

CVS's Negligent Handling of its 2019 Formulary Change in Coverage for Diabetes Test Strips

by
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Summary

Around the first week in August for the past four year, CVS has made an official announcement of its next year's formulary changes. It posts these changes on its own websites.

But that changed in 2018. During an August 8th [3Q2018 Earning Conference Call](#), CVS said that 2019 formulary details would be available around October 1, 2018.

But, CVS waited until November 26, 2018 to post details on its own website. We believe that there has been a willful intent by CVS to minimize attention to upcoming formulary changes fearing bad publicity would delay government approval of their merger with the insurance company Aetna. The review included the Department of Justice, [state attorney generals](#) and [Judge Richard Leon](#) of the U.S. District Court of the District of Columbia and other state authorities.

In particular, CVS has been negligent in giving ample warning to diabetes patients of an upcoming switch in blood glucose test strips from LifeScan's OneTouch brand to Roche's Accu-Chek brand. We estimate that this change is going to affect up to 7.2% of CVS's 94 Million covered lives, or 6.8 Million people who have Type I or Type II diabetes, as they require constant blood glucose monitoring via a glucometer and test strips.

We conclude with the question of the impact CVS's negligent handling of this formulary switch on state "frozen formulary laws".

What is a formulary?

One of the most effective cost-controls employed by pharmacy benefit managers (PBMs) are their national formularies. Formularies are lookup tables embedded in software at the retail and mail order point of sale that alerts pharmacists as to which drugs are covered by a customer's drug benefit insurance plan.

Via formularies embodying what insurance covers and what it does not, PBMs' have the power to affect the demand for patented, but therapeutically equivalent drugs. This power enables them to negotiate rebates with pharmaceutical manufacturers (Pharma) in return for formulary placement. Placement entails more than just inclusion vs exclusion, but also a whole array of other conditions including prior authorization, step therapy, and quantity limits.

The more a PBM shelters a given drug from competition via its array of formulary controls, the higher Pharma is willing to pay via rebates to avoid those controls.

PBM formulary switches and exclusions are growing

It has only been since 2012 that PBMs began to make significant formulary exclusions of FDA-approved prescription drugs. Before that, they would include non-preferred drugs in the non-preferred Tier III of a formulary which carried the highest copayments.

In our 2005 paper [The Effect of Corporate Structure on Formulary Design](#), we looked at key therapeutic classes with small molecule brands having close therapeutic equivalents -- proton pump inhibitors (PPI), COX-2 inhibitors, and 2nd generation antihistamines. We found that PBMs practiced what we called the "the Soprano approach" to negotiation -- threaten harm to all, but negotiate payoffs to abstain from harm.

We called this negotiation strategy a "[sin of omission](#)" as there was no evidence of harm like formulary exclusions. It was a sin of omission in that PBMs should have excluded high cost brands in formulary therapeutic classes where there were generics that were close therapeutic equivalents. For example, in the mid-2000s, PBMs should have excluded the high cost brand PPI Nexium in favor of other PPIs that had gone generic like omeprazole (Prilosec).

Below is a spreadsheet from a 2005 paper [The Effect of Corporate Structure on Formulary Design](#) indicating a tendency in the mid-2000s for PBMs not to exclude brands that were close therapeutic equivalents.

