PENNSYLVANIA DEPARTMENT OF HUMAN SERVICES
Pharmacy & Therapeutics Committee Recommendations
Friday, June 21, 2019
10:00 a.m. to 4:00 p.m.

Committee Members Present:

Ivonne Acrich, MD	Ad Hoc Child/Adolescent Psychiatrist
Christopher Antypas, PharmD	Community Pharmacist
Lawrence Appel, MD, SFHM	Medical Director, Office of Long-Term Living
Cheston Berlin, Jr., MD	Pediatrician
Christopher Casella, PharmD	Health Partners of Philadelphia Pharmacist
Terri Cathers, PharmD, Chair	OMAP Pharmacy Director
Sharon Connor, PharmD	Academic Pharmacist
Jessica Daw, PharmD	UPMC For You Pharmacist
Donald Gerhart, RPh	Community Pharmacist
James Hancovsky, RPh, MBA	United Health Care Pharmacy Director
Rosemary Keffer, MD	Ad Hoc Adult Psychiatrist
David Kelley, MD	OMAP Chief Medical Officer
Peter Kreckel, RPh	Community Pharmacist
Andrew Maiorini, PharmD	Keystone/AmeriHealth PerformRx Pharmacist
Perry Meadows, MD	Medical Director, Geisinger Health Plan (delegate for Kevin Szczecina, RPh)
Meghan McNelly, PharmD	Pennsylvania Health and Wellness Pharmacist
Michele Musheno, RPh, MS	Academic/Hospital Pharmacist
Natalie Nkurunziza, PharmD	Aetna Pharmacist
Amy Saracino, DO	Ad Hoc Adult Psychiatrist, OMHSAS
Mahmood Usman, MD, MMM	Medical Director, Office of Mental Health & Substance Abuse Services
Lloyd Wertz	Consumer/Family Advocate
Eric Yarnell, RPh, MPH	Vice President of Pharmacy, Gateway Health Plan (delegate for Jaymie Lako, PharmD)

Committee Members Not Present:

Andrea Fox, MD	Internist
David Haverstick, MD	Family Practitioner
Jaymie Lako, PharmD	Gateway Health Plan Pharmacist
Ian Paul, MD	Pediatrician
Adam Raphael Rom, MD	Family Practitioner
Kevin Szczecina, RPh	Geisinger Health Plan Pharmacist
Andreas Wali, MD	Cardiologist

Public Testimony Heard by the Committee:

Juan Avila (UCB) – Cimzia
Elizabeth Beil (Epilepsy Foundation Eastern PA) – Treatment options for epilepsy
Edward Casey (Pfizer, Inc.) – Eliquis, Genotropin, Xeljanz
Erin Crown (Oasis LifeCare, LLC) – Long-Acting Injection Antipsychotics
Aaron Dershak (Actelion Pharmaceuticals, Ltd.) – Opsupmit, Uptravi
Christine Dube (AstraZeneca) – Bydureon BCISE, Farxiga, Lokelma
Stephanie Dehoux (Tris Pharma, Inc.) – Dyanavel XR
Kelly Hollenack (Greenwich Biosciences) – Epidiolex
Keith Huff (Bristol-Myers Squibb) – Orencia
Scott Kern (Eli Lilly and Company) – Taltz
Russell Knoth (Eisai) – Fycompa
Melissa Legin (Novo Nordisk) – Ozempic, Tresiba
Rhonda Lemmo (Trividia Health) – True Metrix Air Glucose Meter
TinaMarie Lieu (UCB Pharmaceuticals, Inc.) – Briviact, Vimpat
Yvonne Luu (Amgen) – Enbrel
Ingrid Ma (Sunovian Pharmaceuticals, Inc.) – Aptiom, Latuda
Domenic Mantella (Novartis) – Mayzent
Shannon Mendes (Supernus) – Oxtellar XR
Deborah Mentzer (Wellspan Philhaven) – Brand Antipsychotics
Deb Neustadter – Antihemophilia Agents
Valerie Ng (Indivior) – Sublocade
Jinesh Patel (Aerie Pharmaceuticals) – Rocklatan
Rachel Peacock (Sanofi) – Admelog
Marty Porter (Horizon) – Ravicti
Faisal Riaz (Takeda) – Adynovate
Ted Riley (GlaxoSmithKline) – Anoro Ellipta, Breo Ellipta, Trelegy Ellipta
Zack Spurlin (Abbvie) – Orilissa
Janet Traynor (Sobi) – Kineret
Jawad Wunej (Janssen Scientific Affairs) – Spravato
Matthew Zimmerman (Merck) – Segluromet, Steglatro

