MINUTES OF THE MEETING OF THE
COLORADO MEDICAID P&T COMMITTEE

Department of Healthcare Policy and Financing
303 East 17th Avenue, 7th Floor Conference Room

January 10, 2017

1. Call to Order

A quorum being present, the meeting was called to order at 13:05.

2. Roll Call

Committee member introductions were made and there are 2 new committee members.

A. Members Present

Gwen Black, PharmD
Andrew Davis, PharmD, MD
Roy J. Durbin Jr., MD
James Feinstein MD
Scott Humphreys, MD
Jennifer Hyer, MD
Kimberley Jackson, DO
Patricia Lanius, RPh
Steven Russell, MD
Deanna Tolman, FNP
Michelle Hilaire, PharmD (VIA conference call)

B. Members Excused

Lynn Parry, MD

C. Staff Present

Medicaid Pharmacy Department

Brittany Schock, PharmD

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Magellan RX Management

Brad Robinson, PharmD
Rand Fingles, RPh, MBA

3. Announcements

B. SCHOCK told the committee that the Chair and Vice-Chair serve for one year and would like to get nominations to serve for this year. K. JACKSON made a recommendation to vote for Chair first then Vice-Chair so if the person doesn’t get chair they can run for Vice-Chair. Recommendation was agreed. P. LANIUS asked for any volunteers/nominations for Chair. K. JACKSON volunteered for Chair. R. DURBIN volunteered for Chair if L. Parry is not interested. S. RUSSELL nominated L. Parry. P. LANIUS called for vote. L. Parry was chosen by votes to continue Chair. B. SCHOCK said if L. Parry declines will vote again next meeting.

P. LANIUS called for nominations for Vice-Chair. K. JACKSON nominated herself. Committee voted for K. JACKSON for Vice-Chair.

4. Approval of Minutes

B. SCHOCK asked for approval of the minutes from the October 4, 2016 meeting. P. LANIUS asked for a motion to approve minutes. K. JACKSON motioned for approval. S. RUSSELL second. The minutes were approved with no audible dissent.

5. Department Updates

B. SCHOCK reviewed updates from last meeting.

- Anti-Emetics
- New Generation Antidepressants
- Anti-Herpetic Agents (Oral)
- Anti-Platelets
- Epinephrine Products
- Fluoroquinolones (Oral)
- Pancreatic Enzymes
- Protein Pump Inhibitors
- Pulmonary Arterial Hypertension Therapies
- Targeted Immune Modulators
- Triptans
B. SCHOCK reported these changes went into effect 1/1/2017.

B. SCHOCK reviewed update of P&T Policy and Procedures. With the transition of the management of the P&T meetings to Magellan Rx Management, the Department is still ultimately responsible for the P&T Committee and the PDL process, including making the decisions about which drugs are preferred and non-preferred. Magellan will assist with the management of the process and will provide many of the clinical documents for your review. In addition, the duties of the P&T committee remain the same – the Committee is charged with making clinical recommendations to the Department and it shall not discuss cost nor Prior Authorization criteria. These discussions occur at a different meeting and is under responsibility of the Drug Utilization Review Board. The P&T Committee P&P document is located online on our public HCPF website.

B. SCHOCK reviewed updates from the Prior Authorization Call Center.
- Prior Authorization Requests for Pharmacy Benefits can be faxed or called-in, in most cases
- 87% PARs approved and 13% denied
- Average hold time for the call center for the past month was 16 seconds
- Average call length was 5 minutes and 1 second

B. SCHOCK reviewed Magellan update.
- POS claim and PAR processing was postponed from 10/31/16 until 2/25/17. The pharmacy call center and fax line has not changed, but will change on 2/25/17. PAR forms will be updated with the new Magellan phone and fax numbers.
- The 60-day provider notice with details about the transition to Magellan was sent out on 1/6. Another provider notice will be sent out 30 days prior to go live.
- Training will be offered to providers in February. More details can be found on the Department website under the pharmacy transition tab.
- P&T committee meetings and supplemental rebate contracting has already been transitioned.
6. Rules

P. LANIUS presented rules for drug classes that are up for preview and will contain public testimony, class updates and market share, and Committee discussion.

- Oral presentations are restricted to products that are being reviewed for PDL status.
- Presentations will be limited to 3 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

P. LANIUS presented Committee Discussion and Recommendations for each Class should address the following questions:
1. Do the agents differ in efficacy or effectiveness?
2. Do the agents differ in safety or adverse effects?
3. Are there subgroups for which one agent is associated with fewer adverse events?

