Pharmacy and Therapeutics Committee (P&T)
Meeting Minutes

Date: **Time:** **Presiding:** **Location:**	**2/18/2020** **8:00am ET** **April Cox, PharmD, Director of Pharmacy (covering for Dr. Whyte)** **Stephanie Whyte, Deputy Chief Medical Officer** **Founders Building, University of Louisville Shelby Campus**	**Attendance:** April Cox, PharmD, Director of Pharmacy Ted Cummings, RPh, Sr. Director of Pharmacy Avril Anthony-Wilson, MD, Medical Director Mamata Majmundar, MD, Medical Director Lori Shook, MD, Medical Director Jenny Qiu, PharmD, Pharmacy Resident **Guest Attendance:** David Roy, Joe Joseph, John Minneci, John-Michael Moore, Keven Yoder, Glenn Belemjian **Absent:** Kelly Gannon, Director Clinical Health Services Stephanie Whyte, MD, Deputy Chief Medical Officer

* Nonvoting members

TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION
I. Call to Order	April Cox	Dr. Whyte called the meeting to order at 8:03am EST.	None
II. Review and Approval of Minutes	April Cox	Dr. Cox presented minutes from 10/30/19 meeting. Dr. Majmundar made a motion to approve, with a 2nd from Ted.	The P&T meeting minutes from 10/30/19 were approved as presented.
III. Old Business	April Cox	No old business to present.	None

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IV. New Business	April Cox		
A. New Molecular Entities	April Cox	**<u>New Drug Reviews</u>** The following new agents have been reviewed and are being recommended as NON-formulary as they are drugs that are expected to be covered as medical benefits based on the nature of their use and administration requirements. • **Wakix®** (Pitolisant 4.45mg, 17.8 mg) Tablet ○ **Indication**: The treatment of excessive daytime sleepiness (EDS) in adult patients with narcolepsy ○ **Efficacy**: The efficacy of pitolisant for the treatment of EDS was established in 2 placebo-controlled, active control trials of 8 weeks duration. In both trials, pitolisant significantly improved EDS measured according to the least-squares mean final Epworth Sleepiness Scale (ESS) used by patients to rate their perceived likelihood of falling asleep during usual daily life activities, with lower scores indicating less severe disease. Final mean ESS scores at week 8 were 12.4 (1.01 SE) and 15.5 (1.03) for pitolisant- and placebo-treated patients, respectively, with a significant subtracted difference of -3.1 (95% CI -5.73; -0.46) for study 1. Final mean ESS scores at week 8 were 13.3 (1.19) and 15.5 (1.32) for pitolisant- and placebo-treated patients, respectively, with a significant subtracted difference of -2.2 (95% CI -4.17; -0.22) for study 2. ○ **Proposal**: Non-preferred ○ **Place in Therapy and Pharmacy Formulary Alternatives:** Based on the American Academy of Sleep Medicine Report (2008), modafinil, amphetamine, methamphetamine, dextroamphetamine, and methylphenidate are preferred options for the therapy of hypersomnia of central origin. All are available on the formulary. • **Aklief (trifarotene 0.005%)** Cream ○ **Indication:** topical treatment of acne vulgaris in patients 9 years of age and older ○ **Efficacy:** The efficacy of Aklief Cream is supported by data from the two pivotal Phase 3 clinical trials of once-daily Aklief Cream in patients with moderate acne on the face and trunk. The two identical 12-week,	New Molecular Entities were approved as presented.

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		randomized, multicenter, parallel group, double-blind, vehicle-controlled clinical trials of 2,420 patients showed that Aklief Cream significantly reduced inflammatory lesions as early as two weeks on the face and four weeks on the back, shoulders and chest compared to vehicle ($p<0.05$). Aklief Cream was well tolerated when used on the face, back, shoulders and chest. The most common adverse reactions (incidence >1%) included application site irritation, application site pruritus (itching) and sunburn. ○ **Proposal: Non-preffered** ○ **Place in Therapy and Pharmacy Formulary Alternatives:** 2016 American Academy of Dermatology acne treatment guidelines, the first line treatments are topical retinoids and topical antimicrobials. Formulary drugs: Adapalene cream 0.1% and Benzoyl peroxide gel 10%. • **Beovu** (brolucizumab 6mg/0.95mL) Solution for Injection® ○ **Indication:** Exudative age-related macular degeneration (AMD) ○ **Efficacy:** The safety and efficacy of Beovu were assessed in two randomized, multi-center, double-masked, active-controlled studies in 1817 patients with neovascular AMD. Patients were treated for two years (1088 on Beovu and 729 on control). . Approximately half of the patients were treated with Beovu and the other half with aflibercept (an approved drug for wet AMD treatment) for two years. Both studies demonstrated efficacy in the primary endpoint defined as the change from baseline in Best Corrected Visual Acuity (BCVA) at Week 48, measured by the Early Treatment Diabetic Retinopathy Study (ETDRS) Letter Score. In both studies, Beovu treated patients had a similar mean change from baseline in BCVA as the patients treated with aflibercept 2 mg (fixed every 8 weeks ○ **Proposal: Non-preffered** ○ **Place in Therapy and Pharmacy Formulary Alternatives:** There is a medical clinical policy bulletin on VEGF inhibitors and the treatment of AMD. Aetna considers aflibercept (Eylea), bevacizumab (Avastin), pegaptanib (Macugen), and ranibizumab (Lucentis) medically necessary for those members who meet the precertification criteria. Review Beovu for medical necessity.	

