The Teva Biosimilars Trend Report:

Perspectives from Managed Care, Providers & Employers

SECOND EDITION

teva

Dear Colleague,

On behalf of Teva Pharmaceuticals, we are pleased to present the second edition of *The Teva Biosimilars Trend Report*. This report examines the latest issues, challenges, and developments in the rapidly evolving biosimilars market from the perspective of managed care professionals, healthcare providers, and employers. The goal of the report is to provide key insights into the issues affecting biosimilar coverage, prescription, and utilization from each of the 3 groups of stakeholders.[1]

***The Teva Biosimilars Trend Report,* second edition, features:**

National surveys conducted in the summer of 2024 with 54 decision-makers at managed care plans, 73 prescribers of biologic therapies (from rheumatology, gastroenterology, and dermatology specialties), and 39 executives representing employers and business coalitions. The report includes:

- Sections covering the perspectives of managed care payers, healthcare providers, and employers.
- Responses analyzed by independent experts representing each topic area. Nine experts also provide commentary on the findings and share their own experiences in the biosimilars space.
- An insightful article on the real and potential effects of the Inflation Reduction Act on biosimilar development and market access.
- A critical discussion of biosimilar sustainability, with a focus on prospects for the pharmacy benefit–covered products.

DID YOU KNOW?

To date, there have been more than 70 approvals in the US biosimilar market, including approximately one-fifth with an interchangeable designation.[2]

Current data show:

- The reference product with the greatest cost-savings potential, Humira®, still has 81% of the market 2 years after adalimumab biosimilar introduction. This represents far slower adoption than has been seen with other biosimilars in competitive categories and may have implications for future biosimilar introductions.[3]
- After 18 months on the market, the existence of adalimumab biosimilar competition alone has accounted for approximately $11 billion in savings (but without the utilization of biosimilars that it implies).[4]
- According to IQVIA data, the rate of annual price reductions (expressed as average sales prices) for medical benefit drugs subject to biosimilar competition has been consistent. Falling at a moderate rate, they reach a pricing floor at around 70% of the reference product's list price prior to biosimilar launch. This is not the case with the pharmacy benefit–covered biosimilars.[5]
- In 2025, biosimilar competition is scheduled to be launched for Stelara®, Prolia®/Xgeva®, and Eylea®, which account for more than $17 billion in US net sales revenues, representing extraordinary opportunities for specialty drug savings.[6-8]

At Teva Pharmaceuticals USA, we appreciate the critical role you play in the delivery of quality healthcare and managing the appropriate use of high-cost specialty pharmaceuticals. We hope that the information in this report will help inspire change, generate solutions, and create opportunities for payers, providers, and managed care decision-makers to collaborate and collectively improve the current state of care and clinical outcomes for patients.

Sincerely,

Thomas Rainey
Senior Vice President US Biosimilars
Teva Pharmaceuticals USA

W. C. (Bill) Williams III, MD
Executive Vice President
National Association of Managed Care Physicians

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Sonnenreich P, Leo S, Sebor C, Mehr S, eds.
The Teva Biosimilars Trend Report, Second Edition. 2025.

Executive Summary

Biosimilars have produced $36 billion in savings to the US healthcare system since their introduction in 2015 to 2023. That number only continues to grow. An estimated $11 billion in savings was accrued in just 18 months from the launch of the first biosimilar for Humira® (adalimumab) in January 2023.[4,9]

Uptake levels and market shares of biosimilars that have been marketed for more than 3 years range from very high (> 80%) for oncology care agents to very low for ranibizumab biosimilars (1%).[10]

In 2025, the potential savings from biosimilar competition to Stelara® (ustekinumab), Eylea® (aflibercept), and Prolia®/Xgeva® (denosumab) could be substantial. However, this is not assured, as the biosimilar industry is facing several challenges, including decisions from payers and pharmacy benefit managers (PBMs) regarding pharmacy benefit coverage that affect biosimilar utilization, net cost recovery issues for providers who engage in buy-and-bill for medical benefit biosimilars, and the unintended consequences of regulation to control Medicare prescription drug costs.[10-12]

The experience of adalimumab biosimilars on the market from 2023-2024 may offer an indication for what to expect for other biosimilars that will launch in the near future and be covered under the pharmacy benefit.[5]

Utilization of the newly marketed adalimumab biosimilars lagged at 2% for 15 months, before the launch of private-labeled and co-branded versions in April 2024 by CVS Health's Cordavis. This created an immediate spike in biosimilar utilization, but one that leveled out quickly. The addition of other private-labeled and co-branded adalimumab copies have yet to improve biosimilar uptake. Therefore, the development of this PBM subsidiary as a new channel for biosimilar distribution may boost biosimilar utilization but not offer wide enough access and acceptable revenues for biosimilar manufacturers.[13,14]

It is possible that other new biosimilars covered fully (or partially) under the pharmacy benefit may be subject to similar market-uptake conditions (e.g., ustekinumab, tocilizumab, denosumab). For ustekinumab, Evernorth has already announced that its Quallent subsidiary will offer an ustekinumab biosimilar at an 80% discount upon launch. These types of moves have been shown to influence drug development decisions of prospective biosimilar manufacturers.[5,15]

Providers' responses to Teva's survey conducted in 2024 show that their attitudes towards biosimilars seem to be improving, which may mean that the educational efforts of the Food and Drug Administration (FDA) and industry are having their intended effect. This may also be impacting patient resistance to biosimilars, which both physicians and payers described as less of a concern in 2024 compared with Teva's 2023 survey.[16]

Interchangeability continues to be cited by payers and providers as a tool to improve biosimilar uptake, likely via automatic substitution for the reference product. Automatic substitution, however, has not yet been utilized widely for any interchangeable product. Interchangeability is a complex subject, as the requirements for the designation are changing and the very need for the designation is being reconsidered on several fronts. The FDA is actively deemphasizing the designation and it may be subject to legislation that would eliminate it altogether.[17,18]

