**Pharmacy and Therapeutics (P&T) Committee Meeting Record**

**Date:** Friday, May 20, 2016

**Time:** 9:00 a.m. – 3:30 p.m. **Location:** Idaho Medicaid, 3232 Elder Street, Boise, Idaho, Conference Room D

**Moderator:** Phil Petersen, M.D.

**Committee Members Present:** Phil Petersen, MD-Chair; Tami Eide, PharmD; Brian Crownover, MD; Cali Bradberry, PA; Christopher Streeter, MD; Kevin Ellis, PharmD; Leigh Morse, MD; Mark Turner, MD; Stephen Carlson, PharmD, Perry Brown, MD

**Committee Members Absent:** Alex Adams, PharmD; David Calley, PharmD

**Others Present**: Richard Pope, PharmD, Magellan Health Services; Mark England, PharmD, Magellan Medicaid Administration; Chris Johnson, PharmD, Division of Medicaid; Jane Gennrich, PharmD, Division of Medicaid; Wendy Estrellado, Division of Medicaid

| AGENDA ITEMS | PRESENTER | OUTCOME/ACTIONS |
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| *CALL TO ORDER* | *Phil Petersen, MD* | *Dr. Petersen called the meeting to order.* |
| **Committee Business** | | |
| ➢ *Roll Call* | *Phil Petersen, MD* | Dr. Petersen completed the roll call and welcomed the P&T Committee members. |
| ➢ *Reading of Confidentiality and Mission Statements* | *Phil Petersen, MD* | Dr. Petersen read the Confidentiality and Mission Statements. |
| ➢ *Approval of Minutes from April 15, 2016 Meeting* | *Phil Petersen, MD* | The April 15, 2016 meeting minutes were reviewed. The minutes were accepted as proposed. |

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| ➢ *DERP Update* | *Tami Eide, PharmD* | **DERP Update**<br>Dr. Eide did not have a DERP update this meeting. |
| ➢ *Overview of CDC Guidelines for Prescribing Opioids for Chronic Pain* | *Tami Eide, PharmD* | **Overview of CDC Guidelines for Prescribing Opioids for Chronic Pain**<br>Dr. Eide presented the CDC Guidelines for Prescribing Opioids For Chronic Pain that were published in March of this year. She reviewed the following guideline goals:<br>• Ensure clinicians provide safe and effective treatment<br>• Improve patient outcomes<br>• Reduce the instance of<br>  ○ Opioid Use Disorder<br>  ○ Overdose<br>  ○ Opioid-related adverse events<br><br>The guidelines were grouped into three main topic areas.<br>• Determination of when to initiate and continue opioids for chronic pain<br>• Opioid selection, dosage, duration, follow-up and discontinuation<br>• Assessment of risks and addressing harms of opioid use<br><br>Dr. Eide also reported on other agencies plans which include the FDA and NIH strategy.<br><br>The committee requested a report on the total number of prescriptions for these agents within the Medicaid population as a way to see the progress that is being made in this area over the next year. |
| ***Public Comment Period*** | *Phil Petersen, MD*<br>*Chris Johnson, PharmD* | **Public Comment Period**<br>One (1) person signed up to speak during the public comment period. Public testimony was received from the following speaker:<br><br>Speaker \| Representing \| Agent \| Class<br>Dr. Ron Kristensen \| Himself \| Eliquis \| Anticoagulants |

