COLORADO
Department of Health Care Policy & Financing

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

Department of Health Care Policy and Financing
Virtual Meeting via Zoom
July 14, 2020

1. Call to Order

A quorum being present, Lynn Parry officially called the meeting to order at 13:02 MT.

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
David Elwell, MD
James Feinstein, MD
Thuy McKitrick, PharmD
Lynn Parry, MD (Chairperson)
Davin Patel, PharmD
Morgan Payne, PharmD
Kelet Robinson, MD
Steven Russell, MD
Dan Severn, DO
Marisa Wiktor, MD

B. Members Excused

Andrew Davis, PharmD
Kimberley Jackson, DO (Vice-Chairperson)

C. Staff Present

Medicaid Pharmacy Department

Jim Leonard, PharmD
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 April 7, 2020 meeting. D. SEVERN motioned for approval. M. WIKTOR seconded. The minutes were approved with no audible dissent.

4. Department Updates

J. CZECHOWSKI and B. SCHOCK reviewed updates from last meeting.

- Non-Opioid Analgesics
- Opioids, Long-Acting, Oral
- Opioids, Short-Acting, Oral
- Tetracyclines
- Angiotensin Modulators/Angiotensin Modulator Combos – ACEIs & Combinations, ARBs and Combinations, Renin Antagonists and Combinations
- Acne Agents, Topical
- Isotretinoins, Oral
- Androgenic Agents – Topical, Oral, Injectable
- Respiratory Inhalants - Inhaled Anticholinergics & Anticholinergic Combinations, Inhaled $Beta_2$ Agonists (short-acting), Inhaled $Beta_2$ Agonists (long-acting), Inhaled Corticosteroids and Combinations
- Mass review drug classes:
  - Skeletal Muscle Relaxants
  - Rosacea Agents, Topical
  - Antihistamines, Newer Generation and Combinations
  - Topical Immunomodulators
  - Phosphate Binders
  - Benign Prostatic Hypertrophy (BPH) Agents

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 2020
  - 75% approvals, 20% denials, 5% change in therapy
  - Average hold time for the call center for the past quarter was 38 seconds
  - Average call length was 6 minutes and 47 seconds

B. SCHOCK discussed Policy and Procedure proposed updates and changes with a reminder that a final version will be presented, reviewed, and voted on at the October P&T meeting.

- Additional language added:
  - Current COI policy
  - Written policy for meetings between P&T Committee members and representatives from pharmaceutical manufacturers.
- Clarification language regarding deadline for testimony: At least 3 business days prior to meeting. Specific date will be provided in the posted agenda.
- Mass review process: Discussion around biosimilars and if they should be in mass review. Committee unanimously agreed to mass review unless biosimilar indications do not reflect all indications of reference product or other disqualifications pull them out.
- Electronic language added for the preparation and materials due to virtually held meetings.
- Addition of the Sunshine Law.

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 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 **Anticonvulsants**. CANDICE ZIZILAS from Aquestive Therapeutics spoke on Sympazan. STEPHANIE KENNEDY from Greenwich Biosciences spoke on Epidiolex. SARAH KLEIN from the Epilepsy Foundation of Colorado spoke to maintain open access for epilepsy patients. BARBARA YAEGER from UCB spoke on Vimpat and Briviact. DR. CHAD BUSH neurologist from CU Anschutz/UC Health spoke to continue open access, without restrictions, for epileptic agents for patients. RON KAUFMAN from SK Life Science spoke on Xcopri. B. SCHOCK asked for any disclosures. No disclosures noted. J. CZECHOWSKI reviewed utilization and updates. J. FEINSTEIN made a motion that a brand name medication be preferred when used with the diagnosis of epilepsy. K. ROBINSON seconded. The motion passed with no audible dissent. K. ROBINSON made a motion that at least one medication for epilepsy be available for women of childbearing age with a low risk of fetal abnormalities or potential side effects. D. SEVERN seconded. The motion passed with no audible dissent. J. FEINSTEIN made a motion that all dosage forms be available as preferred agents. T. MCKITRICK seconded. The motion passed with no audible dissent. A recommendation was made to the DUR board to reduce all barriers to access to all epilepsy medications.

