November 14, 2018

Item Name: Strategy for Prescription Drug Reference Pricing by Therapeutic Class
Program: Health Benefits
Item Type: Information

Executive Summary

Presently, there is limited use of reference pricing for prescription drugs in the United States. California Public Employees’ Retirement System (CalPERS) team members recently recommended beginning a pilot in 2019 with inhaled corticosteroids (a subclass of Corticosteroids), thyroid agents, and oral estrogen (a subclass of Estrogen). The Pension and Health Benefits Committee (PHBC) subsequently requested additional information about working with an additional vendor as well as information about a solicitation that would encompass a full program for Reference Pricing of more therapeutic drug classes. This agenda item provides information on the proposed Reference Pricing Program and provides timelines for implementing a pilot with three drug classes and subclasses as well as a project encompassing a full program solicitation with more drug classes. The piloting of the subclasses above would launch in January 2020. A full solicitation would launch in January 2021.

Strategic Plan

This item supports the CalPERS 2017-2022 Strategic Goal “Transform Health Care Purchasing and Delivery to Achieve Affordability.”

Background

At the September 25, 2018, PHBC meeting, CalPERS team members gave an update on four options for administering a program of Reference Pricing pharmaceuticals by therapeutic class. CalPERS team members and OptumRx selected UMASS, based on their experience with customized, results-oriented prescription drug management programs and services.

For nearly 20 years, the UMASS Clinical Pharmacy Services team has provided prescription drug management support and services that have helped payors, including MassHealth (MA Medicaid), operate clinically effective and cost-efficient pharmacy programs. In their work with MassHealth alone, UMASS supported more than 1.3 million members and $1.9 billion in spend. The UMASS expert team includes Clinical Pharmacists, Physician Advisors, and Rebate and Systems Analysts and their expertise includes:
• Pre-Market Drug Pipeline Tracking and aligned budget impact forecasting: this allows clients to anticipate the impact of the changing market
• Formulary Recommendations
• Rebate Management
• Retrospective Drug Utilization Review, Quality Assurance, and Program Integrity
• Development of regulations and Public/Provider relations
• Prospective DUR & Prior Authorization
• Clinical Programs: member-level medication tracking, prescriber engagement, outcomes monitoring, and adherence support
  ➢ Hepatitis C Medication Management
  ➢ Pediatric Behavioral Health Medication Initiative
  ➢ Opioid Management and may others

Following their discussion about the Reference Pricing Program, the Committee directed CalPERS team members to provide information on a full Reference Pricing solicitation. Please refer to Attachment 1 – CalPERS Reference Pricing History for additional background.

Analysis
Research and Data

The 2017 total prescription drug costs for all CalPERS Basic plans were $1.25 billion; an increase from $1.01 billion in 2013.

As noted in Attachment 5, CalPERS worked with UC Berkeley (UCB) to provide analysis and data related to reference pricing pharmaceuticals. CalPERS team members conducted further research based on the UCB analysis, including meeting with other organizations that have experience in reference pricing drugs specifically UCB, OptumRx, and RxTE. A full Reference Pricing Program offered by one vendor consisted of 70-80 drug classes. Attachment 2 listed our top 70 classes by savings and illustrated what a full program would resemble. CalPERS Reference Pricing Program will be built with patient safety and health care quality first and foremost. As such there may be classes that will never be implemented. Below are examples of drug classes that we may not implement for Reference Pricing:

• **Insulins.** There are different subclasses within Insulins (e.g. rapid, intermediate, long-acting, and combinations). Insulins are not readily interchangeable across subclasses. Too much insulin may result in life threatening hypoglycemia. While insulins within the same subclass may be readily interchangeable from a clinical perspective, prescribers who treat or patient with diabetes are unwilling to switch product due to brand loyalty and the fear of hypoglycemic events.

• **Miscellaneous Skin and Mucous Membrane Agents.** Miscellaneous Skin and Mucous Membrane Agents are a board group of drugs with multiple subclasses and lacks standard classification.

• **Anticonvulsants.** Anticonvulsants are used to treat seizure disorders with board treatment guidelines. These drugs often require dose adjustment needed by adjusting dose needed to control seizure or achieve therapeutic serum blood drug
concentration. Additionally, prescribers who treat or patient who have seizures are unwilling to switch drugs because such change may jeopardize seizure control

- **Corticosteroids.** Corticosteroids have different subclasses and route of administration with a range of indications. The different dosage forms or subclasses (e.g. oral, topical, inhalation, and injections) are not readily interchangeable. The subclass inhaled corticosteroids most commonly used for seasonal allergies have adequate generic options, readily interchangeable within the subclass, and have over-the-counter alternatives. The subclass inhaled corticosteroids may be suitable for Reference Pricing while the Corticosteroids Class may not.

