MILLIMAN REPORT

Evaluation of the Appropriateness of EmpiRx's Clinical Savings Tracker for Estimating Ingredient Cost Savings

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Commissioned by EmpiRx

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Executive Summary

SCOPE AND PURPOSE

EmpiRx Health, LLC (EmpiRx) is a pharmacy benefit manager (PBM) focused on pharmacy care management services. EmpiRx engaged Milliman to review the methodology associated with the Clinical Savings Tracker (CST) component of EmpiRx's Clinical Care Management (CCM) program. The CCM program identifies drug cost savings opportunities based on client experience data. The CST quantifies realized savings resulting from EmpiRx's clinical management programs.

This report provides an independent review of the processes EmpiRx uses to calculate savings under the CST. Our review includes commentary on the appropriateness of EmpiRx's methodology and processes for calculating CCM program ingredient cost savings.

SUMMARY OF FINDINGS

EmpiRx uses the CST to quantify estimated ingredient cost savings resulting from EmpiRx's clinical pharmacy management programs. Estimated savings represents the difference in ingredient cost between denied claims and subsequent paid claims, if applicable, resulting from clinical edits. Based on our review of the information provided by EmpiRx, we believe the CST approach is an appropriate methodology for estimating clinical program ingredient cost savings. While there are many approaches that could be appropriate measures of clinical savings, we did not compare these to EmpiRx's as they are outside the scope defined by EmpiRx and would be variable to each client/PBM relationship. Key components of the CST methodology to consider when interpreting the estimated savings amount include:

- The CST considers ingredient cost savings resulting from EmpiRx's clinical management programs. The savings represents estimated reductions in ingredient cost for most claims, partially offset by ingredient cost increases for certain claims. It accounts for changes in quantity or days supply due to changes in drug therapy.
- The CST quantifies point of sale (POS) ingredient cost savings only. As such, it does not account for changes in rebates, member cost sharing, or administrative costs.
- The CST retroactively quantifies estimated savings relative to a baseline in which EmpiRx's clinical management programs are not in place.
- The CST is based on realized savings from prescriber changes in baseline drug therapy to those in the EmpiRx clinical management program.

ITEMS NOT REVIEWED

We focused our review on the appropriateness of the methodology used to quantify realized savings through the CST. We did not review the following items:

- **CCM program effectiveness.** We did not evaluate the results of EmpiRx's CCM program. As our review was limited to the appropriateness of the methodology of the CST, we did not confirm whether or not the CCM program produces savings.
- **Medical savings.** EmpiRx's CST focuses exclusively on estimating pharmacy savings. As such, our review does not consider the potential effect of changes in pharmacy benefit management on medical claim costs.
- **Specific clinical criterion.** We did not review individual drug therapy specific savings in the CST. As the development and implementation of clinical review is a dynamic process, we did not review the details of each individual pharmacy management tactic. This was outside the scope of our project and the criterion could change on a daily basis.
- **Clinical edit assignment.** We did not review the criteria for identifying claims affected by EmpiRx's clinical management programs (step therapy, prior authorization, and quantify limits).
- **Formulary.** We did not perform a detailed review of EmpiRx's formulary / formularies. We assume the formulary is comprised of cost-effective and clinically appropriate drugs. Client-specific formularies and benefits may impact the projected or actual clinical savings and rebates.

- **Prospective savings.** We did not review EmpiRx's RX Efficiency Calculator (which estimates potential drug cost savings for prospective clients) nor did we conduct a review of EmpiRx client historical data (which is used as a basis for the targeted clinical management program calculations).
- **Savings guarantees.** We did not review items related to potential risk sharing or savings guarantees between EmpiRx and its clients. For example, we did not review how EmpiRx might compare prospective savings estimates from the RX Efficiency Calculator to realized savings estimates calculated through the CST.

Clinical Savings Tracker Overview

The following is our interpretation of the CST used for 2018 claims based on information provided by EmpiRx.

EmpiRx uses the CST to quantify estimated ingredient cost savings resulting from EmpiRx's clinical pharmacy management programs. Estimated savings represents the difference in POS ingredient cost between denied claims and subsequent paid claims, if applicable, resulting from the following CCM program clinical edits.

Step Therapy (ST)

EmpiRx flags claims that it considers requiring a ST. A pharmacy claim that has a ST would require the patient use another clinically appropriate product (Drug B) before the claim for the original prescription (Drug A) is approved. Often it involves EmpiRx requiring the member to try a therapeutically similar generic or lower cost brand drug prior to receiving the drug requiring a ST. The more affordable drug is a clinically appropriate alternative within the same therapeutic class for most patients with a similar condition. The goal is to avoid the higher cost brand-name drug, when a more affordable and clinically effective drug is available to treat the patient's condition. EmpiRx focuses on shifting utilization to the most efficient drug therapy through its comprehensive, evidence-based clinical protocols.