2. L. PARRY moved to discuss **Stimulants and Related Agents.** DEB PROFANT from Jazz

Pharmaceuticals spoke on Sunosi. B. SCHOCK asked for any disclosures. No disclosures noted. J. CZECHOWSKI reviewed utilization and updates. D. SEVERN 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. J. FEINSTEIN seconded. The motion passed with no audible dissent. J. FEINSTEIN made a motion that at least one agent with pediatric indication that has a non-oral route of administration be preferred. D. PATEL seconded. The motion passed with no audible dissent. D. ELWELL made a motion that at least two non-controlled agents be preferred including one alpha$_2$ adrenergic agonist. D. SEVERN seconded. The motion passed with no audible dissent.

3. L. PARRY moved to discuss **Contraceptives, Oral.** B. SCHOCK asked for any disclosures. No disclosures noted. No speakers. J. CZECHOWSKI reviewed utilization and updates. K. ROBINSON made a motion to cover at least two in each category of the low 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. D. ELWELL seconded. The motion passed with no audible dissent.

4. L. PARRY moved to discuss **Diabetes Management Classes – DPP-4 Inhibitors**. B. SCHOCK asked for any disclosures. No disclosures noted. No speakers. J. CZECHOWSKI reviewed utilization and updates. There were no motions made or voted upon by the committee.

5. L. PARRY moved to discuss **Diabetes Management Classes – GLP-1 Analogues**. RYAN FLUGGE from NovoNordisk spoke on Victoza, Ozempic and Rybelsus. ANTHONY WHEELER from Lilly spoke on Trulicity. B. SCHOCK asked for any disclosures. No disclosures noted. J. CZECHOWSKI reviewed utilization and updates. M. PAYNE made a motion that at least one GLP-1 extended-release once-weekly product be preferred. K. ROBINSON seconded. The motion passed with no audible dissent. J. FEINSTEIN made a motion that at least one GLP-1 indicated in the pediatric population be preferred. D. PATEL seconded. The motion passed with no audible dissent. K. ROBINSON made a motion that 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. D. PATEL made a motion that at least one oral GLP-1 formulation be preferred. K. ROBINSON seconded. The motion passed with no audible dissent. D. ELWELL made a motion that at least one GLP-1 with cardiovascular benefits be preferred. M. PAYNE seconded. The motion passed with no audible dissent.

6. L. PARRY moved to discuss **Diabetes Management Classes – Hypoglycemic Combinations**. RYAN FLUGGE from NovoNordisk spoke on Xultophy. B. SCHOCK asked for any disclosures. No disclosures noted. J. CZECHOWSKI reviewed utilization and updates. D. PATEL made the motion to prefer none of the combination products. D. ELWELL seconded. The motion passed with no audible dissent.

7. L. PARRY made a motion to discuss **Diabetes Management Classes – SGLT-2 Inhibitors.** ERIN HOHMAN from Janssen/Johnson & Johnson returned her time to the committee and declined to speak. B. SCHOCK asked for any disclosures. No disclosures noted. J. CZECHOWSKI reviewed utilization and updates. D. ELWELL made a motion that there is at least one preferred agent that does not have increased risk of lower extremity amputation. M. WIKTOR seconded. The motion passed with no audible dissent. M. PAYNE made a motion that at least one SGLT-2 be preferred that has evidence for cardiovascular as well as renal benefit. G. BLACK seconded. The motion passed with no audible dissent.

   Break at 15:32 and meeting resumed at 15:45.

