STATE OF CALIFORNIA GAVIN NEWSOM, *Governor*

DEPARTMENT OF INDUSTRIAL RELATIONS
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Pharmacy and Therapeutics Advisory Committee
MINUTES OF MEETING
Tuesday, November 16, 2021
Via Video/Audio Conference

In Attendance:

DWC:
George Parisotto
DWC Administrative Director
Jackie Schauer
DWC Legal Counsel
Kevin Gorospe, Pharm.D.
DWC Consultant

Committee Members:
Raymond Meister, M.D., DWC Executive Medical Director, Chair
Basil R. Besh, M.D.
Joyce Ho, M.D.
Lori Reisner, Pharm.D.
Todd Shinohara, Pharm.D., MA.
Raymond Tan, Pharm.D.

Absent:
Julie Fuller, M.D.

I. Welcome and Introductions

George Parisotto, Administrative Director, DWC

- Conflict of Interest reminder and advise P&T Committee members to review it; requirement to resubmit annually
- State and federal Antitrust Law advisement

II. Approval of Minutes from the July 21, 2021 Meeting

Dr. Raymond Meister, Executive Medical Director, DWC

Motion: Approval of the minutes from the July 21, 2021 meeting

Vote: The committee members in attendance voted unanimously for approval of the minutes from the July 21, 2021 meeting. Dr. Joyce Ho was not present during the time of the vote.

Related briefing: July 21, 2021 Minutes of Meeting
https://www.dir.ca.gov/dwc/MTUS/Meetings/July-2021/Meeting-Minutes.pdf

III. Discussion

- COVID-19 Vaccine Update
    - Vaccination numbers, including children from ages 5+, show almost 67% of California's population to be fully vaccinated, and approximately another 8% to be partially vaccinated.
    - ACOEM treatment recommendations
        - Medications that have been incorporated into the formulary
        - Only the patient-administered medications will be reflected on the MTUS Drug List. Some of the medications are IV medications, and will not appear on the drug list.
    - Utilization of Ivermectin – Not a complete data set; diagnosis not shown on pharmacy claims; prescriptions for Ivermectin examined were not for COVID-19; only 37 total claim lines for Ivermectin.
    - Consensus Statement on Vaccination – "As an advisory body of healthcare professionals and consistent with the current evidence-based recommendations of the MTUS-ACOEM COVID-19 Guideline, the Division of Workers' Compensation Pharmacy and Therapeutics Committee strongly supports the use of vaccination for the prevention of COVID-19."

Motion: Approval of the consensus statement on vaccination.

Vote: The committee members in attendance voted unanimously for approval of the consensus statement on vaccination.

- Topical Analgesic Update
    - P&T requested clarification regarding brand ingredient match-ups for camphor, menthol, and methyl salicylate
    - Per ACOEM, the intent was to represent "sports creams" by adding camphor, menthol, and methyl salicylate
    - Based on ACOEM's response, any product considered a "sports cream" that contains capsaicin, camphor, menthol, or methyl salicylate should be considered as part of the MTUS formulary
    - How should these products be represented on the MTUS List?
        - Needs to be narrowed down to what drug should be on list
        - Leaving it as a broad group ("sports cream") – tendency for misuse
        - Potential for abuse on the compounded side, and special commercially-available versions of drugs
        - Do we have access to enough detail to differentiate the various products, so the committee can essentially choose?
            - DWC to provide a list, grouping the products by content for committee review
- Special Fill/Peri-Op Days Supply
    - Why is 4 days the standard?
        - Predates the committee during the initial drafting of the regulations – wanted to incorporate the concept of a Special Fill
        - UR process typically takes 5 days, and an emergent request takes 3 days – added an extra day (to 4 days) in the instances where a decision may not be available by the end of the third day
    - Suggestion to have the committee consider altering the current standard of the 4-day Special Fill standard
    - Suggestion for DWC to draft language for a footnote/header note pertaining to

