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Pharmacy and Therapeutics Advisory Committee
MINUTES OF MEETING
Wednesday, January 19, 2022
Via Video/Audio Conference

In Attendance:

DWC:	**Committee Members:**
George Parisotto	Raymond Meister, M.D., DWC Executive Medical Director, Chair
DWC Administrative Director	Basil R. Besh, M.D.
Jackie Schauer	Julie Fuller, M.D.
DWC Legal Counsel	Joyce Ho, M.D.
Kevin Gorospe, Pharm.D.	Lori Reisner, Pharm.D.
DWC Consultant	Todd Shinohara, Pharm.D., MA.
	Raymond Tan, Pharm.D.

I. Welcome and Introductions

George Parisotto, Administrative Director, DWC

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

II. Approval of Minutes from the November 16, 2021 Meeting

Dr. Raymond Meister, Executive Medical Director, DWC

Motion: Approval of the minutes from the November 16, 2021 meeting

Vote: The committee members in attendance voted unanimously for approval of the minutes from the November 16, 2021 meeting. Lori Reisner was not present at the time of the vote.

Related briefing: November 16, 2021 Minutes of Meeting
https://www.dir.ca.gov/dwc/MTUS/Meetings/November-2021/Meeting-Minutes.pdf

III. Discussion

- COVID-19 Vaccine Update
  - About 9% of the total workers' compensation claims in 2021 were from COVID claims
  - COVID claims by industry bar chart (1/21-11/21) shows that public (safety/government) and healthcare make up almost half the COVID claims
  - ACOEM currently working on version 9 of the updated COVID-19 Guideline
- November Meeting Follow-Up
  - MTUS header – Committee requested added language for Special Fill/Peri-Op to include dispensing the smallest commercially available product marketed by the manufacturer and the fact that the MTUS list uses the ACOEM drug categories as a base
    - Added the following language to the model MTUS list header:
      - MTUS Guidelines is the basis for the "Therapeutic Classification" listing. MTUS Guidelines, FDA approved labeling and UpToDate were used as sources for the "Pharmacological Category" listing
      - Special Fill and Perioperative Fill drugs that must be dispensed in a manufacturer's original package (e.g., ophthalmic solutions) must be prescribed/dispensed in the smallest commercially available package size
  - Standard and Expedited Review Timelines
    - For an expedited review, the review needs to occur within 72 hours of receipt of the request, and the communication back to the prescriber/provider needs to occur within 24 hours of the decision
  - Generic First Policy
    - AB 1124 indicated that the use of generics or the brand should be considered where it was medically necessary and cost-effective
      - Brands can be used where medically necessary if the doctor has written Dispense as written/Do Not Substitute. The doctor would need to justify in the reports the patient's specific factors for use of the brand versus generic.
      - Exempt section clarifies by referencing to the brand that Exempt means generally generic unless these conditions are satisfied for this brand being necessary
    - Summary: Generic first, unless brand use can be justified
    - Committee member proposal to add a statement around the preferred use of interchangeable biosimilar agents
      - Currently only one interchangeable biosimilar approved; one more expected next year.
      - DWC would need to adopt a biosimilar interchange rule through a regulatory process
    - Another scenario to consider is where there is a generic available, but not in that particular brand. AB-rated generics versus non-AB-rated generics like in the case of generic diclofenac, which is available, then brand-only ZIPSOR. Would this fit the line of thinking with generic first policy from that stance? There is no generic

