HHSC: Drug Utilization Review Board, May 27, 2020

The Drug Utilization Review Board develops and submits recommendations for the preferred drug list, suggests clinical prior authorizations on outpatient prescription drugs, recommends education interventions for Medicaid providers, and reviews drug usage across Medicaid programs.

The DUR board is composed of 20 total members: 18 physicians and pharmacists providing services across the entire population of Medicaid and representing different specialties; two representatives from Medicaid managed care organizations as nonvoting members; and a consumer advocate representing people enrolled in the program.

Physician/pharmacist positions

- Robert L. Hogue, M.D., F.A.A.F.M. (Brownwood) (**Chair**)
- J. Nile Barnes, Pharm. D., BCPS (Dripping Springs)
- Scott Blaszczyk, Pharm.D., BCGP (Dallas)
- Deborah E. Briggs, M.D. (Austin)
- Marlo Brawner, M.D. (Livingston)
- Deeatra S. Craddock, Pharm. D, BCACP (Carrollton)
- Jennifer Fix, Pharm. D (Burleson)
- Connie Gelineau, Pharm.D. (Richardson)
- Heather Holmes, M.D. (Amarillo)
- Summer A. Keener, Pharm. D (San Antonio)
- Alejandro D. Kudisch, M.D., D.F. A.P.A. (McAllen)
- Jill N. Lester, Pharm. D. (Dallas)
- Thanhhao T. Ngo, Pharm. D. (Austin)
- Richarad Noel, M.D. (Spring)
- Kim Pham, D.O. (Dallas)

Managed care positions

- Salil V. Deshpande, M.D., M.B.A. (Sugar Land)
    - UnitedHealthcare
- Joseph J. Vazhappilly, Pharm. D., M.B.A. (Irving)
    - Molina Healthcare of Texas

Consumer advocate position

- Dennis A. Borel (Austin)

Texas Insight only covers the public comment on drug classes to be reviewed for the Medicaid PDL and subsequent Board recommendations. For the second part of the meeting, only the meeting materials are provided.

Call to order. The meeting was called to order by the Chair, Robert Hogue.

Approval of minutes from January 24, 2020. The minutes were approved as written.

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Announcement: Drug Utilization Review Board Conflict of Interest Policy Review. Staff stated that the conflict of interest policy is being reviewed under the Texas Administrative Code. Persons appointed to the board must be free of conflicts of interest. Federal and state law govern the conflict of interest policy. The modifications will be made and will be published for public review.

New business:

Public comment on drug classes to be reviewed for the Medicaid (PDL). To access detailed information about each drug class, please follow the live link:

Anti-allergens, oral. No commenters.

Antibiotics, inhaled. No Commenters.

Anticoagulants.

Three commenters:

Dr. David Chiu, Houston Methodist Hospitals Stroke Unit. He stated that the basic properties should be its use to prevent stroke and bleeding events. There is agreement that Eliquis (Apixaban) is the best choice. He cited the Aristotle Trial as supporting his position.

Maria Posey, Pfizer, spoke in support of Eliquis (Apixaban) requesting continuing Eliquis as preferred.

Shannon Sanz,[1] Janssen, spoke in support of Xarelto and provided data to support her position. It is now available to people with renal impairment.

Eliquis (apixaban) blocks the activity of certain clotting substances in the blood. Eliquis is used to lower the risk of stroke or a blood clot in people with a heart rhythm disorder called atrial fibrillation. Eliquis is also used to lower the risk of forming a blood clot in the legs and lungs of people who have just had hip or knee replacement surgery. Eliquis is used to treat blood clots in the veins of your legs (deep vein thrombosis) or lungs (pulmonary embolism), and lower the risk of them occurring again. Learn more here.

XARELTO® is approved by the FDA to help reduce the risk of blood clots in common conditions like atrial fibrillation (AFib), deep vein thrombosis (DVT), and pulmonary embolism (PE). It is also approved to reduce the risk of major cardiovascular events in

[1] Spelling uncertain.

conditions for which no other anticoagulant has been approved before, such as coronary artery disease (CAD) and peripheral artery disease (PAD). More than 40 million people worldwide have been prescribed XARELTO®. Learn more here.

Antidepressants, other. No Commenters.

Antidepressants, selective serotonin reuptake inhibitors. No Commenters.

Antidepressants, tricyclic. No Commenters.

Antihyperuricemics. No Commenters.

Antiparkinsons agents. No commenters.

Antivirals, oral/nasal

Two Commenters.

Dana Evans, Genentech spoke in support of Xofluza (influenza medication). He provided research updates and a safety profile. He listed some reactions to, and precautions for, the medication. It has one-time dosing and he recommended it be a preferred agent. They have filed an application for pediatric dosing.

