

# **COLORADO MEDICAID P&T COMMITTEE MEETING MINUTES**

**January 7, 2014**

## **Members Present**

Lynn Parry, MD  
Shilpa Kinikar, PharmD, BCPS  
Patricia Lanius, RPh  
Jennifer Hyer, MD  
Michael McGuire, MPA  
Leslie Moldauer, MD, MBA  
Neil Stafford, MD  
Roy J. Durbin Jr., MD  
Kimberly Nordstrom, MD, JD  
Katy Trinkley, PharmD

## **Medicaid Pharmacy Department**

Robert Lodge, PharmD  
Swanee Grubb, PharmD

## **Members Absent**

David Fox, MD  
Irene Girgis, PharmD  
Stacey Seggelke, MS, RN, CNS, DCE, BC-ADM

## **GENERAL ORDERS and NEW BUSINESS**

The meeting of the CO Medicaid P&T Committee was held on January 7, 2014 at 225 E. 16<sup>th</sup> Ave., 1<sup>st</sup> Floor Conference Room, Denver, Colorado. A quorum being present, K. Nordstrom officially called the meeting to order at 13:04.

S. Kinikar nominated K. Nordstrom for chairperson. J. Hyer seconded. All in favor. Motion passed with no audible dissent. K. Nordstrom nominated S. Kinikar for vice-chairperson. J. Hyer seconded. All in favor. Motion passed with no audible dissent.

K. Nordstrom asked for approval of the minutes from the July 9, 2013 and October 8, 2013 meetings. The minutes were approved with no audible dissent.

## **UNFINISHED BUSINESS**

S. Grubb gave an update on the PDL changes for the following:

- Antiherpetics
- Fluoroquinolones
- Antiemetics
- New Generation Antidepressants
- Antiplatelets
- Pancreatic enzymes

- Proton Pump Inhibitors
- Pulmonary Arterial Hypertension Therapies
- Targeted Immune Modulators for Rheumatoid Arthritis
- Triptans

## **NEW BUSINESS**

S. Grubb gave updates about the prior authorization helpdesk call statistics. The prior authorization numbers from the previous month were about the same as usual. This being about 83% approvals and 17% denials.

K. Nordstrom presented guidelines for manufacturer and public presentations. Oral presentations will be restricted to products that are being reviewed for PDL status. Presentations will be limited to a maximum of three minutes per representative per drug product. Representatives will be called to present in the order in which they signed in by drug class. Presentations must be limited to verbal comments. No visual aids, other than designated handouts, are permitted. Presentations should follow the one page summary that was submitted to the Department. The audience will be considered a reference tool for the committee. The committee will discuss topics and audience participation will be allowed if P&T members ask for clarification. S. Grubb disseminated recently received public comments to the committee members.

K. Nordstrom moved to discuss Insulin's a new drug class to be added to the PDL. With no speakers present S. Grubb gave updates and utilization. L. Parry asked pharmacists about insulin use. R. Durbin has very high diabetic patient load and uses all of them. He supports open access. K. Trinkley supports multiple options of one pen and one vial for all the durations of action. J. Hyer states she uses regular in all pregnancies. K. Trinkley made a motion for multiple options for short, intermediate, long acting, and mixtures. R. Durbin seconded. The motion passed with no audible dissent. K. Trinkley made a motion that regular insulin needs to be available for the pregnant population. S. Kinikar seconded. Motion passed with no audible dissent.

K. Nordstrom moved to discuss Alzheimer's agents. C. McSpadden, from Forest Pharmaceuticals spoke about Namenda and Namenda XR. Regarding Namenda XR RCT that showed improvement with combination cholinesterase inhibitor. The capsule can be opened and sprinkled on applesauce. He requested unrestricted access because caregivers come in only once daily so daily dosing is helpful. N. Stafford asked about the AUC, C. McSpadden said it was a 40% increase. S. Grubb gave FDA updates, utilization information, and current preferred products. L. Moldauer made the motion that one NMDA antagonist be included as preferred. L. Parry seconded. The motion passed with no audible dissent. S. Kinikar made the motion that a cholinesterase inhibitor should be considered for addition to the formulary with consideration given to multiple dosage forms and a better side effect profile. K. Trinkley made a friendly amendment to give preference to a cholinesterase

inhibitor that is indicated for severe Alzheimer's. S. Kinikar denied. K. Trinkley seconded the motion. The motion passed with no audible dissent. L. Moldauer made the motion that all cholinesterase inhibitors are considered to have similar efficacy. S. Kinikar seconded. The motion passed with no audible dissent. L. Parry made a motion that at least one product be available with daily dosing due to caregiver issues. S. Kinikar seconded. The motion passed with no audible dissent. P. Lanius said we need to align with Medicare because most all these patients will be dual-eligible. S. Kinikar said it would be hard to do because of so many plans. K. Trinkley made a motion to give preference to a cholinesterase inhibitor with an indication for severe Alzheimer's disease. L. Parry seconded. The motion passed with no audible dissent. K. Trinkley said that Donepezil is superior in terms of tolerability. S. Kinikar does not agree entirely. K. Trinkley states GI is tolerated better. K. Trinkley retracts.

