STATE OF CALIFORNIA GAVIN NEWSOM, *Governor*

DEPARTMENT OF INDUSTRIAL RELATIONS
Division of Workers' Compensation
1515 Clay Street, 17th Floor, Oakland, CA 94612
Telephone: 510-286-7100
Formulary Email Address: Formulary@dir.ca.gov
Formulary Website: https://www.dir.ca.gov/dwc/MTUS/MTUS- Formulary.html

MAILING ADDRESS:
P. O. Box 420603
San Francisco, CA 94142

Pharmacy and Therapeutics Advisory Committee
DRAFT - MINUTES OF MEETING
Wednesday, January 15, 2025
Via Tele/Video-Conference

In Attendance:

DWC:
George Parisotto
DWC Administrative Director
Sue Honor-Vangerov
DWC Legal Counsel
Kevin Gorospe, Pharm.D.
DWC Consultant

Committee Members:
Raymond Meister, M.D., DWC Executive Medical Director, Chair
Basil R. Besh, M.D.
Julie Fuller, M.D.
Joyce Ho, M.D.
Todd Shinohara, Pharm.D., MA.
Raymond Tan, Pharm.D.
Lori Reisner, Pharm.D

I. Welcome and Introductions
George Parisotto, Administrative Director, DWC

A. Acknowledgement of the tragic ongoing fires currently devastating Los Angeles and the loss that many people are experiencing. Thank you to first responders for their efforts and hope for the weather conditions to improve.

B. DWC Pharmacy Fee Schedule Regulations have been finalized and will be effective on July 1, 2025.
   a. The Fee Schedule update highlights include:
      i. preserving the previous methodology for pharmaceuticals dispensed prior to July 1, 2025
      ii. regulations have adopted new Maximum fees based on medical methodology for pharmaceuticals dispensed on or after July 1, 2025
      iii. adoption of an updated pharmaceutical fee data file format, setting forth lowest cost and no substitution cost based on medical methodology that will be posted on a weekly basis

iv. adopted an increased dispensing fee for physicians; adopted medical two-tier dispensing fee for pharmacies; and
v. adopted rules related to compounded drugs to carry out labor code provisions and clarify applicability of medical methodology for compounding fees

b. Pharmacy Fee Schedule (PFS) drug pricing data will be made available prior to implementation
   i. There are sample pharmaceutical fee data files and NPI files posted with the rule making materials which stakeholders may utilize for programming internal systems.
   ii. We anticipate posting an updated pharmaceutical fee calculator for the convenience of the public by the July 1, 2025, effective date.
   iii. The text of regulations and the final statement of reasons, with common charts, can be found on our DWC approved regulations page. I will work
c. Upon implementation, data will be updated on a weekly basis
d. Data file formats, data definitions and related links will be available on the PFS data website

C. Conflict of Interest reminder and advise P&T Committee members to review it; need to submit annually

D. State and federal Antitrust Law advisement

E. Currently accepting applications for the P&T Committee 2023-2025 term

II. Approval of Minutes from the October 16, 2024, Meeting

Dr. Raymond Meister, Executive Medical Director, DWC

Motion: Approval of the minutes from the October 16, 2024, meeting.

Vote: The committee members in attendance voted unanimously for approval of the October 16, 2024 meeting minutes.

Related briefing: October 16, 2024, Minutes of Meeting - DRAFT (https://www.dir.ca.gov/dwc/MTUS/Meetings/January-2025/October-16-2024-Minutes-of-Meeting-DRAFT.pdf)

III. Discussion: Biosimilars and Generics

A. Biosimilars Different than Generics
   a. Both are versions of a brand-name drug
   b. Generics are often referred to as "small molecule" drugs while Biosimilars are larger more complex molecules
   c. The FDA approval pathway is different between the two
   d. Both drug approval pathways are considered "abbreviated", meaning the manufacturer is not required to perform certain clinical trials which reduces

the initial cost of a generic or biosimilar

B. Generic Approvals
    a. Synthesized from chemicals resulting in the same active ingredient as the brand-name product
    b. Manufacturer of a generic drug must demonstrate the generic is bioequivalent to the brand-name drug
    c. FDA reviews generics through the Abbreviated New Drug Application (ANDA) process
    d. Approved Generics and other small molecules are listed in the FDA Orange book

