Pharmacy and Therapeutics Committee (P&T)
Meeting Minutes

Date: **Time:** **Presiding:**	**07/25/2017** **5:30 PM** **Heather Gross, Pharmacy Director**	**Telephonic Attendance:** Chandra Kee, MD, Interim CMO; Richard Buzard, MD; Robert Schrieber, RPh, Burns Pharmacy; Oluwatoyin Fadeyibi, Pharm.D, MPH; Brad Tabaac, RPh, Friendly Pharmacy; Ramoni George, MD; Anthony L. Sico, DO; Maislyn Christie, MD; Audrey Moore, Director Medical Management; Gina Masciangelo, Interim Clinical Liaison; Eileen Carroll, RN, Scribe* **Absent:** Eric Deppert, MD; Barbara Wingate, MD; Rajiv Vyas, MD; F. Ferry, MD

* Nonvoting members

TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION	DATE DUE
I. Call to Order	H. Gross	H. Gross called the meeting to order at 5:33 pm.	None	N/A
II. Announcements	H. Gross	Roll call was completed and quorum was established. There were no announcements made at this time.	None	N/A
III. Review and Approval of Minutes	H. Gross	H. Gross presented the minutes from the May 2, 2017 meeting for approval. C. Kee, MD, motioned to approve the minutes as presented, seconded by B. Tabaac, RPh. The motion carried without opposition.	The P&T meeting minutes from 5/2/2017 were approved as presented.	Complete
IV. Old Business- ***not applicable for this meeting***				
V. New Business				
A. Pharmacy and Therapeutics Charter and Policy	H. Gross	2017 Pharmacy and Therapeutics Committee Charter H. Gross presented the 2017 Pharmacy and Therapeutic Committee Charter. She stated the purpose of the committee is to formulate and review policies that promote the use of safe and effective Food and Drug Administration (FDA) approved medications for Aetna Better Health/Aetna Better Health Kids. Sections regarding the committee's major responsibilities, clinical	The 2017 Pharmacy and Therapeutics Committee Charter and Policy were	Complete

<table>
<tr><th>TOPIC FOR DISCUSSION</th><th>SPEAKER</th><th>DISCUSSION</th><th>ACTION</th><th>DATE DUE</th></tr>
<tr><td>A. Pharmacy and Therapeutics Charter and Policy – Cont'd</td><td>H. Gross</td><td>procedures, membership, documentation, and reporting were highilghed during the presentation.

Discussion: C. Kee, MD questioned if the charter membership could be changed from CMO (Chief Medical Officer) to state CMO or designated medical director. The charter was updated as requested.

<u>Policy A-PA PA CHIP 7600.30 Pharmacy and Therapeutics Committee</u>
H. Gross presented the 2017 version of the Pharmacy and Therapeutics Committee policy. She explained that the policy has been approved by DHS (Department of Human Services) and changes were limited to the 2017 NCQA (National Committee for Quality Assurance) statement updates and definition updates as aligned with the Pennsylvania HealthChoices agreement. She outlined the committee's responsibilities in relation to the formulary. She added that in regards to committee membership, external members act as advocates for both providers and members. She explained that to ensure members have their voice heard in regards to advocate selection, the external P&T committee members will be presented at the next HEMAC (Health Education Member Advisory Committee) meeting in September 2017, of which consumer members participate, for review and vote.

R. Buzard, MD motioned to accept the committee charter and policy as presented with revisions, seconded by B. Tabaac, RPh. The motion carried without opposition.</td><td>approved as presented with revisions.</td><td></td></tr>
<tr><td>B. Formulary Change – Generics</td><td>H. Gross</td><td><u>Formulary Changes - Generics</u>
H. Gross stated that the following generics were added to the Aetna Medicaid formularies where permitted by state regulations in the previous quarter, as they provided a value add to our members with no negative impact.

