1. Call to Order

A quorum being present, Lynn Parry officially called the meeting to order at 12:59.

2. Roll Call

Board introductions were made. There were sufficient members for a quorum with eleven members participating and two members excused.

A. Members Present

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

B. Members Excused

Steven Russell, MD
Jed Ward

C. Staff Present

Medicaid Pharmacy Department

Brittany Schock, PharmD

Cathy Traugott, RPh, JD

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3. Approval of Minutes

L. PARRY asked for approval of the minutes from the April 2, 2019 meeting. M. PAYNE motioned for approval. M. WIKTOR seconded. The minutes were approved with no audible dissent.

4. Department Updates

B. SCHOCK reviewed updates from last meeting.

- Acne Agents, Topical
- Isotretinoins, Oral
- Tetracyclines, Oral
- Rosacea Agents, Topical
- Non-Opioid analgesics
- Opioids, Long-Acting
- Opioids, Short-Acting
- Benign Prostatic Hypertrophy (BPH)
- Phosphate Binders
- Respiratory Inhalants
- Androgenic Agents – Topical, Oral, Parenteral
- Mass review drug classes:
  - Angiotensin Modulators/Angiotensin Modulator Combos
  - Antihistamines, Newer Generation
  - Skeletal Muscle Relaxants
  - Topical Immunomodulators

5. NEW BUSINESS

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
- 2nd Quarter of 2019
  - 70% approvals, 28% denials, 2% change in therapy (same as 1st Quarter 2019)
  - Average hold time for the call center for the past month was 51 seconds
  - Average call length was 6 minutes and 33 seconds
B. SCHOCK asked for discussion around modifying criteria which disqualified classes from Mass Review.

- New biosimilars: The committee felt that they should be reviewed and also commented that they should revisit the topic in 1 year
- New products with same active ingredient: The committee agreed these could be mass reviewed if the products were new, branded products with same active ingredient or same indication, route of administration, and dosage form.

B. SCHOCK updated the committee on the results of the clinical materials survey.

- All but 1 member opted in to electronic resources
- Streamlined binders were provided to the committee
- The option for a full set of printed materials is always available for any committee member

L. PARRY presented Drug Classes Up for Review.

Each Review will contain:

- Oral presentation 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

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.

- 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.
- 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 recently 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:
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 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 a 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 Diabetes Management Classes – DPP-4 Inhibitors.
   J. CZECHOWSKI reviewed utilization and updates. There were no motions made or voted upon by the committee.

2. L. PARRY moved to discuss Diabetes Management Classes – GLP-1 Analogues. RYAN FLUGGE from NovoNordisk spoke on Ozempic and Victoza. ANTHONY WHEELER from Lilly spoke on Trulicity. J. CZECHOWSKI reviewed utilization and updates. M. PAYNE made a motion to have one GLP-1 extended-release once-weekly product be preferred in applicable patients. G. BLACK seconded. The motion passed with no audible dissent. M. WIKTOR made a motion for a GLP-1 indicated in the pediatric population be preferred. K. ROBINSON seconded. The motion passed with no audible dissent. M. PAYNE made a motion for at least one GLP-1 with auto-injector formulation for those with limited dexterity or visual impairment be preferred in order to increase compliance. D. SEVERN seconded. The motion passed with no audible dissent.

3. L. PARRY moved to discuss Diabetes Management Classes – Hypoglycemic Combinations. RYAN FLUGGE from NovoNordisk spoke on Xultophy. J. CZECHOWSKI reviewed utilization and updates. D. SEVERN made the motion to prefer none of the combination products. M. WIKTOR seconded. The motion passed with 8 Ayes, 1 Nay, and 2 Abstaining.
4. L. PARRY made a motion to discuss **Diabetes Management Classes — SGLT-2 Inhibitors.** CHARLIE RYON from Janssen/Johnson & Johnson spoke on Invokana. J. CZECHOWSKI reviewed utilization and updates. D. SEVERN made a motion that there is at least one preferred agent that does not have increased risk of lower extremity amputation. J. FEINSTEIN seconded. The motion passed with 10 Ayes and 1 Abstaining. A. DAVIS made a motion that at least one SGLT-2 be preferred that has evidence for CV benefit. M. WIKTOR seconded. L. PARRY made a recommendation to DUR to review new trial evidence regarding lower extremity amputation. J. FEINSTEIN made a comment to request that combination products be reviewed in the Hypoglycemic Combinations class.

