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Pharmacy and Therapeutics Advisory Committee

DRAFT - MINUTES OF MEETING

Wednesday, July 21, 2021

Via Video/Audio 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.
Lori Reisner, Pharm.D.
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
- The July 21, 2021 meeting will be the last virtual meeting. October 20, 2021 is expected to be scheduled for in-person

II. Approval of Minutes from the April 21, 2021 Meeting

Dr. Raymond Meister, Executive Medical Director, DWC

Motion: Approval of the minutes from the April 21, 2021 meeting

Vote: The committee members in attendance voted unanimously for approval of the minutes from the April 21, 2021 meeting. Lori Reisner and Raymond Tan were not present during the vote.

Related briefing: [April 21, 2021 Meeting of Minutes](#)

III. MTUS Drug List v9

- Added medications for the treatment of COVID-19. These medications were added to the ACOEM formulary
- Included a few deleted drug recommendations that ACOEM made
- There was a diclofenac variant that was Exempt, and now made Non-Exempt

IV. Discussion

- COVID-19 Vaccine Update
 - As of 6/24/21, 57.8% of people are fully vaccinated in the state (CA). Currently, the number of fully vaccinated individuals increased to 61.5%. About 9% of the population are partially vaccinated
 - Current vaccination progress by age group:
 - 12-17: About 38% are fully vaccinated
 - 18-49: About 58% are fully vaccinated, 9% partially vaccinated
 - 50-64: About 72% are fully vaccinated
 - 65+: About 70% are fully vaccinated
 - Booster dose update – Too early to make that decision
 - Delta variant
 - About 60% more easily passed from one person to another
 - A person with the Delta variant can infect up to 6 others, whereas a person with the original variant can infect up to 2-3 others
 - Increased the odds that an infected person would need to be hospitalized or die from the infection by 50%, when compared to older variants (also regardless of vaccination status)
 - A person with the Delta variant tested positive more quickly than their predecessors
 - While the vaccines are effective, the Delta variant appears to be able to escape some of the antibodies that are made in response to vaccinations.
 - Vaccine is about 80% effective against the Delta variant, 94% for hospitalization
 - Committee suggestion for a consensus statement in support of vaccination for COVID-19

Motion: Develop a resolution or statement that the P&T Committee supports vaccination for COVID-19

Vote: The committee members in attendance voted unanimously to develop a resolution or statement that the P&T Committee supports vaccination for COVID-19.

- What are the specifics with respect to COVID-19 and pharmaceuticals that are pertinent to our domain? Are we considering COVID-19 contracted in the workplace to be a work-related injury? Are we needing to exempt any medications in the treatment of COVID-19 related to an injury from a work-related event?
- DWC incorporated all the non-physician-administered medications that ACOEM recommended into the MTUS Drug List v9
- Those medications that are recommended for the acute phase of the illness, are made Exempt
- COVID-19 is largely covered as a work-related illness given the fact that the individual is working outside the home at the request of the employer and has

