PENNSYLVANIA DEPARTMENT OF HUMAN SERVICES
Pharmacy & Therapeutics Committee Recommendations
Wednesday, May 15, 2019
10:30 a.m. to 4:00 p.m.

Committee Members Present:

Christopher Antypas, PharmD	Community Pharmacist
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
Andrea Fox, MD	Internist
Donald Gerhart, RPh	Community Pharmacist
David Haverstick, MD	Family Practitioner
David Kelley, MD	OMAP Chief Medical Officer
Peter Kreckel, RPh	Community Pharmacist
Jaymie Lako, PharmD	Gateway Health Plan Pharmacist
Andrew Maiorini, PharmD	Keystone/AmeriHealth PerformRx Pharmacist
Meghan McNelly, PharmD	Pennsylvania Health and Wellness Pharmacist
Michele Musheno, RPh, MS	Academic/Hospital Pharmacist
Natalie Nkurunziza, PharmD	Aetna Pharmacist
Ian Paul, MD	Pediatrician
Adam Raphael Rom, MD	Family Practitioner
Kevin Szczecina, RPh	Geisinger Health Plan Pharmacist
Mahmood Usman, MD, MMM	Medical Director, Office of Mental Health & Substance Abuse Services
Michael Verba, RPh	United Healthcare Pharmacist (delegate for James Hancovsky, RPh, MBA)
Andreas Wali, MD	Cardiologist
Lloyd Wertz	Consumer/Family Advocate

Committee Members Not Present:

Ivonne Acrich, MD	Ad Hoc Child/Adolescent Psychiatrist
Lawrence Appel, MD, SFHM	Medical Director, Office of Long-Term Living
James Hancovsky, RPh, MBA	United Health Care Pharmacy Director
Rosemary Keffer, MD	Ad Hoc Adult Psychiatrist

Public Testimony Heard by the Committee:

Paul Amato (ViiV Healthcare) – Dovato
Christine Cazeau (Pierre Fabre) – Hemangeol
Maria Cho (AstraZeneca) – Fasenra
Jessica Freyer Most (Jane & Leonard Korman Respiratory Institute) – Fasenra
Daniel Flores (Amgen, Inc.) – Aimovig
Timothy Horwedel (Veloxis Pharmaceuticals) – Envarsus XR
Patricia Jacob (Allergan) – Botox
Fawad Malik (Teva Pharmaceuticals) – Ajovy
Domenic Mantella (Novartis Pharmaceuticals) – Entresto
Arlene Price (Janssen Pharmaceuticals) – Symtuza
Matthew Zimmerman (Merck) – Pifeltro
Natalie Wheeler (Dova Pharmaceuticals) – Doptelet

Welcome and Introduction	Dr. Terri Cathers welcomed the Committee and the members introduced themselves.
Approval of November 2018 Minutes	The Committee unanimously approved the minutes from the November 2018 meeting without revision.
Statewide Preferred Drug List (PDL) Introduction	Dr. Cathers announced the following: • The Department of Human Services (DHS) is implementing a Statewide Preferred Drug List (PDL) on January 1, 2020. The Statewide PDL will be utilized by the Fee-for-Service program and all MA Managed Care Organizations (MCOs), including both Physical Health HealthChoices MCOs and Community HealthChoices MCOs. Currently each MCO is permitted to establish its own formulary or PDL, and the Fee-for-Service (FFS) program has a preferred drug list (PDL). • Nearly 20 other states have already successfully implemented Unified or Statewide PDLs. • A Statewide PDL will: o Simplify prescribers' reference to one PDL and one set of prior authorization requirements rather than 8 different PDLs and prior authorization guidelines. o Provide consistency in coverage of drugs for Medicaid beneficiaries, so moving from one MCO to another or from FFS to an MCO will not result in a disruption in drug therapy. o Support transparency. o Generate annualized net savings of $118 million total; $43 million state funds beginning in FY 20-21. Savings is expected through net cost evaluations of the drugs on the PDL from both DHS and MCO perspectives. The state is looking to lower its overall net expenditures for pharmaceuticals. Every PDL decision will take into account not only rebates collected by the state but also the impact on reimbursement costs to providers. Only