C. Biological Listings / Definitions
    a. All approved biologicals are listed in the FDA Purple Book - https://purplebooksearch.fda.gov/
    b. Reference product - is the single biological product licensed by the FDA under against which a proposed biological product is evaluated (i.e. the original approved biological product)
    c. Biosimilar - the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components, and there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity and potency of the product
    d. Interchangeable - biological product is a product that has been shown to be biosimilar to the reference product and can be expected to produce the same clinical result as the reference product in any given patient

D. Biosimilar Approval
    a. Typically manufactured from living systems
    b. Due to small variations in production, biosimilars are not exact copies of the reference product and, thus, are not generically equivalent
        i. This same variation occurs within the reference product
    c. Manufacturers must demonstrate that the biosimilar is highly similar to the reference product
    d. Manufacturers must demonstrate there are no meaningful clinical differences between the biosimilar and reference drug in terms of purity, safety, potency
    e. Biosimilars are approved through the Biological License Application process

E. Interchangeability
    f. Generic drugs are considered fully interchangeable with the brand-name drug because they are identical or bioequivalent
    g. Biosimilars are not considered interchangeable until the FDA provides that designation
    h. The Biologics Price Competition and Innovation Act of 2009 identifies that a biosimilar can be deemed interchangeable if the information submitted in the application or supplement is sufficient to show

i. That the biological product can be expected to produce the same clinical result as the reference product in any given patient, and
ii. That for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch

h. MTUS Biosimilars Interchangeability chart discussion, slide 14.
   i. A number of biosimilar products have been listed as they currently appear on the MTUS, and the products determined to be interchangeable are noted as such

j. California Substitution Statute – Generics
   i. Business and Professions Code section 4073, allows pharmacists to dispense an approved generic product for brand-name product without contacting the physician because they have the same active chemical ingredients
   ii. a pharmacist filling a prescription in order for a drug product prescribed by its trade or brand-name may select another drug product with the same active chemical ingredients of the same strength, quality, dosage form, and of the same generic drug name as determined by the United States Adopted Names (USAN) and accepted by the federal Food and Drug Administration (FDA), of those drug products having the same active chemical ingredients

k. California Substitution Statute – Biosimilars
   i. B & P Code section 4073.5
   ii. A pharmacist filling a prescription order for a prescribed biological product may select an alternative biological product only if all of the following:
      - The alternative biological product is interchangeable.
      - The prescriber does not personally indicate "Do not substitute," or words of similar meaning, in the manner provided in subdivision (d).

l. Biosimilars Savings
   i. Association for Accessible Medicines report (complied by IQVIA) 2023 showed:
      - Biosimilars generated a total of $23.6 Billion from 2015 - 2022
      - Reported that adoption of biosimilars was low, with an average market share of 20% across the treatment areas they were available
      - Average sales price for biosimilars is on average 50% less than the reference brand biologic price was at the time of biosimilar launch

ii. For more details the report can be found at https://accessiblemedsorg/resources/reports/2023-savings-report

m. Adalimumab Pricing

iii. Previous pricing presentation did not account for the pricing file using two different units of measure, each syringe versus per milliliter

iv. Pricing adjusted to reflect per syringe pricing for review

v. For all but one strength (10mg/0.1ml) there are biosimilar drugs that are significantly lower in price than the reference drug HUMIRA

vi. Review of chart that corrects for pricing discrepancies by equalizing units of measure, which in some instances, the pricing is significantly lower and, in other instances, demonstrates no significant difference in pricing

vii. When reviewing the chart, any name containing simply Adalimumab is the original reference product and any name containing a dash with a four-letter designation afterward represents a Biosimilar product

- Committee member raises the question are products containing a dash and for letter designation are they all interchangeable?
- DWC responds that not all of these are interchangeable, as determined by the FDA. Currently, only adalimumab biosimilar products are considered interchangeable are indicated as such on slide 14 of this presentation.
- Committee member requests clarification of pricing table listed on slide 19 of this presentation, with respect to which Biosimilars listed are considered interchangeable.
- DWC clarifies that not all the biosimilars listed on slide 19 of this presentation, not all of them are interchangeable. To determine interchangeability, slide 14 would need to be used as a cross reference
- Committee member expresses curiosity about if all the requests are interchangeable products and if some of the requests are non-interchangeable products. The question being, how would the committee and DWC look at non-interchangeable products differently?
- Committee member requests clarification of the unit amount used in Adalimumab price amount spreadsheet on slide 19.
- DWC clarifies that the Adalimumab price amount spreadsheet is broken down to price per dose.
- Committee member raises concern about potential for drug acquisition being dependent upon rebates and it being unclear whether these prices are dependent upon rebates.