- a positive COVID-19 test
- There was an Executive Order early on from the Governor making COVID-19 a presumptive work-related illness, and now adopted as Senate Bill 1159
- Topical Pain Control
 - In the April 2021 P&T meeting, the committee was asked to look at Topical Analgesics to make them more widely available
 - 5 products on the MTUS list that are considered Topical Analgesics
 - Counterirritants: camphor, capsaicin, menthol, methyl salicylate
 - NSAID: diclofenac sodium
 - [Current MTUS v9 Topical Analgesics](https://www.dir.ca.gov/dwc/MTUS/Meetings/July-2021/Current-MTUS-v9-Topical-Analgesics-DRAFT-For-Discussion.xlsx)
(<https://www.dir.ca.gov/dwc/MTUS/Meetings/July-2021/Current-MTUS-v9-Topical-Analgesics-DRAFT-For-Discussion.xlsx>)
 - When looking at the Guidelines, the two products with broader recommended use are capsaicin and diclofenac sodium (topical) products
 - Utilization of Topical Analgesics (2019 data)
 - Pharmacy Dispensed Drugs – Top 20 by Total Bill Lines
 - Capsaicin oleoresin/menth/camph (TIGER BALM PATCH) – 1st
 - Pharmacy Dispensed Drugs – Top 20 by Total Paid
 - Diclofenac products were the highest paid products
 - Pharmacy Dispensed Drugs – Top 20 by Average Paid
 - Diclofenac products were the highest average paid products
 - The idea that topical analgesics are less expensive might not be necessarily true
 - Pharmacy Dispensed – Summary/Observations
 - Diclofenac patches had a significant portion of billed lines (18.3%) and paid amount (27%)
 - Two Diclofenac products (XYRILIX 1.5% kit and PENNSAID 2% pump) had very high costs and significant portion of the Total Paid category
 - Diclofenac products were 6 of the top 7 in average paid per line
 - Diclofenac 1.5% solution was skewed by 2 specific NDCs
 - Diclofenac patches
 - FLECTOR and LICART (both 1.3% diclofenac epolamine patches) – currently listed by FDA
 - Not identified in the ACOEM guidelines – diclofenac gel is the preferred agent
 - With regard to efficacy, safety, and cost, are these topical analgesics all effective?
 - Non-capsaicin and non-diclofenac products are marginally effective
 - Capsaicin and diclofenac products have shown much better efficacy than the other products
 - All are relatively safe, from a FDA safety standpoint
 - [Topical Analgesics](https://www.dir.ca.gov/dwc/MTUS/Meetings/July-2021/Topical-Analgesics-DRAFT-For-Discussion.xlsx) (<https://www.dir.ca.gov/dwc/MTUS/Meetings/July-2021/Topical-Analgesics-DRAFT-For-Discussion.xlsx>)
 - Based on the outliers in cost, which products would be recommended to be Non-Exempt?
 - Diclofenac sodium has a single NDC with an average paid of \$3561.92, whereas another NDC has an average paid of \$12.85
 - Is it the exception or the rule that the committee cover OTC drugs? Under the California Workers' Comp law, both prescription and non-prescription

medications could be appropriate and would be covered. Whether a medication is prescription or non-prescription is irrelevant. We need to review based on efficacy, safety, and cost

- All are relatively effective and safe, but there is a wide variability in terms of cost. Which ones should we be making Non-Exempt based on NDC?
- Right now the MTUS list does not have the diclofenac topical solution or the patch
- What is the best categorical method in order for this committee to be able to make outliers based on cost Non-Exempt, and keep innocuous and efficacious medications that are reasonably priced accessible to the injured worker?
- What if the cost of a specific NDC changes over time? Should we set some kind of threshold for medications to be Exempt or Non-exempt?
 - Maintenance is an issue
 - The fee schedule is built off the Medi-Cal system. Once the fee schedule is fully adopted, DWC can take a look at the products available for a particular class. The NDC prices do vary, but maintenance is already being done within the Medi-Cal system. Medi-Cal doesn't necessarily pay for all the NDCs. Within a class of drugs, the Medi-Cal options should be used before the non-Medi-Cal options
 - Would like to see the regulations identify the approved manufacturers in the Medi-Cal program and must be used to rule out prior to prescribing something that is not a preferred manufacturer
 - For example, if we just look at diclofenac, it comes as a 1.5% solution, 1.3% patch, 2% solution and various kit products. The 1% diclofenac gel is both prescription and OTC. The NDC list shows this to have very favorable pricing in terms of people's money. All the other strengths are Non-Exempt, and the other only one Exempt on the MTUS list is the 1%. The 3% is also Non-Exempt. If we took the lowest effective dose (1%) first, which is Exempt, any strength higher than 1% will require an RFA to medically justify why the 1% is not sufficient
 - The 3% diclofenac (SOLARAZE) is listed as Exempt, but not actually approved for pain. Recommendation to convert this to Non-Exempt. Removed from list completely based on indication
- [Current MTUS v9 Topical Analgesics](https://www.dir.ca.gov/dwc/MTUS/Meetings/July-2021/Current-MTUS-v9-Topical-Analgesics-DRAFT-For-Discussion.xlsx)
(<https://www.dir.ca.gov/dwc/MTUS/Meetings/July-2021/Current-MTUS-v9-Topical-Analgesics-DRAFT-For-Discussion.xlsx>)
 - Menthol, camphor, and methyl salicylate shows evidence for the Hand, Wrist, Forearm Disorder Guideline, but no effect for all the other conditions. There is very limited evidence, and also very specific to certain conditions
 - Capsaicin and diclofenac products are recommended for certain conditions
 - Under Topical Analgesics – Prescriber Top 20 by Total Bill Lines spreadsheet, these are prescriber-submitted claims. Diclofenac gel is first.
 - Under Topical Analgesics – Prescriber Top 20 by Average Paid