<table>
<tr><th>Generic Name</th><th>Branded Name</th></tr>
<tr><td>Olopatadine Ophth Soln 0.2%
UM (Utilization Management) Edit: ST (step therapy) through ketotifen QLL (quantity level limit) 2.5mL</td><td>Pataday</td></tr>
</table>
</td><td>Formulary Change – Generics was approved as presented.</td><td>Complete</td></tr>
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<table>
<tr><th>TOPIC FOR DISCUSSION</th><th>SPEAKER</th><th>DISCUSSION</th><th>ACTION</th><th>DATE DUE</th></tr>
<tr><td>B. Formulary Change – Generics – Cont’d</td><td>H. Gross</td><td>
<table>
<tr><td>Melphalan Tablet 2mg</td><td>Alkeran</td></tr>
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H. Gross stated that the following generics were NOT added to the Aetna Medicaid formularies in the previous quarter, as they did not provide added value to our members.

<table>
<tr><th>Generic Name</th><th>Branded Product Name</th></tr>
<tr><td>Zileuton ER Tab</td><td>Zyflo</td></tr>
<tr><td>Tazarotene Cream</td><td>Tazorac</td></tr>
<tr><td>Ezetimibe/Simvastatin Tab</td><td>Vytorin</td></tr>
<tr><td>Rivelsa
Fayosim</td><td>Quartette</td></tr>
<tr><td>Desvenlafaxine</td><td>Pristiq</td></tr>
<tr><td>Prednisolone Sol 20mg/5mL</td><td>Veripred</td></tr>
<tr><td>Prednisolone Sol 10mg/5mL</td><td>Millipred</td></tr>
<tr><td>Desoximetasone Cream</td><td>Topicort</td></tr>
<tr><td>Atomoxitene Capsule</td><td>Strattera</td></tr>
<tr><td>Buprenorphine TD Patch</td><td>Butrans</td></tr>
</table>

H. Gross clarified that pharmacy will continue to track the generics that were not added for the next 6-9 months, and that they could possibly be added to the formulary at a later date.

C. Kee, MD motioned to accept formulary change – generics as presented, seconded by B. Tabaac, RPh. The motion carried without opposition.</td><td></td><td></td></tr>
<tr><td>C. Drug Class Reviews</td><td>H. Gross</td><td><u>Drug Class Reviews</u>
H. Gross stated that Drug Class reviews look at all agents either within a therapeutic class or classes to assure that the formularies are optimized for each therapeutic treatment area.

Drug classes that underwent review <u>without</u> formulary change recommendations:
• Anticoagulants
• ARBs (Angiotensin II receptor blockers)
• IL5-Antagonist (interleukin-5)</td><td>Informational; no action required</td><td>Complete</td></tr>
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TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION	DATE DUE
C. Drug Class Reviews – Cont'd	H. Gross	• Idiopathic Pulmonary Fibrosis • Long-Acting Injectable Atypical Antipsychotics • Long-Acting Opioids • Platelet Inhibitors • Direct Renin Inhibitors • Proton Pump Inhibitors (PPIs) • Hemophilia Factors Drug classes that underwent review *with* formulary change recommendations: • Anti-emetics • Transmucosal Immediate Release Fentanyl • Topical Steroids • Vancomycin • Oral beta-2 agonists		
D. Formulary Additions	H. Gross	H. Gross stated that as part of the formulary revisions, the committee wanted a recommendation from the National P&T committee regarding Fentanyl, Doxylamine and Pyridoxine. She explained that the addition of these drugs was related to clinical prior authorization guidelines. She added that there needs to be a first line alternative available for formulary drugs. Formulary Additions: • Fentanyl Citrate Lozenge - Add all strengths to formulary with PA (prior authorization) and QLL of 4 lozenges per day • Doxylamine 25mg - Add to formulary • Pyridoxine 25mg - Add to formulary C. Kee, MD motioned to accept formulary additions as presented, seconded by B. Tabaac, RPh. The motion carried without opposition.	Formulary Additions was approved as presented.	Complete
E. Formulary Change Proposals	H. Gross	Formulary Change Proposals H. Gross presented the following formulary change proposals – clinical edits: Naproxen Suspension • Summary of the initiative: ADD STEP THERAPY to Naproxen suspension (125mg/5ml) through Ibuprofen suspension 100mg/5ml. • No Grandfather existing users	The Formulary Change Proposals were approved as presented.	Complete

TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION	DATE DUE
E. Formulary Change Proposals – Cont'd	H. Gross	Duloxetine Capsules • Summary of the initiative: ADD QL of #30/30 days on all strengths of duloxetine capsules (20mg, 30mg, 40mg, and 60mg); and • ADD Duloxetine 40mg capsules (generic Irenka) if not currently on a plan's formulary • Grandfather existing users exceeding 60mg capsules #30/30 days only • Per Package insert: There is no evidence that doses greater than 60 mg/day confers additional benefit, and higher doses may be associated with a higher rate of adverse events. **C. Kee, MD questioned how members currently on 90mg of Duloxetine will be managed, as there are large number of members on that dosage. H. Gross replied that existing members on that dosage will also be granfathered.** Terbutaline and Albuterol Tablets • Summary of the initiative: Remove Terbutaline tablets (2.5mg and 5mg) and Albuterol tablets (2mg, 4mg, 4mg ER, 8mg ER) with steerage to albuterol syrup 2mg/ml. • Grandfather existing users • Background: Both Asthma and COPD (Chronic Obstructive Pulmonary Disease) national guidelines prefer oral inhaled albuterol (SABAs [short-acting beta agonists]), and state that there is no proven advantage of systemic beta-2 agonist therapy over inhalation therapy. Vancomycin Capsules • Summary of the initiative: To REMOVE Vancomycin capsules (125mg and 250mg) with steerage to First Vancomycin oral solution (25mg/ml and 50mg/ml) • No Grandfather existing users C. Kee, MD motioned to accept the Formulary Change Proposals as presented, seconded by B. Tabaac, RPh. The motion carried without opposition.		

TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION	DATE DUE
F. Drug Class Review – Topical Corticosteroids	H. Gross	Drug Class Review – Topical Corticosteroids H. Gross presented the following Drug Class review for Topical Corticosteroids. Summary of the initiative: • To review the Topical Steroid class to standardize Aetna Medicaid formularies for cost effectiveness, by removing costly products and ensuring plans have appropriate available alternatives. • No Grandfather existing users ; with the exception of Fluocinolone Oils (Low Potency) and Clobetasol Cream/Ointment/Gel (Very High Potency) • Removing 30 GPIs (Generic Product Indicator) and 1 NDC (National Drug Code); Adding Step Therapy to 3 GPIs; and QL to 13 GPIs Background: • Topical Corticosteroids were reviewed by the standard four potency groups (low, medium, high, and very high), and evaluated for cost effectiveness as products within each group typically offer no significant advantage over other products outside of formulation differences • The intent is to have at least 2 formulary options for each formulation (cream, Oint, Solution/Lotions) within each potency group, and pediatric use. • QLs: were added for all remaining Very High potency products (based on largest package size per month with 90% of use not affected, and also added to certain High Potency agents for safety). Indications: • The majority of the products are indicated for the broad term of "Corticosteroid-responsive dermatologic disorders" which encompasses atopic dermatitis, contact dermatitis, severe Rhus dermatitis (due to plants like poison ivy), lichen planus, eczematous conditions, keloids, severe pruritus, psoriasis, seborrheic dermatitis, sunburn, urticaria, etc. • High and Very High Potency products also have indication for plaque-type psoriasis.	The Drug Class Review for Topical Corticosteriods was approved as presented.	Complete

TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION	DATE DUE
F. Drug Class Review – Topical Corticosteroids	H. Gross	• Note: Clobetasol is the most utilized product in Very High Potency group and is the most potent topical steroid on market. (so grandfathered current members, and added STEP vs formulary removal) R. Shcriber, RPh motioned to approve the Drug Class Review for Topical Corticosteroids as presented, seconded by C. Kee, MD. The motion carried without opposition.		
G. 3Q Coverage Guideline/Criteria Reviews (Summary of Guideline Reviews)	H. Gross	<u>Coverage Guideline/Criteria Reviews</u> H. Gross stated that annual review of guidelines considers national treatment recommendations/guidelines as applicable for topic at hand, factoring in formulary composition of like or related drug/drug classes. Guidelines were also reviewed with respect to impact to operational efficiencies relative to utilization control benefits provided. <u>Annual Guideline Reviews and Updates</u> H. Gross stated that the following PA Guidelines were reviewed and required no changes: • Entresto • PPI's • Topical NSAID's (Nonsteroidal Antiinflammatory Drugs) • Diabetic Supplies • Oral Vancomycin • Hemophilia Factors • LA (long acting) Opiods H. Gross added that both long acting opiods and hemophilia factors will likely be brought back to committee with a full drug class and prior authorization guideline review/update in the 4th Quarter 2017 or 1st Quarter 2018 in light of new information received that may bring about some changes. She explained that once the core team has completed their work on the policies, she will then go back and make sure that nothing needs to be added in regards to state-specific contractual obligations. <u>Summary of Guideline Reviews</u> H. Gross stated that the following Guidelines were reviewed by the Clinic	The 3Q Coverage Guideline/ Criteria Reviews (Summary of Guideline Reviews) were approved as presented.	Complete

TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION	DATE DUE
G. 3Q Coverage Guideline/Criteria Reviews (Summary of Guideline Reviews) – Cont'd	H. Gross	Subcommittee and were presented for the their annual review with little to no changes. Changes were limited to updating FDA indications, adding new products (new generics/new branded), formatting edits and changes to language to clarify intent: *The Summary of Changes was presented for the following **Revised** guidelines:* <u>Anticoagulants-Oral</u> • Removed the AFIB (atrial fibrillation) requirement for determining the CHADS risk factor • Removed requirement for trial and failure of warfarin for DVT/PE (deep vein thrombosis/pulmonary embolism) • Added criteria that renal monitoring will be performed and dosing adjusted accordingly <u>Antidepressants (Non-Formulary)</u> • Removed Pristiq and Khedezla requirement for trial and failure of desvenlafaxine fumarate • Added forfivo Xl to the criteria • Added QLL for the nefazodone <u>Anti-Hyperlipidemia agents</u> Rosuvastatin • Updated the age limit from 10 years old to 7 years old • Removed criteria for failure to achieve LDL (low density lipoprotein) goal • Removed criteria requiring evidence or need for high intensity statin (e.g. ASCVD [atherosclerotic cardiovascular disease], familial hypercholesterolemia) • Added criteria that member has had a 3 month trial and failure or intolerance to high intensity atorvastatin Other non-statins (hypertriglyceridemia) • Added Omtryg to the list of medications • Removed niacin as a recommended agent • Updated initial approval from 6 months to 3 months		

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G. 3Q Coverage Guideline/Criteria Reviews (Summary of Guideline Reviews) – Cont'd	H. Gross	• Added renewal requirement of lipid panel in past 90 days showing improvement in fasting lipids AND claims history supporting adherence to other lipid lowering therapies • Added quantity limit <u>ARBs (non-formulary)</u> • Removed requirement for diagnosis with HTN (hypertension) with CKD (chronic kidney disease) or without CKD • Added diagnosis is for an FDA approved indication • Removed trial of HCTZ (hydrochlorothiazide), CCB (calcim channel blockers), ACEI (Angiotensin converting enzyme inhibitors) as first line <u>Daliresp</u> • Updated age limit from 40 years of age to 18 years of age • Removed the specialty provider requirement • Removed the spirometry requirement • Added a trial of LABA (long-acting beta adrenoceptor agonists) + ICS (inhaled corticosteroids) to be included with LABA + LAMA (long acting muscarinic antagonist) + ICS • Added concurrent treatment may also include LABA + ICS <u>Direct Renin Inhibitors</u> • Removed requirement for trial of HCTZ, CCB, or Beta Blocker as first line • Added trial of 2 formulary alternatives (ACEI or an ARB) <u>Esbriet and Ofev (Idiopathic Pulmonary Fibrosis)</u> • Updated diagnosis to simply state Idiopathic Pulmonary Fibrosis • Added diagnosis to be confirmed by demonstration of usual interstitial pneumonia (UIP) on HRCT (high resoluation computed tomography) or surgical lung biopsy with (UIP) • Added criteria for PFT (pulmonary function tests) Carbon Monoxide Diffusion Capacity DLco (diffusing capacity of the lung for carbon monoxide) > 30% • For renewal added member must be compliance and adherence to		

