

**PENNSYLVANIA DEPARTMENT OF HUMAN SERVICES**  
**Pharmacy & Therapeutics Committee Meeting Recommendations**  
**Tuesday, August 11, 2020 12:00 p.m. to 4:00 p.m.**  
**Wednesday, August 12, 2020 9:00 a.m. to 2:00 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
Tony Byler, MD	PerformCare Psychiatrist
Terri Cathers, PharmD, Chair	OMAP Pharmacy Director
Sharon Connor, PharmD	Academic Pharmacist
Oluwatoyin Fadeyibi, PharmD, MPH	Community Behavioral Health Pharmacist
Andrea Fox, MD	Internist
Romani George, MD**	Senior Medical Director, Community Care Behavioral Health Organization (delegate for Geoffrey Neimark, MD)
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
Hannah Livengood, PharmD	Health Partners of Philadelphia Pharmacist
Andrew Maiorini, PharmD	Keystone/AmeriHealth Perform Rx Clinical Pharmacist
Erin McConnell, PharmD	UPMC For You 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
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	Beacon Health Options Psychiatrist
Andreas Wali, MD	Cardiologist
Lloyd Wertz	Consumer/Family Advocate

\*Only in attendance on Tuesday August 11

\*\*Only in attendance on Wednesday August 12

**Committee Members Not Present:**

Lawrence Appel, MD, SFHM      Medical Director, Office of Long-Term Living  
David Haverstick, MD            Family Practitioner  
Rosemary Keffer, MD            Ad Hoc Adult Psychiatrist

**Written Testimony Received by the Committee:**

AbbVie Inc. – Mavyret/Oriahnn/Rinvoq ER/Skyrizi  
Actelion Pharmaceuticals – Opsumit/Uptravi  
Adlon Therapeutics – Adhansia XR  
Alliance for Patient Access – Migraine Treatment and Prevention  
Amgen – Aimovig/Enbrel/Neulasta Onpro/Otezla/Repatha  
Andrea Synowiec, DO, FAAN (Allegheny Health Network) – Migraine Acute Treatment  
Anna Wood, CRNP – Vraylar  
Anto Bagic, MD, PhD, FAES, FACNS (University of Pittsburgh Comprehensive Epilepsy Center) - Anticonvulsants  
Aquestive Therapeutics – Sympazan  
Associates in Medical Toxicology – Lucemyra  
Astellas Pharma – Xtandi  
AstraZeneca – Brilinta  
Azurity Pharmaceuticals – Katerzia  
Behrang Saminejad, MD – Botox  
BeiGene – Brukinsa  
Biocodex – Diacomit/Orencia  
Biogen – Vumerity  
Biohaven Pharmaceuticals – Nurtec ODT  
Brian Jameson, DO (Geisinger Health) – Ozempic  
Bristol Myers Squibb – Eliquis/Sprycel/Zeposia  
Covis Pharma – Alvesco  
Daniel Schwartzman, MD (Planned Parenthood Keystone) – Anovera  
Deena Masciocchi MSN, CRNP, PMHNP-BC (Lower Bucks Wellness) – Vraylar  
Denise Vanacore, PhD, CRNP, PMHNP-BC – Vraylar  
Donald Dworek, MD – Nurtec ODT  
Dova Pharmaceuticals – Doptelet  
Eli Lilly and Company – Emgality/Reyvow/Trulicity  
Epilepsy Association of Western and Central PA – Anticonvulsants  
Epilepsy Foundation – Anticonvulsants  
Eyevance Pharmaceuticals – Tobradex/Zerviate  
Genentech – Ocrevus  
Global Blood Therapeutics – Oxbryta  
Indivior – Perseris ER/Sublocade  
Intra-Cellular Therapies – Caplyta  
Ironshore Pharmaceuticals – Jornay PM  
James Valeriano, MD – Anticonvulsants/Valtoco

