Division of Workers' Compensation Pharmacy and Therapeutics Committee

April 20, 2022

12:30pm to 2:30pm

California Department of Industrial Relations

State of California
Gavin Newsom
Governor

Agenda

- **Welcome and Introductions**
  George Parisotto, Administrative Director, DWC
- **Approval of Minutes from the January 20, 2022 Meeting**
  Dr. Raymond Meister, Executive Medical Director, DWC
- **Discussion**:
  - RFA Form Review - *Dr. Raymond Meister, Executive Medical Director, DWC*
  - California Generic/Biosimilar Substitution Statute - *Kevin Gorospe Pharm D, DWC Consultant*
  - Topical Analgesic - *Kevin Gorospe Pharm D, DWC Consultant*
  - MTUS Listings – Corrections - *Kevin Gorospe Pharm D, DWC Consultant*
  - MTUS Listings – Category Listings - *Kevin Gorospe Pharm D, DWC Consultant*
- **Additional Public Comments**
- **Review of Committee Recommendations**
- **Adjourn**

Welcome and Introductions

George Parisotto

Administrative Director, DWC

California Department of Industrial Relations

Approval of Minutes

Dr. Raymond Meister

Executive Medical Director, DWC

California Department of Industrial Relations

RFA Form Review

Dr. Raymond Meister
Executive Medical Director, DWC

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RFA

Requested Treatment (see instructions for guidance; attached additional pages if necessary)				
List each specific requested medical services, goods, or items in the below space or indicate the specific page number(s) of the attached medical report on which the requested treatment can be found. Up to five (5) procedures may be entered; list additional requests on a separate sheet if the space below is insufficient.				
Diagnosis (Required)	ICD-Code (Required)	Service/Good Requested (Required)	CPT/HCPCS Code (If known)	Other Information: (Frequency, Duration Quantity, etc.)

Requested Treatment: The DWC Form RFA must contain all the information needed to substantiate the request for authorization. If the request is to continue a treatment plan or therapy, please attach documentation indicating progress, if applicable.

- List the diagnosis (required), the ICD Code (required), the specific service/good requested (required), and applicable CPT/HCPCS code (if known).
- Include, as necessary, the frequency, duration, quantity, etc. Reference to specific guidelines used to support treatment should also be included.
- For requested treatment that is: (a) inconsistent with the Medical Treatment Utilization Schedule (MTUS) found at California Code of Regulations, title 8, section 9792.20, et seq.; or (b) for a condition or injury not addressed by the MTUS, you may include scientifically based evidence published in peer-reviewed, nationally recognized journals that recommend the specific medical treatment or diagnostic services to justify your request.

California Generic/Biosimilar Substitution Statute

Kevin Gorospe Pharm D
DWC Consultant

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Background

- Committee previously discussed generic first policy
- Committee also discussed the positive fiscal impact of biosimilar drugs
- Regarding the substitution of a biosimilar for a reference drug
- FDA has been slow at identifying biosimilars as being interchangeable to the reference drug
  - For example, seven products biosimilar to Humira® (adalimumab) will begin entering the market in January 2023.
  - The FDA has identified only one of the seven Cyltezo® as interchangeable with Humira and is anticipated to hit the market in July 2023
- A primary question is, “Can a non-interchangeable biosimilar be substituted in California?”

Business and Professions Code Section 4073

- The regular generic substitution statute allows that when a drug is prescribed by its trade name, the pharmacist can select another drug if it has the same active chemical ingredients, at the same strength, quantity and dosage form and has the same FDA accepted generic name.
- The pharmacist dispensing the generic drug must inform the patient of the substitution.

Business and Professions Code Section 4073.5

- There are different provisions for the substitution of biosimilar drugs when a prescription is written for the brand name drug.
- A pharmacist may substitute a biosimilar only if:
  - The biosimilar is interchangeable
  - The prescriber has not indicated "Do Not Substitute"
- The pharmacist must tell the patient of the substitution
- Additionally, the pharmacist has to notify the prescriber within 5 days regarding the specific product provided to the patient.

The key requirement has to do with the interchangeability of the products.

Committee Discussion

Public Comments

Topical Analgesics

J. Kevin Gorospe, PharmD
DWC Consultant

California Department of Industrial Relations

Topical Analgesics Listing

- The Committee requested that the topical analgesics be "rolled up" under specific RxCUI numbers
- There are 89 different listings when rolled up by strength and specific dosage forms

Ingredient Description	Dosage Forms	Ingredient Strengths	RxCUI
benzocaine/capsaicin/lidocaine/methyl salicylate	Cream	benzocaine 2%/capsaicin 0.035% /lidocaine 2% /methyl salicylate 10%	1595784
benzocaine/menthol	Spray	benzocaine 20%/menthol 0.5%	199864
camphor	Solution	camphor 10%	204935
camphor	Solution	camphor 3.1%	2059145
camphor/capsaicin/menthol	Gel	camphor 0.02%/capsaicin 0.01%/menthol 2.5%	416207
camphor/dimethicone/lidocaine/menthol	Gel	camphor 3%/dimethicone 3%/lidocaine 4%/menthol 1%	2186001

