

PENNSYLVANIA DEPARTMENT OF HUMAN SERVICES
Pharmacy & Therapeutics Committee Minutes
November 10, 2016

Committee Members Present:

Ivonne Acrich, M.D.	Ad Hoc Child/Adolescent Psychiatrist
Dale Adair, M.D.	OMHSAS Acting Chief Medical Officer
Cheston Berlin, Jr., M.D	Pediatrician
Gene Bishop, M.D.	Internist/Consumer Advocate
Thuy Bui, M.D.	Internist
Terri Cathers, Pharm.D.,Chair	OMAP Pharmacy Director
Andrea Fox, M.D.	Internist
Donald Gerhart, R.Ph.	Community Pharmacist
Heather Gross, Pharm.D.	Aetna Clinical Pharmacist
James Hancovsky, R.Ph., MBA	United Health Care Pharmacy Director
David Haverstick, M.D.	Family Practitioner
Rosemary Keffer, M.D.	Ad Hoc Adult Psychiatrist
Jaymie Lako, Pharm.D.	Gateway Health Plan Pharmacist
Andrew Maiorini, Pharm.D.	Keystone/AmeriHealth Perform Rx Clinical Pharmacist
Ian Paul, M.D.	Pediatrician
James Schuster, M.D., Vice Chair	Psychiatrist
Kevin Szczecina, R.Ph.	Geisinger Health Plan Pharmacist
Lloyd Wertz	Consumer/Family Advocate
Matthew Zimmerman, Pharm.D.	Health Partners of Philadelphia Pharmacist

Committee Members Not Present:

Jessica Daw, Pharm.D.	UPMC For You Pharmacist
David Kelley, M.D.	OMAP Chief Medical Officer
Joshua Liao, M.D.	Internist
Michele Musheno, R.Ph., M.S.	Academic/ Hospital Pharmacist

Public Testimony Heard by the Committee:

Gretchen Knobb representing Epilipsey Foundation spoke on behalf of Anticonvulsants.
Jason Moyer representing UCB spoke on behalf of Briviact.
Romy Nocera representing Sunovian spoke on behalf of Aptiom.
Jason Moyer representing UCB spoke on behalf of Neupro.
Sherry Andes representing Acadia spoke on behalf of Nuplazid.
Timothy Birner representing Alkermes spoke on behalf of Aristada.
Christopher Kant representing Allergan spoke on behalf of Vraylar.
Patricia Rohman representing Otsuka spoke on behalf of Abilify.
Lagenia Bailey representing Sunovian spoke on behalf of Latuda.
Lisette Bunting-Perry representing Ipsen spoke on behalf of Dysport.
Patricia Jacobs representing Allergan spoke on behalf of Botox.
Michael Pellegrino representing Merz spoke on behalf of Zeomin.
Ia Dac-Korytko representing AstraZeneca spoke on behalf of Bevespi Aerosphere.
Shelly Baugh representing Celgene spoke on behalf of Otezla.
Denise Mervis representing Bristol-Myers Squibb spoke on Orenzia.
Rhonda Lemmo representing Trividia Health spoke on behalf of Tru Metrix.
Katherine Klem representing Bristol-Myers Squibb spoke on behalf of Daklinza.
Karen Partyka representing Exelixis spoke on behalf of Cabometyx.
Art Shumsky representing Takeda spoke on behalf of Ninlaro.
Sharad Rastogi representing Shire spoke on behalf of Xiidra.
Edward Casey representing Pfizer spoke on behalf of Quliilchew ER.
George Kehner representing Neos spoke on behalf of Adzenys XR-ODT.
Pat Trifunov representing Tris Pharma spoke on behalf of Dyanavel XR.