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| ➢ *CMS Best Practice for Addressing Prescription Opioid Overdoses, Misuse and Addiction* | *Tami Eide, PharmD* | **<u>CMS Best Practice for Addressing Prescription Opioid Overdoses, Misuse and Addiction</u>**<br>Dr. Eide presented information on the CMS Information Bulletin on Best Practices for Addressing Prescription Opioid Overdose, Misuse and Addiction. The purpose of this CMS directive is to highlight emerging Medicaid strategies for preventing opioid related harms. The Bulletin points out that the opioid epidemic has a disproportionate impact on Medicaid beneficiaries who are prescribed painkillers at twice the rate of non-Medicaid patients and are at a 3-6 times higher risk of prescription painkiller overdose.<br><br>The directive discusses strategies which include:<br>• Provider education<br>• Preferred Drug Lists<br>• Clinical Criteria<br>• Step Therapy<br>• Prior Authorization<br>• Quantity Limits<br>• Drug Utilization Review<br>• Increased Access To and Use of State PDMPs (Prescription Drug Monitoring Programs)<br>• Patient Review and Restriction Programs (“lock-in” )<br>• Increased Use of Naloxone to Reverse Opioid Overdose<br>• Expanding Coverage and Access to Opioid Use Disorder Treatment |
| ➢ *Update on Department Activities to Improve Opioid Prescribing* | *Tami Eide, PharmD* | **<u>Update on Department Activities to Improve Opioid Prescribing</u>**<br>Dr. Eide presented information on activities taken by the department to improve the current opioid prescribing practices within the Medicaid population. The department has completed activities in the following areas:<br>• <u>Long Acting Opioids</u>: Implemented a hard edit to not allow more than one long-acting opioid per patient; requiring manual prior authorization of Oxycontin and transdermal fentanyl and moving methadone to non-preferred status.<br>• <u>Buprenorphine</u>: No longer allow concurrent opioids; perform quarterly PMP checks on cash payment of opioids, discontinuing buprenorphine payment when it occurs; restrict buprenorphine without naloxone to pregnant women only and block concurrent buprenorphine with benzodiazepines.<br>• <u>DUR</u>: Completed study of top 150 utilizers.<br>• <u>Oxycodone IR</u> was moved to non- preferred.<br>• <u>Carisoprolol</u> denies for any patient concurrently taking an opioid. |

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| | | Activities in the following areas are also in process:<br>• Methadone: Prescribers are being encouraged to switch current users to a different opioid and/or taper to dose of less than 40 mg daily. Completion of a Re-Authorization form which includes a current ECG, documentation of pain and functionality and reasoning for not using other opioids will be required.<br>• New patients will be denied at point of sale and a prior authorization is required.<br>• Top 150 Utilizers: An interventional letter will be sent to prescriber listing specific problems identified with the patient and requesting specific action and response.<br>• Working with the Board of Pharmacy, Program integrity and possibly the DEA on cash paying patients.<br>• DUR: Patients using benzodiazepines in combination with opioids.<br>• Placing electronic morphine equivalent calculator on website.<br>• Redesign of "Lock-In" (patient review and restriction) Program.<br><br>Future Plans include the following activities:<br>• Daily Morphine Equivalents:<br>o Reduce quantity limit per drug and dose (GSN) to 90 daily morphine equivalents<br>o Reduce cumulative amount of all opioids to < or = to 120 daily morphine equivalents<br>• Other Activities:<br>• Hard edit on benzodiazepine/opioid combinations<br>• Block two or more immediate release concomitant opioids<br>• Duration limits for acute and chronic use<br><br>The committee discussed other future activities including:<br>• Tapering guidelines and education<br>• Exploring Pharmacist Medication Therapy Management (MTM) opportunities<br>• Prior Authorization Requirements<br>o Require prescribers to calculate morphine equivalents of all drugs and enter on PA form.<br>o Require prescribers to validate that they have checked the PMP before prescribing the prior authorized opioid |

