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**Pharmacy and Therapeutics Advisory Committee**
**MINUTES OF MEETING**
**Wednesday, July 20, 2022**
Via Tele/Video-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.
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

- 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 April 20, 2022 Meeting

Dr. Raymond Meister, Executive Medical Director, DWC

Motion: Approval of the minutes from the April 20, 2022 meeting

Vote: The committee members in attendance voted unanimously for approval of the April 20, 2022 meeting minutes. Lori Reisner was not present during the vote.

**Related briefing:** April 20, 2022 Meeting Minutes
(*https://www.dir.ca.gov/dwc/MTUS/Meetings/April-2022/Meeting-Minute.pdf*)

## III. Discussion

- Artificial Tears Utilization (see Artificial Tears Utilization 02.01.2021 to 01.31.2022 – DRAFT for Discussion)
    - Committee wanted to see some utilization and pricing data
    - Identified over 600 potential NDCs that would fall into the category of artificial tear products
    - Only 85 NDCs showed any utilization during 2/1/21-1/31/22
    - Claim count fairly low with the exception of 3 products
    - From the solutions, ointments, and gels, the solutions had the most claims
    - The ones that say not applicable are products that indicate that the NDC may be discontinued
    - We don't want to take it as a full inclusion, but to exclude some of these also seems like it's always going to be a challenge based on categorizing NDCs and the sheer number of different codes and unique codes that could be there.
    - Is there a recommendation of how we could roll this up and just include them in a way that protects us from abusing the system by price? Not sure if this is a more legislative issue, or if it goes against the way the fee schedule is written, but allow all these artificial tears, drops, and gels, but to a max cost limit, so that those outliers are kind of contained. Anything that already falls below the max threshold would follow the fee schedule so that it simplifies the way the formulary is built.
    - One way is to restrict by ingredient, and go from there.
    - Looking at row 26 and row 27, one is $178.56 and the other $17.42. The $178.56 is an anomaly. We would have to dig into the actual claim that was paid that created this high dollar amount and it could just be an error that was not corrected.
    - Go by Column I (Price/pkg) and Column J (Avg. Paid/Claim) because this is what should be paid under the reimbursement structure that's being adopted by DWC.
    - At this point, we don't have regulatory authority to do so, but one option to explore as we move forward relative to the list would be the potential for setting price limitations for certain products.
    - We could tier this by ingredients, and that was part of the discussion during the last meeting or the meeting before regarding generics.
    - When sorted by CVS, the results would be a certain list of propylene glycol plus PEG, etc. If you did the exact same thing, but then you saw the national brand name, whether it be GENTEEL or REFRESH, then obviously the price/package is higher for those. Is the CVS brand considered generic and the rest branded? There is a big preference of whether or not these are branded versus CVS generic.
    - From a regulatory perspective, they are neither branded because these are OTC products, and they fall under a certain regulatory framework. They're called store brands vs. national brands.
    - Store brands have a tendency to be less expensive because those are pseudo-generic.
    - Some of these store brands or any house brands will be catalogued as brand name products in the different drug catalogs. If we were to take a stand and say no branded products, then it would get coded in the back end by different PBMs or different drug catalog vendors. It's problematic because it'll automatically exclude these house brand products, which are catalogued as brand even though we would consider them generic. We have to be careful because the way it gets back-end catalogued isn't what we intended to be sometimes.
    - If sorted by preservative-free, it would be a grouping of fewer than 10. Sorting by gels would be fewer than 10 as well. All the remaining agents had over 60 in the