Welcome and Introduction	Dr. Terri Cathers called the meeting to order at 10:09am. She welcomed the Committee and the members introduced themselves.
Approval of May 2016 Minutes	The Committee approved the minutes from the May 2016 meeting without revision.
Drug Class Reviews, Public Testimony, Discussion and Voting:	
“No Change Classes”	<p>Dr. Cathers described a new procedure proposed by Change Healthcare that is intended to make the P&T review process more efficient. Currently the P&T Committees reviews, discusses when necessary, and makes a motion on each class of drugs separately. However, in several of the drug classes there are no changes or updates to the class of drugs scheduled for review. Some other states create a list of classes of drugs with no changes and instead of voting on each class separately, the P&T Committee votes on the full list of classes of drugs with no changes. Dr.Cathers proposed that the DHS P&T Committee adopt this same procedure. DHS staff created a list of classes of drugs scheduled for review that have no changes from the last review. The criteria used to identify classes of drugs with no changes include all of the following: no new clinical information, no changes to the designated PDL status of the drugs in the class, and no registered testimony. Dr. Cathers proposed that rather than voting on each class, the Committee will vote on the full list of classes that meet these criteria. Committee members will still have the opportunity to ask questions or initiate discussion on any of the classes of drugs on the “no change list” before the vote. The same procedure is required for the list as is required for an individual class of drugs: a motion, a second to the motion, and a Committee vote. The intent is to make reviews more efficient and allow the time needed for classes of drugs that demand a more in-depth discussion as part of the review and final recommendations.</p> <p>The committee unanimously voted to approve the new process as presented by Dr. Cathers.</p>
Alzheimer’s Agents	The Committee reviewed the Alzheimer’s Agents class and unanimously approved adding the new rivastigmine patch and memantine solution to non-preferred status.
Anticonvulsants	The Committee reviewed the Anticonvulsants class and unanimously approved adding Briviact, Spritam and Fycompa Suspension to non-preferred status. The Committee also approved moving Tegretol XR and Zarontin from preferred to non-preferred status and moving gabapentin tablets, carbamazepine XR, carbamazepine tablets, Epitol tablets, carbamazepine suspension and ethosuximide capsules from non-preferred to preferred status.
Antihistamines, Minimally Sedating	The Committee reviewed the Antihistamines, Minimally Sedating class and unanimously approved adding fexofenadine-pseudoephedrine ER to non-preferred status.
Antihyperuricemics	The Committee reviewed the Antihyperuricemics class and unanimously approved adding Mitigare to the PDL with preferred status.
Antiparkinson’s Agents	The Committee reviewed the Antiparkinson’s Agents class and unanimously approved moving Selegiline capsules and carbidopa/levodopa/entacapone from non-preferred to preferred status and moving amantadine tablets and Stalevo from preferred to non-preferred status.
Antipsoriatics, Oral	The Committee reviewed the Antipsoriatics, Oral class and unanimously approved moving 8-MOP (methoxsalen) from non-preferred to preferred status.
Antipsoriatics, Topical	The Committee reviewed the Antipsoriatics, Topical class and unanimously approved adding Enstilar Foam to non-

