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
MINUTES OF MEETING
Wednesday, April 20, 2022

Elihu Harris State Building
1515 Clay Street, Conference Room 1, Second Floor
Oakland, California 94612

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.
Julie Fuller, M.D.
Joyce Ho, M.D.
Todd Shinohara, Pharm.D., MA.
Raymond Tan, Pharm.D.

Absent:
Lori Reisner, Pharm.D.

I. Welcome and Introductions
George Parisotto, Administrative Director, DWC

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

II. Approval of Minutes from the January 19, 2022 Meeting
Dr. Raymond Meister, Executive Medical Director, DWC

Motion: Approval of the minutes from the January 19, 2022 meeting

Vote: The committee members in attendance voted unanimously for approval of the January 19, 2022 meeting minutes as amended with a small change from Dr. Fuller's name to Dr. Ho's name under the last bullet on the last page.

Related briefing: January 19, 2022 Meeting Minutes
(*https://www.dir.ca.gov/dwc/MTUS/Meetings/January-2022/Meeting-Minutes.pdf*)

III. Discussion

- RFA Form Review
  - Per the comments made during the previous meeting, problems occasionally arose when the medication was listed, but the dose, quantity or instruction were not given. This happened in cases for Special Fill medications, there was no way to determine whether the quantity was appropriate for the circumstance.
    - After review of the DWC RFA form, those details should be provided on the form.
    - The language on the form states "Include, as necessary…" – Who determines what's necessary?
  - The standard prior authorization form for commercial health plans requires every box to be filled, and has very specific boxes for dosage, quantity, etc.
  - Suggestion to make more explicit on the form the information for frequency, duration, quantity, etc. as always necessary. Reason is to match the RFA to the MTUS with that level of detail to make everything appropriately correspond.
    - DWC in the process of updating Utilization Review regulations – will consider and incorporate into the regulations
  - Can the instructions be changed without affecting the form? The RFA form and instructions are codified in the regulations.
  - DWC is currently working on updating the Physician Reporting Form to include a Request for Authorization. There will be a separate area for pharmaceuticals. DWC will consider the comments/suggestions to make the form more specific.
    - Will this replace the RFA form? Yes.
    - With this new Physician's Reporting Form, will it allow for requests for multiple services, not just one particular drug?
    - This will go through formal rulemaking, and will open it up for public comment.
  - Would a physician still have an opportunity to just submit a Request for Authorization form or will the entire Physician Reporting Form need to be completed?
    - Ability to only submit the part that is needed
  - Match the upcoming form with the language of the incomplete RFA
    - What fits under the bullet points of an incomplete RFA vs. what is required on the form under two different statutes
  - Public comment:
    - What is the timeline for adoption of the form and would they have time to implement it in their systems? Would it impact UR letter generations and would they have time to adjust the letters accordingly? The other question was, you do not have to use the form if you have all the required data elements, and it is not the paper or electronic form, but substantially the same with all the correct data elements, that you can use your own version of it like IMRs, will it be the same for RFAs?
      - *DWC response*: We have a provision in the regulations in 9785 …it says that reports can be made by the treating physician and the claims administrator in a fashion that they agree upon, as long as required data elements are present.
- California Generic/Biosimilar Substitution Statute
  - FDA has been fairly slow at identifying interchangeable products

        - 7 HUMIRA® (adalimumab) biosimilars will be entering the market beginning January 2023
        - FDA identified one of seven CYLTEZO® as interchangeable with HUMIRA® - anticipated to hit the market in July 2023
    - Can a non-interchangeable biosimilar be substituted in California?
        - Business and Professions Code Section 4073
            - Regular generic substitution allows that when a drug is prescribed by its trade name, the pharmacist can select another drug if it has the same active chemical ingredients, at the same strength, quantity, and dosage form, and has the same FDA accepted generic name
            - The pharmacist must inform the patient of the substitution
        - Business and Professions Code Section 4073.5
            - Pharmacist may only substitute a biosimilar only if the biosimilar is interchangeable, and the prescriber has not indicated "Do Not Substitute"
            - The pharmacist must notify the patient of the substitution
            - The pharmacist must notify the prescriber within 5 days
        - A lot of this may be controlled at the formulary level, where a payer may want to make the biosimilar the primary product, and the referenced drug the non-preferred product.
        - For generics, the Orange Book is the approved FDA resource, and the Purple Book for biosimilars. There are many biosimilars, but not a lot of interchangeability.
- Topical Analgesics (see *Rollup Topical Analgesics*)
    - The committee previously requested the topical analgesics to be rolled up under specific RxCUIs
    - Some say "Not Applicable" because some RxCUIs were not found in the RxCUI definitions. Found 89 different listings rolled up by strength and specific dosage forms.
    - ACOEM had recommended the use of "sports creams" – What to ask ACOEM in terms of how do get more definitive
        - Currently, they list individual ingredients, which are components of these various sports creams, with the exception of capsaicin
        - Committee member asked would it only be up to ACOEM to do it, or could it be up to the committee or DWC to recommend in particular which of these 89 versions would be appropriate based on availability, distribution, or significant financial difference
        - If there is nothing showing that there is a difference on 0.5%, should there also be a significant financial difference? Some of these could be 0.5% difference, and could cost between $5-$1000
        - Looking at it from ACOEM's point of view, this may not be something that they would need to weigh in on. May be more of an internal decision from DWC. ACOEM generally will not weigh in on cost considerations, but will note them
        - Committee member stated the purview of ACOEM is safety and efficacy. What is the range of efficacy? There are only seven ingredients in the 89 listings. There may be no significant difference in either safety or efficacy. We don't need ACOEM to weigh in on the finances, but just to arm the committee with the differences with safety and efficacy data. Looking for substantial differences