ZIPSOR, but there is a generic version of diclofenac available. That would imply the generic first policy promotes the generic diclofenac product, but if the brand is available and medically necessary, then we could go that direction as well
    - Committee member suggestion to include in the authorized generic piece and making sure that it's clearly defined as Exempt or Non-Exempt or included or not included
    - Within that provision from AB 1124, it does comment on cost effectiveness. It's implied, but not very specific.
    - There was a previous conversation surrounding cost effectiveness, not specific to biosimilars or something specific like ZIPSOR, but a different NSAID. The NSAID was more or less equally supported by CA MTUS, but the cost of the NSAID was very different.
        - Example: generic diclofenac 1% topical versus a branded-only diclofenac 2%
    - Committee member looking for some clarity related to 4-day supply. Requesting DWC to look at the RFA form because within 9785.5, the RFA form suggests frequency is optional in what is being requested. If we don't know the frequency of use, we cannot calculate a 4-day supply. Requesting review of requirements to be on an RFA form in relationship to drugs. Currently, the way the chart is written, it says the drug and the strength are required, but not the frequency or the daily dose to determine quantity and day supply.
    - An argument could be made that when frequency of dose is not included on the RFA, it should be considered incomplete. Looking to DWC for clarity on whether or not the frequency of dose on an RFA is required.
    - Another committee member stated that if the dosage is not supplied (unless there is only one dosage for the medication), then it would be considered incomplete. There were times when frequency was not provided, and it would become a bit of a guessing game to determine proper supply.
    - Another committee member supports having the frequency and dosing because some people require medications at a higher frequency and dose, and that would clarify how long the patient needs the medicine, what quantity of tablets per period of time. Support in the name of clarity and safety.
    - The standard prior authorization form in California that all managed care organizations are required to utilize for prescription drugs, has both dosage and frequency as required fields.
- Topical Analgesics (*See Topical Analgesics spreadsheet*)
    - Committee requested an expanded list of all topical analgesics that contain methyl salicylate, camphor, and menthol, which represent ingredients for sports creams as referenced in the ACOEM guidelines
    - Products containing these ingredients are classified as Irritants/Counter-Irritants
    - Billing unit prices pulled from most recent Medi-Cal file (11/9/21); most of

these prices are probably wholesale acquisition cost based pricing

- Some products fairly inexpensive, and some incredibly expensive (price per package, from a couple dollars to a couple thousand dollars per tube)
- List contains OTC products currently on market; excluded prescription data
- Since the drug combinations on this list are not part of the actual MTUS Drug List, is the Committee to recommend which combinations to put on the formulary or use the formulary as is, and then look at these products to see which ones would make sense to roll up the RxCUI in some way?
- Need clarification on the drug list stating that one cannot just combine drug ingredients from the drug list to create a combination dug
- Should the drug list reflect the various combinations, where the committee would say which ones make sense and which do not? Would there be a maximum price point to consider? It would not make sense to have a $925.00 camphor/menthol when something else is available for $1.75.
    - Example: SALONPAS – very specific combination of methyl salicylate, menthol, and camphor. Price point is not too bad. Suggesting to put a specific combination of medications or generic equivalents on the drug list
    - Committee member voiced concern over possibly giving the impression that certain topical compounds are favored over another. Also, if the committee decides to put a version of a specific topical compound on the formulary, companies may create a whole new generic compounded topical that's more expensive than the original
    - When a doctor is writing a prescription, and the pharmacist is filling this, what are they going to see? Would it be a drop-down box like a physician order entry, where they would be able to put these percentage elements together and search for a generic versus the brand if there is one available?
    - Under the MTUS Drug List, the ingredient and dosage form would be specific to a combination in terms of string
    - Value of the RxCUI would help distinguish between equivalent strengths
    - Is there anything that would preclude any of these including the expensive ones from being denied on a medical necessity basis even if we do not approve it as a part of the formulary? There is no way a reviewer is going to be able to take cost into account. This feels like a legislative problem. Can the committee make a recommendation to DWC for a legislative change in this space? The worst kept secret is folks who exploit compounding for profit. There's one group of practitioners who will use what is available at their hospitals, and the other folks who choose to carry and dispense themselves
    - If the ingredients are Non-Exempt, then we can only look at what is Exempt. Non-Exempt would require Utilization Review. Only capsaicin is Exempt on the MTUS
    - Discussion of possibly making some type of topical analgesic other than capsaicin Exempt

