th>
<th>Representing</th>
<th>Recommendations</th>
<th>PDL Class</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jennifer Ward</td>
<td>Eli Lilly</td>
<td>Reyvow</td>
<td>Antimigraine Agents, Other</td>
</tr>
<tr>
<td>Colleen Smith</td>
<td>Allergan</td>
<td>Ubrelvy</td>
<td>Antimigraine Agents, Other</td>
</tr>
</tbody>
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Agenda Item 6: Therapeutic and clinical drug reviews and updates
Dr. Hogue 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 7: Executive Work Session
Dr. Hogue announced the Board will go into closed session at 11:06 a.m. Dr. Hogue read the legislation granting the Board the ability to meet in executive session.

Agenda Item 8: Announcements of drugs recommended for the Medicaid PDL
Dr. Hogue reconvened the meeting from executive session at 12:48 p.m. Mr. Chacón conducted roll call and announced that there was a quorum of the board. Mr. Chacón 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 May 22, 2020.

Dr. Hogue requested a motion.

MOTION: Dr. Richard Noel motioned to approve and accept the proposed recommended drug list. Dr. Alejandro Kudisch seconded. Mr. Chacón conducted a roll call vote and announced that the motion carried unanimously with no objections and abstentions.

Agenda Item 9: Retrospective DUR
Dr. Hogue introduced and turned the floor over to Dr. Mariya Baranova, Pharm D., MCMP-II, Conduent, LLC. Dr. Baranova referenced the PowerPoint and a, Texas DUR Board Meeting Proposed Retrospective DUR Interventions May 22, 2020.

Agenda Item 9a: Report on recent retrospective DUR interventions
Dr. Baranova covered the report of recent interventions:
1. Prevention of Adverse Drug Events in Patients Receiving Opioids: intervention letters were mailed out on 1/08/2020 to 9 providers, impacting 9 patients.
2. Opioid Pain Management: intervention letters were mailed out in 2/28/2020 to 54 providers, impacting 57 patients.
3. Monitoring of Psychotropic Drugs in Youth: intervention letters were mailed out in 3/23/2020 to 222 prescribers, impacting 272 patients.

**Agenda Item 9b: Report on recent retrospective DUR outcomes**
Dr. Baranova reported on the both the cost savings and the clinical outcomes associated with the following interventions:
1. Psychotropic Drugs in Adults: mailed 4/1/2019 (positive state savings and positive change of 27.3% in the clinical indicators)
2. Medication Adherence: mailed 4/10/2019 (negative amount due to nature of the intervention, promoting more drug utilization and positive change of 23.6% in the clinical indicators)
3. Mental Health Disorder Therapy Management: mailed 6/4/2019 (positive state savings and positive change of 21.6% in the clinical indicators)
4. Respiratory Disease Management: mailed 6/21/2019 (positive state savings and positive change of 29.3% in the clinical indicators)

**Agenda Item 9c: Retrospective DUR proposals**
Dr. Baranova proceeded with retrospective DUR proposals.

**Agenda Item 9ci: Asthma**
Dr. Baranova highlighted the following performance indicators:
1. Overutilization of short-acting beta₂-agonist (SABA) inhalers in patients with asthma
2. Underutilization of inhaled Corticosteroid (ICS) in patients with asthma
3. Use of Long-Acting Beta-Agonist (LABA) inhaler without SABA Inhaler and/or
4. Asthma medication non-adherence
5. Increased risk of adverse drug events with asthma therapy
6. Overutilization of oral glucocorticoids in patients with asthma
7. Duplicate ingredient inhalers in patients with asthma
8. History of smoking in patients with asthma

Members discussed:
- Dr. Hogue asked how to identify clients who smoke as in #8, using diagnosis code on claims?
- Dr. Baranova replied it would be from pharmacy claims if client has received paid claim for smoking cessation or from medical diagnosis of smoking on medical claims.
- Dr. Hogue voiced concern over the accuracy of the claim information due to limitations with the number of diagnosis codes allowed on a claim (opportunity for identification of a smoking diagnosis would be minimal).
- Dr. Baranova agreed that the data might be difficult to obtain with the available information but have a small number of estimated hits to work with.
- Dr. Hogue recommended voting after each proposal presentation.

Dr. Hogue requested a motion to approve this proposed intervention if no further questions from Board.

**MOTION:** Dr. James Barnes motioned to accept proposal as presented, Dr. Deborah Briggs and Mr. Dennis Borel seconded the motion. Mr. Chacón conducted a roll call vote and announced that the motion carried unanimously with no objections and abstentions.
Agenda Item 9cii: Nonsteroidal Anti-inflammatory Drugs (NSAIDS)

Dr. Baranova focused on the following performance indicators:

1. Increased risk of ADE: NSAIDs and GI toxicity
2. Use of a COX-2 inhibitor in the absence of risk factors for GI toxicity
3. Increased risk of ADE: NSAIDs and recent myocardial infarction
4. Increased risk of ADE: NSAID and bisphosphonate
5. Increased risk of ADE: NSAID-induced GI toxicity in patients with tobacco or alcohol use
6. Therapeutic Duplication: Concurrent use of > 1 NSAID
7. NSAID use in patients with cardiovascular risk
8. NSAID use in patients with CHF and:
   • Those with ER visits or hospitalizations;
   • Those with hypertension
   • Those with renal impairment

Dr. Hogue requested a motion to approve this proposed intervention with no further questions from Board.

