

DEPARTMENT OF INDUSTRIAL RELATIONS

Division of Workers' Compensation

1515 Clay Street, 17<sup>th</sup> Floor

Oakland, CA 94612

Telephone: 510-286-7100

Email: [Formulary@dir.ca.gov](mailto:Formulary@dir.ca.gov)Website: <https://www.dir.ca.gov/dwc/MTUS/MTUS-Formulary.html>

MAILING ADDRESS:

P. O. Box 420603

San Francisco, CA 94142



## 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.