HHSC Psychiatric Executive Formulary Committee Minutes

The HHSC Psychiatric Executive Formulary Committee (PEFC) convened on July 28, 2023 via MS Teams. The meeting was called to order by Dr. Moron, Chair at 9:30 a.m.

Members

Member Names	Attendance	Member Names	Attendance
Yekini Adeyemi, RN	Present	David Moron, MD- Chair	Present
Angela Babin, RPh	Present	Leah Nunez, PharmD	Present
John Bennett, MD	Present	Brittany Parmentier, PharmD	Present
Giovanna Betancourt, PharmD	Present	Kasey L. Pena, PharmD- Secretary	Present
Rakesh Chadalavada, MD	Present	Kenda Pittman, PharmD	Present
German Corso, MD	Absent	Sangeetha Rajan, MD	Present
Brad Fitzwater, MD	Present	Rishi Sawhney, MD	Absent
Catherine Hall, PharmD	Absent	Lesia Trickett, MD	Present
Dana Hopkins, RN	Present	Ashton Wickramasinghe, MD	Present
Jeffery Matthews, MD	Absent	Patrick Young, MD	Absent

Guests Present: Tonya Barrios, State Hospitals Central Administration; Kristen Neumeister, PharmD, North Texas State Hospital, Wichita Falls; Mitchell Crouch, PharmD, The Harris Center for Mental Health and IDD; Jackie Dabney, PharmD, The Harris Center for Mental Health and IDD; Candace Jones, MD, PGY-4 Adult Psychiatry Resident, Dell Medical School; Nina Jo Muse, MD, Co-Chair Parameters Workgroup, Chief Medical Officer, Texas State Hospital System; Angela Campbell, PharmD, Clinical Psychiatric Pharmacist, Campbell Pharmacy Consulting, LLC

Opening

Introduction and Other Information

Dr. Guidry has left his position at North Texas State Hospital, Vernon and has resigned his position on the committee. Dr. Carmen Zegarra, Austin State Hospital, has been selected as the new state hospital physician to the committee beginning in October.

Conflict of Interest Disclosures

The committee members present did not disclose any new conflicts of interest.

Review of Minutes

The minutes from the April 28, 2023 meeting were approved as previously distributed.

Unfinished Business

Stimulants Audit Criteria

Reviewed below.

New Drug Applications for New Brand Names of Active Ingredients Already on Formulary

The committee discussed instances when NDAs are received for new brand names of active ingredients that are already on formulary. After discussion, the committee agreed the clinical pharmacists of this committee will meet to decide if it's appropriate to present an abbreviated monograph on a case-by-case basis after a review of available information and data. The committee reserves the right to request a full monograph.

New Business

New Drug Applications

Monograph template revisions

The committee reviewed and approved revisions made to the monograph template.

New Drug Check list revisions

The committee reviewed and approved revisions made to the New Drug Check list.

Progesterone micronized NDA

The committee has received an NDA for progesterone micronized (Prometrium) indicating that this medication be used for hormonal therapy for gender therapy. The committee was asked for their experiences with this medication for this indication. Dr. Pena has reached out to the HHSC legal team for direction regarding this NDA.

Adverse Drug Reaction Reports

None received.

Psychotropic Medication Audit Criteria & Guidelines Review

The committee reviewed and approved recommended revisions to the following audit criteria documents:

- Stimulants
- Benzos

- Gabapentin
- Buspirone
- Sedating antihistamines (diphenhydramine, hydroxyzine)
- Non-benzo sedative hypnotics (eszopiclone, zolpidem)

The updated documents will be posted to the PEFC website.

Psychotropic Monitoring Guidelines Review

The committee reviewed and approved updates to the Psychotropic Monitoring Guidelines that were based on revisions to the audit criteria approved at this meeting.

The updated document will be posted to the PEFC website.

Drug Formulary Sectional Review

In reviewing the formulary drug listings for Antiparkinson and Cardiovascular Agents, the following changes were approved:

- Antiparkinson Agents
  - Selegiline – remove brand name Eldepryl
  - Trihexyphenidyl – remove brand name Artane
- Cardiovascular Agents – Diuretics-Carbonic Anhydrase Inhibitors
  - Acetazolamide – remove brand name Diamox
- Cardiovascular Agents – Calcium Channel Blockers
  - Amlodipine – remove extended release
  - Nifedipine – remove brand name Adalat CC
  - Verapamil – remove brand names Calan, Isoptin, Calan SR, Isoptin SR
- Cardiovascular Agents – Beta-Adrenergic Blockers
  - Labetalol – remove brand name Normodyne
- Cardiovascular Agents – Angiotensin Converting Enzyme Inhibitors
  - Captopril – remove brand name Capoten
  - Lisinopril – remove brand name Prinivil
- Cardiovascular Agents – Vasopressors
  - Dopamine – remove brand name Intropin
- Updated Cost Index of several items

The updated formulary will be posted on the PEFC website.

Other Formulary Changes

- Igalmi: The committee received an email from the field requesting clarification of the Guidelines for Use phrasing for dexmedetomidine (Igalmi), which was previously approved for reserve use at the April meeting. After discussion, the committee added clarification that monitoring should be done by a RN or LVN. No further reserve use criteria changes were made.

- GLPs: The FDA approved GLPs indicated for weight loss (Wegovy, Saxenda) are currently not on the formulary and use would require non-formulary justification. An email from the field inquired about the use of formulary Ozempic for an off-label indication of weight loss. After discussion, the committee, declined to add reserve use criteria for Ozempic and determined that any criteria related to off-label use would be at the discretion of the prescriber or facility.

The updated Guidelines for Use for Igalmi will be posted on the PEFC website.

