

Division of Workers' Compensation Pharmacy and Therapeutics Committee

November 20, 2019
12:30pm to 2:30pm



State of California
Gavin Newsom
Governor

Agenda

- **Welcome and Introductions**
George Parisotto, Administrative Director, DWC
- **Approval of Minutes from the July 24, 2019 Meeting**
Dr. Raymond Meister, Executive Medical Director, DWC
- **MTUS Drug List v6 – *Dr. Raymond Meister***
- **Danish Study Update on Diclofenac – *Dr. Raymond Meister***
- **Discussion:**
 - Inclusion of Antiemetics to Exempt List - *Basil R. Besh, M.D., Precision Surgicenter*
 - Special Fill and Peri-Op 4-Day Supply Allowance – *Raymond Tan, Pharm.D., Zenith Insurance Co.*
 - MTUS Drug List Formats - *Kevin Gorospe, DWC Consultant*
- **Public Comments**
- **Review of Committee Recommendations**
- **Adjourn**

Welcome and Introductions

George Parisotto

Administrative Director, DWC

Approval of Minutes

Dr. Raymond Meister

Executive Medical Director, DWC

MTUS Drug List v6

Dr. Raymond Meister

Executive Medical Director, DWC

MTUS Drug List Accessible Formats

Drug Ingredient	Brand Example	Exempt/Non-Exempt*	Special Fill**	Peri-Op***	Drug Class	Reference in ACOEM Guidelines *	Dosage Form	Strength	Unique Pharmaceutical Identifier(s)
acetaminophen	Tylenol	Exempt	Not applicable	Not applicable	Analgesics - NonNarcotic	Ankle and Foot Disorders (R), Cervical and Thoracic Spine Disorders (R), Chronic Pain (R), Elbow Disorders (R, Not R), Hand, Wrist, and Forearm Disorders (R, Not R), Hip and Groin Disorders (R), Knee Disorders (R), Low Back Disorders (R), Shoulder (R)	Not applicable	Not applicable	Not applicable
acetyl l-carnitine	Not applicable	Non-Exempt	Not applicable	Not applicable	Psychotherapeutic and Neurological Agents - Misc	Chronic Pain (Not R)	Not applicable	Not applicable	Not applicable
acyclovir	Zovirax	Non-Exempt	Not applicable	Not applicable	Antivirals	Chronic Pain (No R)	Not applicable	Not applicable	Not applicable
adalimumab	Humira	Non-Exempt	Not applicable	Not applicable	Analgesics - Anti-Inflammatory (TNF-alpha blocker)	Hip and Groin Disorders (Not R), Knee Disorders (Not R), Low Back Disorders (Not R)	Not applicable	Not applicable	Not applicable
albuterol sulfate	Proventil	Exempt	Not applicable	Not applicable	Antiasthmatic and Bronchodilator Agents	Work Related Asthma (R)	Not applicable	Not applicable	Not applicable
alcaftadine	Lastacaft	Exempt	Not applicable	Not applicable	Antihistamine and/or mast cell stabilization	Eye (R)	Not applicable	Not applicable	Not applicable
alclometasone dipropionate	Aclovate	Non-Exempt	Not applicable	Not applicable	Dermatologicals	Ankle and Foot Disorders (R)	Not applicable	Not applicable	Not applicable
alendronate sodium	Fosamax	Non-Exempt	Not applicable	Not applicable	Endocrine and Metabolic Agents- Misc. (Bisphosphonate)	Chronic Pain (R), Hip and Groin Disorders (R, No R), Knee Disorders (No R), Low Back Disorders (Not R), Shoulder (R)	Not applicable	Not applicable	Not applicable

MTUS Drug List Accessible Formats

Drug Ingredient	Change Log
amitriptyline hcl	Delete: "Not Recommended" status from the Hip and Groin Disorder Guideline
baclofen	Delete: "Not Recommended" status from the Hip and Groin Disorder Guideline
bupropion hcl	Delete: "Not Recommended" status from the Hip and Groin Disorder Guideline Add: "No Recommendation" status to the Hip and Groin Disorder Guideline
calcitonin-salmon	Delete: "Recommended" status from the Hip and Groin Disorder Guideline
camphor	Delete: "No Recommendation" status from the Hip and Groin Disorder Guideline

Danish Study Update on Diclofenac

Dr. Raymond Meister

Executive Medical Director, DWC

Inclusion of Antiemetics to Exempt List

Basil R. Besh, M.D.

