**STATE OF CALIFORNIA** GAVIN NEWSOM, *Governor*

DEPARTMENT OF INDUSTRIAL RELATIONS
**Division of Workers' Compensation**
1515 Clay Street, 17th Floor, Oakland, CA 94612
Telephone: 510-286-7100
Formulary Email Address: Formulary@dir.ca.gov
Formulary Website: https://www.dir.ca.gov/dwc/MTUS/MTUS- Formulary.html

*MAILING ADDRESS:*
*P. O. Box 420603*
*San Francisco, CA 94142*

# Pharmacy and Therapeutics Advisory Committee
# DRAFT - MINUTES OF MEETING
# Wednesday, April 19, 2023

Via Tele/Video-Conference

**In Attendance:**

**DWC:**
George Parisotto
DWC Administrative Director
Kevin Gorospe, Pharm.D.
DWC Consultant

**Committee Members:**
Raymond Meister, M.D., DWC Executive Medical Director, Chair
Basil R. Besh, M.D.
Julie Fuller, M.D.
Joyce Ho, M.D.
Todd Shinohara, Pharm.D., MA.
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. Currently accepting applications for the 2023-2025 term

## II. Approval of Minutes from the January 18, 2023 Meeting

Dr. Raymond Meister, Executive Medical Director, DWC

Motion: Approval of the minutes from the January 18, 2023 meeting with the amendment around the artificial tear recommendation to include a statement similar to "the committee may reach out to an ophthalmic or optometry professional to review."

Vote: The committee members in attendance voted unanimously for approval of the January 18, 2023 meeting minutes with the one edit.

**Related briefing:** January 18, 2023 Meeting Minutes

(https://www.dir.ca.gov/dwc/MTUS/Meetings/January-2023/Meeting-Minutes.pdf)

## III. Discussion

A. COVID Update
   a. ACOEM recently updated their COVID guideline
   b. DIR in the process of adopting the guideline into the MTUS Drug List, but public hearing was postponed and will be rescheduled for a later date

B. Artificial Tears Update and Utilization
   a. Before jumping into the artificial tear update, we will skip the Agenda item "MTUS Listings – Categories" today
      i. Had some communication related to the listings online - how they're being identified, how they're using Medispan GPI, and how we might move forward with them on that
      ii. Pending some clarification and additional work on the categories
   b. Committee requested review of coverage by other workers' compensation organizations – looked at New York and Washington (available online)
   c. ACOEM references the use of artificial tear ointments, carboxymethylcellulose solutions, sodium chloride solutions for various conditions
      i. Generally, the evidence in support is to support its use, but there's insufficient evidence related to that support
      ii. The reference studies all differ to those studies using sodium chloride solutions, which is different than many other products
      iii. Artificial tear ointments equal to REFRESH PM, which is their reference brand, have been discontinued
      iv. Only two non-solution products, both hypromellose gels, show as currently being active in the system
   d. New York State Formulary
      i. Shows as these products being covered:
         - artificial Tear ophth
         - carboxymethylcell/glycerin/polysorb 80
         - carboxymethylcellulose
         - glycerin (ophth lubricant)
         - glycerin/hypromellose/PEG 400
         - hypromellose
         - methylcellulose
         - polyethylene glycol 400
         - polyethylene glycol/polyvinyl alcohol
         - polysorbate 80
         - polyvinyl alcohol
         - polyvinyl alcohol/povidone
         - white petrolatum/mineral oil [REFRESH PM product, which is no longer on the market]
   e. Washington State Formulary

i. Anything that falls within the artificial tear therapeutic category is approved for use

f. We narrowed our look to these three products, carboxymethylcellulose, polyvinyl alcohol, and polyvinyl alcohol and povidone.
g. Pulled additional utilization for the most recent 12 months (June 1, 2021 – May 31, 2022)
h. Pulled sodium chloride ophthalmic utilization and pricing just as a reference that product is listed separately in the MTUS
i. Calculated the cost per day. Estimated based on how the products are used.
j. Utilization limited to 4 product ingredient combination strengths. 98% of claims for two products. No ophthalmic ointments in utilization.
k. Hypromellose ophthalmic gel – non-solution alternative on the market
l. Sodium chloride – smaller number of sodium chloride ophthalmic ointment and solution claims
m. On the news, there are a number of artificial tear products that have undergone recall due to infection risk. Will our data tell us how often those have been utilized in workers' compensation?
n. We don't have a list of those specific products and have to look at those specific products.
o. Per committee member, the products that were recalled were both carboxymethylcellulose products from Ezra Care.
p. Artificial Tears Spreadsheet
    i. When doing retroactive review, were the majority of these the preservative or preservative-free types of prescriptions?
        - The only product that's preservative-free would be REFRESH. Very limited use – only 7 claims for the entire year.
    ii. When you roll up the products under an RxCUI, it's really two products that are most commonly used (polyvinyl alcohol 1.4%, and polyvinyl alcohol (0.5%) and povidone (0.6%) combination) – products are solutions
    iii. Is there a higher RxCUI rollup value like the First Data Bank value?
        - If you wanted to restrict to the two most common products, you would list two RxCUIs.
    iv. Would that be too restrictive to have only two particular RxCUIs (142004 and 598050)?
        - Issue could be allergies to these products
    v. Looking at the polyvinyl alcohol 1.4% (rows 3-8), there's no real difference between them besides package size. They're all 1.4% solution. Would we be choosing one of six, or would we just roll them up?
        - We would roll up and that would encompass all 6 of those products.
        - Committee member suggested to have at least a preservative-free option and a preservative-regular option, and also a solution and gel option.

