

## Dialogue

## **Understanding Pricing of Pharmaceuticals**

Pharmaceuticals today are increasingly becoming a larger component of total medical treatment costs and a seemingly cost effective means of treating and managing injuries and illnesses.



Claims Administrators handling disability claims need to be extremely vigilant in tracking prices paid for pharmaceuticals from pharmacies and pharmacy benefit managers ("PBMs"), and request the National Drug Code ("NDC") for the dispensed medication in order to thoroughly understand the pricing variations between manufacturers, distributors and repackagers.

This article looks at the pharmaceutical price differences between suppliers of some of the highest paid and most frequently dispensed medications identified by the National Council

on Compensation Insurance ("NCCI") and the Workers' Compensation Research Institute ("WCRI") to treat work related injuries and illnesses.

The price for 100 generic meloxicam 7.5mg tablets can vary from \$3.98 up to \$262.99 depending on the manufacturer or distributor, excluding repackagers.

In the United States, the Food and Drug Administration ("FDA") regulates all pharmaceuticals sold to consumers and is responsible for assuring the safety, efficacy and security of all drugs. Since the Drug Listing Act of 1972 the FDA has required that all drugs, including over-the-counter ("OTC") drugs have an NDC. Those authorized to distribute pharmaceuticals in the United States are allowed to set their own prices, so ultimately, as with all free markets, the consumer establishes the price for a product by either choosing to buy or seeks an alternative - "Caveat Emptor [let the buyer beware]".

#### The NDC consists of three elements:

- the name of the labeler, which is the registered drug establishment for the specific drug,
- the name of the drug or product given by the labeler and
- 3. the receptacle type and content or package size.

#### NDC segment format

NDC	Labeler Name	Product Description	Package Size
00093-0058-01	Teva Pharmaceuticals	Tramadol HCI 50mg tablet	100 tablets bottle
00378-4151-01	Mylin Pharmaceuticals	Tramadol HCI 50mg tablet	100 tablets bottle
16714-0111-05	Northstar Rx	Tramadol HCI 50mg tablet	500 tablets bottle

The FDA assigns a labeler code to each registered establishment, some of which may have more than one labeler code. The second and third elements of the NDC are established at the labeler's discretion. Using the current California Workers' Compensation Official Medical Fee Schedule ("OMFS") for pharmaceuticals, the three NDCs used for Tramadol HCl 50mg tablets have the same unit price of 9 cents each. This amounts to \$9 for 100 tablets and \$45 for 500 tablets plus a dispensing fee of \$7.25 (except for skilled nursing homes or an intermediate care facility, which is \$8). Each of these NDCs has a different Average Wholesale Price ("AWP"), which in these examples appear to be significantly higher than the OMFS price.

Of the three general suppliers of medications, repackagers have been targeted by workers' compensation claims administrators as significantly contributing to the high pharmaceuticals cost in treating injured workers. This article suggests that claims administrators need to be equally aware of the prices paid for drugs and negotiate accordingly, regardless of whether paying for medications dispensed by a pharmacy, PBM or physician.

The FDA regards establishments that repackage medications (i.e. repackagers), as drug manufacturing operations which are subject to current Good Manufacturing Practice ("cGMP") regulations. These regulations require that repackagers 1) retain reserve samples from each lot or batch of drug product repackaged, 2) retain reserve samples from each shipment of each lot or batch of drug product received and 3) retain additional reserve samples of each separate repackaging operation, if the bulk drug product is not completely repackaged in a single operation.

Repackagers are <u>required to assign an NDC</u> for each of the drugs they repackage. In this process they establish their own price for each product and then sell their products on to pharmacies as well as physicians for dispensing from their offices.

PDRX and Stat Rx USA shown in the list of repackagers are subsidiaries of PPS World Medicine Inc (Physician Sales and Services), which were acquired by McKesson Corporation (<a href="https://www.mckesson.com">www.mckesson.com</a>) in February 2013.

Other establishments registered with the FDA as labelers include:

- Home Depot (42584), Workforce Essential Hand Sanitizer (NDC 42584-6409-8)
- Staples Office Superstore (49514), Antiseptic Hand Sanitizer (NDC 45914-253-09)
- Toys "R" Us (51334), Babies "R" Us Pain and Fever (NDC 51334-590-16) [liquid, acetaminophen 160mg in each 5ml]

#### Sample list of current repackagers

Labeler	NDC Labeler Code
Aidarex Pharmaceuticals	33261
A-S Medication Solutions	54569
Core Pharmaceuticals	33358
DRX	55045
PDRX	43063, 55289
Physician Partner	21695, 42254
Physicians Total Care	54868
Quality Care	35356,49999
Stat Rx USA	16590

## Dispensing of pharmaceuticals from a physician's office

began in 1982 and without the assistance of modern technology, made it less practicable than today. The introduction of computerized point-of-service (POS) systems, such as QuiqMeds Onsite Digital Pharmacy, which operates along the same principles as a vending machine, being able to stock between 500 and 700 receptacles of pre-packed drugs, allows physicians to dispense medications from their offices with minimal effort.

With physicians increasingly dispensing medications for both occupational and non-occupational injuries and illnesses, there has been a <u>pharmaceutical income shift</u> from pharmacies and PBMs to physicians. With this streamlined approach of medications being dispensed by physicians, there should in theory be a significantly lower price paid for pharmaceuticals compared to the prices being offered by pharmacies or PBMs, but according to workers' compensation claims administrators, this is not the case.

Pharmacies and PBMs have responded to this pharmaceutical income shift with aggressive efforts to emphasize the importance of the roles they each play. Further to this, pharmacies such as Walgreens and CVS Caremark have expanded their drug store walk-in clinics which are run by nurse practitioners and physician assistants. CVS Caremark have over 600 walk-in clinics called "MinuteClinic" which handle a variety of common illnesses and injuries and Walgreens have over 300 walk-in clinics called "Healthcare Clinic" which treat chronic diseases such as diabetes, asthma, high blood pressure in addition to ankle sprains, sinus infections and other minor conditions.

