STATE OF CALIFORNIA GAVIN NEWSOM, Governor

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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. Todd Shinohara, Pharm.D., MA. Raymond Tan, Pharm.D. Lori Reisner, 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;
 need to submit annually
- State and federal Antitrust Law advisement

II. Approval of Minutes from the July 20, 2022 Meeting

Dr. Raymond Meister, Executive Medical Director, DWC

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

<u>Vote</u>: The committee members in attendance voted unanimously for approval of the July 20, 2022 meeting minutes. Lori Reisner and Julie Fuller were not present during the vote.

Related briefing: July 20, 2022 Meeting Minutes

(https://www.dir.ca.gov/dwc/MTUS/Meetings/July-2022/Meeting-Minutes.pdf)

III. Discussion

- Inflation Reduction Act
 - No direct impact on workers compensation programs
 - o Most of it is aimed at Medicare and a little bit at Medicaid
 - Medicare
 - The control or the changing of pricing within the Medicare program could have effects on other purchasers. Unclear with capping Medicare drug costs will affect other health sector costs.
 - Some of the issues related to inflation based rebates
 - Cap in out-of-pocket Part D spending
- Artificial Tears (See Artificial Tears DRAFT for Discussion)
 - At the last meeting, the committee asked for pricing to be rolled up in RxCUI
 - Process
 - Used same list of NDCs used to generate reports for July meeting
 - Cleared out anything that was obsolete or did not have current pricing
 - Used Medi-Cal maximum allowed price and we rolled up the values for these products under each RxCUI
 - Sheets were created for the solutions, preservative-free (PF) solutions, and gels
 - Rolled up under the RxCUI for the products we could identify that were still active in the system
 - Solutions by RxCUI tab, under line 18, why is this product so much more expensive compared to the others?
 - It looks like this is a branded product and the only one within that RxCUI. Not sure why the product is priced at that rate.
 - Is there some recommendation about how we're going to eventually fill in the RxCUIs, if one line now turns into 30 lines?
 - o One of the processes would be looking at the ingredients
 - Solutions by RxCUI tab It looks like most of these agents are OTC, and a few may be prescription.
 - Is there a way to get input from an optometrist or ophthalmologist to see which ones they could provide recommendations? Identifying agents other than their dosage forms (solution, gel, ointment, and PF).
 - Although we don't have any eye doctors immediately available, we could reach out to some to get their input.
 - There are certain combinations out there that may be duplicative in nature or preferred over others. There are some nuances that could be brought out with that type of input.
 - One of the problems we had with the MDGuidelines is that they weren't very clear in terms of ingredient.
 - o Going back to the MTUS Drug List, it just says artificial tear ointments as a

blanket catch-all under Drug Ingredient. How do we really start commercializing the use of the formulary if it's vague and there's no detail behind it? By doing this exercise with what seems to be benign on artificial tears, it creates this difficulty in detailing it out, whereas it's supposed to be all, some, or how do we even start filling in the RxCUI component of the formulary?

- The last time when we were looking at this, one suggestion/preference was having at least a reference product available for at least one of each of the dosages. You have a group of ointments, group of gels, group of PF solutions, and a group of regular solutions.
- What does the utilization pattern look like and how many claims are there for this?
 - It's not in the data set that we have here. Data was presented during the July 2022 meeting.
- [See <u>Artificial Tears Utilization July 2022 Meeting</u>]
 - For carboxymethyl cellulose, this is the utilization from before. It was the number one product. Carboxymethylcellulose products would probably be the most likely used.
 - From a use perspective, plain polyvinyl alcohol, polyvinyl alcohol/ povidone and carboxymethylcellulose seem to be the most popular products.
- So with the formulary referencing a brand product, should that hold any
 weight on what RxCUI is picked or is that kind of not supposed to hold that
 much weight in regards to what's printed on the MTUS Drug List? For
 artificial tears, it specifically references REFRESH PM and REFRESH PLUS. So
 those will have unique RxCUIs.
 - Whoever initially made the reference in the guidelines just picked a name. Don't think it was intentional that it was that specific. We've seen that with some other products where they may have picked a brand product name that doesn't necessarily match. It's supposed to be an example, but not the product.
- O Going back to the Solutions by RxCUI tab These products, especially the OTC products, change frequently. Some of the products that were previously on the list are not noted as being obsolete. The RxCUI changed. Some of them have the same product name, but their ingredients completely changed. It's sometimes a moving target. So again, the polyvinyl alcohol and carboxymethylcellulose-containing products are practically everything on the list.
- Is there a recommendation about how you would roll it up or don't roll it up at all? How would you start filling in the detail of something like this? This might be a bigger example than most others. We got here because the drug ingredient was artificial tear. That's the most non-specific you could get on the formulary.
 - One way we could roll it up is under the two primary ingredients, polyvinyl alcohol and carboxymethylcellulose. Then, pick a higher rollup RxCUI, and not so granular.