q. We pulled data to include carboxymethylcellulose products and it doesn't include any utilization of it.
r. Going back to the theme of looking for outliers that aren't uniquely situated such that we absolutely need them – If things, in order of magnitude, are more expensive, do we need that one? (referring to RxCUI – 630977) Are we being overly restrictive if we eliminate something at 2.7% and 2%, when we have something that is 1.4% and 0.6%, and you can just use it more frequently? Does that percentage make such a difference that this committee would somehow be misguided in saying why one cost 10x more the amount than the other?
s. Committee proposal to the rest of the committee would be to add the 4 RxCUIs to the formulary, which will add 4 lines. Hypromellose is a gel and sodium chloride has its own listing on the MTUS under ophthalmic agents, and not listed under Artificial Tears. At that point, we would be able to encompass all of those that are generally seen in the last year, and then at a subsequent meeting, we would be able to review the kind of abuse among that one and how severe that abuse would be to make that Non-Exempt at that point. How would that look as a written proposal to just those RxCUIs already identified as being used so that we could see how it looks drafted on the MTUS formulary?
t. Under Artificial Tears, we would list these four RxCUIs for the solution (142004, 598050, 630977, 359969). Should artificial tears be listed as ophthalmic agents?
u. Categorizations right now are really broad. Will look to see if we can add more definition to those categories.
v. Motion to list these four RxCUIs for the artificial tears solution (142004, 598050, 630977, 359969). We could always refer our decision to an outside expert or consultant to either support, uphold, or add to the decision.
w. So the MTUS is more narrow in coverage than what our data shows? If we want to make the MTUS reflect what is being utilized, it will be these products (142004, 598050, 630977, 359969). There should be an artificial tears solution and have that be more encompassing. This is where DIR would go back to ACOEM and ask if we could change carboxymethylcellulose into a more general category that says artificial tears solution, which would encompass more products and the products that are being utilized.
x. So could the presentation of what we found as the used products influence them to decide how to properly fix the rows and columns?
    i. From a philosophical perspective, our formulary should reflect the general practice of what we're trying to achieve.
    ii. A formulary should be specific enough to prescribe from, especially with our other columns that are still to be decided in terms of dosage form and strength.
y. Recommendation by the committee to not only add these four RxCUIs (142004, 598050, 630977, 359969) for this particular drug ingredient group for artificial tears solutions, but to ensure that the MDGuidelines listings reflect this. Then take this information to ACOEM and request that listing

to be added, so that the MTUS Drug List and the MDGuidelines are aligned.

z. Currently, the MTUS treats all artificial tears as Non-Exempt because those are solutions and they are unlisted. Only the gel is Exempt. Technically, only artificial tear ointments are on the formulary.

aa. So if the ask happens, the MTUS would then be subsequently updated from an RxCUI perspective to include these four RxCUIs.

bb. Reach out to MDGuidelines to see how we can better clarify these products (artificial tear solutions, gels/ointments including sodium chloride), and also clarification on the categorization process.

C. Public Comment (*Artificial Tears Update and Utilization Discussion*)

a. Can someone offer a brief explanation of how the RxCUI would be used by the prescriber or the payer?

i. DWC response: The RxCUI is more on the payer side identifier. It tries to allow the payer to identify all the national drug codes, 11 digit NDC's that would fall under that descriptor. So from a MTUS formulary perspective, we don't have to try to list every available NDC on the market because they change, especially over the counter products change frequently. Instead of NDC, we will group like products together. The publicly available source we use is the RxCUI.

b. When and if the RxCUI is added to the formulary as a column, if the prescription has not been processed in real time, meaning that the patient gets the medication from a pharmacy and it's not processed while the patients waiting or it comes in as a paper bill for example, the patient has already received the medication, then what is the process on how to handle that because it is after the fact?

i. DWC response: This is more of a claim adjudication post dispensing or looking at products that have already left, that is less of a RxCUI perspective. RxCUI is intended to allow payers to code their system, pre-identify products that fall within the formulary as listed. They can do it within their system. We show the products that fall within the formulary. After the fact process would be a retro review process.

ii. DWC response: We can't answer this right now. Please send this to us as a question and we will work on it as a team

D. Topical Analgesics

a. The highest products with utilization. There seems to be four outliers. Are these dosages or delivery method necessary? The $9.00 patch seems to be easily replaced with a patch that's $1.61. Gels tend to be better drivers of absorption.