Responses also show that the average sales prices (ASPs) of biosimilars and their reference biologics are being closely watched, by providers in particular. The purchase and reimbursement of products under the buy-and-bill system exposes providers to the possibility of financial loss, as there is a 6-month lag time in the reporting of current ASPs by the Centers for Medicare & Medicaid Services. This could mean that a clinic or health system purchases a biologic for one price, and

by the time it is reimbursed, the ASP may have dropped, lowering the provider's reimbursement (possibly to the point of paying more for the drug than they receive in reimbursement). This may especially be the case for products whose ASPs have not yet reached a pricing floor, which has historically been between 60% and 70% below the original wholesale acquisition cost (WAC) price.[10]

Through the Inflation Reduction Act of 2022 (IRA), the Biden Administration sought to leverage the negotiating power of Medicare to obtain discounts for its most costly prescription drugs while protecting biosimilar competition. For example, the increase in provider reimbursement from ASP + 6% to + 8% may induce the prescription of biosimilars in a buy-and-bill practice. However, the IRA included ustekinumab in its initial price negotiation list, despite the fact that ustekinumab biosimilars are launching in the first quarter of 2025, a year before a Medicare-negotiated price will take effect.[19]

Furthermore, the IRA's provisions for removing the coverage gap from its financing has created unintended incentives for payers to favor reference products over biosimilars and created a 20% "tax" on manufacturers in the catastrophic coverage phase. This additional payment by manufacturers, in the presence of exceedingly tight margins with highly discounted products, may deter drug makers from developing biosimilars in the future.[11,20-22]

Despite the important potential effects of the IRA on future biosimilar development and competition, the responses of payers, healthcare providers, and employers surveyed in 2024 reveal they are generally unaware of its implications. Whereas 26% of payers in the survey reported being very aware of the potential impact of the IRA on biosimilars, about 60% of payers and providers could not venture what the effects might be (vs 84% of employers).

THE MANAGED CARE SURVEY

Key Findings

- Negative perceptions related to biosimilar efficacy and safety are fading, and 63% of managed care executives and PBM executives indicated low or very low levels of concern regarding provider resistance.
- Although managed care executives appreciate the efficacy and safety characteristics of biosimilars, they were cautiously optimistic when asked whether biosimilars will shift utilization away from reference products, with an average rating of 5.5 on a 7-point scale (7 = strongly agree). The majority of payers agreed or strongly agreed, providing ratings of 6 or 7. This response may be related to the willingness of reference manufacturers to offer deeper drug rebates in an effort to retain market share in the short term.[5]
- For the drugs covered under the pharmacy benefit, the top factors having the greatest impact on biosimilar utilization were price discounts and rebates (74%), payer/PBM coverage of the biosimilar (63%), payer/PBM preference of biosimilars or exclusion of the reference product (41%), and interchangeability (41%).
- The emphasis on interchangeability is not well understood, owing to the FDA's current efforts to make any approved biosimilar interchangeable with its reference product and the lack of use of automatic substitution as a benefit of interchangeability. From their perspective, the payers believe "simpler, faster non-medical conversions" is the most important benefit of the interchangeability designation.
- To overcome barriers to biosimilar adoption in commercial plans, the respondents considered net pricing of > 25% less than the reference product the most likely to work, earning a mean score of 7.9 out of 10 (10 = most effective strategy). This applied to both Medicare and commercial plans. The production of real-world evidence, use of low-WAC pricing, and reduced biosimilar cost sharing for patients were tied for the second spot (mean score, 6.9 each).
- Unexpectedly, PBM respondents actually ranked low-WAC pricing higher than plan participants did (mean scores, 8.0 vs 6.8, respectively). The PBM representatives also seemed to value dual pricing to counter barriers to biosimilar adoption (mean scores, 7.9 vs 5.3, respectively).
- There seems to be a disconnect between health plan executives' perception of adalimumab biosimilar market share and actual uptake. One-quarter of the respondents indicated that all

biosimilar market share was above 61% in the adalimumab category. A total of 29% reported adalimumab biosimilar market shares between 31% and 60%.

- Yet, national prescription data reflect a non-branded Humira® or biosimilar uptake figure closer to 25%. Furthermore, 48% responded that they already prefer 1 or more Humira® biosimilars over the innovator, whereas 37% believe they will at some point in 2025.[13]
- Despite their relative comfort with biosimilars, payers ranked switching patients with stable conditions to a biosimilar ranked as their number 1 concern in covering these agents (24%), followed by a clinician's willingness to prescribe a biosimilar (15%), and lack of economic benefit to the payer (13%). While the first two concerns may be related, none of these stated concerns were agreed to by more than one-quarter of the respondents.
- For medical benefit–covered biosimilars, the most highly ranked considerations were also related to price: WAC price vs the reference product (mean ranking, 2.0), rebates vs the reference product (mean ranking, 2.9), and lowest ASP (mean ranking 2.9).
- For the upcoming Stelara® and Actemra® biosimilars, 66% and 13% of payers surveyed anticipated they would exclude coverage of the respective reference products at some point in 2025. Forty-one percent for each believed they would require failure of one biosimilar first, before accessing the reference products.
- The most common response regarding expected cost savings for near-term new biosimilar drug categories was 26% - 50%, which was reported by up to 24% to 31% of respondents. Those categories were ustekinumab, aflibercept, eculizumab, tocilizumab, denosumab, and golimumab. An additional 19% to 26% believed savings would be between 16% and 25%.
- Among a broad range of predictions on what will happen with future PBM legislation efforts, a few common themes emerged. The 2 most commonly held beliefs of managed care respondents were that PBM legislation would result in more restrictions or regulations (21%) and greater transparency (11%).

