



# California Division of Workers' Compensation

Department of Industrial Relations

## Medical Treatment Utilization Schedule – Drug Formulary

Webinar Presentations: December 13<sup>th</sup> and 14<sup>th</sup>, 2017

Presented by:

George Parisotto, DWC Administrative Director  
Raymond Meister, MD, MPH, DWC Executive Medical Director  
Jacqueline Schauer, DWC Legal Counsel  
Lucy Shannon, Director, ReedGroup

## Overview of Webinar Presentation

- Background – Assembly Bill 1124
- Overview of MTUS and role as foundation for formulary
- MTUS Drug List
- Related Rules
  - Brand/Generic
  - Compounded Drugs
  - Physician-Dispensed Drugs
  - Special Fill and Perioperative Fill Policies
  - Off Label use of Drugs
  - Transition for workers injured before January 1, 2018.
- ReedGroup demonstration of MD Guidelines Website including ACOEM Guidelines and Formulary
- P&T Committee and Updates to the Formulary

### George

Good morning. I am George Parisotto, Administrative Director for the California Department of Industrial Relations, Division of Workers' Compensation. Welcome to the Division's educational webinar on the Medical Treatment Utilization Schedule Drug Formulary. We will be posting the slides and recorded webinar on the Division's website for later viewing.

Let me introduce our presenters for today:

Dr. Raymond Meister is the Executive Medical Director of the Division of Workers' Compensation.

Jacqueline Schauer is an attorney in the DWC Legal Unit and has been working on the formulary rulemaking action.

Lucy Shannon is with the Reed Group, and is the Director of Editorial Research and Development. The Reed Group is the publisher of the American College of Occupational and Environmental Medicine (ACOEM) Guidelines.

Today we will be providing some information regarding the legislative background to the new workers' compensation drug formulary, and will explain how it fits within the larger framework of the Medical Treatment Utilization Schedule. Dr. Meister and Jackie Schauer will discuss the details of the MTUS Drug List and ancillary formulary rules.

We are happy to have Lucy Shannon of the Reed Group here to demonstrate the very

useful features of the online ACOEM Treatment Guidelines and formulary tools.

## Background to the MTUS Drug Formulary

- Assembly Bill 1124 – DWC to adopt evidence-based drug formulary
- Senate Bill 1160 – expedited process for evidence-based updates to the MTUS
- MTUS evidence-based updates adopting ACOEM Guidelines effective December 1, 2017
- Formulary Regulations
  - Rulemaking
  - Approved by Office of Administrative Law – December 7, 2017
  - Effective January 1, 2018

AB 1124, which was signed by Governor Brown on October 6, 2015, requires that the Division adopt an evidence-based drug formulary as part of the Medical Treatment Utilization Schedule. The MTUS Drug Formulary is the result of many months of study, consultation with the public, and formal rulemaking to receive public comment. It is important to note that the Drug Formulary is part of the MTUS.

The Drug Formulary and the MTUS Treatment Guidelines work together to guide treatment decisions.

We are pleased that effective December 1, 2017, the Division has adopted updated treatment guidelines of the American College of Occupational and Environmental Medicine.

Dr. Meister will provide an overview of the MTUS and the recent evidence-based updates to the guidelines, which provide the backbone to the drug formulary. Last month, the Division presented a webinar focused on the MTUS updates, which is available for viewing on the DWC website. Although some of the material today overlaps with the MTUS webinar, please bear with us, as the formulary is an integral part of the MTUS, and successful implementation is founded upon use of the MTUS Treatment Guidelines and the MTUS rules.

Now Dr. Meister will provide an overview of the MTUS.

## What is the MTUS?



- The MTUS is a set of regulations found within the California Code of Regulations.
- Contains definitions, establishes the primary role of the **treatment guidelines** in the MTUS, provides a **Medical Evidence Search Sequence** and a **Methodology for Evaluating Medical Evidence** when there are conflicting recommendations.
- Is based on the principles of evidence-based medicine (EBM).
- Adopts and incorporates by reference the treatment guidelines of the American College of Occupational and Environmental Medicine

### Dr. Meister

What is the MTUS?

When most people think of the MTUS, they think of medical treatment guidelines...but, it is more than that! It is a set of regulations that provide the clinician with an analytical framework for the evaluation and treatment of injured workers in the California workers' compensation system. It is found within the California Code of Regulations, title 8, beginning at section 9792.20. As of January 1, 2018, the MTUS will also include the regulation sections that constitute the MTUS drug formulary.

## Why is the MTUS important?



- It is the primary source of guidance for treating physicians and physician reviewers in workers' compensation.
- It provides the pathway to providing appropriate patient care and getting treatment requests approved.

The MTUS was developed to establish evidence based, peer-reviewed, nationally recognized standards of care to guide the evaluation and treatment of injured workers. The core of the MTUS is the medical treatment guidelines.

So, why is the MTUS important?

California law requires use of the MTUS treatment guidelines. California Labor Code section 4600(b) states “medical treatment that is reasonably required to cure or relieve the injured worker. . . means treatment that is based upon the guidelines adopted by the administrative director. . . “

In addition, Labor Code section 4604.5(a) makes it clear that recommendations found in the MTUS guidelines are “presumed correct” on the issue of extent and scope of medical treatment. The term “presumed correct” means that recommendations found in the MTUS guidelines will automatically be applied to guide patient care, unless the treating physician disagrees with the recommendation and wishes to challenge it. The Treatment Guidelines are based on a robust literature review and analysis of efficacy and safety to determine which treatments are recommended for the conditions in the guideline. The application of

evidence-based medicine through use of the ACOEM guidelines is intended to improve patient care. For conditions not covered by the guidelines, or if a guideline recommendation is being challenged, the MTUS is important because it sets forth a scientifically sound method of evaluating medical evidence.

The MTUS is important because it is the primary source of guidance for treating physicians and physician reviewers in California's workers' compensation system. The MTUS provides the pathway to providing appropriate patient care and getting treatment requests approved.

## Evidence-Based Updates to MTUS

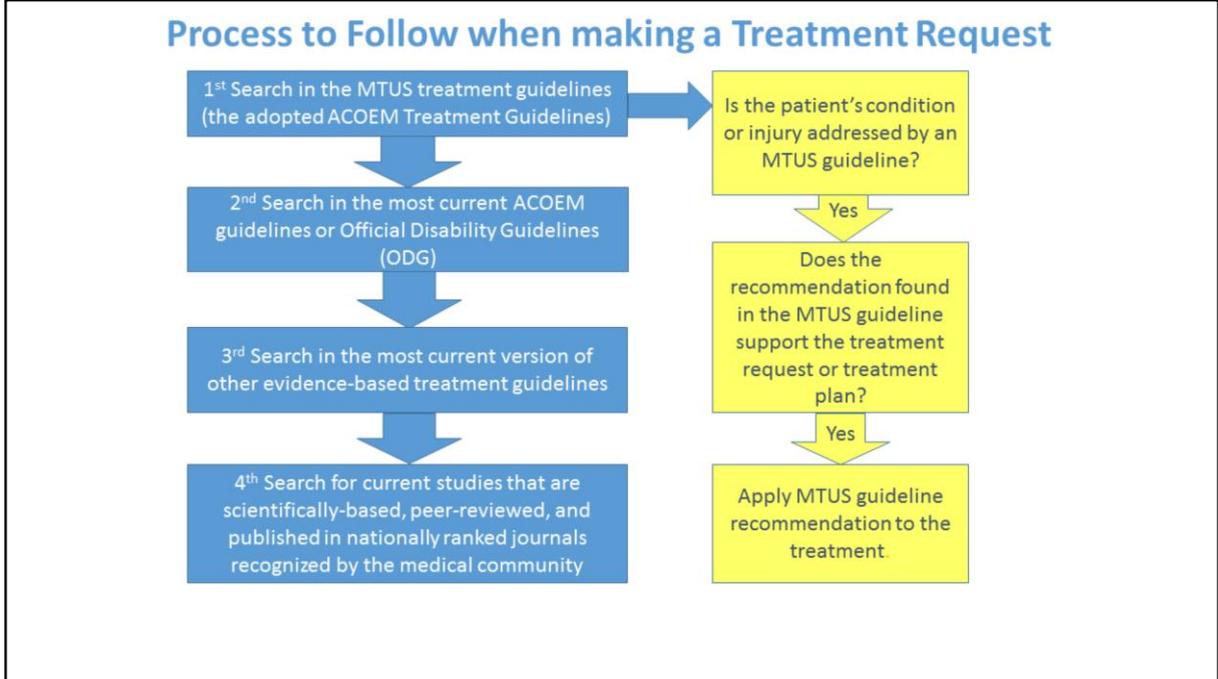
### **ACOEM Treatment Guidelines** (Adopted effective December 1, 2017)

- Cervical and Thoracic Spine Disorders Guideline
- Shoulder Disorders Guideline
- Elbow Disorders Chapter
- Hand, Wrist, and Forearm Disorders Guideline
- Low Back Disorders Guideline
- Knee Disorders Guideline
- Ankle and Foot Disorders Guideline
- Eye Disorders Chapter
- Chronic Pain Medical Treatment Guideline
- Opioids Treatment Guideline
- Initial Approaches to Treatment
- Hip and Groin Guideline
- Occupational/Work Related Asthma Guideline
- Occupational Interstitial Lung Disease Guideline

As of Dec 1, 2017, the DWC incorporated by reference the most recent American College of Occupational and Environmental Medicine's medical treatment guidelines (which we will refer to as ACOEM guidelines) into the MTUS. The new treatment guidelines are effective for all medical services rendered on or after December 1, 2017.

Available in the handouts section is a Resources guide, with a link to a web page where you can find the Administrative Director's Order which includes the regulatory amendments.

Let's look at how the MTUS regulation adopting a Medical Evidence Search Sequence guides evidence-based medical treatment decisions.



