

# *Newsletter*

## This Quarter's Articles

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Robert Kordella, RPh

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Lindsey Butler, PharmD, CSP, AAHIVP

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Joe Schmidt, MBA



## Barriers to Biosimilars, and What You Can Do

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Despite all of the excitement earlier this year surrounding the launch of biosimilar versions of Humira (adalimumab), there has been extraordinarily little uptake of those products across our book of business in calendar year 2023 (through October 31, 2023.) Here is a glimpse at the magnitude of the indifference that has greeted the launch of biosimilar adalimumab products:

- In total, our clients dispensed slightly over 97% of adalimumab claims using Humira and fewer than 3% of claims using a biosimilar adalimumab product during the analysis period. By contrast, when generic versions of a non-specialty drug are launched, we typically see 90% or more claims switch to the generic version in a similar amount of time.
- A single client accounted for over half of those biosimilar adalimumab claims. This client dispenses the medications out of their own pharmacy, so they have more control than most plan sponsors.
- Fewer than 10% of our clients had any utilization of a biosimilar version of Humira.
- Among those clients that had any biosimilar adalimumab utilization, most had fewer than ten claims.

### WHAT HAPPENED? IS THIS WHAT YOU EXPECTED?

It was not what I expected, so I asked each of the PBMs who attended our most recent PBM Summit three questions to try to understand what was happening from their perspective. Those questions were:

1. Are you keeping Humira “at parity” (meaning, at the same formulary tier, having identical copay/coinsurance levels, and with identical utilization management rules) to your preferred biosimilar adalimumab products on your formulary?
2. Are you actively offering patients and providers the opportunity to switch from Humira to a potentially less expensive biosimilar adalimumab product?
3. How much has the market share of Humira changed across your book of business since the launch of biosimilar adalimumab products?

The unanimous responses to these three questions by all PBM attendees were: 1) Yes, 2) No, and 3) Very little.

Rather than focusing on the particular details surrounding the terms built into PBM rebate contracts, and what PBMs may and may not do as a result of those contracts, let’s focus on what you can do to help raise the awareness among Humira utilizers within your membership of the availability of biosimilar adalimumab products and pierce any barriers that may exist.

Your PBM should have communicated which biosimilar adalimumab products they will be covering in their formulary that will be effective for your membership as of 1/1/2024. As a way to heighten visibility of the recent launch of biosimilar alternatives to Humira, some at a potentially lower cost to members, you may want to craft a brief communication to your membership alerting them that these biosimilars will be available.

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Let's face it – some members who are using Humira will not want to switch to a biosimilar, since some of them may have been stable and thriving on Humira for close to 20 years, and its cost is not an issue for them. That is understandable. However, some members and their physicians may welcome the opportunity to consider using a potentially lower-cost option. Since you are always free to communicate with your pharmacy benefit plan membership about your plan's details, you should specifically call out the biosimilar adalimumab opportunity. Let your membership know that the option exists, and advise them to talk with their physician to see if a lower-cost option may be clinically and economically suitable for them. Those members who are willing to switch simply might not know that such an option exists unless you point it out to them and may be grateful when you do.

We have prepared a brief, clear communications template that you can use to get the word out about this opportunity. Just reach out to your account team and we will be happy to share it with you.



**Robert Kordella, RPh, MBA**  
**Senior Vice President and Chief Clinical Officer**

Bob has more than 35 years of diverse experience in the pharmacy industry. Over the course of his career, Bob has led clinical and PBM operations teams in successfully managing more than \$4 billion in annual drug spend. Additionally, his efforts have limited per-member-per-year spending growth to levels that have simultaneously drawn industry acclaim and consistently high levels of member and payer satisfaction.



## A New Option for Members with Diabetes Requiring Mealtime Insulin

Administering insulin regularly can be very hard for members, and up until two years ago, the choices for delivery insulin were limited to vial and syringe, pen or continuous delivery via a pump. For those choosing multiple daily insulin injections, remembering to take your insulin with you or just not wanting to take insulin outside of the house is a large burden<sup>1,2</sup>. Missing just four injections on average per week will raise the A1C by almost 1%<sup>3</sup>. Now there is a new option for people to wear their insulin for up to three days: the CeQur Simplicity 3-day wearable mealtime insulin patch. It is approved for both type 1 and type 2 diabetes in adults over 21 years of age requiring bolus insulin.



CeQur Simplicity holds between 100-200 units of rapid-acting insulin (cleared for Humalog and Novolog U100 insulins) and administers 2U of insulin per click. The insulin is provided separately, and the patient fills the patch with rapid-acting insulin. The patch is thin and lightweight and can be worn discreetly under clothing. When worn for three days, each CeQur Simplicity patch replaces at least nine mealtime injections and makes it even easier to deliver snack and correction doses that often get skipped when not at home. CeQur Simplicity fits easily into people's lifestyles, allowing them to shower, sleep, swim and exercise, ensuring they always have their mealtime insulin with them. These features lead to better adherence to members' prescribed insulin regimens<sup>4</sup>.

