

PENNSYLVANIA DEPARTMENT OF HUMAN SERVICES
Pharmacy & Therapeutics Committee Recommendations
Tuesday, September 14, 2021
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
Sharon Connor, PharmD	Academic Pharmacist
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 Haverstick, MD	Family Practitioner
Rosemary Keffer, MD	Ad Hoc Adult Psychiatrist
David Kelley, MD	OMAP Chief Medical Officer
Peter Kreckel, RPh	Community Pharmacist
Renee Licwinko, RPh	Gateway Health Plan Pharmacist
Andrew Maiorini, PharmD	Keystone/AmeriHealth Perform Rx Clinical Pharmacist
Meghan McNelly, PharmD	PA Health & Wellness Pharmacist
Michele Musheno, RPh, MS	Academic/Hospital Pharmacist
Geoffrey Neimark, MD	Community Care Behavioral Health Psychiatrist
Natalie Nkurunziza, PharmD	Aetna Better Health Pharmacist
Kateryna Olchowecky, PharmD	Health Partners of Philadelphia Clinical Programs Pharmacist (delegate for Hannah Livengood, PharmD)
Louis Parrott Jr., MD, PhD	Magellan Healthcare Psychiatrist
Ian Paul, MD	Pediatrician
Adam Raphael Rom, MD	Family Practitioner
Amy Saracino, MD	Ad Hoc Adult Psychiatrist, OMHSAS
Kevin Szczecina, RPh	Geisinger Health Plan Pharmacist
Mahmood Usman, MD, MMM	Medical Director, Office of Mental Health & Substance Abuse Services
Andreas Wali, MD	Cardiologist
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
Hannah Livengood, PharmD	Health Partners of Philadelphia Pharmacist

PENNSYLVANIA DEPARTMENT OF HUMAN SERVICES
Pharmacy & Therapeutics Committee Recommendations
Wednesday, September 15, 2021
9:00 a.m. to 3:00 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
Sharon Connor, PharmD	Academic Pharmacist
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 Haverstick, MD	Family Practitioner
Rosemary Keffer, MD	Ad Hoc Adult Psychiatrist
David Kelley, MD	OMAP Chief Medical Officer
Peter Kreckel, RPh	Community Pharmacist
Renee Licwinko, RPh	Gateway Health Plan Pharmacist
Andrew Maiorini, PharmD	Keystone/AmeriHealth Perform Rx Clinical Pharmacist
Meghan McNelly, PharmD	PA Health & Wellness Pharmacist
Michele Musheno, RPh, MS	Academic/Hospital Pharmacist
Geoffrey Neimark, MD	Community Care Behavioral Health Psychiatrist
Natalie Nkurunziza, PharmD	Aetna Better Health Pharmacist
Kateryna Olchowecky, PharmD	Health Partners of Philadelphia Clinical Programs Pharmacist (delegate for Hannah Livengood, PharmD)
Louis Parrott Jr., MD, PhD	Magellan Healthcare Psychiatrist
Ian Paul, MD	Pediatrician
Adam Raphael Rom, MD	Family Practitioner
Amy Saracino, MD	Ad Hoc Adult Psychiatrist, OMHSAS
Kevin Szczecina, RPh	Geisinger Health Plan Pharmacist
Mahmood Usman, MD, MMM	Medical Director, Office of Mental Health & Substance Abuse Services
Andreas Wali, MD	Cardiologist
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
Hannah Livengood, PharmD	Health Partners of Philadelphia Pharmacist

Public Testimony Presented to the Committee:

Ann Wicker (Pfizer) – Orgovyx
Archie Stone (Aurinia Pharmaceuticals Inc.) – Lupkynis
Bob James (US WorldMeds) – Lucemyra
Cheri Perron (Lupus Foundation of America, Philadelphia Tri-State Chapter) – Lupkynis
Jaimee Reiley (Pfizer) – Myfembree
Jim Dowdle (United Therapeutics Corporation) – Tyvaso
Joseph Cirrincione (Otsuka) – Abilify Maintena
Kris Washington (Vertice Pharma) – Thyquidity
Kristina Rosa Bolling (Bayer) – Jivi
Margaret Olmon (Allergan) – Linzess, Rinvoq ER, Skyrizi, Ubrely, Vraylar
Niki Hwang (Bristol-Myers Squibb) – Zeposia
Patrick Harvey (Supernus Pharmaceuticals) – Qelbree ER
Paul Isikwe (Teva) – AirDuo Digihaler, Ajoy, ArmonAir Digihaler
Philip Moore (Gaudenzia, Inc.) – Lucemyra
Rene Vasquez (Kala Pharmaceuticals) – Eysuvis
Santreis Booze (Global Blood Therapeutics) – Oxbryta
Stephen Silberstein (Jefferson Headache Center) – Migraine Prevention Agents
Vilasini Shetty (Pfizer Oncology) – Braftovi, Mektovi

