PENNSYLVANIA DEPARTMENT OF HUMAN SERVICES
Pharmacy & Therapeutics Committee Recommendations
Tuesday, September 12, 2023
12:00 p.m. to 4:00 p.m.

Committee Members Present:

Ivonne Acrich, MD	Ad Hoc Child/Adolescent Psychiatrist
Dale Adair, MD, FAPA	Medical Director, Office of Mental Health & Substance Abuse Services
Christopher Antypas, PharmD	Community Pharmacist
Cheston Berlin Jr., MD	Pediatrician
Terri Cathers, PharmD, Chair	OMAP Pharmacy Director
Michael Colvin, PharmD	AmeriHealth Caritas & Keystone First HealthChoices & Community HealthChoices Pharmacist
Sharon Connor, PharmD	Academic Pharmacist
Molly DiMatteo, DO	Family Practitioner
Oluwatoyin Fadeyibi, PharmD, MPH	Community Behavioral Health Pharmacist
Andrea Fox, MD	Internist
Donald Gerhart, RPh	Community Pharmacist
James Hancovsky, RPh, MBA	United Healthcare Pharmacy Director
David Kelley, MD	OMAP Chief Medical Officer
Peter Kreckel, RPh	Community Pharmacist
Renee Licwinko, RPh	Gateway Health Plan Pharmacist
Meghan McNelly, PharmD	PA Health & Wellness Pharmacist
Michele Musheno, RPh, MS	Academic/Hospital Pharmacist
Geoffrey Neimark, MD	Community Care Behavioral Health Psychiatrist
Ian Paul, MD, Vice Chair	Pediatrician
Adam Raphael Rom, MD	Family Practitioner
Amy Saracino, MD	Ad Hoc Adult Psychiatrist, OMHSAS
Christopher Squillaro, DO	Magellan Behavioral Health of PA Medical Director
Kevin Szczecina, RPh	Geisinger Health Plan Pharmacist
Fallan Vaisberg, PharmD, RPh	Health Partners Plans Formulary Pharmacist
Andreas Wali, MD	Cardiologist
Verlyn Warrington, MD	Obesity Specialist
Lloyd Wertz	Consumer/Family Advocate
Lauren Zandier, PharmD	UPMC For You Pharmacist

Committee Members Not Present:

Lawrence Appel, MD, SFHM	Medical Director, Office of Long-Term Living
Tony Byler, MD	PerformCare Psychiatrist
Rosemary Keffer, MD	Ad Hoc Adult Psychiatrist
Mahmood Usman, MD	Beacon Health Psychiatrist

PENNSYLVANIA DEPARTMENT OF HUMAN SERVICES
Pharmacy & Therapeutics Committee Recommendations
Wednesday, September 13, 2023
9:00 a.m. to 4:00 p.m.

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Public Testimony Presented to the Committee:

Yusara Abidi, MD (Emmaus Medical, Inc.) – Endari
Diane Ammerman (Genentech) – Ocrevus
Valerie Barnes (Gilead Sciences, Inc.) – Sunlenca
Timothy Birner, PharmD, MBA (Alkermes) – Lybalvi
Jenna Bowen (Marinus) – Ztalmy
Sanjay Chandragiri, MD (Advanced Community Services Associates) – Vraylar
Erin Conley (Amgen) – Repatha
Ash Dave (Amgen) – Amjevita, Otezla, Tezspire
Belkys Dean (Janssen Scientific Affairs, LLC) – Invega Hafyera, Opsumit, Spravato, Symtuza
John Deason (Neurocrine Biosciences) – Ingrezza
Mariham Fahim (Abbott) – Freestyle Libre
Daniel Flores, PharmD, MSc (Amgen) – Neulasta Onpro, Xgeva
Robbie Graves (The Depression and Bipolar Support Alliance) – Antidepressants, Other
Amanda Haikalis (Medunik USA) – Pheburane, Siklos
Jim Hart (Pfizer) – Ibrance
Sunny Hirpara (AstraZeneca) – Fasenra
Cristina Kowalczyk (Novartis Pharmaceuticals) – Leqvio
Willis Lonzer, PhD (Horizon Therapeutics) – Ravicti
Margaret Martin (Intra-Cellular Therapies) – Caplyta
Michael Mazowiecki (UPMC Somerset Neurology) – Qulipta, Ubrelvy
Paul Miner (Ascendis Pharma) – Skytrofa
Alisa Nguyen (Azurity Pharmaceuticals) – Konvomep
Olawemimo “Mimo” Odebiyi, PharmD (Teva Pharmaceuticals) – Ajovy, Uzedy ER
Punit Patel (AbbVie) – Oriahnn, Rinvoq, Skyrizi
Christine Rauscher (Allegheny Health Network Allergy, Asthma, & Immunology) – Tezspire
Kartik Shenoy (Temple Lung Center) – Fasenra
Kimberly Simpson (United Therapeutics Corporation) – Tyvaso DPI
Roy Thomas (Dexcom, Inc.) – Dexcom
Kristi Totten (Azurity Pharmaceuticals) – Triptodur

