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Pharmacy and Therapeutics Advisory Committee

DRAFT - MINUTES OF MEETING

Wednesday, April 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

II. Approval of Minutes from the January 20, 2021 Meeting

Dr. Raymond Meister, Executive Medical Director, DWC

Motion: Approval of the minutes from the January 20, 2021 meeting

Vote: The committee members in attendance voted unanimously for approval of the minutes from the January 20, 2021 meeting. A committee member noted that a diclofenac product is still listed as exempt on the MTUS Drug List, although the recommendation was previously made for all oral diclofenac to be changed to non-exempt status.

Related briefing: [January 20, 2021 Meeting of Minutes](https://www.dir.ca.gov/dwc/mtus/Meetings/January-2021/Meeting-Minutes.pdf)

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III. MTUS Drug List and Therapeutic Category Reference

- MTUS v9 has not been released
 - May include medications associated with the ACOEM COVID treatment guideline
- Next RxCUI and expanded therapeutic drug categories model will utilize MTUS v9
- Establishing a primary drug categorization reference source relative to the MTUS Drug List
- Anticipate ACOEM will release an update to their formulary by the end of the month to include COVID-19 medications; DWC will then look to review and incorporate that list of medications into the MTUS Drug List
- Online MTUS List Application
 - Committee expressed a desire to implement an interactive online application to filter the MTUS Drug List
 - No near-term solution due to DIR IT resource issues
- MTUS Therapeutic Categories
 - Previous request to break out the therapeutic categories and make corrections for every drug
 - Need to ensure that the categories are non-proprietary listings
 - Several categories available through RxNORM, which is the source of RxCUI and RxCLASS
 - RxCLASS contains a variety of drug classification sources:
 - Anatomical Therapeutic Chemical (ATC)
 - Veterans Administration drug classes – limited and does not cover all drug classes
 - MedRT
 - RxCLASS classifications not widely used for formulary management and complex
 - USPDC (United States Pharmacopeia Drug Classification)
 - Widely used
 - Initially developed as a classification system for Medicare Part D
 - Utilized by states to identify the level of coverage for prescription drugs by health plans in comparison to each state's Essential Health Benefits Benchmark plan
 - Provides 3 levels: Category, Class, and for some drugs subclassified into Pharmacotherapeutic Group
 - Provides alignment file that contains drugs by RxCUI
 - [USPDC Alignment File](#)
(<https://www.dir.ca.gov/dwc/MTUS/Meetings/April-2021/USPDC-Alignment-File-DRAFT-for-Discussion.xlsx>)
 - Strength and dosage form level
 - Brand and generic RxCUIs
 - Does not roll up RxCUI at the ingredient level
 - Over-the-counter drugs not listed
 - [MTUS Partial Listing Sample](#) (<https://www.dir.ca.gov/dwc/MTUS/Meetings/April-2021/MTUS-Partial-Listing-Sample-DRAFT-for-Discussion.xlsx>)
 - Created with two USPDC columns (Category and Class (Pharmacotherapeutic Group) added for comparison

- Some products are in multiple categories
- Example: amoxicillin (AUGMENTIN) currently listed with Antibiotics (Penicillins) under the Drug Class column on the MTUS Drug List
 - Added USP columns:
 - USP Category: Antibacterials
 - USP Class (Pharmacotherapeutic Group): Beta-lactam, Penicillins
- Example: apixaban (ELIQUIS) currently listed with Anticoagulants under the Drug Class column on the MTUS Drug List
 - Added USP columns:
 - USP Category: Blood Products and Modifiers
 - USP Class (Pharmacotherapeutic Group): Anticoagulants (Factor Xa Inhibitors, Direct)
- Committee member asked if the USPDC is to be adopted as a way of categorizing the formulary? Are there other alternatives?
 - The idea is to find something that is publicly available, and readily utilized in the industry. USPDC is the closest option.
- Since ACOEM put together the template for Drug Class, is there a way for ACOEM to standardize the drug classifications?
 - ACOEM formulary is put together by Healthsystems. They review each guideline and medications associated with that guideline. Unsure what classification scheme they use.
 - Can make suggestions and work with ACOEM to get some changes going that would be helpful.
 - Develop a more consistent classification scheme to be adopted
 - Does it have to be a publicly-available source, or could it be within the DWC to standardize it to what makes sense for our industry?
 - USPDC or some other product to be used as a starting point and then make adjustments
 - Committee suggestion to start with what currently exists with ACOEM and then modify from there, rather than utilizing a completely new system.
 - What the committee would like to see in the next meeting: expanded list points to where some products leave listed in ACOEM, and others may use refinements based on what USPDC might have, and go from there.
 - Suggestion to create a sample sheet showing current Drug Class, Proposed listing, USP Category, and USP Class (Pharmacotherapeutic Group)