	preferred status.
Antipsychotics	The Committee reviewed the Antipsychotics class and unanimously approved adding pimozide, molindone, paliperidone ER, Vraylar and Aristada to non-preferred status. The Committee also unanimously approved moving Abilify tablets from preferred to non-preferred status and the generic equivalent, aripiprazole tablets, from non-preferred to preferred status. The Committee also discussed Nuplazid and the treatment of Parkinson's Disease Induced Psychosis. The Committee unanimously approved adding Nuplazid to non-preferred status.
Anxiolytics	The Committee reviewed the Anxiolytics class and unanimously approved moving clorazepate from preferred to non-preferred status.
Bile Salts	The Committee reviewed the Bile Salts class and unanimously approved adding Ocaliva to non-preferred status, moving ursodiol tablets and capsules from non-preferred to preferred status and moving Urso, Urso Forte and Actigall from preferred to non-preferred status.
COPD Agents	The Committee reviewed the COPD Agents class and unanimously approved adding Bevespi to non-preferred status, moving Anoro Ellipta and Incruse Ellipta from non-preferred to preferred status and moving Tudorza Pressair from preferred to non-preferred status.
Cytokine and CAM Antagonists	The Committee reviewed the Cytokine and CAM Antagonists class and unanimously approved adding Xeljanz XR, Taltz and Stelara to non-preferred status and moving Xeljanz from non-preferred to preferred status.
Glucocorticoids, Inhaled	The Committee reviewed the Glucocorticoids, Inhaled class and unanimously approved moving Aerospan from preferred to non-preferred status.
Glucocorticoids, Oral	The Committee reviewed the Glucocorticoids, Oral class and unanimously approved moving methylprednisolone 16 mg tablets, Dexamethasone Intensol Drops and methylprednisolone 8 mg tablets from non-preferred to preferred status.
Hepatitis C Agents	<p>The Committee reviewed the Hepatitis C Agents class. Change Healthcare recommended the following changes to the PDL: adding Viekira XR and Epclusa to preferred status, moving Ribavirin tablets from non-preferred to preferred status and moving Daklinza from preferred to non-preferred status.</p> <p>The Committee asked about the status of the P&T Committee's recommendation at the May 2016 meeting to revise the prior authorization guidelines, specifically to remove the guideline related to disease severity. Several members indicated that their understanding was that the Secretary did not accept the recommendation and they requested an update and explanation from the Department. Dr. Cathers reported that the Secretary has accepted the recommendations from the Committee, but the administration has not yet made a decision regarding the prior authorization guidelines. Dr. Cathers clarified that the recommendation is still under consideration and reminded the Committee that there is a provision for case-by-case review for medical necessity by a physician reviewer if the prior authorization guidelines are not met. The Committee requested follow-up from the Department regarding the May 2016 recommendation. Their requests/questions are as follows:</p> <ol style="list-style-type: none"> 1. The Committee would like a formal communication about the status of the guideline recommendations. 2. The Committee would like to know the reason for the 6 month delay for the decision. Is it strictly a cost issue or are there clinical issues as well, such as the ability to monitor adherence, sufficient numbers of specialists to treat and provide quality care that results in cure?

	<p>3. The Committee would like an explanation of how the Centers of Excellence (COE) for Opiate Use Dependency will address screening for Hep C and if the patient is positive, what is the expectation for the COEs in terms of coordinating Hep C treatment?</p> <p>Department staff agreed to relay these requests to the administration.</p>
Intranasal Rhinitis Agents	The Committee reviewed the Intranasal Rhinitis Agents class and unanimously approved adding mometasone spray to non-preferred status and moving Nasonex Spray from preferred to non-preferred status.
Macular Degeneration Agents	The Committee reviewed the Macular Degeneration Agents class and unanimously approved adding Visudyne to preferred status.
NSAIDs	The Committee reviewed the NSAIDs class and unanimously approved adding diclofenac gel and Vivlodex capsules to non-preferred status, moving diclofenac drops and naproxen DR from non-preferred to preferred status and moving naproxen oral suspension from preferred to non-preferred status.
Oncology Agents, Breast Cancer	The Committee reviewed the Oncology Agents, Breast Cancer class and unanimously approved adding Soltamox Solution to non-preferred status.
Oncology Agents, Oral	The Committee reviewed the Oncology Agents, Oral class and unanimously approved adding Odomzo, Venclexta, Cotellic, Ninlaro, Lonsurf, Alecensa, Tagrisso and Cabometyx to preferred status and adding imatinib to non-preferred status. The Committee recognized the brand imatinib, Gleevec, is more cost effective for the Department and is currently preferred. The Committee also approved moving temozolomide from non-preferred to preferred status.
Ophthalmics, Allergic Conjunctivitis	The Committee reviewed the Ophthalmics, Allergic Conjunctivitis class and unanimously approved adding olopatadine to preferred status and moving Pazeo and Pataday from preferred to non-preferred status.
Ophthalmics, Antibiotics	The Committee reviewed the Ophthalmics, Antibiotics class and unanimously approved moving Ciloxan ointment from non-preferred to preferred status and moving Moxeza drops, gentamicin sulfate drops and ofloxacin drops from preferred to non-preferred status.
Ophthalmics, Anti-inflammatory	The Committee reviewed the Ophthalmics, Anti-inflammatories class and unanimously approved adding Ozurdex Implant to non-preferred status and moving Ilevro drops and prednisolone sodium phosphate drops from non-preferred to preferred status.
Ophthalmics, Glaucoma Agents	The Committee reviewed the Ophthalmics, Glaucoma Agents class and unanimously approved moving Alphagan P 0.1% drops from non-preferred to preferred status and moving Simbrinza drops, Isopto Carpine drops and Timolol gel from preferred to non-preferred status.
Ophthalmics, Immunomodulators	The Committee reviewed the Ophthalmics, Immunomodulators class and unanimously approved adding Xiidra to non-preferred status.
Otic Antibiotic Preparations	The Committee reviewed the Otic Antibiotic Preparations class and unanimously approved adding Otiprio to non-preferred status and moving Cipro HC and Coly-Mycin S from non-preferred to preferred status. After clinical discussion around not using steroids when there is perforation, the Committee unanimously voted to keep Ciprofloxacin droplets in preferred status.
Progestational Agents	The Committee reviewed the Progestational Agents and unanimously approved adding hydroxyprogesterone caproate to preferred status and moving Makena from preferred to non-preferred status. The Committee discussed the FDA approval