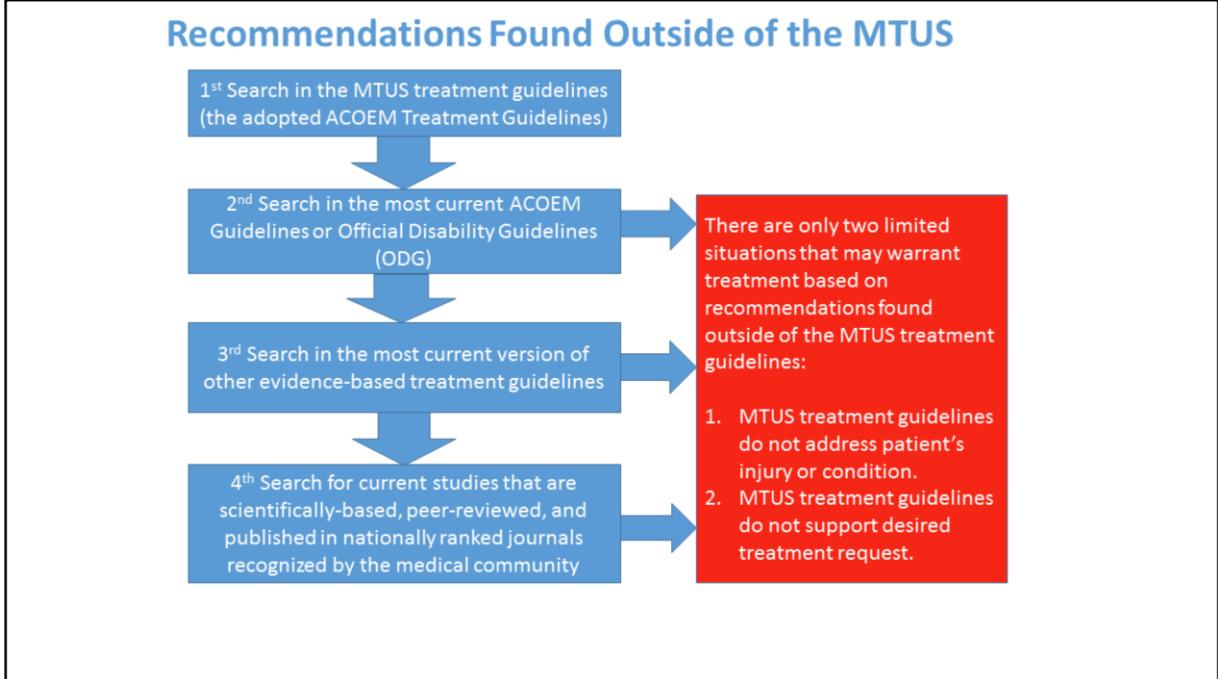
This flow chart graphic illustrates the Medical Evidence Search Sequence mandate to always begin by searching in the adopted MTUS guidelines. Now that the DWC has adopted the most recent ACOEM guidelines, the patient’s injury or condition will most likely be addressed in the ACOEM guidelines adopted into the MTUS.

Take a look at the yellow flow-chart on the right-hand side of the slide. Ask yourself, “Is the patient’s condition or injury addressed by an MTUS guideline?”

If the answer is yes, then ask yourself “Does the recommendation found in the MTUS guideline support the treatment request or treatment plan?”

If the care the doctor wishes to provide IS supported by the MTUS guidelines, then simply apply the MTUS guideline recommendation to the treatment of your patient! There is no mystery to this. In fact, it is a very simple process.

However, let me emphasize! Without proper documentation, your request for authorization (RFA) can still be denied even if you’ve followed this process. Proper documentation is the key to approval.



Before we turn to the use of recommendations found outside of the MTUS guidelines, take a look at the second blue box which states, “search in the most current ACOEM Guidelines or Official Disability Guidelines.” You may ask yourself, why would I need to search the most current ACOEM guidelines when I already did that in step #1, the top blue box? Here’s the difference, an ACOEM guideline is NOT yet part of the MTUS until the DWC formally adopts it.

Currently, all of the MTUS guidelines are ACOEM guidelines. However, there may be ACOEM guidelines that have not been adopted into the MTUS. For example, the Traumatic Brain Injury Guideline was just published by ACOEM, but the DWC has not yet adopted the ACOEM Traumatic Brain Injury Guideline into the MTUS. Until we do, the Traumatic Brain Injury Guideline is NOT considered an MTUS guideline.

OK, we now turn to the use of recommendations found outside of the MTUS guidelines for patient treatment. Here is a slide that shows the Medical Evidence Search Sequence again. But this time, the treating provider is searching for treatment recommendations outside of the MTUS guidelines.

There are only two limited situations that may warrant treatment based on recommendations found outside of the MTUS guidelines. Take a look at the red box on the right-hand side of the slide.

The first situation is when the patient's medical condition is not addressed in the MTUS guidelines. The physician should continue through the search sequence to find evidence-based approaches to care.

The second situation is when the patient's medical condition is addressed in the MTUS guidelines but the recommendations do not support the physician's desired treatment plan. Recommendations found in the MTUS guidelines are "presumed correct". So, if the doctor disagrees with these recommendations he or she may challenge them by finding recommendations outside of the MTUS that are supported with a higher level of evidence. The treating physician bears the burden of proving the medical necessity of treatment requests when challenging the adopted treatment guidelines.

In both situations, the physician will need to find recommendations outside of the MTUS guidelines that support the treatment plan. In order for the treatment plan to be approved, the recommendation must be supported by the best available evidence.

## Structure of the MTUS Drug Formulary and Role of the ACOEM Treatment Guidelines

- ACOEM Treatment Guidelines – The Backbone
  - Presumed correct on scope of medically necessary treatment
- MTUS Drug List – guides the prospective review requirements
  - “Exempt” drugs – No Prospective Review if in accord with MTUS
  - “Non-Exempt” & Unlisted Drugs – Prospective Review required
  - “Special Fill” & “Perioperative Fill” of specified Non-Preferred drugs
- Ancillary Formulary Rules
  - Special Fill policy
  - Perioperative Fill policy
  - Physician dispensed drugs
  - Generic/Brand selection
  - Compounded drugs
  - Off-label use of drugs

You may be wondering why this webinar on the Formulary is discussing the MTUS Treatment Guidelines in such depth.

It is important to understand that the MTUS Formulary is a component of the Medical Treatment Utilization Schedule.

The regulations define the MTUS Drug Formulary to include the MTUS Drug List and the formulary rules.

In addition, the formulary rules make it clear that the MTUS regulations, including the Medical Evidence Search Sequence and the MTUS Methodology for Evaluating Medical Evidence, are applicable to determine the medical necessity of pharmaceutical treatment.

We can think of the MTUS Drug Formulary as having 3 essential parts, The ACOEM Treatment Guidelines which are the backbone of the formulary, the MTUS Drug List, which guides prospective review requirements, and, the Ancillary Formulary Rules.

The MTUS Drug List is not a stand alone document, it must be used in conjunction with the adopted ACOEM Treatment guidelines, which are presumed correct on the scope of medical treatment.

For conditions not covered by the MTUS guidelines, or if the physician challenges the treatment recommendation in the ACOEM guidelines, the MTUS Medical Evidence Search

Sequence illustrated in the previous slide is applicable, and guides the selection of evidence-based pharmaceutical treatment.

## Scope of the MTUS Drug Formulary and Effective Date

- MTUS Drug Formulary applies to drugs dispensed on or after January 1, 2018
  - Applies to all DOIs (except as specified for ongoing course of treatment)
  - For DOIs before 1/1/2018, if injured worker is on an ongoing course of treatment with Non-Exempt drug, unlisted drug, or compounded drug, the treatment is subject to the phased implementation rule
- MTUS Drug Formulary applies only to drugs *dispensed for outpatient use* at home or outside a clinical setting
  - Not applicable to physician-administered drugs
  - Not applicable to drugs self-administered within a facility, e.g. hospital
- MTUS rules other than formulary rules apply to physician-administered drugs

The MTUS Drug Formulary regulations were approved by the Office of Administrative Law and filed with the Secretary of State on December 7, 2017.

The regulations become effective on 1/1/2018.

The MTUS Drug Formulary will apply to drugs dispensed on or after 1/1/2018, regardless of the DOI. However, for injured workers who are receiving an ongoing course of treatment with a Non-Exempt drug, an unlisted drug or a compounded drug, there is a regulation addressing the physician's duty to submit an updated treatment plan so that there is a phased implementation of the formulary as guided by the newly adopted ACOEM treatment guidelines.

The MTUS Drug Formulary applies to drugs dispensed for outpatient use at home or outside of a clinical setting.

The MTUS Drug Formulary does not apply to physician-administered drugs. However, it should be noted that physician-administered drugs are often subject to the ACOEM treatment guidelines adopted in the MTUS, for example, recommendations for use of steroid injections into a joint.

### MTUS Drug List ( 8 CCR §9792.27.15)

The MTUS Drug List must be used in conjunction with 1) the MTUS Guidelines, which contain specific treatment recommendations based on condition and phase of treatment and 2) the drug formulary rules. [See 8 CCR §9792.22 – §9792.27.23.] "Reference in Guidelines" indicates guideline(s) which discuss the drug. In each guideline there may be conditions for which the drug is Recommended (✓), Not Recommended (✗), or No Recommendation (□). Consult guidelines to determine the recommendations for the condition to be treated and to assure proper phase of use are.

\*Example: Non-Exempt

\*Example: Exempt drug may be prescribed/dispensed without seeking authorization through Prospective Review if in accordance with MTUS.

1) Physician dispensed "Exempt" drug listed in one 7-day supply at initial visit within seven days of the date of injury without Prospective Review.

2) Prescription/dispensing of brand name "Exempt" drug where generic is available requires authorization through Prospective Review.

\*Non-Exempt" or "Informed" drug requires authorization through Prospective Review prior to prescribing or dispensing. [See 8 CCR §9792.27.1 through §9792.27.23 for complete rules.]