dispensing Special Fill products that come in predetermined package sizes
    - Committee request to clarify the prospective review as 5 days and the expedited review as 72 hours for the next meeting
- MTUS Drug Categories/RxCUI – MTUS RxCUI List (*https://www.dir.ca.gov/dwc/MTUS/Meetings/november-2021/MTUS-Updated-Categories-and-RxCUI-DRAFT%20-Discussion.xlsx*)
    - Previous request to expand the categories to a second level "pharmacological category" to create even more filtering to make it more easily accessible online
    - First step is to identify those categories – somewhat based on existing therapeutic categories (ACOEM-based), including additions from FDA labeling, consultant knowledge, and Up To Date online reference (MTUS List New Categories Extract - *https://www.dir.ca.gov/dwc/MTUS/Meetings/november-2021/MTUS-List-New-Categories-Extract-DRAFT%20-Discussion.xlsx*)
    - Reference brand name should match if we are adding RxCUIs. Suggestion from the committee to double-check brand dosage form products to make sure that they match. If the committee has specific products for ACOEM list, we can reach out to ACOEM with suggested changes. We will memorialize that we are using ACOEM as a primary source for categorization.
- Cost-Effective Formulary Consideration
    - To our understanding, ACOEM/Reed group did not facilitate a cost-effective formulary for New York
    - Currently, the statute does not identify cost as a factor in establishing the formulary. However, there is nothing in the statute that specifically precludes it from being done.
    - We are to have an evidence-based formulary. However, to the extent that for example; two products that are the same that have vastly different costs could be taken into consideration. There is no reason a more expensive product that is identical is more effective.
    - Generally, in developing a formulary, efficacy and safety are considered, and then cost. If we see products that have similar or same efficacy and safety, then cost becomes a factor. It is difficult when there are disparities. How we weigh those disparities is the key.
    - Private label companies set their own price, up to 66 times higher than over-the-counter products. Price based on AWP. Any medicine could theoretically be approved. To close the loophole on these higher-priced products, we can only make them non-exempt on the formulary. However, utilization process does not consider price. DWC welcomes ideas from the committee and the public relating to our pharmaceutical fee schedule or the utilization schedule on how we can potentially control this kind of activity. The public can email us at formulary@dir.ca.gov.
    - DWC will check to see if the language states, "If a lower cost generic is available"
    - Exempt Drug Criteria
        - If a drug that is recommended in acute phase for injury or illness and if there is no safety concerns, it will be an exempt medication. The criteria now doesn't have cost considerations for exempt or non-exempt designations

IV. Review of Recommendations

- Take NSAID information using what is found in ACOEM guidelines and current cost factors from the updated medical pricing to create a hierarchical list for the committee to look at.
- To create an expanded list of topical analgesics to present to the committee

- Two additions to the header notes to the MTUS list:
    - Source of drug class
    - Special fill – to identity that the smallest commercially available product should be dispensed
- Memorialize that we are using ACOEM's base to the therapeutic categories
- Clarify for committee the five day and expedited 72 hour review process
- Clean up list on brand name dosage strength form perspective
- Look at language of generic first policy
- Suggestion to discuss closing the loophole at the next meeting

V. Public comments

- Wanted to know if anyone looked into KETOPROFEN and FENOPROFEN after the earlier discussion of these high cost drugs?
    - DWC Response: This discussion is about if we can introduce cost into the decision-making
    - Member: Suggestion to add a discussion on cost considerations to the agenda for the next meeting
- Could there be categorizing or some type of hierarchical order based on if all things are alike? What generic would be the highest priority or the one that is most utilized. Using cost effective medications first.
    - Member comment: There are two ways to do this:
        - Adjusting the legislation so that the formulary is not only exempt and non-exempt, but certain medications that are not on the formulary at all.
        - Petition ACOEM to take cost into consideration.
    - DWC Response: Will update the previous NSAID information and create hierarchical list for the Committee to look at.