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Pharmacy and Therapeutics Advisory Committee
DRAFT - MINUTES OF MEETING
Wednesday, October 16, 2024

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
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

A. Physician and Pharmaceutical Fee Schedule Update – Notice of Proposed Rulemaking update

B. After the initial 15-day comment period and review of comments received during that period, some additional modifications to those proposed changes have been made

C. Changes include: Modifying provision relating to the fee for unfinished drug products used in compounded drugs to eliminate the use of documented pay costs as the pricing benchmark, modifying the schedule to specify that the fee for drug products used in compounded drugs be based upon the same pricing applied to other drugs, and revising the sample pharmaceutical fee data file to include unfinished bulk pharmaceutical drug products that are used in compounded drugs such as active pharmaceutical ingredients and excipients

   a. Proposed modifications to regulations and associated documents can be viewed at https://www.dir.ca.gov/dwc/DWCPropRegs/2024/Pharmaceutical-Fee-Schedule/Index.htm

b. Now observing a second 15-day public comment period and the comment period will close at 11:59pm on October 23, 2024

D. Conflict of Interest reminder and advise P&T Committee members to review it; need to submit annually

E. State and federal Antitrust Law advisement

II. Approval of Minutes from the April 17, 2024 Meeting

Dr. Raymond Meister, Executive Medical Director, DWC

Motion: Approval of the minutes from the April 17, 2024, meeting with the amendment around the artificial tear recommendation to include a statement similar to "the committee may reach out to an ophthalmic or optometry professional to review."

Vote: The committee members in attendance voted unanimously for approval of the April 17, 2024, meeting minutes.

Related briefing: April 17, 2024 Meeting Minutes (*https://www.dir.ca.gov/dwc/MTUS/Meetings/January-2023/Meeting-Minutes.pdf*)

III. MTUS Drug List V12

A. Version 12 of the MTUS Drug list was posted on October 1, 2024.

a. Version 12 of MTUS Drug list is up to date with medication recommendations associated with the Anxiety Disorders in the MTUS ACOEM guideline.
b. Version 12 of MTUS Drug list also updates opioids to bring them consistent with the most recent update to the MTUS ACOEM opioids guideline.

B. MTUS Drug list Version 12 becomes effective on November 1, 2024 and is available for review on the DWC Medical Treatment Utilization Schedule – Drug List page, DWC medical treatment utilization schedule - Drug Formulary

C. Model MTUS Drug List with RxCUI – Updated on MTUS Drug List v12

a. Added and removed drugs pursuant to the MTUS v12 Drug List
b. Some errors were cleaned up
    i. Allowed amounts on special fill for liquid opiates had tablet quantities instead of liquid quantities and these were fixed.
c. Expanded product listing for oxycodone er based on changes made to MTUS v12 Drug List.
    ii. Broad RxCUI for Oxycodone oral previously used incorporated both extended and immediate release products.

iii. Differences in ACOEM reference guidelines and special fill/peri op allowances made it necessary to expand the list to more specific RxCUIs.

D. MTUS Biosimilars

a. Biosimilars on MTUS list
   i. Listings for biosimilars added or updated.
   ii. Two of the listed ingredients have biosimilars: Adalimumab (HUMIRA) and Etanercept (ENBREL).
   iii. "Interchangeable" added to Reference Brand Name for biosimilars identified as interchangeable per FDA Purple Book.
   iv. Pricing for adalimumab retrieved for comparison; etanercept biosimilars not yet in pricing data.

b. Biosimilar Pricing - There was a question regarding pricing for biosimilars during our April meeting.
   i. Prices for reference and biosimilars retrieved – Product amounts and how they are being priced in medical system; however, there are potential errors in the product listing, so accuracy is questionable.
   ii. Medi-Cal reference prices were primarily based on Wholesale Acquisition Cost (WAC).

E. Committee Discussion

c. Committee expressed curiosity regarding much press around Humira and biosimilar competition, for MTUS formulary where is positioning of Humira in comparison to biosimilars so that our physicians can choose wisely with stewardship in mind.
   iii. DWC suggests that, per the MTUS, biosimilars are nonexempt and will require authorization. This is more of a payer issue than an MTUS issue; however, we are listing biosimilars and interchangeable biosimilars so that payers can better make decisions.
   iv. DWC holds no position, but interchangeability is listed on MTUS as providers may have a preference when prescribing.

d. Committee expressed viewpoint for consideration, DWC maintains a position regarding Generic vs. Brand name prescriptions and a question remains. As an advisory board, should DWC take a similar stance on biosimilars vs. innovator product, as there is a substantial difference in pricing?
   v. DWC requests clarification – Biosimilars are not considered generic, is that correct?
      - Committee explains Biosimilars – while similar to generic drugs, are defined differently because they are biologic agents and have larger molecules.