Written Testimony Received by the Committee:

AbbVie – Creon, Humira, Linzess, Mavyret, Oriahnn, Orilissa, Rinvoq, Skyrizi, Vraylar
Abdallah Geara, MD (Penn Medicine) – Lupkynis
Alcinto Steven Guirand, MD (Conemaugh Physician Group) – Ajoy
Aleksandr Mikhaylovskiy, MD (South Hills Pain and Rehab Association) – Ajoy
Alkermes – Aristada, Vivitrol
Allergan – Botox, Ubrely
Alvin Kingcade, PA-C, MS (Bebashi – Transition to Hope) – Symtuza
Amgen – Aimovig, Enbrel, Lumakras, Neulasta Onpro, Otezla, Repatha
Amy Jean, MD (UPMC Children’s Hospital of Pittsburgh) – Gvoke
AstraZeneca – Breztri Aerosphere, Brilinta, Fasenra, Lokelma
Aurinia – Lupkynis
Baxter Drew Wellmon, II, DO (Wellmon Medical Associates) – Ajoy
Beth Sylvester, MSN, CRNP (Thomas Jefferson University) – Lupkynis
Bethany Robine (UPMC Neurology) – Ajoy
Bristol Myers Squibb – Eliquis, Zeposia
Cynthia Matossian, MD, FACS (Matossian Eye Associates) – Eysuvis
Daniel Norden, MD, FACR, FACP (Einstein Montgomery Medical Center) – Lupkynis
David Lee Scher, MD, FACP, FACC, FHRS, FESC (Pennsylvania State University College of Medicine) – Ajoy
David Tabby, DO (Optimum Neurology) – Nurtec ODT
Eastern and Western PA Bleeding Disorders Foundations – Antihemophilia Agents
Edara Anusha, MD (Conemaugh Health System) – Ajoy
Elizabeth Kline, CRNP (Conemaugh Memorial Medical Center) – Ajoy
Elliot Michel, MD (Valley Neurology) – Nurtec ODT
Epilepsy Association of Western and Central Pennsylvania – Anticonvulsants
Gina Simoncini, MD, MPH, FACP (AIDS Healthcare Foundation) – Symtuza
Gary Gordon, MD, FACP, FACR (Main Line Rheumatology and Osteoporosis) – Lupkynis

Genentech – Ocrevus
Global Blood Therapeutics – Oxbryta
Greenwich Biosciences – Epidiolex
Hep Free PA Coalition – Hepatitis C Agents
Hepatitis C Allies of Philadelphia – Hepatitis C Agents
Hikma Specialty – Kloxxado
Hutton Healthcare – Opioid Dependence Treatments
Indivior – Perseris, Sublocade
Ironshore Pharma – Jornay PM
James Deom, OD (The Scleral Lens Institute) – Eysuvis
James Iannazzi, MD (Indiana Regional Medical Center) – Ajovy
Janssen – Invega Sustenna, Invega Trinza, Opsumit, Ponvory, Spravato, Symtuza, Upravi
Jason Ignatius, DO (Penn Highlands Healthcare) – Ajovy
Jessica Grover, PA-C (Guthrie Medical Group) – Ajovy
Jennifer Kwan-Morley, MD (Paoli Hospital) – Lupkynis
Joel Lebed, DO, FACOG, FACOOG (Planned Parenthood Southeastern Pennsylvania) – Annovera
John Chawluk, MD, FAAN (Lehigh Valley Hospital) – Ajovy
Joseph Clark, MD (UPMC Altoona and Penn Highlands Tyrone) – Ajovy
Kala Pharmaceuticals – Eysuvis
Kaleigh Fairman, PA-C (Punxsutawney Physician Group Neurology) – Ajovy
Karam Mounzer, MD (Jonathan Lax Treatment Center) – Symtuza
Lifescan – OneTouch
Lupus Foundation of America – Lupkynis
Maggie Jalowsky (Sick Cells) – Adakveo, Endari, Oxbryta
Marianne Santioni, DO (Santioni Rheumatology) – Lupkynis
Mary Grace Murphy, PA-C (Blair Medical Associates) – Ajovy
Merck – Delstrigo, Pifeltro
Michael Sauter, MD (Indiana Regional Medical Center) – Ajovy
Mihaela Pendor, FNP (New Directions Treatment Services) – Hepatitis C Agents
Myovant Sciences – Myfembree, Orgovyx
Nancy Marcus Newman, Esq., CRS, CFRS (Resident of Newtown Square) – Lucemyra
Nathan Petula, PA-C (Wellmon Medical Associates) – Ajovy
National Multiple Sclerosis Society – Multiple Sclerosis Agents
Neurelis – Valtoco
Neurocrine Biosciences – Ingrezza
Novartis – Cosentyx, Entresto, Kesimpta, Xiidra
Novo Nordisk – Esperoct, Norditropin FlexPro, Novoeight, Novoseven RT, Rebinyn
Oksana Palatna, DO (Penn Highlands Healthcare) – Ajovy
Pamela Lorditch, CRNP (Conemaugh Health System) – Ajovy
Pfizer – Benefix, Bosulif, Braftovi, Eucrisa, Ibrance, Inlyta, Lorbrena, Mektovi, Nivestym, Nyvepria, Retacrit, Talzenna, Xalkori, Xeljanz, Xeljanz XR, Xtandi, Xyntha
Rachael Lamkin-Weaver, PA-C (Blair Medical Neurology) – Ajovy
Shenggao Han, MD, MPH, FACP (CareSalus Primary Care) – Ajovy
Stacey Trooskin, MD, PhD, MPH (Philadelphia FIGHT) – Hepatitis C Agents
Sunovion Pharmaceuticals – Aptiom, Kynmobi, Latuda
Supernus Pharmaceuticals – Qelbree ER
Takeda – Advate, Adynovate, Vonvendi

