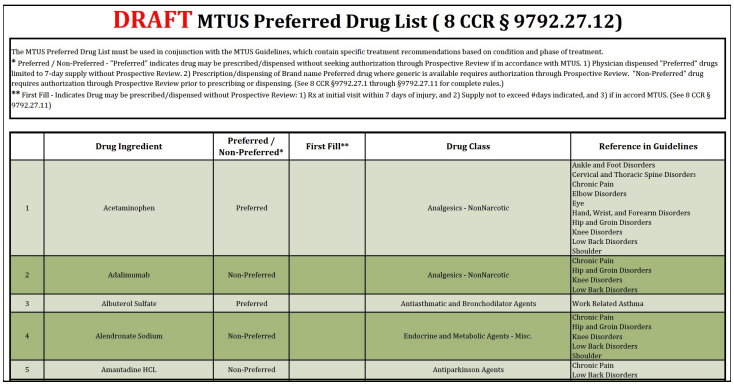
MINDER
Managing Disability

Dialogue

California Drug Formulary, A Novel Approach

Comments submitted to the DWC[1] Drug Formulary forum closed on September 16, 2016 with 67 submissions received from individuals expressing their opinions on the proposed approach. This article discusses solutions to some raised concerns.



DRAFT MTUS Preferred Drug List (8 CCR § 9792.27.12)

The MTUS Preferred Drug List must be used in conjunction with the MTUS Guidelines, which contain specific treatment recommendations based on condition and phase of treatment.
* Preferred / Non-Preferred - "Preferred" indicates drug may be prescribed/dispensed without seeking authorization through Prospective Review if in accordance with MTUS. 1) Physician dispensed "Preferred" drugs limited to 7-day supply without Prospective Review. 2) Prescription/dispensing of Brand name Preferred drug where generic is available requires authorization through Prospective Review. "Non-Preferred" drug requires authorization through Prospective Review prior to prescribing or dispensing. (See 8 CCR §9792.27.1 through §9792.27.11 for complete rules.)
** First Fill - Indicates 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) if in accord MTUS. (See 8 CCR § 9792.27.11)

	Drug Ingredient	Preferred / Non-Preferred*	First Fill**	Drug Class	Reference in Guidelines
1	Acetaminophen	Preferred		Analgesics - NonNarcotic	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
2	Adalimumab	Non-Preferred		Analgesics - NonNarcotic	Chronic Pain Hip and Groin Disorders Knee Disorders Low Back Disorders
3	Albuterol Sulfate	Preferred		Antiasthmatic and Bronchodilator Agents	Work Related Asthma
4	Alendronate Sodium	Non-Preferred		Endocrine and Metabolic Agents - Misc.	Chronic Pain Hip and Groin Disorders Knee Disorders Low Back Disorders Shoulder
5	Amantadine HCL	Non-Preferred		Antiparkinson Agents	Chronic Pain Low Back Disorders

In February 2015, Assembly-Member Henry T. Perea introduced AB1124 to establish an evidence-based drug formulary for California Workers' Compensation. His website stated, *"The central purpose of our workers' comp system is to ensure injured workers regain health and get back to work. When workers get addicted to dangerous medications, goals of the program are not met. An evidence based formulary has proven to be an effective tool in other states and should be considered in California."* In December 2015, Assembly-Member Perea resigned his seat before serving out the remaining year of his term and accepted a position on political advocacy in California, Arizona and Nevada with Pharmaceutical Research and Manufacturers of America (PhRMA).

"Will this novel approach create the turning point for improved claims management?"

To address AB1124 requirements, the DWC's formulary structure differs from the ODG[2] drug formulary used by Texas and some other states in that it does not reference NDCs[3]. It identifies drug names (or drug ingredients) which are cross-referenced to MTUS[4] medical condition guidelines. The approach of identifying a drug name (e.g. Diclofenac) in preference to listing NDCs is consistent with many published Group Health pharmacy formulary lists.

---

[1] Division of Worker' Compensation, Department of Industrial Relations, State of California.

[2] Official Disability Guidelines from Work Loss Data Institute.

[3] National Drug Code.

[4] Medical Treatment Utilization Schedule, Division of Workers' Compensation.