The September 2013, NCCI report titled, "Workers' Compensation Prescription Drug Study: 2013 Update", identified drugs that were dispensed during 2011 by total paid ranking. The report separated the top 10 drugs dispensed by physicians from the top 20 drugs dispensed in total by pharmacies, mail-order, physicians and others combined. The drugs listed below have been selected for price comparison between manufacturers and distributors (excluding repackagers unless stated otherwise) based on the California OMFS for pharmaceuticals.

#### Ranking by Dollars Paid in 2011

Drug	Physician Dispensed (Top 10)	Total Combined Dispensed (Top 20)
Oxycontin	Not in the top 10	1
Lidoderm	4	2
Gabapentin	3	4
Hydrocodone- Acetaminophen	6	5
Meloxicam	1	8
Omeprazole	7	Not in the top 20
Cyclobenzapine	8	11

This article refers to terms such as "generic", "brand name" and "trademark name" when describing medications. The concept of a generic drug versus a brand name drug is often confused and interpreted to mean that a generic drug is cheaper than a brand name drug. The following outline gives a brief description of the differences between these terms.

When a new drug is marketed, it has three names, 1) a chemical name, 2) a generic name and 3) a brand name. The chemical name is a scientific name based on the compound's chemical structure and is almost never used to identify the drug in a clinical or marketing situation. The generic name is granted by organizations, such as the United States Adopted Names Council (USAN). These organizations select simple, informative and unique nonproprietary names for drugs by establishing logical nomenclature classifications based on pharmacological and/or chemical relationships. For example, the chemical name Nacetyl-p-aminophenol is known by the generic name "paracetamol" by the International Nonproprietary Name (INN), Australian Approved Name (AAN) and British Approved Name (BAN), whereas in the United States (USAN) and in Japan (Japanese Adopted Name [JAN]) it is known as "acetaminophen". The company that patents the drug creates the brand name (trademark). This trademark name is used by the innovator company for the life of the drug, but more importantly, is used for the period it has either a drug patent or drug exclusivity on the medication. A drug such as acetaminophen (aka Paracetamol) is sold under many brand names including Tylenol and Panadol.

When a physician prescribes a medication, they may either state a generic name, such as acetaminophen or brand name such as Tylenol. If the physician prescribes a brand name drug, they also have the option to identify whether another generic drug can be substituted for the prescribed brand name.

If the physician prescribes a medication using either a generic name or a brand name and allows substitution, then the physician is allowing the pharmacist or PBM to dispense a particular brand they may have in stock, which may not necessarily be the lowest price for the medication as illustrated in this article.

The Non-steroidal Anti-Inflammatory ("NSAID") Analgesic Meloxicam available in both 7.5mg and 15mg strengths is sold as a generic drug and under the trademark name "Mobic". It is used to treat a number of medical conditions including rheumatoid arthritis. In the 7.5mg strength, repackager Physician Partner offers five package sizes ranging from 14 to 60 tablets, while repackager Stat Rx USA offers nine package sizes from 10 through to 100 tablets. Unichem Pharmaceuticals (a non-repackager) only offers two package sizes,

NDC 29300-0124-01 containing 100 tablets and NDC 29300-0124-10 containing 1,000 tablets. A random sample of 17 NDCs for Meloxicam 7.5mg selected for OMFS price comparison showed that in all cases, the AWP was higher than the OMFS price. The OMFS does not pay more for the trademark name "Mobic" than for its generic equivalent. However, if "no substitute" is stated on a prescription against a specific NDC, then the OMFS per tablet price changes significantly. For example, for the trademark name "Mobic" the price difference for 100 tablets changes from \$14.25 to \$573.48. For other generic brands, the price changes from \$3.98 (Zydus Pharmaceuticals) to \$262.99 (Lannett) for 100 tablets.

Boehringer Ingelheim Pharmaceuticals trademark name drug "Mobic", NDC 00597-0029-01 has the same OMFS price (\$0.1425) as a number of generics, except when "no substitute" is stated on the prescription, in which case the per tablet price increases to \$5.7348.

Lupid Pharmaceuticals (NDC 68180-0501-01) reduced their price from \$0.1425, effective December 11, 2013.

Zydus Pharmaceuticals NDC 68382-0050-01 and Lupid Pharmaceuticals NDC 68180-0501-01 sell Meloxicam for the lowest price of \$0.0398 per tablet. Unichem Pharmaceuticals NDCs 29300-01240-01 and 29300-0124-10 are the second lowest price per tablet at \$0.0498.

#### Meloxicam 7.5mg tablet

weloxicam 7.5mg tablet								
Labeler	NDC	Package Size	OMFS Price per Tablet	OMFS No Substitute Price				
Apotex (60505)	60505-2553-01	100	\$0.1425	\$2.6298				
Aurobindo Pharm (65862)	65862-0097-01	100	\$0.1425	\$2.6265				
Boehringer Ingelheim Pharmaceuticals (00597)	00597-0029-01	100	\$0.1425	\$5.7348				
Breckenridge (51991-0404-01)	51991-0404-01	100	\$0.1425	\$2.3118				
Carlbad Technologies (61442)	61442-0126-01	100	\$0.1425	\$2.3118				
Dr. Reddy's Laboratories (55111)	55111-0233-01	100	\$0.1425	\$2.6154				
Glenmark Pharmaceuticals (68462)	68462-0140-01	100	\$0.1425	\$2.5862				
International Labs Inc (54458)	54458-0965-10	30	\$0.1425	\$0.2770				
Lannett (00527)	00527-1419-01	100	\$0.1425	\$2.6299				
Lupid Pharmaceuticals (68180)	68180-0501-01	100	\$0.0398	\$0.0398				
Mylan (00378)	00378-1066-01	100	\$0.1425	\$2.6265				
Mylan Institutional (51079)	51079-0457-01	1	\$0.1425	\$2.6008				
Mylan Institutional (51079)	51079-0457-20	100	\$0.1425	\$2.6008				
Teva Pharmaceuticals (00093)	00093-7234-01	100	\$0.1425	\$2.6300				
Unichem Pharmaceuticals (29300)	29300-0124-01	100	\$0.0498	\$0.0498				
Unichem Pharmaceuticals (29300)	29300-0124-10	1,000	\$0.0498	\$0.0498				
Zydus Pharmaceuticals (68382)	68382-0050-01	100	\$0.0398	\$0.0398				