THE HEALTHCARE PROVIDER SURVEY

Key Findings

- Physician comfort with autoimmune biosimilar prescribing is very high. Eighty-six percent of the physician respondents reported comfort ratings of 5 or above on a 7-point scale (7 = very comfortable). Forty-two percent overall assigned the highest comfort rating of 7.0. Rheumatologists indicated a slightly higher mean rating (6.1) than gastroenterologists (5.7) and dermatologists (5.7).
- Similarly, physicians believe that patient acceptance of biosimilars are improving as well, with 57% indicating little or no concern with patient acceptance, with ratings of 1–3 on a 7-point scale (7 = extremely concerned). This represents a significant shift from the 2023 survey when no more than 9% of gastroenterologists, rheumatologists, or dermatologists indicated a similar comfort level around patient acceptance.[16]
- For patient-administered biosimilars, the greatest barriers to adoption by physicians and patients seem to be the overriding payer coverage (88%), possible patient savings (88%), and patient-support services (87%). The potential for patient cost savings in commercial plans (rather than Medicare plans) is less of a factor because of the widespread use of co-pay coupons or assistance. Indeed, which medications the payer decides to cover is the greatest factor in determining whether the patient will receive a biosimilar.
- Prior authorization burdens for biosimilars were generally on par with those of the reference products, registering a mean score of 4.0 on a 7-point scale (7 = much better, relative to prior authorizations for reference products).
- However, physician respondents rated increased prior authorization requirements as their greatest concern over the next 12 months (62%), followed by reduced reimbursement (44%), decreased insurance coverage for treatments (37%), and increased use of medication step therapy (33%).
- When asked what market events or trends would impact their practices over the next 12 months, physicians responded that changes

to formulary exclusions (48%) and alterations in insurance coverage policies and designs (45%) represented their top concerns. Other items that were listed as important trends were drug expense management (22%) and the introduction of new and more-effective biologics (21%).

THE EMPLOYER SURVEY

Key Findings

- The majority of employer survey respondents (70%) use OptumRx, CVS Caremark, or Express Scripts as their pharmacy benefit administrator, which is reflective of national trends.
- Employers, in particular self-funded (or self-insured) employers, possess significant leverage in healthcare coverage and decision-making with their health plan and PBM partners. However, they continue to rely heavily on their PBMs for formulary recommendations: Survey respondents indicated a mean score of 5.5 on a 7-point scale (7 = very high influence), with 26% giving them the highest influence rating. Only 5% reported rating scores of 1 or 2. Furthermore, 89% of self-insured respondents rated PBM influence at 5 or above, compared with 59% of fully insured respondents.
- Employer respondents also rely on their employer benefits consultants for recommendations and PBMs for clinical assistance to help achieve a greater understanding about newly FDA-approved biosimilars (56% and 41%, respectively).
- Likely a result of the PBM's and/or benefit consultant's recommendation, 62% of all employers participating in the survey (and 81% of self-insured organizations) indicated that they receive rebate guarantees from their PBMs on certain products, and 38% denied receiving rebate guarantees.
- Only 12% of employer respondents indicated they were likely to move away from a reliance on rebate guarantees in the next 3 years.
- In cases when a PBM is both negotiating rebates (which have not yet passed through) on behalf of its employer client and is dictating the formulary that employer uses, the PBM is more likely to choose drugs for the formulary that are in its own best financial interest.
- Compared with the 2023 survey results, 82% of the employers surveyed in 2024 indicated their preference for achieving the lowest net cost without a reliance on rebates versus 65% of the employers surveyed in 2023.[16]
- In general, the employers participating in the survey rated their knowledge and familiarity with biosimilars as moderate, with a mean rating of 4.4 on a 7-point scale (7 = extremely knowledgeable). Seventy-six percent of the sample recorded scores of 3 to 5.
- The employers' overall perception of biosimilars is highly positive, with a mean rating of 5.4 on a 7-point scale (7 = extremely favorable), with 56% offering ratings of 6 or 7.
- However, employer understanding of any one biosimilar-related issue (e.g., interchangeability, comparative costs, legislation affecting biosimilars) was moderate at best, with mean scores ≤ 4 of 7 (7 = extremely knowledgeable).
- Of employers surveyed, 87% indicated they were greatly or extremely concerned over the escalating drug trend. The scale of their concern may be amplified because of the spotlight currently on glucagon-like peptide-1 (GLP-1) agonist medications.
- Nearly half (49%) of the employer respondents do not know (or cannot guess) the savings they may have realized from adopting adalimumab biosimilars versus the reference product Humira®. Twenty-six percent believe that their savings was 0% to 5%. This is likely related to the lack of transparency in PBM reporting and contracts.

The Teva Biosimilars Trend Report

The first edition of *The Teva Biosimilars Trend Report* published in 2023 examined the current developments in the rapidly evolving biosimilars market from the perspective of managed care professionals, healthcare providers, and employers.

The report featured national survey results and independent expert analysis, with discussions of the challenges and opportunities in biosimilar adoption.

Winner, MarCom Gold Award, 2023, Association of Marketing and Communication Professionals

Part I. The Managed Care Perspective

The managed care survey was fielded in August 2024. Fifty-four executives completed the survey: 66% worked for managed care or health insurance plans or an administrative-services organization (ASO), 15% worked for a pharmacy benefit management (PBM) organization, 13% worked for integrated health networks, and 6% listed miscellaneous other affiliations. Of the respondents themselves, their titles included pharmacy director or vice president of pharmacy (59%), medical director or chief medical officer (24%), clinical pharmacist (13%), and other (4%).

Of those working in PBM organizations, 87% (7 of 8) represented national organizations. Of the 34 health plan, insurer, and ASO respondents, 8 were national (23%), 24 regional (70%), and 2 multiregional (6%) in scope. The geographic coverage of the respondents indicated a diverse population, with approximately one-third covering members throughout the nation. For those regional plans, the West was represented by about one-third of the total respondent population, the South by 15%, Northeast by 11%, and Midwest by 7%.

In terms of types of membership, those surveyed indicated their organizations had the following average breakdown: 47% commercial, 25% Medicaid, 24% Medicare, and 4% "other." The average number of beneficiaries or members enrolled was 2.85 million, with a total of 147.33 million covered lives.