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| | | ○ Prescribers to indicate that they have checked for non-pain primary diagnoses (mental health with pain as symptom)<br>○ Methadone prior authorization forms to include list of other drugs with QTc interval prolongation to ensure not getting concurrently<br>• Create a list of patients with known opioid overdoses (at risk for future adverse effects and/or abuse)<br>• Education<br>○ Tapering<br>○ Hyperanalgesia<br>○ Non-drug therapy alternatives<br>○ Pain contracts<br>○ CDC Guidelines in general |
| ➢ *Disease-modifying Drugs for Multiple Sclerosis* | *Shelly Selph, MD Pacific Northwest Evidence-based Practice Center* | **<u>Disease-modifying Drugs for Multiple Sclerosis</u>**<br>Dr. Selph presented the third update on this drug class. She reviewed the key questions, the methods for the review and the inclusion criteria. She reported on the major findings, effectiveness of the drugs and the harms. Dr. Selph reported that the study included 25 new publications of which 10 were new trials and a Center network meta-analysis for relapse and withdrawals due to adverse events. The study included two new drugs not yet approved by the FDA and two newly approved drugs/drug formulations.<br><br>Take home points new to this review:<br>• Ocrelizumab and daclizumab are promising new therapies<br>• Pegylated interferon and glatiramer 40 mg thrice weekly outperform placebo<br>• Fingolimod exposure in utero may lead to poor fetal/neonatal outcomes<br>• Head-to-head comparisons are limited |
| ***Drug Class Reviews and Committee Recommendations*** | *Phil Petersen, MD* | **Drug Class Reviews and Committee Recommendations**<br>Committee members were asked to base their recommendations for each drug class on the answers to the following questions:<br>1. Is there comparative evidence to support clinically significant differences in efficacy or effectiveness between agents?<br>2. Is there comparative evidence to support clinically significant differences in safety between agents? |

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| | | 3. Are there any agents that the committee feels strongly must be preferred or non-preferred?<br>4. Are there any recommendations for changes to PA requirements? |
| ➢ *Multiple Sclerosis Agents* | *Richard Pope, PharmD* | **<u>Multiple Sclerosis Agents</u>**<br>Dr. Pope reviewed the utilization of both the injectable and oral products in this class of drugs. He announced that Copaxone is now available generically (including Glatopa). He also reported that the FDA has recommended that additional information be added to the Warnings/Precautions and Patient Counseling sections of the label due to Novartis reports of one confirmed case and one probable case of progressive multifocal leukoencephalopathy (PML) in patients taking Gilenya who had not been previously treated with an immunosuppressant. There are now four PML cases with Tecfidera.<br><br>**Committee Recommendations**<br>The committee concluded that the evidence for approved agents did not support differences in efficacy or effectiveness. They concluded that there were safety differences between the agents, including fetal and cardiac toxicity with Gilenya. The committee recommended that Copaxone 40 mg be added to the preferred drug list. The recommendation was also made to grandfather patients using the brand name products and that they are not switched to the generic preferred agent, unless indicated by the prescriber. |
| ➢ *Analgesics, Narcotic long-acting* | *Richard Pope, PharmD* | **<u>Analgesics, Narcotic long-acting</u>**<br>Dr. Pope provided a review of the current products and utilization of drugs in this class. He also reported on one new drug in this class. Belbuca is buccal form of buprenorphine and is indicated for the management of severe pain that requires around-the-clock, long term opioid treatment. He also reviewed the black box warning for this drug as well as the contraindications, warnings and dosing instructions. There is no comparative evidence available for Belbuca with other drugs in the class. Dr. Pope provided two product updates. Conzip is now available generically and OxyContin is now indicated for use in patients 11 years and older (previously indicated only in adults).<br><br>**Committee Recommendations**<br>The committee concluded that there were no differences in efficacy, effectiveness or safety between the agents. They did not feel there was a need for an abuse deterrent agent as preferred. The committee recommended that there be a requirement to reevaluate and resubmit prior authorizations for these agents every 90 days for chronic non-cancer pain. The |