Factual Inaccuracy:

P. LANIUS presented Factual Inaccuracy. During a Committee meeting, if a stakeholder believes that a factual inaccuracy has been stated by a Committee member, the stakeholder may hand a note to the Department representative or Committee Chair or Vice Chair. The stakeholder must provide the factual inaccuracy or a summary of the inaccuracy on the note. The Department representative will forward any comment to the Chair or Vice Chair. The Committee Chair/Vice Chair will then determine if there is need to publicly hear the inaccuracy prior to moving forward with motions and discussion. The Chair/Vice Chair will state the purported factual inaccuracy and will ask the Committee if they want to hear testimony regarding the factual inaccuracy. When providing testimony, the stakeholder must provide evidence to support the claim of inaccuracy and cannot provide opinions on the drug class being considered.
A. DRUG CLASSES FOR REVIEW

1. B. ROBINSON reviewed utilization and updates for Alzheimer’s agents. J. HYER made the motion that one NMDA antagonist be included as preferred. D. TOLMAN seconded. No discussion. The motion passed with no audible dissent. J. HYER made the motion that at least one cholinesterase inhibitor should be considered for addition to the formulary with consideration given to multiple dosage forms and a better side effect profile. D. TOLMAN seconded the motion. No discussion. The motion passed with no audible dissent. J. HYER made a motion that at least one product be available with once daily dosing due to caregiver issues including one NMDA inhibitor and at least one cholinesterase inhibitor. D. TOLMAN seconded. No discussion. The motion passed with no audible dissent.

2. P. LANIUS moved to discuss Atypical Antipsychotics. BEN Skoog, Acadia, spoke about Nuplazid. LYLE LAIRD, Sunovion, spoke about Latuda. KRISTEN PAREJA, Otsuka, spoke about Rexulti. S. RUSSELL made a comment about the Clozapine website. B. ROBINSON reviewed utilization and updates for Atypical Antipsychotics. J. FEINSTEIN made the motion that at least one orally disintegrating tablet in the pediatric population and at least for adults be on the preferred list. K. JACKSON seconded. No discussion. The motion passed with no audible dissent. J. FEINSTEIN made the motion that at least one agent be preferred that is approved in children down to five years of age. A. DAVIS seconded. No discussion. The motion passed with no audible dissent. J. FEINSTEIN made the motion that clozapine be considered preferred due to its proven efficacy in specific populations. S. HUMPHREYS seconded. No discussion. The motion passed with no audible dissent. J. HYER made the motion that at least one agent should be on the preferred list that is regarded as weight neutral. J. FEINSTEIN seconded. The motion passed with no audible dissent. K. JACKSON made the motion at least one agent with sedating properties be preferred. J. HYER seconded. The motion passed with no audible dissent. D. TOLMAN made the motion at least one agent known with lower risk of EPS side effects including tardive dyskinesia, should be preferred. A. DAVIS seconded. The motion passed with no audible dissent. J. HYER discussed that they have gone away from the pregnant categories and commented regarding making recommendations based on the categories. K. JACKSON made a motion that at least one agent for FDA approved indications be preferred. The motion passed with no audible dissent. S. RUSSELL made a motion that one agent indicated as adjunctive therapy used for Major Depressive Disorder and schizophrenia be preferred. D. TOLMAN seconded. The motion passed with no audible dissent.

3. P. LANIUS moved to discuss Growth Hormones. JIGNESH PATEL, Novo Nordisk spoke about Norditropin Flexpro. B. ROBINSON reviewed utilization and updates for Growth Hormones. J. FEINSTEIN made the motion to consider the ease of use, storage, and handling requirements when selecting preferred products. D. TOLMAN seconded. The motion passed with no audible dissent.
4. P. LANIUS moved to discuss **Insulins**. JASON LURK, Novo Nordisk spoke on Tresiba. SCOTT CHARLAND, Sanofi spoke on Toujeo. B. ROBINSON reviewed utilization and updates for Insulins. D. TOLMAN made a motion that at least two rapid acting, intermediate acting, and long acting agents available in pen and vial form be preferred. J. HYER seconded. The motion passed with no audible dissent. J. HYER made a motion that regular insulin needs to be available for the pregnant population. K. JACKSON seconded. R. DURBIN discussed that regular insulin does not have a place in pregnancy. The motion passed with 2 nays and 1 abstention. P. LANIUS made the motion that multiple options for insulin mixes are available in pen and vial form. J. HYER seconded. No discussion. The motion passed with no audible dissent. A. DAVIS made a motion that at least one agent be preferred for special population of pediatrics and pregnancy patients. J. Hyer seconded. No discussion. The motion passed with no audible dissent.

5. P. LANIUS moved to discuss **Intranasal Corticosteroids**. B. ROBINSON reviewed utilization and updates for Intranasal Corticosteroids. A. DAVIS made a motion that special consideration be given to agents with FDA indications down to age 2. J. FEINSTEIN seconded. The motion passed with no audible dissent. S. RUSSELL made motion that a nasal corticosteroid in combination with an antihistamine be on the preferred list. J. HYER seconded. The motion passed with no audible dissent.

6. P. LANIUS moved to discuss **Leukotriene Modifiers**. B. ROBINSON reviewed utilization and updates for Intranasal Corticosteroids. J. FEINSTEIN made the motion that at least one agent be preferred for children down to age 1 year. D. TOLMAN seconded. The motion passed with no audible dissent.

Break taken at 1428 and meeting resumed at 1440.