Expert Analysis

Providing commentary on the survey findings are 3 payer experts, all of whom have considerable experience on health plan Pharmacy & Therapeutics Committees and making pharmaceutical coverage decisions:

- **Maria Lopes, MD, MS,** Former Chief Medical Officer, MagellanRx
- **Dan Lewis, RPh, MBA,** Former Pharmacy Director, Dean Health Plan
- **Steven Evans, MD,** Chief Medical Officer from a large West Coast health plan

Survey Questions

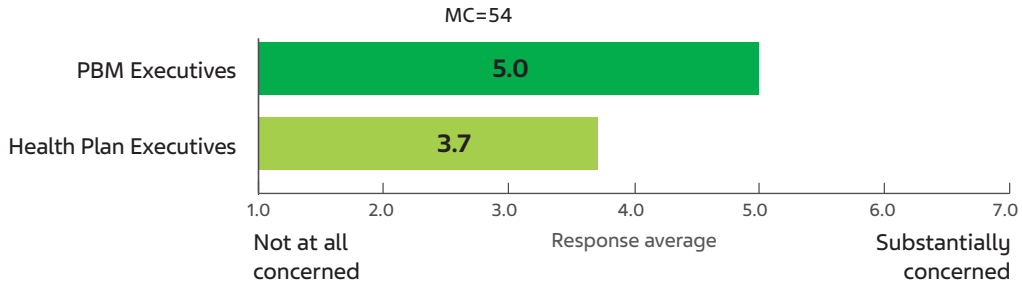
Patient and Provider Acceptance of Biosimilars. When considering the coverage of biosimilars by health plans, PBM executives, and insurers, a key concern has been the avoidance of patient disruption with a change in therapy. For the payers responding to the survey, 39% still had higher levels of concern about this issue. Based on a 1 to 7 scale (with 7 = substantially concerned), health plan executives expressed a mean score of 3.7; PBM respondents registered a mean score of 5.0 (mean for all respondents, 3.9) **(Figure 1)**.

Dr. Lopes remarked, "Especially over time, I'd expect this to change as provider acceptance improves and we see greater comfort levels overall as well as payer adoption of preferred biosimilars and formulary management with step therapy."

The former pharmacy director of a Midwestern plan, Dr. Lewis, expressed skepticism that this is still an issue. He said, "I don't know why anybody is substantially concerned about it. Biosimilars are not new. [In the autoimmune area], we've had infliximab biosimilars for maybe eight years now." He also pointed out that "in the case of a medical benefit biosimilar, patients generally wouldn't even know if they're receiving an ophthalmic injection of [compounded bevacizumab], Avastin®, Lucentis®, or a Lucentis® biosimilar. Because of the way the medical benefit works, there's very few acceptance issues from patients."

Figure 1

How concerned are you about patient acceptance of biosimilars?[1]



He added that lower patient cost sharing for biosimilars on the pharmacy benefit side "generally obviates most questions about patient acceptance."

Barriers to Biosimilar Acceptance. With 2.7 billion patient days of experience using biosimilars to date, the managed care executives answering the survey expressed little doubt that biosimilars were safe and effective.[9]

Provider acceptance was slightly more of a concern (mean rating, 4.0 on a 7-point scale), with about one-third of managed care and PBM executives indicating they still had high levels of concern. Negative perceptions related to biosimilar efficacy and safety are fading, with 63% of respondents indicating low or very low levels of concern (ratings of 2.9 to 3.2 on a 7-point scale) **(Figure 2)**.

The result is unsurprising to Dr. Lewis, who stated, "For 30 years now, we have had automatic switches to generic drugs with little to no problems. Even though these are biosimilars, these [product switches] are looking more and more like generic drug switches. If you were to have asked this question five years ago, people would have been more concerned."

The East Coast CMO, Dr. Lopes, agreed that provider acceptance of biosimilars is advancing, "even among inflammatory bowel disease (IBD) specialists. In stable IBD members in remission, it is sometimes challenging to switch but given similar outcomes many accept the change to biosimilars particularly for new starts and overall, they are much more accepting of using the biosimilar dictated by the patient's insurance coverage. The needle is moving."

Figure 2

How concerned are you about the following biosimilar medication issues?[1]

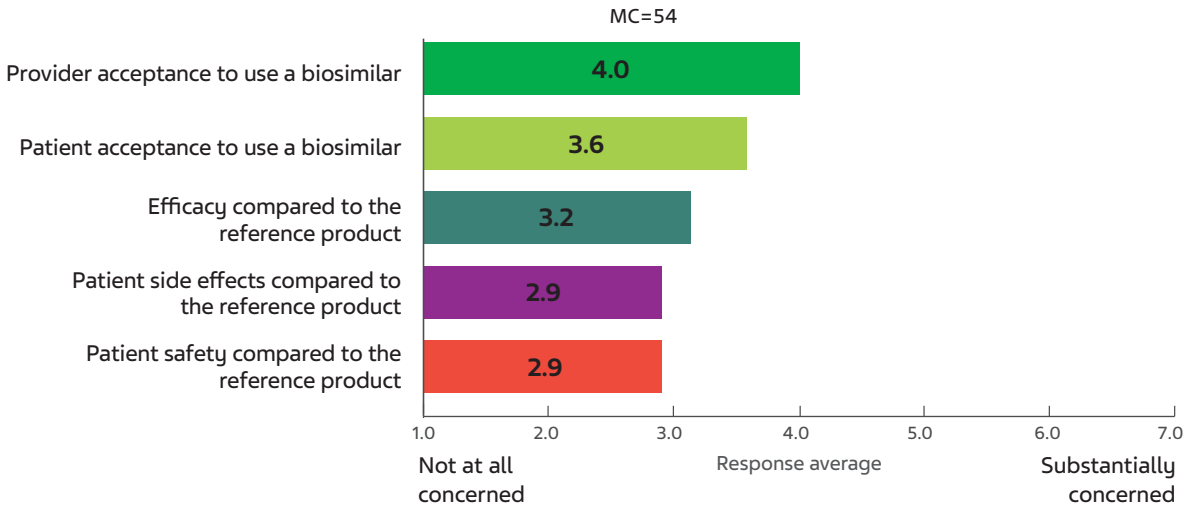
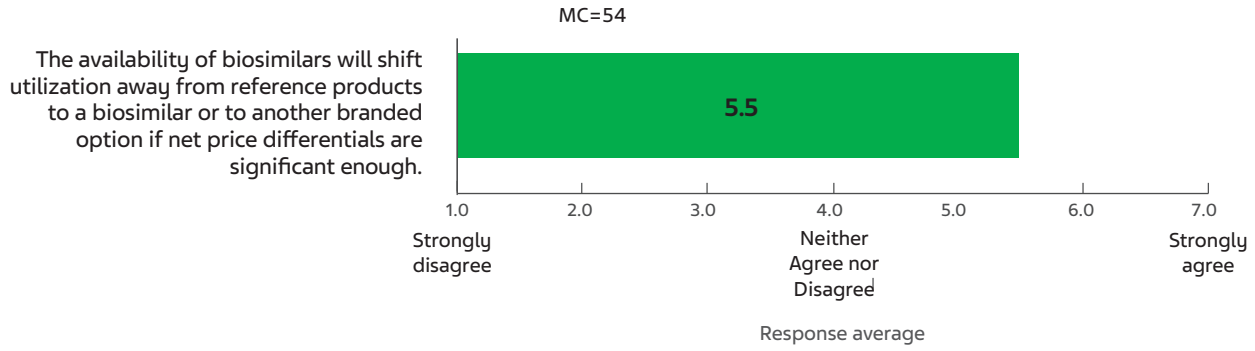