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| | | recommendation was also made to make changes to the PA form to document non-pharmacological therapies for treating chronic pain patients. |
| ➢ *Analgesics, Narcotic short-acting* | *Richard Pope, PharmD* | **<u>Analgesics, Narcotic short-acting</u>**<br>Dr. Pope provided a review of the current products and their utilization. Dr. Pope announced that Oxaydo (formerly known as Oxecta) is now available as an abuse deterrent formulation that contains an inactive ingredient that may cause nasal burning when snorted. He also reported on an FDA announcement regarding a class-wide label change for immediate release opioid analgesics that will add a black box warning regarding risk of misuse, addiction, overdose and death.<br><br>**Committee Recommendations**<br>The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. The committee recommended that hydromorphone be made a non- preferred agent with a 30 day time limit. They recommended that following other priorities with the opioids that the Department look at limiting the duration of all short-acting narcotic analgesics. |
| ➢ *Opiate Dependence Treatments* | *Richard Pope, PharmD* | **<u>Opiate Dependence Treatments</u>**<br>Dr. Pope provided a review of the current products and their utilization. He reported on one new product in this class. Narcan (naloxone) nasal spray is indicated for the emergency treatment of known or suspected opioid overdoses. Dr. Eide informed the committee that this product can be prescribed by a licensed pharmacist who has gone through the required training and certification. Dr. Pope reviewed the contraindications, warnings and dosing instructions. Dr. Pope provided a product update for Zubsolv which is now indicated for the initial treatment of opioid dependence (previously indicated only for maintenance treatment).<br><br>**Committee Recommendations**<br>The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. It was recommended that Narcan nasal spray be made preferred. |
| ➢ *Skeletal Muscle Relaxants* | *Richard Pope, PharmD* | **<u>Skeletal Muscle Relaxants</u>**<br>Dr. Pope provided a review of the current products and their utilization. There was not any |

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| | | recent information of significance in the class to report on. Dr. Johnson reported that there has been a preliminary DUR study on these agents and that a more in depth study will be done.<br><br>**Committee Recommendations**<br>The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. The committee recommended that tizanidine be considered for non-preferred status due to hypotension problems seen with this drug. The committee asked that the DUR Board look at chronic use for musculoskeletal issues vs spasticity. |
| ➢ *Antimigraine Agents, Triptans* | *Richard Pope, PharmD* | **Antimigraine Agents, Triptans**<br>Dr. Pope provided a review of the current products and their utilization. He also reported on one new drug in this class. Zecuity (sumatriptan) is a transdermal product that is indicated for acute migraine treatment with or without aura in adults. Dr. Pope also reported on some product updates for this class. He announced that Treximet and Zomig nasal spray are both now indicated for acute treatment of migraine with or without aura in patients 12-17 years old (previous only approved for 18 years and older). He also announced that both Axert and Frova are now available generically.<br><br>**Committee Recommendations**<br>The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. They stated that transdermal Zecuity should not be preferred since it has a longer onset of action and no other clinical advantages. |
| ➢ *Antiemetics/Antivertigo* | *Richard Pope, PharmD* | **Antiemetics/Antivertigo**<br>Dr. Pope provided a review of the current products and their utilization. He reported that there is one new product in this class. Varubi (rolapitant) is indicated to be used in combination with other antiemetics for the prevention of delayed nausea/vomiting associated with initial and repeat courses of emetogenic chemotherapy in adults including, but not limited to highly emetogenic chemotherapy. Contraindications, warnings, drug interactions, dosing and adverse effects were also reviewed. He reported that there is no comparative clinical data available. Dr. Pope also reviewed several product updates for this class. Metozolv ODT is now available generically. Emend is now indicated for use in patients 12 years and older and patients under 12 years who weigh at least 30 kg (previously indicated only for adults). Akynzeo has been added to the 2015 National Cancer Comprehensive Network guidelines as a treatment option for highly emetogenic chemotherapy. Varubi and Akynzeo have been added to the 2015 American Society |

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| | | of Clinical Oncology guidelines as treatment for highly emetogenic chemotherapy. Emend injection is now indicated in combination with other antiemetics for prevention of delayed nausea and vomiting in adults receiving initial and repeat courses of moderately emetogenic chemotherapy (previously indicated only for highly emetogenic chemotherapy).<br><br>**Committee Recommendations**<br>The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents in their respective subclasses. It was recommended that it be specified on the PDL document that promethazine will not be approved for patients under 2 years old. There was a discussion within the committee regarding the use of ondansetron in infants less than 2 months old and the recommendation was made to do a DUR review on the usage of ondansetron in infants less than 1 year old. |
| ➢ *Hereditary Angioedema Agents* | *Richard Pope, PharmD / Jane Gennrich, Pharm D* | **<u>Hereditary Angioedema Agents</u>**<br>Dr. Pope provided a review of the current products and their utilization. There were no new drugs and no recent information of clinical significance in this class.<br><br>Dr. Gennrich reviewed the Department's therapeutic criteria and guidelines for treatment of acute attacks and prophylaxis of Hereditary Angioedema (HAE). She reviewed the short-term prophylaxis criteria – prior to elective dental and surgical procedures and long-term prophylaxis criteria for initiation of therapy as well for continuation of therapy. She also reviewed the therapeutic criteria for the treatment of acute attacks.<br><br>**Committee Recommendations**<br>The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. The committee approved the therapeutic criteria. |
| ➢ *Immunosuppressives, Oral* | *Richard Pope, PharmD* | **<u>Immunosuppressives, Oral</u>**<br>Dr. Pope provided a review of the current products and their utilization. He reported on one new product in this class. Envarsus XR (tacrolimus) is indicated for the prophylaxis of organ rejection in kidney transplant patients converted from tacrolimus immediate-release in combination with other immunosuppressants. There is a black box warning on this drug regarding increased risk of serious infections and malignancies. The contraindications, warnings, drug interactions, dosing and most common adverse effects were reviewed. The clinical trial |