Written Testimony Received by the Committee:

Amgen – Amjevita, Evenity, Lumakras, Neulasta Onpro, Otezla, Prolia, Repatha, Tezspire, Xgeva
Apellis Pharmaceuticals – Syfovre
AstraZeneca – Brilinta, Fasenra, Lokelma
Azurity Pharmaceuticals – Triptodur
Axsome Therapeutics – Auvelity ER
Biogen – Vumerity
Coherus Biosciences – Cimerli
Cortney Smith, PMHNP, CRNP (Centerville Clinics) – Auvelity
Duchesnay USA – Bonjesta
Emmaus Medical Inc. – Endari
Horizon Therapeutics – Ravicti
Intra-Cellular Therapies – Caplyta
Jennifer Malloy, CRNP (Temple Health Comprehensive HIV Program) – Symtuza
Latino Commission on AIDS/Hispanic Health Network – HIV/AIDS Antiretrovirals
Marinus – Ztalmy
Medunik USA – Pheburane, Siklos
MiniMed Distribution Corporation (a division of Medtronic Inc.) – Guardian CGM

National Hemophilia Foundation/Hemophilia Federation of America/Eastern & Western PA Bleeding Disorders Foundations – Antihemophilia Agents
Novartis Pharmaceuticals – Cosentyx, Kesimpta, Leqvio
Novo Nordisk – Ozempic
Sanofi – Altuviiio, Dupixent
UCB Pharma – Briviact, Nayzilam

Welcome and Introduction	Dr. Terri Cathers welcomed the Committee and the members introduced themselves.
Approval of September 2022 Minutes	The Committee voted in favor to approve the minutes from the September 2022 meeting without revision.
Drug Class Reviews, Public Testimony, Discussion, and Voting	The below attachment includes the P&T Committee's recommendations for preferred and non-preferred statuses for drugs and products in the Statewide Preferred Drug List (PDL) classes reviewed during the September 2023 meetings, including the addition of the Continuous Glucose Monitoring Products and Tubeless Insulin Delivery Devices classes to the PDL.  Penn Statewide PDL 2024 v1 with highlig **Significant points of discussion by drug class:** Antidepressants, Other – A motion was made to prefer all medications in the Antidepressants, Other class and require no prior authorization in this class. The Committee recognized the 24-hour prior authorization turnaround time and the availability of temporary supplies at the pharmacy to allow for the prior authorization process. Members discussed the benefits of prior authorization review and safety concerns associated with some drugs. The Committee questioned whether there is adequate clinical benefit associated with the newer antidepressants to warrant preferred status for all agents. Committee members highlighted the prices of the newer agents and the need for the drug manufacturers to address the rising costs. The motion to prefer all Antidepressants, Other did not pass. A second motion was made to approve the PDL recommendations as presented by Change Healthcare. This motion passed (1 opposed). Then the Committee voted to approve the proposed revisions to the prior authorization guidelines (1abstained). Antipsychotics – The Committee discussed the prior authorization process, specifically the requirement that MCOs must provide a prior authorization decision within 24 hours. Dr. Cathers confirmed that all prior authorization monitoring conducted by DHS indicates that the MCOs are responding to prior authorization requests within 24 hours of receipt. Some Committee members agreed that a response is provided within in 24 hours, but a helpful, more detailed response is sometimes needed. The Committee then discussed Lybalvi (olanzapine and samidorphan), which currently is non-preferred on the Statewide PDL. Studies have shown the addition of samidorphan to olanzapine reduced weight gain compared to olanzapine alone. The Committee discussed the place in therapy of Lybalvi and metabolic side effects. The Committee discussed whether Lybalvi is an option for patients stable on olanzapine but experiencing weight gain. Members considered whether there are better strategies and drugs to address metabolic side effects, such as metformin. A motion was ultimately made to approve the recommendations as presented. The motion passed (2 opposed, 1 abstained). Anxiolytics – The Committee unanimously approved the PDL recommendations. The Committee then discussed the proposed revisions to the prior authorization guidelines to add guidelines for benzodiazepines prescribed for beneficiaries under 21 years of age for anxiety. The Committee discussed use of benzodiazepines in children and adolescents and