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		• **Adakeveo (crizanlizumab-tmca 10mg/1mL) Intravenous Solution** ○ **Indication:** Reduce the frequency of vasoocclusive crises in adults and pediatric patients aged 16 years and older with sickle cell disease ○ **Efficacy:** The efficacy of Adakeveo was evaluated in patients with sickle cell disease in SUSTAIN [NCT01895361], a 52-week, randomized, multicenter, placebo-controlled, double-blind study. Patients were randomized 1:1:1 to Adakeveo 5 mg/kg (N = 67), Adakeveo 2.5 mg/kg (N = 66), or placebo (N = 65) administered over a period of 30 minutes by intravenous infusion for 52 weeks. Efficacy was evaluated in the SUSTAIN study by the annual rate of VOCs leading to a healthcare visit. Patients with sickle cell disease who received Adakeveo 5 mg/kg had a lower median annual rate of VOC compared to patients who received placebo (1.63 vs. 2.98) which was statistically significant (p = 0.010). Reductions in the frequency of VOCs were observed among patients regardless of sickle cell disease genotype and/or hydroxyurea use. ○ **Proposal: Non-preffered** ○ **Place in Therapy and Pharmacy Formulary Alternatives:** Based on the 2014 "Evidence-Based Management of Sickle Cell Disease," Hydroxyurea and L-glutamine are first line agents. Drug names are available on the formulary. • **Givlaari (givosiran 189mg/mL) Solution for Injection** ○ **Indication:** adults with acute hepatic porphyria (AHP) ○ **Efficacy:** The efficacy was based on a Phase 3, randomized, double-blind, placebo-controlled, multinational study enrolled 94 patients with AHP at 36 study sites in 18 countries. 48 patients received 2.5 mg/kg Givlaari and 46 patients received placebo, administered once monthly via subcutaneous injection for up to 6 months. Patients received Givlaari for a median of 5.5 months (range 2.7-6.4 months). Efficacy in the 6-month double-blind period was measured by the rate of porphyria attacks that required hospitalizations, urgent healthcare visit, or intravenous hemin administration at home. Patients treated with Givlaari had 70% fewer porphyria attacks compared to those on placebo.	

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		○ **Proposal: Non-preferred** ○ **Place in Therapy and Pharmacy Formulary Alternatives:** The drug of choice for AHP is Hemin (panhematin), align Givlaari with PA guideline. • **Oxbryta® (voxelotor 500 mg) tabs** ○ **Indication:** Treatment of sickle cell disease in adults and pediatric patients 12 years of age and older. ○ **Efficacy:** Efficacy was evaluated in a randomized, double-blind, placebo-controlled, multicenter trial. In the study 274 patients were randomized to receive Oxbryta® or placebo. Approximately two-thirds were already receiving hydroxyurea. Efficacy was based on hemoglobin (Hb) response rate defined as a Hb increase of > 1 g/dL from baseline to Week 24. The response rate for Oxbryta® was 51.1% (46/90) compared to 6.5% (6/92) in the placebo group ($p < 0.001$). Oxbryta® had a statistically significant effect compared to placebo on additional efficacy points including change in Hb indirect bilirubin and percent reticulocyte count from baseline to Week 24. ○ **Proposal: Non-Preferred** ○ **Place in Therapy and Pharmacy Formulary Alternatives:** Glutamine/L-Glutamine Caps; Hydroxyurea caps on formulary ○ Hydroxyurea is the mainstay therapy for treatment of sickle cell disease. Patients with persistent vaso-occlusive complications despite hydroxyurea may benefit from L-glutamine or other agents. • **Vumerity® (diroximel fumarate 231 mg) caps** ○ **Indication:** Treatment of relapsing forms of multiple sclerosis (MS), to include clinically isolated syndrome, relapsing-remitting disease, and active secondary progressive disease, in adults ○ **Efficacy**: Clinical trials were conducted using dimethyl fumarate delayed-release capsules, which has the same active metabolite as Vumerity®. Efficacy was demonstrated in two studies. Both studies were a 2-year randomized, double-blind, placebo-controlled studies. In Study 1 patients received dimethyl fumarate twice daily or three times daily, or placebo. In Study 2 patients received dimethyl fumarate twice daily or	