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G. 3Q Coverage Guideline/Criteria Reviews (Summary of Guideline Reviews) – Cont'd	H. Gross	treatment <u>Hep (Hepatitis) C</u> • Added requirement for screening of Hep B and vaccinated if not immunized <u>IL5-Antagonist</u> • Simplified requirement to state trial and failure of a med or high dose ICS + LABA, or other controller medications (e.g., LTRA [Leukotriene Receptor Antagonists] or theophylline) if LABA is contraindicated • Added requirement that members with a history of exacerbations must try and fail tiotropium • Added requirement that member will not receive in combination with Xolair or another IL-5 inhibitor <u>Juxtapid/Kynamro</u> • Updated the wording for evidence of diagnosis of HoFH (Homozygous familial hypercholesterolemia) to match that of PCSK9 (Proprotein convertase subtilisin/kexin type 9) inhibitors • Updated the definition of statin intolerance to include documentation of skeletal muscle symptoms that resolved when statin was discontinued and documentation that the member has been re-challenged with at least two different statins at an equivalent or lower dose • Extended duration of trial and failure of two high intensity statin from 60 days to 90 days • Extended duration of trial and failure of Repatha from 60 days to 90 days • Update adjunctive therapy to also LDL Apheresis (for Juxtapid only) • Removed "women of child bearing age: Negative pregnancy test" • For criteria stating Juxtapid will not be used with 3A4 (Cytochrome P450 3A4) inhibitors: provided examples of moderate to strong 3A4 inhibitors in the reviewer notes • Added a 30% LDL reduction from baseline to renewal criteria • Claims history supporting adherence to BOTH Juxtapid/Kynamro and		

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G. 3Q Coverage Guideline/Criteria Reviews (Summary of Guideline Reviews) – Cont'd	H. Gross	other lipid lowering therapies • Simplified renewal criteria requiring ALT (Alanine aminotransferase)/AST (aspartate aminotransferase) <3x ULN (upper limit of the normal) • Added quantity limit for both agents <u>Lidocaine Patch</u> • Removed requirement for trial of tramadol and OTC (over the counter) capsaicin as a formulary alternative for Diabetic Neuropathy <u>Long-Acting Injectable Atypical Antipsychotics</u> • Added continuity of care language • Added requirement for metabolic screening and that provider must agree to do follow-up screening • Updated the initial approval duration (1 year) and renewal of 1 year; Renewal will require documentation of metabolic screening <u>Movantik</u> • Added requirement that member must be taking an opioid for at least 4 weeks • Increased additional trial from 2 formulary agents to 3 • Renewals require continuation of opioid therapy <u>Platelet Inhibitors (P2Y)</u> • Removed the CYP2C19 (cytochrome P450 family 2 subfamily C member 19] poor metabolizers as a criteria for intolerance to clopidogrel; genetic testing is not recommended by 2016 ACC/AHA (American College of Cardiology/American Heart Association) • Updated criteria for Aspirin to not exceed 100mg per day for both Brilinta and Effient • Removed the comment regarding the Age limit of> 75 and high thromboembolic risk, this is not an absolute contraindication; similarly with the Cyp3A4 (Cytochrome P450 3A4) inducers and statins • Recommended approval for members stabilized in the hospital		

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G. 3Q Coverage Guideline/Criteria Reviews (Summary of Guideline Reviews) – Cont'd	H. Gross	Restasis and Xiidra • Added age limit of 16 and 17, to Restasis and Xiidra, respectively • Added diagnosis of Dry Eye Disease for Xiidra • Removed requirement for slit lamp evaluation • Removed requirement regarding high viscosity ingredient • Added criteria that a trial of 2 different forms must be tried such as gels, ointments, or liquids Vivitrol • Updated substance abuse to substance 'use' • Decreased initial approval duration from 90 days to 60 days • Decreased renewal duration from 1 year to 6 months Xolair • Added IgE (Immunoglobulin E) levels ranging from 30-1500 Iu/mL • Removed requirement for the non-smoking • Updated language to simply state trial and failure of med or high dose ICS + LABA or another controller agent if intolerant to a LABA • Added comment that Xolair will not be used with Cinqair or Nucala Chronic Urticaria: • Removed the requirement for the trial of anti-histamines in combination with immunosuppressant's i.e., sulfasalazine, cyclosporine *New Guideline Reviews:* Neudexta May be authorized when all of the following criteria is met: • Member is 18 years of age or older • Diagnosis of pseudobulbar affect (PBA) • Documentation that member has at least ONE underlying neurologic conditions associated with PBA • Amyotrophic lateral sclerosis (ALS) • Multiple Sclerosis (MS) • Cognitive assessment to evaluate for the presence of PBA; Center for Neurologic Study-Lability Scale (CNS-LS) ≥ 13 • Member does not have any contraindication to therapy (e.g., QT prolongation, Atrioventricular (AV) block or currently on MAOI		