Figure 3

Rate your level of agreement with the following statement.[1]

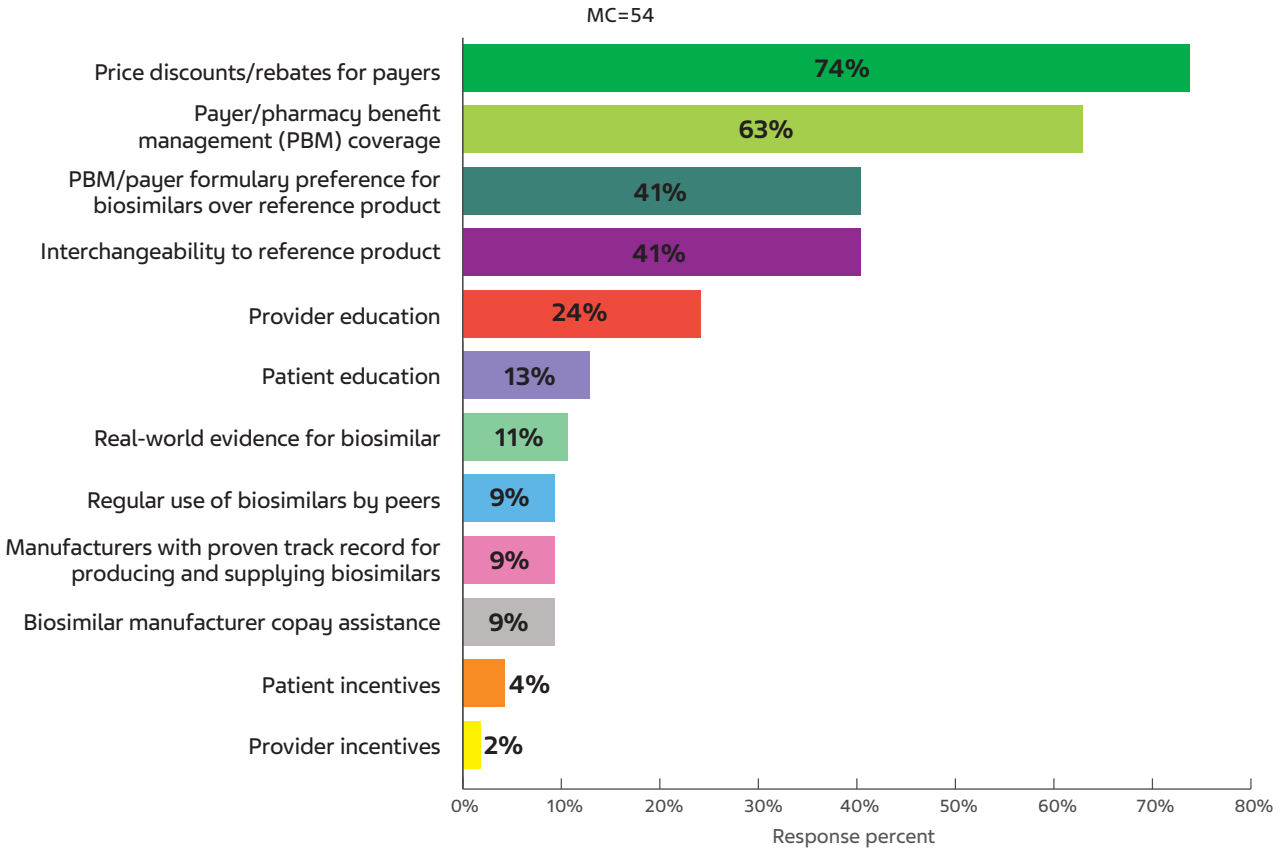


Will Biosimilars Shift Utilization Away From Reference Products? Payers seem to be optimistic, tempered by actual experience, when asked whether they agreed with the basic hypothesis: With a significant net price differential, biosimilars will shift utilization away from reference products.

On a 7-point scale, the mean response was 5.5—a good level of agreement but not a strong consensus **(Figure 3)**. Still, nearly 58% of payers provided ratings of 6 or 7. This may reflect the willingness of reference manufacturers to offer deeper drug rebates in an effort to retain market share.[5]

Figure 4

For self-administered drugs, which factors do you think will be most impactful in shifting utilization to biosimilars?[1]



Dr. Evans, the West Coast plan CMO, said, "The rationale and the thought behind biosimilars was to provide lower-priced options, so it was all about price. That is why the laws were written."

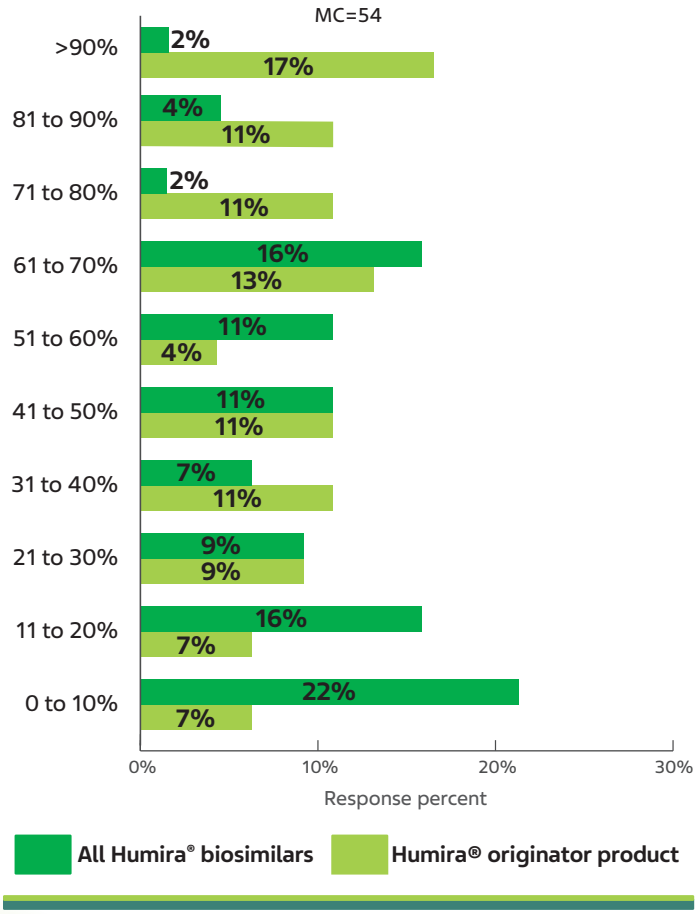
Dr. Lopes commented, "We need biosimilars to drive to lower prices."