\*\*Special FR: Indicates the Non-Exempt drug may be prescribed/dispensed without Prospective Review: 1) If at initial visit within 7 days of injury; and 2) Supply not to exceed dates indicated; and 3) In a generic or single source brand, or brand where physician substantiates medical necessity; and 4) If in accord with MTUS. [See 8 CCR § 9792.27.12.]

\*\*\*Participative FR: Indicates the Non-Exempt drug may be prescribed/dispensed without Prospective Review: 1) If in brand during the participative period (4 days before through 4 days after surgery); and 2) Supply not to exceed #days indicated; and 3) In a generic or single source brand, or brand where physician substantiates medical necessity; and 4) In in accord with MTUS. [See 8 CCR § 9792.27.13.]

	Drug Ingredient	Reference Brand Name	Exempt/Non-Exempt*	Special FR**	Part-Opr**	Drug Class	Reference in Guidelines	Dosage Form	Strength	Unique Pharmaceutical Identifier(s)
1	Acetaminophen	Tylenol	Exempt			Analgesic - Non-Narcotic	✓ Cervical and Thoracic Spine Disorders ✓ Chronic Pain ✓ Elbow Disorders ✓ Eye ✓ Hand, Wrist, and Forearm Disorders ✓ Hip and Groin Disorders ✓ Knee Disorders ✓ Low Back Disorders ✓ Shoulder			
2	Adalimumab	Humira	Non-Exempt			Analgesic Anti-Inflammatory (TNF-alpha Inhibitor)	✓ Chronic Pain ✓ Hip and Groin Disorders ✓ Knee Disorders ✓ Low Back Disorders			
3	Albuterol Sulfate	Proventil	Exempt			Anticholinergic and Bronchodilator Agents	✓ Work Related Asthma			
4	Aluminum Hydroxide	Acholate	Non-Exempt			Dermatologic	✓ Ankle and Foot Disorders			
5	Aluminum Sulfate	Fomanex	Non-Exempt			Endocrine and Metabolic Agents - Misc. (Phosphorylase)	✓ Chronic Pain ✓ Hip and Groin Disorders ✓ Knee Disorders ✓ Low Back Disorders ✓ Shoulder			
6	Amoxicillin HCl	Symmetrel	Non-Exempt			Antiviral Agents (NMDA receptor antagonist)	✓ Chronic Pain ✓ Low Back Disorders			
7	Amoxicillin	Cyclovent	Non-Exempt			Dermatologic	✓ Ankle and Foot Disorders			
8	Amitriptyline HCl	Emitl	Non-Exempt			Antidepressants (TCA)	✓ Cervical and Thoracic Spine Disorders ✓ Chronic Pain ✓ Hip and Groin Disorders ✓ Low Back Disorders ✓ Shoulder			
9	Amphetamine Sulfate	Nonexan	Non-Exempt			Cation Channel Blockers	✓ Hand, Wrist, and Forearm Disorders			
10	Amoxicillin/Clavulanate P	Augmentin	Exempt			Antibiotics (Penicillin)	✓ Ankle and Foot Disorders ✓ Hand, Wrist, and Forearm Disorders ✓ Low Back Disorders			
11	Analecta	Elevent	Non-Exempt			Analgesic Anti-Inflammatory	✓ Knee Disorders			
12	Apixiban	Elipix	Non-Exempt		14 Days	Anticoagulants	✓ Ankle and Foot Disorders ✓ Hip and Groin Disorders ✓ Knee Disorders			
13	Artificial Tear Solutions	Refresh PM	Exempt			Ophthalmic Agents (Artificial Tears)	✓ Eye			
14	Ascorbic Acid	Vitamin C	Non-Exempt			Vitamins	✓ Ankle and Foot Disorders ✓ Cervical and Thoracic Spine Disorders ✓ Chronic Pain ✓ Low Back Disorders			

Now let's examine the MTUS Drug List, which is adopted into the formulary regulations. This slide shows the first page of the Drug List. The list is posted on the DWC website in PDF and Excel formats.

### MTUS Drug List ( 8 CCR §9792.27.15)

The MTUS Drug List must be used in conjunction with 1) the MTUS Guidelines, which contain specific treatment recommendations based on condition and phase of treatment and 2) the drug formulary rules. (See 8 CCR §9792.20 - §9792.27.23.) "Reference in Guidelines" indicates guideline topic(s) which discuss the drug. In each guideline there may be conditions for which the drug is Recommended (✓), Not Recommended (X), or No Recommendation (⊖). Consult guideline to determine the recommendation for the condition to be treated and to assure proper phase of care use.

\*Example/Non-Example

"Example" indicates drug may be prescribed/dispensed without seeking authorization through Prospective Review if in accordance with MTUS.

1) Physician dispensed "Example" drug limited to one 7-day supply at initial visit within seven days of the date of injury without Prospective Review.

2) Prescription/dispensing of Brand name "Example" drug where generic is available requires authorization through Prospective Review.

"Non-Example" or "Unlisted" drug requires authorization through Prospective Review prior to prescribing or dispensing. (See 8 CCR §9792.27.1 through §9792.27.23 for complete rules.)

\*\*Special Fill - Indicates the Non-Example drug may be prescribed/dispensed without Prospective Review: 1) Rx at initial visit within 7 days of injury, and 2) Supply not to exceed #days indicated, and 3) is a generic or single source brand, or brand where physician substantiates medical necessity, and 4) if in accord with MTUS. (See 8 CCR § 9792.27.12.)

\*\*\*Perioperative Fill - Indicates the Non-Example drug may be prescribed/dispensed without Prospective Review: 1) Rx issued during the perioperative period (4 days before through 4 days after surgery), and 2) Supply not to exceed #days indicated, and 3) is a generic or single source brand, or brand where physician substantiates medical necessity, and 4) is in accord with MTUS. (See 8 CCR § 9792.27.13.)

	Drug Ingredient	Reference Brand Name	Exempt/Non-Exempt*	Special Fill**	Peri-Op***	Drug Class	Reference in Guidelines	Dosage Form	Strength	Unique Pharmaceutical Identifier(s)
1	Acetaminophen	Tylenol	Example			Analgesic-Nonsteroidal	<ul style="list-style-type: none"> <li>✓ Pain and Fever Disorders</li> <li>✓ Cervical and Thoracic Spine Disorders</li> <li>✓ Chronic Pain</li> <li>✓ Eye Disorders</li> <li>✓ Eye</li> <li>✓ Head, Neck, and Postural Disorders</li> <li>✓ Hip and Groin Disorders</li> <li>✓ Knee Disorders</li> <li>✓ Low Back Disorders</li> </ul>			

The MTUS Drug List must be used in conjunction with 1) the MTUS Guidelines, which contain specific treatment recommendations based on condition and phase of treatment and 2) the drug formulary rules. (See 8 CCR §9792.20 - §9792.27.23.) "Reference in Guidelines" indicates guideline topic(s) which discuss the drug. In each guideline there may be conditions for which the drug is Recommended (✓), Not Recommended (X), or No Recommendation (⊖). Consult guideline to determine the recommendation for the condition to be treated and to assure proper phase of care use.

\* Exempt/Non-Exempt  
 "Exempt" indicates drug may be prescribed/dispensed without seeking authorization through Prospective Review if in accordance with MTUS.  
 1) Physician dispensed "Exempt" drugs limited to one 7-day supply at initial visit within seven days of the date of injury without Prospective Review.  
 2) Prescription/dispensing of Brand name "Exempt" drug where generic is available requires authorization through Prospective Review.  
 "Non-Exempt" or "Unlisted" drug requires authorization through Prospective Review prior to prescribing or dispensing. (See 8 CCR §9792.27.1 through §9792.27.23 for complete rules.)

\*\* Special Fill - Indicates the Non-Exempt drug may be prescribed/dispensed without Prospective Review: 1) Rx at initial visit within 7 days of injury, and 2) Supply not to exceed #days indicated, and 3) is a generic or single source brand, or brand where physician substantiates medical necessity, and 4) if in accord with MTUS. (See 8 CCR § 9792.27.12.)

\*\*\* Perioperative Fill - Indicates the Non-Exempt drug may be prescribed/dispensed without Prospective Review: 1) Rx issued during the perioperative period (4 days before through 4 days after surgery), and 2) Supply not to exceed #days indicated, and 3) is a generic or single source brand, or brand where physician substantiates medical necessity, and 4) is in accord with MTUS. (See 8 CCR § 9792.27.13.)

14	Ascorbic Acid	Vitamin C	Non-Exempt			Vitamins	<ul style="list-style-type: none"> <li>✓ Pain and Fever Disorders</li> <li>✓ Cervical and Thoracic Spine Disorders</li> <li>✓ Chronic Pain</li> <li>✓ Low Back Disorders</li> </ul>			
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At the top of the MTUS Drug List, is a condensed narrative overview of ancillary formulary rules such as Physician Dispensing rule, Generic vs. Brand rule, and Special Fill and Perioperative Fill Policies.

### MTUS Drug List ( 8 CCR §9792.27.15)

The MTUS Drug List must be used in conjunction with 1) the MTUS Guidelines, which contain specific treatment recommendations based on condition and phase of treatment and 2) the drug formulary rules. [See 8 CCR §9792.22 - §9792.27.23.] "Reference in Guidelines" indicates guideline(s) which discuss the drug. In each guideline there may be conditions for which the drug is Recommended (✓), Not Recommended (✗), or No Recommendation (□). Consult guideline to determine the recommendation for the condition to be treated and to assure proper phase of use only.

\*Exempt/Non-Exempt  
 "Exempt" indicates drug may be prescribed/dispensed without seeking authorization through Prospective Review if in accordance with MTUS.  
 1) Physician dispensing "Exempt" drug limited to one 7-day supply at initial visit within seven days of the date of injury without Prospective Review.  
 2) Prescription/dispensing of "Exempt" drug where generic is available requires authorization through Prospective Review.  
 "Non-Exempt" or "Informed" drug requires authorization through Prospective Review prior to prescribing or dispensing. [See 8 CCR §9792.27.1 through §9792.27.23 for complete rules].