Tamara Appalsammy, PharmD, AAHIVP (AHF Pharmacy, Philadelphia) – Symtuza
 Taylor Keen, PA-C (Carlisle Neurocare) – Ajovy
 Teva – AirDuo Digihaler, Ajovy, ArmonAir Digihaler, Austedo, Cinqair, Granix
 TherapeuticsMD – Annovera
 Tolmar Pharmaceuticals – Fensolvi
 Travis Rudge, PA-C (Conemaugh Health System) – Ajovy
 UCB Pharma – Briviact, Nayzilam, Vimpat
 Upsher-Smith Laboratories – Tosymra
 US Worldmeds – Lucemyra
 Vertice Pharma – Thyquidity
 Vitaliy Koss, MD, FAHS (Lehigh Valley Health Network) – Nurtec ODT
 Zealand Pharma – Zegalogue
 Zogenix – Fintepla

Welcome and Introduction	Dr. Terri Cathers welcomed the Committee and the members introduced themselves.
Approval of August 2020 Minutes	The Committee unanimously approved the minutes from the August 2020 meeting without revision.
Vice Chairperson Nomination	Dr. Ian Paul, MD, was nominated as Vice Chairperson of the P&T Committee. The Committee unanimously approved Dr. Paul as Vice Chairperson of the Committee.
Drug Class Reviews, Public Testimony, Discussion, and Voting	<p>The below attachment includes the P&T Committee’s recommendations for preferred and non-preferred drugs within the drug classes reviewed during the September 2021 meetings.</p> <p>Significant points of discussion by drug class:</p> <ul style="list-style-type: none"> • Antibiotics, GI and Related Agents – The Committee discussed the place in therapy of Dificid (fidaxomicin) for the treatment of <i>Clostridioides difficile</i> infection (CDI). The Committee recommended revisions to the proposed prior authorization guidelines to account for patients with risk factors for recurrent CDI. • Antipsychotics – The Committee discussed the proposed change to non-prefer Abilify Maintena. The Committee recognized that this PDL class is grandfathered and discussed the differences between Abilify Maintena and Aristada, including dosing, patient and provider preference, and plasma levels. A motion was made to maintain preferred status for Abilify Maintena. This motion passed (3 opposed, 2 abstained). • COPD Agents – The Committee reviewed the proposed changes to the prior authorization guidelines and discussed the renewal guidelines for Daliresp (roflumilast). The Committee recommended revisions to the proposed prior authorization guidelines for assessing the efficacy of Daliresp (roflumilast). • Cytokine and CAM Antagonists – The Committee reviewed the proposed changes to the prior authorization guidelines and discussed the revisions recommended by specialists. The Committee considered the input of the specialists and the current national treatment guidelines. A motion was made to amend the proposed prior authorization guideline revisions and maintain several existing guidelines. This motion passed (2 abstained). • Growth Hormones – The Committee discussed the prior authorization guidelines. The Committee questioned the guidelines for insulin-like growth factor-1 (IGF-1) deficiency and recommended these guidelines be reviewed by a pediatric endocrinologist and presented at the next DUR Board meeting. • Hepatitis C Agents – The Committee discussed the prior authorization requirement for Hepatitis C agents. DHS proposed revisions to the prior authorization guidelines to streamline the prior authorization process, limiting

guidelines to those aimed at ensuring approval of the appropriate drug, dose, and duration for beneficiaries' clinical situations. DHS clinicians assured the Committee that the goal of the prior authorization is to approve requests for Hepatitis C Agents and address quality of care concerns when the incorrect drug/duration is prescribed. Dr. Cathers proposed use of a standardized prior authorization request fax form for Hepatitis C Agents that would be used by Fee-for-Service (FFS) and all of the managed care organizations (MCOs). The goal of this form is to improve efficiency for providers by identifying the necessary information for prior authorization and utilizing a standard form for all Medical Assistance payers. MCO representatives supported use of the standardized fax form. A motion was made to approve the revisions to the prior authorization guidelines. The motion passed (1 opposed, 1 abstained).