For example: there is a high WAC price and a low WAC price and each one of those is dependent upon rebates. Are any of the prices represented will okay in the table rebate dependent?

- DWC states that these are the prices at which the products would be reimbursed at or a reflection of pre-rebate pricing. We don't have access to rebate pricing because rebate contracts are confidential.
- Committee member questions if the MTUS cover page needs to be updated. Given that products are non-exempt, meaning that at the moment they all go through prospective review. In the future should it become exempt for any reason, should the cover page of MTUS also have 'generic and interchangeable biosimilars' included?
- DWC comments that it is a reasonable idea and DWC will discuss.
- Committee member wonders if the committee should take a position on biosimilar first type of thinking, given the goal to increase competition to lower prices. Like when generics first came on the scene, it was the embracement of generics that cultivated the competition that drove down prices. What we would be saying with a biosimilar first approach, we would be professing that despite many mechanisms in place to keep Biosimilars off the market, we want competition to exist. This approach would encourage manufacturers to produce more biosimilars and further encourage price competition and deter product innovators from guarding their market share by suppressing competition.
- DWC will consider the recommendation that DWC take a biosimilar first will approach, for biosimilars deemed interchangeable, that would be similar to the approach taken with generic drugs. DWC will consider if there is anything the department needs to do to interpret, amend or change related policy language.
- Committee member adds that a lot of what is being discussed is already encompassed with brand versus generic categorization. Isn't it already part of the RFA process if a brand needs medical necessity if a generic is available?
- DWC clarifies that the question remains: does the department need to provide an interpretation that biosimilars should be treated like generic drugs in the RFA process? That is something the department needs to explore further.
- Committee member suggests proceeding with a vote for a takeaway advisory item. Doing this for biosimilars would bring to light that this an ongoing requirement that has

already been established through other administrative processes and regulations in the DWC. Committee member also suggests that biosimilars fit this established pathway, because it is analogous to being generic for a biologic.

- Committee member raises the question is it correct that drugs with interchangeable biosimilars do not also have a generic substitute?
- DWC asserts that this is correct.
- Committee member questions if these medications with expired patents?
- DWC explains that biosimilars and generics, alike, can be marketed when the patent has expired and after any exclusivity provided by the FDA approval has expired.
- Committee member expresses curiosity about what would make a company make a biosimilar versus a generic.
- DWC elucidates that biosimilars and generics are different kinds of molecules. Generic drugs are small molecule chemical structures that are easily replicable, whereas biosimilars are biologic developed products that aren't always exactly the same. They have different pathways to approval.
- Committee member requests clarification of circumstances under which a company would choose to make a biological instead of a generic.
- DWC responds there is no generic equivalency. Aspirin has very specific chemical structure. Adalimumab, on the other hand, has a much more complex, larger proteinaceous molecule that might have slight variations which precludes the ability to create the same structure with a generic drug. That's why the biosimilar pathway is different, because you aren't creating the same molecule, but you're getting very close. Thus, biosimilars only exist when they are trying to make a product that is similar to an existing biological product. You cannot replicate or come close to replicating a biologic product with a generic drug. Generic drugs are created through chemistry and biologics are created through biology.
- Committee member clarifies that biosimilars are an alternative, just like a generic is an alternative. Thus, there is nothing prohibiting the committee from recommending that, given we already have rules concerning generics in place, in the case of biologic medications we could, analogously, recommend that we have a biosimilars first policy as well.
- DWC confirms this is the recommendation other committee members are leaning towards. The only potential caveat being that we may not want to adopt a full biosimilar first

approach but perhaps an interchangeable biosimilar first approach, given the laws surrounding biosimilar substitutions. DWC's interpretation of committee members' recommendation is that DWC adopt an interchangeable biosimilar first approach, analogous to DWC's generic first approach.