Psychoactive Medication Utilization Parameters for Children and Youth in Texas Public Behavioral Health - Tables Revisions

The committee reviewed and approved recommended revisions to the tables in the Psychoactive Medication Utilization Parameters for Children and Youth in Texas Public Behavioral Health.

The updated tables will be posted on the PEFC website.

Quarterly Non-Formulary Drug Justification Report

For the third quarter of fiscal year 2023 (March 2023 to May 2023), only the state hospitals reported use of non-formulary agents. The state supported living centers (SSLCs) currently do not have the capability to obtain non-formulary drug usage reports from their computer system but are working with the vendor to make this reporting possible. The following were the top five non-formulary agents, by number of orders, that were prescribed in the state hospitals during the third quarter of fiscal year 2023:

- Molnupiravir
- Paxlovid
- Quercetin
- Zinc gluconate
- Pediatric electrolyte

PEFC Membership Composition discussion

The committee reviewed the composition of this committee and considered the addition of advance practitioner registered nurse (APRN). After discussion, the committee approved the addition of one APRN from the state hospitals and one APRN from the state supported living centers. Dr. Pena will contact the state hospital associate commissioner for approval.

Issues from the Chief Medical Officer, State Hospitals

Dr. Matthews was not present to present a report.

Issues from the Medical Services Coordinator, SSLCs

Dr. Wickramasinghe reminded the committee of the trainings he has been presenting with CME on The Fatal Five. The next presentation will be on Dementia, on August 23.

Drug Shortages, Recalls, and FDA Safety Communications

The FDA has issued the following safety communications and recalls that may impact our facilities:

Shortages

The following medication is not available:

- Lisdexamfetamine (Vyvanse) **(NEW)**

The following medications are in shortage but are still available to be ordered:

- Albuterol sulfate inhalation solution
- Amphetamine salt combos
- Amoxicillin oral powder for suspension
- Clonazepam
- Diazepam rectal gel **(NEW)**
- Lidocaine injection
- Lidocaine viscous oral topical solution **(NEW)**
- Liraglutide (Victoza) **(NEW)**
- Lorazepam injection
- Olanzapine ODT
- Sterile water for injection

Recalls

- Akorn Specialty Generics issued a voluntary nationwide recall of various commonly used drugs due to company shutdown.
  (link: **https://www.fda.gov/media/167863/download**)
- Dronabinol 2.5mg and ziprasidone 20mg from Major pharmaceuticals due to labeling mix-up, may contain incorrect product.

Safety-related Labeling Changes

- Rexulti: *Added information regarding increased risk of somnolence in patients for agitation associated with dementia due to Alzheimer's disease.* In a 12-week, placebo-controlled clinical studies of REXULTI in patients with agitation associated with dementia due to Alzheimer's disease, the incidence of orthostatic hypotension-related adverse reactions in patients treated with REXULTI compared to patients treated with placebo included: dizziness (3% versus 3%), orthostatic hypotension (1% versus 1%), and syncope (0.2% versus 0.8%).

- Vimpat: *Added information related to loading doses.* Loading doses should be administered with medical supervision because of the possibility of increased incidence of adverse reactions including CNS reactions, cardiovascular reactions, and rash.
- Lexapro: Adverse reactions in pediatric patients were added based on a double-blind placebo-controlled trial of pediatric patients aged 6 to 17 years but labeling still indicates that safety and effectiveness not established in patients less than 12 with MDD or less than 7 with GAD.
- FDA updating warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions: "The FDA is requiring updates to the Boxed Warning and other information to ensure the prescribing information is made consistent across the entire class of these medicines to address continuing concerns of misuse, abuse, addiction, and overdose of prescription stimulants."

News Briefs

The following information was shared with the committee members:

Triple Agonist Retatrutide Hits New Weight-Loss Highs
Medscape (6/26/2023). Eli Lilly's retatrutide is an investigational agent combining agonism to three hormones influencing eating and metabolism. In a two phase-2 studies with 600 people who were overweight or obese receiving retatrutide 12mg, patients without type 2 diabetes lost 24% of their bodyweight over 48 weeks and patients with type 2 diabetes lost 17% of their body weight over 36 weeks of treatment. Retatrutide works by concurrently activating the glucagon-like peptide-1 (GLP-1), glucose-dependent insulinotropic peptide (GIP), and the glucagon (Gcg) receptors. Other examples of GLP-1 receptor agonists include Ozempic, Victoza, Trulicity. An example of GIP-GLP1 receptor agonist is Mounjaro.

Do Oral Contraceptives Increase Depression Risk?
Medscape (7/3/2023). Study published in Epidemiology and Psychiatric Sciences suggested that the use of OCs may increase the risk of depression, especially in the first two years, although findings are inconsistent.

Promising Phase 3 Results for Alzheimer's Drug Donanemab
Medscape (7/17/2023). Eli Lilly's monoclonal antibody donanemab (anti-amyloid) was shown to slow cognitive and functional decline for patients with early symptomatic Alzheimer's disease in a phase 3 study (TRAILBLAZER-ALZ 2: 1736 patients with MCI or mild dementia with PET showing amyloid and tau pathology). Some safety concerns were also seen with more patients in the active drug group experiencing amyloid related imaging abnormalities and microhemorrhage. Three deaths were determined to be drug related (patients developed serious ARIAS or brain bleeding/swelling). This drug has been submitted for approval to the FDA.

Open Forum

None.

Next Meeting Date

The next meeting is scheduled for October 20, 2023.

Adjourn

There being no further business, the meeting was adjourned at 2:09 p.m.

Approved: *David Moron*

David Moron, MD, Chairman

Minutes Prepared by:
Tonya Barrios, PhTR
Reviewed by:
Kasey L. Pena, PharmD