Gabapentin is an anti-convulsant medication often taken to treat nerve pain and is sold in tablet and capsule form in various dosages. Capsule strengths include 100mg, 200mg and 300mg and are sold by over 25 repackagers and over 30 non-repackagers including two labelers owned by McKesson Corporation. Repackagers, RxPak McKesson (65084), and non-repackager McKesson Packaging Service

(63739) both have drugs listed in the OMFS. Compared to four labelers selected at random, RxPak McKesson (repackager) has the lowest price for Gabapentin 300mg capsules at \$0.0614 per unit. The "no substitute price" ("OMFS No Sub Price") is significantly higher for two of the labelers, whereas for Actavis Elizabeth and West-Ward, there is no difference in the "no substitute" price.

#### Gabapentin 300mg Capsule

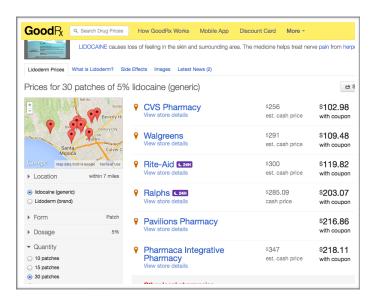
Labeler	NDC	OMFS Price per Capsule	OMFS No Sub Price	Comment
Major Pharmaceuticals (00904)	00904-5632-89	\$0.1238	\$1.7530	Added to OMFS in April 2014
McKesson Packaging Service (63739)	63739-0375-10	\$0.1238	\$1.3778	Identified as a non-repackager
Actavis Elizabeth (00228)	00228-2666-11	\$0.0872	\$0.0872	
West-Ward (00143)	00143-9993-01	\$0.0822	\$0.0822	
RxPak McKesson (65084)	65084-0370-14	\$0.0614		Identified. as a repackager. OMFS price reduced from \$1.1022 on March 31, 2010. All four package sizes are priced at \$0.0614 per capsule. Removed from OMFS in May 2014.

Litoderm is the trademark name for a Transdermal patch (topical dosage) containing the drug Lidocaine 5%, manufactured by Endo Pharmaceuticals (63481). Lidocaine is an anesthetic acting only on the local area it is applied to. Litoderm is repackaged by at least 18 repackaging establishments. The NDC is 63481-0687-06 and the OMFS price is \$8.6323 per patch. There was no generic equivalent until September 15, 2013.

A generic Lidocaine 5% Transdermal patch is now available from Watson Laboratories (owned by Actavis), NDC 00591-3525-30 with the OMFS price being \$7.4584 per patch. The website "GoodRx" shows pharmacies selling a pack of 30 Lidocaine 5%



Transdermal patches, ranging in price from \$102.98 to \$218.11. Using the OMFS price of \$7.4584 per patch, a pack of 30 would cost \$223.75, which is over 100% higher than the lowest available from a pharmacy. As an alternative, Lidocaine 5% is also available as an



ointment from Labeler Fougera Pharmaceuticals (00168) in a 35.44 grams tube (1½ oz), NDC 00168-0204-37 at the OMFS price of \$1.6862 per gram. Tube price \$59.76.

**Hydrocodone-Acetaminophen ("APAP")** is a combination of the two drugs Hydrocodone and Acetaminophen. Acetaminophen is also known as Paracetamol and more commonly by the brand names Tylenol and Panadol. Hydrocodone-APAP is available through at least 16 non-repackagers and 29 repackagers in a number of strength combinations ranging from 2.5mg/325mg to 10mg/750mg of Hydrocodone and Acetaminophen respectively.

The FDA has instigated two initiatives regarding Hydrocodone-APAP, 1) lower the maximum strength of Acetaminophen to 325mg to reduce the risk of liver damage and 2) reclassify Hydrocodone-APAP from a Schedule III to a Schedule II drug according to the U.S. Controlled Substances Act. Prescriptions for Schedule II medications cannot be refills. A new prescription is required to continue to take a Schedule II medication. This reclassification of Hydrocodone combination products to Schedule II also applies to Hydrocodone with Ibuprofen (NSAID), which is available in milligram strength combinations of 7.5/250 and 10/200 of Hydrocodone and Ibuprofen respectively.

APAP can also be combined with Codeine in solution and tablet form and are currently classified as Schedule V and Schedule III drugs respectively. According to publications available from sites such as the National Center for Biotechnology Information (<a href="www.ncbi.nim.nih.gov">www.ncbi.nim.nih.gov</a>) the efficacy and tolerability of APAP-Codeine are comparable to Hydrocodone-APAP combinations. The following tables show price comparisons between strengths of Hydrocodone-APAP and APAP with Codeine. Lowest prices for each strength are highlighted in blue. The drugs listed for Hydrocodone-APAP, showed no differences in price for the "no substitute" option.

#### Hydrocodone-Acetaminophen (various strengths, package size 100 unless stated otherwise)

Package sizes available for Hydrocodone-Acetaminophen from all labelers combined (manufacturers, distributors and repackagers): 1 (blister), 2, 3, 4, 5, 6, 7, 8, 9, 10, 12, 14, 15, 16, 18, 20, 21, 24, 25, 27, 28, 30, 32, 35, 36, 40, 42, 45, 48, 50, 56, 58, 60, 70, 75, 80, 82, 84, 90, 96, 99, 100, 112, 120, 126, 135, 140, 150, 160, 168, 180, 200, 224, 240, 252, 270, 300, 360, 500, 750, 1000

Drug strengths available for Hydrocodone-Acetaminophen (in Milligrams): 2.5-325, 2.5-500, 5-300, 5-325, 5-400, 5-500, 7.5-300, 7.5-325, 7.5-400, 7.5-500, 7.5-650, 7.5-750, 10-300, 10-325, 10-400, 10-500, 10-650, 10-660, 10-750

Qualitest Pharmaceuticals (00603) and Boca Pharmaceuticals (64376) are both owned by Endo International (60951,63481,99826). Endo Generic Products (60951) sell Oxycodone-Acetaminophen tablets in milligram strengths of 5-325, 7-325, 7.5-325,10-325 and 10-650.