- Technically, we could roll up all of the plain carboxymethylcellulose ophthalmic products all under one RxCUI.
- If we wanted to do it by content, there are a number of products where we could roll up them up into 3 RxCUIs.
- What we can do later is after it's been rolled up, at another subsequent meeting, we could see if there's any of those outlier products and then we could discuss whether or not, if it's that much of an outlier, should that be excluded?
- If we could come to some kind of agreement here, it makes sense to move forward and start filling out the MTUS Drug List, so we can start really looking at what the rollup value look like or at least with the Exempt drugs first. From a programming standpoint, we really need the detail on the Exempt drugs first, and then all the Non-Exempt drugs could be kind of a catch to be excluded. The RxCUI detail is really important for the Exempt drugs to be populated.
- It appears that carboxymethylcellulose alone, polyvinyl alcohol alone, and polyvinyl alcohol with povidone were the 3 most-used products. Those can be rolled up under a single RxCUI under those 3 product types and it should capture all the dosage forms.
- Preservative-free agents are probably going to be the more expensive agents. They are unit-dosed packaged.
- DWC consultant to roll up the 3 most common product ingredient groups, and create a spreadsheet to just validate where the pricing is and then report on it the next time.
- Do you think we could look for that professional input once we get to a stage when we're perhaps ready to show something, just to make sure we're not missing anything?
 - DWC consultant will do some research if there are any recommendations. There may be some recommendations from professional organizations.
- Topical Analgesics (See Topical Analgesics and Lidocaine DRAFT for Discussion)
 - Committee asked for pricing to be rolled up into RxCUIs
 - Products were separated into multi-ingredient (including capsaicin), capsaicin only, and lidocaine and lidocaine-containing products.
 - [See Multidrug tab] Several of the multidrug topical analgesics have capsaicin, lidocaine, menthol, methyl salicylate included, which were all listed as separate standalone ingredients on the MTUS Drug List
 - Per Dr. Meister's communication with the ACOEM, those were supposed to be examples related to sports creams, as we know are all these varieties of different combinations of products.
 - Can we roll these up into smaller groups? Capsaicin is easy because there is only a handful of capsaicin products. It is really this group of products that are going to be complex. For example, looking at the first 2 rows, they both have different amounts, but they both contain capsaicin, menthol, and methyl salicylate. Technically, they could be rolled up unit a single dosage.
 - When we're looking at capsaicin, for example, and it's talking about average