Precision Surgicenter

Committee Member

Exempt Medications Drug Formulary

- Surgeries
 - Drug Formularies – typically address issues/testing involving a particular surgical procedure.
 - But not the effects of a patient going through the surgical procedure.
- This causes pharmaceuticals commonly needed by a post-surgical patient – not to be included as an exempt medication in drug formularies.
- Examples of these medications include:
 - anticoagulants
 - antiemetics

Post Surgical Patient Needs

- When post-surgical patients need these medications, they are needed quickly – no time for utilization review.
- Utilization review companies will not always approve these medications as part of the pre-authorization surgical request.
- If patients do not have access to the medications, they could easily end up in the emergency room or suffer a life-threatening event.

ACOEM Guidelines

- COA discussed this problem with DWC/ACOEM as California's Drug Formulary was being developed.
- ACOEM acknowledged that their treatment guidelines do not consider the effects of going through a surgery.
- Expected that ACOEM will address this issue in future updates to their treatment guidelines.

MTUS List

- DWC agreed that anticoagulants should be included as an exempt medication in the Drug Formulary, but not antiemetics.
- COA is asking that antiemetics be added to the list of exempt medications so injured workers have ready access to these medications when needed.

Post Operative Guidelines

J. Kevin Gorospe, PharmD

DWC Consultant

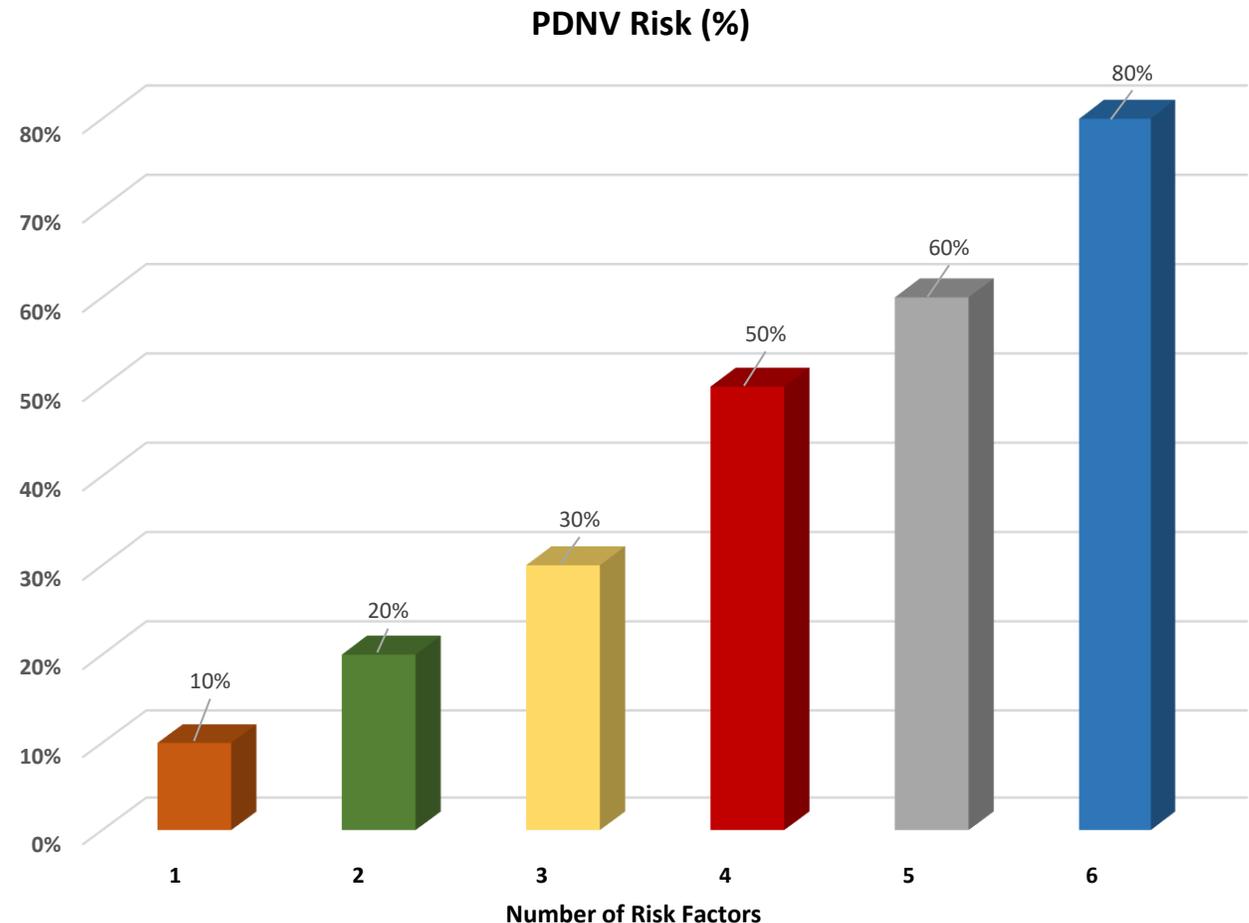
Post-Operative Nausea & Vomiting (PONV)