Eder Hernandez, Practitioner, Valley Med Urgent Care. He spoke in support of Xofluza because of its efficacy addressing influenza A and B. It has one-time dosing and inhibits viral replication at the source. It is for use for patients over the age of 12. He recommended the drug for the PDL without prior authorization.

Xofluza® is indicated for the treatment of acute uncomplicated influenza in patients 12 years of age and older who have been symptomatic for no more than 48 hours and who are:

- otherwise healthy, or
- at high risk of developing influenza-related complications [see Clinical Studies (14.2)].

Anxiolytics - No commenters.

Beta blockers - No Commenters.

Bile salts - No Commenters.

Benign prostatic hyperplasia treatments - No commenters.

Bronchodilators, beta agonist - No Commenters.

Chronic obstructive pulmonary disease agents - No Commenters.

Cough and cold agents - No commenters.

Erythropoiesis stimulating proteins - No Commenters.

Glucagon agents

Two commenters:

Kunal Ramani, Xeris Pharmaceuticals, spoke in support of Gvoke. He provided some data about diabetes in Texas. Gvoke will be available as an autoinjector in July. It is prefilled and premixed with a treatment effect in less than 14, minutes and showed a 99% success rate. Requested moving Gvoke to preferred.

Jennifer Ward, Eli Lilly, spoke in support of Baqsimi Nasal glucagon, with a 90% administration success rate in clinical testing. Administration takes 30 seconds.

Gvoke is an antihypoglycemic agent indicated for the treatment of severe hypoglycemia in patients with diabetes ages ≥ 2 years Glucagon nasal powder **(Baqsimi**) is a portable, dry nasal spray form of glucagon available in a single, fixed-dose intranasal device that does not require reconstitution or inhalation.

Glucocorticoids, inhaled - No Commenters

Hereditary angioedema treatments - No Commenters

Immune globulins, intravenous - No Commenters

Immunomodulators, asthma

One Commenter:

Kirsten Mar, AstraZeneca, spoke in support of Fasenra. She provided information from the package insert.

FASENRA is an add-on maintenance treatment for patients 12 and older with severe eosinophilic asthma. See more

Lincosamides/oxazolidinones/streptogramins - No Commenters.

Lipotropics, other - No Commenters.

Lipotropics, statins - No Commenters.

Pulmonary arterial hypertension agents, oral and inhaled

Two Commenters:

Terry Garza,[2] **Actelion (Janssen),** spoke in support of Ventavis and Opsumit. She described the PAH condition and the need for access to all medications. She relayed information from the package inserts and cited studies that supported her position.

Amy Heidenreich, United Therapeutics, spoke in support of Orenitram. She stated that the FDA has responded favorably to the medication that reduces disease progression. She asked for Orenitram to be moved to preferred for PAH patients

Ventavis, Opsumit and Orenitram are all indicated to address pulmonary arterial hypertension (WHO Group I) to improve exercise capacity

Pancreatic enzymes - No Commenters.

Pediatric vitamin preparations - No Commenters.

Prenatal vitamins - No Commenters.

Sedative hypnotics - No Commenters.

Sickle cell anemia treatments

Four Commenters:

[2] Spelling uncertain.

Jennifer Nelson,[3] **Global Blood Therapeutics,** spoke in support of Oxbryta. (Part of her presentation was inaudible due to background noise). It is a once-daily oral tablet. There is no titration and she asked for consideration to add it to the PDL.

Melissa Frei-Jones, Pediatric Hematologist, discussed Oxbryta, stating that this medication offers hope to patients who do not tolerate Hydroxyurea. She questions some of the Magellan criteria used to regulate the use of medications in this class.

Dr. Facipee,[4] **Pediatric Hematologist,** described Sickle Cell Disease. Complications can be seen in any organ of the body. There is miseducation about Sickle Cell Disease. He stated that he was asking to support open access for all treatments. This is a matter of parity and the emphasis should be on the complexity of the disease.

Charles Stark, Emmaus Life Sciences / Emmaus Medical, spoke in support of Endari stating that they have three years of experience with Endari and they requested it to be on the PDL without restrictions.

Voxelotor (Oxbryta), a hemoglobin S (HbS) inhibitor, is indicated for the treatment of sickle cell disease (SCD) in adults and pediatric patients 12 years of age and older. The approval from the United States (US) Food and Drug Administration (FDA) was accelerated based on voxelotor's ability to increase hemoglobin (Hb) levels. The FDA has indicated that continued approval of voxelotor will be contingent upon additional results from confirmatory trial(s).