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		three times daily, an open-label comparator, or placebo. The primary endpoint for Study 1 was the proportion of patients relapsed at 2 years and for Study 2 was the annualized relapse rate at 2 years. Both studies demonstrated that dimethyl fumarate had a statistically significant effect on the primary endpoints for relapse compared to placebo ($p<0.001$). Both studies showed that three times daily dosing of dimethyl fumarate offered no additional benefit over twice daily dosing of dimethyl fumarate. ○ **Proposal:** Non-preferred ○ **Place in Therapy and Pharmacy Formulary:** Tecfidera® (dimethyl fumarate) on formulary • **Pretomanid® 200mg tabs** ○ **Indication:** Indicated as part of a combination regimen with bedaquiline and linezolid for the treatment of adults with pulmonary extensively drug resistant (XDR),treatment-intolerant or nonresponsive multidrug-resistant (MDR) tuberculosis (TB) ○ **Efficacy:** Study 1 was an open-label study conducted in South Africa in patients with XDR, treatment-intolerant MDR, or non-responsive MDR pulmonary TB. Patients received a combination regimen of Pretomanid, bedaquiline, and linezolid for 6 months (extended to 9 months in 2 patients) with 24 months of follow-up. Of the 107 patients assessed, outcomes were classified as success for 95 (89%) patients and failure for 12 (11%) patients. Treatment failure was defined as the incidence of bacteriologic failure (reinfection – culture conversion to positive status with different M.tuberculosis strain), bacteriological relapse (culture conversion to positive status with same M.tuberculosis strain), or clinical failure through follow-up. Treatment success was defined as culture negative status at 6 months post treatment. ○ **Proposal:** Non-Preferred ○ **Place in Therapy and Pharmacy Formulary Alternatives:** Isoniazid tabs; Rifampin caps; Pyrazinamide tabs; Ethambutol tabs on formulary Isoniazid, rifampin, pyrazinamide, and ethambutol are first-line agents used to treat active susceptible TB. Patients with MDR-TB or XDR-TB are	

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		typically administered at least five drugs comprised of susceptible first-line drugs if any, a fluoroquinolone, bedaquiline, linezolid, and additional oral agents (et. clofazimine, cycloserine, terizidone). • **Trikafta®** (elexacaftor 100mg/tezacaftor 50 mg /ivacaftor 75mg) tabs ○ **Indication:** Treatment of cystic fibrosis (CF) in patients aged 12 years and older who have at least one F508del mutation in the CFTR gene. ○ **Efficacy:** Efficacy was evaluated in two Phase 3, double blind, controlled trials (Trials 1 and 2). Trial 1 was a 24-week trial where patients received Trikafta® or placebo. Trial 2 was a 4-week trial where patients received tezacaftor/ivacaftor during a 4 week run-in period and then Trikafta® or tezacaftor/ivacaftor for a 4 week treatment period. For Trial 1 the primary endpoint assessed at the time of interim analysis was mean absolute change in ppFEV1 from baseline at Week 4. The final analysis for Trial 1 tested all key secondary endpoints. For Trial 2 the primary endpoint was mean absolute change in ppFEV1 from baseline at Week 4. Trial 1 and Trial 2 demonstrated that Trikafta®had a statistically significant treatment difference compared to placebo and tezacaftor/ivacaftor, respectively, for all primary and secondary endpoints (p <0.0001). ○ **Proposal:** Non-Preferred ○ **Place in Therapy and Pharmacy Formulary Alternatives:** Orkambi® (lumacaftor/ivacaftor) tabs is the preferred agent Symdeko® (tezacaftor/ivacaftor) tabs; Kalydeco® (ivacaftor) tabs are non-formulary Orkambi® is for patients 2 years and older who are homozygous for F508 del mutation. Symdeko® is for patients 6 years and older who are homozygous for F508 del mutation. Ivacaftor is for patients 6 months and older who have one mutation in the CFTR gene that is responsive to ivacaftor. **Question: No questions**	

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B. New Generics	April Cox	<u>New Generic Report</u> The following New Generics were released to market since the previous P&T. Clinical Subcommittee approved the following formulary placement on the Standard Core Formulary and each Plan Formulary where permitted by state regulations, based on their ability to add clinical value to our members. <u>Formulary Change Proposals- New Generics added in the previous quarter</u> • EVEROLIMUS TAB(PA,QL) • ETHINYL ESTRADIOL/ETONOGESTREL 0.015/0.12MG RING(QL) • IVERMECTIN CREAM 1% (NP) • PSSE-GUAIFEN TAB 60-375MG (NP) • DEFERASIROX TAB (NP) • ISOSORBIDE DINITRATE 40MG TAB (NP) • CHLORZOXAZONE 375MG, 750MG TABLETS (NP) • TRAVOPROST 0.004% (NP) <u>New Biosimilars</u> The following New Biosimilars were released to market since the previous P&T. Clinical Subcommittee approved the following formulary placement on the Standard Core Formulary and each Plan Formulary where permitted by state regulations, based on their ability to add clinical value to our members. • OGIVRI INJECTION (NP) • ZIEXTENZO INJECTION (NP) **Questions:** None	New Generics were approved as presented.