- Committee member inquires about the rules for dispensing biosimilars, as it relates to interchangeable and non-interchangeable biosimilars.
- DWC communicates that not having a biosimilars first approach would leave the decision up to the payers' rules. That means that the rules of dispensing biologics and biosimilars, as outlined in California law, would apply.
- Committee member expresses curiosity about whether any states have a biologics first approach for interchangeable biologics and similar biologics.
- DWC indicates that we don't have information about what other states' Workers' Compensation policies, at this time. What pharmacies can do legally with interchangeable biologics is notify the patient of the change. In some states they have to notify the physician after the fact. If it is a non-interchangeable product, the physician must be notified in advance and get their approval.
- Committee member seeks confirmation that no states have a process, such that, if the product is not interchangeable, pharmacies could go ahead and notify the physician after the fact.
- DWC confirms they do not have any knowledge of states doing this.
- Committee member opines that it would behoove us to adopt a policy such that interchangeable biosimilars are treated like generics and member requests if all committee members are in consensus.
- Committee member agrees 100% but makes clear a slight nuance that should be added, as currently biologics are not exempt and suggests committee members consider this rephrased proposal based on formulary language: if the biologic drug becomes exempt future, the interchangeable biologic would be the exempt product, meaning the interchangeable biologic first. Not interchangeable or brand drug would remain non-exempt, considering Pharmacy and Therapeutics Language. The intent being that the interchangeable biologic product is akin to a generic product, establishing the need to medically justify the brand product over the interchangeable product.
- Committee member elaborates that if you are prescribing a

nonexempt medication, you would either accept the biosimilar interchangeable substitute or make a case as to why you want the brand name product at the associated higher cost. The interchangeable first policy would still apply whether it is exempt retrospectively or nonexempt prospectively.

- DWC surmises that the committee would like to bring a motion to adopt a policy that identifies interchangeable biosimilars as analogous to generic drugs in how they are treated under both the MTUS formulary and when being reviewed through an RFA.
- Committee member expresses curiosity about the process through which the FDA identifies a Biosimilar product as interchangeable. Committee member also expresses curiosity why would anyone pursue creating a biosimilar that has no interchangeability, as it is not clear that there are circumstances under which a prescription for a noninterchangeable biosimilar would be written.
- DWC explains that it would be unlikely for a physician to write a prescription for adalimumab-ATTO because they don't know. Typically, they would write a prescription for a brand name product that happens to be a biosimilar, but they might just write Humira. The bottom line being that physicians may not know which products are interchangeable biosimilars. Secondly, in the commercial market, physicians are going to look to see what the patient's health plan says regarding what prescriptions they should be writing. As far as being proven as a Biosimilar product by the FDA, it has proven as clinically effective, it just hasn't been proven as interchangeable with the branded product. Every biologic can be considered as a standalone brand name product. All that the FDA is doing is deciding about interchangeability with the original product. How long the process takes is dependent upon the manufacturer supplying the necessary information and the accuracy of the information provided to the FDA to make the determination. For context, the FDA is making decisions quickly, given that Humira has been out for only two years, there are currently six biosimilars to Humira.

Motion: DWC will adopt a policy that identifies interchangeable biosimilars are analogous to generic drugs when it comes to MTUS formulary and the RFA review.
Vote: Committee members voted unanimously to approve the motion.

IV. Discussion: Naproxen and Naproxen Sodium

A. Naproxen Differences
   a. Primary difference between Naproxen and Naproxen Sodium is absorption rate
      viii. Naproxen Sodium reaches peak plasma concentration after 1 hour or it acts a little bit faster than Naproxen
         a. From an acute perspective, Naproxen Sodium is technically a better choice
         b. From a chronic standpoint, it doesn't matter
      ix. Naproxen reaches peak plasma concentration after 2 hours
      x. Enteric coated and controlled release formulations of Naproxen take longer to hit peak concentration
      xi. The pharmacokinetics after reaching peak are the same for both
   b. Earlier peak makes naproxen sodium better for acute pain.
   c. Naproxen dose equivalents are noted in the presentation.
   d. Committee member clarifies that the dosage on the left side of the chart for Naproxen is equivalent to the corresponding naproxen Sodium dosage listed on the right side of the chart except for the final entry where 500 mg of Naproxen should be equivalent to 550 mg of Naproxen Sodium.
   e. DWC affirms that there is a typo in the final line of this chart.