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| | | used for Envarsus XR approval was reviewed. Dr. Pope provided a product update for Rapamune which is now indicated for the treatment of lymphangioleiomyomatosis, a rare, progressive lung disease. It is the only drug approved for this condition (previously only indicated for prophylaxis of organ rejection in patients 13 years and older receiving renal transplant).<br><br>**Committee Recommendations**<br>The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. |
| ➢ *Platelet Aggregation Inhibitors* | *Richard Pope, PharmD* | **<u>Platelet Aggregation Inhibitors</u>**<br>Dr. Pope provided a review of the current products and their utilization**.** He reported on one new product in this class. Durlaza (aspirin ER) is indicated for the reduction of risk of death and myocardial infarction in patients with chronic coronary artery disease; and reduction of risk of death and recurrent stroke in patients who have had an ischemic stroke or transient ischemic attack. The contraindications, warnings, drug interactions, dosing and the most common adverse effects were reviewed. There is not any comparative clinical data available. Dr. Pope provided two product updates for Brilinta which can now be crushed and administered in water by swallowing or via nasogastric tube. Brilinta is also now indicated to reduce the rate of cardiovascular death, myocardial infarction, and stroke in patients with acute coronary syndrome or history of myocardial infarction following the results of the PEGASUS (TIMI-54) study. Dr. Pope also announced that Aggrenox is now available generically.<br>Guidelines updates from the American College of Cardiology/American Heart Association on duel antiplatelet therapy were reviewed. They included new recommendations for Brilinta and Effient.<br><br>**Committee Recommendations**<br>The committee concluded that there was evidence to support differences in efficacy, effectiveness and safety between the agents. It was recommended that Brilinta be added as preferred agent. |
| ➢ *Newer Oral Anticoagulant Drugs* | *Marian McDonagh, PharmD Pacific Northwest Evidence-based Practice Center* | **<u>Newer Anticoagulant Drugs</u>**<br>Dr. McDonagh presented a drug class review on Newer Oral Anticoagulant Drugs (NOAC's). She reviewed the key questions, methods for inclusion criteria and the literature search methodology. 53 studies were included in the report including 44 randomized controlled trials, 4 observational studies and 5 systematic reviews. Dossiers from Janssen, Boehringer Ingelheim, |