	agreed that use for anxiety/agitation should be short term. The Committee recognized that medical literature also recommends acute use only. Psychiatrists on the Committee reported that benzodiazepine use in children should be very infrequent and last line, citing concerns about efficacy and risk. MCO representatives explained that they do receive prior authorization requests for benzodiazepines for children with the diagnosis of anxiety and explained that revisions to the prior authorization guidelines to address these situations would be helpful in reviewing these prior authorization requests. The Committee approved revisions to the guidelines for benzodiazepines for beneficiaries under the age of 21 to include a section for the treatment of symptoms of severe acute anxiety. The Committee recognized the importance of a comprehensive evaluation and prescribing by or in consultation with a psychiatrist given the safety concerns (1 abstained). Antiemetic/Antivertigo Agents – *Post Meeting Note:* Following the meeting, DHS clinicians identified significant cost savings associated with changing Cinvanti injection to non-preferred status and fosaprepitant injection to preferred status. Generic fosaprepitant injection is a more cost-effective alternative for the prevention of chemotherapy-induced nausea and vomiting. Therefore, the DHS pharmacy team advises amending the P&T Committee's recommendation and changing Cinvanti injection to non-preferred status and fosaprepitant injection to preferred status. Bone Density Regulators – *Post Meeting Note:* During the meeting, the Committee heard public testimony that Xgeva (denosumab) is now NCCN-recommended first line (over zoledronic acid) for bony metastases in several cancers. Following the meeting, Department clinicians confirmed this update. The guidelines for determination of medical necessity for Xgeva (denosumab) were subsequently revised to delete the requirement for first line use of zoledronic acid. Continuous Glucose Monitoring Products (CGM) – CGM was proposed as a new class to the Statewide PDL to standardize coverage and availability across Fee-for-Service and the MCOs and collect market share rebates on these products. The PDL recommendations and proposed prior authorization guidelines for CGMs were developed in consultation with two specialists from Allegheny Health Network (an endocrinologist and PharmD) with experience managing patients using these products. Dr. Poornima Rao is an endocrinologist at Allegheny Health Network's Center for Diabetes and Endocrine Health. Dr. Rachael Cardinal is clinical pharmacy specialist working in ambulatory care at Allegheny Health Network. Both Dr. Rao and Dr. Cardinal had no conflicts of interest to disclose. The goal of the proposed guidelines is to ensure that patients with diabetes can access these products. Preferred CGMs were proposed to require a clinical prior authorization. The specialists recommended an automated prior authorization based on history of diabetic medication and additional prior authorization guidelines. Dr. Hoover presented that DHS is committed to offering this technology uniformly to Medical Assistance beneficiaries to help support them in meeting their diabetes treatment goals and realize positive clinical outcomes down the road. Many payers limit CGM to patients receiving insulin. However, the specialists shared, "benefits of CGM in patients on basal insulin are established, but benefits for patients on non-insulin therapy have also been shown in several studies to not only decrease A1c, but also lead to fewer hypoglycemic events and lead to long-term lifestyle interventions." The specialists also shared that they've observed that when CGM is initiated in patients on non-insulin medications who are not at goal with their A1c, CGM has decreased the progression into needing insulin therapy and slowed progression of diabetes complications, which can decrease costs long-term. There was significant discussion by the P&T Committee regarding the proposed prior authorization guidelines. The Committee discussed using CGM in patients not receiving insulin and the recommendation to approve CGM based on use of any diabetes medication. Ultimately the Committee approved the guidelines with a revision to extend the duration of prior authorization approval from 6 months to 12 months– 2 members opposed (UHC, UPMC) and 1 abstained. *Post Meeting Note*: Following the meeting, DHS clinicians inquired with the MCOs regarding their system capabilities for automated approvals, as there seemed to be some concern over what type of approvals could be issued at the pharmacy