B. Naproxen Pricing
   a. Spreadsheets showing most recent Medi-Cal based pricing, as of last month, that will be implemented July 1, 2025.
   b. Generic drug pricing based on WAC or Generic NADAC.
   c. Brand drug pricing based on WAC or Brand NADAC
      i. WAC is Wholesale Acquisition Cost as reported by manufacturer
      ii. NADAC is the National Average Drug Acquisition Cost as reported by the Centers for Medicare and Medicaid Services (CMS) for use by states
      iii. Federal Law requires states reimburse at average actual acquisition cost-based reimbursement.
         a. States can do it themselves through surveys, like Alabama does or they can just adopt the NADAC pricing that CMS provides, which California does.
         b. In California it is going to be NADAC pricing for generic and branded products or the wholesale acquisition cost as reported by the manufacturer.
      iv. Some may question why not all products have NADAC prices. NADAC pricing is only applied to products of manufacturers who have signed a federal rebate agreement.
   d. Tables are broken out by strength for comparative purposes as well as a column showing the price to reach a 500mg dose
   e. Repackaged products (products typically repackaged for physician dispensing) are also identified
   f. 220 MG products are Over the counter; all others are prescription only

a. Spreadsheets discussed are available in the Materials section of our Pharmacy and Therapeutics website for today's meeting, DWC Pharmacy and Therapeutics Committee public meetings
b. Committee member requests to view the outlier section represented by suspension notation and, given the pricing differentials, requests to know, with respect to, Naproxen prescription 125 MG/5 ML, how do they know which one to choose?
c. DWC acknowledges that it is a good question, the difficulty being that the difference between the options isn't necessarily something that was included in the tables. DWC speculates that the reason we may have outliers like this is because the manufacturer may not have signed the Federal Rebate Agreement; therefore, the dosage price may be based on wholesale acquisition costs rather than the NADAC price. The difficulty in our pricing structure within the DWC program is that we provide pricing for all products regardless of their Federal Medicaid drug rebate program participation.
d. Committee member inquires whether a NADAC first principal clause might be something that could be proposed.
e. DWC communicates that there are two ways to potentially get to that solution:
    i. DWC doesn't have the capability to price spread to non-federal rebate products.
    ii. To adopt a NADAC first policy there are a couple of avenues that could be taken, but both are complicated.
f. Committee member voices concern over being forced to pay more for something that is available at a lower price
g. DWC considers that the payers have their own contractual arrangements with pharmacies in terms of reimbursement. A payer may have maximum acquisition cost (MAC) pricing in place.
h. Committee member expresses curiosity about whether any of the five products being viewed are dispensed by the medical facility, due to potential vested interest in dispensing the most expensive option.
i. Committee member expresses concern regarding instances where this is taken advantage of. Some of these billers will choose not to send it through a PVM and bill it directly to someone to bypass the max schedule. Member also expresses concern about problem with adopting the Medi-Cal Fee schedule is that a gap is created, since we are not adopting all of the Medi-Cal parameters around the fee schedule. Medi-Cal is very specific about what manufacturers can and cannot be dispensed, so the methodology works great for Medi-Cal but is counterproductive for Workers' Compensation because DWC allows the outliers carved out of medical, to be priced at a

different outlier rate. The issue being that Workers' Compensation allows payers to pay different rates due to a legal requirement, based on the regulations, because we are not adopting the other components of the Medi-Cal fee schedule.

j. DWC shares interesting information about the physician utilization data on Naproxen, there were none of the suspensions and the pharmacy utilization data shows that low-cost options were dispensed. DWC also questions whether a lot of money is being spent on products with higher pricing, as the pharmacy utilization information does not support that. With some exceptions, the physician utilization information is consistent.
k. DWC confirms committee members' concern regarding having adopted the pricing, but not all the policies related to the Medicaid program regarding reimbursement. That does create a gap that allows for products which may be statutory and not regulatory.
l. Committee member requests to view the Utilization schedules after sorting from high to low under total amount paid, then requests DWC look at the price paid per unit for of the top ten highest total paid amounts and notes that the first three are amount paid per unit outliers. This view highlights that 1.5 million dollars was paid out on medications that are approximately ten times the average price per unit.
m. DWC considers that the top three products in question are controlled release products; thus, are not equivalent nor comparable to non-controlled release products. Additionally, two of the three products have been discontinued by the manufacturer. The final product is less than the current price on file.
n. Committee member suggests that it would make sense to revisit these utilization schedules after the new fee schedule's effective date to see how things have shifted, as the current numbers might be skewed due to impending changes in July 2025.
o. DWC suggests looking at the data again in just over a year from now to see what impact the July 1, 2025, changes in reimbursement maximums have. We want to keep the focus on making sure billers are choosing lower cost generically equivalent products. DWC requests to table this issue for now, relative to utilization history and how much payers are paying.
p. No public comments on this issue