- **Antypical Antipsychotics.** Antypical Antipsychotics are used for bipolar disorder, depression, schizoaffective disorder, and schizophrenia. The vulnerability of these patients and the use of combination therapies make this drug class not suitable for reference pricing.

CalPERS asked OptumRx for Reference Pricing analysis and recommendations. OptumRx evaluated the previous top 10 savings drug classes (Attachment 3) from UCB. OptumRx recommended not to target Insulins, Miscellaneous Skin and Mucous Membrane Agents, and SGLT2 Inhibitors for reference pricing due to formulary incompatibility, significant rebate impact including different guarantees, and additional administrative fee. OptumRx recommended the following drug classes for reference pricing: Inhaled corticosteroids, Contraceptives, and Thyroid agents. While Contraceptives are the fifth top saving drug class on the UCB top 10 savings drug classes, they have many subclasses with different route of administration and mechanism of action. Drugs within each subclass may be readily interchangeable from a clinical perspective. We chose to exclude Contraceptives for reference pricing because of potential member confusion with the mandated Women’s Preventive Services Initiative requiring the coverage of specified Contraceptives at zero copay. OptumRx also analyzed CalPERS claims data from January and February 2018 to identify drug classes for opportunities. Thyroid, Sympathomimetics, Estrogens, Amphetamines, and Acne are drug classes where generic rate is less than CalPERS' overall generic rate.

While the three selected classes are not top savings drug classes, UCB and OptumRx also identified them as opportunities for Reference Pricing. The CalPERS Clinical Team selected these three drug classes based on analysis of the CalPERS claims data (impact), clinical considerations for each class (quality), the interchangeability of drugs within class or subclass (quality), the relative safety of drug class (patient safety), low generic utilization within drug class (opportunity), compatibility with current formulary (cost), rebate impact (cost), and administrative fee (cost).

On September 10, 2018, James C. Robinson published an issue brief titled, “Pharmaceutical Reference Pricing: Does It Have a Future in the U.S.?” In it, Dr. Robinson discusses the implementation of reference pricing by a private employer, limitations, and extensions of reference pricing, reference pricing roadblocks, and the horizon for reference pricing of specialty drugs.

See Attachment 4 – Heat Map for comprehensive listing of drug classes that may and may not be suited for Reference Pricing.

**Reference Pricing Requirements**
Implementing a prescription drug reference pricing requires five key functions:

1. Data research on prescription drug therapeutic classes and subclasses, including the most critical component of patient safety, to identify which drug classes should be included in the program
2. Claims evaluation of CalPERS population's drug utilization to gather prescribing patterns and costs.
3. Member, Prescriber, pharmacy, and education and outreach
4. Appeals management
5. Monitoring and reporting of outcomes and success of the program, including cost savings, patient safety, and member satisfaction

The chart below summarizes the tasks at a high level, and the division of responsibility for the Pharmacy Benefit Manager (PBM) and external vendor.

<table>
<thead>
<tr>
<th>Task</th>
<th>PBM</th>
<th>Vendor</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data research on therapeutic classes, subclasses, and patient safety</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Claims evaluation; clinical &amp; financial analysis; claim system setup</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Marketing to physician, pharmacy, and member</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Appeals administration and member service support</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Program monitoring and evaluation</td>
<td>X</td>
<td>X</td>
</tr>
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**Pilot vs. Project**

A pilot is a phased approach to develop a quality, cost-effective program and assess the viability of expanding to the entire CalPERS population. The pilot would have targeted a small number (three) of therapeutic drug classes that are clinically low risk for patient safety concerns, highly interchangeable within the drug class, compatible with the current formulary and minimal rebate impact. The pilot approach would allow CalPERS and the PBM to study the program in a production environment using real experience. The pilot phase provides an opportunity to refine systems, communications and administration while maintaining minimal member disruption. A pilot can be accomplished within existing resources and, depending on the outcome, may never be implemented on a broader scale.

A full project requires more lead time to conduct research on a broader scale. A project would require a full solicitation to explore various innovative approaches that would work for CalPERS diverse population and identify vendors with experience in this industry that can assist the PBM with implementation. It can have a phased approach but is a commitment to implement more therapeutic drug classes over time. In this case, CalPERS would need to fully research cost and patient safety in each therapeutic drug class. In a full project, CalPERS may consider targeting a few therapeutic drug classes in the first year, and systematically increase the number of target drug classes over the next five years.

**Components of a Solicitation**

To conduct a full solicitation, CalPERS would engage in the following activities.