8. L. PARRY moved to discuss **GI Motility, Chronic.** B. SCHOCK asked for any disclosures. No disclosures noted. No speakers. J. CZECHOWSKI reviewed utilization and updates. J. FEINSTEIN made a motion that at least one agent that has a non-oral route be preferred. M. WIKTOR seconded. The motion passed with no audible dissent. D. PATEL made a motion that at least one preferred product be available for each of the indications (IBS-C, IBS-D, CIC, and OIC). M. PAYNE seconded. The motion passed with no audible dissent.

9. L. PARRY moved to discuss **Anticoagulants**. ERIN HOHMAN from Janssen/Johnson & Johnson spoke on Xarelto. TIM HARTMAN from BMS spoke on Eliquis. B. SCHOCK asked for any disclosures. No disclosures noted. J. CZECHOWSKI reviewed utilization and updates. D. ELWELL made a motion that at least one DOAC be preferred as a first line agent. T. MCKITRICK seconded. The motion passed with no audible dissent. D. ELWELL made a motion that at least one agent with a lower risk of GI bleed be preferred. D. PATEL seconded. The motion passed with no audible dissent. K. ROBINSON made a motion that at least one low molecular weight heparin be preferred as a first line agent. G. BLACK seconded. The motion passed with no audible dissent.

10. L. PARRY made a motion to discuss **Colony Stimulating Factors**. B. SCHOCK asked for any disclosures. No disclosures noted. No speakers. J. CZECHOWSKI reviewed utilization and updates. G. BLACK made a motion that one long-acting CSF agent be preferred. D. PATEL seconded. The motion passed with no audible dissent.

11. L. PARRY moved to discuss **New Hereditary Angioedema (HAE) Agents.** JOHN WILLIAMSON from US HAEA spoke on open access for patients with hereditary angioedema. B. SCHOCK asked for any disclosures. No disclosures noted. J. CZECHOWSKI reviewed utilization and updates. J. FEINSTEIN made a motion that at least one product be preferred with FDA indication for pediatric population. M. WIKTOR seconded. The motion passed with no audible dissent. D. PATEL made a motion that at least one product with increased safety in pregnancy for women of childbearing age be preferred. D. SEVERN seconded. The motion passed with no audible dissent. J. FEINSTEIN made a motion that at least one product be available for treatment and one product available for prophylaxis per guidelines. D. ELWELL seconded. The motion passed with no audible dissent. J. FEINSTEIN made a motion that at least one product with IV route and

one product with SC route of administration be preferred. T. MCKITRICK seconded. The motion passed with no audible dissent.

12. L. PARRY moved to discuss **Ophthalmic Immunomodulators.** MELISSA SOMMERS from Novartis spoke on Xiidra. B. SCHOCK asked for any disclosures. No disclosures noted. J. CZECHOWSKI reviewed utilization and updates. There were no motions made or voted upon by the committee.

13. L. PARRY moved to discuss **Mass Review Categories**.
    - Bone Resorption Suppression and Related Agents – Motions:
        - 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:
        - Include as preferred both an extended and immediate release agent
    - Diabetes Management Classes – Meglitinides – Motions:
        - Keep all products non-preferred
    - Diabetes Management Classes – TZDs – Motions:
        - At least one TZD agent be preferred
    - Erythropoiesis Stimulating Agents – No Motions
    - Prenatal Vitamins - Motions:
        - An agent with each iron salt form be available as preferred.
        - Have as many different dosage forms as possible (capsule, softgel, tablet, solution, etc.) preferred.
        - Prenatal Vitamins should be allowed according to FDA-approved indications.
    - Overactive Bladder Agents – Motions:
        - 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
        - At least one medication with non-oral route of administration be preferred

D. SEVERN made a motion to approve the mass review classes with motions from last year's meeting. M. WIKTOR seconded. The motion passed with no audible dissent.

B. SCHOCK announced next meeting date, Tuesday October 6th; 1:00 p.m.-5:00 p.m.

L. PARRY adjourned the meeting 16:42 MT.

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.