5. L. PARRY moved to discuss **Anticonvulsants.** JULIE MILD from Greenwich Biosciences spoke on Epidiolex. MARILYN SEMENCHUK from Biocodex spoke on Diacomit. DEBANJANA CHATTERJEE from Eisai spoke on Fycompa. SIBIN STEPHEN from UCB spoke on Briviact and Vimpat. SARA KLEIN from Epilepsy Foundation of CO spoke to maintain open access for Epilepsy patients. DR. EDWARD MAA from Denver Health/UC Denver spoke about removing specialist prescriber requirements as there are access issues in rural areas. GAETHA MILLS from SMC/HealthOne Cares spoke about opposing any management on prescribing in this protected class. DANIELLE MCDERMOTT from UC Denver spoke to continue open access for epileptic agents for patients. J. CZECHOWSKI reviewed utilization and updates. K. JACKSON made a motion that brand name medication be preferred when used with the diagnosis of epilepsy. L. PARRY seconded. The motion passed with no audible dissent after some discussion. K. JACKSON made a motion that there are no barriers to access for diagnosis of epilepsy. D. SEVERN seconded. The motion passed with no audible dissent. A. DAVIS made a motion to offer as many dosage forms (e.g. suspension, solution, ODT, etc.) available as preferred. L. PARRY seconded. The motion passed with no audible dissent.

Break at 15:06 and meeting resumed at 15:14.

6. L. PARRY made a motion to discuss **Colony Stimulating Factors.** JEFF MARTIN from Amgen spoke on Neulasta. J. CZECHOWSKI reviewed utilization and updates. M. WIKTOR made a motion to approve a colony stimulating factor with single administration per cycle of chemo treatment to the preferred list. G. BLACK seconded. The motion passed with no audible dissent.

7. L. PARRY made a motion to discuss **Erythropoiesis Stimulating Proteins.** J. CZECHOWSKI reviewed utilization and updates. There were no motions made or voted upon by the committee.

8. L. PARRY moved to discuss **Hereditary Angioedema (HAE) Agents.** DAVID GRIFFIN from Takeda spoke on Firazyr and Takhzyro. J. CZECHOWSKI reviewed utilization and updates. J. FEINSTEIN made a motion that at least one preferred product be preferred with FDA indication for pediatric population. K. JACKSON seconded. The motion passed with no audible dissent. K. JACKSON made a motion that at least one product with increased safety in pregnancy for women of childbearing age be preferred. D. ELWELL seconded. The motion passed with no audible dissent. A. DAVIS made a motion that products be available for both treatment and prophylaxis.
per guidelines. K. ROBINSON seconded. The motion passed with no audible dissent. K. JACKSON made a motion that products with different routes of administration (IV and SC) be preferred. A. DAVIS seconded. The motion passed with no audible dissent.

9. L. PARRY moved to discuss **Ophthalmic Immunomodulators**. J. CZECHOWSKI reviewed utilization and updates. There were no motions made or voted upon by the committee.