\*\*Special Fill: Indicates the Non-Exempt drug may be prescribed/dispensed without Prospective Review: 1) for an initial visit within 7 days of injury, and 2) supply not to exceed days indicated, and 3) in a generic or single source brand, or brand where physician substantiates medical necessity, and 4) if in accord with MTUS. [See 8 CCR § 9792.27.12.]

\*\*\*Perioperative Fill: Indicates the Non-Exempt drug may be prescribed/dispensed without Prospective Review: 1) the brand during the perioperative period (4 days before through 4 days after surgery) and 2) supply not to exceed #days indicated, and 3) in a generic or single source brand, or brand where physician substantiates medical necessity, and 4) in in accord with MTUS. [See 8 CCR § 9792.27.13.]

Drug Ingredient	Reference Brand Name	Exempt/Non-Exempt*	Special Fill**	Peri-Op***	Drug Class	Reference in Guidelines	Dosage Form	Strength	Unique Pharmaceutical Identifier(s)
Acetaminophen	Tylenol	Exempt			Analgesic - NonNarcotic	✓ Cervical and Thoracic Spine Disorders ✓ Chronic Pain ✓ Knee Disorders ✓ Hip and Groin Disorders ✓ Wrist, Wrist, and Forearm Disorders ✓ Hip and Groin Disorders			
Albuterol Sulfate	Proventil	Non-Exempt			alpha 2-agonist	✗ Knee Disorders ✗ Low Back Disorders			
Albuterol Sulfate	Proventil	Exempt			Antiarrhythmic and Bronchodilator Agents	✓ Work Related Injuries			
Albuterol Sulfate	AccuNeb	Non-Exempt			Antiarrhythmic	✓ Ankle and Foot Disorders			
Albuterol Sulfate	Proventil	Exempt			Endocrine and Metabolic Agents - Misc. (Ephedrine/ephedrine)	✓ Cervical and Thoracic Spine Disorders ✓ Chronic Pain ✓ Hip and Groin Disorders ✓ Knee Disorders ✓ Low Back Disorders ✓ Shoulder			
Amoxicillin HCL	Symonol	Non-Exempt			Anticancer Agents (NSAID receptor antagonist)	✗ Chronic Pain ✗ Low Back Disorders			
Amoxicillin	Cyclocol	Non-Exempt			Antimicrobials	✓ Ankle and Foot Disorders			
Amoxicillin HCL	Elavil	Non-Exempt			Antidepressants (TCAs)	✓ Cervical and Thoracic Spine Disorders ✓ Chronic Pain ✓ Hip and Groin Disorders ✓ Low Back Disorders ✓ Shoulder			
Amoxicillin Sulfate	Novoran	Non-Exempt			Calcium Channel Blockers	✓ Hand, Wrist, and Forearm Disorders			
Amoxicillin/Clavulanic Acid	Augmentin	Exempt			Antibiotics (Penicillins)	✓ Ankle and Foot Disorders ✓ Hand, Wrist, and Forearm Disorders ✓ Low Back Disorders			
Anesthetics	Elavil	Non-Exempt			Antipsychotics - Atypical	✓ Knee Disorders			
Apixiban	Elipix	Non-Exempt	14 Days		Anticoagulants	✓ Ankle and Foot Disorders ✓ Hip and Groin Disorders ✓ Knee Disorders			
Artificial Tear Substances	Bathub PW	Exempt			Anticholinergic Agents (Anticholinergic)	✓ Ankle and Foot Disorders ✓ Hip and Groin Disorders			
Ascorbic Acid	Vitamin C	Non-Exempt			Vitamins	✓ Cervical and Thoracic Spine Disorders ✓ Chronic Pain ✓ Low Back Disorders			

Looking at the headings we can see that the MTUS Drug List is:

- Organized by active drug ingredient
- Lists a Reference Brand name for most of the drugs
- Designates the Exempt or Non-Exempt status for each drug
- It designates drugs which are eligible for the Special Fill & Perioperative Fill by including a “# of days supply” entry
- The Drug class is listed
- The Reference in Guidelines column lists the ACOEM Treatment Guidelines adopted into the MTUS that address the drug, and each entry includes a symbol to indicate the type of ACOEM recommendations that are in each guideline. We will discuss this column in greater detail shortly.

### MTUS Drug List ( 8 CCR §9792.27.15)

The MTUS Drug List must be used in conjunction with 1) the MTUS Guidelines, which contain specific treatment recommendations based on condition and phase of treatment and 2) the drug formulary rules. [See 8 CCR §9792.22 - §9792.27.23.] "Reference in Guidelines" indicates guideline(s) which discuss the drug. In each guideline there may be conditions for which the drug is Recommended (✓), Not Recommended (°), or Not Recommended (X). Consult guideline to determine the recommendation for the condition to be treated and to assure proper phase of use only.

\*Example: Non-Example  
 \*Example†: Indicates drug may be prescribed/dispensed without seeking authorization through Prospective Review if in accordance with MTUS.  
 † Physician dispensing "Example" drug listed in row 1- day supply at initial visit within seven days of date of injury without Prospective Review.  
 ‡ Prescription/dispensing of brand name "Example" drug where generic is available requires authorization through Prospective Review.  
 †† Non-Example†† or "Indirect" drug requires authorization through Prospective Review prior to prescribing or dispensing. [See 8 CCR §9792.27.1 through §9792.27.23 for complete rules].  
 ††† Special PEI: Indicates the Non-Example drug may be prescribed/dispensed without Prospective Review: 1) for an initial visit within 7 days of injury, and 2) supply not to exceed 30 days indicated, and 3) in a generic or single source brand, or brand where physician substantiates medical necessity, and 4) if in accord with MTUS. [See 8 CCR § 9792.27.12.]  
 †††† Participative PEI: Indicates the Non-Example drug may be prescribed/dispensed without Prospective Review: 1) for an initial visit within 7 days of injury, and 2) supply not to exceed 30 days indicated, and 3) in a generic or single source brand, or brand where physician substantiates medical necessity, and 4) in is in accord with MTUS. [See 8 CCR § 9792.27.13.]

	Drug Ingredient	Reference Brand Name	Exempt/Non-Exempt†	Special PEI**	Part-Opr**	Drug Class	Reference in Guidelines	Dosage Form	Strength	Unique Pharmaceutical Identifier(s)
1	Acetaminophen	Tylenol	Exempt			Analgesic - Non-Narcotic	✓/✓ Neck and Foot Disorders ✓/✓ Cervical and Thoracic Spine Disorders ✓/✓ Chronic Pain ✓/✓ Elbow Disorders ✓/✓ Eye ✓/✓ Hand, Wrist, and Forearm Disorders ✓/✓ Head and Neck Disorders ✓/✓ Shoulder			
2	Adalimumab	Humira				alpha Interferon	✓/✓ Shoulder ✓/✓ Low Back Disorders			
3	Albuterol Sulfate	Proventil	Exempt			Anticholinergic and Bronchodilator Agents	✓/✓ Work Related Injuries			
4	Alendronate Diphosphate	Arcorate	Non-Exempt			Teratogenic†	✓/✓ Ankle and Foot Disorders			
5	Alendronate Sodium	Fosamax	Non-Exempt			Endocrine and Metabolic Agents - Misc. (Biphosphonates)	✓/✓ Chronic Pain ✓/✓ Hip and Groin Disorders ✓/✓ Knee Disorders ✓/✓ Low Back Disorders ✓/✓ Shoulder			
6	Amoxicillin HCl	Symoviol	Non-Exempt			Antibiotic - Penicillin	✓/✓ Chronic Pain ✓/✓ Low Back Disorders			
7	Amoxicillin	Cyclovent	Non-Exempt			Antibiotic - Penicillin	✓/✓ Ankle and Foot Disorders			
8	Amitriptyline HCl	Elavil	Non-Exempt			Antidepressants (TCA)	✓/✓ Cervical and Thoracic Spine Disorders ✓/✓ Chronic Pain ✓/✓ Hip and Groin Disorders ✓/✓ Low Back Disorders ✓/✓ Shoulder			
9	Amitriptyline Hydrochloride	Normon	Non-Exempt			Calcium Channel Blocker	✓/✓ Hand, Wrist, and Forearm Disorders			
10	Amoxicillin/Clavulanate P	Augmentin	Exempt			Antibiotic (Penicillin)	✓/✓ Ankle and Foot Disorders ✓/✓ Hand, Wrist, and Forearm Disorders ✓/✓ Low Back Disorders			
11	Analecta	Elavil	Non-Exempt			Analgesic - NSAID - Selective	✓/✓ Knee Disorders			
12	Apixiban	Elipix	Non-Exempt		14 Days	Anticoagulants	✓/✓ Ankle and Foot Disorders ✓/✓ Hip and Groin Disorders ✓/✓ Knee Disorders			
13	Artificial Tear Substances	Refresh PM	Exempt			Ophthalmic Agents (Artificial Tears)	✓/✓ Eye			
14	Ascorbic Acid	Vitamin C	Non-Exempt			Vitamins	✓/✓ Ankle and Foot Disorders ✓/✓ Cervical and Thoracic Spine Disorders ✓/✓ Chronic Pain ✓/✓ Low Back Disorders			

- The last 3 columns, with the headings “Dosage Form”, “Strength” and “Unique Pharmaceutical Identifier” currently do not have data. They are reserved for future use, and the Division intends to consult with the Pharmacy & Therapeutics Committee on using these columns to enhance the usefulness of the Drug List.

All of the drugs contained in the MTUS Drug List are drugs that are addressed by the ACOEM treatment guidelines that have been adopted into the MTUS. The MTUS Drug List is not a stand alone document, and must be used in conjunction with the ACOEM treatment guidelines adopted in the MTUS. Later in the presentation Lucy Shannon of the REED Group will be demonstrating the ACOEM guidelines and formulary tool and will explain how to obtain a license from the REED Group. Next we will examine some important features of the MTUS Drug List in greater depth.