Qualitest Pharmaceuticals (00603, a non-repackager) make the following tablet packages by strength (many of these package sizes would be suitable for dispensing through technologies available for physician dispensing): 2.5-100: 100 5-325: 30, 60, 90, 100, 120, 500, 1000 5-500: 30, 50, 60, 90, 100, 120, 180, 500, 1000 7.5-325: 90, 100, 120, 500, 1000 7.5-500: 60, 90, 100, 120, 500, 1000 7.5-650: 100, 500 10-325: 60, 90, 100, 120, 150, 180, 500, 1000 10-500: 30, 60, 90, 100, 120, 150, 500,

10-650: 30, 60, 90,100, 120, 180,500, 1000

1000

10-660: 100, 500

Labeler	NDC	Strength mg	OMFS price per tablet	Comment
KLE 2 (76218)	76218-1828-01	2.5-325	\$2.6872	Single manufacturer for this strength
Qualitest (00603)	00603-3880-21	2.5-500	\$0.2190	
Watson Labs (00591)	00591-0388-01	2.5-500	\$0.1918	
Boca Pharmaceuticals (64376)	64376-0648-01	5-300	\$1.5856	Single manufacturer for this strength
Qualitest (00603)	00603-3890-02	5-325	\$0.4500	
Mallinckrodt Pharm (00406)	00406-0365-01	5-325	\$0.4499	
Watson Labs (00591)	00591-3202-01	5-325	\$0.2989	
Endo Pharmaceuticals (63481)	63481-0668-70	5-400	\$0.5807	Trademark Name "Zydone". No OMFS price from March 1, 2014
Lortab (50474)	50474-0902-01	5-500	\$0.4763	No OMFS price from March 1, 2014
Mallinckrodt Pharm (00406)	00406-0357-01	5-500	\$0.2635	No OMFS price from March 1, 2014
Mallinckrodt Pharm (00406)	00406-0357-05	5-500	\$0.2635	No OMFS price from March 1, 2014. Package size 500
Abbott Laboratories (00074)	00074-3043-13	7.5-300	\$1.7964	Trademark Name "Vicodin ES"
Boca Pharmaceuticals (64376)	64376-0649-01	7.5-300	\$1.7784	
Mallinckrodt Pharm (00406)	00406-0366-01	7.5-325	\$0.5132	
Qualitest (00603)	00603-3891-02	7.5-325	\$0.5134	
Watson Labs (00591)	00591-2605-01	7.5-325	\$0.3376	
Endo Pharmaceuticals (63481)	63481-0669-70	7.5-400	\$0.5807	Trademark Name "Zydone". No OMFS price from March 1, 2014
Lorbat (50474)	50474-0907-01	7.5-500	\$0.6424	No OMFS price from March 1, 2014
Mallinckrodt Pharm (00406)	00406-0358-01	7.5-500	\$0.3556	No OMFS price from March 1, 2014
Watson Labs (00591)	00591-0358-01	7.5-500		Not in OMFS
Boca Pharmaceuticals (64376)	64376-0643-01	10-300	\$2.2945	Single Manufacturer for this strength
Mallinckrodt Pharm (00406)	00406-0367-01	10-325	\$0.5831	
Qualitest (00603)	00603-3887-02	10-325	\$0.5802	
Watson Labs (00591)	00591-0853-01	10-325	\$0.3188	
Endo Pharmaceuticals (63481)	63481-0698-70	10-400	\$0.7795	Trademark Name "Zydone". No OMFS price from March 1, 2014
Lorbat (50474)	50474-0910-01	10-500	\$0.5129	No OMFS price from March 1, 2014
Mallinckrodt Pharm (00406)	00406-0363-01	10-500	\$0.4421	No OMFS price from March 1, 2014
Qualitest (00603)	00603-3888-32	10-500	\$0.3991	No OMFS price from March 1, 2014. Package size 1,000

#### Acetaminophen with Codeine (various strengths, package size 100)

Labeler	NDC	Strength mg	OMFS price per tablet	OMFS No Sub Price
Teva Pharmaceuticals (00093)	00093-0050-01	300-15	\$0.1500	\$0.2527
Mallinckrodt Pharm (00406)	00406-0483-01	300-15	\$0.1500	\$0.4267
Teva Pharmaceuticals (00093)	00093-0150-01	300-30	\$0.2137	\$0.3000
Mallinckrodt Pharm (00406)	00406-0484-01	300-30	\$0.2137	\$0.5096
Teva Pharmaceuticals (00093)	00093-0350-01	300-60	\$0.3833	\$0.5301
Mallinckrodt Pharm (00406)	00406-0485-01	300-60	\$0.3833	\$0.9010
Qualitest (00603)	00603-2339-21	300-60	\$0.3833	\$0.5302

Omeprazole is an OTC drug used for a number of medical conditions including the treatment of ulcers and heartburn. There are over

20 repackagers and 30 non-repackagers selling Omeprazole 20mg in various forms (i.e. Tablet, Capsule, Suspension) and package sizes.

The FDA granted approval to Perrigo and its partner Dexcel Pharma Technologies Ltd to sell Omeprazole 20mg delayed-release tablets as a private label. In 2008 as the exclusive marketer and distributor, Perrigo began shipping to all the largest U.S. chain drug stores.

There were price variations <u>between labelers</u> for the <u>same package</u> size as illustrated with Walgreens and Target and also, variations between the <u>same labeler</u>, for the <u>same drug</u> with <u>different package</u> sizes as shown with Walgreens.