Request for Information (RFI)
The first step in a solicitation of this type is to develop a RFI to solicit information from vendors about the services they provide in the pharmacy benefit administration industry, in addition to any innovations they currently employ or are contemplating employing to control drug costs. This RFI seeks to find a vendor capable of establishing reference pricing, monitoring and adjusting the reference price, claims adjudication, prescriber, member, and pharmacy education/outreach, customer service to support prescriber, member and pharmacy questions, outcome measures (health care outcome, prescription change to lower cost agent, paying higher out of pocket cost, adverse events, savings for CalPERS and members). The RFI provides supporting documentation needed to develop the business and financial requirements of the solicitation.

Phase I Minimum Qualifications
Phase I announces CalPERS intent to solicit bids from vendors that are capable of performing work described in the solicitation; establishes the minimum qualifications needed from vendors; and requires vendors to certify their intent to bid; and obtains necessary confidentiality and information security agreements. Vendors that do not pass Phase I will not proceed to Phase II of the solicitation.

Phase II Business and Financial Plans
Phase II provides detailed program requirements and structured business and financial plans that the vendors must submit with their proposal. Phase II requires bidders to demonstrate: their understanding of CalPERS needs and goals to provide health benefit sustainability; how their company will strategize and implement delivery of the program; how their work will be effectively integrated with the PBM’s functions; and their commitment to perform the work in an efficient and timely manner with short turnaround times. During Phase II, CalPERS will conduct a formal evaluation of the proposals to identify the most feasible solution and cost-effective bidders.

Phase III Contract and Competitive Negotiations
Phase III gives CalPERS the opportunity to competitively negotiation with bidders on pricing and contract requirements. CalPERS will provide the contract terms and conditions that bidders must accept. Phase III allows CalPERS to negotiate with the highest-ranked bidders to reach the best and final solution for the program.

Timeline
In addition to conducting the solicitation, sufficient lead time is needed to implement the program. Any program of significant magnitude such as this would require at least one year to develop and implement. Typically, benefit changes take effect on January 1, at the beginning of a calendar year. The benefit changes are reviewed, approved and announced in June each year through CalPERS Rate Development Process. The PBM needs a minimum of four months to code and test claim systems, update member-facing documents and web portals, and develop member communications. CalPERS and the PBM would communicate with members about the program prior to Open Enrollment in September-October. The external vendor will conduct outreach to prescribers and pharmacies and will develop program evaluation and monitoring tools (e.g. member survey).

Given the time frame required to implement a pharmacy benefit change, CalPERS can move forward with a pilot of three subclasses to be effective January 2020. CalPERS health program has limited resources to engage in multiple solicitations at the same time. In order to maximize
utilization of existing resources and ensure appropriate attention is given to each program, CalPERS must plan project timelines based on priority to meet our mandated workload while also focusing on long-term goals. CalPERS is currently engaged in a solicitation that will select a third-party administrator for CalPERS’ Preferred Provider Organization health plans effective January 2020. In addition, the current PBM contract expires in December 2021, which means that CalPERS must begin the solicitation process no later than July 2020. Given competing priorities, it may be prudent to delay a full solicitation for reference pricing of drugs to coincide with the PBM solicitation.

Budget and Fiscal Impacts
Outpatient prescription drug costs continue to increase. The reasons for the increase include lack of price control in the United States, limited competition, and high-cost generics. The use of generics, biosimilars, and evidence-based pharmacy benefit management strategies are critical to staying ahead of increasing prescription drug costs. The reference pricing program is expected to mitigate future years’ prescription drug costs and is consistent with the CalPERS 2017-2022 Strategic Plan; however, specific budget and fiscal impacts are unknown at this time.

Benefits and Risks
The benefits include:

- Lowers or stabilizes CalPERS prescription drug costs
- Supports the CalPERS 2017-2022 Strategic Goal to transform health care purchasing and delivery to achieve affordability
- Provides greater transparency of drug cost to members
- Supports member savings and choice
- Provides alternative solutions to adding drug cost tiers
• Eliminates Members Pays the Difference and some utilization management

The risks include:

• Increase in member complaints and appeals with increased call volume to member services
• Implementation of this program would be pushed out to January 2021 or possibly January 2022 if implemented as part of new PBM contract.
• Failure to implement sooner due to competing workloads
• Potential for increasing CalPERS prescription drug costs due to delayed implementation

Attachments
Attachment 1 – CalPERS Reference Pricing History
Attachment 2 – Full Program – 70 Drug Classes
Attachment 3 – Top 10 Drug Classes and Subclasses
Attachment 4 – Full Program – 70 Classes – Heat Map
Attachment 5 – Reference Pricing Program PowerPoint

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