STATE OF CALIFORNIA

GAVIN NEWSOM, Governor

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Pharmacy and Therapeutics Advisory Committee DRAFT - MINUTES OF MEETING Wednesday, April 17, 2024

Via Tele/Video-Conference and in-person

In Attendance:

DWC:	

George Parisotto DWC Administrative Director Jackie Schauer DWC Legal Counsel Kevin Gorospe, Pharm.D. DWC Consultant Raymond Meister, M.D., DWC Executive Medical Director, Chairman Basil R. Besh, M.D. Julie Fuller, M.D. (not in attendance) Joyce Ho, M.D. Todd Shinohara, Pharm.D., MA. (not in attendance) Raymond Tan, Pharm.D. (had to leave early) Lori Reisner, Pharm.D.

Committee Members:

I. Welcome and Introduction

George Parisotto, Administrative Director, DWC

- A. Physician and Pharmaceutical Fee Schedule Update Notice of Proposed Rulemaking Update
 - a. Announcement released February 26, 2024
 - b. 45-day comment period ended April 11, 2024
 - c. Public hearing also occurred on April 11
 - d. DWC is reviewing all comments on the proposed regulations
 - e. IF DWC decides to make modifications to the proposed regulations based on comments, an additional 15-day public comment period will occur for review of the modifications.
 - f. Proposed Regulations and associated documents can be viewed at <u>https://www.dir.ca.gov/dwc/DWCPropRegs/2024/Pharmaceutical-Fee-</u> <u>Schedule/Index.htm</u>
- B. State and federal antitrust law advisement

II. Approval of Minutes from the January 17, 2024 Meeting

Dr. Raymond Meister, Executive Medical Director, DWC

Motion: Approval of the minutes from the January 17, 2024 meeting

<u>Vote:</u> The committee members in attendance voted unanimously for the approval of the January 17, 2024 meeting minutes.

III. Physician and Pharmaceutical Fee Schedule Update

A. Topic already addressed during Welcome and Introduction. Committee decides to move on.

IV. Discussion

- A. Modeling Expanded Capsaicin MTUS product listings *Kevin Gorospe Pharm D, DWC Consultant*
 - a. In line with previous discussions, DWC has examined the potential to expand the Capsaicin listings to include specific products. These products are currently classified as exempt. Sample list showed several creams and patches.
 - i. 8% Topical patch excluded as previously discussed.
 - b. Capsaicin Pricing
 - i. Pricing is from the most recent price of a particular NDC based on the Medi-Cal program pricing rules.
 - ii. Some NDCs have high prices compared to equivalent products because they are not part of the federal Medicaid program and therefore do not have certain pricing benchmarks e.g. NADAC.
 - iii. The columns "days supply" and "price per day" assume use of 2 GM of cream, 4ML of liquid, or 1 patch per day. These values are for price comparison only and do not reflect actual product consumption per day.
 - iv. Price per day is rounded to two decimal points.
 - v. Review of pricing trends and patterns. Patches cost the most.
 - vi. Committee asked if DWC can stratify utilization by NDC to trace high and low cost variations
 - DWC: Theoretically, but external price factors will make data less useful in that context. The WCIS data shows what is paid by the payer. A variety of things go into reimbursement, such as contracts or if a provider overbills or underbills. It makes it uneven to do this analysis predictably. This is why we use the Medi-Cal pricing because it is a predictable amount to analyze relative costs.
 - vii. Committee asked if it was possible to see which physicians prescribed capsaicin products.
 - DWC: No.
 - viii. Committee noted disparity in prices of similar Capsaicin formulations, discussed merits of potential motion for making the more expensive formulations non-exempt, if it would fit within the Committee's scope, and impact of such a motion on availability. Committee asked why the wide disparity in cost within single

strength and what tools does this committee have to address that? There is a hundred-fold disparity.

