1. Call to Order

A quorum being present, Lynn Parry called the meeting to order at 13:00 MT.

2. Roll Call

New board member introductions by Lynn Parry:
  Kelet Robinson, MD
  Dan Severn, DO, MPA
  Morgan Payne, PharmD, BCACP

Remaining board introductions conducted.

There are sufficient members for a quorum with twelve members participating.

A. Members Present

Gwen Black, PharmD
Andrew Davis, PharmD
David Elwell, MD
James Feinstein MD
Kimberley Jackson, DO
Patricia Lanius, RPh
Lynn Parry, MD
Morgan Payne, PharmD
Kelet Robinson, MD
Steven Russell, MD
Dan Severn, DO
Marisa Witkor, MD
B. **Members Excused**

None

C. **Staff Present**

**Medicaid Pharmacy Department**

Brittany Schock, PharmD  
Cathy Traugott, RPh, JD

**Magellan RX Management**

Jessica Czechowski, PharmD  
Bob Rocho, RPh

3. **2019 Chairpersons**

B. SCHOCK asked for approval of new 2019 chairpersons, and L. PARRY opened for nominations. K. Jackson moved to self nominate for Vice Chairperson, and S. Russell seconded the nomination. J. Feinstein moved to nominate L. PARRY for Chairperson, and A. DAVIS seconded the nomination. The nominations were approved with no audible dissent.

4. **Approval of Minutes**

L. PARRY requests a change to the October minutes in the **Targeted Immune Modulators (TIMs)** section, in the recommendation in the last sentence, change ‘review’ to ‘re-evaluate’. Changed from: Recommendation to DUR board to review failure and next step criteria in this class of medication. Changed to: Recommendation to DUR board to re-evaluate failure and next step criteria in this class of medication.

L. PARRY asked for approval of the minutes from the October 2, 2018 meeting. K. JACKSON motioned for approval. G. BLACK seconded. The minutes were approved with no audible dissent.

5. **Department Updates**

B. SCHOCK reviewed updates from last meeting.

- Anti-Depressants
  - Newer Generation
  - Monoamine Oxidase Inhibitors (MAOIs)
  - Tricyclics (TCAs)
- Anti-Emetics
Antihyperuricemics
- Antipsoriatics
  - Oral
  - Topical
- Epinephrine Auto-Injector Products
- Fluoroquinolones
- Hepatitis C Virus Treatments
  - Direct-Acting Antivirals
  - Ribavirin-Containing Agents
- NSAIDs
  - Oral
  - Non-Oral
- Proton Pump Inhibitors
- Pulmonary Arterial Hypertension (PAH) Agents
- Targeted Immune Modulators (TIMs)
- Ulcerative Colitis Agents
  - Oral
  - Non-Oral
- Mass review drug classes:
  - Anti-Herpetics
  - H. Pylori Treatments
  - Anti-Platelets
  - Pancreatic Enzymes
  - Triptans

6. NEW BUSINESS.

A. B. SCHOCK reviewed P&T Policies and Procedures Update. P&P updates/changes, written comments, one page summary/clinical comments
Asks for any discussion regarding the lead time required for submission of 1-page written testimony.
  a. P. LANIUS made a motion to define COB as 17:00 MT. J. FEINSTEIN seconded. The motion passed with no audible dissent.
B. B. SCHOCK also drew attention to the clarification in the P&T Policies and Procedures regarding the clarifying point around the written comments.
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.
  - Last quarter: 70% PARs approved, 29% denied and 2% change in therapy.
  - Average hold time for the call center for the past month was 1 minute.
  - Average call length was 6 minutes and 38 seconds.
7. 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.