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| | | and BMS/Pfizer were also received and evaluated.<br><br>Since evidence directly comparing NOACs is unavailable the current evidence is limited to indirect comparisons so the strength of evidence could at best be rated as a low strength of evidence.<br><br>Report Conclusions:<br><br>• In atrial fibrillation, edoxaban 30 mg had a higher risk of stroke or embolism.<br>• Low-strength evidence suggests apixaban and rivaroxaban had lower risk of VTE (venous thrombolic events) and mortality in orthopedic patients.<br>• Differences in effectiveness were not found among the drugs in initial or extended treatment of VTE.<br>• Apixaban, edoxaban, and lower-dose dabigatran have lower rates of major bleeding across the populations.<br>• Evidence on other comparisons and outcomes were insufficient to draw conclusions. |
| ➢ *Anticoagulants* | *Richard Pope, PharmD* | **<u>Anticoagulants</u>**<br>Dr. Pope provided a review of the current products and their utilization**.** He also provided two product updates. Praxbind, an intravenous reversal agent for Pradaxa, is now available. Pradaxa is now indicated for prophylaxis of DVT/PE in patients who have undergone hip replacement surgery, along with a new 110 mg strength for dosing convenience. Dr. Pope also reported that select portions of the American College of Chest Physicians guidelines were updated in 2016 to include Savaysa as a treatment option along with other oral anticoagulants for DVT/PE treatment.<br><br>**Committee Recommendations**<br>The committee concluded that the evidence did not support differences in efficacy or effectiveness between the agents, but that Eliquis and Xaralto had definite safety advantages. The recommendation was made that Eliquis and Xaralto remain preferred and that enoxaparin be available for pediatrics. |
| ➢ *Cystic Fibrosis, oral agents* | *Richard Pope, PharmD* | **<u>Cystic Fibrosis, oral agents</u>**<br>Dr. Pope provided a review of the current products and their utilization**.** He gave an overview of |

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| | | Cystic Fibrosis. Dr. Brown added additional disease state and treatment information for the committee's understanding. Dr. Pope presented information on the two new drugs used for treatment, Kalydeco and Orkambi. He reviewed the contraindications, warnings and dosing instructions for both drugs. He also reviewed clinical studies on both drugs which have both been compared to placebo, but not studied in head to head comparisons due to genetic mutation specificity indications. It was noted that there are no good clinical outcome measures to use for reauthorization, but that non-adherence should be looked at.<br><br>**Committee Recommendations**<br>The committee recommended that there be no restrictions on the agents other than FDA label indications and dosing for the specific genetic mutation. |
| ➢ *Antibiotics, Inhaled* | *Richard Pope, PharmD* | **Antibiotics, Inhaled**<br>Dr. Pope provided a review of the current products and their utilization**.** He also provided a product update for Kitabis Pak which is now available generically. Dr. Pope reported that the current guidelines now include one published randomized, controlled trial of cycled therapy with aztreonam/tobramycin from 2008.<br><br>**Committee Recommendations**<br>The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. The committee recommended that if it is cost effective Tobi Podhaler be available to adults and adolescents needing portability. |
| ➢ *Antibiotics, Topical* | *Richard Pope, PharmD* | **Antibiotics, Topical**<br>Dr. Pope provided a review of the current products and their utilization**.** There was no recent clinically significant information in this class to report on.<br><br>**Committee Recommendations**<br>The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. |
| ➢ *Antibiotics, Vaginal* | *Richard Pope, PharmD* | **Antibiotics, Vaginal**<br>Dr. Pope provided a review of the current products and their utilization**.** He reviewed the 2015 CDC STD (sexually transmitted disease ) guidelines which continue to recommend |

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| | | metronidazole (oral or vaginal) or clindamycin (vaginal) as preferred treatment options for bacterial vaginosis.<br><br>**Committee Recommendations**<br>The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. |
| ➢ *Cephalosporins and Related Agents* | *Richard Pope, PharmD* | **<u>Cephalosporins and Related Agents</u>**<br>Dr. Pope provided a review of the current products and utilization**.** He announced that Suprax suspension is now available generically. He reported that the 2015 CDC recommendation for gonorrhea is ceftriaxone and azithromycin dual treatment. This is based on an increased incidence of increased treatment failures with cefixime or ceftriaxone monotherapy. The American College of Obstetricians and Gynecologist opinion summary makes the same recommendation.<br><br>**Committee Recommendations**<br>The committee concluded that the evidence did not support differences in efficacy or effectiveness for the agents for susceptible infections. They recommended that at least one agent be available in each of the three generations. |
| ➢ *Fluroquinolones, Oral* | *Richard Pope, PharmD* | **<u>Fluroquinolones</u>**<br>Dr. Pope provided a review of the current products and their utilization. He provided a product update announcing that Avelox is now indicated for prophylaxis and treatment of plague due to *Yersinia pestis* in adults.<br><br>**Committee Recommendations**<br>The committee concluded that the evidence did not support differences in efficacy or effectiveness between the agents for susceptible organisms. Safety-wise there are some tendonitis issues which may or may not be a class effect. The committee recommended that a drug utilization study of this class be done to see if usage changes with tendonitis concerns. |
| ➢ *Macrolides* | *Richard Pope, PharmD* | **<u>Macrolides</u>**<br>(note that the only ketolide on the market has been removed) Dr. Pope provided a review of the current products and their utilization. There are no new products and no new significant clinical information for this drug class to review. |