Unsurprisingly, the greatest factors that will drive biosimilar adoption in the self-administered, pharmacy benefit–covered categories will be price discounts and rebates (74%), payer/PBM coverage decisions (63%), and formulary preferences (41%), the latter tied to interchangeability (41%) **(Figure 4)**.

According to Dr. Evans, "Discounts for payers are always number 1. If people were being honest, that was always the case. A lot of times, they will say 'efficacy,' but if you have equal efficacy, discounts are always the most important. Personally, I would argue coverage is equally as important. If you don't have coverage, then nothing else on this chart matters."

Figure 5

What is the current market share of all adalimumab (Humira®) biosimilars in your plan?[1]



Dr. Lewis added, "What this also tells us is that people are going to follow what the PBM says."

Interchangeability is an interesting case on its own. Dr. Evans admitted, "I would have put interchangeability higher, because that is the buzzword of biosimilars in the last couple years." Yet the automatic substitution benefit of any interchangeable-designated biosimilar has not yet resulted in a rapid shift away from a reference product. The evolution of US Food and Drug Administration's (FDA's) thinking in this area may result in far less emphasis on interchangeability in the near future. Dr. Lopes said, "Interchangeability is rated highly here, but I am not sure why. The interchangeability status is something that the FDA is debating and probably will go away. If that occurs, where will this 41% go? Even more heavily to pricing considerations."[23,24]

Dr. Lopes noted some strategies include private-label biosimilars, as the Cordavis' contract with Sandoz illustrates. "If you are a CVS client, this is a strategy that has rapidly converted market share away from Humira® and has resulted in significant savings," she said.

Considering private-label biosimilars, the payers noted that adalimumab biosimilar market share is increasing, and 35% of surveyed executives indicated that these biosimilars represented greater than 50% of adalimumab utilization in their organizations. Almost an equal percentage (38%) reported that adalimumab biosimilar uptake was still 20% or below **(Figure 5)**.

Strategies to Overcome Barriers to Biosimilar Adoption. Payers have expressed certain preferences for pharmacy benefit–covered biosimilars, which would help ensure adoption.

Significantly lower net price (>25% difference from the reference product) was clearly the highest-rated strategy (mean rating, 7.9 on a 10-point scale; 10 = most effective) **(Figure 6A** and **Figure 7)**.

Overall, little differentiation was seen among the following strategies: reduced patient cost sharing for biosimilars, low-WAC or high-WAC pricing, and additional clinical or real-world data (mean rankings, 6.6-6.9) **(Figure 6A)**.

Surprisingly, PBM executives' ratings of both low-WAC/low-rebate pricing and high-WAC/high-rebate pricing were higher than that for health plans or insurers (low-WAC pricing, 8.0 for PBMs vs 6.8 for

plans; high-WAC pricing, 7.6 for PBMs vs 6.5 for plans). The simultaneous availability of low- and high-WAC pricing was also more valued by PBMs than health plans (7.9 vs 5.3, respectively) **(Figure 6B)**.

Dr. Lopes thought the emphasis on one factor (real-world evidence) was misleading: "You look to real-world evidence for confirmation or unexpected findings, but the legacy of biosimilars outside of the United States is that they are similar and have been adopted by other countries." This may indicate a further desire to bolster the health system's confidence in biosimilar outcomes.

The greatest difference of opinion between PBM and plan executives involved the availability of a private label biosimilar, with a total mean ranking of 5.1 **(Figure 6A)** (PBMs, 6.9; health plans, 4.8 [data on file]). This makes sense, as the big 3 PBMs instituted this model for increasing biosimilar

Figure 6A

Which strategies will have the best chance of overcoming barriers to biosimilar adoption in Commercial or Privately Funded Benefit Plans?[1]