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G. 3Q Coverage Guideline/Criteria Reviews (Summary of Guideline Reviews) – Cont'd	H. Gross	(Monoamine oxidase inhibitors)(therapy
		• Initial Approval: 3 months; Renewal: 1 year; requires documentation to support CNS-LS score improvement or decreased PBA episodes
		
		<u>Diclegis</u>
		May be authorized when all of the following criteria are met:
		• Member is at least 18 years of age
		• Diagnosis of nausea and vomiting in pregnancy
		• Documentation to support member had an inadequate response or intolerable side effects to dietary and lifestyle changes (e.g. avoiding stimuli/triggers, avoiding spicy and fatty foods, eating frequent small meals, an inadequate response to ginger)
		• Member has had an inadequate response or intolerable side effects to:
		• A combination of OTC doxylamine and OTC pyridoxine (vitamin B6) **AND** at least 1 of the following:
		  • H1 Antihistamines (e.g., diphenhydramine, meclizine, dimenhydrinate) **OR** ondansetron
		• Initial Approval**:** 3 months; renewal**:** 3 months; *Requires:* Member is still pregnant and continues to have nausea and vomiting symptoms
		
		<u>Dupixent</u> (SQ [subcutaneous] Injection)
		May be authorized when <u>all</u> of the following criteria is met:
		• Member is at least 18 years of age
		• Diagnosis of moderate to severe atopic dermatitis
		• Prescribed by, or in consultation with, a dermatologist, allergist or immunologist
		• Patient had an inadequate response or intolerable side effects to ALL of the following:
		  • Two preferred (medium to very high potency) topical corticosteroids (e.g. triamcinolone, clobetasol, mometasone, betamethasone, fluocinonide)
		  • One topical calcineurin inhibitors (e.g., tacrolimus)
		• <u>Initial Approval:</u> 4 months; <u>Renewals:</u> 6 months; *Requires:* Compliance and adherence to treatment; At least 20% symptom improvement (e.g., reduction in lesions) or Investor's Static Global		

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G. 3Q Coverage Guideline/Criteria Reviews (Summary of Guideline Reviews) – Cont'd	H. Gross	Assessment (ISGA) of 0 or 1 'clear' or 'almost clear'
		• Dosing: Initial: 600 mg SQ ; Maintenance: 300 mg SQ every 2 weeks
		
		Eucrisa (Topical Ointment)
		May be authorized when all of the following criteria is met:
		• Member is at least 2 years of age
		• Diagnosis of mild to moderate atopic dermatitis
		• Prescribed by, or in consultation with, a dermatologist, allergist or immunologist
		• Member had an inadequate response or intolerable side effects to ALL of the following:
		  • Two preferred (medium potency) topical corticosteroids (e.g. hydrocortisone, triamcinolone, mometasone, betamethasone, fluticasone)
		  • One topical calcineurin inhibitors (e.g., tacrolimus)
		• Initial Approval: 4 weeks; Renewals: 3 months; *Requires:* Improvement in lesions; Compliance and adherence to treatment Investor's Static Global Assessment (ISGA) of 0 or 1 'clear' or 'almost clear' or at least 20% symptom improvement (e.g., reduction in lesions)
		• Quantity Limit: 60 gm tube per month, 100 gm tube per month
		
		TIRF (transmucosal immediate release fentanyl)
		o Abstral (fentanyl) sublingual tablets
		o fentanyl citrate lozenge
		o Fentora (fentanyl) buccal tablets
		o Lazanda (fentanyl citrate) nasal spray
		o Subsys (fentanyl) sublingual spray
		
		TIRF agents are opioid analgesics that are approved for the management of breakthrough cancer pain in patients who are receiving and are tolerant to opioid therapy for underlying persistent cancer pain. TIRF agents are available only through a restricted TIRF REMS (Risk Evaluation and Mitigation Strategy) Access program. The preferred formulary product is the generic fentanyl citrate with PA.		