#### Omeprazole 20mg Delayed Release Tablet

Labeler	NDC	Name	Packet Size	OMFS Price per Tablet	Comment
Walgreens (00363)	00363-0915-01	Omeprazole	14	\$0.6516	
Walgreens (00363)	00363-0915-03	Omeprazole	42	\$0.4939	
Perrigo (00113)	00113-0915-30	Omeprazole	28	\$0.5463	
CostCo (63981)	63981-0915-55	KLS Omeprazole	42	\$0.4601	Packaging labeling states "Distributed by Perrigo for CostCo Wholesale Corporation"
Target (11673)	11673-0915-30	TGT Omeprazole	28	\$0.4695	Now branded "Up & Up"
Target (11673)	11673-0915-55	TGT Omeprazole	42	\$0.2869	
Wal-Mart (49035)	49035-0915-01	EQ-Omeprazole (Equate)	14		No price for this NDC in the OMFS
Wal-Mart (49035)	49035-0915-03	EQ-Omeprazole (Equate)	42		No price for this NDC in the OMFS

#### Cyclobenzaprine HCl is a musculoskeletal agent often dispensed as an adjunct to physical therapy for the relief of muscle spasm.

A random sample of 15 labelers selling Cyclobenzaprine HCl 10mg tablets showed that apart from three, all were priced in the OMFS at \$0.1035 per tablet for a pack of 100 tablets, regardless of their

AWP. The lowest price was 0.0443. In most cases, the OMFS "no substitute" price difference was <u>significantly higher</u>.

Amerisource Health Services (68084) is distributed by American Health Packaging, a subsidiary of AmerisourceBergen, one of the largest drug distributors in the U.S.

KVK Tech (10702), Amerisource Heath Services (68084) and Camber Pharmaceuticals (31722) sell below the \$0.1035 price.

#### Cyclobenzaprine HCI 10mg tablet (Package size 100)

Labaler	NDC	OMFS Price per Tablet	OMFS No Sub Price
Amerisource Health Services (68084)	68084-0397-01	\$0.0623	\$0.0623
Amneal Pharmaceuticals (65162)	65162-0541-10	\$0.1035	\$0.9541
Aurobindo Pharma (65862)	65862-0191-01	\$0.1035	\$0.9608
Breckenridge (51991)	51991-0468-01	\$0.1035	\$0.9608
Cadista Pharmaceuticals (59746)	59746-0177-06	\$0.1035	\$0.9610
Camber Pharmaceuticals (31722)	31722-0283-01	\$0.0700	\$0.0700
Glenmark Pharmaceuticals (68462)	68462-0553-01	\$0.1035	\$0.9534
KVK Tech (10702)	10702-0007-01	\$0.0443	\$0.0443
Major Pharmaceuticals (00904)	00904-7809-61	\$0.1035	\$1.0039
Marlex Pharmaceuticals (10135)	10135-0507-01	\$0.1035	\$0.1195
Mylan (00378)	00378-0751-01	\$0.1035	\$0.9059
McKesson Packaging Service (63739)	63739-0066-10	\$0.1035	\$1.1322
Qualitest (00603)	00603-3079-02	\$0.1035	\$0.960
Sandoz (00781)	00781-1324-10	\$0.1035	\$0.9128
Teva Pharmaceuticals (50111)	50111-0563-01	\$0.1035	\$0.950

The trademark name OxyContin manufactured by Purdue Pharma is a tablet designed to provide controlled 12 hour delivery of the

opioid analgesic, Oxycodone HCl. It is used to treat persistent moderate to severe pain over an extended period, as opposed to the immediate release Oxycodone HCl which can be used to treat pain on an "as needed" basis. OxyContin has patent protection with the earliest patent expiring in 2017 and the latest in 2025. There are currently no generic equivalent drugs for OxyContin, however, there are 10 repackagers who sell OxyContin in addition to Purdue Pharma. As it is a drug still under patent, the "no substitute" price is not applicable.

Like any product sold in a free market and as clearly illustrated in this article, the demand for a drug and number of manufacturers competing for market share, directly influences the price paid for a drug.

OxyContin is manufactured in 10mg, 15mg, 20mg, 30mg, 40mg, 60mg and 80mg strengths. Purdue Pharma sells all strengths in both 20 and 100 bottle lots. Repackagers sell OxyContin in a number of sizes as shown, making it available for physicians to dispense through their automated process. However, OxyContin did not rank within the NCCI top 10 drugs dispensed by physicians, yet ranked number 1 out of 20 in the NCCI's combined dispensers (i.e. pharmacies, PBMs and physicians).

#### OxyContin 100 tablets (Purdue Pharma [59011])

NDC	Strength mg	OMFS price per tablet
59011-0410-10	10	\$2.2720
59011-0415-10	15	\$3.4025
59011-0420-10	20	\$4.3476
59011-0430-10	30	\$6.1536
59011-0440-10	40	\$7.7142
59011-0460-10	60	\$11.2255
59011-0480-10	80	\$14.5067

Package Sizes:

10mg: 2, 10, 14, 15, 20, 30, 60, 84, 90, 100, 120

15mg: 20, 60, 100

20mg: 5, 10, 20, 30, 56, 60, 84, 90, 100, 112,120

30mg: 10, 20, 30, 60, 90, 100, 120

40mg: 10, 20, 30, 40, 56, 60, 84, 90, 100, 120

60mg: 10, 20, 30, 60, 90, 100

80mg: 10, 20, 30, 60, 90, 100, 120, 270

The price variations for OxyContin in the OMFS compared to the AWP are not as significant as the variations for some other drugs illustrated in this article. Although Oxycodone HCl is a generic drug, the same smaller price variation between the OMFS and the AWP applies. A sample list including the strengths and OMFS prices for Oxycodone HCl tablets are shown, with lowest prices highlighted in blue.

#### Oxycodone HCl, like Hydrocodone HCl is often combined with either Acetaminophen or Ibuprofen to increase analgesia.

Combined with Acetaminophen, Oxycodone HCl is commonly known by the trademark name "Percocet". Combined with Ibuprofen, it was commonly known under the trademark name "Combunox", however, is only available now as a generic from labelers Actavis Elizabeth (00228) and Teva Pharmaceuticals (00093), who both manufacture the same combination strength of 5mg Oxycodone and 400mg Ibuprofen. Oxycodone HCl combined with Acetaminophen is available in seven strength combinations from 2.5mg of Oxycodone HCl with 325mg of Acetaminophen through to 10mg of Oxycodone HCl with 650mg of Acetaminophen. Combinations available under the trademark name "Percocet" are also available as generics.

