STATE OF CALIFORNIA GAVIN NEWSOM, Governor

DEPARTMENT OF INDUSTRIAL RELATIONS

Division of Workers' Compensation

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# Pharmacy and Therapeutics Advisory Committee DRAFT - MINUTES OF MEETING Wednesday, April 16, 2025

Via Tele/Video-Conference

#### In Attendance:

#### **DWC:**

George Parisotto
DWC Administrative Director
Sue Honor-Vangerov
DWC Legal Counsel
Kevin Gorospe, Pharm.D.
DWC Consultant

#### **Committee Members:**

Raymond Meister, M.D., DWC Executive Medical Director, Chair Julie Fuller, M.D. Joyce Ho, M.D. Raymond Tan, Pharm.D. Lori Reisner, Pharm.D

#### I. Welcome and Introductions

George Parisotto, Administrative Director, DWC

- A. Conflict of Interest reminder and advise P&T Committee members to review it; need to submit annually
- B. State and federal Antitrust Law advisement
- C. Reminder that Pharmacy Fee Schedule revised regulations will be effective July 1, 2025.
  - a. More details about the Pharmacy Fee Schedule are available on the DWC website, including sample pharmaceutical fee data files and NPI files posted with rule making materials which stakeholders may use in updating internal systems.
  - b. DWC anticipates posting an updated Pharmaceutical Fee Schedule calculator for the convenience of the public by the effective date.
- D. DWC staff and P and T Committee member introductions

### II. Approval of Minutes from the January 15, 2025 Meeting

Dr. Raymond Meister, Executive Medical Director, DWC

Motion: Approval of the minutes from the January 15, 2025 meeting.

<u>Vote</u>: The committee members in attendance voted unanimously for approval of the January 15, 2025 meeting minutes.

# Related briefing: January 15, 2025 Meeting Minutes

(https://www.dir.ca.gov/dwc/MTUS/Meetings/April-2025/Meeting-Minutes-January-2025.pdf)

#### III. Discussion

#### A. Biosimilars Statement

#### c. Biosimilar Use Review

- Substituting a biosimilar biologic product for a reference brand biologic is not the same as substituting a generic drug for brand drug.
- ii. Some, not all, biosimilar products have been determined by the FDA as "interchangeable" with the reference biologic product.
- iii. The relationship between an interchangeable biosimilar to the reference brand can be viewed in a similar manner as the generic substitution dynamic.

# d. P&T Draft Policy Statement

- Given the increase in numbers of interchangeable biosimilars, the P&T committee wanted to provide a statement in support and encourage their use.
- ii. A cursory review did not find specific policies in other workers' compensation programs related to interchangeable biosimilars
- iii. It is of note that the Federal Employee Compensation Administration notes in their FECA Bulletin 22-02 that "In general, the formulary favors biosimilar biologic products over the biological reference product."
- iv. A statement was crafted for review by the P&T Committee and is worded as encouragement to consider interchangeable biosimilars as first line agents and not as a mandate.

#### e. Statement for Review

i. "Workers' compensation plans are encouraged to increase their use of cost-effective treatments by using biosimilars when these products are identified as both interchangeable and more cost effective than branded reference biologic products."

#### f. Committee Discussion

- Committee member expresses concern for lack of clarity and suggests that "providers" be added to the statement above to improve clarity.
- ii. DWC agrees to update statement for clarity
  - Updated statement: Workers' compensation plans and providers are encouraged to increase their use of cost-

effective treatments by using biosimilars when these products are identified as both interchangeable and more cost effective than branded reference biologic products.

- g. Public Comment
  - i. no public comment
- B. Cannabis Guideline Brief Update
  - a. ACOEM cannabis guideline is going through rule making process for adoption into MTUS. Our plan is to adopt that guideline into MTUS. If anyone is curious about that guideline, it is available on our website.
  - b. Committee Discussion
    - i. No committee comment
  - c. Public Comment
    - i. No public comment
- C. Topically Applied Drugs Spending
  - a. A question was asked about the amount being spent on topically applied drugs
  - b. When reviewing both pharmacy and physician dispensed topical drugs, there were two pharmaceutical categories that account for most of the total payments
    - i. Topical Local Anesthetics
      - Examples include lidocaine, lidocaine/prilocaine, benzocaine
    - ii. Topical Anti-inflammatory, Non-Steroidal
      - Includes diclofenac and diclofenac combination products
  - c. P&T Committee has covered these categories in previous meetings
    - i. Considering physician dispensed drugs, these two categories account for approximately 80% of topical drugs dispensed
    - ii. Considering pharmacy dispensed drugs, these two categories account for approximately 79% of topical drugs dispensed
  - d. Committee Discussion
    - i. Committee member expresses concern that the California MTUS does not seem to address the various types of lidocaine available, such as a patch versus a cream or ointment. Also, when comparing ingredients of over-the-counter private label topical, it looks to be the same ingredient and same percentage. For example, a lidocaine 5% ointment for \$1900. The example highlights that the guideline seems to have gaps and it would be helpful to fill these gaps to avoid having someone pay \$1900 for the same product available for \$30. Committee member confirms that it was not a compounded product, but a private label. Therefore, it does not identify the other ingredients.
    - ii. Committee member expresses curiosity about whether the example case of \$1900 5% lidocaine was a compounded product, as they can be more expensive. Committee member

- confirms that it was not a compounded product, but a private label and does not identify the other ingredients.
- iii. Committee member expresses worry over potential gaps in the guidelines related to the various applications of lidocaine.

  Lidocaine patch, cream, and ointment have different effects and penetration characteristics, despite having the same active ingredients. Committee member suggests that there may be an opportunity for the guidelines to be more detailed about the various applications of lidocaine delivery methods to improve guidance.
- iv. Committee member expresses their agreement adding that the penetration characteristics of patches versus creams and ointments are very different.
  - DWC clarifies what the ask is here, given that the guidelines provide references to the various studies used to develop the guidelines. Perhaps what is needed here is to pull the references and provide a summary for the committee to see if it helps clarify, for the committee, the information provided in the guidelines. Then we can move forward with how to address any issues the committee has at that point.
- v. DWC will pull the references for the two categories of topically applied drugs noted above, Topical Local Anesthetics and Topical Anti-inflammatory, Non-Steroidal.
- vi. Committee member conveys that diclofenac with different formulations that have different indications, and concern that the current California MTUS may not adequately distinguish the applicable uses of the various concentration levels.
  - DWC confirms that the references for this topical will also be pulled, a summary written and a matrix of some kind to help visualize and compare so that the committee can review and consider any changes that might need to be recommended.
  - DWC reminds committee members of two things: cost is not really a factor when developing the guidelines, and ACOEM is responsive to questions they get about their guidelines. If a committee member or anyone else would like to put together some thoughts and send them to ACOEM. ACOEM will typically respond.
- vii. DWC requests to know if there are any other categories that the committee would like to look at during next quarter's meeting.

# **IV.** Public Comment

A. No public comment

# V. Review of Recommendations

- A. No recommendations
- B. To-Do List
  - e. Go to the guidelines to summarize reference material related to Topical Local Anesthetics and Topical Anti-inflammatory, Non-Steroidal to provide that information in our next quarterly Pharmacy and Therapeutics quarterly meeting
  - f. Pull more detail on usage and pricing of the same topicals for the committee to look over relative to the guidelines say

# VI. Meeting adjourned