- price per unit and min/max price, are we also looking at each one of these has a 30,60 or 90 gram tube form that's coming in?
- 30,60 or 90 gram tube only makes a difference if you're talking dispensed quantities.
- Some of them may only be 30 gram tubes. These are rollups. The RxCUI doesn't have packages size.
- O Going back to the communication between Dr. Meister and the ACOEM, was there anything more specific they said about starting out with single agent products, which is why it was listed that way versus going to these multi-agent products? Should we start with single agents versus having quadruple agents available right off the bat?
- ACOEM's intent was to represent the availability of sports creams. That's why some of the single agent products list as a brand product. Example: BENGAY (single or multi-agent).
- O Pricing also does not reflect the number of ingredients. Some patches have only a single agent like the methyl salicylate and priced at \$41/patch. Then there's another patch with a couple more ingredients and priced at less than one dollar each. How is this pricing even determined?
- Largely talking about retail pricing. However manufacturers want to set up their products from a retail perspective. Some charge more and some charge less.
- If the evidence does not support that we have to start with a single agent, or with a multi-agent, it would be convenient to roll it up and then have a price cut-ff. If the doctor wants to prescribe a single-ingredient product or multi-ingredient product, they can as long as it's at a reasonable cost.
- O Going back to creams, gels, lotions, ointments, patches, and sprays, the multidrug topical analgesics list may need a representation of one or two of each of those dosage forms, and perhaps that could be filtered by what the claims are in each of those sections. For example, under the 7 creams listed, we could look for the most popular one that's being claimed. We can see how it's being prescribed as the most popular and then put that up against the price and then move on to gels.
- We could roll them up by ingredient regardless of strength and give you some sense of where that is in terms of, for example, the first two products on the list you would roll up under a single RxCUI. There's 3 NDCs and we can revalidate with any new data.
- DWC consultant to pull all again and pull the NDCs again for these products by therapeutic category. Will roll them up by ingredient and dosage form and then look at the pricing.
- Prices seem fairly consistent with some low-side outliers. For example, the lotions are in the \$2-\$3 range except for one.
- The patches are consistently more costly compared to the other products. I don't think there are studies to show that patches are really superior to the other forms. DWC consultant to look at information regarding patches.
- The downside to creams, lotions, gels, and sprays are you are relying on the patient to apply it in the right amount, and in the right time frame.
- The value of a patch is you stick the patch on and it's delivering what it

delivers.

Lidocaine

- ACOEM does not designate medications to be Exempt or Non-Exempt, but do provide recommendations for which medications are supported to be used during the acute phase of treatment of an injury or illness.
- If they (ACOEM) recommend a medication for acute use and it's deemed to be a safe and effective medication, then the DWC will designate that medication as an Exempt medication to the MTUS Drug List.
- You could also have a medication that's recommended for the chronic phase of an illness, but if it's not recommended for the acute phase, then the medication would by default be a Non-Exempt medication.
- Need clarification on the brand example for lidocaine. Brand example is listed for LIDODERM. So the comment about carpal tunnel, those patches are hard to cut for the hand. Maybe we could differentiate LIDODERM versus the other versions for the next meeting. Right now, it's kind of an all-encompassing lidocaine exemption status.
- It is an exemption for treatment for the recommended injuries, not recommended to be exempt for everything and anything.
- Under the MTUS, it is the prescriber's choice to prescribe cream, gel or patch for pain. Cream and gel are a cost-effective alternative to the patch.
- Separate for discussion how to clarify the Lidoderm row. The
 differentiation is between the four percent, five percent and the gels. We
 will reorganize similar products together to look at what these products are,
 their pricing and how they are in relationship to regular Lidoderm. There
 are a lot of combo products and patches.
- Some systems are looking at swapping out the four percent patches for the five percent patches, but anticipate that the four percent would work just as well. The New York formulary lists the four percent versus the five percent. Maybe ACOEM or MD guidelines can share why this was listed.
- Studies were done with lidocaine patches. If we restrict ourselves to only the patch, then the list would be evidence based and much smaller.
- We will aim the MTUS at the patches. Look at four percent and five percent split, cost ranges and any evidence that would prefer one to the other.
- How do we navigate diagnosis specific utilization on an end user basis?
 Pharmacists generally do not know what the diagnosis is.
 - Each medication on MTUS drug list has a set of recommended or not recommended indications. For exempt medications, they are directly tied to indications for usage for that specific medication for that specific diagnosis. How can we use Lidocaine for carpel tunnel in acute phase and then use it in acute phase for shoulders but expect pharmacists to know that lidocaine for carpel tunnel is exempt but lidocaine for shoulders is not exempt? It can always be retrospective reviewed and brought to the attention of the treating physician, that without additional supporting documentation, lidocaine is not an exempt medication for a shoulder injury. The