group. How many drops do we need?
    - Do we roll these up into a handful of ingredient generic name combinations? Do we have the ability to match products a little bit on the back-end to sort these?
    - Committee member suggestion to have a quick item on the agenda that says artificial tears based on what was paid based from the data for that quarter. If there are outliers, then we could have a discussion and make a recommendation that since there are these other alternatives, that particular outlier should be Non-Exempt and not to be included in the rolled-up artificial tear.
    - We can roll the products up into single individual groupings and arranging the range of pricing for each generic strength description. There are about 15 categories and currently nothing falls out as an inappropriate price.
    - Committee request to roll these up into the generic product identifier type categories pricing ranges, separated out preservative-free, non-preservative free, etc.
    - At some point, we have to roll up the RxCUI, so that we can see what it will look like. How would the actual final product or formula look with that information?
    - Preservative-free agents are going to be the highest-priced because they're individually packaged versus a multi-dose.
    - To recap, the committee would like to see the products rolled up by generic strength description, and RxCUI. Provide a pricing for those products within the category given. Arrange per range of price per ml, including high, low, and median.
- Topical Analgesics (see Topical Analgesic List – DRAFT for Discussion)
    - Committee had previously asked DWC to reach out to ACOEM regarding any research or recommendations regarding strength of drugs used in sports creams. ACOEM indicated that they have never looked at the various individual strengths of various ingredients and topical analgesic sports creams.
    - Committee also wanted to see some updated utilization data. DWC looked at a broader inclusion of NDCs to ensure nothing was missed. The number of NDCs (3316) DWC searched was significantly greater than those that we normally would have searched for under the topic of sports creams.
    - Capsaicin was included in those searches, even though as a single ingredient, has its own listing on the MTUS. Wanted to ensure that we captured any potential combinations that have capsaicin in them.
    - Data pulled for both pharmacy and physician-dispensed products during period: 2/1/21-1/31/22
        - 328 NDCs found, 287 showed an amount paid
        - Zero-paid NDCs were excluded from review
        - Drugs that fall in the Irritant/Counter-Irritant category accounted for 151/287 NDCs
    - The current issue related to the MTUS list is that it lists essentially 3 or 4 single agents. ACOEM included them because those are common ingredients in sports creams.
        - How do we restructure the list to be more reflective in terms of sports creams, which are going to be multi-ingredient?
        - Looking at safe, generally effective products. Amongst those combinations of products, what are the cost factors?
    - We would begin with a list that is all inclusive. Of all the different combinations (328 NDCs), we would only whittle away the ones that are cost outliers.
    - For some products the last price update was 2004. So that is why some of these may be anomalies in the data we're getting in the data feed.

- Looking at row 55. Do we need a $342 menthol, when we're surrounded by all these other menthols that are in the $10-$20 range, or $3 range?
- The problem with the $3 range is that we're going to have to pick some threshold. There are a bunch in the $3 range, so $342 is an outlier.
- We're certainly not limiting access to these medications for patients and prescribers. What we're doing is stretching the dollar so that all workers can get the care they need.
- There are about 6 menthols between $24-$37. Anything above $37, does it need to be on the formulary?
- Many times being a purchaser, you keep purchasing the same agents, but if you're not looking at the cost sheet, and the price is going up year after year. You just keep paying for it because that's what you are used to buying, whereas you're surrounded by all these other agents that aren't taking advantage like that. It's good to review and just pick out the ones that are outliers.
- Compounding pharmacies or doctors come up with products with a very high price point and abuse the system. If we could come up with some sort of cap on cost would make a lot of sense.
- We can also roll these up into very discrete generic descriptions - strength - product ingredients. By doing that, it would get away from the all-inclusive description that would include any of the compounded products. Compounded products are going to require some kind of approval. And then the question will be how come you can't use something like that on the list?
- Irritant/Counter-Irritant category – there were 151 that had utilization during that time frame.
- Looking at the list, filtered to combine the like products and their strengths, and then from highest to lowest in terms of pricing. Able to see the lower-priced alternatives in each category.
- How badly do we need a combination camphor/capsaicin/menthol? There is only one, and it's pricey.
    - We don't need that. They can get capsaicin separately.
- Capsaicin/methyl salicylate/menthol products are all very expensive. There are no cheap alternatives within that category.
- Setting a cap would be more useful because even if there's a problem with the claim, and it turns out that one of those products doesn't actually cost that much, it may be within the acceptable range.
    - Concern is that making sure that we have an alternative in every category. If there is no alternative, then we as a group can indicate a workaround by mixing individual ingredients. That's the only downside of just setting an across-the-board cap.
- We're finding that these drugs are falling into two categories, $5 or $400.
- List will be cleaned up and with updated pricing data.
- To delineate some of these products to specify which are Exempt or Non-Exempt, it will be problematic because we are parsing down to almost the NDC level. Suggestion to create a roll-up similar to the artificial tears list and decide which ones are to be Exempt and Non-Exempt.
- Go through Column K by average paid per claim to see if they match identically.
- Committee looked at products utilized in past year and identified that most fall around or below $30 per package and/or average paid/claim level. Committee decided to provide buffer above that level to $50 to capture as many more products as possible to assure access to these products. DWC will restructure this under MTUS structure with appropriate RxCUIs and notes with products that might

fall under the $50 limit. The committee will revisit this in about one year to see how it is moving forward.
    - Memorialize why we chose $50 as the cap.

Motion: Set $50 limit per package as Exempt.

Vote: The committee members in attendance voted unanimously in favor. Dr. Meister abstained from the vote.