- Consensus Guidelines for the management of PONV and published in 2014 by the Society of Ambulatory Anesthesia (SAMBA)
- The guidelines primarily cover the prevention of PONV and Post-Discharge Nausea and Vomiting (PDNV)
- 1/3 to 1/2 who undergo ambulatory surgery experience PDNV
- Systematic review of all studies assessing PDNV found
 - 17% of patients experience nausea (range, 0%–55%)
 - 8% have vomiting (range, 0%–16%)
- The guidelines also address risk factors for PDNV

PDNV Risk

- PDNV Risk Factors
 - Female gender
 - History of PONV
 - Age less than 50
 - Use of opioids in PACU*
 - Nausea in the PACU
- Risk scores are not completely predictive
- Other clinically relevant aspects should be taken into consideration, for example, patients
 - with wired jaws
 - with increased intracranial pressure, or
 - post gastric or esophageal surgery.

*PACU = Post Anesthesia Care Unit



Most Common Drugs

- aprepitant (EMEND)
- granisetron (KYTRIL)
- granisetron hydrochloride (SANCUSO)
- metoclopramide hydrochloride (REGLAN)
- netupitant / palonosetron hydrochloride (AKYNZEO)
- ondansetron (ZOFRAN)
- ondansetron hydrochloride (ZOFRAN)
- prochlorperazine (COMPAZINE, COMPRO)
- prochlorperazine maleate (PROCOMP)
- promethazine hydrochloride (PHENERGAN, PROMETHGAN)
- rolapitant hydrochloride (VARUBI)

PDNV Treatment Guidelines

- As mentioned, SAMBA guidelines are primarily focused on PONV/PDNV prevention
- PDNV treatment would be the focus for the MTUS Formulary
- Many of the guidelines on treatment come from oncology and OB/Gyn specialties
- The only gastroenterology guidelines focus on gastroparesis treatment
- Most of the listed drugs are indicated for use in chemotherapy induced nausea and vomiting
- ondansetron & ondansetron hydrochloride are the only products with indications for use in PONV
- prochlorperazine, prochlorperazine maleate & promethazine hydrochloride have general indication for nausea and vomiting

ACOEEM – Hip and Groin Disorders Appendix 2

- Notes wide variety of antiemetic agents used “to prevent and treat peri-operative nausea and vomiting”
- Treatment recommendations
 - Moderately recommended for peri-operative nausea and vomiting
 - Evidence level “B”
 - Confidence Level “High”
- Indications: Pre-, peri- and post-operative nausea and emesis
- Adverse effects: vary based on type of medication. Common adverse effects include drowsiness, dry mouth, urinary retention, blurred vision, sedation, tremor