IV. Discussion

- Review of January 2021 Recommendations
 - Consolidation of Pregabalin
 - Not consolidated into a single RxCUI because the controlled release product has different ACOEM Guideline uses

- RXCUI does not differentiate between controlled release and non-controlled release oral products
 - Consolidating pregabalin into a single RxCUI would mislead a prescriber that the controlled release form has a guideline reference other than what is currently listed
 - Separate listings will stand
 - Committee member suggestion to roll up the pregabalin (LYRICA) and pregabalin (LYRICA CR) separately, but utilizing the same RxCUI
- Remove Salt (acetate) from Pred Mild
 - Some websites and RxNAV list Pred Mild as prednisolone
 - Pred Mild listed as prednisolone acetate in the FDA Orange Book
 - Current listing of salt from (acetate) will stand
- MTUS Effect on Drug Utilization
 - Workers' Compensation Insurance Rating Bureau (WCIRB) released a report in February 2021. Findings include:
 - Decline in pharmaceutical costs
 - Share of drugs not subject to utilization review (UR) increased, which means people were looking more towards those Exempt products
 - Opioids, compounds, and brand name drugs also dropped
 - Downward trend in pharmaceutical costs overall
- COVID-19 Update
- From 1/1/2020 - 02/24/2021, 14% denial rate on workers' compensation claims, and 33% denial rate for COVID-19 claims during this 14-month period. Downward trend in number of COVID-19 claims from 12/2020 through 02/2021.
- As of 02/2021, total COVID-19 cases in California was 3.56 million, and about 51,884 deaths. CA COVID-19 death rate is 1.48%.
- Current death rate of COVID-19 claims in workers' compensation is 0.53%.
- Current death rate of non-COVID-19 claims in workers' compensation is 0.1%.
- Denial rate for non-COVID-19 claims from 01/01/2020 through 02/24/2021 is 10.5%. Rate is normally 12%.
- Average denial rate for COVID-19 claims from 01/01/2021 through 02/24/2021 is 31%. Downward trend in denial rates in the recent months.
 - COVID-19 claims do require a positive COVID-19 test. Failure to provide a positive COVID-19 test will result in denial of the claim.
 - COVID-19 claims are equally distributed among female and male workers in the various age groups.
 - The 25-34 year old age group has the highest number of workers' compensation COVID-19 claims.
 - More deaths among male workers than female workers, especially in the 55-64 age group.
 - As of 03/22/2021, there were 139,203 claims reported. Deaths reported: 804.
 - Healthcare workers make up 31.9% of the claims. Public (safety/government) workers make up 16.9% of the claims. Totaling both of these groups is about 50% of the claims.
 - Los Angeles County is the largest county in the state, has the highest population, and also the highest number of claims.
 - ACOEM has a COVID-19 guideline, and has been updated frequently. DWC plans to move forward to adopt the COVID-19 Guideline into the MTUS.