1. L. PARRY moved to discuss Atypical Antipsychotics. B. SCHOCK asked for any disclosures. No disclosures noted. NIK SEIFTER from Sunovion spoke on Latuda. RICK KEGLER from Otsuka spoke on Rexulti. J. CZECHOWSKI reviewed utilization & market share. S. RUSSELL made a motion that multiple dosage forms including an orally disintegrating tablet (ODT) and oral solution be included on the preferred list for the pediatric and adult populations. D. SEVERN seconded. The motion passed with no audible dissent. J. FEINSTEIN made a motion that at least one agent be preferred that is approved in children down to 5 years of age. A. DAVIS seconded. The motion passed with no audible dissent. S. RUSSELL made a motion that Clozapine be considered preferred due to its proven efficacy in specific populations. D. SEVERN seconded. The motion passed with no audible dissent. A. DAVIS made a motion that at least one agent should be on the preferred list that is regarded as weight neutral. M. WIKTOR seconded. P. LANIUS made a motion that at least one agent known with lower risk of EPS side effects including tardive dyskinesia, should be preferred. K. JACKSON seconded. The motion passed with no audible dissent. D. SEVERN made a motion that at least one agent for Parkinson’s disease psychosis that has an FDA approved indication or efficacy be preferred. D. ELWELL seconded. The motion passed with no audible dissent.

2. L. PARRY moved to discuss CGRP Inhibitors. ANTHONY WHEELER from Lilly spoke on Emgality. DON MORAN from Teva spoke on Ajovy. J. CZECHOWSKI review utilization and market share. D. ELWELL made a motion that there is
insufficient data to make a recommendation for Preferred status at this time. M. PAYNE seconded. The motion passed with no audible dissent.

3. L. PARRY moved to discuss **Growth Hormones.** RYAN Flugge from NovoNordisk spoke on Norditropin. J. CZECHOWSKI reviewed utilization and market share. P. LANIUS made a motion to consider the ease of use, storage, and handling requirements when selecting preferred products. K. JACKSON seconded. The motion passed with no audible dissent – M. WIKTOR was not present for the vote.

4. L. PARRY moved to discuss **Hypoglycemics, Insulins.** RYAN FLUGGE from NovoNordisk spoke on Fiasp and Tresiba. J. CZECHOWSKI reviewed utilization and market share. G. BLACK. Made a motion that at least two agents in pen and vial form be available for all classes. K. ROBINSON seconded. The motion passed with no audible dissent. A. DAVIS made a motion that at least one agent in each class be preferred for special populations of pediatrics and pregnant patients. M. WIKTOR seconded. The motion passed with no audible dissent.

Break at 14:47 MT and reconvened at 15:00 MT.

5. L. PARRY moved to discuss **Intranasal Rhinitis Agents.** Mary Porter from Optinose spoke on Xhance. J. CZECHOWSKI reviewed utilization and market share. J. FEINSTEIN made a motion that at least one agent be preferred with indication for age 2 and above. P. LANIUS seconded. The motion passed with no audible dissent. K. ROBINSON made a motion that at least one non-steroidal agent be preferred. J. FEINSTEIN seconded. The motion passed with no audible dissent.

6. L. PARRY moved to discuss **Lipotropics and Bile Salts.** No speakers. J. CZECHOWSKI reviewed utilization and market share. K. JACKSON made a motion that agents be preferred in each drug class that are capable of going through a feeding tube, where available. S. RUSSELL seconded. The motion passed with no audible dissent. K. ROBINSON made a motion to have one available agent to treat cholestasis of pregnancy. P. LANIUS seconded. The motion passed with no audible dissent.

7. L. PARRY moved to discuss **Multiple Sclerosis.** TAMI SOVA from Biogen spoke on Tecfidera. CAROLINE KICKLIGHTER from Novartis spoke on Gilenya. JANET
RITTER from SanofiGenzyme spoke on Aubagio. J. CZECHOWSKI reviewed utilization and market share. L PARRY made a motion that secondary to the variability in individual patients, step therapy approach is not recommended, based on recent AAN guidelines for Disease-Modifying Therapy (DMT). P. LANIUS seconded. The motion passed with one abstain. M. WIKTOR made a motion to make products with varying mechanisms of action be preferred due to patient variability, response and adverse effects, especially with concern for pediatrics and patients of child-bearing age. M. PAYNE seconded. The motion passed with no audible dissent.