Oxycodone HCl is a pure opioid agonist analgesic, Schedule II drug requiring a new prescription each time it is dispensed. Unlike non-opioid analgesics, where there is a limit to the analgesic effect with increasing strengths, there is no defined maximum strength with Oxycodone HCl. The ceiling to maximum strength is imposed only by side effects which include dizziness, dry mouth, constipation, somnolence, nausea, vomiting as well as "opioid-induced hyperalgesia".

#### Oxycodone HCI tablets Package of 100

Labeler	NDC	Strength mg	OMFS price per tablet	OMFS No Sub Price
Mallinckrodt Pharm (00406)	00406-0552-01	5	\$0.2399	\$0.4491
Mylan (00378)	00378-6112-01	5	\$0.2399	\$0.4491
Qualitest (00603)	00603-4990-21	5	\$0.2399	\$0.4491
Caraco (57664)	57664-0370-88	10	\$0.5188	\$0.5188
KVK Tech (10702)	10702-0056-01	10	\$0.4492	\$0.4492
Actavis Elizabeth (00228)	00228-2878-11	15	\$0.6695	\$0.7877
Mallinckrodt Pharm (00406)	00406-8515-01	15	\$0.6695	\$1.5727
Mylan (00378)	00378-6113-01	15	\$0.6695	\$1.5727
Caraco (57664)	57664-0371-88	20	\$0.9155	\$0.9155
Zydus Pharmaceuticals (68382)	68382-0796-01	20	\$0.8789	\$0.8789
KVK Tech (10702)	10702-0057-01	20	\$0.8237	\$0.8237
Mylan (00378)	00378-6114-01	30	\$1.3094	\$2.9791
Qualitest (00603)	00603-4992-21	30	\$1.3094	\$2.9791
Actavis Elizabeth (00228)	00228-2879-11	30	\$1.2311	\$1.2311

Opioid-induced hyperalgesia is a medical condition where "pain medication causes pain". Once this condition is recognized, opioid pharmacologic treatment needs to be modified, and may include pain management compounding, which is the process of preparing customized medications to meet a person's specific needs. In this situation, the pharmacist's role changes from dispensing manufactured dosage forms to preparing customized medications in collaboration with a physician in treating pain.

For claims administrators however, compounded medications create further challenges which require an understanding of the efficacy and tolerability of the medications on a person's health as well as how they may affect their work capacity. Understanding the combination of drugs used in a compound and whether they are all necessary, further complicates the process of determining the price for the compounded medication.

Under what circumstances would a claims administrator 1) be prepared to pay for the compounded drug described below, 2) know the contribution of the efficacy of individual components and 3) decide how much to pay?

At the 2013 California Workers' Comp Forum (October 24-25), San Diego, CA), CureRxPharmacy who promoted themselves as compounding specialists of topical medications, had the following lotion/gel exhibited: "Pain Formula - Non-stick day A.M. lotion". Compounds in the Solaraze vehicle consisted of:

- Ketamine 2.75%
- Cyclobenzaprine 2.25%
- EMLA 3.5%
- Lidocaine 1.25%
- · Amitriptyline 1.25%
- Diclofenac 3.625%
- Baclofen 1%
- Dexamethasone 0.2%

in 37.5% Solaraze 3% gel; qs with PLO. Disp 180grams/30D. 4RF

A search for drugs containing a combination of Ketamine and Lidocaine as a topical medication, identified the trademark name "LidoProfen", (NDC 51021-0985-14) from Sircle Laboratories (51021) with the active ingredients Ketoprofen (NSAID) 5%, Ketamine 5% and Lidocaine 2% available as a 114gram (4oz) cream. LidoProfen is a schedule III drug and is not listed in the OMFS, however, is priced on the internet at around \$294, which is significantly less than its AWP.

Although Ibuprofen did not appear in the NCCI report, it was still identified as the second largest dispensed drug by physicians in the

September 2013 WCRI study into physician dispensed drugs. Ibuprofen is an NSAID available as both an OTC medication up to 200 mg as well as a prescription medication in 400 mg, 600 mg and 800 mg strengths. Ibuprofen selected in various strengths and package sizes from the OMFS showed that prices varied significantly, including the "no substitute" price.

#### Ibuprofen in various strengths in tablet dosage unless stated otherwise

Labeler	NDC	Name	Strength mg	Packet Size	OMFS price per tablet	OMFS No Sub Price	Comment
Walgreens (00363)	00363-0291-15	Wal-Profen	200	50	\$0.0828	\$0.0828	No OMFS after May 2014
Walgreens (00363)	00363-0291-12	Wal-Profen	200	100	\$0.0705	\$0.0705	No OMFS after May 2014
CVS (50428)	50428-0028-24	Ibuprofen	200	100	\$0.0429	\$0.0429	Dosage Capsule
Major Pharmaceuticals (00904)	00904-5323-24	Ibuprofen	200	100	\$0.0407	\$0.0407	Dosage Capsule
CVS (50428)	50428-2070-77	Ibuprofen	200	750	\$0.0149	\$0.0149	No OMFS after May 2014
CostCo (63981)	63981-0604-90	KLS Ibuporfen	200	500	\$0.0120	\$0.0120	No OMFS after May 2014
Avkafe (42291)	42291-0337-50	Ibuprofen	400	500			No OMFS price available
Major Pharmaceuticals (00904)	00904-5853-40	Ibuprofen	400	500	\$0.0345	\$0.1609	
Polygen Pharmaceuticals (52605)	52605-0121-05	Ibuprofen	400	500	\$0.0345	\$0.2040	
Major Pharmaceuticals (00904)	00904-5186-60	Ibuprofen	600	100	\$0.0417	\$0.2273	
Major Pharmaceuticals (00904)	00904-1748-60	Ibuprofen	600	100	\$0.0345	\$0.1609	
Marksans Pharma (25000)	25000-0122-12	Ibuprofen	600	500			No OMFS price available
Major Pharmaceuticals (00904)	00904-5187-40	Ibuprofen	800	100	\$0.0638	\$0.2984	
Interpharm Inc (53746), distributed by Amncal Pharm (65162)	53746-0466-00	Ibuprofen	800	10,000	\$0.0638	\$0.6661	
Avkane (42291)	42291-0339-15	Ibuprofen	800	15			No OMFS price available