- treating physician could either supply supporting documentation or not use that medication.
- Suggestion to educate the retail pharmacies and providers on how to make the difference between exempt and non-exempt actually relevant
 - Recommendation to reach out to CBHA (California Pharmacist Association) next year for the April pharmacy exchange.
- PUBLIC COMMENT: What is the question about the pharmacy and the PBM when the injured worker is utilizing the pharmacy after they have been discharged and the topicals.
 - DWC committee member response: The pharmacies are not dispensing the medications until the adjuster has reviewed the RFA and either say yes or no. Some of the adjusters are sending these to utilization review and once they give the go ahead on the RFA, they will put the code in for Optum. The retail pharmacy understands they can put it out then but they will not do it before that point. Sometimes it will take a day or two to get that done. Right now how we are managing that is once the patient is admitted under workers' compensation, we start the RFA. The problem with this is that we can't really send in until we know what the final discharge medications are going to be. If I send it two days early and the patient does not tolerate for example, hydrocodone, then I have to change it to a different analgesic. I have to resend the RFA with an update. Sometimes we are waiting hours or days for the adjuster to signal to Optum or the PBM that this is approved.
 - Public comment response: That makes sense to me. I wasn't following but that's just the way we have programed our systems for both the pharmacies and us and for the insurer is that if it's a drug that is not supposed to be dispensed without an RFA, we make sure that when it comes across from the pharmacy (not all pharmacies may not necessary know the whole listing, the perioperative and all the different factors that go into it) we will pause that
 - DWC committee member response: They do not. In looking up the perioperative, I see N codes but that does not seem to really matter.
 - Public comment response: It should. In our systems, we have programmed it to the formulary so depending on the specific medication and the perioperative, that should flow through if it is permitted. The only time we would pause, is if it is not supposed to be dispensed. We then wait on the adjuster or the carrier to make a decision. Were just looking for if they authorize it. If they send it to UR we recommend they send it on the back end if it's not medically necessary or related to the claim

- DWC committee member response: It does not go to UR for the majority of the time for us. Most of the time the adjuster makes the decision
- DWC committee member response: Does the diagnosis get programmed into your system? Can your system pick up the difference from the lidocaine patch for carpel tunnel syndrome or shoulder?
- If we get the diagnosis. Sometimes that is not on the prescription.
 If the pharmacy cannot ascertain what the diagnosis code is, then to confirm, we alert
- We will look at the lidocaine patches:
 - the four and five percent
 - any evidence
 - review the MTUS list and the uses to see how they are referencing it
- Even some of the ones with no recommendations, is related to the patch and not other products. It may be that all of the conditions there reference the patch.
- PUBLIC COMMENT: With specific types of patches, we have seen some pharmacies maximize use of the five percent over the four and half percent because the five percent is \$700 and the four and half percent is \$52. Just to note as you look at the different RXCUIs and NDCs
- MTUS Listings Categories
 - o Potential Recategorization
 - To list these medications as autoimmune diseases, not analgesics and anti-inflammatory. We can go back to ACOEM and see if they would reconsider revising. It may that they are basing their recommendations on studies.
 - We are trying to closely match the ACOEM classifications as possible but some of the anti-fungals need to be updated.
 - PUBLIC COMMENT: ACOEM classification looks like Medi-Span GPI two naming convention for any given drug
 - DWC response: They may have used Medi-Span initially. Not sure, what is being used now.
 - Dermatologicals are very broad so we were trying to separate those out into analgesic, anesthetics, etc. In terms of the pharmacological, we will look at more of these and clean them up. There are some errors. We will start pulling some of these and reach out to ACEOM

IV. Public Comment

No additional public comments.

V. Review of Committee Recommendations

- Artificial Tears:
 - Rolling up products into the three most common used products
 - o Reviewing the Utilization
 - Checking professional recommendations as to which products they recommend. The committee may reach out to an ophthalmic or optometry

professional to review.

- Topical Analgesics:
 - Rollup of ingredients
 - o Pricing and utilization
 - o Evidence related to a patch as a delivery system versus regular products

• Lidocaine:

- Focusing on the four percent and five percent patches. Looking at both pricing.
- Lidoderm product and all the uses in the guidelines to see if all the references are to the patch.

MTUS Listings:

- We can make a list of the TNF agents and Dr. Meister can reach out to ACOEM on these
- o Clean up to make consistency across the recommended categories

• For future meetings:

o In depth discussion about interaction of pharmacy and prescriptions