

Dialogue

Recent WCRI Study leaves room for misinterpretation

A January 2015 Workers' Compensation Research Institute (WCRI) study which focused on three new medication strengths has again questioned the practice of physicians dispensing medications. The study titled "Are Physician Dispensing Reforms Sustainable?" prompted Michael Gavin (President of PRIUM, a subsidiary of Ameritox) to author an article titled "Physician Dispensing: I've changed my Mind" published on the website "insurancethoughtleadership.com".



Michael Gavin made the following three comments in his article in reference to the three new medication strengths. (1) "... *that drug repackagers in California created novel dosages of certain medication to evade the constraints of the physician dispensing regulations*", (2) "...*allowing repackagers to create new NDC codes and charging exorbitant amounts of money for drugs that would have*

been substantially cheaper had they been secured through a retail pharmacy" and (3) "*Worse, utilization of these medications skyrocketed as a result of the revenue incentives for physicians (my conclusion, not WCRI's)*".

Having an understanding of the National Drug Code ("NDC") and the differences between manufacturers and repackagers can assist in interpreting reports relating to pharmaceuticals.

This article analyses the Cyclobenzaprine HCL medication with emphasis on the new generic 7.5mg strength reviewed in the WCRI study and which Ramona Tanabe from WCRI refers to in the article "Loophole for Doctors on Drug Dispensing" also published on the website "insurancethoughtleadership.com".

The 7.5mg Cyclobenzaprine HCL was first made available as a generic by the pharmaceutical company “KLE 2 Pharmaceuticals” (website (www.kle2.com)). Their mission statement reads “*It is our goal to provide new therapies via unique strengths, delivery methods and or new formulations.*” Their website only lists four medications including the 2.5mg-325mg Hydrocodone-Acetaminophen medication which appears on page 6 of my report titled “Understanding Pricing of Pharmaceuticals” available from the website "managingdisability.com" under the Dialogue tab.

KLE 2 identified a marketing opportunity to meet the needs of those who found that the 5mg strength was not as effective and that the 10mg was too strong. There is evidence on the internet of people who take Cyclobenzaprine HCL, attempting to split the tablet to reduce its strength with limited success.

From late 2011 through to early 2013, KLE 2 was the only manufacturer of the generic Cyclobenzaprine HCL 7.5mg strength which was included in the Medi-Cal formulary and used for California workers’ compensation claims.

In April 2013, the manufacturer Mylan also released a generic 7.5mg strength which was also included in the Medi-Cal formulary.

The 7.5mg Cyclobenzaprine HCL (NDC 76218-1219-01) manufactured by KLE 2 has a Medi-Cal price of \$3.2153 per tablet and the Mylan 7.5mg strength (NDC 00378-0761-01) has a Medi-Cal price of \$3.99 (\$0.7747 more or 24% higher than the KLE 2 price). The brand name “Fexmid” (NDC 59630-0950-10) by Sciele Pharma owned by Shionogi & Co, has a Medi-Cal price of \$4.4383 per tablet.

Mylan has manufactured a number of strengths of Cyclobenzaprine HCL beginning with the 10mg in 1991 followed by 5mg in 2006 and 7.5mg in 2013.

Pharmaceutical pricing in the United States is unregulated which creates a competitive market for generic medications. The more manufacturers there are, the lower the price to the consumer. In the case of the 7.5mg strength Cyclobenzaprine HCL there are currently only two manufacturers, so the price will remain high until more manufacturers produce this strength or there is less demand for it.

The 10mg strength in comparison, has currently around 17 manufacturers including Mylan. The average Medi-Cal price for 10mg is \$0.1035 including Mylan (NDC 00378-0751-01) while the lowest Medi-Cal price for 10mg is \$0.0468 from the manufacturer KVK Tech. Refer to page 7 of "Understanding Pricing of Pharmaceuticals" for a Medi-Cal price comparison of 10mg Cyclobenzaprine HCL.

The 5mg strength is manufactured by about 11 pharmaceutical companies including Mylan with the average Medi-Cal price for 5mg being \$0.1586, which includes Mylan (NDC 00378-0771-93). In 2006 however, Medi-Cal's price for Mylan was \$1.3616 per tablet and has dropped to \$0.1586 today (a reduction of \$1.2030 or 88%), but still has a “no substitute price” of \$1.3616. The current lowest Medi-Cal price for a 5mg strength tablet is \$0.0468 and is again from KVK Tech.

I mentioned earlier that attempts to split either a 5mg or 10mg tablet in half have not been successful. It has been well documented that the coating applied to the 5mg and 10 mg Cyclobenzaprine HCL tablets does not allow them to be easily cut regardless of the device used. The opportunity therefore for cutting a 5mg in half in order to take 1½ tablets of 5mg of Cyclobenzaprine HCL and accurately administer a strength of 7.5mg is not possible. The release of the 7.5mg strength addresses this need.

