1. Call to Order

A quorum being present, Lynn Parry officially called the meeting was called to order at 13:09.

2. Roll Call

Board introductions were made. There were sufficient members for a quorum with eleven members participating. L. LATTs, Chief Medical Officer for the Department of Health Care Policy and Financing, introduced herself to the committee.

A. Members Present

Kelet Robinson, MD  
Thuy McKitrick, PharmD  
Morgan Payne, PharmD  
Gwen Black, PharmD  
Andrew Davis, PharmD  
David Elwell, MD  
James Feinstein, MD  
Kimberley Jackson, DO (Vice-Chairperson)  
Lynn Parry, MD (Chairperson)  
Steven Russell, MD  
Marisa Wiktor, MD

B. Members Excused

Dan Severn, DO  
Jed Ward
C. Staff Present

**Medicaid Pharmacy Department**

Brittany Schock, PharmD

**Magellan RX Management**

Jessica Czechowski, PharmD
Diana Kastendieck, PharmD

3. Approval of Minutes

L. PARRY asked for approval of the minutes from the July 9th, 2019 meeting. K. JACKSON motioned for approval. D. ELWELL seconded. The minutes were approved with no audible dissent.

4. Department Updates:

B. SCHOCK reviewed updates from last meeting.

- Diabetes Management Classes: DPP-4 Inhibitors, GLP-1 Analogues, Hypoglycemic Combos, SGLT-2 Inhibitors
- Anticonvulsants (Oral)
- Colony Stimulating Factors
- Erythropoiesis Stimulating Agents
- Newer Hereditary Angioedema (HAE) Agents
- Ophthalmic, Immunomodulators
- Anticoagulants
- Contraceptives (Oral)
- GI Motility (Chronic)
- Stimulants and Other ADHD Agents
- Mass review drug classes:
  - Bone Resorption Suppression and Related Agents
  - Diabetes Management Classes: Amylin, Biguanides, Meglitinides, Thiazolidinediones
  - Overactive Bladder Agents
  - Prenatal Vitamins

5. NEW BUSINESS

A. B. SCHOCK announced that C. TRAUGOTT will be leaving the Department of Health Care Policy and Financing. Pharmacy Office Director position to be posted.
B. B. SCHOCK announced term expirations and open positions for January 2020.
   • Pharmacists (2 positions)
   • Member Representative (1 position)
   • Other Specialty Physicians (3 positions)

C. 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.
   • 3rd Quarter of 2019
     o Last quarter: 71% approvals and 26% denials, 3% change in therapy
     o Average hold time for the call center for the past quarter was 44 seconds
     o Average call length was 6 minutes and 48 seconds

D. B. SCHOCK spoke on Policy and Procedure Update
   • Reminded the committee about the Mass Review changes that were proposed during the July 2019 P&T meeting and what criteria disqualified classes from Mass Review.
     o New biosimilars: These should be reviewed
     o New products with same active ingredient: These could be mass reviewed if the new products were new, branded products with the same active ingredient or same indication, route of administration, and dosage form.
     o K. JACKSON made a motion to adopt the Policy and Procedure updates as written. A. DAVIS seconded. The motion passed with no audible dissent.

6. Rules

L. PARRY presented rules for drug classes that are up for review and will contain public testimony, class updates and market share, and Committee discussion.
   ➢ Each review will contain:
     • Opportunity for disclosures by Committee members and speakers.
     • Oral presentations by manufacturers, providers and public.
     • Overview for each Drug Class including market share and FDA updates.
     • Committee Discussion and Recommendations for each Class.

   ➢ Mass review Drug classes will only include:
     • Overview for each Drug Class including market share and FDA updates.

   ➢ Rules for presentation:
     • 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 will be limited by verbal comments.
• No visual aids other than designated handouts are permitted.
• Presentations should follow the one page summary that was submitted to the Department.

❖ Stakeholders comments are to:
  ♦ Be limited to clinical information only;
  ♦ Exclude any reference to cost
  ♦ Exclude anecdotal content
  ♦ Exclude general drug or disease specific economic information

➢ 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.
➢ The Department disseminated recently received public comments to the Committee members prior to the meeting.

L. PARRY presented Committee Discussion and Recommendations for each Class should address the following questions:
• Do the agents differ in efficacy or effectiveness?
• Do the agents differ in safety or adverse effects?
• Are there subgroups for which one agent is associated with either differences in efficacy or effectiveness, or differences in safety or adverse effects?