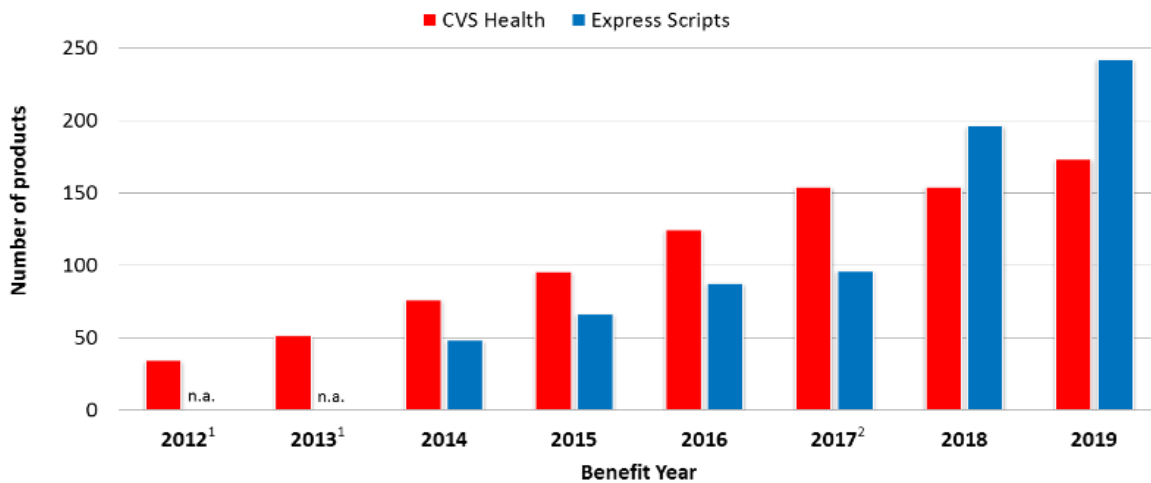
Table 2: Formulary Tier 2 Preference in Selected Therapeutic Classes									
in Tier 2		Proton Pump Inhibitors				Cox-2 Inhibitors		2nd Gen Antihistamines	
		AcipHex	Prevacid	Protonix	Nexium	Celebrex	Bextra	Allegra	Clarinetx
	KEY:								
4	Caremark Rx Primary/ Preferred Drug List (4/2005)		X		X	X		X	
6	Medco Preferred Prescription Formulary (2004-5)			X	X	X	X	X	X
6	2005 Express Scripts National Preferred Formulary		X		X	X	X	X	X

Formulary design has changed significantly since the mid-2000s. Now, there is a decided tendency among the Big 3 PBMs to grant exclusivity to drugs in formulary therapeutic classes where there are a number of therapeutic equivalents.

In our 2017 paper [Three Phases of the PBM Business Model](#), we argued that the trend of formulary exclusions stemmed from fundamental shift in the PBM business model after 2010. PBMs shifted from a reliance gross profits from mail order generics to a renewed reliance on retained rebates, this time from high list priced specialty drugs.

In addition to outright increases in net exclusions (see graph below), PBMs have become more aggressive in making one-for-one switches between 2 therapeutic equivalents resulting in no net change in the total number of exclusions.

Number of Products on PBM Formulary Exclusion Lists, 2012 to 2019



1. Express Scripts did not publish exclusion lists for 2012 and 2013.

2. Express Scripts data for 2017 have been restated. Its 2018 list initially had 159 products, then grew to 196 products with midyear additions.

Source: Drug Channels Institute analysis of company reports.

Published on Drug Channels (www.DrugChannels.net) on August 16, 2018.



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CVS's upcoming formulary switch of branded diabetes test strips

This paper focuses on CVS's handling of one upcoming formulary switch effective January 1, 2019. It involves the replacement of LifeScan's OneTouch branded diabetes glucometer and test strips with Roche's Accu-Chek branded glucometer and test strips.

It is by no means the only upcoming switch as "leaked" (more on this later) on a PBM consultant blog and on websites of various plan sponsors using CVS as their PBM.

By far, it is this test strip switch that will affect the most people. We estimate that this change will affect up to 7.2% of CVS's 94 Million covered lives, or 6.8 Million people who have Type I or Type II diabetes, as they require constant blood sugar monitoring



The switch in coverage for a medical diagnostic device requires patients to invest a lot more time and energy than a switch between therapeutic equivalent pills. First, users will have to order the new glucometer and have it arrive before being able to use the new test strips. There is not telling how long that will take.

Then users will have to spend time learning how to calibrate and read their new glucometer. Finally, if users have installed OneTouch software on their PCs with histories of readings, they will have to transfer that data to Accu-Chek software which will be no easy feat.

Why did CVS decide to switch coverage for test strips?