Biopharmaceutical drugs (also known as "Biologics" or "Specialty Drugs") have not appeared in or been discussed in any recent NCCI, WCRI or California Workers' Compensation Institute ("CWCI") research reports, however, because of their current high cost there is much hype about biopharmaceuticals by PBMs regarding their possible future impact on workers' compensation pharmaceutical costs. This article illustrates that although their prices are high, there are opportunities to negotiate favorable prices. Much has been published in recent times about the advantages of treating with biologics over small molecule, chemical drugs and a number of pharmaceutical companies have already begun developing biologics for treating psoriasis, melanoma and other cancers. Amgen (USA) are developing biologics for melanoma and recurrent ovarian cancer and AstraZeneca through their subsidiary Medimmune invest around 48% of their drug development into biologics. As Biologics are made from a living organism or its products, it is unlikely they will ever become generics.

The biopharmaceutical drugs Orencia (FDA approved 2005), Humira (FDA approved 2012), Enbrel (FDA approved 1998) and Remicade (FDA approved 1999) have all been approved for the treatment of rheumatoid arthritis and are listed in the top 100 drugs by

total revenue for the fourth quarter of 2013 in the U.S. (source: drugs.com).

Treating rheumatoid arthritis pharmacologically generally commences with NSAIDs such as Naprosyn (Naproxen), Voltaren (Diclofenac), or Feldene (Piroxicam). If these drugs do not control the arthritis, then slow acting anti-rheumatic drugs (SAARDs) or disease modifying anti-rheumatic drugs (DMARDs) can be introduced along with NSAIDs, as SAARDs and DMARDs may take six to eight months to evoke a response.

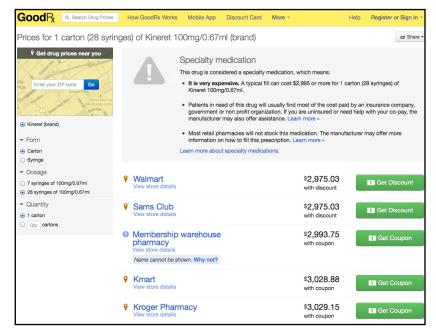
Traditional SAARDs and DMARDs include Ledertrexate

(Methotrexate), Myocrisin (Gold injections) and Plaquenil (Hydroxychloroquine). Enbrel and Remicade are Biologic DMARDs that work on the immune system by blocking proteins that contribute to the disease process, however, by suppressing the immune system, patients are at a greater risk of getting serious infections. Although the price of biologics as shown appear high, frequency of use needs to be taken into consideration as well as their efficacy and safety when compared to treating with small molecule, chemical drugs.

Comparing the OMFS prices for Kineret (NDC 66658-0234-01) to prices published on the website  $\underline{GoodRx.com}$ , shows a price of \$2,975.03 for 28 syringes compared to the OMFS price of \$4,210.26 (28 x \$150.3663) for 28 syringes. A saving of \$1,235.23 .

#### **Biologic (Specialty Drug)**

Trademark Name	Labeler	Therapeutic Drug Group	NDC	Administration Route	OMFS price per unit (as at Oct '13)	OMFS price per unit (as at Apr '14)
Actemra	Genentech	Anti-Inflammatory - Analgesics	50242-0135-01	Intravenous	\$71.5294	\$71.5294
Cimzia	UCB Pharma	Gastrointestinal Agents-Miscellanoeus	50474-0700-62	Subcutaneous	\$2,211.1200	\$2,758.0734
Enbrel	Immunex Corp	Anti-Inflammatory - Analgesics	58406-0425-34	Subcutaneous	\$294.2475	\$314.5472
Humira	Abbott Labs	Anti-Inflammatory - Analgesics	00074-3799-02	Subcutaneous	\$1,165.8595	\$1,246.2990
Kineret	Biovitrum AB	Anti-Inflammatory - Analgesics	66658-0234-01	Subcutaneous	\$136.9748	\$150.3663
Orencia	ER Squibb	Anti-Inflammatory - Analgesics	00003-2187-10	Intravenous	\$641.1086	\$672.5158
Remicade	Centocor	Gastrointestinal Agents-Miscellanoeus	57894-0030-01	Intravenous	\$840.1758	\$881.3438
Rituxan	Genentech	Antineoplastics & Adjunctive Therapies	50242-0051-21	Intravenous	\$66.5062	\$68.3347
Simponi	Centocor	Anti-Inflammatory - Analgesics	57894-0070-01	Subcutaneous	\$5,050.9152	\$5,399.4322



The term "Wholesale Price" generally refers to the price charged by a distributor (wholesaler) for a product sold to a retailer. The term "Average Wholesale Price" generally refers to the price charged by a distributor averaged out over all the retailers they sell to. In the case of pharmaceuticals, however, in investigating the use of the AWP for determining Pharmaceutical pricing for Medicare/Medicaid, the U.S. General Accounting Office ("GAO") stated that it may be neither the "average" nor the "wholesale" price. Further to this, pharmaceutical manufacturers and distributors may apply various discounts, rebates and reimbursement formulas to purchasers of pharmaceuticals such as federal and state agencies (e.g. Medicare/Medicaid and Medi-Cal), PBMs (e.g. ExpressScript and CVS Caremark), pharmacy chains (e.g. Walgreens, WalMart, Safeway) and others. The final price for medications by these buyers may therefore not be fully reflected in the AWP, OMFS price or other drug pricing method.