point of sale (POS). DHS confirmed that effective 1/1/24, the MCOs will be able to implement an automated approval at the POS based on a diagnosis of diabetes or a diabetes medication in claims history within the past 90 days. Therefore, the DHS pharmacy team and Dr. Kelley recommend revising the guidelines approved by the P&T Committee to allow for automated approvals for CGM based on a diabetes diagnosis or diabetes medication in claims history. This strategy is in the best interest of Medical Assistance beneficiaries and providers. Any claims that are not approved at the pharmacy POS would be submitted for a manual prior authorization review using the same prior authorization guidelines.

Growth Hormones – The Committee approved the PDL recommendations as presented and discussed the corresponding prior authorization guidelines. The Committee questioned the prior authorization guideline for non-preferred growth hormone products. The Committee discussed nuances with this class as most of the products contain the same active ingredient. The Committee discussed how to handle failure due to inability to appropriately use the device versus true therapeutic failure. The Committee recommended the DHS DUR Board review the prior authorization guidelines at their next meeting.

Hereditary Angioedema (HAE) Agents – During discussion of the prior authorization guidelines for HAE Agents, a committee member asked if the guideline should be revised to ensure beneficiaries are not taking an angiotensin receptor blocker (ARB). The Department posed this question to Dr. Timothy Craig, an allergist/immunologist affiliated with Penn State Milton S. Hershey Medical Center, with whom the Department has previously consulted for revision of the HAE Agents prior authorization guidelines. Dr. Craig responded that there is a small chance of edema with ARBs but not by affecting bradykinin like with ACE inhibitors. For that reason, ARBs are not contraindicated, and it should not be added to the prior authorization guidelines.

Hypoglycemia Treatments – The Committee confirmed the availability of Gvoke and recommended preferred status for all Gvoke products. Gvoke is indicated for children with diabetes ages 2 years and above.

Hypoglycemics, Incretin Mimetics/Enhancers – The P&T Committee had a robust discussion regarding this class, specifically the use of GLP-1 agonists (like Ozempic) for obesity. Change Healthcare proposed preferred status for Ozempic with no prior authorization requirement. Preferring Ozempic would allow DHS to take advantage of a supplemental rebate offer. Ozempic is currently non-preferred, and despite the non-preferred status, it still has high utilization in the MA program (more than 3,000 Rxs/quarter). In addition, Ozempic is the most cost-effective GLP-1 agonist commonly used in the treatment of obesity; however, this use is off-label. The same active ingredient is marketed under the brand name Wegovy, which is double the cost of Ozempic. DHS clinicians supported this recommendation recognizing that if Ozempic is available without a prior authorization, prescribers will shift to Ozempic for patients with obesity to avoid a prior authorization requirement, and patients with diabetes will have open access to it.