Janssen Pharmaceuticals, Inc. – Invega Sustenna/Invega Trinza/Invokana/Spravato/Symtuza/Xarelto  
Karam Mounzer, MD (Jonathan Lax Treatment Center) – Symtuza  
Kelly Amspacher, RN, MSN – Migraine Treatment and Prevention  
Kelly Heath, MD (Penn Medicine) – Botox  
Krys Zaradzki, BS Pharm, PharmD (UPMC Magee-Womens Hospital) - Vonvendi  
LifeScan – OneTouch Meters and Test Strips  
Margaret Ragni, MD, MPH (The Hemophilia Center) – Vonvendi  
Marsha Lue – Migraine Treatment and Prevention  
Matthew Shore, DO – Vraylar  
Matthew Steele – Anticonvulsants  
Michael Palumbo, MD (Allergy and Clinical Immunology Associates) – Eucrisa  
Miles for Migraine – Migraine Treatment and Prevention  
Neurelis – Valtoco  
Neurocrine Biosciences – Ingrezza  
Novartis – Adakveo/Cosentyx/Entresto/Gilenya/Norditropin Flexpro  
Novo Nordisk – Esperoct/Novoeight/Novoseven/Ozempic/Rebinyn/Rybelsus  
Otsuka – Abilify Maintena  
Paul Carney Jr. – Migraine Treatment and Prevention  
Pfizer – Braftovi/Eucrisa/Ibrance/Inlyta/Lobrena/Mektovi/Nivestym/Talzenna/Xeljanz  
Pierre Fabre – Hemangeol  
RedHill Biopharma – Movantik/Talicia DR  
Relypsa, Inc. – Veltassa  
Richard Solga, DNP, CRNP – Vraylar  
Sally Schaeffer (SUDEP Institute) – Anticonvulsants  
Sanofi Genzyme – Dupixent  
Sarah Horvath, MD, MSHP (Penn State University Hershey Medical Center) – Annovera  
Takeda – Vonvendi/Vyvanse  
Teva Pharmaceuticals – Ajoyv/Austedo/Granix  
The Frost Medical Group LLC – Buprenorphine-Naloxone  
The Headache & Migraine Policy Forum – Migraine Treatment and Prevention  
Thomas Holdbrook, MD – Vraylar  
UCB – Briviact/Nayzilam  
United Therapeutics – Orenitram  
Upsher-Smith – Tosymra  
US WorldMeds – Lucemyra  
Veloxis – Envarsus XR  
ViiV Healthcare – Rukobia ER  
Vishal Datta, MD (Einstein Physicians Network) – Ozempic  
Vitality Kloss, MD, FAHS – Nurtec ODT/Ubrelyvy  
Xeris Pharmaceuticals, Inc. – Gvoke  
Zogenix – Fintepla

<b>Welcome and Introduction</b>	Dr. Terri Cathers welcomed the Committee and the members introduced themselves.
<b>Approval of June 2019 Minutes</b>	The Committee unanimously approved the minutes from the June 2019 meeting without revision.
<b>Drug Class Reviews, Discussion, and Voting</b>	<p>The P&amp;T Committee’s recommendations for preferred and non-preferred status for the drugs included on the Statewide Preferred Drug List (PDL) are included in the attached document. Recommended changes are highlighted in yellow. If the recommendations are approved, the changes would be implemented January 2021 by the MCOs and Fee-for-Service Pharmacy Programs. Written public testimony was provided to the Committee members in advance of the meeting due to the virtual format of the meeting.</p> <p>Significant points of discussion by drug class:</p> <ul style="list-style-type: none"> <li>• <b>Analgesics, Opioid Short-Acting</b> – The Committee reviewed the Analgesics, Opioid Short-Acting class and corresponding prior authorization guidelines. The Committee discussed the duration of prior authorization approvals. The revisions proposed by the Department included extending prior authorization approvals from “up to 3 months” to “up to 6 months” for beneficiaries with a diagnosis of active cancer and those receiving palliative care or hospice services. The Committee recognized the need for re-evaluation of patients prescribed opioids. A motion was made to also extend prior authorization approvals to “up to 6 months” if the beneficiary is on a dose less than 50 morphine milligram equivalents per day (MME/day). For all other beneficiaries, requests will be approved for up to 3 months. The motion passed (11 in favor, 6 opposed, 9 abstain).</li> <li>• <b>Hypoglycemics, Incretin Mimetics/Enhancers</b> – The Committee reviewed the Hypoglycemics, Incretin Mimetics/Enhancers class and voted unanimously in favor of moving Ozempic, Trulicity, and Victoza to preferred status and Bydureon and Byetta to non-preferred status. The Committee recommended adding a prior authorization requirement for therapeutic duplication in this drug class.</li> <li>• <b>Hypoglycemics, Insulin and Related Agents</b> – The Committee reviewed the Hypoglycemics, Insulins and Related Agents class and voted in favor of changing the status of Regular insulin U-100 vials and NPH insulin (Humulin R, Novolin R, Humulin N, and Novolin N) vials from non-preferred to preferred status.</li> <li>• <b>Intra-Articular Hyaluronates</b> – The Committee reviewed the Intra-Articular Hyaluronates class and corresponding prior authorization guidelines. The Committee discussed the place in therapy and effectiveness of these products. The Committee recognized that these products are approved by the FDA as devices and not as drugs. As such, they are not Medicaid covered outpatient drugs and do not have a federal rebate agreement. These products are an optional Medicaid benefit that Pennsylvania has elected to cover in the past. The Committee felt that these products were associated with painful injections with little to no clinical benefit. The Committee also identified that these products are no longer recommended in national treatment guidelines. The Committee questioned whether Pennsylvania Medical Assistance should cease coverage of these products. Dr.Cathers stated that she would relay the Committee’s concerns to the administration, consult with an orthopedic specialist, and investigate options and next steps. <b><i>Post Meeting Note: OMAP Pharmacy Clinicians consulted with Dr. Ronald Lippe, board certified hip and knee surgeon at Orthopedic Institute of Pennsylvania (OIP) and UPMC. Dr. Lippe reported no conflicts of interest. He explained that while hyaluronate knee injections have not shown in research to be effective at significantly reducing pain or improving function, many patients report pain relief with the procedure and thus prolong the need for surgery. He also reported that two local commercial insurers attempted to discontinue coverage a few years ago and were met with backlash from providers and patients. They ultimately reversed their decision and are again paying for the hyaluronate injections. He agreed with the current prior authorization requirements used by both FFS and</i></b></li> </ul>