MOTION: Dr. Jennifer Fix motioned to accept proposal as presented and Dr. Alejandro Kudisch seconded motion. Mr. Chacón conducted a roll call vote and announced that the motion carried unanimously with no objections and abstentions.

Agenda Item 9ciii: Post-Traumatic Stress Disorder (PTSD)

Dr. Baranova focused on the following performance indicators:

1. Use of benzodiazepines in PTSD
2. Use of antidepressants other than SSRIs or venlafaxine in PTSD
3. Use of sedative-hypnotics in PTSD
4. Use of an antipsychotic without an SSRI or venlafaxine in PTSD unless there is a history of schizophrenia or bipolar

Dr. Hogue requested a motion to approve this proposed intervention if no further questions from Board.

MOTION: Dr. Richard Noel motioned to accept proposal as presented, Dr. Holmes and Dr. Alejandro Kudisch seconded the motion. Mr. Chacón conducted a roll call vote and announced that the motion carried unanimously with no objections and abstentions.

Agenda Item 10: Prospective prior authorization proposals (clinical edits)

Dr. Hogue introduced and turned the floor over to Dr. Christina Faulkner, Health Information Designs, LLC. Dr. Faulkner referenced the PowerPoint and handout, Texas HHSC DUR Board Meeting Prospective Prior Authorization Proposals May 22, 2020.

Agenda Item 10a: Monoclonal Antibody Agents for Asthma - new criteria

Dr. Faulkner presented an overview of the Fasenra/Nucala drug information, the guidelines for the treatment and management of Asthma, the guidelines for treatment of Eosinophilic granulomatosis with polyangiitis (EGPA), and clinical prior authorization (PA) approval criteria for Fasenra and Nucala.

Dr. Hogue requested a motion to approve this proposed intervention with no further questions from Board.
MOTION: Dr. James Barnes motioned to accept proposal as presented and Dr. Alejandro Kudisch seconded the motion. Mr. Chacón conducted a roll call vote and announced that the motion carried unanimously with no objections and abstentions.

Agenda Item 10b: Ophthalmic Immunomodulators - new criteria

Dr. Faulkner presented an overview of Ophthalmic Immunomodulators Cequa, Restasis, and Xiidra drug information, drug claim information, the guidelines for the treatment of Dry Eye in Sjögren’s syndrome, and clinical PA approval criteria for Ophthalmic Immunomodulators. Members discussed:

- Dr. Hogue questioned who may normally prescribe these drugs and for confirmation on the process of subsequent PA requests.
- Dr. Faulkner replied PA approved for 1 year at a time and assumes started with ophthalmologists or optometrist and continued PA approval can be handled by call or fax. Once approved for the year it does not matter who subsequently prescribes or which pharmacy dispensed.
- Dr. Fix asked on question #2 of criteria, if there is a duration for the check if prescribed in conjunction by or with ophthalmologist or optometrist or if duration can be extended 24 or 36 months. Ms. Assadi asked for clarification. Dr. Faulkner replied as presented there is no time limit for the specialty provider. Dr. Vazhappilly suggested adding a check for if prescribed in conjunction by or with ophthalmologist or optometrist to only the initial prescription.
- Dr. Faulkner said she will modify #2 of criteria to add “for initial prescription only” by ophthalmologist or optometrist as recommended. Members agreed with modification.

Dr. Hogue requested a motion to approve this proposed CPA with modification mentioned with no further questions from Board.

MOTION: Dr. Richard Noel motioned to accept proposal as presented with edits and Dr. Deborah Briggs seconded the motion. Mr. Chacón conducted a roll call vote and announced that the motion carried by a majority vote with no objections and one abstention from Dr. Thanhhao Ngo.

Agenda Item 10c: Transthyretin Agents - new criteria

Dr. Faulkner presented an overview of the Transthyretin Agents, including Vyndamax/Vyndaqel and Tegsedi drug information, the guidelines for the treatment of Amyloid Cardiomyopathy, and the clinical PA approval criteria for Vyndamax/Vyndaqel.

Dr. Hogue requested a motion to approve Vyndamax/Vyndaqel clinical PA with no further questions from the members.

MOTION: Dr. Jennifer Fix motioned to accept proposal as presented and Dr. James Barnes seconded the motion. Mr. Chacón conducted a roll call vote and announced that the motion carried unanimously with no objections and abstentions.

Dr. Faulkner continued to present the Tegsedi clinical PA criteria of Transthyretin agents clinical PA.

Dr. Hogue requested a motion to approve the Tegsedi portion of the Transthyretin agents CPA with no further questions from the members.