K. Nordstrom moved to discuss Atypical Antipsychotics. L. Laird, from Sunovion spoke about Latuda. He said there are 5 approved studies for efficacy and 7 long term safety studies. Latuda has a new approval for bipolar I depression in monotherapy and combination therapy. There is a black box warning regarding the elderly with dementia and suicidality in children. S. Kinikar asked about the mechanism of action and the answer is unknown. Michael from Mental Health was here for Moe Keller the Deputy Director of Policy. He spoke about more patients that will be gaining access to public insurance and there will be a huge need for flexibility. C. Gray a psychiatrist from Cedar Springs Hospital in Colorado Springs spoke. He sees people that are barely keeping out of the hospital. He is a big proponent of long acting injectable agents. C. Henderson the MSL with Otsuka spoke regarding Abilify. Abilify has 14 FDA approved indications and a new long acting injectable. Pharmacoeconomic analyses show a cost saving with respect to reducing hospitalizations. L. Moldauer asked about akathisia and C. Henderson stated if dosed appropriately then probably less than 5%. S. Grubb gave FDA updates, utilization information, and current preferred products. S. Kinikar made the motion for at least one orally disintegrating tablet be on the preferred drug list. P. Lanius asked why an ODT? K. Nordstrom and L. Moldauer said there is a need for acute agitation and diversion. J. Hyer seconded. The motion passed with no audible dissent. L. Parry made the motion that the current evidence suggests that all atypical antipsychotics, with the exception of clozapine are similar in efficacy, however there are not all equally effective in individual patients or for individual indications. L. Moldauer brings up that point that they are not all similar in all indications. L. Moldauer seconded. The motion passed with no audible dissent. L. Parry made the motion that at least one agent be preferred that is approved in children down to six years. S. Kinikar seconded. The motion passed with no audible dissent. L. Moldauer made the motion that clozapine be considered preferred due to its proven efficacy. L. Parry seconded. The motion passed with no audible dissent. L. Parry made the motion that at least two agents should be on the preferred list that have been shown to be metabolically/weight neutral. S. Kinikar seconded. The motion passed with no audible dissent. L. Parry made the motion at least one agent with sedating properties be preferred. P. Lanius seconded. The motion passed with no audible dissent. L. Moldauer made the motion at least one agent

known with lower risk of EPS side effects including tardive dyskinesia, should be preferred. S. Kinikar seconded. The motion passed with no audible dissent. S. Kinikar made the motion that at least one pregnancy category B be preferred. L. Moldauer seconded. The motion passed with no audible dissent. There was discussion about making motions with regard to specific indications. K. Trinkley made the motion that at least one agent with no case reports of QTC prolongation be available. S. Kinikar seconded. The motion passed with no audible dissent.

K. Nordstrom moved to discuss Growth Hormones. R. Hansen from Pfizer spoke about Genotropin. He wants access because of multiple devices, it does not need refrigeration. Pfizer has a support program for device support 24/7/365 and in home training. The Miniquick is a pre-filled single dose syringe. J. Patel from Novo Nordisk spoke regarding Norditropin. All are now room temperature stable. Norditropin has 4 pediatric and 1 adult indication. M. Fuzeo from US BioServices a local specialty pharmacy. She spoke how patient like the disposable pens. The room temperature stability has been helpful. 95% of the practice uses Norditropin Flexpen. S. Grubb gave FDA updates, utilization information, and current preferred products. N. Stafford made the motion that all growth hormone products are comparable from a safety and efficacy standpoint. R. Durbin seconded. The motion passed with no audible dissent. P. Lanius made the motion to consider the ease of use and storage when selecting preferred products. K. Trinkley seconded. The motion passed with no audible dissent. R. Durbin argues for restrictions because these are over utilized and he would like them to require a prior authorization. J. Hyer made the motion that due to safety concerns, the committee strongly urges DUR to analyze the off label use. S. Kinikar seconded the motion. The motion passed with no audible dissent.

K. Nordstrom moved to discuss Intranasal Corticosteroids. With no speakers present S. Grubb gave FDA updates, utilization information, and current preferred products. P. Lanius made the motion that all products were comparable in safety and efficacy, and that special consideration should be given to agent's doses down to age 2 and agents with pregnancy category B. L. Moldauer seconded the motion. The motion passed with no audible dissent.

K. Nordstrom moved to discuss Leukotriene Modifiers. With no speakers present S. Grubb gave FDA updates, utilization information, and current preferred products. S. Kinikar made the motion that all products are comparable for efficacy. J. Hyer seconded. The motion passed with no audible dissent. P. Lanius made the motion that special consideration should be given to safety and flexibility of dosing with respect to pediatric dosing. L. Moldauer seconded. The motion passed with no audible dissent. There was discussion about how nothing stands out with regards to safety issues.