L-glutamine oral powder (Endari) is an amino acid indicated to reduce the acute complications of sickle cell disease (SCD) in adults and children 5 years and older.

Thrombopoiesis stimulating proteins

One Commenter:

Sarika Klein, Dova Pharmaceuticals, spoke in support of Avatrombopag and provided information from the package insert.

Avatrombopag is indicated for treatment of thrombocytopenia in adults with chronic immune thrombocytopenia (ITP) who have had an insufficient response to a previous treatment as well as treatment of thrombocytopenia in adult patients with chronic liver disease (CLD) who are scheduled to undergo a procedure.

[3] Spelling uncertain.
[4] Spelling uncertain.

Urea cycle disorder, oral

One Commenter:

Marty Porter, Horizon Therapeutics, spoke in support of Ravicti.

Ravicti is indicated for chronic management of patients with urea cycle disorders (UCDs) who cannot be managed by dietary protein restriction and/or amino acid supplementation alone; must be used with dietary protein restriction and, in some cases, dietary supplements (e.g., essential amino acids, arginine, citrulline, protein-free calorie supplements).

Public comment and therapeutic and clinical drug reviews on new drugs to be reviewed for the Medicaid preferred drug list. Click on the link for details on each pharmaceutical product.

Absorica LD (oral) / Acne agents, oral

No Comments.

Reyvow (oral) / Antimigraine agents, other

Jennifer Ward, Eli Lilly, spoke in support of Reyvow.

Ubrelvy (oral) / Antimigraine agents, other

Colleen Smith, Allergan, spoke in support of Ubrelvy.

Secuado (transdermal) / Antipsychotics agents

No Comments.

Gabacaine Kit (miscellaneous) / Neuropathic pain agents

No Comments.

Ziextenzo syringe (subcutaneous) / Colony stimulating

No Comments.

Therapeutic and Clinical Drug Reviews and Updates: Matt Lennertz, Pharm. D., Magellan Medicaid Administration. Updates were presented related to drugs that had not been commented on by company representatives.

Executive work session:
Pursuant to Texas Government Code Section 531.071, and in accordance with Texas Administrative Code Title 1, Part 15, Subchapter F, Section 354.1941(c)(2), the Drug Utilization Review (DUR) Board may meet in executive session on one or more items listed under new business as permitted by the Texas Open Meetings Act.

Announcements of drugs recommended for the Medicaid PDL: Matt Lennertz, Pharm. D., Magellan Medicaid Administration. Only changes are noted. There were two changes recommended that we were not able to report on due to technical difficulty.

- **Anti-allergens**, **oral** - no change.
- **Antibiotics, inhaled** - no change.
- **Anticoagulants**
  - Bevyxxa Recommended as nonpreferred.
- **Antidepressants, other**
  - Venlafaxine oral recommended PDL.
- **Antidepressants, selective serotonin reuptake inhibitors**
  - Fluoxetine 60mg oral recommended nonpreferred.
- **Antidepressants, tricyclic** - no change.
- **Antihyperuricemics**
  - Gloperba oral recommended nonpreferred.
- **Antiparkinsons agents**
  - Bromocriptine oral recommended nonpreferred.
- **Antivirals, oral/nasal**
  - Tamiflu capsule recommended for nonpreferred.
  - Valcyte Oral Solution recommended for PDL.
- **Anxiolytics** - no change.
- **Beta blockers** - no changes.

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- **Bile salts** - no changes.

- **Benign prostatic hyperplasia treatments** - no change.

- **Bronchodilators, beta agonist** - no change.

- **Chronic obstructive pulmonary disease agents** - no change.

- **Cough and cold agents**
  - Ed A-Hist Liquid Oral recommended nonpreferred.
  - Mucus Chest Congestion Liquid recommended for PDL.

- **Cough and cold Non-Narcotic**
  - Guaifen/Dextromethorphan/PE OTC Oral.
  - Guaifenesin/DM Tablet ER 12H OTC Oral.
  - Mucenix Fast Max Severe Cold Liguid recommended as nonpreferred.

- **Erythropoiesis stimulating proteins**
  - Aranesp Disp (Injection) recommended for PDL.
  - Aranesp Vial (injection) recommended for PDL.
  - Procrit (Injection) recommended nonpreferred.

- **Glucagon agents**
  - Baqsimi (Nasal) recommended for PDL.
  - Glucagon (Injection).
  - Glucagon Emergency (Fresenus) (Injection) recommended as nonpreferred.
  - Glucagon Emergency (Lilly) (Injection) recommended for PDL.
  - Gvoke Pen (subcutaneous) recommended as nonpreferred.
  - Gvoke Syringe (subcutaneous) recommended as nonpreferred.
  - Proglycem Suspension (oral) recommended for PDL.