Welcome and Introduction	Dr. Terri Cathers welcomed the Committee and the members introduced themselves.
Approval of May 2019 Minutes	The Committee unanimously approved the minutes from the May 2019 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 drugs within the drug classes reviewed during the June 2019 meeting. Significant points of discussion by drug class: • **Anticoagulants** – The Committee discussed the clinical merits and associated costs of the novel oral anticoagulants. A motion was made to make Eliquis (apixaban) non-preferred. The Committee discussed the safety, efficacy, and cost of Eliquis in comparison to similar agents. Ultimately the motion to make Eliquis non-preferred did not pass. The Committee voted to approve the PDL statues as recommended (including Eliquis as preferred). • **Antidepressants, Other** – The Committee discussed the place in therapy and availability of safety and efficacy data for Spravato (esketamine) for the treatment of treatment-resistant depression. The Committee recommended that the Department's Drug Utilization Review (DUR) Board review and develop guidelines specific to Spravato. • **Antihemophilia Agents** – The Committee reviewed Antihemophilia Agents and the corresponding prior authorization guidelines. The Committee discussed the role of prophylactic treatment and the place in therapy of Hemlibra. The Department consulted with several hemophilia specialists and their input was shared with the Committee. Dr. Jacquelyn Hedlund, a hematologist with Change Healthcare, was also in attendance and shared her experience with these agents. The Committee recommended revisions to the proposed prior authorization guidelines. • **Antipsychotics** – The Committee discussed olanzapine and the associated adverse effects. Providers shared that the medical community is aware of the metabolic effects of olanzapine and felt that prior authorization is not needed. A motion was made to prefer olanzapine, and this motion passed unanimously. The Committee also discussed the role of Latuda (lurasidone) and its use in clinical practice. A motion was made to prefer Latuda. This motion did not pass. • **Oncology Agents, Oral** – The Committee voted unanimously in favor of the proposed recommendations that included non-preferred status for Tykerb (lapatinib) and Vizimpro (dacomitinib). **Post Meeting Note:** Department staff confirmed that Tykerb is a preferred treatment option for a specific type of recurrent or stage IV breast cancer and Vizimpro is a first-line treatment for a specific type of metastatic non-small cell lung cancer; therefore, Department staff recommend Tykerb and Vizimpro be statused as preferred. Prior authorization applies to all Oncology Agents, Oral to ensure appropriate utilization. • **Opiate Dependence Treatments** – The Committee reviewed the oral buprenorphine/naloxone combination formulations in the class. The proposed recommendations included preferred status for the brand Suboxone film, generic buprenorphine/naloxone tablet, and buprenorphine-naloxone film (Alvogen labeler only), clonidine tablets, naltrexone tablets, and Vivitrol injection. The Committee discussed the role of Sublocade (buprenorphine extended-release injection). Department staff reported that Sublocade requires prior authorization but, despite its non-preferred status, trial and failure of an oral buprenorphine agent or other preferred product is not required.

	The prior authorization guidelines that apply to Sublocade are intended to verify appropriate prescribing based on package labeling. The Committee discussed the Department of Corrections' pilot program for parole violators to receive Sublocade before release back into the community. However, the FDA has required a REMS (risk evaluation and mitigation strategy) program to ensure all providers that dispense Sublocade are certified in the REMS program, Sublocade must be obtained through a restricted distribution program, and it is never dispensed directly to a patient. A motion was made and seconded to prefer Sublocade. The Committee voted 7 in favor and 13 opposed. Sublocade was recommended as non-preferred. A community pharmacy representative expressed potential operational issues with preferring only Alvogen's generic film product because not all wholesalers carry all manufacturers' generic products. A motion was made and seconded to prefer brand Suboxone film, generic buprenorphine/naloxone tablets, and the other proposed non-buprenorphine agents. The vote resulted in a tie of 9 in favor and 9 opposed. The members that opposed the vote said they thought that Alvogen's generic film should be preferred for the pharmacies that are able to stock it. The tie-breaking Chair voted in opposition to the motion, resulting in the recommendation of preferred status for brand Suboxone film, generic buprenorphine/naloxone tablet, and buprenorphine-naloxone film (Alvogen labeler only), clonidine tablets, naltrexone tablets, and Vivitrol injection. **Post Meeting Note**: Lloyd Wertz, Consumer Advocate P&T Committee member, announced at the June 27th MAAC meeting that he is concerned about the non-preferred recommendation for Sublocade because of the Department of Corrections Sublocade pilot program. There is low utilization of Sublocade, mainly because of the restricted dispensing and limited distribution. Department staff recommended Sublocade be statused as preferred to take advantage of the supplemental rebate paid by the manufacturer whenever FFS or the MCOs pay claims for Sublocade. On March 6, 2020, Governor Tom Wolf issued a public health emergency declaration in response to the presence of COVID-19 in Pennsylvania. In order to mitigate the spread of COVID-19 and follow the governor's stay-at-home orders, the Department implemented several changes to pharmacy services for MA beneficiaries. One of these changes included Sublocade. The prior authorization guidelines for Opioid Dependence Treatments were revised to indicate that prescriptions for Sublocade injection that do not exceed the quantity limit no longer require prior authorization. • **Pituitary Suppressive Agents, LHRH** – The Committee reviewed the Pituitary Suppressive Agents, LHRH class and discussed the role of Orilissa (elagolix oral tablet) for the treatment of endometriosis in comparison to injectable agents in this class. The Committee recommended that the Department's DUR Board evaluate Orilissa and recommend prior authorization guidelines. • **Stimulants and Related Agents** – The Committee discussed the need for liquid/chewable formulations for pediatric beneficiaries. A motion was made prefer Quillivant XR suspension (methylphenidate) and Quillichew ER chewable tablet (methylphenidate). This motion passed. Prior authorization guidelines reviewed and approved by the P&T Committee are listed below. These guidelines are available on the MAAC listserv for the June 27th meeting for public comment: • Anticoagulants • Antihemophilia Agents • Antihyperuricemics • Estrogens • GI Motility, Chronic Agents

	• Hypoglycemics, Meglitinides • Intranasal Rhinitis Agents • Iron Chelating Agents • Multiple Sclerosis Agents • Oncology Agents, Breast Cancer • Ophthalmic Anti-Inflammatories • Potassium Removing Agents • Stimulants and Related Agents • Urea Cycle Disorder Agents
Meeting Adjourned	Dr. Cathers thanked the Committee for their participation and adjourned the meeting.