In keeping with Utilization Review practices (also known as Utilization Management) first introduced in California workers' compensation in 1993, the MTUS Preferred Drug List (i.e. Formulary) which is based on medical conditions, identified 259 drug ingredients. There were 73 ingredients identified as preferred and 186 as non-preferred, of which seven were identified with a first fill dispensing limit. Medications identified as preferred or first fill, adhere to the same DWC rules applicable to prior authorization, whereby a treating physician, pharmacy or PBM[5] will be assured of appropriate reimbursement. This approach provides an opportunity to significantly streamline and lower the excessively high claims administration costs currently experienced in California. The California Workers' Compensation Institute reported that medical cost containment expenses increased by 347% between 2002 and 2014.

A study[6] using data provided by the WCIRB[7] identified that in 2014, only 53 cents of each premium dollar was spent on injured workers' benefits of which 18 cents was spent on medical treatment during the recovery period. A follow-up study[8] using 2015 data identified injured workers' benefits had reduced to 51 cents and 17 cents respectively, suggesting overall costs to administer the Property & Casualty workers' compensation insurance product were excessive, accounting for 47 cents of each premium dollar in 2014 and 49 cents in 2015. The MTUS Preferred Drug List provides an opportunity to lower claims administrative costs by processing the vast majority of pharmaceutical invoices automatically using readily available technology with minimal human intervention.

The most common medical conditions treated under workers' compensation relate to sprains, strains, fractures, contusions, lacerations and punctures with between 75% and 85% of injured workers returning to work within one week[9]. With employers and physicians in California having 5 days to submit claim forms[10] to claims administrators, the vast majority of injured workers may well receive medical services including medications and return to work before the claims administrator is made aware of a claim. With this in mind, it appears the DWC has attempted to identify medications that would most generally be used in pharmacotherapy in the first week or weeks of medical treatment for a specified medical condition.

While some respondents suggest inclusion of the NDC in the drug list, the DWC approach which lists names of medications provides better monitoring of physician prescribing and pharmacy/PBM dispensing practices by claims administrators. California has used the Medi-Cal[11] formulary for pricing since 2004, whereas states such as Texas continue to use the Average Wholesale Price ("AWP"). In contrast to the Medi-Cal pricing list which is freely available from the DWC website, access to the AWP is generally obtained through some form of licensing agreement with organizations such as Medi-Span. Other organizations which have provided the AWP include Red Book from Truven Health Analytics and Blue Book from First DataBank. Computer systems such as the Minder system used here to illustrate the implementation of the MTUS, require access to the AWP as well as Medi-Cal pricing to approve and monitor prices paid for medications. In addition to Minder utilizing the AWP provided by Medi-Span, it uses other pharmaceutical data including data known as the "Generic Product Identifier ("GPI")".

While a number of respondents emphasized the need for the DWC to list preferred medications by NDCs, only three made reference to the GPI. While it is essential to have a code such as the NDC, Universal Product Code ("UPC") or Health Related Item ("HRI") at time of payment approval, it is not necessary for prior or pre-authorization of a drug ingredient. In fact, using an NDC during prior or pre-authorization could hinder or unnecessarily over complicate both these processes. A GPI is generally divided into a number of segments. In the case of Medi-Span, the first segment relates to a Drug Group, such as Migraine Products, Analgesics/Anti-inflammatory, Ophthalmic Agents and Ulcer Drugs. Each NDC is assigned a GPI code allowing drug ingredients to be matched by manufacturers for

---

[5] Pharmacy Benefit Manager.

[6] managingdisability.com Dialogue, Could Employers Cite Bad Faith with the P&Cs' Worker Comp Product in CA?

[7] Workers' Compensation Insurance Rating Bureau, California.

[8] managingdisability.com Dialogue, Benefits continue to decline as a percentage of premiums.

[9] insurancethoughtleadership.com Are Workers' Comp Systems Broken? July 6, 2016, Dr. Richard A. Victor, Sedgwick Institute.

[10] Employer's Report of Occupational Injury or Illness (Form CA5020), Doctor's First Report of Occupational Injury or Illness (Form 5021).

[11] California's Medicaid welfare program.

price comparisons, medication strengths as well as their drug combinations. Through this process, claims administrators can easily monitor pharmacies/PBMs to ensure they are dispensing the lowest priced medication, whether generic, brand name or trademark name. The Workers' Compensation Research Institute ("WCRI") reported through one of their studies that California claims administrators were paying between 35 cents and 70 cents for 5mg and 10mg cyclobenzaprine while at that time, the Medi-Cal unit price was 10 cents for 10mg and 15 cents for 5mg.