Our search of past formularies confirmed that CVS gave LifeScan's OneTouch exclusive formulary placement between 2015-2018. OneTouch likely enjoyed exclusive coverage going back even longer. Our cursory view of the formularies of the other two big PBMs -- Express Scripts and OptumRx -- indicated that for the past few years the other 2 PBMs also included OneTouch on their formularies, although not always exclusively.

Finally only CVS decided to make a switch in 2019.

Obviously, gross rebates and related net costs to CVS were important factors in making this impactful switch. Although [we are a leading critic](#) of the PBM practice of making formulary choices on the basis of gross rebates rather than net costs after rebates, we give CVS the benefit of the doubt here.

Give the inconvenience that this switch will cause to users, we just cannot fathom CVS making this switch based on small differences in net costs. CVS made the switch because Roche's likely decided that 2019 was the year to go "all in" with rebates. Note that it looks like Roche's substantial rebate commitment to win CVS over in 2019 likely left Roche in no position to offer substantial rebates to the other 2 Big PBMs as they both continue their exclusive coverage for OneTouch in 2019.

But, quality may have been another significant factor involved in CVS's decision to switch. While LifeScan was the pioneer in electrochemical glucometers and test strips, it has lost its lead to the likes of Accu-Chek, Contour, a division of Panasonic Health Products, and FreeStyle Lite, a division of Abbott.

Evidence to support this comes from [results](#) of a [Blood Glucose Monitor System Surveillance Program](#) conducted by the respected Diabetes Technology Society. (see below). They found that only 6 out of 18 meters tested passed their 90% accuracy threshold. Contour and Accu-Chek were at the top. Both LifeScan OneTouch brands failed the accuracy threshold test.

The devices that passed were:

- **Contour Next** from Ascensia (formerly Bayer) – 100%
- **Accu-Chek Aviva Plus** from Roche – 98%
- **Walmart ReliOn Confirm (Micro)** from Arkray – 97%
- **CVS Advanced** from Agamatrix – 97%
- **FreeStyle Lite** from Abbott – 96%
- **Accu-Chek SmartView** from Roche – 95%

The devices that failed were:

- **Walmart ReliOn Prime** from Arkray – 92%
- **OneTouch Verio** from LifeScan – 92%
- **Prodigy Auto Code** from Prodigy – 90%
- **OneTouch Ultra 2** from LifeScan – 90%
- **Walmart ReliOn Ultima** from Abbott – 89%

Another factor in CVS's decision to switch might have been a change in ownership in LifeScan in 2018. According to [Wikipedia](#) entries, after first being put up for sale in 2017, LifeScan, a division of Johnson & Johnson, was bought finally by the private equity firm Platinum Equity in June 2018.

The reason why this sale might have been a factor is that large Pharma companies have developed a strategy of bundling rebates to lock in exclusive formulary placements for an array of their drugs. The new private equity firm who bought LifeScan in 2018 was in no position to compete with Roche on basis of bundled rebates.

We wish to be reiterate that our problem with CVS is not its choice to replace OneTouch with Accu-Chek. The switch looks good both from a net cost and well as from a quality standpoint. The problem we have is CVS's **handling** of the switch as we describe below.

CVS delayed for four months an official announcement of its 2019 formulary removals

Around the first week in August for the past four years, CVS has made an official announcement of its next year's formulary changes. It posts details of these changes on its own websites. Plan sponsors using CVS as their PBM follow suit soon thereafter. This practice is similar to that of the 2 other big PBMs -- [Express Scripts](#) and [OptumRx](#)

- July 31, 2014 official announcement [2015 Formulary List of New Removals](#)
- August 3, 2015 official announcement [2016 Formulary List of New Removals](#)
- August 2, 2016 official announcement [2017 Formulary List of New Removals](#)
- August 1, 2017 official announcement [2018 Formulary List of New Removals](#)

But that changed in 2018.

During a [3Q2018 Earning Conference Call](#) on August 8, 2018, CVS said that formulary change details would be available around October 1, 2018.