spreadsheet, prescribers are dispensing lower-priced products overall

- Camphor, menthol, and methyl salicylate products – Guidelines indicate evidence provides minimal utility with exception of diclofenac and capsaicin
 - Usually used in a variety combinations products, not as a solo product
 - How tightly do we want to control those? Keep the others Non-Exempt and rely on the diclofenac gel as the Exempt product?
 - Medications are Exempt if used as recommended in the Guidelines. If a guideline does not address it and there is other evidence, the reviewer can look at that other evidence. In general, Non-Exempt products go through the utilization review process to look at clinical history of patient to match indications of ACOEM guidelines
 - Committee wants ACOEM to clarify that brand name column and generic column should be a one to one match and also to clarify dosage combination
 - Does the committee feel that we should ask ACOEM to weigh in on other products (such as solutions or patches) other than the diclofenac gel?
 - Suggestion to leave gel on and not list any other additional diclofenac topical products. If ACOEM has not added them yet, then they go under unlisted. Leaving only the 1% gel to be the lowest gel to be Exempt

Motion: To not expand other topical diclofenac products but just to maintain diclofenac gel as the Exempt product. If ACOEM adds them, then we make them Non-Exempt until we can revisit.

Vote: The committee members in attendance voted unanimously to not expand other topical diclofenac products, but just to maintain diclofenac gel as the Exempt product.

- [NSAID Pricing](https://www.dir.ca.gov/dwc/MTUS/Meetings/July-2021/NSAIDs-DRAFT-For-Discussion.xlsx) (https://www.dir.ca.gov/dwc/MTUS/Meetings/July-2021/NSAIDs-DRAFT-For-Discussion.xlsx)
 - We are seeing some very high cost products being prescribed.
 - We can pull data for prescriber dispensed, but not sure about pharmacy dispensed
 - Committee to discuss ketoprofen, fenoprofen and extended release naproxen sodium in terms of Exempt or Non-Exempt status.
 - Suggestion to request that ACOEM look at it at a comparative value to consider cost effectiveness with what they produce.
 - Concern that the basis of the formulary is to be evidence-based, even though these drugs are abusive to the system under Exempt status. Is making them Non-Exempt when ACOEM has reviewed them as being evidence-based, undermining the evidence-based guidelines?
 - Request data pertaining to ACOEM's relationship with New York's formulary

Motion: To ask ACOEM if they are going to move to a cost effective formulary for California.

Vote: All voted in favor, except for Dr. Ray Meister who voted not in favor. Todd Shinohara was not present to vote.

V. Review of Recommendations

- We will make adjustments to the style of brand and generic to April meeting minutes
- Develop a consensus statement for COVID-19 so that the committee is comfortable with this statement
- Pertaining to topical analgesics, we will clarify with ACOEM the brand ingredient match-ups for camphor, menthol, methyl salicylate, remove the SOLARAZE and query on the strengths on the products that are recommended for use
- Ask ACOEM about a cost effective formulary for California and inquire whether ACOEM had included cost considerations in the New York formulary

VI. Public comments

- In states that do not have a formulary or some type of control of the topicals, we are seeing an increased utilization of high end NDCs.
- Even in an exempt realm, there are medications where it appears that they are skirting the system by going toward higher cost medications. A suggestion was made that the committee looks into this.
- Will there be a future opportunity to discuss a cost effective formulary for California and allow for public comments once you hear back from ACOEM?
 - DWC responded that once we hear back from ACOEM this will definitely be on the agenda