



HHSC Psychiatric Executive Formulary Committee Minutes

The HHSC Psychiatric Executive Formulary Committee (PEFC) convened on July 9, 2021 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	Jeffery Matthews, MD	Present
Angela Babin, RPh	Present	David Moron, MD- Chair	Present
Jean Baemayr, PharmD- Secretary	Present	Leah Nunez, PharmD	Present
John Bennett, MD	Absent	Brittany Parmentier, PharmD	Present
Giovanna Betancourt, PharmD	Present	Kenda Pittman, PharmD	Present
Rakesh Chadalavada, MD	Present	Rishi Sawhney, MD	Absent
German Corso, MD	Present	Glenn Shipley, DO	Present
Brad Fitzwater, MD	Absent	Lesia Trickett, MD	Present
Catherine Hall, PharmD	Present	Ashton Wickramasinghe, MD	Present
Dana Hopkins, RN	Present	Patrick Young, MD	Present
Vicky Litton, MD	Absent		

Guests Present: Tonya Barrios, State Hospitals Central Administration; Monica Dulaney, P4 PharmD Student, UT Tyler Fisch College of Pharmacy; Raul Olmos, P4 PharmD Student, UT Tyler Fisch College of Pharmacy

Opening

Introduction and Other Information

Dr. Patrick Young, Betty Hardwick Center, has been selected as a local authority practitioner member of the committee.

Conflict of Interest Disclosures

The committee members present did not disclose any new conflicts of interest. The committee reviewed the Conflict of Interest Disclosure form submitted by Dr. Young.

Review of Minutes

The minutes from the April 30, 2021 meeting were approved as previously distributed.

Unfinished Business

Reserve Use Criteria – methadone (April 2021)

The Reserve Use Criteria for methadone has been pended until the October meeting.

New Business

Format of future meetings

The committee discussed the format of future meetings and the consensus was to offer a hybrid of both an in person and virtual meetings, with one meeting annually designated specifically as in person with the goal of providing an opportunity for all committee members to meet face to face. A trial hybrid meeting will be held in Austin in October.

Adverse Drug Reaction Reports

None reported.

Psychotropic Medication Audit Criteria & Guidelines Review

The MUE subcommittee members met to discuss the references used to determine the indications for use that are included in the criteria. The members recommended that moving forward, indications that are not FDA-approved will be clearly labeled “off label.” Additionally, there will be an initial peer review of the audit criteria prior to presentation to the PEFC. The subcommittee acknowledged that off label use will vary depending on the practice guidelines referenced and the population served.

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

- Typical antipsychotics-Thioridazine
- Typical antipsychotics-Decanoates
- Typical antipsychotics

The updated documents will be posted to the PEFC website.

Quarterly Non-Formulary Drug Justification Report

For the third quarter of fiscal year 2021 (March 2021 through May 2021), 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 2021:

- Magnesium oxide
- Acetaminophen/caffeine/pyrilamine (Midol Menstrual Complete)

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- Flaxseed oil
 - Listerine Zero
 - Ketorolac tromethamine (Acular)

New Drug Applications

None reviewed this meeting. At the recommendation of Dr. Wickramasinghe, a monograph for ezetimibe (Zetia) will be prepared for review at the October meeting.

Drug Formulary Sectional Review

In reviewing the formulary drug listings for gastrointestinal and muscle relaxant agents, the following changes were approved:

- Histamine (H2) Antagonists-Other Agents
 - ▶ Ranitidine- remove brand name Zantac.
- Laxatives-bulking agents
 - ▶ Methylcellulose powder- remove specific descriptors "with sucrose and maltodextrin, sugar free with phenylalanine"
- Laxative-surfactants
 - ▶ Docusate sodium (Colace)- remove "syrup, oral" leaving "liquid, oral"
- Antidiarrheals
 - ▶ Kaolin-Pectin oral suspension- remove from formulary
 - ▶ Pramoxine (Anusol) rectal ointment, suppository- remove from formulary
 - ▶ Saccharomyces boulardii (Florastor)- Move from Miscellaneous Gastrointestinal Agents section to Antidiarrheals section
- Updated Cost Index of several items

The updated formulary will be posted on the PEFC website.

Other Formulary Changes

The committee also approved the following changes to the formulary:

- Add Epinephrine (Epi-Pen) to the Antidotes therapeutic classification table.

The updated formulary will be posted on the PEFC website.

Issues from the Chief Medical Officer, State Hospitals

No issues to report.

Issues from the Medical Services Coordinator, SSLCs

Dr. Shipley reported that due to rising resistance, the use of the monoclonal antibodies bamlanivimab and etesevimab are no longer approved to treat COVID-19 infections and several SSLC facilities have obtained the currently recommended medications REGEN-COV (casirivimab and imdevimab) and sotrovimab.

Drug Shortages, Recalls, and FDA Safety Communications

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

Shortages

None reported

Recalls

Metformin ER: Viona Pharmaceuticals is recalling two lots of metformin extended-release tablets 750 mg because it has been found to contain levels of Nitrosodimethylamine (NDMA) impurities above acceptable daily limits. This product was manufactured by Cadila Healthcare Limited, Ahmedabad, India in November 2019, for U.S. distribution by Viona Pharmaceuticals Inc.

NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. NDMA is a known environmental contaminant and found in water and foods, including meats, dairy products, and vegetables. To date, neither Viona Pharmaceuticals, nor Cadila Healthcare Limited have received any reports of adverse events related to this recall.