MOTION: Dr. James Barnes motioned to accept proposal as presented and Dr. Jennifer Fix seconded the motion. Mr. Chacón conducted a roll call vote and announced that the motion carried unanimously with no objections and abstentions.
Agenda Item 10d: Tricyclic antidepressants - new criteria

Dr. Faulkner presented an overview of the Tricyclic Antidepressants' drug and claim information, the guidelines for the management of Major Depressive Disorder, and the Tricyclic Antidepressants clinical PA approval criteria.

Members discussed:

- Dr. Hogue asked if the age restriction presented were from the package insert.
- Dr. Faulkner replied that all drugs were, except for amitriptyline. A clinical literature-based search was performed and all followed FDA guidelines but did find information supporting the use of amitriptyline down to the age of nine.
- Dr. Briggs asked if presented age restrictions were just for depression or looking at dosing and commented on using very low doses of tricyclics as a migraine preventative. Is this criteria for any usage of amitriptyline?
- Dr. Faulkner replied they are just looking at age and not dose or diagnosis.
- Dr. Briggs commented she is not sure of other prescribers but as a migraine preventative, amitriptyline, it’s one of her favorites but you don’t use much of it.
- Dr. Hogue commented he may use low dose amitriptyline for bed wetting or with use of EKG check for safety in children. Furthermore, he prescribes doxepin for dermatologic uses with itching or chronic hives as package insert indicates. Low doses are not used for depression but commonly used for other indications. Dr. Hogue agreed, if it is outside of the package insert, a call for PA.
- Dr. Faulkner commented the literature searches support to include the lowest ages to ensure the safety edit.
- Dr. Brawner commented that amitriptyline is used by neurologists for migraines for teenagers, not less than 9 years of age, so agrees with the 6 years of age range restrictions.
- Dr. Fix commented the drugs are in a low-cost category and making the edits are not of great value.
- Dr. Faulkner replied it is a safety reason not cost.
- Dr. Barnes asked if there was any data or evidence of safety problems.
- Dr. Faulkner said they do see the drugs being used for patients less than 9 years of age but because of the side effect profile and risk of overdose this PA is being proposed as safety double check.
- Dr. Barnes said he understands safety issues and asked if there’s any data on the medical claims side supporting or signaling an issue.
- Ms. Assadi stated this was a clinical PA recommended by MCOs and asked if members would like the MCOs surveyed for more information for next time.
- Dr. Barnes agreed to survey to collect information from MCOs to understand why this clinical PA is being recommended.
- Dr. Vazhappilly commented some MCOs accomplish this check as a DUR review program outside of the clinical process (PA) and may be in place already. Some MCOs may just want the consistency if done by a clinical PA.
- Dr. Briggs agrees with more information needed.

Dr. Hogue recommended tabling to get more information.

MOTION: Dr. Jennifer Fix motioned to table for more information and Dr. Heather Holmes seconded the motion. Mr. Chacón conducted a roll call vote and announced that the motion carried unanimously with no objections and abstentions.

Agenda Item 11. Retrospective drug use, criteria for outpatient use in Vendor Drug Program:
Dr. Hogue introduced and turned the floor over to Dr. Jenifer Seltzer, Pharm.D., University of Texas at Austin College of Pharmacy. Dr. Seltzer referenced the PowerPoint and handout, *Texas Medicaid Vendor Drug Program Drug Utilization Review Board Meeting – Retrospective Drug Use Proposals May 22, 2020.*

Dr. Hogue suggested to vote after presentation of all drug use criteria.

Dr. Seltzer announced her retirement and her replacement, Dr. Justin Pedigo.

Dr. Seltzer started presentation by stating the compendia was revised in April 2020 and can be found in the member meeting materials.

Dr. Seltzer continued presentation of the revised six retrospective criteria sets updated for posting on the vendor drug webpage.

1. Benzodiazepines (not including sedative/hypnotics)
2. Complement inhibitor and enzyme/protein replacement therapy
3. Direct oral anticoagulants
4. Hydroxy-methylglutaryl coenzyme A (HMG-COA) reductase inhibitors
5. Low-molecular-weight heparins
6. Nebulized bronchodilators

Dr. Hogue opened the floor to public comments and questions of the criteria sets.

Members discussed:

- Dr. Briggs questioned in the revision of the Benzodiazepines, if clobazam oral film use was only based on FDA approved indications because in the epilepsy world for a lot of patients, usage can be outside of normal limitations.
- Dr. Seltzer confirmed criteria sets are based on FDA indications and not to include off label use.
- Dr. Briggs also asked if Nayzilam Nasal Spray is included because it is used to treat seizure clusters.
- Dr. Seltzer confirmed that is not included but can be added.

Dr. Hogue requested a motion to accept with addition of Nayzilam.

**MOTION:** Dr. Richard Noel motioned to accept proposal with addition of Nayzilam to Benzodiazepine criteria set and Dr. James Barnes seconded the motion. Mr. Chacón conducted a roll call vote and announced that the motion carried unanimously with no objections and abstentions.

**Agenda Item 12: Adjournment**

Dr. Hogue adjourned the meeting at 3:04 p.m.

Below is the link to the archived video of the May 22, 2020 Drug Utilization Review Board (DURB) that will be available for viewing approx. two years from date of meeting.

[Drug Utilization Review Board](#)