## MTUS Drug List - Exempt Drugs

- Exempt Drug Criteria
  - Being noted as a first line therapy weighs in favor of being Exempt.
  - Recommended for most acute and or acute/chronic conditions addressed in clinical guidelines weighs in favor of being Exempt.
  - A safer adverse effects (risk) profile weighs in favor of being Exempt.
  - Drugs listed for the treatment of more common work-related injuries and illnesses weighs in favor of being Exempt.
- No Prospective Review (PR) if in accord with MTUS (But, note PR requirements for exempt Physician Dispensed and Brand Name Drugs)

To assist in the provision of timely care, and with a focus on the critical acute phase of treatment, we have designated certain medications as Exempt Drugs on the MTUS Drug list.

Criteria considered in designating a drug as Exempt are listed on this slide.

In short, Exempt Drugs are those that are generally safe and effective in the treatment of the acute phase of common work-related injuries and illnesses.

Exempt Drug status should be of benefit to providers and their patients in that these medications will be provided to the injured worker with No Prospective Review as long as they are ordered in accord with the recommendations of the MTUS guidelines. However, the Physician Dispensing rule and Brand Drug rule need to be consulted for drugs otherwise designated as “Exempt”.

Let me note here that there may certainly be situations where a Non-Exempt drug will be appropriate and supported by the guidelines.

## Reference in Guideline

Drug Ingredient	Strength	Form	Route	Indication	Reference in Guidelines
Acetaminophen	325 mg	Tablet	Oral	Acetaminophen	✓⊗ Ankle and Foot Disorders ✓ Cervical and Thoracic Spine Disorders ✓ Chronic Pain ✓× Elbow Disorders ✓ Eye ✓× Hand, Wrist, and Forearm Disorders ✓ Hip and Groin Disorders ✓ Knee Disorders ✓ Low Back Disorders ✓ Shoulder

- (✓) Recommended
- (×) Not Recommended
- (⊗) No Recommendation

Drug Ingredient
Acetaminophen

Reference in Guidelines
<ul style="list-style-type: none"> <li>✓⊗ Ankle and Foot Disorders</li> <li>✓ Cervical and Thoracic Spine Disorders</li> <li>✓ Chronic Pain</li> <li>✓× Elbow Disorders</li> <li>✓ Eye</li> <li>✓× Hand, Wrist, and Forearm Disorders</li> <li>✓ Hip and Groin Disorders</li> <li>✓ Knee Disorders</li> <li>✓ Low Back Disorders</li> <li>✓ Shoulder</li> </ul>

Now let's take deeper look at the Reference in Guidelines column

This column indicates which ACOEM Guidelines address the drug.

Taking the example of acetaminophen, we see that 10 different guidelines address the medical evidence for use of acetaminophen.

The Reference in Guideline Column cannot be used on its own. It must be used in conjunction with the underlying ACOEM Guideline adopted in the MTUS. This column is intended to be a quick reference for determining which guideline topics should be consulted for a particular disorder or condition.

The legend for the symbols is set forth in the narrative information at the top of the MTUS Drug List.

We have enlarged them here.

These symbols indicate which types of evidence-based recommendations are contained in each guideline.

“Recommended” means that the drug has sufficient evidence-based support to use the drug for one or more of the conditions in the guideline.

“Not Recommended” means that the medical evidence is sufficient to have a recommendation against use of the drug for one or more conditions in the guideline.

And “No recommendation” means that there is not sufficient evidence for a recommendation for or against use of the drug for one or more of the conditions covered in the guideline. But again, you have to go to the applicable guideline and review the entire

recommendation to properly use a medication on the MTUS Drug List.

## Reference in Guideline – Example Acetaminophen

- Listed as “Exempt” on the MTUS Drug List

Reference in Guidelines
✓⊙ Ankle and Foot Disorders
✓ Cervical and Thoracic Spine Disorders
✓ Chronic Pain
✓× Elbow Disorders
✓ Eye
✓× Hand, Wrist, and Forearm Disorders
✓ Hip and Groin Disorders
✓ Knee Disorders
✓ Low Back Disorders
✓ Shoulder

- Consult the ACOEM Elbow Disorders Guideline adopted in the MTUS to determine if acetaminophen is recommended for the condition to be treated, and for the phase of care

Let’s look at the example of the entry for Acetaminophen on the MTUS Drug List. It is listed as “Exempt”. This means it is exempt from prospective utilization review as long as its use is consistent with the ACOEM Guideline adopted in the MTUS.

The Reference in Guideline column shows that 10 guidelines have evidence based recommendations for use of Acetaminophen.

Each guideline addresses many different types of conditions or injuries, and Acetaminophen may have evidence of benefit for some but not all of the conditions. If we look at the Elbow Disorders guideline, we would see that many conditions are covered, including ulnar neuropathy at the elbow.

Based on the evidence reviews, the guidelines contain recommendations on whether to use Acetaminophen to treat the conditions, which may depend on the phase of care.

Let’s look at a few screen shots from the MDGuideline’s website to illustrate some of these points.

The screenshot displays the MDGuidelines website interface. At the top, there is a search bar with the text "Search for a topic or medical code...". Below the search bar, there are navigation tabs: "DURATION VIEWS", "ICD MAPPING", "CROSSWALKS", "DART", and "FORMULARY". The "FORMULARY" tab is selected. Below the navigation tabs, there is a "Powered by ACOEM" logo and a link to "Learn more about the Formulary Change Report (May 20, 2017)".

The main search area has two tabs: "Search by Condition" (selected) and "Search by Drug". Below the tabs, there is a "Drug Name:" field containing "ACETAMINOPHEN (Tylenol)". There is a checkbox labeled "I have read and accepted the Terms of Use" which is checked. A "Go" button is located below the checkbox.

The search results are displayed under the heading "Drug Detail ACETAMINOPHEN (Tylenol)". Below the heading, there is a "Class" field with the value "ANALGESICS - NonNarcotic" and an "Avg. Estimated Cost" field with the value "\$0.07".

Below the class and cost information, there is a filter section with the text "Filter or sort by column headers". There are five filter columns: "Category", "Condition", "Phase", "Pain Classification", and "Evidence Support". Each column has a dropdown menu. The "Category" dropdown is set to "Elbow Disorders", "Condition" is set to "Ulnar Neuropathy at the Elbow", "Phase" is set to "All", "Pain Classification" is set to "All", and "Evidence Support" is set to "All".

Below the filter section, there is a table with three rows of results. Each row has a plus sign icon on the left. The first row shows "Elbow Disorders" for "Ulnar Neuropathy at the Elbow" with "Acute" phase, "Post-operative" pain classification, and "Yes, insufficient Evidence (1)" evidence support. The second row shows "Elbow Disorders" for "Ulnar Neuropathy at the Elbow" with "Acute" phase, "No pain classification", and "No, insufficient Evidence (1)" evidence support. The third row shows "Elbow Disorders" for "Ulnar Neuropathy at the Elbow" with "Chronic" phase, "No pain classification", and "No, insufficient Evidence (1)" evidence support.

At the bottom of the page, there is a footer with contact information: "1-800-442-4519 | guidelines\_sales@reedgroup.com | guidelines\_support@reedgroup.com | 10355 Westmoor Drive, Westminster, CO 80021". There are also links for "Terms of Use" and "Privacy Policy", and a copyright notice: "© 2001-2017 Reed Group, Ltd. All Rights Reserved."

First, here is what you would see if you searched for the use of Acetaminophen within the Elbow disorders chapter for the condition of Ulnar Neuropathy at the Elbow.

This screen shot shows that there are times that Acetaminophen is Recommended and other times it is Not Recommended for the treatment associated with the same condition.

MDGuidelines Search for a topic or medical code... Print Resources - HI, Raymond -

DURATION VIEWS ICD MAPPING CROSSWALKS DART FORMULARY

Search by Condition Search by Drug

Drug Name: ACETAMINOPHEN (Tylenol)

I have read and accepted the Terms of Use

Go

Drug Detail  
ACETAMINOPHEN (Tylenol)

Class ANALGESICS - NonNarcotic

Avg. Estimated Cost \$0.07

Filter or sort by column headers

Category	Condition	Phase	Pain Classification	Evidence Support
Elbow Disorders	Ulnar Neuropathy at the Elbow	All	All	All

Elbow Disorders Ulnar Neuropathy at the Elbow Acute Post-operative ✔ Yes, Insufficient Evidence (1) [Print](#)

Comments for Prescriber  
Caution is warranted for patients with liver disease, acetaminophen may not be indicated, or lower doses are recommended.  
May be preferable initial treatment for elderly patients and patients with increased gastrointestinal bleeding risks.  
Recommended for routine use to manage post-operative pain.  
Scheduled dosage is preferred for most patients, as needed is reasonable for mild to moderate symptoms.

Comments for Claims Professional  
Duration is generally limited to 2 to 6 weeks following surgical procedure.  
Recommended for routine use to manage post-operative pain.

ICD-9  
354.2

ICD-10  
G56.20, G56.21, G56.22

References  
p. 11, 125-126.

Elbow Disorders	Ulnar Neuropathy at the Elbow	Acute	No pain classification	<span style="color: red;">✘ No, Insufficient Evidence (1)</span>
Elbow Disorders	Ulnar Neuropathy at the Elbow	Chronic	No pain classification	<span style="color: red;">✘ No, Insufficient Evidence (1)</span>

In this slide , I have expanded the information available on the “Yes” recommendation...

MDGuidelines<sup>®</sup> Search for a topic or medical code... Print Resources - HI, Raymond -

DURATION VIEWS ICD MAPPING CROSSWALKS DART FORMULARY

**Ulnar Neuropathy at the Elbow**

... > DISORDERS > ELBOW DISORDERS > DIAGNOSIS AND TREATMENT RECOMMENDATIONS > ULNAR NEUROPATHY AT THE ELBOW > TREATMENT RECOMMENDATIONS

Overview  
Risk and Causation  
Signs and Symptoms  
Diagnosis  
Diagnostic Recommendations  
**Treatment Recommendations**  
Treatment Evidence  
Prognosis  
Follow-up Care  
Job Analysis

**NSAIDs and Acetaminophen for Treatment of Acute, Subacute, or Chronic Ulnar Neuropathies at the Elbow**

**Not Recommended.** NSAIDs and acetaminophen are not recommended as a primary treatment for acute, subacute, or chronic ulnar neuropathies at the elbow.