- Effective January 1st, we plan to remove **23** products from our Standard Control Formulary, while adding back **4** products that have been previously removed

- Not providing list of drug changes at this time; list will be available around October 1st

However, on **October 1, 2018, there was no official announcement.** Instead, CVS posted a .pdf update of its 2018 formulary exclusions accessed via the following URL.

https://www.caremark.com/portal/asset/Formulary_Exclusion_Drug_List.pdf

Then, on or after November 26, 2018, CVS deceptively posted the long delayed 2019 formulary change details using THE SAME URL previously used to access its October refresh of the 2018 formulary.

In other words, it deceptively replaced a 2018 formulary .pdf with 2019 formulary .pdf leaving no audit trail that there was sequencing of postings.

The document number at the bottom of 2019 .pdf was 106-25923A and the date used was 100119. v2. It also had a document date of November 16, 2018

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Document date: November 16, 2018

106-25923A 010119 v2

www.caremark.com



Fortunately we downloaded the 2018 refresh which now can be accessed only from our website

https://c1c0481a-8d34-49dc-ad66-d6c488c905a9.usrfiles.com/ugd/c1c048_546aba2d715449c781fd71db67995390.pdf

The document number at the bottom of the 2018 refresh pdf was 106-25923A and the date used was 10/01/18.

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106-25923A 100118

www.caremark.com



Here is a the timeline indicating that an October 1st announcement would have come toward the end of CVS's efforts to gain government approval for earlier announced merger with the insurance company Aetna.

October 26, 2017 [WSJ first reports merger talks between CVS and Aetna](#)

December 3, 2017 [Negotiations complete, submit to DOJ for approval](#)

October 1, 2018 CVS scheduled to announce 2019 removals. Instead posts refresh of 2018 removals using the following URL

https://www.caremark.com/portal/asset/Formulary_Exclusion_Drug_List.pdf

October 10, 2018 [DOJ approves merger](#)

October 18, 2018 [Multi-state coalition of Attorney Generals approves merger](#)

November 16, 2018 CVS posts actual 2019 Formulary Exclusion List using same URL as the 2018 formulary refresh

November 28, 2018 [CVS announces close of merger agreement with Aetna](#)

November 29, 2018 [Federal Judge raises prospect of not approving merger](#)

Any bad publicity from a October announcement of 2019 formulary changes might have derailed the conclusion of the government approval process. As it turned out, the merger was approved. The absence of the October 1st announcement might have helped.

In our opinion, CVS's failure to announce this major change is a case of negligence. There has been a willful intent on CVS's part to downplay this switch in order to minimize potential bad publicity during a period where CVS's merger with the insurance company Aetna was being reviewed.

"Leaks" of CVS's 2019 Formulary Switches

While CVS delayed posting the official announcement until November 16, 2018, there has been a series of "leaks" in the form of PBM consultant blog posts and postings of .pdfs on websites of plan sponsors using CVS as their PBM. Basically, a PBM consultant and plan sponsors "jumped the gun" in these announcement thinking that CVS would made it official by October 1, 2018.

We were first alerted to the test strip switch on September 27, 2018. Knowing that CVS had promised to announced details by October 1st, our online search that day turned up the following [blog post](#) by the CEO of the largest pure PBM contract consultant Pharmaceutical Strategy Group (PSG).

"CVS is changing their only covered test strips, One-Touch to Accu-Check where members will need to obtain a new meter and learn any new or different features of the new preferred products."

Further searches revealed other "leaks" of details in the form of .pdf files. Below is a listing of some of our findings. Each files was stamped with CVS's logos and marked with CVS-generated document numbers and date.

- [West Chester Area School District \(WCASD\)](#) 106-46444F 092118
- [John Hopkins Employee Health Plan](#) Document 106-40278A 092819
- [Carnegie Mellon University](#) 106-25923A 010119

- [The Vanguard Group](#) Document 106-25923A 010119
- [Wisconsin University - Madison](#) 106-31697B 010119

What should have CVS done?

With a few exceptions (see below), the following footnote at the end of the each .pdf on plan sponsor sites is the only effort to date to inform and guide consumers through this switch.