Factual Inaccuracy:

L. PARRY 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

L. PARRY moved to discuss Drug Classes for Review.

J. FEINSTEIN made a motion that at least one agent with pediatric indication be preferred. M. WIKTOR seconded. The motion passed with no audible dissent. J. FEINSTEIN made a motion that alternate dosage forms for all ages be available such as, liquid, ODT and patch. M. WIKTOR seconded. The motion passed with no audible dissent. L. PARRY made a motion that multiple mechanisms of action in multiple dosage forms be preferred. K. JACKSON seconded. The motion passed with no audible dissent. A. DAVIS made a motion that at least one agent for the prevention of delayed nausea and vomiting be available. S. RUSSELL seconded. The motion passed with no audible dissent. G. BLACK made a motion that at least one agent be preferred for the indication of nausea and vomiting associated with pregnancy. M. WIKTOR seconded. The motion passed with no audible dissent.

2. L. PARRY moved to discuss Anti-platelets. B. SCHOCK asked for any disclosures. No disclosures noted. No Speakers. J. CZECHOWSKI reviewed utilization and updates. D. ELWELL made a motion that multiple agents be available due to varying levels of efficacy and safety. K. ROBINSON seconded. The motion passed with no audible dissent.

3. L. PARRY moved to discuss Anti-Psoriatics (Oral and Topical). B. SCHOCK asked for any disclosures. No disclosures noted. No speakers. J. CZECHOWSKI reviewed utilization and updates. K. JACKSON made a motion that because product formulation may affect ease of use and absorption, multiple formulations be considered for preferred status. No second, motion did not carry. A. DAVIS made a motion that various formulation be available as preferred based on application site. J. FEINSTEIN seconded. The motion passed with no audible dissent.

4. L. PARRY moved to discuss Epinephrine Products. B. SCHOCK asked for any disclosures. No disclosures noted. No speakers. J. CZECHOWSKI reviewed utilization and updates. G. BLACK made a motion that the product device, ease-of-use, expiration date and needle-protection, be considerations when choosing a preferred product. K. JACKSON seconded. The motion passed with no audible dissent. K. JACKSON made a motion that products with different preservatives and inactive ingredients be considered when choosing a preferred product. K. ROBINSON seconded. The motion passed with no audible dissent. K. ROBINSON made a motion that consideration for weight appropriate based product be made available as preferred. M. PAYNE seconded. The motion passed with no audible dissent. Recommendation to allow visual aids/testimony to assess product preference.

5. L. PARRY moved to discuss Hepatitis C Agents – Direct Acting Antivirals. B. SCHOCK asked for any disclosures. No disclosures noted. LAURA HILL, Medical Liaison for...
Our mission is to improve health care access and outcomes for the people we serve while demonstrating sound stewardship of financial resources.

J. CZECHOWSKI reviewed utilization and updates. J. FEINSTEIN made a motion that the Preferred Drug List include a medication indicated for pediatric patients 12 and over. K. JACKSON seconded. The motion passed with no audible dissent. A. DAVIS made a motion that the Department of Health Care Policy and Financing consider screening and treatment that is consistent with AASLD-IDSA guidelines. M. WIKTOR seconded. The motion passed with no audible dissent.

L. PARRY moved to discuss Non-Steroidal Anti-Inflammatory Drugs (NSAIDS) (oral and non-oral). B. SCHOCK asked for any disclosures. No disclosures noted. No speakers. J. CZECHOWSKI reviewed utilization and updates. K. JACKSON made a motion that multiple agents with lower GI risk be preferred. A. DAVIS seconded. The motion passed with no audible dissent. K. JACKSON made a motion that multiple agents that do not have evidence of increased CV risk be preferred. No second, motion did not carry. K. JACKSON made a motion that at least one topical NSAID be a preferred product. M. PAYNE seconded. The motion passed with no audible dissent. A. DAVIS made a motion that consideration be given that there is at least one preferred product for the treatment of gout even if there is not an FDA indication for gout. D. ELWELL seconded. The motion passed with 10 Ayes and 1 Abstaining. J. FEINSTEIN made a motion that at least one agent with a pediatric indication be preferred. S. RUSSELL seconded. The motion passed with no audible dissent.

Break at 14:47 and meeting resumed at 15:01.

L. PARRY moved to discuss Pulmonary Arterial Hypertension (PAH) Agents including guanylate cyclase. B. SCHOCK asked for any disclosures. No disclosures noted. JOHN HARTNEY, from Actelion Pharmaceuticals spoke on Opsumit and Uptravi. J. CZECHOWSKI reviewed utilization and updates. S. RUSSELL made a motion that at least one from each of the four classes (endothelin antagonists, prostanoids, guanylate cyclase stimulator (sGC) and phosphodiesterase inhibitors) be preferred. M. PAYNE seconded. The motion passed with no audible dissent. J. FEINSTEIN made a motion that at least one agent with a pediatric indication be preferred. S. RUSSELL seconded. The motion passed with no audible dissent. S. RUSSELL made a motion that all dosage forms across all classes be available as preferred. K. JACKSON seconded. The motion passed with no audible dissent.