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G. 3Q Coverage Guideline/Criteria Reviews (Summary of Guideline Reviews) – Cont'd	H. Gross	May be authorized for members when all of the following criteria is met:
		• Member is at least 16 years old (for Actiq or generic fentanyl citrate lozenge) and at least 18 years old (for Abstral, Fentora, Lazanda, and Subsys)
		• Prescribed by, or in consultation with, an oncologist or pain specialist
		• Documentation to support diagnosis of cancer and that treatment will be used for breakthrough cancer pain
		• Member is on a long-acting opioid around-the-clock for treatment of cancer pain
		• Members must be considered opioid-tolerant and are considered opioid-tolerant if they have received at least <u>one week</u> of treatment on <u>one</u> of the following medications:
		  • Morphine sulfate at doses of at least 60 mg/day
		  • Fentanyl transdermal patch at doses of at least 25 mcg/hour
		  • Oxycodone at doses of at least 30 mg/day
		  • Oral hydromorphone at doses of at least 8 mg/day
		  • An alternative opioid at an equianalgesic dose for at least a week (e.g., oral methadone at doses of at least 20 mg/day)
		AND for all other non-formulary agents
		• Member had inadequate response or intolerable side effects with generic fentanyl citrate lozenge.
		**NOTE: TIRFs are not covered for the management of acute or postoperative pain including migraine headaches or for members who are not tolerant to opioids and who are not currently on opioid therapy.
		• **<u>Initial Approval:</u>** 6 months; **<u>Renewals:</u>** 1 year; Requires:Documented improvement in breakthrough cancer pain
		Continued use of a long-acting opioid around-the-clock while on treatment
		<u>QLL</u>: Abstral: 4 tablets/day; Actiq: 4 lozenges/day; Fentora: 4 tablets/day; Lazanda: 1 bottle/day; Subsys: 4 sprays/day
		
		Discussion: Oluwatoyin Fadeyibi, Pharm.D questioned why the initial approval for TIRF drugs was for 6 months, but the renewal would be authed for one year.
		H. Gross replied that after the initial 6 months, a reassessment is required whereby they are looking for the provider to still be involved with the		

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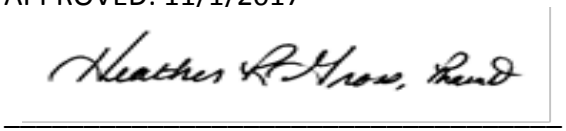
G. 3Q Coverage Guideline/Criteria Reviews (Summary of Guideline Reviews) – Cont'd	H. Gross	**member's care and that urine drug screenings are performed. She explained that it is more of a safety check, rather than re-establishing the clinical need for the product.** **C. Kee, MD stated that this was also the reason behind the change in auth timeframes for vivitrol. She explained that when you look at the data on vivitrol, it wasn't intended to be a maintenance medication. At some point the member should be able to switch to oral agent; unlike buprenorphine, and much more costly.** C. Kee, MD motioned to approve the 3Q Coverage Guideline/Criteria Reviews (Summary of Guideline Reviews) as presented with a second from R. Buzard, MD. The motion carried without opposition.		
H. New Drug Coverage Provisions/ Abbreviated Drug Reviews	H. Gross	<u>New Drug Coverage Provisions/Abbreviated New Drug Reviews</u> H. Gross presented the New Drug Coverage Provisions/Abbreviated New Drug Reviews. She stated that: • New Drugs to the market default to Non-formulary status and our standard non-formulary process until they can under go their formal P&T review. • The standard non-formulary process is to review for the following criteria: The drug is being used for it's FDA approved indication. • The member has tried and failed at least two formulary alternatives that treat the same condition. • Specialty/High Cost medications also require MDR (Medical Director Review) for all requests regardless of the decision. • The Subcommittee will work to create interim guidelines for the clinical pharmacists and Medical Directors use until formal criteria can be developed and approved by the P&T either at a quarterly meeting or by ad hoc e-vote. H. Gross presented abbreviated drug reviews for the following new drugs including detail and explanation for class, indication, efficacy, formulary alternative(s) and pertinent comments. She added that all of these drugs are currently listed as non-preferred. • Alunbrig® (brigatinib) *Indication:* anaplastic lymphoma kinase (ALK)-positive metastatic non-small cell lung cancer (NSCLC) who have progressed on or are	The New Drug Coverage Provisions/ Abbreviated Drug Reviews were approved as presented.	Complete

TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION	DATE DUE
H. New Drug Coverage Provisions/ Abbreviated Drug Reviews – Cont'd	H. Gross	intolerant to Xalkori (crizotinib) • Austedo™ (deutetrabenazine) *Indication:* Chorea associated with Huntington's disease • Bavencio® (Avelumab) *Indication:* Metastatic Merkel cell carcinoma (MCC) and locally advanced or metastatic urothelial carcinoma, in patients with disease progression on or following platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy • Dupixent® (Dupilumab) *Indication:* Moderate-to severe atopic dermatitis whose disease is not adequately controlled with topical prescription therapies or are unable to take topical therapies • Emflaza™ (deflazacort) *Indication:* Duchenne muscular dystrophy (DMD) in patients 5 years of age and older • Imfinzi® (durvalumab) *Indication:* Locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy or have disease progression within 12 months of neoadjuvant or adjuvant treatment with platinum-containing chemotherapy • Ingrezza™ (Valbenazine) *Indication:* Tardive dyskinesia *Comment:* Ingrezza 's monthly cost is ~12,660, keep non-preferred; grant approval through PA w/o a trial of formulary agents as it is the only FDA-approved medication for this diagnosis. • Kevzara® (sarilumab) *Indication:* Moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to one or more disease-modifying antirheumatic drugs (DMARDs) • Kisqali® (Ribociclib) *Indication:* in combination with an aromatase inhibitor as initial endocrine-based therapy for the treatment of postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative advanced or metastatic		

TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION	DATE DUE
H. New Drug Coverage Provisions/ Abbreviated Drug Reviews – Cont'd	H. Gross	breast cancer • Ocrevus™ (ocrelizumab) *Indication:* Relapsing multiple sclerosis (RMS) and primary progressive multiple sclerosis (PPMS) • Radicava™ (Edaravone) *Indication:* Amyotrophic lateral sclerosis (ALS) • Rhofade® (oxymetazoline) *Indication:* persistent facial erythema associated with rosacea in adults • Rydapt® (Midostaurin) *Indication:* Newly diagnosed acute myeloid leukemia (AML) that is FLT3+, in combination with standard cytarabine and daunorubicin induction and cytarabine consolidation *Indication:* Aggressive systemic mastocytosis (ASM), SM-AHN (systemic mastocytosis with an associated hematologic neoplasm) , or MCL (mantle cell lymphoma) • Siliq™(brodalumab) *Indication:* moderate to severe plaque psoriasis in adult patients who are candidates for systemic therapy or phototherapy and have failed to respond or have lost response to other systemic therapies • Tymlos™ (abaloparatide) *Indication:* Osteoporosis in postmenopausal women at high risk for fracture • Xadago®(safinamide) *Indication:* adjunctive treatment to levodopa/carbidopa in patients with Parkison's disease (PD) experiencing "off" episodes • Xermelo™ (telotristat ethyl) *Indication:* carcinoid syndrome diarrhea in combination with somatostatin analog (SSA) therapy in patients inadequately controlled by SSA therapy • Zejula™ (niraparib) *Indication:* recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who have had a complete or partial response to platinum-based chemotherapy The above listed presentation of new drugs with recommendations was		

TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION	DATE DUE
		approved with a motion from C. Kee, MD and a second from B. Tabaac, RPh. The motion carried without opposition.		
VI. Open Forum	All	The floor was opened for questions and discussions. There were no additional topics for discussion or review.	None	Complete
VII. Adjournment	All	H. Gross motioned to adjourn; the motion carried without opposition. There being no further business, the meeting adjourned at 6:28 pm.	None	N/A
VIII. Next Meeting	H. Gross	The next P&T Committee meeting is scheduled for 10/24/2017.	None	N/A

APPROVED: 11/1/2017



H. Gross, PharmD, Director of Pharmacy, Chair P&T

Eileen Carroll, RN, BSN; Scribe