	when the rebates available to the state significantly exceed the impact on provider reimbursement will higher gross cost products be preferred over lower gross cost options. o Reduce uncertainty for DHS if the federal Safe Harbor Proposed Rule is passed and the Medicaid MCOs are no longer able to collect market share rebates. • The Safe Harbor Proposed Rule, released by CMS on February 6, 2019: o Is based on President Trump's Blueprint to Lower Drug Prices that was published in May 2018. o Is intended to eliminate drug rebates for Medicaid MCOs, Medicare Part D, and their PBMs. CMS hopes that this will result in lower drug prices from manufacturers and lower out-of-pocket expenses for consumers at the pharmacy counter. o Is proposed to be implemented 60 days following the effective date of the rule, currently proposed to be January 1, 2020. o Will result in no change to the federal Medicaid rebate collected by states. States can continue to contract with manufacturers and collect supplemental rebates for drugs included on a PDL. o Will likely increase Medicaid MCO Capitation rates in states without Statewide PDLs to offset Medicaid MCO/PBM lost rebates. • The DHS P&T Committee will develop the Statewide PDL. • The P&T Committee meeting format will remain the same. A few noteworthy differences include: o Combined FFS and MCO utilization will be considered by the Committee. o The proposed PDL status of the products in each class will consider both the net cost to DHS and the potential increased cost to the MCOs in the "paid per Rx" column of the cost sheets for each drug class provided to Committee members at each meeting. o Where new or revised prior authorization guidelines are required to support the Statewide PDL, the Committee will review, discuss, and vote on whether to adopt or revise the guidelines proposed by DHS. These prior authorization guidelines will be presented at a future Medical Assistance Advisory Committee (MAAC) meeting for review and public comment. o The semi-annual meeting schedule will change. The Committee will continue to review the entire Statewide PDL annually. Two options for future meeting schedules include: (1) a single full-day meeting in September and a second full-day meeting in October; or (2) two consecutive-day meetings in either September or October (depending on location availability). Committee members will weigh in with their preference, and the decision will be posted on the DHS P&T Committee webpage. • MCOs will be required to utilize the FFS prior authorization guidelines to determine medical necessity of drugs and classes included in the Statewide PDL. • MCOs will continue to maintain full responsibility for providing access to covered outpatient drug services. The MCOs and FFS will: o Publish the Statewide PDL on their websites and include information on how to request a prior authorization.

	○ Notify Medicaid beneficiaries and providers of any changes in coverage for drugs. ○ Receive and review prior authorization requests and determine medical necessity. ○ Follow the current process for appeals and grievances.
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 May 2019 meeting. Significant points of discussion by drug class: • Long-Acting Opioids – The Committee discussed the role of tramadol ER. Gateway reported provider requests for this product; however, other Committee members reported they have not seen utilization in their populations. The Committee ultimately voted for non-preferred status for tramadol ER. • Angiotensin Modulators – The Committee discussed the prior authorization guidelines for Entresto as well as its place in therapy. Several MCOs reported that they recently removed prior authorization requirements for Entresto. Dr. Wali, a P&T Committee member and cardiologist, conveyed to the Committee that he prefers to use Entresto over an ACE inhibitor or ARB for most of his patients with heart failure. The Committee voted to remove the prior authorization requirement for Entresto. Entresto remains preferred on the PDL. • Antibiotics, Inhaled – The Committee discussed the recommendation to prefer generic inhaled tobramycin (generic Tobi) products only from specific manufacturers. Community pharmacy representatives reported that pharmacy wholesalers often only offer products from a few generic manufacturers and that access may be an issue if only certain generic tobramycin products are designated as preferred. The Committee voted to accept the recommendations as presented with the caveat that DHS will address if access issues arise. Following the meeting, DHS staff confirmed that community pharmacies may not be able to obtain the products voted as preferred and recommends that all generic tobramycin products (generic Tobi) be designated as preferred. • Antivirals, Influenza – The Committee discussed the role of Xofluza and the corresponding prior authorization guidelines. The Committee recommended that 5-day supplies of this medication should not be permitted. Xofluza is a single-dose product that is indicated for treatment of uncomplicated flu. The Committee did not consider the need for Xofluza to be emergent and recognized that the 5-day supply could be used inappropriately to bypass the prior authorization process. • Beta Blockers – The Committee discussed the availability of Hemangeol for infant patients. The Committee recommended preferred status for Hemangeol and referral to DUR Board for development of prior authorization guidelines. • Enzyme Replacements, Gaucher Disease – The Committee reviewed the proposed revisions to the prior authorization guidelines and discussed the potential need for additional guidelines regarding confirmation of diagnosis and specialist involvement with prescribing. The Committee recommended the DUR Board review the guidelines and recommend additions. Prior authorization guidelines reviewed and approved by the P&T Committee are listed below. These guidelines will be available on the MAAC listserv for the May 23rd meeting for public comment: • Acne Agents, Oral • Antimalarials

	• Antimigraine Agents, Other • Antivirals, CMV • Antivirals, Herpes • Antivirals, Influenza • Bone Density Regulators • HIV/AIDS Antiretrovirals • Local Anesthetics, Topical • Penicillins • Thalidomide and Derivatives • Vitamin D Analogs
Meeting Adjourned	Dr. Cathers thanked the Committee for their participation and adjourned the meeting.