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Pharmacy and Therapeutics Advisory Committee
MINUTES OF MEETING
Wednesday, July 24, 2019

Elihu Harris State Building
1515 Clay Street, Conference Room 11, Second Floor
Oakland, California 94612

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	Rajiv P. Das, M.D.
DWC Legal Counsel	Steven Feinberg, 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

- Registration for MDGuidelines: https://www.mdguidelines.com/MTUS
- Conflict of Interest Statements of P&T Committee members to review terms and update form annually
- State and federal Antitrust Law advisement

II. Approval of Minutes from the April 24, 2019 Meeting

Dr. Raymond Meister, Executive Medical Director, DWC

Motion: Approval of the minutes from the April 24, 2019 meeting

Vote: The committee members in attendance voted unanimously for approval of the minutes from the April 24, 2019 meeting.

Related briefing: https://www.dir.ca.gov/dwc/MTUS/Meetings/April-2019/Meeting-Minutes.pdf

III. NSAID Ophthalmic Daily Cost

- In response to the April meeting committee request for ophthalmic drug cost per day amounts, review of manufacturer drug information indicates the standard drop size is 0.05ml for each drug listed on the formulary.
- Drug cost per day ranges from $0.32 to $6.61.

- Determining exempt and non-exempt status between the different ketorolac tromethamine strengths. Ketorolac tromethamine (0.5%) has a generic available, while the lower dosage strengths (0.4% and 0.45%) do not.
- Determining exempt and non-exempt status between ketorolac tromethamine and bromfenac sodium.
- ACOEM recommendations summary chart discussed; recommendations substantially homogenous across the conditions.
- Discussion of cost differential in light of ACOEM's evaluation of best available evidence which results in same usage recommendations for the two drugs and other ophthalmic NSAIDS. Discussion of whether the magnitude of the price differential is sufficient to distinguish bromfenac sodium and ketorolac tromethamine (0.4% and 0.45%) from the other ophthalmic NSAIDS
- Suggestion to move bromfenac sodium and ketorolac tromethamine (0.4% and 0.45%) from exempt to non-exempt status based on cost differential between these and the other ophthalmic NSAIDS. These drugs will still be available, but just with an added layer of procedure to obtain authorization, which should serve to discourage use of the non-exempt drug and encourage use of the exempt drug.
- DWC fee schedule is based on Medi-Cal, but Medi-Cal has changed methodology where retroactive pricing back to April 2017 is applied. DWC will not do retroactive pricing. However, DWC intends to adopt the new Medi-Cal methodology prospectively, after rulemaking is conducted.
- Safety procedures, including checks and balances, already in place for non-exempt drugs. Strength of evidence considered.

Motion: Move bromfenac sodium from exempt to non-exempt status.

Vote:
In Favor: Basil Besh, Rajiv Das, Steven Feinberg, Lori Reisner, Todd Shinohara, and Raymond Tan
Oppose: None
Abstain: Raymond Meister

Motion: Move ketorolac tromethamine (0.4% and 0.45% strengths) from exempt to non-exempt status.

Vote:
In Favor: Basil Besh, Rajiv Das, Steven Feinberg, Lori Reisner, Todd Shinohara, and Raymond Tan
Oppose: None
Abstain: Raymond Meister

IV. Summary – Diclofenac Study

- Looks at cardiovascular risks between diclofenac and other NSAIDs.
- Diclofenac initiators had a 20% increased rate of major adverse cardiovascular events compared with ibuprofen, a 30% increased rate compared with naproxen, a 20% increased rate compared with acetaminophen, and a 50% increased rate compared with non-initiators. Also, elevated risk of fatal heart failure.
- ACOEM guidelines state not recommended for first or second line therapies due to increased risk of liver damage.
- ACOEM provides the same general cardiovascular warning as other NSAIDs.

Motion: Move all oral systemic diclofenac from exempt to non-exempt status.

Vote:
In Favor: Basil Besh, Rajiv Das, Steven Feinberg, Lori Reisner, Todd Shinohara, and Raymond Tan
Oppose: None
Abstain: Raymond Meister

Motion: Furnish the Danish Study on diclofenac to ACOEM for review.

Vote:
In Favor: Basil Besh, Rajiv Das, Steven Feinberg, Raymond Meister, Lori Reisner, Todd Shinohara, and Raymond Tan
Oppose: None
Abstain: None

V. MTUS Drug List v5

- Effective August 1, 2019
- Primary change reflected in the medications associated with post-traumatic stress disorder (PTSD)
- Suggestion to update the brand name listings to all caps, not just the first letter