- Circling back the to the original questions:
    - How to identify these products?
    - How many, if any, can we make Exempt?
    - How do we prevent the system being gamed to create a giant profit for some individuals?
- What if we made all of these Non-Exempt? These are not urgently-needed medications. They are OTC. What would be the downside of forcing all these through UR? It would be within the purview of this committee to make all these ingredients Non-Exempt, and if there is a legislative solution to this, it would be on the UR side
- Committee member expressed that it wouldn't be right to make them Exempt because ACOEM did not find a basis to make them Exempt; it was clarified that ACOEM does not indicate Exempt/Non-Exempt – they review evidence and indicate recommended or not recommended or no recommendation based on evidence
- Committee member stated that patients like these products and experience relief; but due to extreme price differentials it is a difficult circumstance
- Committee member in support of some topical analgesics to be made Exempt. Even though it only takes 5 days for the medication to go through UR, it is very important to get treatment for the injured worker and the opportunity to return to work as quickly as possible. Going through UR for something like this can possibly cause the injured worker to lose faith in a system that is supposed to help them get better
- Committee member comment that the financial abuse of these products far outweighs the convenience of an injured worker being entitled to a medication within the first 5 days. Most of these medications are for repetitive strain injuries, and not for acute trauma
- It seems unethical to remove a barrier for something that is acquired at $3.00 and reimbursed at $500.00
- Leave listings as they are (as Non-Exempt), and the committee would like to see an aggregate of products by RxCUI to see a range of pricing that falls within there. Will normalize by single package size. Then, have a discussion as to the products that are essentially generically equivalent
- Possibly add reimbursement limitation language to the statute
- Public Comment:
    - California is not alone in facing the topical analgesic pricing issues. Some states have put a reimbursement cap on these items, while other states moved them into a prior authorization request.
    - There are two ways to control the elements out there that are abusing the situation. One would be to require prior authorization, and the other would be to require a fee schedule cap.

        - What is the percentage that these are dispensed by physicians versus being dispensed by retail pharmacies? In California, if dispensed by a physician, then it's going to require prior authorization already. Is it something that the committee could make a recommendation to the commissioner to remind payers that these drugs require prior authorization?
- Oral NSAID Cost Comparison (*See NSAIDs List*)
    - Committee asked to look at these products from a hierarchy of price
    - Pulled together the NSAIDs on the MTUS list by dosage, form, and strength
    - All these products are rolled up because the generic price was the same across all the products listed except for the fenoprofen calcium products
    - Fenoprofen calcium products have the prices for individual NDCs. There was not a uniformity of pricing among those and they are all listed as Exempt. Some of these products are very expensive.
    - Previously listed high cost indomethacin capsules are no longer listed. According to the FDA, those have been withdrawn from the market.
    - The intent of this cost comparison list is to see what products from a hierarchy of price. The reason this came up has to do with the fenoprofen calcium, which has significant pricing issues.
    - Fenoprofen is currently Exempt on the MTUS Drug List. Relative to other products that could be used instead, especially in the acute care of an individual who needs an NSAID, does it make sense to have fenoprofen Exempt at $100/day, when they could use celecoxib for $0.12/day?
    - Committee member stated she was not familiar with a special indication that makes fenoprofen an especially desirable NSAID. One committee member stated she had no experience using fenoprofen. Another committee member stated he's never dispensed it in the pharmacy in 15 years.
    - Some of the PBMs have experience seeing this in their reimbursement, and previous public comment indicated that there was a slow increase of the fenoprofen products because of the pricing.
    - These are prices on file are likely wholesale acquisition based pricing because they are single-sourced generics. The wholesale acquisition cost can be and often is wildly different than what a particular provider is purchasing it for.
        - Example: 200mg fenoprofen calcium capsule (NALFON) with a wholesale acquisition cost of $21.00. Person purchasing and dispensing it could be paying significantly less, possibly $2.00/capsule, which shows the potential incentive for using the product as a profit center.
    - Should fenoprofen and ketoprofen be Non-Exempt, knowing that there are alternative NSAIDs and that the Non-Exempt drugs would be available after prospective view?
        - Committee member stated this was the approach used for some of the anti-emetic drugs, and it may be a reasonable approach for NSAIDs as well.