Prior Authorization (PA)

PA management is similar to an ST edit, but requires the prescriber to submit to EmpiRx predetermined clinical documentation prior to certain drug therapies being adjudicated and dispensed to the patient. This is mainly done for situations related to clinical risk, off-label use, prescriber credentials, safety, and/or high cost. This review is done on a peer to peer basis between an EmpiRx clinician and the prescriber. EmpiRx's goal is to ensure the right patient gets the right drug at the right time. PA management has the potential to deliver cost efficiency by ensuring medical appropriateness across numerous drug classes.

Quantity Limits (QLs)

The EmpiRx CST accounts for situations where a drug therapy needs to have a maximum unit quantity for safety and cost reasons. The QLs for selected drugs are based on the US Food and Drug Administration (FDA) approved dosing guidelines. For example, Tamiflu 75mg one tablet twice a day for 10 days (20 tablets/month) may be prescribed, but the EmpiRx QL would limit the quantity dispensed to 10 tablets per fill. This is a reasonable approach leading to potential improvement in clinical efficiency as the Tamiflu dosing guidelines are only for 5 days. This leads to a decrease in the "tablet burden", and potential increased adherence to clinically appropriate guidelines. Lastly, this has an absolute decrease in cost by eliminating 10 tablets. EmpiRx excludes certain drug therapies from any QL savings calculations if the clinical logic is not likely to yield savings or improve quality.

Flagged claims typically originate from denied claims at the POS. Once claims are flagged as subject to a clinical intervention (i.e., edit), they are assigned to one of three categories for purposes of the savings calculation (Figure 1).

FIGURE 1: INGREDIENT COST SAVINGS CALCULATION

FLAGGED CLAIM CATEGORY	SAVINGS[1]	NOTE
1. Denied, no subsequent paid claim	Ingredient Cost per Day * Average Days Supply	No match identified based on look-forward logic.
2. Denied, subsequent paid claim	[(Rejected Ingredient Cost per Day) - (Paid Ingredient Cost per Day)] * Paid Average Days Supply	Paid claim match identified based on look-forward logic.[2]
3. Approved	$0	Flagged claims that are eventually approved are excluded from the savings calculation.

Average days supply represents the number of days in a year that would typically be dispensed based on EmpiRx's commercial book of business. This approach annualizes savings based on expected one-year utilization rather than reflecting the full 365 days. Therefore, the calculated savings represents approximate savings on an annualized basis. This ensures that flagged claims are not counted as a savings value of 365 days.

For example, consider a case where Farxiga, an antidiabetic drug, is initially denied due to ST, and Januvia, another antidiabetic drug, is filled within the next 90-days. Savings is calculated as the cost per day difference between the denied and subsequent paid claim, annualized by the average days supply of the paid claim (Januvia in this example) (Figure 2).

FIGURE 2: INGREDIENT COST SAVINGS CALCULATION EXAMPLE

	FARXIGA (DENIED)	JANUVIA (PAID)	
Ingredient cost	$1,380	$425	[A]
Days supply	90	30	[B]
Average days supply	218	210	[C]
Ingredient cost per day	$15.33	$14.17	[D] = [A] / [B]
	Annual savings = $245 = ($15.33 - $14.17) * 210		

While the majority of claims follow the savings calculation outlined in Figure 1, savings is adjusted for specific cases based on clinical review. For example, POS rejected claims that might require a clinical review include acute products with QLs and selected medical supplies. Two common cases for possible adjustment are:

1. **Non-recurring claim.** For products that are not used throughout the year, the savings may be set as the ingredient cost (for denied claims with no subsequent paid claim) or as the difference in ingredient cost (for denied claims with a subsequent paid claim). This gives credit for only one fill, without annualizing savings based on average days supply. For example, this adjustment may be used in cases where the dosing for a denied claim differs from that of a paid maintenance medication. This "one fill" savings approach is also used for cases where the average day supply is not known due to lack of historical utilization data.
2. **Savings >$1,000.** Any claims with initial calculated savings over $1,000 are subject to clinical pharmacist review. Some specialty drugs might require the first dose to be dosed higher than other subsequent doses,

[1] Typical savings approach. The calculated savings for certain claims is adjusted, as described in this section. Savings is only calculated for denied claims subject to clinical edits.