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| | | **Committee Recommendations**<br>The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. |
| ➢ *Tetracyclines* | *Richard Pope, PharmD* | **<u>Tetracyclines</u>**<br>Dr. Pope provided a review of the current products and their utilization. There was no recent information of significance in this class to report on.<br><br>**Committee Recommendations**<br>The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. They recommended that at least one doxycycline product be available as preferred. |
| ➢ *Antivirals, Oral* | *Richard Pope, PharmD* | **<u>Antivirals, Oral</u>**<br>Dr. Pope provided a review of the current products and their utilization for the antiherpetic and influenza products. He also reported on the CDC recommendations for the use of oral antivirals in the 2015-2016 flu seasons which did not change significantly from those in the previous seasons.<br><br>**Committee Recommendations**<br>The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents in their respective subclasses. |
| ➢ *Antivirals, Topical* | *Richard Pope, PharmD* | **<u>Antivirals, Topical</u>**<br>Dr. Pope provided a review of the current products and their utilization. There was no recent clinically significant information in this class to report on.<br><br>**Committee Recommendations**<br>The committee did not want to add this class to those that include payment of over the counter products. Therefore Abreva OTC will have no coverage. The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. The committee recommended that additional criteria be added for all topical antiviral therapy requiring documentation of trial and failure of oral antiviral therapy. |

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| ➢ *Antibiotics, Gastrointestinal* | *Richard Pope, PharmD* | **Antibiotics, Gastrointestinal**<br>Dr. Pope provided a review of the current products and utilization. He reported that an authorized generic for Vancocin (vancomycin) is now available. Dr. Pope announced a product update for Xifaxan which is now also indicated for the treatment of irritable bowel syndrome with diarrhea in adults in addition to indications for hepatic encephalopathy recurrence and travelers' diarrhea due to *E coli*. It was noted that the 2015 update to the CDC's sexually transmitted disease guidelines contained no changes on recommended drug therapies.<br><br>**Committee Recommendations**<br>The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. |
| ➢ *Antifungals, Oral* | *Richard Pope, PharmD* | **Antifungals, Oral**<br>Dr. Pope provided a review of the current products and their utilization. He reported on one new product. Cresemba (isavuconazonium sulfate) is indicated for the treatment of invasive aspergilosis or invasive mucormycosis. The dosing, duration of therapy, contraindications, warning, drug interactions and most common adverse effects were reviewed. Dr. Pope also reported on The Infectious Disease Society of America guidelines for candidiasis treatment that were updated. Fluconazole remains a prominent treatment choice in the treatment of non-neutropenic patients.<br><br>**Committee Recommendations**<br>The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents for their disease specific indications. The committee recommended that griseofulvin suspension be moved to non-preferred status due to unreliable and variable absorption of the product. |
| ➢ *Antifungals, Topicals* | *Richard Pope, PharmD* | **Antifungals, Topical**<br>Dr. Pope provided a review of the current products and their utilization. He also announced that Naftin cream and Oxistat are now both available generically.<br><br>**Committee Recommendations**<br>The committee concluded that the evidence did not support differences in efficacy, effectiveness or safety between the agents. |