7. P. LANIUS moved to discuss **Multiple Sclerosis agents**. DONALD MORAN, Teva, spoke on Copaxone. LAURA HILL, AbbVie spoke on Zinbryta. LYNDAA FINCH, Biogen spoke on Tecfidera. JANET RITTER, Sanofi Genzyme spoke on Aubagio. DR. KRISTEN GRASSER, neurologist, spoke about Aubagio and Copaxone 40mg. S. RUSSELL asked to audience that the patient must fail Gilenya to get another oral agent, what oral option does she suggest without using Gilenya? DR. KRISTEN GRASSER responded that she would rather use any other oral agent due to risks associated with Gilenya. TIM VOLLMER, Professor of Neurology, University of Colorado spoke the he wants to have meds with the best outcomes be available and determined that new orals should be available.

B. ROBINSON reviewed utilization and updates for Multiple Sclerosis agents. D. TOLMAN discussed that placing step therapy for MS is a barrier and step therapy is inappropriate. D. TOLMAN discussed the importance to intervene at the

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beginning of treatment. J. HYER commented that L. PARRY submitted a 
comment to the committee which states step approach might not be appropriate. 
Discussion was made about information is not available about which drugs have 
the most efficacy. P. LANIUS states we are tasked to review safety and efficacy. 
A. DAVIS asked when these guidelines will be updated. DR. KRISTEN GRASSER 
stated there are no guidelines. There is not enough sufficient data to formulate 
guidelines. P. LANIUS asked how many mechanisms of actions there are. DR. 
KRISTEN GRASSER states that all the drugs have a different mechanism of action 
except for the group of interferons.

D. TOLMAN made a motion to eliminate the step therapy for Multiple Sclerosis 
class. K. JACKSON spoke about historical attempt to open a class and stop the 
step therapy. No vote was taken. P.LANIUS made a motion that secondary to 
the variability in individual patients step therapy approach is not recommended. 
K. JACKSON seconded. Motion passed with no abstentions and one nay. P. 
LANIUS stated that frequency of dosing was brought up because there is a lot of 
confusion with Copaxone daily and Copaxone three times a week. D. TOLMAN 
made a motion to make drugs with varying mechanism of actions be preferred 
due to patient variability, response and adverse effects. S. RUSSELL seconded. 
The motion passed with no audible dissent. P. LANIUS made a motion that 
consideration be given to oral, injectable and frequency of dosing. J. HYER 
seconded. The motion passed with no audible dissent.

8. P. LANIUS moved to discuss Ophthalmic Allergy class. B. ROBINSON 
reviewed utilization and updates for Ophthalmic Allergy agents. J. FEINSTEIN 
made a motion that at least one agent be preferred for children down to the age 
of two. G. BLACK seconded. The motion passed with no audible dissent. A. 
DAVIS made a motion that consideration be given that there are preferred 
agents from different mechanisms of action. J. HYER seconded. The motion 
passed with no audible dissent.

9. P. LANIUS moved to discuss Sedative/Hypnotics (non-benzodiazepine). B. 
ROBINSON reviewed utilization and updates for Sedative/Hypnotics (non-
benzodiazepine). P. LANIUS discussed sublingual meds. K. JACKSON made a 
motion that at least one sublingual dose form be preferred for patients that 
cannot tolerate solid oral dosage forms. A. DAVIS seconded. The motion passed 
with no audible dissent. G. BLACK asked about dose limits on zolpidem. B. 
SCHOCK said there are not and DUR board to discuss placement in criteria. G. 
BLACK recommended to the DUR board for recent FDA and clinical guidelines to 
review zolpidem products for daily dose and duration recommendations 
especially for female and elderly population. D. TOLMAN requested there be 
consideration to different mechanisms of action of sedative hypnotics added to 
the preferred list. D.TOLMAN made a motion that given to new data on nighttime 
awakenings, risk of falls and better safety profile consideration be given to
adding more drugs with different mechanism of actions to the preferred list. B. SCHOCK asked the audience if anyone had any expertise on Belsomra. No second to the motion. More discussion of Belsomra. P. LANIUS said this motion will not go forward.

10. P. LANIUS moved to discuss Statins/Statin Combinations. B. ROBINSON reviewed utilization and updates for Statins/Statin Combinations. J. HYER made the motion that at least one agent be preferred for the pediatric population be included as preferred. A. DAVIS seconded. No discussion. The motion passed with no audible dissent. A. DAVIS made the motion that one product with reduced drug interaction risk be included as preferred. S. RUSSELL seconded. The motion passed with no audible dissent. S. RUSSELL made the motion to include two high potency statins defined as >50% reduction in LDL. A. DAVIS seconded the motion. The motion passed with no audible dissent.

K. JACKSON made a motion to adjourn the meeting. B. SCHOCK reminded that the next meeting will be on April 4th. P. LANIUS adjourned the meeting 1630.

By: [Signature]
Lynn Parry, MD

Date: 4/4/17

Reasonable accommodations will be provided upon request for persons with disabilities. Please notify the Committee Coordinator at 303- 866-6371 or brittany.schock@state.co.us or the 504/ADA Coordinator hcpf504ada@state.co.us at least one week prior to the meeting.