While the GPI concept is not unique and used by the World Health Organization ("WHO") as well as others, the use of the proprietary Medi-Span GPI code is well suited to the implementation of the DWC formulary, especially by claims administrators who are currently using their computer systems to monitor the cost of medications. The effort to establish the MTUS preferred drug list using the Medi-Span GPI is minimal as illustrated using Minder with very little ongoing maintenance, indicating it is a very cost effective solution.

To illustrate how the GPI can be used for the MTUS, the NSAID[12] medication diclofenac, which was raised in the forum has been selected. Diclofenac is available in potassium and sodium form as well as a free acid. As a potassium salt it is available in a number of medication forms such as tablets, liquid filled capsules and as a soluble powder all intended to treat different medical conditions. At least one respondent suggested this medication could be used in off-label prescribing if the MTUS did not specify the NDC. The specific example raised related to diclofenac potassium in powder form approved by the FDA[13] for treating migraines, with a trademark name of Cambia. In tablet form, it is available under the trademark name of Cataflam as well as other brands sold as generics. It is also available in a liquid filled capsule under the trademark name of Zipsor. Tablet and capsule forms are approved by the FDA as an analgesic/anti-inflammatory.

The following screen prints from the Minder system illustrate how the GPI has been used to automatically authorize pharmaceutical payments based on the MTUS list. Details relating to the claim and provider are fictitious and for illustrative purposes only. Medications shown are also not a true reflection of concomitant medications or quantities dispensed for the medical condition.

Prior and Pre-Authorization

In addressing the issue of overpayment for medical services often referred to as "leakage", most computer systems today provide some integrated means of establishing prior or pre-authorizations for provider services, especially medical services which are then used during bill review and approval. Minder is no exception. The first screen illustrates the method used for MTUS prior authorization for pharmacotherapy as well as pre-authorizations which could be established by a claims administrator. Six medication entries for a specific claim and medical provider are shown. Four entries are identified with a GPI code, the fifth entry is identified by an NDC and the last entry uses the first five digits of the NDC identifying the labeler code which is either the manufacturer, repackager or distributor of a medication. In a technology like Minder, the medical provider assigned to a claim has the option of either prescribing or dispensing prior or pre-authorized medications without impacting claims administration practices or the price of medications.

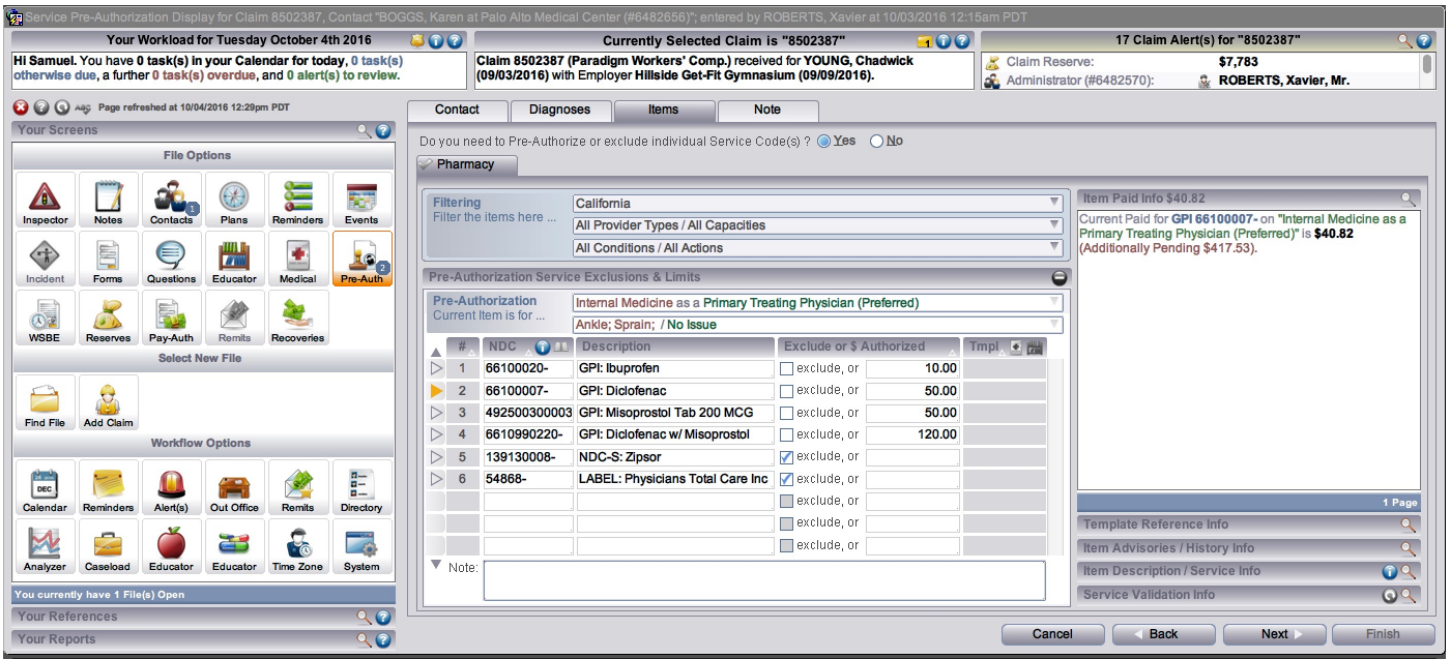
In this example, the Minder system has approved drug ingredient diclofenac as an analgesic/anti-inflammatory for a sprained ankle. Within the MTUS, diclofenac potassium is a preferred drug for ankle and foot disorders. Diclofenac sodium is non-preferred for ankle and foot disorders as well as non-preferred for hand, wrist and forearm disorders. However, diclofenac sodium combined with misoprostol, a medication used to prevent ulcers caused by certain types of medications (trademark name Arthrotec) is a preferred drug for hand, wrist and forearm disorders but not listed for ankle and foot disorders. This suggests there may be some inconsistency in the use of diclofenac sodium in the draft MTUS.