- **Glucocorticoids, inhaled** - no change.

- **Hereditary angioedema treatments**
  - Haegarda (sub Q) recommended for PDL.

- **Immune globulins, intravenous**
  - Asceniv (intraven) recommended as nonpreferred.

- **Immunomodulators, asthma**
  - Fasenra pen (subcutaneous) recommended for PDL.

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  - Nucala Auto-injector (subcutaneous) recommended as nonpreferred.
  - Nucala Syringe(subcutaneous) recommended as nonpreferred.

- **Lincosamides/oxazolidinones/streptogramins** - no changes.

- **Lipotropics, other**
  - Fenofibrate capsule (Lofibra) (oral) recommended for PDL.

- **Lipotropics, statins**
  - Rosuvastatin (oral) recommended for PDL.

- **Pulmonary arterial hypertension agents, oral and inhaled**
  - Ambrisentan (oral) recommended for PDL.
  - Letaris (oral) recommended as nonpreferred.
  - Revatio Suspension (oral) recommended for PDL.

- **Pancreatic enzymes** - no change.

- **Pediatric vitamin preparations**
  - Floriva Plus Drops OTC (oral) recommended as nonpreferred.

- **Prenatal vitamins**
  - Citranatal DHA (oral) recommended as nonpreferred.
  - PNV2/Iron B-G Suc-P/FA/Omega 3 (oral) recommended for the PDL.
  - PNV53/Iron B-G HCL-P/FA/Omega 3 (oral) recommended for the PDL.

- **Sedative hypnotics**
  - Eszopiclone (oral) recommended for PDL.
  - Zaleplon (oral) recommended for PDL.

- **Sickle cell anemia treatments**
  - Droxia (oral) recommended for PDL.
  - Endari (oral) recommended as nonpreferred.
  - Hydroxyurea (oral) recommended for the PDL.
  - Oxbryta (oral) recommended as nonpreferred.
  - Siklos (oral) recommended as nonpreferred.

Thrombopoiesis stimulating proteins - no changes.

Urea cycle disorder, oral - no changes.

New single product drugs that were reviewed for the Medicaid preferred drug list:

- **Absorica LD (oral)** / Acne agents, oral recommended as nonpreferred.
- **Reyvow (oral)** / Antimigraine agents, other recommended as nonpreferred.
- **Ubrelvy (oral)** / Antimigraine agents, other recommended as nonpreferred.
- **Secuado (transdermal)** / Antipsychotics agents recommended as nonpreferred.
- **Gabacaine Kit (miscellaneous)** / Neuropathic pain agents recommended as nonpreferred.
- **Ziextenzo syringe (subcutaneous)** / Colony stimulatin recommended as nonpreferred.

MOTION: *Approve the recommendations as presented – prevailed*. (There were two changes that Texas Insight was unable to report on due to technical difficulty).

***This concludes the meeting coverage by Texas Insight. The following items were presented and discussed by the DORB. Please click on the live link for the details of each proposal or item*.**

Retrospective DUR: Mariya Baranova, Pharm. D., MCMP-II, Conduent, LLC

Report on recent retrospective DUR interventions:

i. Prevention of adverse drug events in patients receiving opioids
ii. Pain management with opioids
iii. Monitoring of psychotropic drugs in youth

Report on recent retrospective DUR intervention outcomes:

iv. Psychotropic drugs in adults
v. Medication adherence
vi. Mental health disorder therapy management
vii. Respiratory disease management

Retrospective DUR proposals

viii. Asthma
ix. Nonsteroidal anti-inflammatory drugs (NSAIDS)
x. Post-traumatic stress disorder (PTSD)

Prospective prior authorization proposals (clinical edits): Christina Faulkner, Pharm. D., BCPS, KEPRO, LLC (vote required)
Monoclonal antibody agents for asthma - new criteria

Ophthalmic immunomodulators - new criteria

Transthyretin agents - new criteria

Tricyclic antidepressants - new criteria

Retrospective drug use, criteria for outpatient use in Vendor Drug Program: Jennifer Seltzer, Pharm. D., University of Texas at Austin College of Pharmacy (vote required)

b. Benzodiazepines (not including sedative/hypnotics)
c. Complement inhibitor and enzyme/protein replacement therapy
d. Direct oral anticoagulants
e. Hydroxy-methylglutaryl coenzyme A (HMG-COA) reductase inhibitors
f. Low-molecular-weight heparins
g. Nebulized bronchodilators

Next meeting date: July 24, 2020.

Adjourn. There being no further business, the meeting was adjourned.

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