ACOEM – Drugs

- ACOEM lists several drugs and dosages from studies
- Some drugs listed are not relevant (IV infusion only, not approved in US, or discontinued)
- The relevant drugs listed are:
 - Aprepitant 40, 80, 125mg and 40mg PO
 - Granisteron 0.1, 1, 3mg and 20, 40 mg/kg (injectable but Patch available)
 - Metoclopramide 10,20mg and 0.25mg/kg and 10mg PO
 - Ondansetron 1, 2, 4, 8mg and 100 mg/kg and 4, 8mg PO
 - Perphenazine 5mg
 - Prochlorperazine 0.1,10mg

Questions/Discussion

- Should products to treat PDNV and general N&V be added to MTUS?
 - No specific guidelines for PDNV due to workers compensation related surgery (ACOEM not yet incorporated as a regular guideline)
 - UpToDate notes “Few high-quality therapeutic trials have compared the efficacy of different drugs in patients presenting acutely with nausea and vomiting.”
- Which products should P&T review?
 - Should review include products that have chemotherapy induced N&V only indications?
 - Should focus be on drugs with general N&V or post-surgery indication?

Committee Discussion

Opioid Utilization Control Efforts

A Brief Background

J. Kevin Gorospe, PharmD
DWC Consultant

SUPPORT Act

- Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act (H.R. 6, the SUPPORT Act, P.L. 115-271)
- Imposes new requirements on government health programs (Medicare, Medicaid, CHIP) and on prescribers
 - e.g. move to electronic prescribing, mandatory checking of PDMP records
- Also emphasizes expanded utilization review and control

Morphine Milligram Equivalents

- Many states have or will be implementing maximum daily Morphine Milligram Equivalents
 - Medi-Cal requirement “treatment of chronic pain, not to exceed 500 MME/daily without prior authorization.” (9/30/2019 All Plan Letter)
 - Alabama Medicaid MME initial limit 250 MME/day with a phase-in target of 90 MME/day
- 90 MME/day is based on a 2016 CDC recommendation
- CDC also recommended to limit first-time opioid prescriptions to 3 days.

ACOEM Opioid Guidelines

- Use lowest effective dose
- Maximum Dose
 - Acute pain (up to 4 weeks of treatment)
 - max 50 MME/day
 - first prescription should not exceed 3 days treatment
 - Postoperative pain (up to 4 weeks of treatment)
 - max 50 MME/day
 - generally dispensing amount sufficient to cover two weeks of treatment
 - Subacute pain and Chronic Pain
 - max 50 MME/day
 - doses up to 90 MME/day can be considered

Special Fill and Peri-Op 4-Day Supply Allowance

Raymond Tan, PharmD

AVP Medical Management-Pharmacy, Zenith Insurance Co.

Committee Member

Special Fill: 4-Day Supply

Drug Ingredient	Brand Example	Exempt/Non-Exempt*	Special Fill**	Peri-Op***
baclofen	LIORESAL	Non-Exempt	4 Days	4 Days
hydrocodone/acetaminophen	NNORCO, VICODIN, XODOL	Non-Exempt	4 Days	4 Days
morphine sulfate	Not applicable	Non-Exempt	4 Days	4 Days
oxycodone hcl	OXYCONTIN, ROXICODONE	Non-Exempt	4 Days	4 Days
oxycodone/acetaminophen	PERCOCET	Non-Exempt	4 days	4 days
tramadol hcl	ULTRAM, ULTRAM ER	Non-Exempt	4 Days	4 Days
tramadol hcl/ac	ULTRACET	Non-Exempt	4 Days	4 Days

- 4-day supply has multiple interpretations
 - Should we include Quantity limits to provide more clarity?
- Is the intent to include ER formulations in the special fill and peri-op?
- Special Fill scenario is the first office visit within 7 days from the injury

Hydrocodone/Acetaminophen

- Hydrocodone 2.5, 5, 7.5, 10 with APAP 300, 325 ratios
- Typical dosing is 1-2 tablets every 4-6 hours as needed for pain
- At max dosing:
 - 12 tablets per day
 - 48 tablets per the 4-day supply allowance of the MTUS Drug List v4
- 5mg tablets at max dose (12/day) is MED 50
- 10mg tablets at max dose (12/day) is MED 120
- 4-day supply leaves interpretation to a dispense of up to MED 120