**NSAIDs and Acetaminophen for Post-operative Management of Ulnar Neuropathy-related Pain**

**Recommended.** NSAIDs and acetaminophen are recommended for post-operative pain management of ulnar neuropathy-related pain.

**Strength of Evidence – Recommended, Insufficient Evidence (I)**

*Indications:* Patients having recently undergone ulnar neuropathy surgical release. Generally, treat for 2 to 6 weeks post-op unless complications occur.

*Frequency/Dose/Duration:* See manufacturer's recommendations.

*Indications for Discontinuation:* Resolution of pain, adverse effects, intolerance

*Rationale:* There are no quality trials that address treatment for ulnar neuropathies. However, there are quality trials for treatment of CTS. A moderate-quality trial found an NSAID ineffective for treatment of CTS(453) and other studies appear to also suggest lack of efficacy (see Hand, Wrist, and Forearm Disorders chapter), thus by analogy, NSAIDs for ulnar neuropathies at the elbow are generally not recommended. However, in patients thought to have an inflammatory mechanism, they may be indicated. NSAIDs are not invasive and have low adverse effects profiles, particularly when used for short courses in occupational populations. Generic or over-the-counter formulations are low cost. A short course of an over-the-counter NSAID may be reasonable for select patients; however, routine use of NSAIDs for treatment of ulnar neuropathies is not recommended. There is one high-quality study in post-operative CTS patients indicating that for post-operative pain management, naproxen is superior to acetaminophen, which in turn is superior to placebo.(454) NSAIDs and acetaminophen may also facilitate the rehabilitation process without the impairments associated with opioids. Thus, by analogy, NSAIDs and acetaminophen are recommended for post-operative pain management of patients with ulnar neuropathy.

In this final shot, I have provided the actual ACOEM Treatment Guideline recommendations regarding Acetaminophen use in Ulnar Neuropathy at the Elbow. **This is what a health care provider would rely on.**

## MTUS Drug List – Non-Exempt Drugs

- Non-Exempt drugs are available to treat the injured worker
  - If use is medically necessary and authorized through Prospective Review
  - If the Special Fill policy is applicable
  - If the Perioperative Fill policy is applicable
- Non-Exempt designation should not be interpreted as meaning the drug is not appropriate; medical necessity of the drug for the patient's condition is determined under the usual MTUS rules

Now let's take a look at what the designation of "Non-Exempt" means.

In short, Non-Exempt Drugs are those medications that are generally used in the chronic phase of care, or have more risks associated with their use, or are used for less common work-related injuries and illnesses.

Drugs listed as Non-Exempt are covered in the ACOEM treatment guidelines and users may obtain guidance and recommendations there.

Let me emphasize that this formulary does not deny access to any FDA-approved drug, all non-exempt and any unlisted medications are available if medically necessary and approved through the usual prospective review process.

Let me also note here that there may certainly be situations where use of a Non-Exempt drug will be appropriate for the patient and supported by the guidelines.

# Spotlight on Opioids

## JOIN THE MOVEMENT

of health care practitioners committed to ending the opioid crisis at [TurnTheTideRx.org](http://TurnTheTideRx.org).



### Drug overdose deaths in the United States continue to increase in 2015

**91 AMERICANS** die every day from an **opioid overdose** (that includes prescription opioids and heroin).

Drug overdose deaths and opioid-involved deaths continue to increase in the United States. The majority of drug overdose deaths (more than six out of ten) involve an opioid.<sup>1</sup> Since 1999, the number of overdose deaths involving opioids (including prescription opioids and heroin) quadrupled.<sup>2</sup> From 2000 to 2015 more than half a million people died from drug overdoses. 91 Americans die every day from an opioid overdose.

We now know that overdoses from prescription opioids are a driving factor in the 15-year increase in opioid overdose deaths. The amount of prescription opioids sold to pharmacies, hospitals, and doctors' offices nearly

**Medication interactions. AVOID CONCURRENT OPIOID AND BENZODIAZEPINE USE WHENEVER POSSIBLE.**

**WHEN YOU PRESCRIBE**

**START LOW AND GO SLOW. IN GENERAL:**

- Start with immediate-release (IR) opioids at the lowest dose for the shortest therapeutic duration. IR opioids are recommended over ER/LA products when starting opioids.
- Avoid  $\geq 90$  MME/day, consider
- If prescribing  $\geq 50$  MME/day, increase follow-up frequency; consider offering naloxone for overdose risk.
- For acute pain: prescribe  $< 3$  day supply; more than 7 days will rarely be required.

**KEY CONCEPT**

**The Opioid Crisis.** Over-prescription of powerful opioid pain relievers beginning in the 1990s led to a rapid escalation of use and misuse of these substances by a broad demographic of men and women across the country.<sup>3</sup> This led to a resurgence of heroin use, as some users transitioned to using this cheaper street cousin of expensive prescription opioids. As a result, the number of people dying from opioid overdoses soared—increasing nearly four-fold between 1999 and 2014.<sup>4</sup>

**More than 40 PEOPLE** die every day from overdoses involving **prescription opioids**.

I'd like to spend a few minutes talking about opioid medications.

All of us have probably seen these disturbing headlines which have been so prevalent over the last several years.

**MDGuidelines** Enter search terms here... [Print](#) [Resources](#) [Hi, Raymond](#)

[DURATION VIEWS](#) [ICD MAPPING](#) [CROSSWALKS](#) [DART](#) [FORMULARY](#)

**Recommendations**

[... > STATE TREATMENT GUIDELINES > CALIFORNIA MTUS > OPIOIDS > TREATMENT RECOMMENDATIONS > ACUTE PAIN \(UP TO 4 WEEKS\)](#)

Comprehensive History and Physical Evaluation  
 Workers in Safety-Critical Jobs  
**Acute Pain (Up to 4 Weeks)**  
 Postoperative Pain (Up to 4 Weeks)  
 Subacute (1-3 Months) and Chronic Pain (>3 Months)  
 Discontinuation and Tapering of Opioids  
 Opioids Medications for Tapering, Treatment of Dependency and Addiction  
 Breakthrough Pain  
 Intrathecal Drugs  
 Prevention of Overdose Fatalities  
 Evidence

## Acute Pain (Up to 4 Weeks)

**Routine Use of Opioids for Treatment of Non-severe Acute Pain**  
**Strongly Not Recommended.**  
 Routine opioid use is strongly not recommended for treatment of non-severe acute pain (e.g., low back pain, sprains, or minor injury without signs of tissue damage).  
*Strength of Evidence – Strongly Not Recommended, Evidence (A)*  
*Level of Confidence – High*  
*Harms – May inadequately treat acute, severe pain.*  
*Benefits – Faster recovery, less debility, reduced accidents risks and risks of dependency or addiction.*

**Opioids for Treatment of Acute, Severe Pain**  
**Recommended.**  
 Opioids are recommended for treatment of acute, severe pain (e.g., crush injuries, large burns, severe fractures, injury with significant tissue damage) uncontrolled by other agents and/or with functional deficits caused by pain. They also may be indicated at the initial visit for a brief course for anticipated pain accompanying severe injuries (i.e., failure of other treatment is not mandatory). Tramadol<sup>®</sup> may be indicated if there is true allergy to nonsteroidal anti-inflammatory drugs (NSAIDs) and acetaminophen, other contraindication to an alternative medication, or insufficient pain relief with an alternative. A Schedule II opioid may be indicated for more severe pain. Recommend to taper off opioid use in 1 to 2 weeks.  
 Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than 7 days will rarely be needed. (CDC, 2016)

Let me show you a screen shot from the ACOEM Opioids Treatment guideline.  
 This is the recommendation on the use of opioids for Acute Pain.  
 Let me zoom in on the last paragraph of this recommendation... (next slide)

## Opioids for Acute Pain

Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than 7 days will rarely be needed. (CDC, 2016)

Let me read this from the ACOEM Opioid Guideline...

“Long-term opioid use often begins with treatment of acute pain. When opioids are used for acute pain, clinicians should prescribe the lowest effective dose of immediate-release opioids and should prescribe no greater quantity than needed for the expected duration of pain severe enough to require opioids. Three days or less will often be sufficient; more than 7 days will rarely be needed. (CDC, 2016)”

As noted in the ACOEM Guideline quoted here, the Centers for Disease Control has found that 3 days or less of opioid use is often sufficient.

## Long-Term Opioid Use Following Treatment of Acute Pain

- CDC MMWR – 3/17/17

- In a representative sample of opioid naïve, cancer-free adults who received a prescription for opioid pain relievers, the likelihood of chronic opioid use increased with each additional day of medication supplied starting with the third day, with the sharpest increases in chronic opioid use observed after the fifth and thirty-first day on therapy...

- <https://www.cdc.gov/mmwr/volumes/66/wr/pdfs/mm6610a1.pdf>

The CDC recommendation I mentioned on the previous slide was published in 2016. In 2017, the CDC released new findings as noted on this slide. They found that in patients being treated for acute pain, who were not previously using opioids, that the risk of still being on opioids a year later started increasing with the third day of opioid use, with a sharp increase on the fifth day.

In light of these findings, and consistent with opioid use recommendations, the MTUS formulary allows the urgent provision of appropriate opioids for severe acute pain without prospective review, but limits the supply to a maximum of 4 days unless authorization is obtained. This Special Fill provision of the MTUS Formulary will be discussed in more detail later in this webinar.

And for that discussion and additional information on the MTUS Formulary rules, I'll now turn the presentation over to my DWC colleague, Jackie Schauer...