Motion: To exclude the four mentioned RxCUIs from the MTUS formulary list.

- methyl salicylate (RxCUI 238542)
- menthol (RxCUI 1148430)

- methyl salicylate menthol (RxCUI 1486874)
- methyl salicylate menthol (RxCUI 853146)

Vote: The committee members in attendance voted unanimously to exclude the following RxCUIs (methyl salicylate (RxCUI 238542), menthol (RxCUI 1148430), methyl salicylate menthol (RxCUI 1486874), methyl salicylate menthol, (RxCUI 853146)) from the MTUS formulary list, except Dr. Meister abstained from the vote.

E. Topical Lidocaine Products
    a. ACOEM review was restricted to patches.
    b. There are several generic versions of the 5%.
    c. The review does not contain combination products that contain lidocaine.
    d. Concern that limiting things to what is already being used versus what can be used. There is an opportunity to re-direct. The 4% is an OTC, but the 5% must be prescribed.
    e. The lidocaine 5% is on the Medi-Cal fee schedule. The price per day is based on current pricing from the Medi-Cal file. Prices are current as of March, 2023.
    f. A payer can make all the 4% products first line except a particular product due to its price.
    g. Recommendation to eliminate the following:
        i. Row 14
        ii. From a listing perspective on our MTUS formulary, any product that falls under that RxCUI is okay. We cannot exclude certain ones under a certain RxCUI. It is not a capability currently within our MTUS listing formulary. From the listing perspective there is no mechanism to exclude a product. However, a payer can do so internally by putting an extra control on particular products. They can indicate in their file that a particular product is not payable because there are several other options to dispense
        iii. Worthy to have a discussion on NDC listings at a future time
        iv. One way is to have an exclusion. Could add a comment field that contains the excluded products. Could have a price threshold and exclude the NDCs over whatever we determine that to be
        v. If given the flexibility to list by NDC, there would be much better work done. More effective.

Motion: To list the 4%, 5% patch on the MTUS, rolled up in RxCUI. Also to explore the potential to have a NDC exclusion column at a future committee meeting

Vote: The committee members in attendance voted unanimously to list the 4%, 5% patch on the MTUS, rolled up in RxCUI, exceptDr. Meister abstained from the vote

F. Public Comment (Topical Lidocaine Products Discussion)
    a. I think heading towards the possibility of an NDC exclusion list is a very practical way of handling outliers. As a point of reference, the Department of Labor's FICA program, has an NDC exclusion list in place. Anytime

anything is managed at the NDC level, that creates the challenge of ongoing maintenance. It is possible to monitor new NDC entries into the market and set a threshold. Watch for those that as soon as they come into the market with an excessive price, evaluate them immediately, make a decision and add them to the exclusion list. It is a great way to manage formulary drugs that has outliers. Just to confirm, that for a formulary drug, for multiple and equivalent NDCs available, and some of those are outliers, a payer can reject the outlier (even though it is a formulary drug), on the basis that there are lower costs available? Is that a correct statement?

i. DWC response: I do not think there is anything in our regulations that state that

b. Perhaps I misunderstood the conversation then. If it is a formulary drug, the payer has to pay for it, even if it is the outlier cost today
    i. DWC response: I do not think there is anything that forces them to do it. I think there is some leeway in utilization control for equivalent products. Don't they, Dr. Meister?
    ii. P&T Committee member response: It is only exempt from prospective review if it meets the guidelines as well. If two medications are absolutely comparable, and one is ten times the price of the other, it would stand to reason that you would not strong arm someone to pay for the more expensive one. If that does not exist, the committee could explore it through the legislative avenues
c. That would be another very good solution for payers
    i. P&T Committee member response: What possible benefit to the injured worker would there be to have two identical medications? If anything, you are misusing resources that could be used in better ways.
    ii. DWC response: We will provide clarification how payers can handle this situation. We will continue this conversation at the next meeting, depending on the outcome of the research.

G. MTUS Listings – Categories
    a. Discussion for next meeting in July 2023

## IV. Public Comment

A. No additional public comments

## V. Review of Committee Recommendations

A. Artificial Tears Review
    a. We will reach out to MDGuidelines to discuss relisting the products to add the four artificial tear products that we noted
    b. Further discuss classification of the products so they all fall under the artificial tears type category
B. Decision to exclude four specific RxCUIs:
    a. 238452

b. 1148430
c. 1486874
d. 853146

C. Topical Lidocaine
   a. We will list both of the 4% and 5% RxCUIs for patches
   b. Exclude listing the 1.8% patch
   c. Discuss lack of requirements that a payer cover a product when there are multiple equivalent products available