According to the manufacturer Pfizer, the pharmacokinetics profiles of Arthrotec are similar to the profiles of the two drugs when they are administered as separate tablets. For this reason, authorization was set for diclofenac instead of diclofenac potassium for approval in treating a sprained ankle. Also, the price difference is significant with diclofenac-misoprostol 50mg-200mcg priced at $2.36 for either

[12] Nonsteroidal Anti-Inflammatory agent.

[13] Food and Drug Administration.

the trademark product or generic compared to a diclofenac sodium 50mg tablet priced at 22 cents and misoprostol 200mcg priced at 86 cents, a total of $1.08 for the two tablets. This is a difference of $1.28 per tablet.



While claims administrators need to be aware of the pharmacodynamics and pharmacokinetics of a medication, pharmacoeconomic evaluation of a medication is important for prices paid being kept in check. This is very easily accomplished using the GPI. While the GPI identifies medications, it does not however identify the labeler of a particular drug. In instances where claims administrators may want to target a specific labeler's medication, they need to use an NDC or portion of the NDC as illustrated, where the trademark name medication Zipsor has been excluded. The claims administrator may also want to target a specific labeler, where medications from the repackager Physician Total Care Inc are excluded, which is also illustrated on the screen.

On the right hand side of the screen, bill review approval details are provided for a listed medication. In this case, the medication diclofenac highlighted with a right-pointing orange arrow, shows $40.82 paid with $417.53 pending review.

While the MTUS associates medical conditions with drug ingredients, Minder takes this further and includes the medical provider's speciality (e.g. Internal Medicine). It also provides a means to identify specific issues with a medical condition such as exaggerated for instance. In the first example, the text "no issues" appears after the medical condition, indicating it has been accepted as genuine. Prior and pre-authorization can be established at any of these additional Minder levels, providing greater granularity in the prior and pre-approval of medications. For example, the MTUS allows specific opioids to be prescribed as first fill for a specified number of days. Minder allows this to be restricted to specific specialties addressing issues raised in a study[14] where the overall top four specialities by volume of Schedule II prescriptions were Family Medicine, Internal Medicine, Nurse Practitioners and Physician Assistants. Through this feature, Minder further advances the objective stated by Assembly-Member Henry T. Perea of avoiding injured workers becoming addicted to dangerous medications. This approach can equally apply to a formulary such as Texas where it allowed Fentanyl transdermal patches (trademark name Duragesic) and morphine sulfate extended-release tablets (trademark name MS Contin) as first-line use. Both medications are described as potent and highly addictive, with fentanyl associated with a number of deaths caused by overdose[15]. Minder