L. PARRY moved to discuss Targeted Immune Modulators (TIMs). B. SCHOCK asked for any disclosures. No disclosures noted. KIMBERLY ROWSOM from UCB spoke on Cimzia. LAURA HILL, Medical Liaison from Abbvie spoke on Rinvoq and Skyrizi. MELISSA LAURIE from BMS spoke on Orenica. COLEEN FONG from Gilead drew the committees’ attention to the FDA Guidance on HCV. ANTHONY WHEELER from Eli
Lilly spoke on Taltz. DR. DUANE PEARSON, practice director for rheumatology at UC Health spoke on JAK-inhibitors. J. CZECHOWSKI reviewed utilization and updates. K. ROBINSON made a motion that for each indication at least 2 agents with different mechanisms of action be preferred. A. DAVIS seconded. The motion passes with no audible dissent. D. ELWELL made a motion that members should not be required to fail the same mechanism of action more than once to get access to another mechanism of action product. G. BLACK seconded. The motion passed with no audible dissent. J. FEINSTEIN made a motion that at least one agent be preferred for pediatric indication. M. WIKTOR seconded. The motion passed with no audible dissent. A. DAVIS made a motion that various routes of administration be considered as first line agents. M. PAYNE seconded. The motion passed with no audible dissent.

9. L. PARRY moved to discuss Ulcerative Colitis Agents (Oral and Non-Oral). No speakers. B. SCHOCK asked for any disclosures. No disclosures noted. J. CZECHOWSKI reviewed utilization and updates. K. JACKSON made a motion that product formulation (oral and non-oral, foam, suppositories, enema, capsule, tablet and a product that can be opened and poured onto applesauce) be considered for preferred status. M. WIKTOR seconded. The motion passed with no audible dissent. M. WIKTOR made a motion that at least one agent with pediatric indication be preferred. J. FEINSTEIN seconded. The motion passed with no audible dissent. A. DAVIS made a motion that at least one preferred agent be available for treatment as well as maintenance therapy. D. ELWELL seconded. The motion passed with no audible dissent.

10. L. PARRY moved to discuss Pancreatic Enzymes. B. SCHOCK asked for any disclosures. No disclosures noted. LAURA HILL from Abbvie spoke on Creon. J. CZECHOWSKI reviewed utilization and updates. S. RUSSELL made a motion that two or more agents be preferred due to the variability in patient response. J. FEINSTEIN seconded. The motion passed with no audible dissent.

11. L. PARRY moved to discuss Mass Review Drug Classes.
   • Anti-Depressants (Newer Generation, Tricyclics, Monoamine Oxidase Inhibitors) –
     Motions:
     • There is no reason to prefer one agent over another based on safety since [the Committee] acknowledges all the medications in this class have some safety concerns.
     • At least two agents with a pediatric indication be available on the preferred drug list.
Because of patient variability and response to these agents, and multiple mechanisms of action, we recommend as many agents as possible being preferred.

- Anti-Hyperuricemics – Motions:
  - Medications are available for acute and maintenance treatment.
  - Label revision and FDA communication for the agents be taken into consideration when determining PDL status.

- Anti-herpetics (Oral and Topical) – Motion:
  - Two or more agents be preferred due to the variability in patient response.

- Fluoroquinolones (Oral) – No motions.

- H. Pylori Treatments – No motions.

- Hepatitis C – Single-Agent Ribavirin Products – No motions

- Proton Pump Inhibitors – Motions:
  - At least one agent with a pediatric indication be preferred
  - Consideration be given to a variety of formulations for people with special needs (such as trouble swallowing and feeding tube).

- Triptans and other Migraine Treatments (Oral and Non-Oral) – Motions:
  - A long acting agent should be available.
  - One preferred agent should have a pediatric indication.
  - That one tablet, one injection, one inhaled, and one oral disintegrating formulation should be preferred.

B. SCHOCK asked for any disclosures. No disclosures noted. K. JACKSON made a motion to approve past motions in Mass Review Drug Classes. M. WIKTOR seconded. The motion passed with no audible dissent.

B. SCHOCK announced the next meeting for January 7, 2020.

L. PARRY adjourned the meeting at 1635.

By: ______________________________
Lynn Parry, MD

Date: ______________________________

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.