## Brand Name Drugs; Generic Drugs

- **Pre-Formulary:** Per AB 1124, Labor Code §4600.1 applies to drugs dispensed *before* January 1, 2018, when the formulary becomes operative
  - 4600.1: Generic drug shall be dispensed unless M.D. specifies brand must be dispensed
- **Formulary:** AB 1124 - Preference for generic drug remains, brand name available if medically necessary and cost effective
  - Doctor may write a “Dispense as Written” (DAW) / “No Substitution” for a brand
  - To support a DAW brand name drug when less costly generic exists, must show *patient-specific factors* to support medical necessity of brand name drug
  - Document medical necessity of DAW brand in medical chart, Form 5021 or PR-2
  - Submit RFA and obtain authorization before the more costly brand name drug is dispensed

### Jackie

Thank you Dr. Meister. I am going to be discussing some of the ancillary rules that work in conjunction with the MTUS Guidelines and the MTUS Drug List.

First we will look at the rule regarding use of brand name and generic drugs.

Both brand name drugs and generic drugs are available to treat the injured worker.

Labor Code §4600.1 currently requires that a generic be dispensed unless the physician specifies the brand name drug must be dispensed.

As of January 1, 2018 the formulary regulation will govern the issue of generic vs. brand instead of Labor Code §4600.1.

The formulary regulations adopt a preference for generic drugs where the brand name drug is more expensive than the generic equivalent.

A doctor can write a prescription for a brand name drug and specify that it must be “Dispensed as Written” or “No substitution”.

However, if there is a less costly therapeutic equivalent, the doctor must substantiate the medical necessity of the more costly brand name drug, including the patient-specific factors that support the need for the brand that could not be met by the generic therapeutic equivalent.

The determination of whether the brand and the generic are therapeutic equivalents is based upon the Food and Drug Administration’s determination that the two drugs are assigned a Therapeutic Equivalence Evaluation Code beginning with the Letter “A”. These

therapeutic equivalence codes are set forth in the FDA's publication called The Orange Book.

## Special Fill of Designated Non-Exempt Drugs

- Special Fill policy allows dispensing without prospective review
  - Drug must be identified as Special Fill eligible on MTUS Drug List
  - Prescribed at the single initial Tx visit, within 7 days of DOI
  - Supply does not exceed limit listed on MTUS Drug List
  - Drug dispensed is generic, single source brand, or physician documents medical necessity of brand
  - Prescribed in accordance with MTUS Treatment Guidelines
- MPN or pharmacy network may provide expanded Special Fill

Drug Ingredient	Reference Brand Name	Exempt/Non-Exempt*	Special Fill**	Class	Reference in Guidelines
Baclofen	Lioresal	Non-Exempt	4 Days	Musculoskeletal Agents (muscle relaxants)	✓/× Cervical and Thoracic Spine Disorders ✓/×⊙ Chronic Pain ✓/× Hip and Groin Disorders ×⊙ Knee Disorders ✓/× Low Back Disorders ✓/× Shoulder

The Formulary regulations adopt a policy that we call “Special Fill”.

Under this policy, designated Non-Exempt drugs may be dispensed without prospective review if they meet the criteria.

In order to be eligible for the Special Fill, the drug must:

- Be designated as Special Fill - eligible on the MTUS Drug List
- the drug must be prescribed at the single initial Tx visit, which occurs within 7 days of the DOI
- The supply of the drug must not exceed the “# of days supply” listed on the MTUS Drug List, and
- The drug dispensed must be the generic drug if a generic version exists and is less expensive than the brand name drug.

However, where a doctor prescribes a more expensive brand name drug and indicates that no substitutions are allowed, he/she must document the medical necessity for the brand name drug rather than the generic drug. The doctor must specify patient-specific factors that support the medical necessity for the brand name drug.

Let’s look at a snip of the MTUS Drug List showing the entry for Baclofen, a muscle relaxant. We can see that it is designated as a Special Fill drug by looking at the Special Fill column of the MTUS Drug List

The Special Fill column indicates that a 4-day supply of Baclofen is eligible for the special fill.

The Reference in Guidelines column indicates which ACOEM Tx Guidelines adopted in the MTUS address Baclofen.

We can see that 5 of the Guidelines have Yes recommendations for use of Baclofen. The physician will need to review the relevant Guideline to see the recommendations for use of Baclofen in light of the patient's specific condition.

The MDGuideline's ACOEM Formulary Tool will allow users to search by drug name, and see recommendations for use of the drug by condition, pain severity, and phase of care.

The excel format of the MTUS Drug List is useful as it can be sorted by the various columns, so that someone wanting to see all the Special Fill eligible drugs can easily sort it by that field.

The Special Fill drugs include selected muscle relaxants, corticosteroids, and opioid analgesics. These drugs have a higher risk profile than many other medications, but may be urgently needed and therefore will not require prospective authorization when the Special Fill criteria are met. Currently all of the Special Fill drugs are specified for a 4-day supply. If the patient needs a longer course of treatment, the physician should obtain authorization, which can be requested on an expedited basis, if expedited review is warranted by the injured worker's condition.

## Perioperative Fill of Designated Non-Exempt Drugs

- Perioperative Fill allows dispensing without prospective review
  - Drug must be identified as Perioperative Fill eligible on MTUS Drug List
  - Prescribed during perioperative period (4 days before to 4 days after surgery – day of surgery is day Zero)
  - Supply does not exceed limit listed on MTUS Drug List
  - Drug dispensed is generic, single source brand, or physician documents medical necessity of brand
  - Prescribed in accordance with adopted ACOEM Treatment Guidelines

Drug Ingredient	Reference Brand Name	Exempt/Non-Exempt*	Special Fill**	Peri-Op***	Reference in Guidelines
Warfarin Sodium	Coumadin	Non-Exempt		14 Days	<input type="checkbox"/> Ankle and Foot Disorders <input checked="" type="checkbox"/> Hip and Groin Disorders <input checked="" type="checkbox"/> Knee Disorders

- MPN or pharmacy network may provide expanded Special Fill

The Perioperative Fill policy adopted in the Formulary regulations is similar to the “Special Fill” policy and covers designated Non-Exempt drugs.

In order to be eligible for the Perioperative Fill, the drug must meet the following criteria:

- the drug must be designated as Perioperative Fill - eligible on the MTUS Drug List
- the drug must be prescribed during the perioperative period, which the regulations define as 4 days before surgery, to 4 days after surgery
- The supply of the drug must not exceed the “# of days supply” listed on the MTUS Drug List
- The drug dispensed must be the generic drug if a generic version exists and is less expensive than the brand name drug.

However, where a doctor prescribes a more expensive brand name drug and indicates that no substitutions are allowed, he/she must document the medical necessity of the brand name drug.

Let’s look at a snip of the MTUS Drug List showing the entry for Warfarin Sodium, an anticoagulant.

We can see that it is designated as a Perioperative Fill drug by looking at the Perioperative Fill column of the MTUS Drug List

The Perioperative Fill column indicates that a 14-day supply of Warfarin Sodium is eligible for the perioperative fill.

The Reference in Guidelines column indicates which ACOEM Tx Guidelines adopted into the MTUS address use of Warfarin Sodium.

We can see that 3 of the ACOEM Guidelines address use of Warfarin Sodium. The Hip and Groin Disorders guideline and the Knee Disorders guideline both contain one or more recommendations supporting use of the drug. The physician will need to consult the guideline to determine which conditions are addressed, and the detailed recommendations for use.

The Reed Group's Formulary Tool will allow users to search by drug name, and see recommendations for use of the drug by condition, pain severity, and phase of care.

The excel format of the MTUS Drug List is useful as it can be sorted by the various columns, so that someone wanting to see all the Perioperative Fill eligible drugs can easily sort it by that field.

The Perioperative Fill drugs include selected anticoagulants, opioid analgesics, a muscle relaxant and an anticonvulsant.

Where a surgery is scheduled, and not performed on an emergency basis, the physician should obtain prospective authorization for the surgery, and for the related medications. However, the Perioperative Fill is available to provide medications where needed for appropriate patient care. For example, there may be an unexpected need for perioperative medication, or a need to change a medication if a patient has an adverse reaction to a previously authorized drug.

## Physician-Dispensed Drugs

- Physician-dispensed drugs must be authorized through prospective review, except as specified
  - Exempt drugs may be dispensed w/o prospective review if requirements met
    - Dispensed at the initial visit
    - Dispensed within 7 days of the date of injury
    - Use is in accordance with MTUS Treatment Guidelines
  - Special Fill
  - Perioperative Fill
- Physician dispensing can be restricted by provisions in a Medical Provider Network or a pharmacy benefit contract pursuant to Labor Code section 4600.2

One of the ancillary formulary rules governs the physician dispensing of pharmaceuticals. The Division is aware that physician dispensing can be convenient for the patient and recognizes that the Business and Professions Code allows a doctor to dispense drugs to patients for conditions the doctor is treating. However, research has shown that physician dispensing may sometimes be influenced by financial incentives. In order to strike a balance between patient convenience and assuring medical necessity of drug treatment, the formulary rules require authorization through prospective review before physician dispensing of a drug, except as set forth in the regulations.

There are 3 exceptions to the requirement for prospective review before the physician dispenses the drug.

- 1) Exempt drugs may be dispensed w/o PR if the drug is dispensed **at the initial visit** and is dispensed **within 7 days of the date of injury**. Use of the drug must be in accordance with the MTUS Treatment Guidelines
- 2) The 2<sup>nd</sup> and 3<sup>rd</sup> exceptions are where the physician is dispensing the drug under the Special Fill policy, or the Perioperative Fill policy.

Another important part of the regulation is the provision that recognizes that physician dispensing may be restricted pursuant to a Medical Provider Network agreement, or a pharmacy benefit contract pursuant to Labor Code § 4600.2.

In workers' compensation, the employer is required to provide reasonable and necessary medical treatment to cure or relieve the employee of the effects of the injury. For pharmaceutical treatment, this can be done through pharmacy-dispensed medications.