        - Committee member brought up that some other states have gone to the extent to say that these kinds of hard-to-categorize things have a max limit or they do special changes to the fee schedule
            - DWC states that would be regulatory
        - Suggestion for DWC to set a maximum allowable cost limit
        - ACOEM may come back and say there is not enough evidence of these different strengths to make an evidence-based distinction
        - Even if they don't have evidence that there is a difference that may be good enough for the purposes of determining value. It would be incumbent on the person to be charging that exorbitantly high amount to show evidence that there is a difference.
    - When talking about "sports creams," how many dosage forms are necessary (creams, patches, and kits)?
        - Some of these may not be efficacious in certain dosage forms
        - Look at what combinations are most frequently requested and prescribed?
        - Agree with approach to look at efficacy and value
        - If there is no difference in efficacy, then the group can look at cost
    - What is most commonly prescribed?
        - TIGER BALM patch (number of billed lines compared to everything else)
        - BIOFREEZE gel
        - SALONPAS patch
    - Dr. Meister to reach out to ACOEM regarding efficacy of the five main ingredients of sports creams that ACOEM has already listed based on range of concentration. Once ACOEM provides a response, rebuild the list and put in price ranges to see where they fit. Adding a Brand Name column would be helpful.
    - Currently on the MTUS Drug List, all the capsaicins are exempt. Per ACOEM's information, the concentration of capsaicin does not matter because there is no correlation to efficacy. If we find that three brands of capsaicin out of 21 are outliers in terms of cost, we could move those to non-exempt.

Motion: The Committee would like DWC to reach out to ACOEM to inquire about the ingredients currently on the MTUS Drug List, which ACOEM has previously noted they include under the general category of "sports creams." The Committee is looking to clarify efficacy of these products in combination as a function of range of concentration.

Vote: The committee members in attendance voted all in favor.

    - Public comment:
        - I like the whole discussion about the direction you are trying to make toward value. Everyone else is doing that and how do we start keeping up with that. I say that as a newbie to this group that including cost, dollar for dollar really does matter. I appreciate that, thanks.
- MTUS Listings – Corrections
    - At the next meeting, we can go through what the list would look like with topical analgesics
    - Artificial tears:
        - Single use are clinically superior
        - We will look at data such as outliers, utilization and pricing. We will list all dosage forms and pull topical utilization and apply to products.
- MTUS Listings – Category Listings
    - Primary categories are taken from the MTUS list and are difficult to find things. They listed them based on what use would be.

- If we have categories that we think are better, we can send them to ACOEM and ask if they agree and want to change that. It is best to keep the listings the same. If they disagree or have a reasoning that we do not agree with then we can decide if we want to change them on our MTUS list. Make it exist in multiple places.
    - Issue would be multiple categories for each product. It could create an overcomplicated listing. When you have a product that potentially has four or five therapeutic areas you might end up having five different listings for a single product. It would be slightly more complicated, but more accurate
- How should these be listed?
    - Accuracy and evidence-based should be the drivers
    - We want something comprehensive, but also user-friendly so the treating physician can easily look up a drug
    - The idea is to make it web-based so people can sort through filters. One product in multiple categories

IV. Public Comments

- No additional public comments

V. Review of Committee Recommendations

- Topical Analgesics: we will be developing an expanded list of brand names and prices and review ACOEM recommendations on ingredient strengths
- Artificial tears: we are going to look for utilization, pricing, discern preservative, preservative free and see where we are with outliers on cost
- Categories: go through categories and try to find inconsistencies and reach out to ACOEM