Raymond Tan, PharmD. Zenith Insurance Company Testimony 3/2/16 Implementing AB 1124 – Joint Oversight Hearing

Introduction

Good morning Honorable Senate and Assembly Committee Chairs and Members. My name is Dr. Raymond Tan. I am a pharmacist and have changed arenas from dispensing role to working as the full-time Director of Pharmacy Benefit Management for Zenith Insurance Company. Zenith is based in Woodland Hills in Los Angeles County and is a long term workers' compensation insurance company that believes in doing the right thing the right way.

I appreciate this opportunity to address the Committee regarding the workers' compensation formulary, an important topic that is near and dear to me because I wish I had this formulary during my dispensing years because a formulary removes a lot of friction from the system. I am a California-educated and licensed pharmacist, who has served patients in our state for more than 15 years in roles encompassing retail pharmacy, a large health plan and now through a workers' compensation insurer, I have seen both the benefits and misuses of medications and the frustration of injured workers at a pharmacy. It is painful professionally and personally to tell a patient they must wait for their medication because the process is not streamlined today. I have been a patient advocate and through my personal experiences, I can share with you approaches that will help ensure the right medications are provided timely to injured workers at a fair price, and decrease the risk of addiction and fraud in the system. Additionally, because Zenith is a national carrier with experience in states where formularies have been implemented with some success, I can provide insight that will help California be more prepared for the implementation of our formulary.

Over the next few minutes I will combine my past experiences and my current position looking at the patient benefit and patient safety perspectives of the following key elements:

1. What is a formulary?
2. Methodology of the formulary
3. Cost-effective selection of specific formulary drugs
4. Implementation timeline

I will also present potential pitfalls, plausible solutions, and pose questions that will require more discussion to help ensure that the state makes an informed decision regarding the details of the formulary. Again this formulary is something that I would have liked to see when I was in a dispensing role because I could have helped more patients.

What is a formulary?

A formulary uses scientifically and evidence-based information to divide drugs into 2 categories: formulary and non-formulary. Formulary drugs have been pre-selected, are preferred for use, and their purpose is to simplify and expedite medication treatment by streamlining the drug delivery process to injured workers. A major goal of the formulary is to keep injured workers safe from the adverse effects of drugs and treatment regimens that are not medically necessary, are over-prescribed, or are ineffective. Formularies are widely used in group health, however a unique perspective in workers' compensation is that prescribed medications must be related to a work-related injury. I would like to emphasize that the formulary keeps doctors in charge and ability to practice medicine while streamlining the access of medications to injured workers.

Non-formulary drugs are not part of the streamlined process and will require pre-authorization. The pre-authorization process should include medical documentation that justifies the need for the non-formulary medication treatment. Some examples are listing treatments that have been tried and failed or providing reasons that the patient cannot use the preferred formulary medication options. For example: Botox is typically considered a cosmetic use drug and commonly non-formulary on most group health plans.

However, certain conditions like head injuries, chronic and migraine headaches can be resistant to the usual formulary treatment regimens. In these situations, a treatment trial of Botox may become appropriate and would be reviewed through the pre-authorization process. This pre-authorization is a prospective Utilization Review (UR).

The formulary streamlines payment to pharmacies and other dispensers that provide formulary medications and electronically bill through a Pharmacy Benefit Manager (PBM) expediting medications into a waiting patient's hands. The payment for first time formulary medications would be automatic and could potentially exposes the system to instances that formulary treatments could be inappropriate for the injured workers' particular circumstance. This also changes the perspective of how UR works when applied to formulary drugs. Formulary drugs are subject to retrospective review that will be applied to the subsequent refills of that formulary medication. For instance, muscle relaxant drugs have formulary status on most group health plans. It would then be expected that an injured worker presenting a prescription for a muscle relaxant for the first time would have no delay in receiving their medication. However, upon retrospective review, if no evidence of muscle spasms or benefit are found then it would be expected that refills would not continue without medical necessity justification being provided by the prescriber.

The formulary should be easy to use for both the prescriber and dispenser. These are two very different views of the same situation. Prescribers navigate from diagnosis to drug choice while dispensers and pharmacists are concerned about therapeutically equivalent drug alternatives. The formulary should have a flexible interface to accommodate both perspectives. For instance if the treatment guidelines state that an anti-inflammatory drug is indicated and the prescribed drug is not on the formulary then the pharmacist must be able to determine what formulary alternatives are covered before calling and discussing the situation with the prescriber. In my experience, this scenario usually occurs when an injured worker is treated by a practice that does not specialize in workers compensation, like a hospital at the time of discharge, an urgent care clinic, the emergency room, or their personal group health doctor.

Methodology of the formulary

The formulary can be developed de novo or purchased from a commercial source. I recommend opting for a commercially available source to promote stability of the formulary framework with regards to remaining evidence-based, scientifically-supported, maintained and updated on a regular basis. I feel the best use of the Pharmacy and Therapeutics (P&T) committee and the state's resources will be in the enhancement of the purchased formulary as seen in the Ohio workers' compensation formulary and most group health plan formularies like California's own Medi-Cal, various Medicare plans, and other commercial HMO and PPO plans. Further research and discussion should occur to determine if a singular source should be used or if a combination of products will be used because either decision has implications and details to be worked out.