V. Discussion: Cannabis Coverage

C. Cannabis
   a. Currently a Schedule 1 (illegal) drug under Federal law.
   b. The federal Department of Justice has proposed moving cannabis to Schedule 3 (proposed rule at https://www.federalregister.gov/documents/2024/05/21/2024-11137/schedules-of-controlled-substances-rescheduling-of-marijuana)
      i. We will have to wait and see what the what happens with this proposed rule.
   c. Schedule 3 drugs are defined as drugs with a moderate to low potential for physical and psychological dependence and an abuse potential is less than Schedule I and Schedule II drugs

D. Coverage Under Workers Compensation
   a. Medical marijuana may be covered as a treatment under California workers compensation.
      i. MTUS Guidance
         - Guidance is based on the principles of evidence-based medicine. Therefore, in cases where there is good and supportive evidence of the efficacy of a medication or treatment then that will be considered if that medication or treatment is requested by a physician. Whether there is a better treatment available for the specific illness or condition will also be considered.

      ii. ACOEM Update
         - Many of the necessary treatments in Workers Compensation are covered in our adopted ACOEM guidelines. There are less than thirty ACOEM treatment guidelines that cover a majority of injuries and illnesses that arise in Workers' Compensation, but not every injury and illness.
         - Cannabis is a new topic and ACOEM is in the process of finishing their first cannabis related treatment guideline. The new guideline is expected to be released in later this month or sometime in February 2025.
         - The guideline is limited in what it looked at. It primarily looked at cannabis as a treatment for pain in more common workplace injuries, such as, back and spine injuries. It did not look into topics, such as cancer pain or nausea and vomiting related to chemotherapy or other topics that cannabis may be used for.
         - DWC's understanding is that they do not find any recommendation to use cannabis for the treatment of pain in Worker's Compensation injuries at this time.
         - When looking at a potential new treatment or medication they go through a very rigorous process to gather the evidence, evaluate the quality of the evidence, and review

that evidence with an expert panel. As with any of the ACOEM guidelines, it is expected to be a well-researched document.

E. Committee Discussion
   a. Committee member expresses desire to share a perspective and ask questions. Marijuana has been a scheduled one drug in the United States and the research has been very limited, because it is very difficult to research on schedule one drug. On the other hand, cannabis is a drug but it's really an herb. It has many different molecules in and certainly many more active components, in addition to many different plant strains which produce different chemicals, and many routes or modes of delivery. Given all this variability, committee member expresses curiosity about how it can be reviewed.
   b. DWC expresses gratitude for the comments and commends member on pointing out the complexity of this topic. DWC also clarifies that when ACOEM puts out a treatment guideline, we do a careful internal review of the item, before making a formal decision on whether to adopt the guideline into the MTUS. Once the document is released, it will give a good starting point to examine the questions and issues raised.
   c. Committee member expounds that within marijuana there are nearly a hundred different cannabinoids and the three most common are: THC, CBD and CBN. CBD is commercially available either by itself or in combination products, at least in Canada and elsewhere. Committee member suggests that research will most likely come from outside the United States. Their guess would be that any research would isolate one or more of those 3 most common components, as much less is understood about the other cannabinoids.
   d. DWC responds that research has been done at UC, San Diego Health had proposed several different trials related to cannabis use in neuropathic pain. This might be a good place to look at various trials and the types of research being done. Once the Federal Government states that they want to make it a schedule three drug, we will begin seeing more clinical trials, because it opens the door for more products to be developed.
   e. Committee member expresses, thinking down the road, eventually there will be enough evidence to reach a conclusion. Should that conclusion be that it will be approved for certain conditions, will there be a discussion about the reimbursement process. Concern for all the variability on how it is being supplied, the active ingredients, how will it be commercialized, how will it be regulated and fear for it becoming a blank check in the system. As other members have voiced, there must be some reimbursement guide developed to capture all of the complexities previously identified. Even if a guideline is produced, there needs to be a discussion about what the adoption process will look like down the road.
   f. DWC confirms that all the issues and topics raised by the committee would need to be considered and discussed.
   g. Committee member raises concern that other states that have had court

orders to reimburse. Having patients that buy cannabis and reimburse it, seems to contradict the underlying principle of Workers' Compensation.