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| ➢ *Antiparasitics, Topical* | *Richard Pope, PharmD* | **Antiparasitics, Topical**<br>Dr. Pope provided a review of the current products and their utilization. He provided a guideline update released by The American Academy of Pediatrics for the treatment of head lice. OTC products (permethrin, pyrethrins) are considered first-line unless resistance is suspected. Ulesfia and malathion are the recommended second line agents. It was noted that the guidelines do factor in the relative cost of treatments.<br><br>**Committee Recommendations**<br>The committee concluded that the evidence in general did not support differences in efficacy, effectiveness or safety between the agents. A recommendation was made to implement a hard edit that would prevent claims for Lindane paying at the pharmacy without prior authorizations due to neurotoxicity safety concerns. |
| ➢ *Other Committee Business* | *Tami Eide, PharmD* | **Other Committee Business**<br>It was announced that the next P&T Committee meeting is scheduled for October 21, 2016.<br><br>The meeting adjourned at 3:02 p.m. |

# Pharmacy and Therapeutics Committee Meeting
# Public Comment

Committee
Tell us where you practice and if you take care of Medicare or Medicaid, and if you are representing anybody or being funded.

Ronald Kristensen, MD
Great, thanks for allowing me to speak today. So I'm Dr. Ronald Kristensen, an orthopedic surgeon. I practice at St. Luke's these days for the orthopedic joint team. I am speaking just on my own here. I have given talks in the past for Eliquis and I am also a representative for Stryker

Navigation. I wanted to just briefly talk about the Xa inhibitors or Eliquis and how it impacts my practice. I have been doing joint replacements for a long time in the valley, for 20 years practicing, and with total knees and total hips; obviously, they're at risk for DVT, PE and so need some sort of agent. Historically, that was Coumadin or Lovenox, and both of those had problems that I saw. The Lovenox, obviously, had problems with compliance from the injections and disposable needles, and Coumadin is very hard to regulate, and has always been a problem. A personal note: My dad had a stroke and was on Coumadin. He was a 91-year-old guy, and every time he gets a new INR, he struggled to get his new dosing right, and I think that's a common problem I've seen in my own practice. So, you know, I've been anxious to see a different agent come out there. I was one of the investigators on the apixaban studies, and in the population of total joint prophylaxis, I found it to be very effective and easy to use for both the practitioner and the patient. It's something that I was pleased to see get the approval. I've been using it since then. As part of the joint team at St. Luke's with our order sets, we have now stratified our patients, so that low-risk patients after total joints are getting aspirin, but in our higher risk patients, we are using Eliquis. This has been an effective agent for us. We looked at our DVT/PE rates last year and we were at about 0.5%, which compares favorably to the national studies. So I would just put out a message there that it has worked well for us and I support the use of the Xa inhibitors, Eliquis in particular, and I hope that can continue to be accessed for our Medicaid patients in the total joint, where we do treat a fair number of Medicaid patients.

Committee
Any questions for Dr. Kristensen?

Question
I do have one: It is listed as a preferred agent.

Roland Kristensen, MD
Yes, is there any talk about moving away from that? A rumor I heard was that they were moving away from the agents we're familiar with and potentially moving to not Eliquis and not Xarelto [correction from panel], to uh, Pradaxa, thank you for that. So that's our concern more as orthopedic surgeons. It's more of a cardiology medication that we don't really use or have familiarity of it. There is a reversal agent now for that one, although it looks like there's a new one coming out soon for the ones that we're familiar with. In the orthopedic world, it's fairly short duration, so it's tended to be 12-35 days of prophylaxis after a hip or knee, and it's really fairly cost effective. If patients get a PE, they go through a whole rigmarole and costs mount up and it puts our joint at risk of infection, [unintelligible] anticoagulated patients. So that's our concern is about moving away from what we're familiar with and know works, and we've seen the safety profile with them.

Committee
So you're not having access issues now?

Roland Kristensen, MD
Right now it's perfect. We just hope for you to keep up the good work.

Committee
Also, one more question is that is there literature in the orthopedic realm showing that this is superior to the others?

Roland Kristensen, MD
So I don't know of any head-to-head comparisons with the Xa inhibitors. The Pradaxa really has not been in my orthopedic world; it's again more of a cardiology agent. [unintelligible] Eliquis I like is just the minimization of risk of recurrent DVT were compared to placebo, you know the bleeding risk was equivalent. So as we've borne out in my practice, we're not seeing a lot of hematomas or bleeds after treatment with this. There's just no head-to-heads.