- DWC: Some products may have federal drug rebate agreements under which they then become part of the Medicaid national acquisition pricing. It can create fairly low prices. Other prices aren't under that, so their prices are strictly at wholesale acquisition price. It's a list price. It isn't necessarily what people are paying for the product.
- Committee questioned whether exempt vs. non-exempt could be for different strengths looking at NDC outliers
- DWC: would be very problematic to maintain a list at the NDC level in light of complexities, weekly price changes and frequency of products entering and leaving the market. The Capsaicin pricing spreadsheet sets forth the products based on RxCUI.
- Committee discussion re feasibility of making some strengths of capsaicin exempt, other strength non-exempt based on cost; past recommendations by committee to make a product exempt based on cost effectiveness where two equally effective products; committee has not advocated making an exempt medication exempt only on cost and not on effectiveness.
- DWC: Approach to exempt medications has been based on medical evidence, not a cost decision. The Committee can make these recommendations and it is up to DWC to decide if the recommendations are consistent with statutes and regulations.
- Committee discussion of the strengths listed on the spreadsheet and the availability of various strengths to ensure appropriate range of strengths will be exempt.
- ix. Committee questions whether there is any carryover into Workers Compensation where the product has to be one of those that is part of the Medi-Cal fee schedule or part of NADAC prior to transitioning or choosing a different one that is not? The outlier ones would be those that are not part of the actual Medi-Cal listing.
 - DWC: No, the statute does not currently contemplate restriction to the authorized manufacturer list as allowed under the Medicaid program. It goes beyond that. That is why we get these disparities.
- c. <u>Motion:</u> Convert Capsaicin 0.025% cream from exempt to non-exempt.
- d. <u>Vote:</u> Committee members in favor: Dr. Besh, Dr. Reisner, Dr. Tan. Committee members abstaining: Dr. Ho, Dr. Meister.
- e. Committee discussed the .025% capsaicin patch and the wide price disparities; agreed that although large cost variation is unsettling, it would not be prudent to make it non-exempt as a patch should be available on the exempt list.

- B. MTUS Drug Lookup Kevin Gorospe Pharm D, DWC Consultant
 - a. DWC displayed updated MTUS Drug Lookup tool.
 - i. As previously discussed, model tool developed in excel to avoid need for custom software.
 - ii. Updated model tool uses the entire MTUS list with RxCUIs
 - iii. Data was expanded to add a route of administration column to provide additional options for choosing products.
 - iv. The tool is keyed to the MDGuidelines Condition Category, meaning the criteria used to filter are based on the selection of a condition category.
 - v. Tool redesigned to run off a single spreadsheet of data, still in draft (needs another review for accuracy)
 - b. The Committee overall expressed approval of the tool, asked if some additional sorting features, formatting changes were possible.
 - i. DWC: in Excel, probably not due to program limitations.
 - c. Someone asked if there was a public rollout date yet for the lookup tool
 - i. DWC: Not yet. Still requires further bug-testing, accessibility work.
- C. Ulcer Drug Category Kevin Gorospe Pharm D, DWC Consultant
 - a. Per committee request earlier, DWC and committee reviewed ulcer drugs.
 - i. Identified drugs on the MTUS list within three categories
 - Ulcer Drugs (H2 receptor blocker)
 - Ulcer Drugs (Proton pump inhibitor)
 - Ulcer Drugs
 - ii. Utilization (claim lines) is from July 1, 2022 to June 30, 2023 WCIS data.
 - iii. All products were aggregated by drug, dosage form, and strength.
 - iv. Low (generic) and High (brand or brand generic) prices were identified.
 - This was done in lieu of an NDC based approach to make the review easier.
 - Drug unit prices are from 2/20/2024 Medi-Cal pricing files.
 - b. Committee reviewed excel table of ulcer drugs.
 - i. Committee asked if the drugs on the table were all exempt.
 - DWC used the MTUS excel tool to find the answer. The answer was yes.
 - ii. Committee expressed concern that the table assumed all the medications were taken once a day, which is not necessarily true. There are prescriptions for medication given twice a day. Would the MTUS talk more about the dosage or frequency for medications?
 - DWC acknowledged the concern but said that it would be too hard to account for without making the spreadsheet overly complicated, and we do not have all the information.
 - The drugs are often prescribed alongside anti-inflammatories
 - iii. Committee expressed curiosity as to why the ratio of physician dispensed ulcer drugs to pharmacy dispensed ulcer drugs was near

equal, unlike with the Capsaicin where it was far more lopsided.

- DWC did not have an answer on hand but speculated that it had to do with the dispensing systems. The dispensing systems may be targeted toward generic oral forms and not creams. Issue impacted by multiple related factors that would make a clear-cut answer hard.
- Committee asked how long the physician had to dispense drugs after a worker's injury.
 - i. Within the first seven days, beyond 7 days if there is authorization.
- iv. A member of the public submitted a comment noting a price disparity between lansoprazole and omeprazole.
- v. A member of the public asked if the RxCUIs included on the ulcer drug spreadsheet will be added to the MTUS drug list.
 - DWC said yes, that is the intention.
 - i. Follow up comment asking about possible ETA. Answer: No ETA at the moment.

V. Additional Public Comments

None

VI. Review of Committee Recommendations

- A. Recommendation to make the 0.025% Capsaicin cream not exempt
- B. Committee will have time to use the lookup tool and provide comments

Interjection regarding the MTUS lookup tool: Users may need to enable macros in order for the spreadsheet to work.

VII. Adjourn