[2] EmpiRx identifies paid claim matches based on Generic Product Identifier (GPI)-level logic for a specific intervention, typically within a 90-day look-forward period. Paid claims are matched with at most one denied claim. The specific paid claim matching criteria were beyond the scope of our review.

often referred to as a loading dose. In this case, the loading dose would be over $1,000, but ongoing doses of the same medication might only be $500. In this situation, the ongoing claims would not be flagged for the "savings > $1,000" review.

Starting with 2019 data, EmpiRx stated that only claims with initial calculated savings over $1,000 are subject to clinical pharmacist review for consistency. This is because the "average days supply" adjustment in the standard savings calculation approach (Figure 1) accounts for most "non-recurring claim" cases.

Review of Clinical Savings Tracker Methodology

Our review confirms that the savings calculation applied in the CST aligns with EmpiRx's stated methodology. Further, we believe the CST approach is an appropriate methodology for estimating clinical program ingredient cost savings based on the information we received from EmpiRx. Overall, the drug clinical management tactics (i.e., PA, ST, QL) are fundamental to managing the drug spend and are dependent on the prescriber authorizing any change with the individual patient drug therapy. The reasoning for which drug clinical management tactic is applied to selected drugs was outside the scope of this review. Generally, this is a dynamic process and could change from time to time as new clinical evidence about a drug is made public.

ALIGNMENT OF CST CALCULATION WITH STATED METHODOLOGY

In our review of the denied claim CST sample data provided by EmpiRx, we found that approximately 97% of claims, or 86% of ingredient cost, follow the logic outlined in Figure 1. The difference between the claim and ingredient cost percentages is driven by the "savings >$1,000" adjustment described above, which results in high-cost claims making up a disproportionate share of claims with adjusted savings (Figure 3).

FIGURE 3: SUMMARY OF DENIED CLAIM CST SAMPLE DATA

	% OF CLAIMS	% OF INGREDIENT COST
Total denied claims[3]	**100%**	**100%**
Savings calculated per Figure 1	96.8%	85.8%
Savings differs from Figure 1, and:		
Non-recurring claim[4]	1.0%	0.5%
Savings >$1,000[5]	0.9%	6.1%
Non-recurring claim *and* Savings >$1,000	1.2%	7.4%
Other[6]	0.1%	0.2%

Figure 3 categories are mutually exclusive. For example, the total percentage of denied ingredient cost for which savings differs from Figure 1 and initial calculated savings is greater than $1,000 is 13.5% (= 6.1% + 7.4%).

We did not review the claim-specific savings adjustments for claims with initial savings greater than $1,000.

METHODOLOGY CONSIDERATIONS

There are many approaches that could be appropriate measures of clinical savings. This section discusses key components of the CST methodology to consider when interpreting the estimated savings amount.

Our understanding is that EmpiRx's savings calculation considers all claims subject to one of EmpiRx's clinical management edits. Therefore, it quantifies savings relative to a baseline in which it is not known if there are any clinical management programs in place under the prior PBM contract. It does *not* compare savings under EmpiRx's programs relative to clinical management programs with prior PBMs.

[3] Includes denied claims resulting from clinical edits with and without corresponding paid claims (categories 1 and 2 from Figure 1).

[4] Represents claims where savings is not annualized for days supply. This could be due to a non-recurring claim or lack of historical average days supply utilization data. Excludes claims with initial calculated savings greater than $1,000.

[5] Represents claims where initial calculated savings (per Figure 1 approach) is greater than $1,000. Excludes claims in the "non-recurring claim" category.

[6] Represents denied claims where calculated savings does not reconcile with the Figure 1 approach and does not fall into the "non-recurring claim" or "savings >$1,000" categories.

The CST considers both savings and costs resulting from EmpiRx's clinical management programs. While most clinical edits result in either no subsequent paid claim or subsequent paid claims with lower ingredient cost compared to the initial denied claim, some edits result in higher cost subsequent paid claims. The savings represents estimated reductions in ingredient cost for most claims, partially offset by ingredient cost increases for certain claims. Of the denied claim CST sample data provided by EmpiRx, approximately 6% of claims result in costs that partially offset the savings generated by other claims, and approximately 1% of claims do not contribute costs or savings.

