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Pharmacy and Therapeutics Advisory Committee

MINUTES OF MEETING

Wednesday, April 24, 2019

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

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
Rajiv P. Das, M.D.
Basil R. Besh, M.D.
Todd Shinohara, Pharm.D., MA.
Raymond Tan, Pharm.D.
Lori Reisner, Pharm.D.

Absent:
Steven Feinberg, M.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 January 23, 2019 Meeting

Dr. Raymond Meister, Executive Medical Director, DWC

Motion: Approval of the minutes from the January 23, 2019 meeting

Vote: The committee members in attendance voted unanimously for approval of the minutes from the January 23, 2019 meeting.

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

III. Discussion: Drug Review Process, Drug Review, and Category Review

a. **Drug Review Process**

- 4 factors in reviewing drugs: efficacy, safety, misuse potential, and cost

- When should cost matter? Only when efficacy, safety, and misuse are relatively equal
- Identify exempt status and make recommendations to the department who will apply the unique pharmaceutical identifier to the recommended products that the department has accepted.

b. **Single Drug Review**. Naloxone used as an example because it has limited dosage forms available. Currently, naloxone hydrochloride (generic name) is exempt. Two brands names – both antidotes self-administered patient drugs. Both equal safety, efficacy and ease of use.
   - Evzio is injectable in one strength
   - Narcan available in 3 different strengths as a nasal spray. (Teva has FDA approved equivalent generic product to Narcan)
   - Price differential is very large (Evzio over $4,000, Narcan under $200).
   - Committee has a responsibility for ensuring proper resource use.
   - Do we want to make Evzio non-exempt?
   - What are the prescribing patterns we are seeing in workers' compensation? DWC to look at data for pattern of usage.
   - If patient has nasal pathology, the efficacy of Narcan may be impaired. For a patient with nasal pathology, the physician would submit an RFA to obtain authorization in advance if Evzio is prescribed and if Evzio is changed to non-exempt status.
   - Look at how many people have nasal pathologies and who need the injectable (those that can't use the nasal spray). Would a 5-day delay to obtain authorization through the RFA process be harmful?
   - Still need an RFA for Narcan, but it is exempt from prospective review.
   - Before the formulary, everything required prospective review.
   - The formulary is evidence-based. To date, cost has not been a consideration. Question whether to go in the direction of including cost consideration in the exempt/non-exempt designation. Evzio is a life-saving medication; therefore concern expressed about recommending that it be non-exempt.
   - How do we penetrate to the end prescriber? We need a mechanism (such as a campaign) to get this information out in terms of cost and comparative efficacy.
   - Drug prices & circumstances can also change and may warrant future discussions.

Motion: Recommend that the Administrative Director keep Narcan (nasal) exempt and change designation of Evzio (auto-injector) from exempt to non-exempt.

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

c. **Category Review NSAIDS**:
   - Widely used – among the top 50 drugs by workers compensation.
   - Several types: including non-selective COX inhibitors, partially selective COX-2 inhibitors and selective COX-2 inhibitors.

- NSAID class broken down into sub-classifications.
- Committee encouraged to look at MDGuidelines. Efficacy being equal among drugs, but differentiates with safety.

Diclofenac

- Denmark study on NSAIDs - 6.3 million people followed relative to NSAID use
    - Diclofenac – found to have increased cardiac issues vs. others (Naproxen).
    - NSAIDS known for cardiac issues for a while, but diclofenac slightly worse than the other NSAIDs.
- Only five oral NSAIDs on the formulary that are "non-exempt."
- Intent of the committee to discuss adding diclofenac and naproxen sodium to MTUS formulary (currently these forms are not listed).
- Cost was not factored into determining exempt and non-exempt status on the current MTUS Drug List.
- Historical cost data not as useful due to changing rate of reimbursement within the Medi-Cal program, which is the basis for the workers' compensation pharmaceutical fee schedule.
- Based on the Danish study, was there a difference in the various forms of diclofenac, or are all diclofenac slightly more cardio toxic than the rest of the NSAIDs? Can ACOEM address the issue?
- Suggestion to have all non-topical diclofenac non-exempt based on possible cardio toxicity issues. Diclofenac previously changed from OTC to Rx in Denmark.

Motion: Make preliminary recommendation to Administrative Director to designate all systemic diclofenac non-exempt. Obtain clarity from the Danish study and feedback from the ACOEM/ReedGroup to have a preliminary determination of systemic diclofenac as non-exempt.

Vote:
In Favor: Basil Besh, Rajiv Das, Lori Reisner, Todd Shinohara
Opposed: Raymond Meister
Abstain: Raymond Tan

Indomethacin

- All indomethacin is current exempt on the formulary. Currently, strengths not included.
- Exorbitant prices on certain strengths may provide financial incentives for prescribing, but not provide clinical benefit over less expensive strengths.
- There is a stewardship issue to consider. Consider whether anything is gained by the "me too" drugs.
- Level of the pharmaceutical identifier: drug ingredient level vs. drug ingredient with the various strengths.
- RxCUI helps to easily clarify the drug ingredient + various strengths in the pharmaceutical identifier column.

Motion: Recommend to the Administrative Director that 20mg and 40 mg indomethacin be changed from exempt to non-exempt.

Vote:
In Favor: Basil Besh, Rajiv Das, Lori Reisner, Todd Shinohara, Raymond Tan
Opposed: None
Abstain: Raymond Meister

Meloxicam

Motion: Recommend to Administrative Director that capsule form of meloxicam (5mg and 10mg strengths) be changed from exempt to non-exempt.

Vote:
In Favor: Basil Besh, Rajiv Das, Lori Reisner, Todd Shinohara, Raymond Tan
Opposed: None
Abstain: Raymond Meister

Further Committee Discussion

- Exempt vs. non-exempt vs. unlisted - Can request anything and put on an RFA (unlisted items included).
- If a drug is similar in efficacy and safety, it does not make sense for one to be exempt and non-exempt and not factor in cost
- Committee request for consistent manner of information presented, for example daily cost of the medication. Committee requested ophthalmic NSAIDs presentation in cost per day at next meeting.
- Issues for future discussion: Listing of forms of: diclofenac; naproxen sodium, naproxen extended release; ophthalmic products

IV. Public Comment:

- Suggestion for presentation data to display column for exempt status.
- Request MDGuidelines access for injured workers.
- Access to MDGuidelines will be available in the 20+ regional office locations in California.
- FDA announcement of tapering of certain opioid medications. Request for more information and communication on avoiding harm to the injured worker while tapering from opioid medications.