Some MCO representatives raised concern regarding open access for Ozempic. Several physicians on the Committee advocated for improved access. The UHC representative made a motion to prior authorize all preferred agents in this class including Ozempic. This motion was seconded by the UPMC representative. The motion did not pass – only 3 Committee members voted in favor of the motion.

A second motion was made by the HPP representative to prefer Ozempic but require prior authorization, with an automated approval based on diagnosis of diabetes or diabetes medication in claims history. This motion was seconded by the Vista representative. Change Healthcare alerted the Committee that if prior authorization is imposed on Ozempic, even with preferred status, the supplemental rebate is not available. This motion passed, although the votes reflect that many on the Committee did not support the proposal – 12 in favor, 3 opposed, 7 abstained. Following the vote, Dr. Cathers informed the Committee that the revised guidelines would be sent to the Committee after the meeting due to the significant revisions they proposed, and the guidelines would be available for public comment via the MAAC process.

Post Meeting Note: The DHS Pharmacy team and Dr. Kelley still believe preferred status for Ozempic with open access is in the best interest of beneficiaries, providers, and the Department. Preferring Ozempic and allowing use for obesity is fiscally responsible. Ozempic is the most cost-effective GLP-1 agonist commonly used for the treatment of obesity. DHS can also take advantage of the supplemental rebate on the significant utilization of Ozempic that already exists. We believe open access for a widely used diabetes medication that is also a cost-effective treatment for obesity makes clinical and fiscal sense and recommend preferred status for Ozempic without a prior authorization requirement.

Monoclonal Antibodies (MABs) – Anti-IL, Anti-IgE, Anti-TSLP – The Committee recognized the need to maintain preferred status of Xolair syringe, in addition to the vial, to support self-administration by beneficiaries.

Multiple Sclerosis Agents – Dr. Cathers relayed feedback from a multiple sclerosis (MS) specialist, Dr. Dina Jacobs, regarding the benefits of Ocrevus. Dr. Jacobs is the Clinical Director at the University of Pennsylvania (UPenn) Multiple Sclerosis and Related Disorders Center. Dr. Jacobs reported that Ocrevus is the only drug approved for primary progressive MS, and the team of physicians at UPenn have found it to be highly effective when used around pregnancy to get the MS in remission and keep things calm during the pregnancy. She shared that in the postpartum period, Ocrevus is safe during breastfeeding. When asked about the alternative treatment Kesimpta, Dr. Jacobs said that it is a very good drug but doesn't have the long half-life that they find optimal for the women she treats. Dr. Jacobs also reported that it is very difficult to get approval of Ocrevus through the MCOs as a NPD agent because of the requirement for trial and failure of preferred MS agents. She disclosed that she has consulted with Genentech where she gave talks on women's issues in MS. She is involved in clinical research trials. All research money goes to the institution, not her.

Change Healthcare presented a recommendation to move Kesimpta from non-preferred to preferred status. The Committee unanimously voted to recommend preferred status for both Ocrevus and Kesimpta.

Prior authorization guidelines reviewed and approved by the P&T Committee are listed below. These guidelines are available on the MAAC listserv for the September 28, 2023, meeting for public comment:

- Antibiotics, GI and Related Agents
- Antidepressants, Other
- Antihemophilia Agents
- Antipsychotics
- Antivirals, CMV
- Anxiolytics
- Bone Density Regulators
- Continuous Glucose Monitoring Products
- Cytokine and CAM Antagonists
- Dupixent (dupilumab)
- Hepatitis C Agents
- Hereditary Angioedema (HAE) Agents
- Hypoglycemics, Incretin Mimetics/Enhancers
- Immunomodulators, Atopic Dermatitis
- Lipotropics, Other
- Macular Degeneration Agents
- Migraine Prevention Agents
- Obesity Treatment Agents
- Sedative Hypnotics
- Tubeless Insulin Delivery Devices

Meeting Adjourned	Dr. Cathers thanked the Committee for their participation and adjourned the meeting at 2:06pm.