K. Nordstrom moved to discuss Multiple Sclerosis agents. B. Buckley, MSL for Biogen spoke about Tecfidera and Avonex. He spoke of the DEFINE and CONFIRM study. L. Parry asked about outcomes. Study 2 had a reference arm with Copaxone. Study 2 excluded patients previously treated with Copaxone because they didn't want to be re-randomized to

the Copaxone arm. The FDA approved for them to combine these data from the 2 studies and this combined data showed significance in disability. Regarding Avonex there was a question about combination therapy with Tysabri which showed PML. C. Kicklighter, from Novartis spoke about Gilenya. She requested open access to Gilenya. It targets S1P receptors reducing CNS inflammation. There is adverse effects of AV block and bradycardia which resulted in a patient specific selection criteria. Studies showed a 52% reduction in relapse versus Avonex with a number needed to treat of 7 so that 1 patient can be relapse free. Another adverse effect of leukopenia shows an initial lymphocyte drop of 20-30% in the first 2 months then they recover over time per C. Kicklighter but S. Kinikar is unaware of a recovery. She said the infection rate versus placebo. L. Parry asked about the patients who. R. Justus is a patient with MS (no disclosures). He started Rebif 10 years ago and had several relapses. Then started Tysabri for 2 years and it helped a lot. He then started on Gilenya. He says it has helped his self-esteem tremendously, he has not had mental side effects. He says he has not had any relapses since starting Tysabri. D. Crawford and MSL from Accorda spoke about Amypra. Ampyra increases walking in MS patients. It has a contraindication with history of seizures. The significance was walking faster 3 out of 4 visits with an average improved walk speed of 25%. E. Kelts is a neurologist with a private practice in Pueblo. His issue is with the 2 step edits. He uses a second step to be aggressive with medications such as Gilenya, Tecfidera, Tysabri. L. Parry asked about PML with Gilenya. Dr. Kelts said he does not know about validity yet...need more info. S. Grubb gave FDA updates, utilization information, and current preferred products. L. Parry made a motion that Gilenya has been shown to be more efficacious in eligible patients than the interferons and should be second line; unless patients demonstrate "severe" disease in which it should be first line. J. Hyer seconded. The motion passed with no audible dissent. R. Durbin asks about Ampyra. S. Kinikar and L. Parry both felt the prior authorization should stay in effect. J. Hyer made a motion that due to safety concerns, Ampyra should maintain its PA status for adjunctive symptomatic therapy. L. Parry seconded. The motion passed with no audible dissent.

K. Nordstrom moved to discuss Ophthalmic Allergy agents. S. Edelhauser from Alcon spoke regarding Patanol and Pataday. He asked to keep both agents preferred. S. Grubb gave FDA updates, utilization information, and current preferred products. J. Hyer made the motion that one mast cell stabilizer is preferred due to its pregnancy category of B, and one ophthalmic antihistamine is preferred because they can be used by contact lens wearers. L. Parry seconded. The motion passed with no audible dissent. S. Kinikar made a motion to include a product of pediatric age indications. J. Hyer seconded. The motion passed with no audible dissent. R. Durbin made a motion that all ophthalmic antihistamines have similar efficacy. K. Trinkley seconded the motion passed with no audible dissent.

K. Nordstrom moved to discuss Sedative/Hypnotics (non-benzodiazepine). With no speakers present S. Grubb gave FDA updates, utilization information, and current preferred products. J. Hyer made the motion that as a class all agents have a similar efficacy and safety, and that consideration should be given to duration of action. K. Trinkley seconded. The motion

passed with no audible dissent. S. Kinikar made a motion that according to the new BEERS's criteria, there are legitimate safety concerns for Zolpidem, Zaleplon, Eszopiclone; for clients  $\geq 65$  years old. L. Parry seconded. The motion passed with no audible dissent. There was a huge discussion that a lot of elderly suffer from insomnia. L. Parry made a motion that due to lack of sustained efficacy, we recommend non continuous use. S. Kinikar seconded. N. Stafford voted nay and all others vote I's.

K. Nordstrom moved to discuss Statins/Statin Combinations. With no speakers present S. Grubb gave FDA updates, utilization information, and current preferred products. S. Kinikar made the motion of at least one product be considered with pediatric indication be included as preferred. J. Hyer seconded. The motion passed with no audible dissent. S. Kinikar made the motion that one product with reduced drug interaction risk be included as preferred. N. Stafford seconded. The motion passed with no audible dissent. S. Kinikar made the motion to include 2 agents with  $>50\%$  reduction in LDL. N. Stafford seconded. K. Trinkley made a friendly amendment for 2 high potency statins defined as  $>50\%$  reduction in LDL. S. Kinikar approves the amendment. The motion passed with no audible dissent. K. Nordstrom abstains.

Adjourn at 17:45.

By: \_\_\_\_\_  
Kimberly Nordstrom, MD, Chair

Date: \_\_\_\_\_