*the MCOs and felt that it would ensure appropriate utilization for the majority of patients. OMAP Pharmacy Division Clinicians also consulted with Dr. Chad Rutter, board certified orthopaedic surgeon and President of OSS Health. Dr. Rutter reported no conflicts of interest. He explained that use of intra-articular hyaluronate injections provide a treatment option for patients who have failed other conservative treatments and are not ready or unable to undergo arthroplasty surgery. For some medically complicated patients where surgery is not an option, these products may be their only treatment option. OMAP Pharmacy Division Clinicians recommend continued coverage of the Intra-Articular Hyaluronates on the Statewide PDL with clinical prior authorization.*

- **Migraine Prevention Agents (formerly Antimigraine Agents, Other)** – The Committee reviewed the Migraine Prevention Agents class and prior authorization corresponding guidelines. The Committee voted unanimously in favor of preferring Aimovig as opposed to the recommendation of Ajovy based on current utilization.
- **Ophthalmics, Antibiotics** – The Committee discussed including a 4<sup>th</sup> generation ophthalmic fluoroquinolone as preferred on the PDL. After discussion, the Committee voted unanimously in favor of the recommendations as well as moving gatifloxacin drops to preferred status.
- **Opioid Dependence Treatments** – The Committee reviewed the Opioid Dependence Treatments class and proposed revisions to the prior authorization guidelines. Dr. Steve Liles, PharmD, Senior Director for Industry Relations with Change Healthcare and Dr. Cathers informed the Committee of the impact of the SUPPORT Act on this class of drugs. CMS' SUPPORT Act amends the federal Medicaid statute and requires Medicaid coverage of MAT drugs for opioid use disorder by creating a new mandatory MAT benefit. This new mandatory benefit was created in a way that is not subject to the National Drug Rebate Agreement. As a result of the loss in rebates, MA's costs for drugs to treat opioid use disorder will increase by an estimated \$39 million annually. Congress must take action before October 2020 to prevent this loss to the Medicaid state and federal partners. The Committee discussed options for mitigating the financial impact to MA. If buprenorphine/naloxone generic film were changed to non-preferred status, the resulting increase to the MA Program would be roughly \$9 million annually. Another option discussed was to non-prefer the generic film formulation, but grandfather patients currently using the generic film products. If beneficiaries are grandfathered (meaning they can continue to use the generic film without a prior authorization), the cost increase to MA is roughly \$23 million annually. The Committee discussed the PDL statuses for buprenorphine/naloxone products and the impact of the SUPPORT Act on both beneficiaries and the Commonwealth. The Committee recognized the vital role that MAT treatments provide as we continue to combat the raging opioid epidemic in Pennsylvania. Several Committee members felt that beneficiaries currently stable on the buprenorphine/naloxone film should not be required to change to the tablet. Some members felt that both the tablet and the film formulation should be preferred so provider and beneficiaries have access to both formulations without a prior authorization. Committee members also requested information about the SUPPORT Act and the potential loss of drug rebates to aid in their own advocacy efforts. The Committee ultimately voted to maintain preferred status for both buprenorphine/naloxone film and tablet. (24 in favor, 4 opposed, 0 abstain)

The 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 September 24<sup>th</sup> meeting for public comment.

- Analgesics, Opioid Long-Acting
- Analgesics, Opioid Short-Acting
- Androgenic Agents
- Anticonvulsants
- Antidepressants, Other

	<ul style="list-style-type: none"> <li>• Anxiolytics</li> <li>• Bone Density Regulators</li> <li>• COPD Agents</li> <li>• Estrogens</li> <li>• H. Pylori Treatments</li> <li>• Hepatitis C Agents</li> <li>• Hereditary Angioedema (HAE) Treatments</li> <li>• HIV/AIDS Antiretrovirals</li> <li>• Hypoglycemia Treatments</li> <li>• Hypoglycemics, Incretin Mimetics/Enhancers</li> <li>• Hypoglycemics, SGLT2 Inhibitors</li> <li>• Hypoglycemics, TZDs</li> <li>• Idiopathic Pulmonary Fibrosis (IPF) Agents</li> <li>• Intra-Articular Hyaluronates</li> <li>• Lipotropics, Other</li> <li>• Migraine Acute Treatment Agents</li> <li>• Migraine Prevention Agents</li> <li>• Multiple Sclerosis Agents</li> <li>• NSAIDs</li> <li>• Opioid Dependence Treatments</li> <li>• Pituitary Suppressive Agents, LHRH</li> <li>• Progestational Agents</li> <li>• Sedative Hypnotics</li> <li>• Sickle Cell Anemia Agents</li> <li>• Stimulants and Related Agents</li> </ul>
<b>Meeting Adjourned</b>	Dr. Cathers thanked the Committee for their participation and adjourned the meeting.