In deciding whether a drug (NDC) will be listed in their formulary, Medi-Cal, for instance looks at whether an acceptable rebate can be negotiated with the suppliers. This is in addition to ignore the AWP established by the drug repackager in determining their payment for a specific drug.

In contrast to Florida, California passed Senate Bill 228 (SB228 [Alarcòn]) in 2004, which adopted the Medi-Cal formulary (California's Medicaid health care program) as the official workers' compensation fee schedule for pharmaceuticals. Regulations were further reviewed by the California Division of Workers' Compensation following a number of studies, including the California Commission on Health and Safety and Workers' Compensation ("CHSWC") titled, "Impact of Physician Dispensing of Repackaged Drugs on California Workers' Compensation, Employers Cost, and Workers' Access to Quality Care", dated July 2006.

Based on these regulations introduced into California and Florida in determining the <u>maximum price for a drug</u> (regardless of whether it is dispensed by a pharmacy, mail order or physician), with identical treatment and before any negotiated discounts are applied to the OMFS price or AWP, Californian workers' compensation pharmaceutical costs should theoretically be <u>significantly lower</u> than Florida's.

# Is it reasonable to expect that employers pay more than the minimum price for a pharmaceutical dispensed through a workers' compensation claim?

the rules Medi-Cal applies to an NDC for determining the drug's efficacy, safety, essential need and potential for misuse. Examples have been presented in this article where a particular drug has been accepted by Medi-Cal, yet a certain supplier's drug has not been included or may have a drug in their formulary in one package size but not in another (refer to the Omeprazole chart). Medi-Cal does not discriminate against the type of supplier whether they are a manufacturer, distributor or repackager of a drug, as in the case of RxPak McKesson (65084), a repackager which has drugs in the Medi-Cal formulary (refer to the Gabapentin chart).

Although use of the AWP to determine a drug price has been the subject of much criticism, it still plays a pivotal role in many Workers' Compensation jurisdictions in establishing a prescription drug price. As an example, Florida passed Senate Bill 662 (SB662 [Hays]) in 2013, to set the maximum price for a physician dispensed drug to be 112.5% of the AWP, set by the original manufacturer of the drug, plus an \$8 dispensing fee. The passing of SB662 effectively allowed the claims administrator to

The CHSWC report stated that the 2006 estimated cost for prescription drugs was \$649 million. Of this amount, it was estimated that \$263 million was paid in excess to physicians who dispensed drugs, compared to the amount paid to pharmacies or mail-order dispensing the same drug. This \$263 million excess amount converts to an estimated increase in employer's premiums of \$490 million. However, what the report did not identify was, which drug prices were selected and which labelers were chosen for comparison between the repackagers' prices and other suppliers. Also, how much could have been further saved had the lowest OMFS been paid for a drug, regardless of the dispenser?

Legislative and regulatory controls focus on establishing the maximum price to be paid for pharmaceuticals. Claims administrators however, blame the high cost of pharmaceuticals on either a lack of legislative or regulatory controls or "loop holes" in the legislation or regulations. The reality of the matter is, that legislative or regulatory controls will never fully control pharmaceutical costs effectively, because by the time a loop hole

has been identified and addressed, another one will have been discovered by unscrupulous pharmacies, PBMs or physicians. It is the claims administrator's responsibility to have a clear and comprehensive knowledge of the pricing of pharmaceuticals, whether they be a brand name, generic or biologic drug, including the suppliers of these drugs, ensuring that the <u>absolute minimum price is paid for the pharmaceuticals required to treat the injured worker.</u>

## Can legislation or regulatory controls address the following or are these matters to be addressed between the physician, dispenser and the claims administrator:

- A physician prescribes Mobic and requests "no substitution" allowed. The prescription is filled by a pharmacy or PBM that regularly stocks Mobic. According to the OMFS, the "no substitute" price for 100 Mobic tablets is \$573.48. If the physician had allowed substitution and the same pharmacy or PBM had dispensed it, the price would have been \$14.25.
- A physician prescribes meloxicam from the labeler Apotex stating the NDC 60505-2553-01 and requests "no substitution" allowed. The prescription is filled by a pharmacy or PBM that regularly stocks the Apotex drug. According to the OMFS, the "no substitute" price for 100 meloxicam tablets from the labeler Apotex is \$262.98. If the physician had allowed substitution and the same pharmacy or PBM had dispensed it, the price would have been \$14.25.
- The physician prescribes meloxicam without specifying a labeler, allowing the pharmacy or PBM to dispense what they have in stock. The pharmacy or PBM dispenses the drug from labeler Mylan (NDC 00378-1066-01) at \$14.25 per 100 tablets, instead of labeler Zydus (NDC 68382-0050-01) at \$3.98 per 100, because the pharmacy or PBM receives a higher rebate from Mylan, increasing the pharmacy's or PBM's profit margin on the sale of the drug.

Legislative or regulatory controls may find it difficult to fully address these types of situations, however, with increased vigilance of pharmaceutical pricing through a combination of advanced technology and effective claims handling practices, claims administrators can ensure that the minimum price is being paid for prescribed medications.

Studies referenced in this article should motivate interested parties, including workers' compensation claims administrators to further investigate the workings of pharmaceutical pricing. Significant price variations for the same generic drugs have been highlighted in this article using the OMFS and AWP schedules.

#### References:

- The California Commission on Health and Safety and Workers' Compensation, Impact of Physician Dispensing of Repackaged Drugs on California Workers'
  Compensation, Employers Cost, and Workers' Access to Quality Care, [Nauhauser, Swedlow, Wynn], July 2006
- National Council on Compensation Insurance, Workers' Compensation Prescription Drug Study: 2013 Update [Lipton, Colón, Robertson], September 2013
- Workers' Compensation Research Institute, The Prevalence and Costs of Physician Dispensed Drugs [Wang, Liu, Thumula], September 2013





Details regarding the prices, packages sizes and the OMFS prices are as at the time of preparing this article and are subject to change at any time. Readers are advised to perform their own investigations into the price information of an NDC, including labeler details as well as how and for what purpose the drug is to be used. For further details, please email <a href="mailto:info@managingdisability.com">info@managingdisability.com</a>