- There are also medications associated with this guideline, and anticipate to include these medications on the MTUS Drug List v9.
 - As of 04/05/2021, there are about 18.5% of the people in California are partially vaccinated, and about 23.3% are fully vaccinated.
 - There are quite a few variants of the virus out there, and vaccine makers are already working on boosters to be hopefully available soon.
 - 23% of people in state are vaccinated and 18.5% of people partially vaccinated. Rates should be increasing about 20% per month
 - Current R naught number is 0.78 – cases are decreasing.
 - Rate of denials for workers compensation claims have averaged more with COVID-19 claims – averaging around 30%
- Introduction of New Pharmacy and Therapeutic Member, Dr. Julie Fuller
- HIV PEP
 - Why aren't HIV PEP meds for occupational exposure exempt on the formulary?
 - The MTUS includes treatment guidelines for injured workers from ACOEM. ACOEM does not have an infectious disease or blood-borne pathogen guideline. Those medications are not part of the ACOEM formulary and therefore they are not considered for our MTUS Drug List. However, DWC accepts complaints regarding utilization review.
 - Title 8 California Code of Regulation Section 9792.27.14 states that the MTUS drug formulary and associated regulations do not relieve an employer of any responsibility pursuant to applicable health and safety regulations such the requirements of the California occupational blood-borne pathogens standard at title 8 California Code of Regulations Section 5193 including responsibility to provide urgent post exposure prophylaxis as needed to protect the health of the employee. It was not our intent to hinder or delay this type of treatment.
 - DWC can make a request to ACOEM to cover this topic
 - What length of time for the treatment would be reasonable?
 - Patient should be on it in the first 72 hours. Treatment is needed for 28 days. Suggestion is to make one week of HIV PEP meds exempt.

Motion: Request for DWC to reach out to ACOEM to establish a guideline for HIV PEP so we can have HIV PEP as an exempt medication or regimen on the MTUS.

Vote: The committee members voted in favor to reach out to ACOEM to establish a guideline for HIV PEP. The drug list is part of the formulary. Just because something isn't on our drug list doesn't mean a patient can't be prescribed that medication. To be on the drug list, it has to be in one of our adopted guidelines.

- [Topicals for Pain Control](https://www.dir.ca.gov/dwc/MTUS/Meetings/April-2021/Topicals-for-Pain-DRAFT-for-Discussion.xlsx) (<https://www.dir.ca.gov/dwc/MTUS/Meetings/April-2021/Topicals-for-Pain-DRAFT-for-Discussion.xlsx>)
 - How can we make exempt more over-the-counter topicals that contain camphor and menthol, such as Tiger balm and Icy Hot?
 - Lack of evidence of efficacy for these products

Motion: Request for DWC to gather data, including costs on menthol and camphor containing products and present at next meeting.

Vote: All committee members voted in favor. Todd Shinohara abstained.

- Review of recommendations
 - Look at consolidating some additional items in the MTUS list under RxCUIs. Adding an additional column to the MTUS list so we can compare current and potential categorization.
 - Looking at drug products cost increases – topic submitted by the public.
 - Reach out to ACOEM to create HIV PEP guidelines
 - Request for data on menthol and camphor containing products with cost analysis.

V. Public Comments

- An article indicated there was a huge uptick in utilization of fenoprofen and ketoprofen this year, specifically in workers' compensation. This might have something to do with the price adjustment on the fee schedule. Does the committee look at these types of anomalies where there is a huge increase in one particular drug?
 - DWC stated this will be included on the next meeting's agenda
- What is the process when a patient comes in and needs immediate dispensing of a needle stick for possible exposure to hepatitis or HIV? When patients come into the clinical setting, is there already a claim that's already been filed with an insurance carrier that you're not getting authorization timely or it just happened and there is no entity to contact to get approval?
 - Committee member stated that it is possible medications may not be approved for the 28 day period
 - DWC stated that aside from filing a complaint with DWC if utilization review is improperly denying, it is possible to file a complaint with CAL OSHA because this blood born standard does put obligations on employer to provide that post exposure prophylactic