10. L. PARRY moved to discuss **Anticoagulants**. The committee opened with discussion about warfarin therapy and new guidelines. CHARLIE RYON from Janssen/Johnson & Johnson returned his time to the committee and declined to speak. Melissa Laurie from BMS spoke on Eliquis. JEREMY VANDIVER from University of Wyoming/St. Joseph’s Hospital spoke on evidence for Apixaban (Eliquis) being preferred first line. J. CZECHOWSKI reviewed utilization and updates. K. JACKSON made a motion that for all women of reproductive age requiring long-term anticoagulation, at least one DOAC with increased safety in pregnancy be preferred as first-line therapy. D. SEVERN seconded. The motion passed with no audible dissent. G. BLACK made a motion that based on currently available evidence for safety and efficacy, at least one DOAC be preferred as a first line agent. A. DAVIS seconded. The motion passed with no audible dissent. M. PAYNE made a motion that at least one agent with a lower risk of GI bleed be preferred. K. ROBINSON seconded. The motion passed with no audible dissent. G. BLACK made a motion that at least one preferred product be available for each of the indications (IBS-C, IBS-D, CIC, and OIC). K. ROBINSON seconded. The motion passed with no audible dissent.

11. L. PARRY moved to discuss **Contraceptives, Oral**. J. CZECHOWSKI reviewed utilization and updates. D. ELWELL made a motion to cover at least two in each category of the low dose estrogen monophasic, high dose estrogen monophasic, biphasic, triphasic/four, extended cycle and continuous cycle, progestin combinations with low and high dose category in monophasic category and progestin singles agents and at least one product that contains iron and at least one product that is chewable. J. FEINSTEIN seconded. The motion passed with no audible dissent.

12. L. PARRY moved to discuss **GI Motility, Chronic**. DAVID CRAM from Takeda spoke on Motegrity. J. CZECHOWSKI reviewed utilization and updates. K. JACKSON made a motion that a product that has an alternate dosage form for patients that have difficulty swallowing (e.g. cannot take pills or require a feeding tube) be preferred. J. FEINSTEIN seconded. The motion passed with no audible dissent. G. BLACK made a motion that at least one preferred product be available for each of the indications (IBS-C, IBS-D, CIC, and OIC). K. ROBINSON seconded. The motion passed with no audible dissent.

13. L. PARRY moved to discuss **Stimulants and other ADHD Agents**. J. CZECHOWSKI reviewed utilization and updates. K. JACKSON made a motion to include at least one liquid, one capsule and one sprinkle for ER and IR forms of methylphenidate, amphetamine and combination products as preferred. A. DAVIS seconded. J. FEINSTEIN made a motion that at least one agent with pediatric indication and has a non-oral route of administration be preferred. G. BLACK seconded. The motion passed with no audible dissent. J. FEINSTEIN made a motion that one alpha2 adrenergic

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agonist be available as preferred. M. WIKTOR seconded. The motion passed with no audible dissent. L. PARRY made a motion that the current prior authorization and step therapy process for indication of narcolepsy should be continued. There was no second. The motion did not carry. J. FEINSTEIN made a motion to include one NRI be available as a preferred drug. L. PARRY seconded. The motion passed with no audible dissent.

14. L. PARRY moved to discuss **Mass Review Categories**. L. PARRY reviewed the policies and procedures for the Mass Review Classes.
   - Bone Resorption Suppression and Related Agents – Motions:
     i. At least one agent for daily, weekly, and monthly dosing be available as well as an agent in liquid form be available
   - Diabetes Management Classes – Amylin – No Motions
   - Diabetes Management Classes – Biguanides – Motions:
     i. Include as preferred both an extended and immediate release agent
   - Diabetes Management Classes – Meglitinides – Motions:
     i. Keep all products non-preferred
   - Diabetes Management Classes – TZDs – Motions:
     i. At least one TZD agent be preferred
   - Overactive Bladder Agents – Motions:
     i. One immediate-release drug, one extended release drug and one for use in pediatrics down to age five years should be given preference on the preferred drug list
     ii. At least one medication with non-oral route of administration be preferred
   - Prenatal Vitamins - Motions:
     i. An agent with each iron salt form be available as preferred.
     ii. Have as many different dosage forms as possible (capsule, softgel, tablet, solution, etc.) preferred.
     iii. Prenatal Vitamins should be allowed according to FDA-approved indications.

D. ELWELL made a motion to approve the mass review classes with motions from last year’s meeting. K. JACKSON seconded. The motion passed with no audible dissent.

L. PARRY adjourned the meeting 1651.

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.