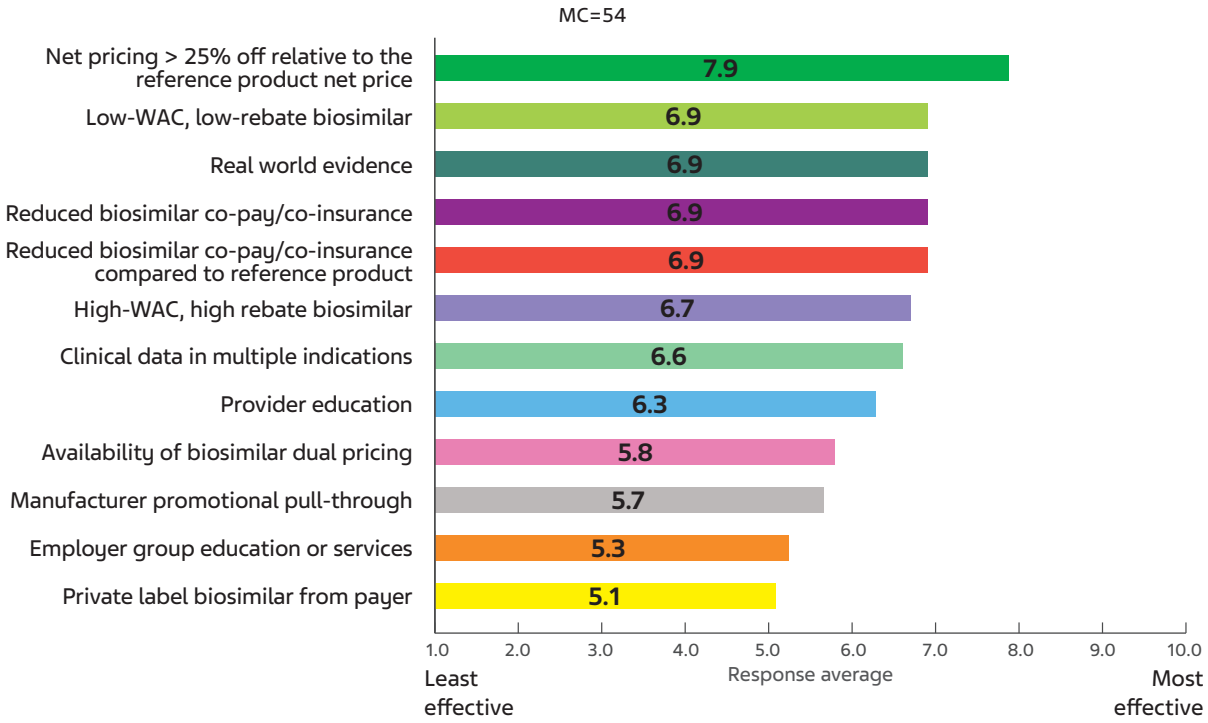


Figure 6B

PBM vs Managed Care ratings on which strategies will have the best chance of overcoming barriers to biosimilar adoption in Commercial or Privately Funded Benefit Plans.[1]

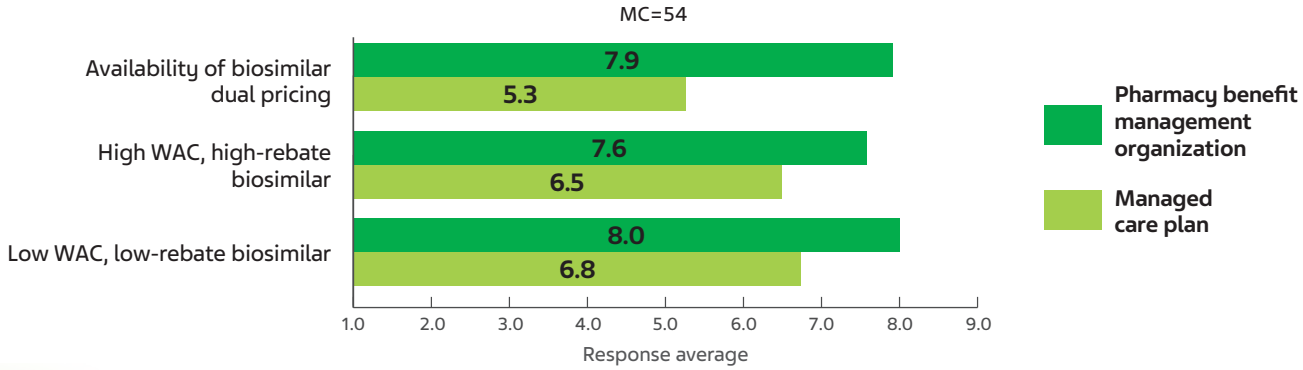
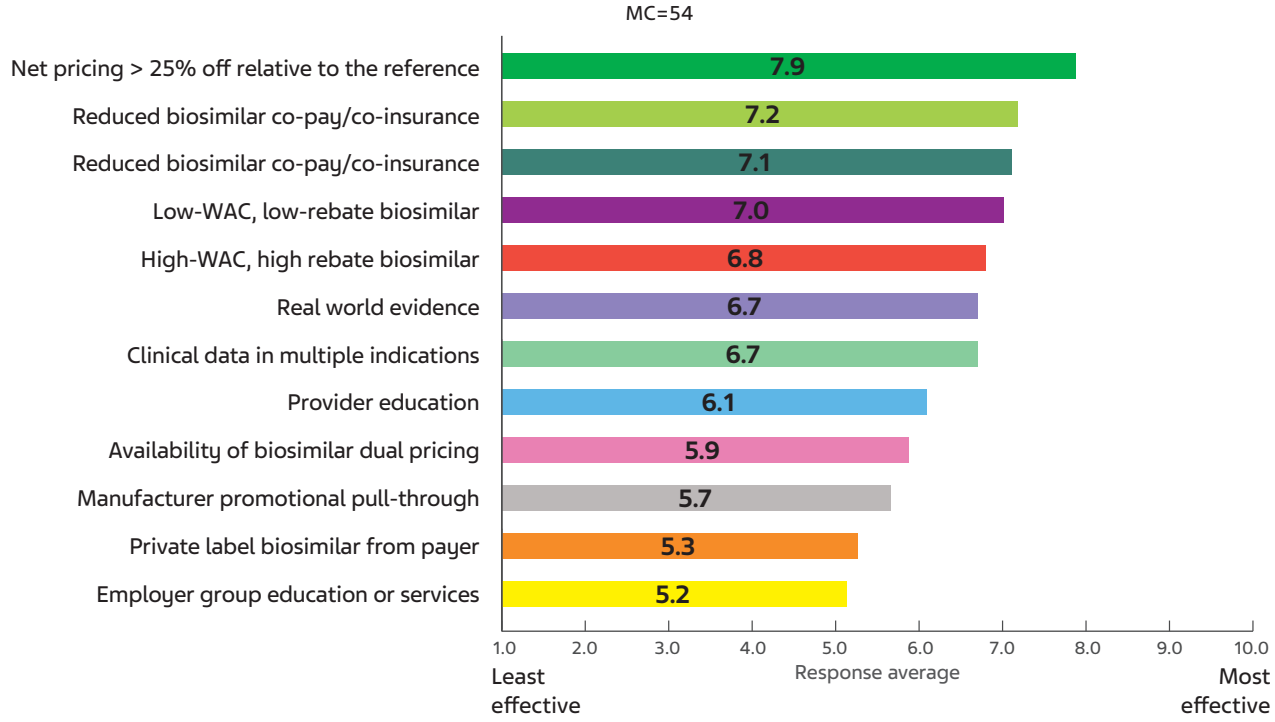


Figure 7

Which strategies will have the best chance of overcoming barriers to biosimilar adoption in Medicare plans?[1]



uptake. Unless the plans themselves are related to these distributors via the vertically oriented parent company, they may not benefit directly from private label biosimilar arrangements.[25]