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C. Drug Class Reviews	April Cox	**Drug Class Reviews** **Drug classes that underwent review *WITHOUT* formulary change recommendations:** • CHELATING AGENTS FOR WILSON'S • CHELATING AGENTS FOR IRON OVERLOAD • ANTIFUNGALS (ORAL) • INFLUENZA • VISCOSUPPLEMENTS • PROGESTINS • ANTITUSSIVES • ANTHELMINTICS **Drug classes that underwent review *WITH* formulary change recommendations:** The following drug classes were reviewed for clinical efficacy, safety and according to national treatment guideline recommendations associated with the conditions treated with these agents. • **Corticosteroids (Systemic)** **Background:** o Annual Review o Steroids are equivalent anti-inflammatories and have similar side effects but differ in potency o Short-acting products like hydrocortisone are the least potent. Prednisone and methylprednisolone, which are intermediate-acting products, are 4-5 times more potent. Dexamethasone is long-acting; its potency is about 25 times greater than short-acting products. **Current Formulary Status:** o **Preferred Products:** Cortisone tab, dexamethasone tab and solution, hydrocortisone tab, methylprednisolone tab, prednisolone syrup, prednisone tab o **Non-Preferred Products:** Budesonide, Emflaza (deflazacort), dexamethasone vials, dexamethasone conc solution, Solu-Cortef vials (hydrocortisone), methylprednisolone vials **Recommended Changes:**	

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		○ **ADD Dexamethasone and Solu-Cortef Vials** ▪ Recommended for patients with adrenal insufficiency to have on hand for adrenal crisis ○ **ADD Dexamethasone Concentrate Solution** • **Tracked as SAI : No** • **<u>Hyperlipidemia</u>** **Background:** ○ Annual review ○ The 2013 ACC/AHA Guideline recommend statins as the first line treatment because of their proven record for both primary and secondary prevention of ASCVD in high risk persons ○ When there is a lower than expected reduction in LDL or statin intolerance, non-statin therapy may be considered (ezetimibe recommended first). However, monotherapy with a non-statin drug, or adding a non-statin to a statin therapy has demonstrated no evidence in reducing ASCVD outcomes. **Current Formulary Status:** ○ **Preferred Products:** Colestipol, cholestyramine, atorvastatin, lovastatin, pravastatin, simvastatin, fluvastatin IR, fenofibrate, gemfibrozil, fish oil, generic slo-niacin, ezetimibe (ST req'd), rosuvastatin (ST req'd) ○ **Non-Preferred Products:** Ezetimibe/simvastatin, Vascepa (icosapent ethyl), colesevelam, Livalo (pitavastatin), fluvastatin ER, Niacin ER, Repatha (evolocumab), Praluent (alirocumab) **Recommended Changes:** ○ **ADD ST Requirement to Fluvastatin IR through any 2 preferred statins** ▪ Other preferred statins are more cost-effective ($0.06-0.47/day vs. $3.80-6.27/day) ▪ Low potency statin ▪ Low utilization (6 members) • **Tracked as SAI : No** • **<u>Antihypertensives</u>** **Background:** ○ Annual Review	

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		○ Several National Treatment Guidelines with slight variations between their recommendations: Eight Joint National Committee (JNC8), American College of Cardiology/American Heart Association (ACC/AHA) and International Society of Hypertension (ISH). ○ 2017 ACC/AHA recommends thiazides (chlorthalidone preferred due to duration of action and positive outcomes data), CCB, ACEI, or ARBs as first-line for those without a compelling indication ○ 2014 JNC8 recommends a thiazide, CCB, ACEI, or ARB as first-line for nonblack individuals and a thiazide or CCB for black individuals ○ Antihypertensives primarily used to control blood pressure to prevent further cardiac disease and stroke are also used for anxiety, angina, migraine prophylaxis, and arrythmias, and a variety of other uses depending on the agent. The breadth of their use was outside the scope of the clinical review but the recommended agents for the common non-hypertensive uses are also represented on the formulary. **Current Formulary Status:** ○ **Preferred Products:** Perindopril, trandolapril, benazepril, enalapril, fosinopril, lisinopril, quina pril, ramipril, labetalol, carvedilol IR, acebutolol, atenolol, metoprolol IR and ER, bisoprolol, propranolol, sotalol, timolol, candesartan, irbesartan, losartan, telmisartan, valsartan, isradipine, nicardipine, nifedipine, nimodipine, amlodipine, diltiazem IR/ER/CD/XR, felodipine, nifedipine, verapamil, methyldopa, clonidine IR, guanfacine IR, clonidine patch (ST req'd), hydralazine, minoxidil, atenolol/chlortalidone, bisoprolol/HCTZ, fosinopril/HCTZ, metoprolol/HCTZ, amlodipine/benazepril, amlodipine/valsartan, benazepril/HCTZ, candesartan/HCTZ, enalapril/HCTZ, irbesartan/HCTZ, lisinopril/HCTZ, losartan/HCTZ, quinapril/HCTZ, valsartan/HCTZ ○ **Non-Preferred Products:** Captopril, moexipril, Epaned (enalapril), Qbrelis (lisinopril), carvedilol ER, betaxolol, Bystolic (nebivolol), nadolol, pindolol, Edarbi (azilsartan), eprosartan, olmesartan, aliskiren, Katerzia susp (amlodipine), nisoldipine, amlodipine/valsartan/HCTZ, amlodipine/olmesartan, captopril/HCTZ, amlodipine/Olmesartan/HCTZ, Olmesartan/HCTZ, telmisartan/amlodipine, telmisartan/HCTZ **Recommended Changes:** ○ **ADD ST** requirement to candesartan and candesartan combinations through 2 preferred ARBs	