h. Committee member expresses gratitude for the discussion on this topic and expresses agreement for what other members have said. Also, voices consideration that the committee's responsibility is to reflect the prescribing practices of physicians we service. On that note, it would be interesting to know what prescribing practices and denials of medical necessity and having and understanding of the trends on future presentations.
i. Committee member suggests that most of the use in California is not by prescription but from dispensaries. By state law there are some limits on dosage per unit and report what that dosage is, but it will still be very hard to gather all of the information.
j. DWC confirms that you are not going to see prescription data and we don't have any relative to Workers' Compensation at this point, because our statutes and regulations require reimbursement of drugs to be FDA approved drugs. This would be a non-FDA approved product, which raises the question of how that might layer in. As the Federal Government moves towards legalizing the product, it opens the door for product development. Pharmaceutical companies will walk through the door and then more research will be done. They will have to provide the additional information, such as, what components are being isolated and how they plan to commercialize it from an FDA perspective. There are questions to be answered before we get into the levels of prescribing that might occur within Worker's Compensation.
k. Committee member expresses that the only data available right now is related to very few prescriptions approved by the FDA which are only available for very specific conditions and none of these are currently used to treat pain.
l. Committee member offers perspective that while the current administration is leaning towards moving cannabis to a schedule three drug, that may not be the case in a couple of weeks when there is a transition of power. As our current rule is to only cover FDA approved medications, we really should let the FDA take the lead. What we do as a committee is based on safety, efficacy, and looking at the data on milligrams and bioequivalence. Until this trend towards regulation and formality of cannabis has significantly progressed, we aren't where we need to be in order to consider it a medication and we should allow the FDA to take the lead on creating those definitions for us.
m. Committee member questions if DWC is really limited to only FDA approved products, since we approve over the counter products that DWC, like Glucosamine. Committee member questions whether these types of over-the-counter products are FDA approved.
n. DWC clarifies that these over-the-counter products are approved but have a different approval process than prescription drugs.
o. Committee member expresses curiosity about DWC's obligatory coverage of FDA approved medications as a matter of California Law, does that apply to

glucosamine.

p. DWC explains that there are rules in place regarding these types of supplements and also food related items. Also, there is some case law about reimbursing. We will just have to keep an eye on what the Federal Government does.
q. Committee member further questions the extent the definition being that FDA is the oversight for what we are obligated to cover, how does that affect the interpretation of how far away we are from having to cover marijuana from a legal perspective.
r. DWC indicates that we may need to investigate the details of our regulations further. If the rule does say FDA approved, we would have to investigate the definition of what FDA approved actually means, and whether something like that exists in our rules that defines what we mean by FDA approved and that may be something that the committee wants to comment on down the line, but we should look into it first.
s. Committee member expresses relief that right now the FDA considers marijuana an illegal substance if it remains a schedule one drug.
t. DWC confirms that a lot of this discussion hinges on whether it shifts to a schedule three drug, and who takes advantage of that shift to work on a drug production and marketing process. For now, it remains something that could happen in the future, but it is something that we should monitor closely.
u. Committee member expresses curiosity about whether there is precedence for another substance going from schedule one to schedule three and how long it takes the FDA to analyze that and put out recommendations.
v. DWC explains that the rule making process relative to Federal rules, for example the DOJ or CMS or another department can put out a suggested final rule, get comments, and then not act on it for years. It's really a matter of how quickly they act on it. Once they act on it, then it depends on how long it takes for the FDA to write guidelines for drug development, and rules about how studies should be conducted. That could take years. Which means it could be five to ten years before we see any FDA approved products.
w. Committee member requests that DWC legal look more closely at the DWC rule requiring us to cover any FDA approved drugs and if there is a clear definition of how we define an FDA approved drug and see if this is something we should even consider in the next five to ten years. If it does really hinge on FDA approval, based on the process outlined by DWC, there doesn't seem to be anything the committee needs to consider for a long time.

VI. Public Comments - none

VII. Review of Committee Recommendations

F. Motion to adopt a policy related to interchangeable biosimilars being analogous to generic drugs relative to the formulary and RFA processes

G. Recommendation that we look at Naproxen and Naproxen Sodium products and possibly other products once we have six months of reimbursement data, including information about which manufacturers are not part of the Medicaid program, relative to the new reimbursement rules effective July 1, 2025.

H. DWC legal look into the details of what the regulations and statutes say regarding FDA approved products and reimbursement requirements under the Workers' Compensation system.

VIII. Adjourn