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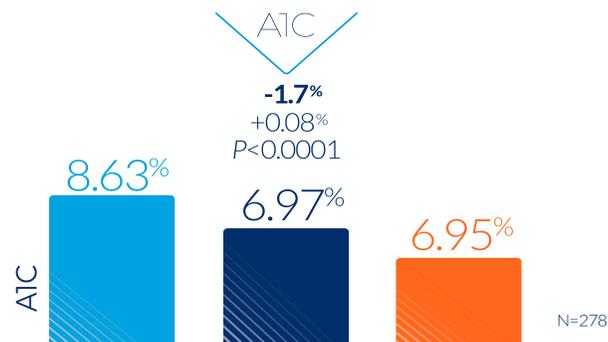
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CeQur Simplicity has been thoroughly tested, with clinical trials showing functional testing, user experiences, randomized, controlled studies and real-world evidence. In a randomized control trial, 278 people with type 2 diabetes were studied using either the CeQur Simplicity patches or insulin pens to deliver their mealtime insulin (basal injections were still delivered 1x/day via pens). The results demonstrated a statistically significant improvement in A1C of 1.7% and a 50% improvement in time-in-range when using the CeQur Simplicity patch<sup>4,5</sup> compared to pens.

CeQur Simplicity could be a great addition to help diabetics on bolus insulin achieve their A1C and overall health goals. Individuals can obtain the patch by talking with their healthcare provider and getting the prescription filled on their pharmacy benefit. It appears on many of the PBM formularies and is comparable in cost to insulin pens.



Source: <https://myceqursimplicity.com/healthcare-professionals/>



**Lindsey Butler, PharmD, CSP, AAHIVP**  
Clinical Pharmacy Consultant

As a Clinical Pharmacy Consultant, Lindsey's focus is to help healthcare clients develop a long-term strategic plan for their pharmacy benefit. Her expertise extends beyond the pharmacy benefit manager (PBM) selection process to also include designing and optimizing in-house pharmacy networks to strategically drive utilization towards owned assets, maximizing 340B programs for covered entities, and clients implementing effective solutions that lead to improved member outcomes. What sets Lindsey apart is her client-centric approach. She listens attentively to each client's unique needs and tailors her solutions accordingly.

<sup>1</sup> Grabner M, et al. 2013. Using Observational Data to Inform the Design of a Prospective Effectiveness Study for a Novel Insulin Delivery Device, ClinicoEconomics and Outcomes Research. 5:471-479.

<sup>2</sup> Randlev J, Poulson J. 2008. How much do forgotten insulin injections matter to hemoglobin a1c in people with diabetes? A simulation study. Journal Diabetes Science and Technology. 2(2):229-35.

<sup>3</sup> Chase HP, Horner B, McFann K, et al. The use of insulin pumps with meal bolus alarms in children with type 1 diabetes to Notimprove glycemic control. Diabetes Care. 2006;29(5):1012-1015.

<sup>4</sup> Bergenstal R, Peyrot M, Dreon D, Aroda V, Bailey T, Brazg R, Frias J, Johnson M, Klonoff D, Kruger D, Ramtoola S, Rosenstock J, Serusclat P, Weinstock R, Naik R, Shearer D, Zraick V, Levy B. 2019. Implementation of Basal-Bolus Therapy in Type 2 Diabetes: A Randomized Controlled Trial Comparing Bolus Insulin Delivery Using an Insulin Patch with an Insulin Pen. Diabetes Technology and Therapeutics 21 (5):1-13.

<sup>5</sup> Bergenstal R., et al Comparing Patch vs Pen Bolus Insulin Delivery in Type 2 Diabetes Using Continuous Glucose Monitoring Metrics and Profiles; Journal of Diabetes Science and Technology 1-7, 2021



## What Does “Lowest Net Cost” Really Mean?

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The pursuit of "lowest net cost" in the realm of pharmacy benefits is an objective seemingly shared by both Plan Sponsors and Pharmacy Benefit Managers (PBMs). However, decoding this concept reveals nuances that resonate differently among the stakeholders – in this case, the plan sponsor, the plan participant, drug manufacturers and the PBM.

Understanding the components that influence the "net cost" of a drug is crucial, with some factors being less apparent than others. For Plan Sponsors and PBMs, net cost represents the ingredient cost of the drug plus the dispensing fee paid to the pharmacy minus the drug manufacturer's rebate on that drug, if any.