- Public Comment:
    - Looking at a subset of topicals, how will that be defined in the outcome of this meeting? I heard you made reference of GPI. I'm trying to avoid an NDC listing because it is so difficult to manage.
        - DWC response: These will be rolled up as RxCUIs. From the RxCUI categories, we will identify any outliers and there will be notes that indicate that packaged products above a certain dollar amount are excluded from exemption. Therefore, it will not be at the NDC level.
    - I noticed that lidocaine products were not included. Will they be examined in the future because there are significant outliers in that grouping as well?
        - DWC response: They were pulled when looking at the data to ensure we did not miss anything that may be a combination. The intent was not to talk about these today.
- ACOEM did not have research on various ingredients of sports creams. If there is no recommendation in the guidelines for them, they will all be Non-Exempt medications. The ordering physician would have to find some high-level evidence to show that it is medically necessary because the UR physician would most likely rely on the ACOEM guidelines that would most likely not support their use. If there are no recommendations in our guidelines for the use of the medication, then we would be recommending to make a product Exempt when we do not provide medical evidence that can be used to determine the medical necessity for that product's use. There would be nothing to rely on in evidence-based medicine to support its use, at least within our guidelines. There are other reasons why medications can be provided despite what is in the guideline. An insurer can certainly approve something they wish to approve. Although the ACOEM guidelines cover many things in workers' compensation care, they do not cover everything. The use of a medication could be supported even if the guidelines do not recommend it.
- In the guidelines, the reference of LIDODERM shows only one item recommended with moderate evidence for neuropathic pain, a few with insufficient evidence and several with no recommendation.
- If we categorize safety, efficacy and cost:
    - Main safety concern with lidocaine (5% patch, LIDODERM brand) contains 700 milligrams of lidocaine. This could be a toxic dose to an adult human being if it is put directly on non-intact/open and broken skin.
        - If used correctly, they are all safe.
    - There is some uncertainty around efficacy.
    - In favor of increasing patient access to those medicines that are effective and have a history of clinically being used
- Keeping lidocaine Non-Exempt is because you have clearly outlined what is expected to see on the RFA. The exempt products are not usable for this patient and this is now a first-line agent for this patient with renal failure, liver failure or taking anticoagulants. If it is not a first-line agent for the majority, I am still in favor of keeping it Non-Exempt.
    - If it is safe, effective and inexpensive, why make people run through hurdles? This

is the true frustration of patients and physicians alike.
    - Table the motion for the lidocaine category that any medication below $50 price per package will be moved to the Exempt list until we hear back from ACOEM upon their reasoning or reasons why they were placed as they were.
    - Find out which lidocaines were denied and IMR overturned as an appeal process to get an idea of how often these were wrongly denied.
    - Using IMR as a gold standard may not be enough. Delays care and medical improvement

## IV. Public Comment

- I really appreciate efforts to deal with these medications and trying to solve this problem we are seeing nationwide. There was a WCRI study that shows that these topicals, patches, lidocaines, etc. are becoming a big issue within workers compensation. Outside of P&T, this topical and patch issue is something that needs to be looked at holistically, as a global perspective. Might be more problematic if you just look at the cost once because they will always find loop holes and work their way around it
    - DWC response: What do you envision if there is a $50 cap in terms of a work around? If it stays below $50, how are they exploiting?
        - I don't have data for just California, but I can provide that if it's helpful for the P&T committee. Looking at a national level, if you go back, prior to the formulary, I don't necessarily know that these drugs were a problem. Were they a cost driver back then? They became a problem because of the formulary. California and other states have cut off compounds, restricted physician dispensing, and controlled the opioids. The formulary is really controlling access to some of the problematic drugs, not just from utilization, but also from a cost perspective. You would not see these five years ago if you put the band-aid on the patch here and there, you are going to see it pop up more and more and continue to have to address it.
- I like the idea of putting the bar of $50, which makes sense. I am wondering from an implementation perspective when UR is looking at this, how do you think they will distinguish this ingredient versus this ingredient and when they have to look at cost as well, how do you envision this occurring. What are your thoughts on how that will look from a UR side of things?
    - DWC response: If it has made it to UR, is not it already the pathway of non-exempt.
        - Many folks may not realize that this is a costly medication and automatically approve it when it should have gone to UR. Where are the stopgaps going to be? Maybe that's what the insurers need to figure out
            - DWC response: If it turns out that products are made exempt with a caveat that products over a certain price point should require a review prior to approval, that kind of edit could be placed in the processor system (PBM), so when the claim came in, if the claim was above a certain level it would get kicked back for review. It can work like that currently. That is one way to control that. It would not be something that DWC would design or handle. That is within in the payers purview to change their systems accordingly
- We are going to have to delay the next topic to the next meeting

## V. Review of Committee Recommendations

- Artificial tears:
    - What it would look like rolled up under RxCUIs

    - Additional pricing information ranges so that we can look at how to final approve that
- Topical analgesics:
    - Committee's move for a $50 price cap
    - Memorialize the motion as we discussed
    - Provide the same level of information relative to the artificial tears RxCUIs rolls-ups
- Lidocaine products:
    - Motion is tabled to revisit and discuss those products where we might set a cap
    - Come back with details from ACOEM's recommendations on how this product should or shouldn't be exempt