## Compounded Drugs – are they available to the injured worker?

- Compounded drugs (Title 8, CCR §9792.27.1 subd. (e))
  - Include any drug subject to federal or state compounding laws
  - Include both sterile and non-sterile compounds Compounded drugs require authorization through prospective utilization review prior to dispensing (Title 8, CCR, §9792.27.9 subd. (a))
- Must document *patient-specific factors* that support medical necessity of compounded drug instead of FDA-approved drug (Rx or OTC) (Title 8, CCR, §9792.27.9 subd. (a))
- Physician-dispensing of compounded drugs can be restricted by provisions of a Medical Provider Network, or pharmacy contract pursuant to Labor Code § 4600.2

The formulary regulations require that a compounded drug be authorized through Prospective Review before it is dispensed to the injured worker.

In order to obtain authorization, the physician must document the medical necessity and include patient-specific factors that require use of a compounded medication instead of a drug approved by the US Food and Drug Administration.

Some examples of situations that may warrant use of a compounded drug are a patient with an allergy to a dye or filler contained in the FDA approved drug, or a patient who cannot swallow a pill and needs a liquid form of a drug that is not available in that dosage form in an FDA-approved product.

The FDA approval process is intended to ensure safety and efficacy of drugs. Compounded drugs do not go through an FDA approval process.

## MTUS Drug Formulary – Off-Label Use

- Off-label Use of a drug shall be in accordance with the ACOEM Treatment Guidelines and MTUS rules
- Off-label use of an Exempt drug does not require Prospective Review if the use is in accordance with ACOEM Treatment Guideline
- Off-label use of Non-Exempt Drug or Unlisted Drug requires Prospective Review to determine medical necessity
  - ACOEM Tx Guideline presumed correct
  - Apply MTUS Medical Evidence Search Sequence, Quality and Strength of Evidence definitions, and MTUS Methodology for Evaluating Medical Evidence

AB 1124 directed the Division to provide “Guidance regarding how an injured worker may access off-label use of prescription drugs, when evidence-based and medically necessary” The formulary regulations implement this directive by tying the off label use into the treatment guidelines and the usual MTUS method for supporting treatment outside the guidelines.

What is “Off Label Use”?

The formulary regulations have a definition , which states that “Off Label Use” means “use of a drug for a condition, or in a dosage or method of administration, not listed in the drug’s FDA-approved labeling for approved use.”

Since the expressed legislative intent is that the off-label use be “evidence based” and medically necessary, the regulations provide that Off-Label Use of Exempt medications do not require Prospective Review if the off-label use is supported by the MTUS Treatment Guideline.

For Non-Exempt drugs or Unlisted Drugs, off-label use requires Prospective Review and the medical necessity will be governed by the usual rules, including the MTUS Medical Evidence Search Sequence, the quality and strength of evidence definitions, and the Methodology for Evaluating Medical Evidence.

## Additional Formulary Provisions

- Waiver of Prospective Review – allowed where a UR plan adopts a “Prior Authorization” program adopted per regulation §9792.7(a)(5)
- Treatment under health & safety regulations such as Cal/OSHA Blood Borne Pathogens standard, e.g. urgent post-exposure prophylaxis
- DWC may maintain and post a listing by NDC, RxCUI, or other unique pharmaceutical identifier, of drug products on the MTUS Drug List
- Updates to the MTUS Drug List will be made at least quarterly
- Pharmacy & Therapeutics Committee
  - Quarterly meetings open to the public
  - 3 Physicians (M.D.s and D.O.s) & 3 Pharmacists
  - DWC is accepting applications – submit on DWC Form MTUS PT-App
  - Role of P&T Committee is advisory

There are several other regulatory provisions that we would like to discuss briefly. One of the regulations is entitled “Waiver of Prospective Review”.

This section provides that prospective review may be waived where a Utilization Review plan adopts a “Prior Authorization” program pursuant to the UR regulation which is in §9792.7, subdivision (a)(5).

Another regulation section clarifies that the Drug Formulary does not relieve the employer of obligations to provide treatment under the California Health & Safety regulations, such as the Cal/OSHA Blood Borne Pathogens standard.

Another formulary regulation states that the DWC may maintain and post a listing of the MTUS Drug List by National Drug Code, RxCUI maintained by the National Library of Medicine, or other unique pharmaceutical identifier. The Division will be considering the usefulness of adopting such a list, and intends to seek input from the Pharmacy and Therapeutics Committee.

The regulations specify that Updates to the MTUS Drug List will be made at least quarterly, and will be adopted by an Administrative Director Order, which will be posted to the DWC web page.

The formulary regulations also address the composition, role and function of the Pharmacy & Therapeutics Committee.

There will be Quarterly meetings open to the public, chaired by the DWC Medical Director.

The role of the P&T Committee is to provide advice to the Administrative Director on updates to the Formulary.

The P&T Committee will be composed of 3 Physicians (M.D.s and D.O.s) & 3 Pharmacists.

DWC is now accepting applications to serve on the committee – The application form to use, and a conflict of interest disclosure form are posted on the DWC web site.

## Phased Implementation for Injuries Prior to January 1, 2018 / Transition Plan

- Injured worker (DOI < 1/1/2018) receiving course of Tx with Non-Exempt drug, unlisted drug, compounded drug
  - Treating physician required to submit the §9785 progress report (PR-2) and a Request for Authorization to address the ongoing drug treatment plan
    - Tx plan shall set forth a medically appropriate weaning, tapering, or transitioning of the injured worker to a drug pursuant to the MTUS, or
    - Tx plan shall provide supporting documentation to substantiate the continued medical necessity of the Non-Exempt drug, unlisted drug, or compounded drug pursuant to the MTUS
- PR-2 and Request for Authorization with Tx plan due with regularly scheduled §9785 progress report, or if not feasible by 4/1/2018

Now we will look at an important regulation relating to transition plans.

AB 1124 specifies that there should be a “phased implementation” for injuries prior to the effective date of the formulary.

This is accomplished by adopting a rule that specifically addresses workers injured before 1/1/2018 who are on an ongoing course of drug treatment.

We want to emphasize that the adoption of the formulary does not mean that all injured workers need to be transitioned to Exempt drugs.

A Non-Exempt drug or an unlisted drug or a compounded drug could be appropriate for the injured worker’s condition. It is important that the treating physician review the injured worker’s treatment plan, looking at the guidance in the applicable adopted ACOEM Treatment Guideline, or consider other evidence-based guidelines or studies if the condition is not covered in the ACOEM guidelines.

The formulary regulations refer to the usual reporting format to present the physician’s treatment plan, which is the Progress Report, or PR-2, required by §9785 of the regulations. Doctors are required by §9785 to submit a PR-2 no less frequently than every 45 days during ongoing treatment. Ideally, the treating physician will submit the transition plan, along with the RFA at the next PR-2 due date. If that is not feasible, the regulations allow the report, treatment plan, and RFA to be submitted by April 1, 2018.

## License for ACOEM Guidelines

- California requires the use of the MTUS Guidelines and MTUS Formulary for the care of workers' compensation patients.
- The MTUS Guidelines and MTUS Formulary are built on the foundation of ReedGroup's ACOEM Practice Guidelines and ACOEM Formulary and incorporates copyrighted ACOEM material.
- Using the MTUS (ACOEM) Guidelines and MTUS Drug List to treat patients, provide pharmacy services, adjust claims, provide legal services, or for UR/IMR decisions is considered a commercial use of the ACOEM material.
- A commercial license from ReedGroup is required to use the MTUS (ACOEM) Guidelines and MTUS Drug List for any of these commercial purposes.
- CA providers who are new subscribers may obtain an annual commercial license to the ACOEM guidelines and formulary at a discounted rate of \$100/year:  
<http://go.reedgroup.com/MTUS>
- Others may obtain license information by contacting ReedGroup / Joe Guerriero via email: [jguerriero@reedgroup.com](mailto:jguerriero@reedgroup.com) or by phone (720) 456-4387

This slide contains information on obtaining a license from the ReedGroup for commercial users of the ACOEM Guidelines and formulary and the MTUS Drug List.

ReedGroup is offering a special discounted price for new California medical provider subscribers. The web page link is set forth on the slide.

Persons and entities who are not medical providers should contact Joe Guerriero of the Reed Group to obtain a license.

Now I am pleased to introduce Lucy Shannon, Director of Editorial Research and Development at the Reed Group. She will demonstrate use of the ACOEM Guidelines and formulary tool.

## Resources

- DWC's Medical Treatment Utilization Schedule web page  
<http://www.dir.ca.gov/dwc/MTUS/MTUS.html>
- Administrative Director Order adopting evidence-based updates to MTUS (with addenda)  
<http://www.dir.ca.gov/dwc/DWCPropRegs/Medical-Treatment-Utilization-Schedule/Medical-Treatment-Utilization-Schedule.htm>
- DWC's Rulemaking web page; Approved Regulations (including MTUS Updates; MTUS Drug Formulary)  
[http://www.dir.ca.gov/dwc/rulemaking/dwc\\_rulemaking\\_approved.html](http://www.dir.ca.gov/dwc/rulemaking/dwc_rulemaking_approved.html)
- Office of Administrative Law for access to California Code of Regulations  
<https://oal.ca.gov/>
- ACOEM Guidelines published by the Reed Group – licensing web page / contact information  
<http://go.reedgroup.com/MTUS> (CA new medical provider subscribers)  
Others may obtain license information by contacting ReedGroup / Joe Guerriero via email:  
[jguerriero@reedgroup.com](mailto:jguerriero@reedgroup.com) or by phone (720) 456-4387

Thank you Lucy for the presentation.

We have compiled a list of useful resources related to the MTUS and formulary. The links will also be posted on the DWC website.

## Thank You for Attending the Formulary Webinar

- The recorded Formulary Webinar and slides will be posted on the DWC website for later viewing
- Please provide feedback and let us know of additional webinar topics that would be useful. Submit suggestions to: [formulary@dir.ca.gov](mailto:formulary@dir.ca.gov)

Thank you for attending today's MTUS Drug Formulary webinar.  
The recorded Formulary Webinar and slides will be posted on the DWC website for later viewing.