The ingredient drug cost is subject to dynamic calculations, varying by the drug type, dispensing pharmacy and even when the drug was dispensed. The AWP (average wholesale price), a reference price for drug pricing, undergoes periodic updates to reflect drug manufacturer price changes. The negotiation dynamics between pharmacies and PBMs, along with the generic competition faced by the drug, play a crucial role in determining the discounted cost off AWP.

Dispensing fees, another net cost component, exhibit variability based on the reimbursement model established between PBMs and pharmacies, local pharmacy competition and the power dynamics at play during contract negotiations. Additionally, the PBM's fee for administering the pharmacy benefit program and processing claims, as well as the dispensing pharmacy's profit margin, can either be embedded in the ingredient cost of a "traditional" (or "spread") pricing model or separately added to the claim charge.

Arriving at the "net cost" also involves factoring in drug manufacturer rebates, which represent additional discounts off brand drug prices that bypass the dispensing pharmacy. These rebates are negotiated in confidential agreements between PBMs and drug manufacturers. They vary by drug and the preferred position over the drug manufacturer's competitors on the PBM's or Plan Sponsor's list of covered drugs.

Rebate amounts are highly dependent on the Plan Sponsor's and their PBM's ability to move market share from non-preferred brands to preferred brands, so the wider the gap between coverage tiers, or the more competing products are not covered, or the more favorable the clinical criteria applied, the more the preferred drug manufacturer is willing to lower the "net cost" by paying more in rebates.

However, rebates are paid to PBMs (and subsequently to Plan Sponsors) well after the drug is dispensed (and the plan participant has paid their copayment), which can lead to unintended consequences.

While the net cost after rebates of the preferred product is less than other branded alternatives, the plan participant only experiences what they pay on the "gross" cost of the drug. If there's a competing drug available for less cost to the plan participant, or if the drug can be purchased for less cost out of pocket if the claim doesn't process against the pharmacy benefit (i.e., by means of a discount card program or member club price), then the value of the Plan Sponsor's pharmacy benefit, as perceived by the plan participant, is diminished. In addition, the participant's decision to use a non-preferred drug can result in lost rebates, which could have been used by the Plan Sponsor to subsidize the cost of the pharmacy benefit for all plan participants.

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Lastly, because the negotiation is led and decided by the PBM and generic drug manufacturers don't participate, the competition is really among branded drug manufacturers to become the lowest cost in a therapy class, so the "lowest net cost" referenced by the PBM may only mean "...of competing branded products" in which they have an interest, rather than the lowest cost of therapy for the Plan Sponsor and the participant.

As drug therapies continue to evolve, navigating towards the lowest "net cost" of a pharmacy benefit requires constant monitoring and response. Consider the following strategies to work toward achieving the lowest net cost:

**INCORPORATE COMPREHENSIVE BENEFIT DESIGN:** Tailor your pharmacy benefit plan designs to align with your overall benefit coverage philosophy, industry competition and budget considerations.

**OPTIMIZE GENERIC COVERAGE:** Adopt a "Generics First" policy. If offered by your PBM, implement a preferred drug list that supports a "Generics First" philosophy that better aligns the financial incentives of both Plan Sponsor and participant. For high-cost generics, add a second generic drug tier that communicates to plan participants the relative higher cost of these generic drugs.

**STRATEGICALLY ASSESS BRAND COVERAGE:** Evaluate the necessity of covering brand drugs within treatment categories where generics are widely accepted. Employ prior authorization and other utilization management tools to ensure cost-effective coverage.

**PRIORITIZE THERAPEUTIC ALTERNATIVES:** Focus on therapeutic alternatives with brand drug competition, as these often generate rebates from drug manufacturers, contributing to reduced net drug costs. This is often achieved with step therapy or prior authorization policies.

**REMEMBER REBATES' ROLE:** Rebates are a means to an end (lowest net cost), not the end itself.

**UTILIZE EXCELSIOR EXPERTISE:** Leverage the experience and expertise of the Excelsior team to make informed benefit decisions, review criteria for appropriateness and achieve a lowest cost, net of rebates, that aligns with your benefit philosophy, competition and budget.

As the pharmaceutical and pharmacy benefit industry landscapes evolve, staying informed and implementing strategic benefit design decisions will be paramount for Plan Sponsors to manage and minimize the cost of your pharmacy benefit.



**Joe Schmidt, MBA**  
**Vice President and Team Lead**

Joe Schmidt joined Excelsior in July 2020 and has over 25 years' experience in the healthcare industry, including pharmacy benefit management, managed care, retail pharmacy and healthcare provider. As a Vice President, Team Lead, Joe guides clients through the PBM procurement process, enabling clients to maximize savings and negotiate contract rights.