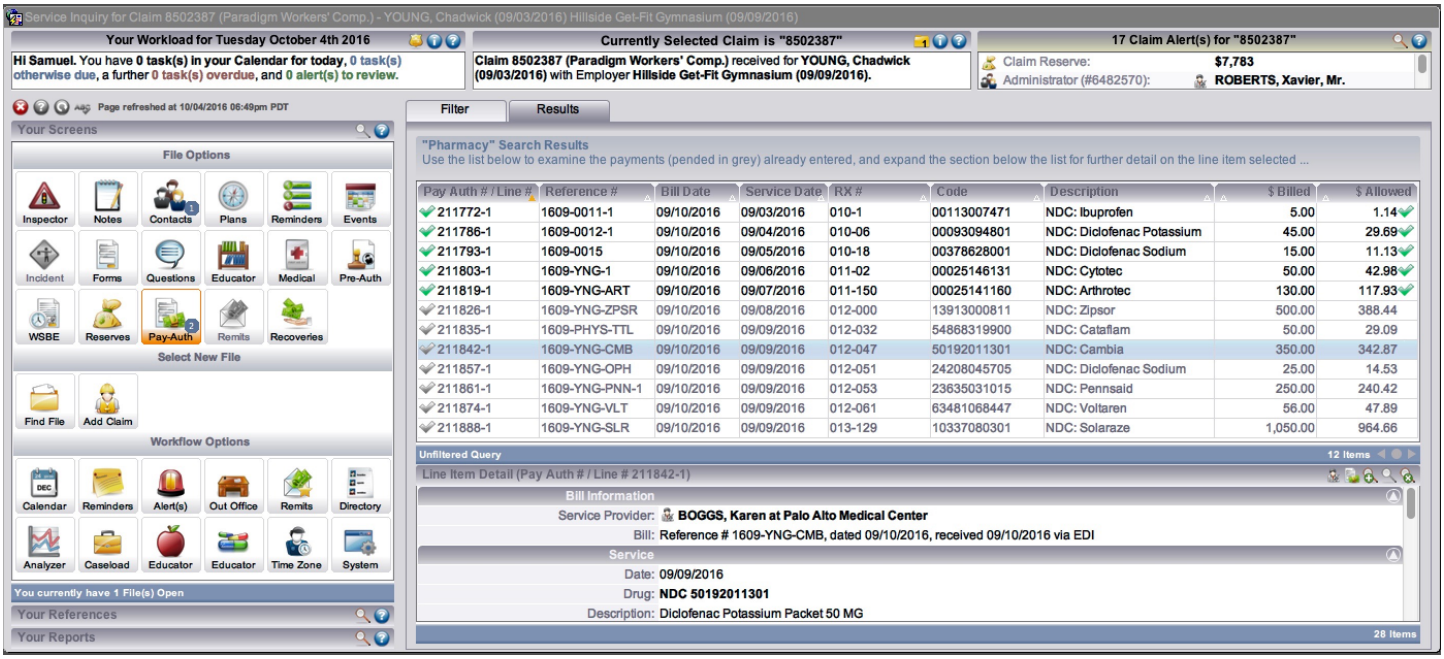
[14] JAMA Internal Medicine, December 2015, Distribution of Opioids by Different Types of Medicare Prescribers.

[15] managingdisabilty.com Dialogue, California Closed Formulary - benefit or detriment? Also, managingdisability.com Dialogue, Could Employers Cite Bad Faith with the P&Cs' Worker Comp Product in CA?, pages 28 - 29.

provides the opportunity to restrict these medications by specialty. Effective from February 1, 2016, the ODG has removed both medications from first-line use.

Pharmacy Inquiry

The second screen illustrates pharmaceuticals submitted for payment approval and how the payment authorization process is integrated with the prior and pre-authorization processes. There are twelve entries displayed of which five are highlighted with a green tick and the remainder appearing in a light grey color. The entries with the tick have been approved and paid automatically by Minder based on the GPI entries in the prior/pre-authorization screen. The two entries for diclofenac with NDC numbers 00093-0948-01 and 00378-6280-01 total $40.82, which is the amount shown as paid in the prior/pre-authorization screen. The two entries with NDC numbers 13913-0008-11 (Zipsor) and 54868-3199-00 (Cataflam) have not been paid as both were excluded in pre-authorization. These total $417.53, the amount shown as pending in the earlier screen print. Although all the remaining medications shown in grey such as Cambia are diclofenac, they have not been approved by the FDA as analgesics/anti-inflammatory medications and therefore have not been approved for treating a sprained ankle.