These formulary enhancements will help ensure that guidelines are implemented in regards to medication trials, length of use, and promoting the lowest effective dose. I believe that we must take a proactive stance and develop safeguards to prevent physical dependence of all drugs. This can be done through enhanced formulary development of initial dosing periods and increasing the frequency of review for particular drug classes like opioids. For example, the initial use of an opioid medication could have the formulary enhancement of dispensing a maximum of 14 days, and pre-authorization for use of more than 14 days. If a follow up appointment is scheduled in 7-10 days, then there would be enough information and time to get pre-authorization before the depletion of the initial supply. The formulary is combining guidelines and safety concerns into a practical application and guide. In regard to opioid use, could prevent physical dependence and potentially prevent abrupt cessation concerns if the opioid was

determined to not be medically necessary. Further research and discussion will be necessary to align the Medication Treatment Utilization Schedule (MTUS) guidelines with the formulary enhancements because is a key factor to maintaining clarity and use of the formulary.

Some coverage examples currently seen in today's formularies are:

1) Medi-Cal's hydrocodone dispense enhancement
    a. 30 tablets maximum per dispense and
    b. 3 dispense maximum in a 90 day period
2) Ohio's alprazolam (Xanax) enhancement of a maximum daily dose of 4 grams

Some enhancements I think should be considered:

1) Opioid enhancement
    a. Diagnosis limitation to moderate to severe injuries like severe strains or fractures.
    b. Immediate Release products only, extended-release products would be non-formulary
    c. Dispense limitation of a 14 day supply, pre-authorization required for extended use.
2) Dose consolidation
    a. Duloxetine capsules cost the same regardless of strength
        i. 2x30mg therapeutically equivalent to 1x60mg
        ii. But 2x30 costs twice as much.

Cost-effective selection of specific formulary drugs

It is expected that multiple drugs within a specific therapeutic class will be selected to be on the formulary. For instance with Non-Steroidal Anti-Inflammatory Drugs (NSAIDS), I would anticipate that more than 10 different options would be appropriate for the formulary. These options could then be broken down into 1st preference and 2nd preference formulary medications. This is "Step Therapy" which is commonly found in group health formularies. If these 10 evidence-based drugs are considered all equivalent therapeutic options then we can group them into a cost-effective and pre-determined "Step Therapy" order. Cost-effectiveness usually implies generic substitution but there are instances where a Brand product is more cost-effective than a generic product. For instance, Brand Nexium OTC (over the counter) is more cost-effective than its generic prescription counterpart.

An important factor to consider when evaluating the cost-effectiveness of the drug formulary list is that there is pricing variability of one drug based on what company manufacturers it. Conversely there are scenarios where there is the same price per pill found across multiple manufacturers. For example, generic Neurontin 300mg (gabapentin) has a price variance of $0.42 to $2.00 per pill, while generic Naprosyn 500mg (naproxen) has a fixed price of $0.08 per pill.

The difference in these examples can be explained by how the state fee schedule is calculated. Pricing is constant when a drug product is listed on the Federal Upper Limit (FUL) price schedule. Price is variable when no FUL value is listed because pricing defaults to the manufacturer's Average Wholesale Price (AWP). California's pharmacy fee schedule is based on the state's Medi-Cal database which depends upon the federally maintained FUL in regards to fixed pricing of drugs. I recommend that state and federal agencies work together to help ensure that the current 2016 FUL Affordable Care Act (ACA) draft recommendations are incorporated into the Medi-Cal database so that full transparency and cost-effective development can be incorporated into the California workers' compensation formulary. The 2016 FUL ACA draft is expected to be finalized by March 31, 2016.

Implementation Timeline

The formulary implementation must be driven by the guidance of the DWC in regards to education of and communication to all stakeholders. In Texas, our office members commented that their Texas DWC provided consistent and frequent guidance and updates related to education, communication and preparation of their formulary implementation. Specifically the Texas DWC maintained one central website where stakeholders would get authoritative answers to their formulary questions. The Texas DWC also developed and provided standard letters, templates and training Power Point presentations that helped industry members comply with state regulation. The guidance and constant communication was key to the success in Texas' formulary implementation and I believe that California can apply this to our own implementation strategy.

Our Texas office felt their 2 year transition was confusing because it created 2 categories of claims: legacy and new claims. Legacy claims had injury dates that preceded the formulary implementation date and were exempt from the formulary until the transition period ended. Our Texas office recommended a much shorter transition to potentially none. A 6 month transition for most situations should be sufficient for patient treatment to discontinue or appropriately transition to a formulary product.

I think there is a lot to discuss here as there will be many different perspectives on an appropriate transition period. However I am in favor of a short transition. The pharmacist side of me feels it would simplify the system as long as the proper education and support materials and website were available for the industry to use.

Conclusion

In closing, our formulary is a conduit to streamline medication delivery to our injured workers'. Our formulary will keep doctors in charge of the treatment regimen from a formulary and non-formulary process. The formulary protects injured workers with its embedded enhancements and ease of use. The formulary also takes into account cost-effectiveness and a step therapy approach with its selected drugs.

There are many benefits to the California formulary for all of our stakeholders, especially the injured workers who are at the center of the workers' compensation system. California's formulary will be more successful through careful consideration of the experience of other states as well as by working collaboratively with other state and federal agencies in regards to cost-setting. I feel we are positioned to set the formulary bar for when other states decide to implement their own state formularies.