VI. Proposed Criteria (Draft) for Exempt Verses Non-Exempt Status

- Current criteria (weighing in favor of exempt status of drug): ACOEM guideline notes drug as first line therapy; ACOEM guideline recommends drug for most acute and/or acute/chronic conditions addressed in the guidelines; safer adverse effects (risk) profile; and drug listed for the treatment of more common work-related injuries and illnesses.
- Utilization and cost are potential additions to criteria to determine exempt status.
- Examples of cost differentials:
- Naloxone HCL has a huge cost difference between the nasal spray and auto injector. Exempt status leans toward the nasal spray for cost difference.
- Indomethacin 20mg and 40mg capsules are much more costly than 25mg and 50mg.
- Utilization data could be considered; impact of high utilization (could possibly indicate abuse, e.g. opioids), or low utilization can be evaluated as it may bear on designation of a drug as exempt/non-exempt.
- Committee members to review products on the drug list using current criteria and also considering utilization and cost criteria for making recommendations on exempt and non-exempt status.
- Discussion of the role of ACOEM in performing the evidence review and role of P&T Committee in making recommendations on exempt/non-exempt status in light of the ACOEM guidelines, current criteria and the utilization and cost criteria.
- DWC can send the committee's feedback to ACOEM for review in regard to particular drugs. Example: Diclofenac study for ACOEM review.
- Discussion of why drugs that are non-exempt and not recommended are on the MTUS Drug List. The MTUS Drug List includes all drugs addressed in the ACOEM guidelines, even if non-exempt and not recommended in ACOEM guidelines, because it is important to alert the physician that the guidelines do address the drug and that there is evidence in the guideline as to why it is not recommended for the condition.

- Discussion of why "unlisted" drugs are not on the MTUS Drug List. Everything on the drug list is addressed in the guidelines. Unlisted drugs are not addressed by ACOEM and have not had the evidence review. Unlisted drugs are available to treat the injured worker; the physician is required to provide medical evidence to support prescribing any unlisted drugs.

Motion: Adding utilization and cost to the list of criteria to determine exempt and non-exempt status.

Vote:
In Favor: Basil Besh, Rajiv Das, Steven Feinberg, Lori Reisner, Todd Shinohara, and Raymond Tan
Oppose: None
Abstain: Raymond Meister

VII. Drug Reviews

- **Artificial Tears:**
  - Drug list currently states artificial tears, but technically not an actual drug ingredient. There are ointments verses solutions. The drug ingredients are in these products. Pharmacist cannot technically dispense artificial tears. A particular product must be specified.
  - Discussion of value of the Committee's role in being good stewards of the resources in light of cost differences. Need evidence on efficacy and safety.
  - Committee questions raised in relation to artificial tears:
    - Is it okay to have these listed out generically as artificial tears on the drug list?
    - What would be determined for RxCUIs?
    - Is there a reason to separate these listings?
    - Are there comparative studies on the safety and efficacy of the products?
  - Committee suggestion to send ACOEM a request for a deeper dive into artificial tears. ACOEM to weigh in on the evidence base, then DWC/committee will be able to apply the criteria, including cost and utilization data, and ultimately stratify them as exempt and non-exempt.
- **Augmentin**:
  - Augmentin is on the MTUS Drug List, but Amoxicillin by itself is not listed.
  - Is it appropriate that only Augmentin is on the formulary or is it odd that amoxicillin is unlisted and actually requires an RFA?
  - Committee suggestion to send to ACOEM to weigh in and possibly add to the current drug list.
  - There are different dosage forms and all are available generically.
  - Discussion was held suggesting that the division ask ACOEM the question of why only Augmentin is addressed by ACOEM and not amoxicillin.

VIII. MTUS Drug List Extracts - Several Iterations of Drug List:

- Discussion of various simplified formats of the MTUS Drug List prepared by DWC Pharmacist Consultant in response to Committee's previous request.
- Example of the drug list sorted by Therapeutic Category, showing which products are exempt or non-exempt within each category.
- These extracts include the existing drugs currently on the MTUS list. The redesign is for viewing convenience across the various groups who may need them. PBMs often have similar list formats.

- Extracts would not include unlisted drugs, and does not include all approved products on the market.
- Suggestion to insert a third column for dose-dependent or dose-specific.
- Concern expressed with oversimplification of the list, in regard to exempt/non-exempt based upon different strengths of the product.
- Discussion of whether the lists should include a disclaimer that the list must be used in conjunction with the guidelines, or whether a disclaimer may not be necessary because rules of drug list usage are defined in the regulations. DWC can reiterate that the MTUS list is not inclusive of all the products available on the market.
- Suggestion to have hyperlinks that lead to different lists.
- Suggestion to include a drill-down for each body part, which will create a larger list.
- If in Excel, physicians can sort or filter out desired list.
- DWC to present some re-designs of the list for further consideration by the Committee.

IX. Public Comment:

- Appreciate that you are trying to control costs.
- Many organizations have already bought the Reed Guidelines. For example, Kaiser already has it built into their system.
- As long as non-exempt drugs are in the guidelines, they will be approved through utilization review. Putting them in non-exempt category is not prohibiting them from being approved because they are still in the guidelines. Physicians are required to submit an RFA no matter what. The patient is the one who will be affected (not getting medication immediately).
- Suggestion to eliminate the RFA requirement for the drugs with exempt status. However, drugs on the non-exempt list will still be subject to the requirement to submit an RFA.