Although the 5mg, 10mg and now 7.5mg strengths are the most commonly dispensed Cyclobenzaprine HCL medications, there are also other strengths such as the 15mg and 30mg extended-release capsules manufactured by Mylan (NDC 00378-8815-91 and 00378-8816-91 respectively) which have a Medi-Cal price of \$8.7899 per capsule. There are also the brand name “Amrix” extended-release 15mg and 30mg capsules manufactured by Cephalon, a wholly owned subsidiary of Teva Pharmaceuticals Industries Ltd, which have a Medi-Cal price of \$25.0163 per capsule for both strengths. These 15mg and 30mg strengths further illustrate a high price arising due to lack of competition for a specific medication.

It is important to note that the Medi-Cal prices stated, apply to all dispensers of California workers’ compensation medications, including pharmacies and physicians. Regardless of dispenser, the same Medi-Cal maximum price has applied since 2007 and is identified in the article titled “The Paradox on Drugs in Worker’s Comp” published on the website "insurancethoughtleadership.com". It is unclear then what

Michael Gavin is referring to in point 1 above. The 7.5mg Cyclobenzaprine HCL is not “made” by a drug repackager as stated in point 1, but is manufactured by KLE 2 Pharmaceuticals and Mylan Pharmaceuticals. Mylan Pharmaceuticals is a subsidiary of Mylan Inc (www.mylan.com).

In the article titled “Loophole for Doctors on drug Dispensing” by Ramona Tanabe, a point of concern relates to the average Californian price paid for Cyclobenzaprine HCL tablets. The WCRI stated prices paid for the 5mg and 10mg strengths were between \$0.35 and \$0.70 cents per tablet, yet we find that the average Medi-Cal price for 10mg is \$0.1035 and \$0.1586 for 5mg with the lowest available Medi-Cal prices of \$0.0468 from KVK Tech for both the 5mg and 10mg strengths. These Medi-Cal prices are significantly lower than the average prices presented by WCRI which warrant further clarification, otherwise, one can assume that claims administrators have been paying significantly more than Medi-Cal's maximum price. The WCRI reported a range of between \$2.90 and \$3.45 for the 7.5mg strength. The \$2.90 price is lower than Medi-Cal's prices and indicates that a competitive price was paid by claims administrators.

A point worth noting is that California workers' compensation does not use the supplier's Average Wholesale Price (AWP) to calculate the maximum price for a medication, but uses prices from "Medi-Cal" which is the name of California's Medicaid welfare program. These prices are the ones the State of California have negotiated before the supplier has applied any off-invoice rebates or discounts to the State of California.

Point 3 of Michael Gavin's comment can be interpreted as meaning that medical treatments provided by physicians who dispense 7.5mg Cyclobenzaprine HCL or the other two medications identified in the WCRI study are inappropriate in treating the injured worker. Earlier studies on claims administrators' use of MPNs by the California Workers' Compensation Institute (CWCI) identified that most physicians treating injured workers were in the claims administrator's medical provider network (MPN). If, as Michael Gavin suggests, MPN physicians are inappropriately treating the injured worker, then this potentially has serious consequences. California legislature was enacted to allow claims administrators to establish MPNs to provide the most appropriate treatment to the injured worker at the most reasonable cost to the employer. Have claims administrators then removed these physicians from

their MPNs and have they also reported them to the California Fraud Assessment Commission?

Also in point 2, Michael Gavin makes the comment that physician dispensed medications cost more than those in retail pharmacies. Obtaining prices of Cyclobenzaprine HCL from a number of retail pharmacies on the website goodrx.com showed the following:

- 10mg strength ranged from \$0.20 from Ralphs through to \$0.5325 from CVS Pharmacy.
- 5mg strength ranged from \$0.20 from Ralphs to \$0.5995 from CVS Pharmacy.

These 5mg and 10mg retail prices are higher than the average Medi-Cal price paid for the same medications to dispensing physicians.

- 7.5mg strength ranged from \$1.89 per tablet from Walgreens to \$3.68 per tablet from Pavillions and Vons.

The Walgreens price is significantly below the Medi-Cal prices from both manufacturers whereas the Pavillions and Vons prices are \$0.46 higher than the KLE 2 Medi-Cal price of \$3.2153 and \$0.31 lower than the Mylan Medi-Cal price of \$3.99.

It needs noting that prices on the website goodrx.com can change at any time and can vary based on availability, medication quantity and pharmacy zip code and are shown here for illustration purposes only. The Medi-Cal formulary can also change at any time in both its suppliers of medications and prices paid.

This analysis of the Cyclobenzaprine HCL medication further reinforces the need for claims administrators to be vigilant when dealing with pharmaceuticals - “Caveat Emptor [let the buyer beware]” and also when interpreting studies produced by organizations such as the WCRI.



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