Morphine

- Immediate Release Tablets – 15, 30mg
- Orally Disintegrating Tablets – 10, 15, 30mg
- Extended Release – Multiple Dosage Forms
 - 12hr – 15, 30, 60, 100
 - 24hr - 10, 20, 30, 40, 45, 60, 75, 80, 90, 120, 130, 150, 200mg
- Oxycodone is similar concept with IR and ER products

Discussion Points

- Discussion, including what additional evidence is required
- Consensus Advisory Vote
 - Should there be defining details to the 4-day supply?
 - Quantity restrictions?
 - MED Restrictions?
 - Other?

Committee Discussion

MTUS Drug List Formats

J. Kevin Gorospe, Pharm.D.

DWC Consultant

Required Formats

- Knox-Keene requires plans and PBMs to follow a specified format
- Does not apply to the DWC MTUS Drug List, however there are design elements that could be helpful
- Design elements from the requirements to consider for MTUS:
 - All capitals for BRAND NAMES of drugs
 - Bold and italicized lowercase for *generic names* of drugs
 - Separate rows for the dosage forms and/or strengths of drugs to clearly identify the differences

MTUS Format Example

- Incorporates the three Knox-Keene design elements
- Separate rows for dosages and strengths allows for variations of Exempt / Non-Exempt within a Drug Ingredient
- Would also provide for variations in Special Fill and Peri-Op within a Drug Ingredient

Drug Ingredient	Brand Example	Exempt/Non-Exempt*	Special Fill**	Peri-Op***	Drug Class	Reference in ACOEM Guidelines *	Dosage Form	Strength	Unique Pharmaceutical Identifier(s) (RxCIJ)
<i>acetaminophen</i>	TYLENOL	Exempt	Not applicable	Not applicable	Analgesics - NonNarcotic	✓ Ankle and Foot Disorders ✓ Cervical and Thoracic Spine Disorders ✓ Chronic Pain ✓X Elbow Disorders ✓X Hand, Wrist, and Forearm Disorders ✓ Hip and Groin Disorders ✓ Knee Disorders ✓ Low Back Disorders ✓ Shoulder	Capsule	325 MG	198436
<i>acetaminophen</i>	TYLENOL	Exempt	Not applicable	Not applicable	Analgesics - NonNarcotic	✓ Ankle and Foot Disorders ✓ Cervical and Thoracic Spine Disorders ✓ Chronic Pain ✓X Elbow Disorders ✓X Hand, Wrist, and Forearm Disorders ✓ Hip and Groin Disorders ✓ Knee Disorders ✓ Low Back Disorders ✓ Shoulder	Capsule	500 mg	198439
<i>acetaminophen</i>	TYLENOL	Exempt	Not applicable	Not applicable	Analgesics - NonNarcotic	✓ Ankle and Foot Disorders ✓ Cervical and Thoracic Spine Disorders ✓ Chronic Pain ✓X Elbow Disorders ✓X Hand, Wrist, and Forearm Disorders ✓ Hip and Groin Disorders ✓ Knee Disorders ✓ Low Back Disorders ✓ Shoulder	Solution	100 MG/ML	238159
<i>acetaminophen</i>	TYLENOL	Exempt	Not applicable	Not applicable	Analgesics - NonNarcotic	✓ Ankle and Foot Disorders ✓ Cervical and Thoracic Spine Disorders ✓ Chronic Pain ✓X Elbow Disorders ✓X Hand, Wrist, and Forearm Disorders ✓ Hip and Groin Disorders ✓ Knee Disorders ✓ Low Back Disorders ✓ Shoulder	Suspension	100 MG/ML	243675

Additional Lists

- Subsets of the detailed list can be made to address prescriber needs
- For Example
 - Exempt drugs only
 - List by Drug Class
 - Special Fill
 - Peri-Op
- Can make more brief lists by removing columns
 - Unique Pharmaceutical Identifier(s)

Committee Discussion

Public Comments

Review of Recommendations

Adjournment