- Committee explains Generic drug is a chemical agent that has identical structure and is a smaller molecule.
- Committee explains that there are some similarities between how generics and biosimilars are viewed, but they are defined differently by the FDA.

vi. DWC considers regulations that give preference to generics and can look into whether a similar regulation would be appropriate for biosimilars.

vii. The committee suggests this should be considered for discussion as a future agenda item with the intent of affecting biosimilars in such a way as to help the market accept these agents in order to increase competition and drive down prices.
- DWC put this item down as an agenda item for our next meeting.

viii. Committee member expressed surprise that not all biosimilars appear to be more competitively priced when compared to brand name alternatives; thus, it is unclear whether biosimilars are less expensive.

ix. DWC notes that there is a difference between the price to the provider and price to the payer and payer price is dependent on how payer pays their providers; with respect to DWC Medi-Cal is the price ceiling for payers, but there can be contracts for rates or pricing below the fee schedule.
- DWC will add to the next meeting's agenda a discussion will do a walkthrough of biosimilar landscape. Therea re only two biosimilar products on MTUS currently. This is an area that is growing, and we should address it early.

F. Public Comments

None

A. MTUS Drug Lookup – Tool Revised
   a. No change in form factor
   b. Updated to incorporate changes to MTUS v12
   c. Working on different Drug Lookup interface that is more interactive

B. MTUS Drug List Use Rates Discussion – The goal is to get committee's input on drugs and/or drug categories that we may want to look at.
   a. Claims were aggregated by ingredient, represented as GENERIC NAME, on the provided spreadsheets. We were agnostic to dosage form and strength to lean towards being more inclusive on the MTUS Drug List.
   b. Spreadsheets are separated by provider type, pharmacy and physician
   c. Each product was identified as matching or not matching an MTUS Drug List ingredient.

d. The aggregation includes all dosage forms and strengths of a particular ingredient, therefore MTUS used products may have slightly higher amounts than if aggregated at a more granular level.
e. Pharmacy MTUS Utilization
    i. Shows that compliance is relatively high at 87% of billed lines are MTUS Drug List products, though low when compared to other non-worker compensation insurances which are typically in the mid 90% range.
        - High compliance is often attributable to patient copayment structures, i.e. high to 100% copayment for non-formulary drugs.
    ii. Interestingly the amount paid for MTUS Drug List drugs accounted for only 55% of the total paid, which shows that a lot of non-MTUS Drug List products are being reimbursed at a higher amount.
        - Non-MTUS Drug List drugs have very high average payment amounts
        - Many are high-cost biological products
    iii. There is a lot of money tied to products that are not included on the MTUS Drug List. This raises the question, is there something that the committee should be potentially looking at and asking whether DWC should reach out to ACOEM to look at.
f. Committee discussion on MTUS Utilization
    i. Committee observes the naproxen sodium the billed lines is low but total pay amount is in the top 5 for the MTUS "yes" on the pharmacy side and is curious about whether this is expected.
        - DWC states that they will take a closer look at the data to see where this is coming from.
    ii. Committee observes, on the MTUS Drug List non-exempt medications list, that some drugs have been bundled with kinesiology tape or other items in order to raise the bundle price significantly, but at least these items are on the MTUS "no" list.
        - DWC has observed that pharmacies are combining an NSAID with something that is not a drug or an oral product and topical product to provide/sell to physicians for dispensing. It's a niche market and they're expensive which is a good reason to not have them on MTUS Drug List.
        - DWC indicates, from an MTUS standpoint, unless the guidelines referenced this combination of products, it wouldn't be something we would address.
        - Committee conveys that these bundled products are on the MTUS Drug List as non-exempt medications, they are subject to prospective review so from that perspective,

this issue is kind of covered on the formulary on an administrative basis. Also, going back to the naproxen question, the posted DWC v12 compared to RxCUI v12, and naproxen sodium is included as an exempt drug on the RxCUI version, but is omitted on the posted DWC v12. What are we missing?

- DWC responds that the reason it's included on the RxCUI version is because when the information was reviewed, when you look at the evidence, they are using either naproxen or naproxen sodium. This may be something that needs to be discussed further and expanded. However, with respect to MTUS Drug List v12, DWC wants to keep it as close to the ACOEM list online as possible.

iii. Committee clarifies that the that naproxen and naproxen sodium are technically 2 different products as per the FDA, the question is do we want to say that they are both exempt or should the base form be exempt as closely tied to the way ACOEM design their formulary and the sodium form be non-exempt as a means of addressing the disproportionality.