Safety-related Labeling Changes

Methylphenidate: *Additions underlined*

Concomitant use of MAOIs and CNS stimulants, including Methylin can cause hypertensive crisis. Potential outcomes include death, stroke, myocardial infarction, aortic dissection, ophthalmological complications, eclampsia, pulmonary edema, and renal failure (see **CONTRAINDICATIONS**). Concomitant use of Methylin with MAOIs or within 14 days after discontinuing MAOI treatment is contraindicated.

Antihypertensive Drugs

Methylin may decrease the effectiveness of drugs used to treat hypertension. Monitor blood pressure and adjust the dosage of the antihypertensive drug as needed.

Risperidone

Combined use of methylphenidate with risperidone when there is a change, whether an increase or decrease, in dosage of either or both medications, may increase the risk of extrapyramidal symptoms (EPS). Monitor for signs of EPS.

News Briefs

The following information was shared with the committee members:

FDA Approves New Drug Application For Ketamine To Manage Levodopa-Induced Dyskinesia In People With Parkinson's Disease

Parkinson's News Today (5/20, Ray) reports the FDA "approved PharmaTher's investigational new drug application for ketamine as a treatment for levodopa-

induced dyskinesia in people with Parkinson's disease." The decision "clears the way for PharmaTher to proceed with a Phase 2 clinical trial to study low-dose ketamine" in patients with Parkinson's disease.

FDA Approves Olanzapine/Samidorphan Combination Treatment For Schizophrenia And Bipolar 1 Disorder In Adults, Company Says

According to Healio (6/8, Gramigna), in a June 1 press release, Alkermes has announced FDA approval of Lybalvi. "an olanzapine/samidorphan combination treatment for schizophrenia and bipolar 1 disorder in adults." In arriving at its "approval decision, the FDA reviewed data from 27 clinical studies, including 18 that evaluated Lybalvi and nine that evaluated samidorphan alone," then "also considered its own findings regarding safety and effectiveness of olanzapine for treating bipolar 1 disorder and schizophrenia." The medication is anticipated to "be available for patients in the fourth quarter of this year."

Oral, Ultra-Long Acting, Extended-Release Risperidone Capsule May Provide Sustained Therapeutic Levels In People With Schizophrenia

Healio (6/14, Gramigna) reports, "An oral, ultra-long-acting, extended-release risperidone capsule provided sustained therapeutic levels of risperidone over one-week dosing intervals" in people with schizophrenia, researchers concluded in a 32-patient, "randomized, parallel group, placebo-controlled study." The findings were presented at the American Society for Clinical Psychopharmacology annual meeting (virtual).

Biogen, Eisai Moving To Speed Up Confirmatory Trial Of Alzheimer's Drug

Reuters (6/23, Roy) reports Biogen and partner Eisai "said on Wednesday they were working to speed up completion of a confirmatory trial of their controversial Alzheimer's drug," Aduhelm, "that was recently given an accelerated approval by the U.S. drug regulator." The FDA approved the drug earlier this month "using its accelerated approval pathway, which requires a study to confirm the drug works as intended, and gave a deadline of nine years ending 2029 for the trial."

House Panel To Investigate FDA Approval Of Aducanumab As Alzheimer's Treatment

Reuters (6/25, Nadeem) reported that the House Committee on Oversight and Reform "on Friday announced an investigation into the approval and pricing of Biogen Inc's Alzheimer's drug, Aduhelm [aducanumab], amid concerns over its steep price and doubts if the clinical evidence proves the drug works." The FDA cleared "the drug, which has a list price of \$56,000 per year," on June 7 "as the first treatment to attack a likely cause of Alzheimer's." The House panel stated that it has "serious concerns about the steep price of Biogen's new Alzheimer's drug Aduhelm [aducanumab], and the process that led to its approval despite questions about the

drug's clinical benefit." The House Committee on Energy and Commerce announced a similar investigation. The Hill (6/25, Sullivan) reported the approval "has provoked an outcry on numerous fronts" as "the FDA has faced questions as to why it approved the drug given doubts about whether it actually works."

Eli Lilly To Seek Expedited FDA Approval For Alzheimer's Drug Donanemab

The Wall Street Journal (6/24, Cooper, Subscription Publication) reports Eli Lilly announced Thursday that the FDA has designated its experimental Alzheimer's drug, donanemab, for its accelerated approval process, and the drugmaker plans to seek market clearance through the program later this year. Donanemab appeared to perform better in its trials than the recently FDA-approved drug Aduhelm (aducanumab) did in its trials. The AP (6/24, Murphy) reports Lilly "will seek approval for donanemab based on results from a mid-stage clinical study of the drug involving 272 patients with an early form of the disease. Researchers said donanemab showed signs of slowing a decline in cognition and daily function for patients who took it compared to those who took a placebo or fake drug." Also reporting is Reuters (6/24, Maddipatla).

Pfizer Halts Distribution Of Varenicline After Finding Carcinogen

STAT (6/24, Silverman) reports, "After finding potential carcinogens in some lots of Chantix [varenicline], Pfizer late last month halted worldwide distribution of" its oral smoking cessation drug. The company, "which is now running tests, took this step after finding nitrosamine levels that were above an 'acceptable' daily intake," and "consequently, regulators in Canada and South Korea, for instance, have posted recall notices for the medicine." Update 7/2/21: The FDA alerted patients and health care professionals to Pfizer's voluntary recall of nine lots of varenicline, to the warehouse level. The FDA recommended Pfizer revise its recall to the consumer level in order to take into account the product currently on the market, but the company has not yet done so.

Open Forum

No items

Next Meeting Date

The next meeting is scheduled for October 15, 2021.

Adjourn

There being no further business, the meeting was adjourned at 1:55 p.m.

Approved: *David Moron*

David Moron, MD, Chairman

Minutes Prepared by:
Tonya Barrios, PhTR
Reviewed by:
Jean Baemayr, PharmD