- **HIV/AIDS Antiretrovirals** – The Committee discussed the place in therapy of the new once monthly injectable medication Cabenuva (cabotegravir/rilpivirine) that was recommended as preferred. A proposed prior authorization guideline stated that the beneficiary would have a documented reason for use of a long-acting injectable. The Committee felt that this was a difficult guideline to operationalize, recognizing the numerous reasons that might be cited. The Committee ultimately voted to require prior authorization of Cabenuva (cabotegravir/rilpivirine) with prior authorization guidelines to verify appropriate indication and dose based on FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.
- **Hypoglycemics, Incretin Mimetics/Enhancers** – The Committee discussed the proposed recommendation to change Ozempic (semaglutide) to non-preferred status. The Committee discussed the preferred status of Trulicity (dulaglutide) and the national treatment guidelines. A motion was made to approve as presented. The motion passed (2 opposed, 2 abstained).
- **Immunosuppressives, Oral** – The Committee recommended prior authorization guidelines for Lupkynis (voclosporin) be drafted for review and discussed at the next DUR Board meeting.
- **Lipotropics, Other** – The Committee reviewed the proposed revisions to the prior authorization guidelines. The Committee discussed the outcomes data for PCSK9 inhibitors and the place in therapy in relation to ACL inhibitors. The Committee recommended maintaining the specialist requirement for the ACL inhibitors and maintaining the guideline for therapeutic failure, contraindication, or intolerance to PCSK9 inhibitors prior to approval of an ACL inhibitor.
- **Monoclonal Antibodies (MABs) – Anti-IL, Anti-IgE** – The Committee discussed the proposed revisions to the prior authorization guidelines for Dupixent and considered the input provided by the specialist consultant. A motion was made to delete the proposed guidelines allowing for approval of Dupixent for moderate to severe atopic dermatitis if the beneficiary has a body surface area of 10% or more that is affected or has involvement of extremely sensitive areas (e.g., eyelids, genital area). This motion passed (1 opposed, 1 abstained).
- **Opioid Dependence Treatments** – The Committee discussed the comparative efficacy and side effect profiles of Lucemyra (lofexidine) and clonidine. The Committee recognized that beneficiaries experiencing hypotension on clonidine could be approved for Lucemyra (lofexidine) through the prior authorization process. FFS and MCO clinicians reported receiving very few prior authorization requests for Lucemyra (lofexidine). The Committee also discussed the significantly higher cost of Lucemyra (lofexidine).
- **Pulmonary Hypertension Agents, Oral and Inhaled** – The Committee reviewed the proposed revisions and considered the input provided by the specialist with whom DHS staff consulted. A motion was made to revise the guidelines for idiopathic PAH. The motion did not carry (3 in favor, 7 opposed, 15 abstained). A subsequent motion was made to approve the proposed guideline revisions as presented. This motion passed (3 opposed).

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 23, 2021, meeting for public comment:

- Alzheimer's Agents
- Antibiotics, GI and Related Agents

- Antifungals, Topical
- Antihemophilia Agents
- Antihyperuricemics
- Antiparasitics, Topical
- Antipsychotics
- Anxiolytics
- Bladder Relaxant Preparations
- Bone Density Regulators
- Botulinum Toxins
- Bronchodilators, Beta Agonists
- COPD Agents
- Cytokine and CAM Antagonists
- Dupixent
- Erythropoiesis Stimulating Agents
- GI Motility, Chronic Agents
- Glucocorticoids, Inhaled
- Hepatitis C Agents
- HIV/AIDS Antiretrovirals
- Immunomodulators, Atopic Dermatitis
- Lipotropics, Other
- Migraine Acute Treatment Agents
- Migraine Prevention Agents
- Monoclonal Antibodies (MABs) – Anti-IL, Anti-IgE
- Multiple Sclerosis Agents
- Opioid Dependence Treatments
- Pituitary Suppressive Agents, LHRH
- Pulmonary Hypertension Agents, Oral and Inhaled
- Ulcerative Colitis Agents
- Tysabri
- Zeposia
- VMAT2 Inhibitors

Meeting Adjourned

Dr. Cathers thanked the Committee for their participation and adjourned the meeting.