- Is it safe to say that the long-term efficacy really does not have a bearing on this committee's decision to make a specific NSAID Exempt or Non-Exempt? Based on the studies and reviews related to NSAIDs and how various entities developed their formularies for drug lists, for short-term perspective, NSAIDs aren't really distinguishable in terms of efficacy.
- Public comment:
    - As far as reimbursing for this drug and how we see it utilized in Workers' Compensation, it was non-existent until the reimbursement for it changed. There was a sudden uptick that accounts for around a 600% increase that California spends on NSAIDs. The drug itself being on the formulary is not so much a clinical decision as it is an exploited one. I cannot find clinical reasons why it would remain on the formulary
- Public comment:
    - When opioid use went down, NSAIDs use went up. Starting in 2016, NSAIDs became the more prominent therapeutic class in the California Workers' Compensation system. By 2018, almost 1/3 of the fills were NSAIDs. Last March, according to CWCI, NSAIDs drug spending increased by almost 70% in under two year. NSAIDs began representing the largest portion of drugs spending in California. When it comes to fenoprofen and ketoprofen, we see that they are prescribed at a significantly higher frequency, which result in a considerable increase in expenditure of the NSAIDs. They are both Exempt on the MTUS and they are not included or overseen on the current medical fee schedule. When it comes to fenoprofen, CWCI average payment price of $200 per prescription in 2016, representing 0.1% of NSAIDs being filled by California injured workers. However, fenoprofen transactions first half of 2020 had an average payment price of nearly $1,500 per prescription, representing over 25% of all NSAID transactions in California workers' compensation system. Ketoprofen spending increased substantially even though the volume stayed the same. For being less than 1% of the NSAID fills, it accounted for nearly 15% of all NSAID spending in the first half of 2020. Ketoprofen had an average payment price of $99 at the beginning of 2016, by end of June 2020 average payment price was $1,000.
- Committee member commented from a physician point-of-view, stating it is okay to target some of these higher-priced drugs, if there is no difference in efficacy and safety. NSAID use went up correlating with decreased use of opioids. Fenoprofen and ketoprofen are outliers in terms of cost and they do not deserve to be Exempt. How they are dealt with in the utilization review process beyond the first 7 days is outside the purview of this committee.
- Committee member stated if we eliminate the most and second most expensive NSAID because someone has been gaming the system, there may be a new one that comes up. It can only be addressed with a fee schedule.
- Committee member stated we can only control our controllables, and the

only decision point before us is which medications do we make Exempt? If another NSAID pops up in the future, we should apply the same rationale to it and say this seems exorbitant and make a determination that it shouldn't be an Exempt medication. This seems like a good middle point between stating that all NSAIDs are bad/expensive versus stating there's nothing we can do and just make them all Exempt.

Motion: To make ketoprofen and fenoprofen Non-Exempt.

Vote: All Committee members in attendance voted in agreement to make ketoprofen and fenoprofen Non-Exempt, except Dr. Ho only voted to make fenoprofen Non-Exempt. Dr. Meister abstained.

- Closing the High-Cost Drug Loophole
  - Re-labeled products are manufactured by generic or brand companies that are re-packaged and re-labeled for physician dispensing
- MTUS Expanded Listings (*See Expanded MTUS Updated Categories*)
  - Committee previously requested a review of the list to correct BRAND to ingredient mismatches
  - Committee member stated an email was sent with a list of some suggested minor changes. For example, some of the benzos on the list are categorized 3 different ways.
    - DWC to go through the list from the email, and take them to ACOEM to see if they would be willing to make some changes.
  - Many of these, especially the initial therapeutic classification, listings are based off the MTUS to ensure there wasn't a significant divergence from what was ACOEM has listed on MDGuidelines

IV. Public Comment

- No additional public comments

V. Review of Committee Recommendations

- DWC to review generic substitution language with interchangeable biosimilars checking the Business and Professions Code section 4073
- Look at the RFA form related to the 4-day supply frequency in dosing issue
- Topical analgesics: Aggregate products under RXCUI and develop a range of pricing to look at, to possibly select one or more combinations for Exempt status in the future
- Recommendation to change ketoprofen and fenoprofen to "Non-Exempt" status on the MTUS Drug List
- Look at Dr. Ho's information related to therapeutic categorization and any other recommendations for changes or corrections to the MTUS list. Can send an email to Formulary@dir.ca.gov.