- DWC suggests that we look more closely at this line item and the pricing. Then we can add this discussion to our next meeting agenda.
- DWC also suggests sending an interim note along to ask why naproxen is listed, but not naproxen sodium.
- DWC notes that there isn't a difference between naproxen and naproxen sodium, from an evidence standard perspective, despite there being a difference according to the FDA, by salt form or chemical standards.
- Committee suggests we consider the disproportionate total cost of these items and consider if we want to say both forms are exempt, or if we want to say the base form is exempt as closely tied to the way ACOEM had designed their formulary and the sodium version should be non-exempt as a means of addressing the disproportionality?
- DWC suggests pulling pricing and specific products that make up the naproxen sodium line to derive more information about why the naproxen sodium cost is so high. Then we can have a committee discussion about addressing the issue and how to approach it.

iv. Committee observes on the physician list under "MTUS yes" tab that camphor without other ingredients and asks if it is purely

menthol. Committee noting that it is very uncommon, and asks if lidocaine, as a menthol product, is on the "MTUS no" tab because it is a combination?

- DWC clarifies it's strictly based on what is listed on MTUS. Anything that is a combination product not listed on the MTUS list is on the "MTUS no" tab. It is noted that a lot, but not all, combination products are listed on the "MTUS no" tab because those combinations are not on the MTUS Drug List.

v. DWC clarifies that these lists are a high-level view. The intent is to give a sense of where things stand and to allow committee members to look through to see if there are aberrations or other items we should look at. Consider that this is very raw data, but we can use these lists to see if there are concerns for uses of items with respect to abnormally large billed lines, whether providers are sticking to MTUS, and whether or not these items fall outside the purview of this committee. Suggest that we don't focus on the paid amounts right now. On the Pharmacy side we're looking at 87% of billed lines conforming to MTUS and we want to look at if this number can be brought closer to 90%.

- DWC highlights a big takeaway from the physicians list data is that 96% of the billed lines are drugs on the MTUS Drug List, which is really good, but on the pharmacy side it looks different. This discrepancy is likely due to the fact that physicians are dispensing a very discrete narrow band of product, whereas the pharmacy is everything else. The pharmacy items are being reviewed and approved through a process.
- Committee requests a clarification of the ask, if the goal is to bring pharmacy side closer to 90% MTUS conformity.
- DWC clarifies that the ask isn't necessarily a need to bring the pharmacy side into the 90th percentile. The question is, looking at the raw data and gathering a sense of standing, does the committee see any aberrations, like naproxen sodium, that we should be concerned about and take a closer look at?
- DWC encourages committee to review the Pharmacy and Physician MTUS utilization to see if there anything that the DWC Medical Director should discuss with the ACOEM development team?
- Committee considers GLP 1 drugs, such as semaglutide, to be discussed and consider that providers may see MTUS as an avenue for access. Concern that these agents

are becoming the top non specialty agents being prescribed, either for diabetes or weight loss, and concern about whether they are being prescribed appropriately.

- DWC indicates that GLP 1 drugs, such as semaglutide, are not MTUS Drug List products. DWC clarifies that committee question is if there should be some type of review for GLP 1 drugs. The MTUS has a well-defined pathway for deciding if a treatment is medically necessary for an injured worker. Medications, such as the one being discussed, would go through the Utilization Review process. This process is in place to determine if the treatment is medically necessary. The MTUS has an elegant way of going through these requests to determine if they are medically necessary.
- DWC suggests that we consider whether use of specific medications is common enough that we would need to have a guideline, or should it be left to be decided by prospective review?
- Committee asks if we have data that shows an increase in the use of semaglutides?
- DWC cautions that the data presented today is aggregated data by national drug code over a year's time. The semaglutide data shows a years' worth of utilization, so for the past 12 months there was 774 claim lines.
- Committee postulates that this number seems to represent an increase in the utilization of this drug.
- DWC concedes that it is interesting that there are that many claims per month, when considering the monthly average for the 12-month total.
- Committee expresses that from a Workers' Compensation, MTUS, and P&T perspective the review of these drugs is covered because it isn't part of any specific guideline; thus, it is subject to prospective review. From that standpoint it is covered. Given that it is a growing concern, if there is no ACOEM guideline, there isn't anything we could advise in terms of making it exempt or non-exempt and it should remain subject to prospective review.

Public Comments

G. Public questions what is the threshold for a drug to be deemed a commonly prescribed medication or is it a judgement call?

H. DWC responds that it would be a judgement call. It would be the injury or illness that would be considered common or not common, as opposed to an individual drug. By looking at the current ACOEM guidelines, you get a pretty good idea of the range of illnesses and injuries that are covered by the guidelines and does a good job of addressing the common work-related injuries and illnesses.

Review of Committee Recommendations – none

DWC To Do List

A. Biosimilar landscape information for committee to have a more robust discussion related to biosimilars and the potential for a biosimilar first approach as a policy.

B. Take a closer look at naproxen vs. naproxen sodium the evidence and pricing related to those in attempt to figure out why the naproxen sodium is priced so high.

Reminder

A. If anyone on the meeting has relevant suggestions for future P&T Meeting discussion topics, please email our office at formulary@dir.ca.gov.

Meeting Adjourned