8. L. PARRY moved to discuss **Neurocognitive Disorder Agents.** B. SCHOCK asked for any disclosures. No disclosures noted. AMY SMITH, a community member, spoke on CYP 2D6 Inhibitors, requesting genetic testing (covered by Medicaid) for all patients who are prescribed those applicable products. J. CZECHOWSKI reviewed utilization and market share. S. RUSSELL made a motion to make products with varying mechanisms of action be preferred due to variability, response and adverse effects. M. WIKTOR seconded. The motion passed with one vote to abstain – J. FEINSTEIN was not present for the vote. P. LANIUS made a motion that products with multiple formulations be available. L. PARRY seconded. The motion passed with no audible dissent – J. FEINSTEIN was not present for the vote. A. DAVIS made a motion that at least one product be available for daily dosing due to caretaker considerations. D. SEVERN seconded. The motion passed with no audible dissent – J. FEINSTEIN was not present for the vote.

9. L. PARRY moved to discuss **Anti-Parkinson’s Agents.** B. SCHOCK asked for any disclosures. No disclosures noted. LAURA HILL from Abbvie spoke on Duopa. J CZECHOWSKI reviewed utilization and market share. M WIKTOR made a motion that products with multiple formulations be available. A. DAVIS seconded. The motion passed with no audible dissent – J. FEINSTEIN was absent for the vote. L. PARRY made a motion that at least one form of carbidopa as a single agent be available. K. ROBINSON seconded. The motion passed with no audible dissent. A. DAVIS made a motion that at least one preferred product be available in each therapeutic category. G. BLACK seconded. The motion passed with no audible dissent. K. JACKSON made a motion that where available in each subclass, agents be preferred that can be delivered by a non-oral route, including administration by a feeding tube. D ELWELL seconded. The motion passed with no audible dissent.

S. RUSSELL departed the meeting at 16:25 MT.

10. L. PARRY moved to discuss **Ophthalmic Glaucoma Agents.** AGNESS BLOCK from Aerie spoke on Rhopressa. B. SCHOCK asked for any disclosures. No
disclosures noted. J. CZECHOWSKI reviewed utilization and market share. K. JACKSON made a motion that preservative-free versions be available for those with sensitivities or allergies. M. PAYNE seconded. The motion passed with no audible dissent. J. FEINSTEIN made a motion that at least one agent with pediatric indications be preferred down to age 2 years. P. LANIUS seconded. The motion passed with no audible dissent. M. PAYNE introduced a motion for consideration of race and ethnicity when choosing preferred products. M. WIKTOR seconded. The motion passed with no audible dissent. A. DAVIS made a motion that there be at least one preferred product in each subclass. G. BLACK seconded. The motion passed with no audible dissent.

11. L. PARRY moved to discuss **Topical Steroids.** No speakers. J. CZECHOWSKI reviewed utilization and market share. J. FEINSTEIN made a motion that at least one agent from each potency category with pediatric indication be preferred. P. LANIUS seconded. The motion passed with no audible dissent. A. DAVIS made a motion that at least one preferred agent be available for each potency category. K. ROBINSON seconded. The motion passed with no audible dissent. M. PAYNE made a motion that consideration be given for multiple formulations to account for application site across potency categories. M. WIKTOR seconded. The motion passed with no audible dissent.

12. L. PARRY moved to discuss the Mass Review Drug Classes.
- **Leukotriene Modifiers**
  - At least one agent be preferred for children down to age 1 year
- **Statins & Statin Combinations**
  - At least one agent be preferred for the pediatric population
  - One product with reduced drug interaction risk be included as preferred
  - Include two high potency statins defined as >50% reduction in LDL
- **Ophthalmic Allergy**
  - At least one agent be preferred for children down to the age of 2
  - Consideration be given that there are preferred agents from different mechanisms of action
- **Sedative Hypnotics**
  - At least one sublingual dosage form be preferred for patients that cannot tolerate solid oral dosage forms

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

B. SCHOCK announced the next meeting for April 10, 2019. L. PARRY adjourned the meeting at 16:51 MT.
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.