EmpiRx states that any adjustments to the CST initial calculated savings are only made in the client's favor. "In the client's favor" refers to a lower CST savings value, because of how the calculated savings might affect potential financial guarantees between EmpiRx and the client. Of the denied claim CST sample data provided by EmpiRx for which savings was adjusted (i.e., differs from the Figure 1 approach), approximately 90% of adjustments result in lower savings than the standard approach, and approximately 10% of adjustments result in higher savings.[7] Lower adjusted savings is often a result of EmpiRx taking credit for only the initial fill savings (and not annualizing) for non-recurring claims. Higher adjusted savings typically results from the same "non-recurring claim" adjustment for cases where the average day supply based on EmpiRx's book of business is lower than the day supply for the denied claim. Higher adjusted savings might also occur if clinical review results in a change to the subsequent matched paid claim, for example.

The CST quantifies POS ingredient cost savings only. As such, it does not account for changes in rebates or member cost sharing. Ingredient cost savings may not correspond to net plan liability savings after accounting for rebates.

The CST relies on average annual days supply by product from EmpiRx's commercial book of business. This may differ from the average annual days supply reflected in a client's experience.

The savings appear to be actual ingredient cost savings to the plan. For denied claims with subsequent paid claims, the CST savings amount reflects any changes in distribution channel (e.g., retail, mail) or dispensing pharmacy (e.g., network discounts). Generally, physician and pharmacist state laws will not allow a pharmacist to change a patient drug therapy without the approval of the prescriber and patient. The subsequent cost savings from this change is reflected in the CST.

EmpiRx and its clients might want to consider business rules with the CST program which might include, but are not limited to, the following:

- Periodically auditing a sample of the CST savings. This could be done to ensure that the calculated savings align with the methodology employed by EmpiRx. This could include a review of how the standard savings calculation may have been adjusted for high-cost claims. This is important as the CST could be used as a basis for future risk-share arrangements.
- With the onboarding of a new client, there are usually certain drug high-level coverage rules and logic that are implemented to avoid paying for drugs which an employer does not want to reimburse. Generally, these should be excluded from the CST savings calculations. For example, Client A does not offer its employees coverage for compounded drugs. The CST savings should not account for these if they are part of coverage exclusion set-up rules.
- Medications that could be covered under both the medical and pharmacy benefit need to be identified and accounted for under the CST. For example, a patient could obtain the Orencia injection at the pharmacy, but if it is denied under the EmpiRx clinical management rules, this denial would count as a savings under the CST. However, the patient still could obtain the Orencia at the physician office, essentially resulting in no savings for the client. The client and EmpiRx will need to assess if this is a CST savings. It could be that the client still paid for the drug, but under the medical benefit.

[7] Excludes claims for products without historical utilization data (i.e., where average day supply is 0).

Caveats and Limitations

This Milliman report has been prepared for the specific purpose of reviewing the methodology associated with the Clinical Savings Tracker (CST) component of EmpiRx's Clinical Care Management (CCM) program. This information may not be appropriate, and should not be used, for any other purpose.

This report may be distributed publicly at the discretion of EmpiRx. If shared externally, the report should be shared in its entirety unless otherwise approved by Milliman. We do not intend this information to benefit, or create a legal liability to, any third party, even if we permit the distribution of our work product to such third party. Any third party recipient of this work product who desires professional guidance should not rely upon Milliman's work product, but should engage qualified professionals for advice appropriate to its own specific needs.

The information in this report is qualitative in nature. No party should rely on this information without requiring a thorough review and understanding of assumptions and methodology of the CST component of EmpiRx's CCM program and extensive knowledge of drug cost evaluation.

In performing this analysis, we relied on data and other information provided by EmpiRx. We have not audited or verified this data and other information but reviewed it for general reasonableness. If the underlying data or information is inaccurate or incomplete, the results of our analysis may likewise be inaccurate or incomplete. We performed a limited review of the data used directly in our analysis for reasonableness and consistency and have not found material defects in the data. If there are material defects in the data, it is possible that they would be uncovered by a detailed, systematic review and comparison of the data to search for data values that are questionable or for relationships that are materially inconsistent. Such a review was beyond the scope of our assignment.

The sample data reviewed for this analysis consists of 10,851 denied claims, corresponding to $4,953,060 in ingredient cost, across four groups for 2018. Our review reflects the CST process used by EmpiRx for 2018 data, which may differ from the process used for future years.

Milliman does not provide legal advice, and recommends that EmpiRx consult with its legal advisors regarding legal matters.

The terms of Milliman's Consulting Services Agreement with EmpiRx dated December 2, 2016 apply to this report and its use.

ACKNOWLEGDEMENT OF QUALIFICATION

Tracy Margiott, FSA, MAAA, is a consulting actuary for Milliman. She is a member of the American Academy of Actuaries and meets the Qualification Standards of the American Academy of Actuaries to render the actuarial opinion contained herein.

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