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		▪ Other preferred ARB's are more cost effective ○ **REMOVE Nimodipine** ▪ GF = Y ▪ More cost-effective products available for HTN and migraine prophylaxis. ▪ It does have unique indication for subarachnoid hemorrhage, but claims do no appear to match the dosing/duration for this indication ▪ Low utilization (2 members) **Tracked as SAI : No** • **<u>Nasal Antiallergy</u>** **Background:** ○ Annual Review ○ American Academy of Otolaryngology-Head and Neck Surgery Foundation (AAO-HNS) Guideline recommends nasal steroids or antihistamines as first-line ○ Combination therapy may be prescribed for patients who have inadequate response to monotherapy. The most effective combination therapy is a nasal steroid + antihistamine. **Current Formulary Status:** ○ **Preferred Products:** Rhinocort OTC (budesonide), flunisolide, fluticasone Rx and OTC, mometasone, Nasacort OTC (triamcinolone), ipratropium, azelastine 0.1%, cromolyn ○ **Non-Preferred Products:** Beclomethasone, Omnaris (ciclesonide), Flonase Sensimist, azelastine 0.15%, olopatadine **Recommended Changes:** ○ **ADD ST requirement to flunisolide through 2 preferred nasal steroids** ▪ Other preferred nasal steroids are more cost effective ▪ Less convenient (2 sprays in each nostril twice a day) ▪ Associated with more burning and nasal irritation **Tracked as SAI : No** • **<u>Cystic Fibrosis</u>**	

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		Background: ○ Annual Review ○ National Treatment Guideline recommendations: ○ Inhaled Tobramycin in patients 6 years of age and older, with moderate to severe lung disease and Pseudomonas aeruginosa persistently present in cultures of the airways ○ Pulmozyme in patients 6 years of age and older, with moderate to severe lung disease ○ CTFR modulators in patients with appropriate mutations **Current Formulary Status:** ○ **Preferred Products:** Kitabis (PA req'd), tobramycin nebs (PA req'd), Pulmozyme (PA req'd with smart PA for members >5 with CF diagnosis) ○ **Non-Preferred Products:** Tobi Podhahler and nebs, Bethkis, Kalydeco, Orkambi, Symdeko, Trikafta **Recommended Changes:** ○ **ADD Orkambi with PA** ▪ Most cost-effective CTFR modulator and indicated in 2 years and up ○ **REMOVE Kitabis** ▪ Generic tobramycin nebs are more cost-effective **Tracked as SAI : No** • **<u>Antipsychotics</u>** **Background:** ○ Antipsychotics, particularly the second generation or Atypical agents are accepted therapies for schizophrenia. Bipolar I disorder, Adjunct for Major Depressive Disorder or treatment resistant depression, Tourette's, and irritability/aggression associated with autism disorder. **Current Formulary Status:** ○ **Preferred Products:** ▪ 1st Generation: haloperidol (tab, soln, IM), clozapine tabs, loxapine cap, fluphenazine IM, perphenazine tab, prochlorperazine (susp and tab), thioridazine tabs, trifluoperazone tabs, thiothixene caps	

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		▪ 2nd Generation: risperidone (tab, soln, ODT, IM), quetiapine tabs, olanzapine (tabs, ODT), ziprasidone cap, paliperidone IM, aripiprazole IM **Recommended Changes:** ○ **ADD aripiprazole tablets; min age of 6 years and standard dose QL** ▪ Often the preferred drug in its class for its tolerability and side effect profile, there is a high utilization and request volume for this product despite its non-formulary status. Price point for the generic tablets has aligned with other generic offerings since the last review. ▪ Will **NOT** add the ODT or solution formulation **Tracked as SAI : No** **Questions:** *Drug reps representing Trikafta had many items they wanted to speak on regarding formulary placement of Trikafta. Ted reminded them that they have to submit request to speak prior to meeting.*	
D. Misc/Formulary Updates	April Cox	<u>Formulary Update Summary</u> The following formulary modification is being presented as a potential SAI. Complete clinical write up for this proposal has been provided as part of the complete meeting materials. • **<u>Lidocaine 5% QL</u>** **Background:** ○ Reason for review: Utilization assessment due to potential for FWA. ○ Product packaged as 30gm or 35.44gm tube or 50gm tub. ○ Lidocaine Ointment 5% is indicated for production of anesthesia of accessible mucous membranes of the oropharynx, anesthetic lubricant for intubation and for the temporary relief of pain associated with minor burns, including sunburn, skin abrasions, and insect bites. ○ Lidocaine 3% and 4% have similar temporary pain relief indications. ○ Single dose should not exceed 5gm with maximum daily dose of 20gm. ○ Excessive dosage or short intervals between doses can result in high plasma levels and serious adverse effects. **Current Formulary Status:**	