Using the DWC approach to identify preferred, non-preferred and first-fill drug ingredients in combination with a GPI allows minimal entry into a computer system as illustrated, with reliance on an NDC only when a specific medication brand requires attention by a claims administrator. NDC code lists can change frequently, including the Medi-Cal formulary, which if the MTUS was based on NDCs would require regular updating by the DWC, unnecessarily adding additional cost to employers' premiums which already account for a very high claims administrative cost. Currently, the Medi-Cal formulary is maintained by the California Department of Health Care Services.

While the MTUS provides opportunity to reduce the conflict between treating physicians and claims administrators with the intention of reducing the frequency for requests for treatment authorization by physicians as well as Independent Medical Reviews ("IMRs"), it must not be overlooked that claims administrators have a responsibility to appoint the most appropriate physicians to their MPN[16]. A review of the medical providers listed in the State Compensation Insurance Fund ("SCIF") MPN published in a study[17], questioned whether there was an adequate mix of specialities and whether adequate screening of providers was taking place prior to appointment. The injured worker is entitled to receive effective treatment and the employer expects this to be provided at the lowest possible cost.

[16] Medical Provider Network.

[17] managingdisability.com Dialogue, Could Employers Cite Bad Faith with the P&Cs' Worker Comp Product in CA?, pages 13 - 21.

For example, while the MTUS provides guidelines regarding preferred medications for specific medical conditions, pharmacotherapy may not always be necessary. A study[18] comparing Celebrex, ibuprofen and a placebo in the treatment of acute pain in grade 1 or grade 2 ankle sprain, suggested that for some, pharmacotherapy may not be necessary, instead treating with rest, ice, compression and elevation ("RICE") and physical therapy. In another double-blind, placebo-controlled comparative study[19], the efficacy and tolerability of 150mg/day of diclofenac potassium given for 7 days was superior to that of 1.2g/day of ibuprofen, concluding with diclofenac potassium to be effective in the treatment of acute ankle sprains with a rapid onset of action and good tolerability.

While guidelines may reference research studies with titles such as:

1. An assessment of the efficacy and safety of diclofenac potassium liquid-filled capsules in patients with various levels of baseline pain intensity,
2. Relative bioavailability of diclofenac potassium from softgel capsule versus powder for oral solution and immediate-release tablet formulation,
3. Prospective, randomized, open-label, pilot clinical trial comparing the effects of dexamethasone co-administered with diclofenac potassium or acetaminophen and diclofenac potassium mono therapy after third-molar extraction in adults,
4. Efficacy and tolerability of a new powdered formulation of diclofenac potassium for oral solution for the acute treatment of migraine: Results from the International Migraine Pain Assessment Clinical Trial (IMPACT),
5. Differential pharmacokinetics of diclofenac potassium for oral solution vs immediate-release tablets from a randomized trial: effect of fed and fasting conditions,
6. Pharmacokinetic comparison of an oral diclofenac potassium liquid-filled soft gelatin capsule with a diclofenac potassium tablet,

the claims administrator must at all times have trust and confidence in the physicians appointed to their MPN. This is best accomplished through a total integrated approach to claims management utilizing technology where guidelines like the MTUS for both treatment and pharmacotherapy are linked to medical conditions, which in turn are constantly measured against the practices followed by individual physicians and their specialty in claims administrators' MPNs. This heeds the principle that every claim is a one-person clinical trial, and by default creates a claims administrator's own evidence-based practice database.

It appears the DWC approach to establishing a formulary has provided an opportunity for claims administrators to take a step forward in achieving the goal of efficient claims management and reducing administrative costs without compromising the quality of medical services or employees' return to gainful and sustainable employment.

[18] Ekman et al (2002) was a 10-day, multicenter, double-blind, randomized, parallel-group, placebo-controlled trial to evaluate the efficacy and tolerability of Celebrex, ibuprofen or placebo in the treatment of moderate-to-severe acute pain in 445 adult patients with grade 1 or grade 2 ankle sprain.

[19] Double-blind comparison of diclofenac potassium, ibuprofen and placebo in the treatment of ankle sprains, Moran M, J, published 1991