Committee Discussion

Public Comments

MTUS Listings - Corrections

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Updated Listings

- Corrected RxCUI numbers
  - clindamycin 300mg tablet
  - frovatriptan succinate 2.5mg tablet
  - naproxen 250mg tablet
- Brand names added or corrected for
  - imipramine pamoate
  - metronidazole creams, gels and lotion
  - moxifloxacin hcl ophthalmic
  - naproxen enteric coated
  - olopatadine hcl ophthalmic
  - sodium chloride ophthalmic

Artificial Tears Ingredients

- Artificial tears are not a true ingredient
- Current MTUS listings include:

Drug Ingredient	Reference Brand Name	Exempt/Non-Exempt*	Therapeutic Classification	Pharmacological Category	Reference in ACOEM Guidelines	Dosage Form	Strength	RxCUI
artificial tears ointments	REFRESH PM	Exempt	Ophthalmic Agents	Ocular Lubricant	(R) Eye	Ointment, ophthalmic	42.5% / 57.3%	702008
carboxymethylcellulose sodium ophthalmic	REFRESH PLUS	Exempt	Ophthalmic Agents	Ocular Lubricant	(R) Eye	Solution, ophthalmic	0.5%	1188426

- There are a variety of combinations that are marketed as “artificial tears”
- ACOEM guidelines do not have a robust body of evidence for use.

ACOEM Summary of Recommendations

Condition	Recommendation
Artificial Tears or Lubrication for Chemical Ocular Burns	Recommended, Insufficient Evidence (I)
Artificial Tears or Lubrication for Extensive Corneal Abrasions, Rust Rings, and Foreign Bodies	Recommended, Insufficient Evidence (I)
Artificial Tears or Lubrication for Thermal Ocular Burns	Recommended, Insufficient Evidence (I)

- Reference studies used a variety of different products:
  - phosphate buffered saline, lactated/balance saline, normal saline, Liquifilm tears (glycerin / hypromellose / polyethylene glycol 400) and “natural tears”

Potential Combinations

- The current brand reference products:
  - Refresh PM – mineral oil and petrolatum
  - Refresh Plus – carboxymethylcellulose sodium
- Neither product matches the studies linked in the ACOEM guidelines
- DWC Identified 15 ingredient combinations used as “artificial tears” available as over-the-counter products
- These products were rolled up under the 15 RxCUIs

Drug ingredient	Dosage Form	Strength	RxCUI
Carboxymethylcellulose sodium	All Ophthalmic Dosage Forms	All Strengths	1151388
dextran 70 / glycerin / hypromellose	All Ophthalmic Dosage Forms	All Strengths	1154555
dextran 70 / hypromellose	All Ophthalmic Dosage Forms	All Strengths	1154558
glycerin / hypromellose / polyethylene glycol 400	All Ophthalmic Dosage Forms	All Strengths	1156225
glycerin / propylene glycol	All Ophthalmic Dosage Forms	All Strengths	1156214
hydroxymethyl cellulose	All Ophthalmic Dosage Forms	All Strengths	1363606
hypromellose	All Ophthalmic Dosage Forms	All Strengths	1160657
lanolin / mineral oil / petrolatum	All Ophthalmic Dosage Forms	All Strengths	1162821
mineral oil / petrolatum	All Ophthalmic Dosage Forms	All Strengths	1164734
polyethylene glycol 400	All Ophthalmic Dosage Forms	All Strengths	1159893
polyethylene glycols / polyvinyl alcohol	All Ophthalmic Dosage Forms	All Strengths	1159894
polyvinyl alcohol	All Ophthalmic Dosage Forms	All Strengths	1160465
polyvinyl alcohol / povidone	All Ophthalmic Dosage Forms	All Strengths	1160464
propylene glycol	All Ophthalmic Dosage Forms	All Strengths	1162939
propylene glycol 400 / propylene glycol	All Ophthalmic Dosage Forms	All Strengths	1159891

Committee Discussion

Public Comments

MTUS Listings – Category Listings

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Category issues

- ascorbic acid, and Vitamins B2, B1, B6, A, D, D3 and E and magnesium listed as “alternative medicines”
- Listing of oral and sublingual drugs should be in different categories
- Janus Kinase Inhibitors are not analgesics
- Should cabergoline be listed as a migraine drug
- Change how benzodiazepines are listed
- Clarify “hormone” category listings
- mifepristone under endocrine and metabolic instead of steroids
- gabapentin listed as a neurological agent

Committee Discussion

Public Comments

Review of Recommendations

Adjournment