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		○ Lidocaine 5% PA and QL 90gm/30 days **Recommended Changes:** ○ Reduce lidocaine 5% QL from 90gm to 50gm per 30 days. No GF **Tracked as SAI : Yes** • **<u>Topical Acne Antibiotics QL</u>** **Background:** ○ Reason for review: Noted utilization management class outliers with potential for FWA ○ Per the American Academy of Dermatology, benzoyl peroxide alone or in combination with topical antibiotics (erythromycin or clindamycin) are effective acne treatments for mild acne. ○ Topical antibiotics monotherapy is not recommended due to risk of bacterial resistance. ○ Limited evidence to support recommendations for topical sulfacetamide in the treatment of acne, but there is some evidence to suggest its efficacy. **Current Formulary Status:** ○ **Preferred Products:** Clindamycin 1% gel, lotion, solution, pad; Erythromycin 2% gel, solution, pad; Sulfacetamide 10% lotion **Recommended Changes:** ○ Add QL of 30g/30 days to clindamycin gel and erythromycin gel. No GF ○ Add QL of 60mL/30 days to clindamycin (lotion, solution), erythromycin solution. No GF ○ Add QL 60 each/30 days to clindamycin pads and erythromycin pads. GF, low utilization ○ Add QL 118 mL/30 days to sulfacetamide lotion. GF, low utilization **Tracked as SAI :** Yes (QL Clindamycin gel, lotion, solution, Erythromycin gel) <u>MCA OTC Wrap</u> The MCA OTC Wrap list was reviewed for clinical efficacy, safety and according to national treatment guideline recommendations associated with the conditions treated with these agents.	

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		Background: ○ MCA OTC Wrap list shared between Mercy Care Plan, ABHNJ, ABHMI, ABHKY ○ This list is utilized in dual eligible members who have Medicare as primary though other MCOs and Medicaid through Aetna **Recommended Changes:** ○ **Remove:** ▪ ENEMEEZ MINI ENEMEA ▪ PEG 3350 POW ▪ Ferrous Sulfate 300/5ml ▪ Diphenhydramine Liquid 6.25mg ▪ Sodium Powder Bicarbonate Powder ▪ Senokot Extra tab 17.2mg ▪ Konsyl /Psyllium Daily Powder 100% ○ **Add** ▪ FERROUS FUMARATE—Cost/rx: $8.80 ▪ GLYCERIN (LAXATIVE)-cost/rx: $7.79 ▪ LOPERAMIDE HCL-cost/rx: $7.29 ▪ PEDIATRIC MULTIPLE VITAMIN W/ MINERALS & C-cost/rx: $2.68 ▪ PSEUDOEPHEDRINE HCL-cost/rx: $6.88 ▪ SODIUM PHOSPHATES-average cost/rx: $14.94 ▪ ZINC OXIDE (TOPICAL)-average cost/rx: $8.01 **Questions:** *Will these drugs be removed from the standard Medicaid formulary?*	
E. 1Q Coverage Guideline/Criteria Reviews	April Cox	Summary of Guideline Reviews All coverage guidelines are provided in the meeting materials in their entirety. Guidelines are reviewed at least annually for clinical appropriateness against national treatment recommendations/guidelines as applicable for topic at hand and the current formulary status of the drug/drug classes. **The following Guidelines were reviewed and were approved by the workgroup and Subcommittee as having no substantive changes. Updates may have included clarifications in wording, references or formatting. There is no change in to the**	

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		intended scope of coverage or criteria for approval since the previously approved version. • Antidepressants Non-Preferred • Hetlioz • Lidocaine 5% Ointment- QLL updated per SAI • Lidocaine Patch • Makena Auto-Injector/Hydroxyprogesterone caproate injection • Non-stimulant ADHD Medications • PCSK9 Inhibitors • Xifaxan **The following Guidelines have been reviewed and updates are being recommended based on clinical evidence, changes in treatment recommendations and/or other related or comparable products available in the market.** • **Afinitor / Afinitor Disperz everolimus** o Updated age exception for the disperz formulation to include Subependymal Giant Cell Carcinoma (SEGA) and Tuberous Sclerosis Complex associated partial onset seizures o For breast cancer, in addition to member being post-menopausal, added criteria per NCCN for pre-menopausal women who are being treated with ovarian ablation/suppression AND for male status o For indications of Waldenstrom Macro-globulinemia – Lymphoplasmacytic Lymphoma, AND Classical Hodgkin's Lymphoma, added specific example of 1st line chemotherapy regimens per NCCN o Added indication for Thyroid Carcinoma per NCCN, w/criteria for locally advanced or metastatic disease AND w/diagnosis being either follicular, Hürthle cell or papillary carcinoma o For indication of Thymomas and Thymic Carcinomas, added examples of 1st line chemotherapy regimens per NCCN o Added indication of endometrial Carcinoma w/criteria to be used in combination w/letrozole o Added indication of Meningioma w/criteria for disease being recurrent or progressive AND surgery or radiation is not possible. o Under disperz tablets for oral suspension, for SEGA associated w/Tuberous Sclerosis Complex, added age criteria of 1 year or older	

TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION
		○ Added new indication for Tuberous Sclerosis Complex associated w/Partial Onset Seizures, w/criteria for age of 2 years or older AND treatment is adjunctive w/an anti-epileptic medication • **Anthelminitics** ○ Under albendazole for roundworm, added ascariasis and toxocariasis as only albendazole and mebendazole are drugs of choice per the CDC ○ Added Bayliscariasis, as only albendazole is indicated for Drug of Choice per the CDC ○ Dosing for Toxocariasis was added for direction • **Atypical Antipsychotics – Oral & Long-Acting Injectables** ○ Added oral aripiprazole as formulary agent ○ Updated QLL for Zyprexa Relprevv ○ For Long-Acting Injectable: Updated language to include the high risk non-adherent patient • **Bonjesta Diclegis** ○ Added generic doxylamine succinate and pyridoxine hydrochloride to list of drugs ○ Took out required documentation for use of individual OTC products ○ For Bonjesta, added requirement of insufficient treatment response to generic prescription doxylamine succinate and pyridoxine hydrochloride ○ For renewals, added documentation that member is still pregnant and continues to have symptoms of N/V • **CNS Stimulants (ADD-ADHD Stimulants)** ○ Added that member must meet DSM5 criteria for ADHD diagnosis for each age group rather than adults only ○ Added new drugs to list (Dyanavel XR, Mydayis, Adhansia XR, Jornay PM, Dyanavel XR, Mydayis, Aptensio XR, Contempla XR-ODT) ○ Removed “Swanson, Nolan, Pelham-IV Questionnaire (SNAP-IV)” as an example under adult ADHD ○ Added evidenced based behavioral therapies as treatment option for those 12 – 18 yoa ○ Amended age for BED to be adults aged 18 or older rather than just those 18 to 55 ○ Added approval durations for idiopathic hypersomnia and fatigue related to multiple sclerosis or cancer	

TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION
		• **Corlanor** o Added new indication for Pediatric members that are 6 months of age or older and have HF d/t dilated cardiomyopathy • **Cystic Fibrosis** o Added new criteria for Trikafta o Updated criteria based on formulary updates: ▪ Added requirement of previous use of Orkambi for Symdeko and Trikafta depending if member is homozygous for the F508del mutation ▪ Kitabis was removed as a trial requirement for tobramycin nebulizer solution, Tobi Podhaler and Bethkis o Added the requirement of medical records for all cystic fibrosis medications • **Cytokine/CAM Antagonists** o Updated Rheumatoid Arthritis trial and failure criteria to only include MTX, rather than 2 non-biologic DMARDs. o Added criteria that medication will be used concurrently with MTX or another non-biologic DMARD such as LEF, SSZ, or HCQ. o For oligoarticular juvenile idiopathic arthritis, updated criteria that if member has intolerance or C/I to MTX, then a documented trial of SSZ or LEF for 3 months is required o Updated Ulcerative Colitis criteria for Steroid Dependency and Steroid Refractory by no longer requiring T/F with azathioprine or mercaptopurine ▪ Also, under Steroid Refractory, T/F w/cyclosporine will no longer be required o Initial and renewal requests were updated to 6 months each o Updated renewal requirement to require documentation indicating member has shown improvement in the signs and symptoms of disease. o Throughout the GL, for indications that only require NF agents, it was clarified that member is not required to have a T/F with formulary agent first. o Updated Familial Mediterranean Fever indication by adding claims history review to support compliance or adherence at maximum dose to colchicine.	

TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION
		○ Added new medication Skyrizi for Plaque Psoriasis indication ○ Kept criteria for Plaque Psoriasis as is, with regards to use of either MTX or cyclosporine for 3 months ○ Added Stelara for Ulcerative Colitis indication • **Direct Renin Inhibitors** ○ Added generic aliskiren to list of medications ○ Combined criteria for members 6 years of age or older as same for adults per the Am College of Cardiology and the Am Heart Association ○ Added criteria for oral pellet use for members that are unable to swallow tablets ○ Eliminated criteria to not be used w/ACEI; this drug-drug interaction will be placed on the DUR list ○ Updated renewal criteria to require member is not pregnant ○ Updated renewal approvals from 1 year to 6 months and removed quantity limits to meet auto ePA approvability • **Egrifta** ○ Added criteria for women of childbearing potential that they are not pregnant, and they are using appropriate contraception ○ Added member should not have pituitary gland disruption or head trauma before starting the treatment • **Emflaza** ○ Now indicated for members 2 years and older ○ Removed tuberculosis as a specific callout under active infection section • **Entresto** ○ Added indication for pediatric patient with symptomatic heart failure and requirement to first use enalapril ○ Added QLL for the 24/26mg tablet for pediatric members to achieve 72/78mg dose • **Epidiolex** ○ Removed requirement that member has had 8 drop seizures in the previous month while stable on antiepileptic therapy ○ Removed requirement that member has had 4 convulsive seizures in the previous month while stable on antiepileptic therapy ○ Documentation now required for medication trials • **Estradiol (Premarin) Vaginal Cream**	

TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION
		○ Updated initial and renewal approvals to 6 months each as recommending for ePA approvability • **Griseofulvin** ○ All durations now 6 months to allow for ePA approval • **Hepatitis C** ○ Ribasphere is no longer available on the market; listed ribavirin 200 mg tabs and caps as the formulary available products ○ Added the following language: sofosbuvir/velpatasvir will be authorized for treatment-naïve and treatment-experienced members, with decompensated cirrhosis (Child-Pugh B and C) in combination with ribavirin for a duration of 12 weeks • **Intravaginal Progesterone** ○ Updated timeframe for history of preterm birth to 34 weeks from 37 • **Juxtapid** ○ Removed Kynamro as no longer available on Market ○ Added criteria for Juxtapid to be used as adjunct to low fat diet and exercise ○ Deleted documentation under diagnosis ○ Deleted criteria to not be used w/concurrent use w/PCSK9; this drug-drug interaction will be placed on the DUR list ○ For renewals, added criteria that member is continuing the low-fat diet and exercise regimen ○ For renewals, also added females of reproductive potential are currently using contraception • **Korlym** ○ Updated criteria to include prescribed by or in consult w/endocrinologist ○ Deleted criteria that member is not on concurrent hormonal contraception or simvastatin or lovastatin or CYP 3A substrates; this drug-drug interaction will be placed on the DUR list • **Monoamine Depletors** ○ Added documentation of the type and duration of the atypical antipsychotic used for Tardive Dyskinesia, for both Ingrezza and Austedo • **Multaq**	

TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION
		○ Added that in addition to those included in guideline that prescriber attests member has no contraindications outlined in the prescribing information • **Multiple Sclerosis Agents** ○ Vumerity was added to guideline as non-preferred product; shares same criteria as Tecfidera ○ Mavenclad was added as non-preferred ▪ It is indicated for relapsing forms of MS but not for clinically Isolated Syndrome ▪ A baseline MRI scan is completed as there is risk of PML w/this drug ▪ Females of reproductive potential are not pregnant and will be using contraception during treatment ▪ Member does not have HIV or other active chronic infections or is breast feeding • **Oncology - general** ○ Hematologist, in addition to oncologist, added as a provider ○ Added the language: If a test with adequate ability to confirm a disease mutation exists, documentation that the test was performed to confirm the mutation; documentation has been provided of the results of required genetic testing where required per the drug package insert) • **Otezla** ○ ○ Deleted criteria to not use in combination with targeted synthetic DMARDs, Biologic DMARDs, and Anti-TNF antagonists; this drug-drug interaction will be placed on the DUR list ○ Updated for new diagnosis for treating oral ulcers associated w/Behçet's disease ▪ Member has disease with active recurrent oral ulcers ▪ Treatment is for adult members ▪ It can be prescribed by, or in consultation with a rheumatologist, dermatologist, or another specialist, due to also other manifestations in the body ▪ Previous trial and failure with a non-biologic DMARD such as MTX, LEF, SSZ, or HCQ	

TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION
		• **Tranexamic Acid** o Removed criteria indicating member is not on concurrent combination hormonal contraception; this drug-drug interaction will be placed on the DUR list **<u>New Guideline Review</u>** **The following Guidelines have been reviewed and updates are being recommended based on clinical evidence, changes in treatment recommendations and/or other related or comparable products available in the market.** **<u>Cablivi</u>** • **Member meets all the following criteria:** o Age is 18 years or older o Medication is prescribed by, or in consultation with a hematologist o Diagnosis is for acquired thrombotic thrombocytopenic purpura (aTTP) o Diagnosis is confirmed by one of the following: ▪ Member has severe thrombocytopenia with microangiopathic hemolytic anemia (MAHA), confirmed by red blood cell fragmentation on peripheral blood smear For example, schistocytes ▪ Testing shows ADAMTS13 activity levels of less than 10% o Medication will be given in combination with plasma exchange and immunosuppressive therapy ▪ For example, systemic glucocorticoids, rituximab o Cablivi will be discontinued if member experiences more than 2 recurrences of aTTP while on treatment with Cablivi o **<u>Initial Approval:</u>** 30 days o **<u>Renewal Approval:</u>** 28 days ▪ Requires: Additional therapy up to a maximum of 28 additional days will be considered when provider submits the following: • Documentation of remaining signs of persistent underlying disease o For example, suppressed ADAMTS13 activity levels	

TOPIC FOR DISCUSSION	SPEAKER	DISCUSSION	ACTION
		• Documentation date of prior episode and date of new episode • Medication will be given in combination with plasma exchange and immunosuppressive therapy o For example, systemic glucocorticoids, rituximab • Member has not experienced more than 2 recurrences while on Cablivi o **Quantity Level Limit:**Total treatment duration per episode is limited to 58 days beyond last therapeutic plasma exchange **Questions**: None	
V. Adjournment	Stephanie Whyte	Motion to adjourn by Ted. Meeting adjourned at 8:41am EST.	None
VI. Next Meeting		**Future Meeting:** **2Q2020: April 28, 2020** **3Q2020: July 28, 2020** **4Q2020: October 27, 2020**	None

APPROVED:

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Stephanie Whyte, MD; Committee Chair

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April Cox, PharmD; Scribe