	<p>of a new generic product hydroxyprogesterone caproate for brand name Delalutin. Brand Delalutin is no longer on the market. The original manufacturer requested the withdrawal of Delalutin from the market in 2000 for reasons unrelated to safety. The Committee also discussed difficulties with the manufacturer of Makena. Ultimately the Committee voted to recommend non-preferred status for Makena but to maintain the current prior authorization guidelines for Makena.</p> <p><u>Post Meeting Note:</u> Following the P&T Committee meeting, the Department decided to maintain Makena as a preferred agent.</p>
Sedative Hypnotics	The Committee reviewed the Sedative Hypnotics class and unanimously approved adding Zolpimist Spray and zolpidem sublingual tablets to non-preferred status.
Steroids, Topical	The Committee reviewed the Steroids, Topical class and unanimously approved adding flurandrenolide cream, Sernivo Spray and Ultravate Lotion to non-preferred status, moving Scalpicin solution, hydrocortisone lotion, clobetasol cream and clobetasol ointment from non-preferred to preferred status and moving alclometasone cream, alclometasone ointment, Elocon Solution, hydrocortisone butyrate ointment, betamethasone dipropionate lotion, Temovate cream and Temovate ointment from preferred to non-preferred status.
Stimulants and Related Agents	The Committee reviewed the Stimulants and Related Agents class and unanimously approved adding Adzenys XR ODT to preferred status, adding Quillichew ER Tablets and Dyanavel XR Suspension to non-preferred status, moving Aptensio XR from non-preferred to preferred status and moving Adderall tablets from preferred to non-preferred status.
“No Change Drug Classes”	<p>The Committee unanimously approved making no changes to the following classes:</p> <ul style="list-style-type: none"> • Anti-Allergens • Antidepressants, Other • Antidepressants, SSRIs • Antihypertensives, Sympatholytic • Botulinum Toxins • Bronchodilators, Beta-Agonists • Diabetic Meters • Diabetic Strips • Emollients • Enzyme Replacement, Gaucher’s Disease • Epinephrine, Self-Injected • Histamine II Receptor Blockers • Idiopathic Pulmonary Fibrosis Agents • Immunomodulators, Atopic Dermatitis • Immunomodulators, Topical • Iron, Oral • Iron, Parental • Leukotriene Modifiers • Methotrexate • Neuropathic Pain Agents • Ophthalmics, Antibiotic-Steroid Combinations • Otic Anti-Infectives & Anesthetics • Smoking Cessation Agents

	<ul style="list-style-type: none">• Thalidomide and Derivatives
Meeting Adjourned	Dr. Cathers thanked the Committee for their participation and adjourned the meeting at 4pm.