“An ACCU-CHEK blood glucose meter may be provided at no charge by the manufacturer for those members currently using a meter other than ACCU-CHEK. For more information on how to obtain a blood glucose meter, call 1-877-418-4746
ACCU-CHEK brand test strips are only preferred options.”

In our search of online websites, we found only Carefirst Blue Cross Blue Shield, one of CVS's largest clients covering 3.2 million in the Mid-Atlantic region and the [State Health Benefits Plan \(SHBP\) of Georgia](#) making a real effort to inform and guide members.

On [November 14, 2018](#), Caremark published a letter that it would be sending via regular mail to every impacted member. Carefirst even labeled the test strip change as constituting “the majority of the negative disruption”

- The majority of the negative disruption is due to the change in the preferred diabetic test strip. Accu-Chek will now be the preferred test strip and One Touch test strips will be excluded.
 - Impacted members will receive the attached letter; refer to the attached FAQs for more information about this change.

Below is a screenshot of the full letter Carefirst said it would be sending to each impacted member.

Effective [DATE], the blood glucose test strips you currently use, [test strip name], will no longer be covered under your prescription benefit plan. If you continue to use your current test strips, you will be responsible for the full cost of the test strips.

Accu-Chek® test strips will be the covered option under your prescription benefit plan.


What to do next:

1. **Order a new Accu-Chek® meter at no cost to you.** Choose one of the following:
 - Fill out and mail the enclosed Diabetes Supply Order Form, or
 - Call the CVS Caremark® Diabetes Meter Team at 1-877-418-4746.
2. **Get a new prescription for Accu-Chek® test strips to fill after [DATE].** Choose one of the following:
 - Log in to www.carefirst.com/myaccount and select "Drug and Pharmacy Resources" and "Request a New Mail Order Prescription" to start delivery by mail,
 - Fill out and mail the enclosed Diabetes Supply Order Form,
 - Call the CVS Caremark Diabetes Meter Team at 1-877-418-4746, or
 - Ask your doctor to send a new prescription to your pharmacy.

Please note: Prescriptions for Accu-Chek® test strips will be covered after [DATE].

To learn more about your prescription benefit, log in to *My Account* at www.carefirst.com/myaccount and click on Drug & Pharmacy Resources under Quick Links or call CareFirst Pharmacy Services at 800-241-3371.

Sincerely,



Brian Pinto, PharmD, MBA

The following is a list of other measures CVS we have come up with that should have undertaken to smooth the transition.

- Like Carefirst, urge all client plan sponsors to send a letter via regular mail to all impacted members informing them of switch and instructions for ordering new meter.
- Upon request, offer December delivery of new Accu-Chek glucometer and one package of test strips. (done by the [SHBP of Georgia](#))
- Get retail pharmacies involved early by offering to build up inventory with new Accu-Chek meters and test-strips.
- Post online videos showing how to use new meters. ([done by the SHBP of Georgia](#))
- Make sure history of readings stored on members' PC can be transferred easily between OneTouch software programs to Accu-Chek software programs.

Will CVS handling of this switch hasten the passage of “frozen formulary” laws?

Currently, there is a smattering of states that have passed legislation limiting how often PBMs can make formulary changes during any plan year and require prior notice before the changes takes effect. Due to the trend toward formulary exclusions, more and more [states are considering adopting their own](#) “frozen formulary” laws.

These [so-called “frozen formulary”](#) laws generally focus on changes **within** any given plan year. We could find no state law dealing with requirements for sufficient notification of formulary changes for the new plan year.

For example, the general rule has been for the Big 3 PBMs to announce new plan year formulary changes around the first week in August, a full 4 months before the new plan year. CVS’s official announcement delay to November 16th occurred only 35 days before the beginning of the new plan year.

As late as this was, it looks like CVS’s November official notification did not violate any existing state laws.

Still, if CVS’s switch in diabetes test strip coverage causes as much disruption and negative publicity as we anticipate, we could see that this event become the spark for a whole slew of “frozen formulary” laws requiring a minimum of 3 months or 90 days prior notification of new plan year formulary changes, including individual letters mailed out to impacted consumers.