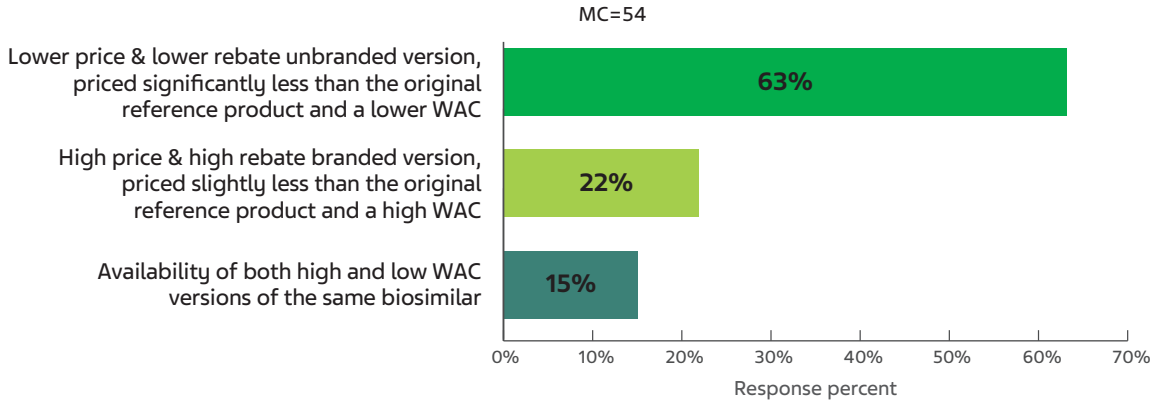
Overall, private label biosimilar, employer group education or services, and manufacturer promotional pull-through efforts were on the third tier. Interestingly, having either a high- or low-WAC biosimilar offering was rated a full ranking position above having both options (dual pricing).

In a separate survey question, 63% of payers responded that they would prefer low-WAC, low-rebate pricing for commercial populations, if net prices were equal **(Figure 8)**.

Compared with the 2023 survey results, the 2024 results for commercial or private payer plans were remarkably consistent. The rankings for net pricing,

Figure 8

Assuming net prices stay the same, what pharmacy benefit biosimilar pricing approach would your organization prefer for your commercial populations?[1]



patient cost sharing, clinical data, and education remained steady. Also, consistent with the 2023 results, none of the choices listed were associated with rankings below 5.0 (data not shown).[16]

Dr. Lewis commented that patients may not see direct cost savings with biosimilars, and that is the main reason they might not switch from the reference product. "Patients expect to save money with biosimilars," but this is not necessarily the case, because of co-pay coupons or parity coverage. "Everything here (except clinical data) is about cost to the payer or patient for most of the important high-ranking factors."

When responding to the same question but regarding a Medicare plan scenario, significant net pricing differences were still ranked number 1, and the other rankings remained virtually the same **(Figure 9)**.

Overcoming Provider Resistance in Self-Administered Biosimilars. For a biosimilar like adalimumab, providers would not administer this agent in their office. These products are expected to be administered at home by the patient or a caregiver. Payers were asked which strategies will have the best chance of overcoming any resistance to self-administered biosimilar prescribing, without a buy-and-bill incentive for purchasing one product over another.

The results were broadly distributed, with interchangeability, inclusion in clinical guidelines, and similar efficacy to reference products mentioned most often (but none represent a majority of responses). Other strategies mentioned by more than 20% of payer respondents were provider-focused education, safety data profiles, and reduced patient cost sharing **(Figure 10)**.

Dr. Evans remarked, "For providers, interchangeability seems to be king, the most important thing when it comes to prescribing. Second is following the professional society's guidelines."

For payers though, this is not so simple. Interchangeability designations do not endorse superior clinical quality over other biosimilars. Nor do they affect the point of prescribing: an interchangeable product can be automatically substituted at the pharmacy (according to state pharmacy laws on prescriber notification). In other words, the designation has less bearing on what the physician actually prescribes—only on what is dispensed. The report commentators acknowledge that if the interchangeability designation was approved based on the conduct of additional switching studies, providers may feel a bit more confident with this evidence base, even though this means little in terms of relative product effectiveness or safety.

The second commonly mentioned factor—inclusion in clinical guidelines—is not in the payer's or drug maker's control. Several years may pass before a drug is added to clinical guidelines. From the biosimilar maker's perspective, a clinical guideline would not list its biosimilar as preferable to a reference product, only as an acceptable option (because the data supports clinical equivalence, not superiority, to the reference biologic).

Figure 9

Assuming net prices stay the same, what pharmacy benefit biosimilar pricing approach would your organization prefer for your Medicare populations?[1]

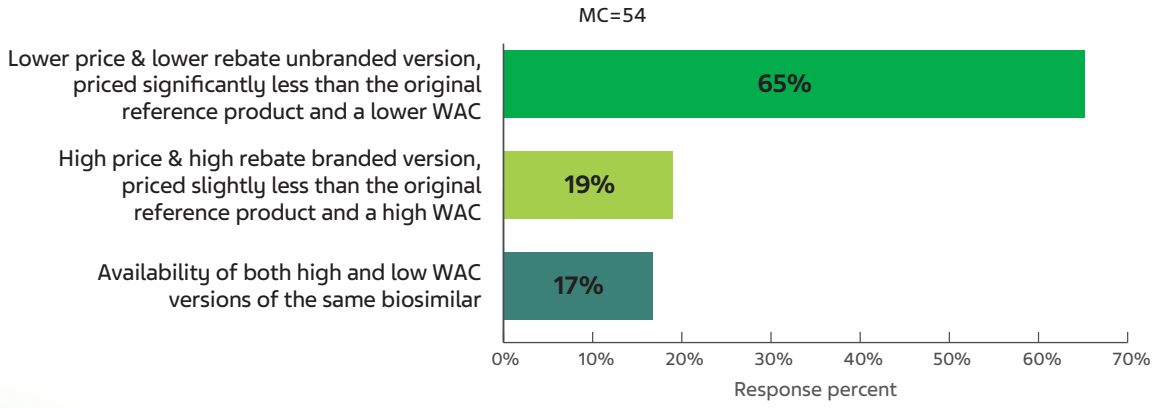
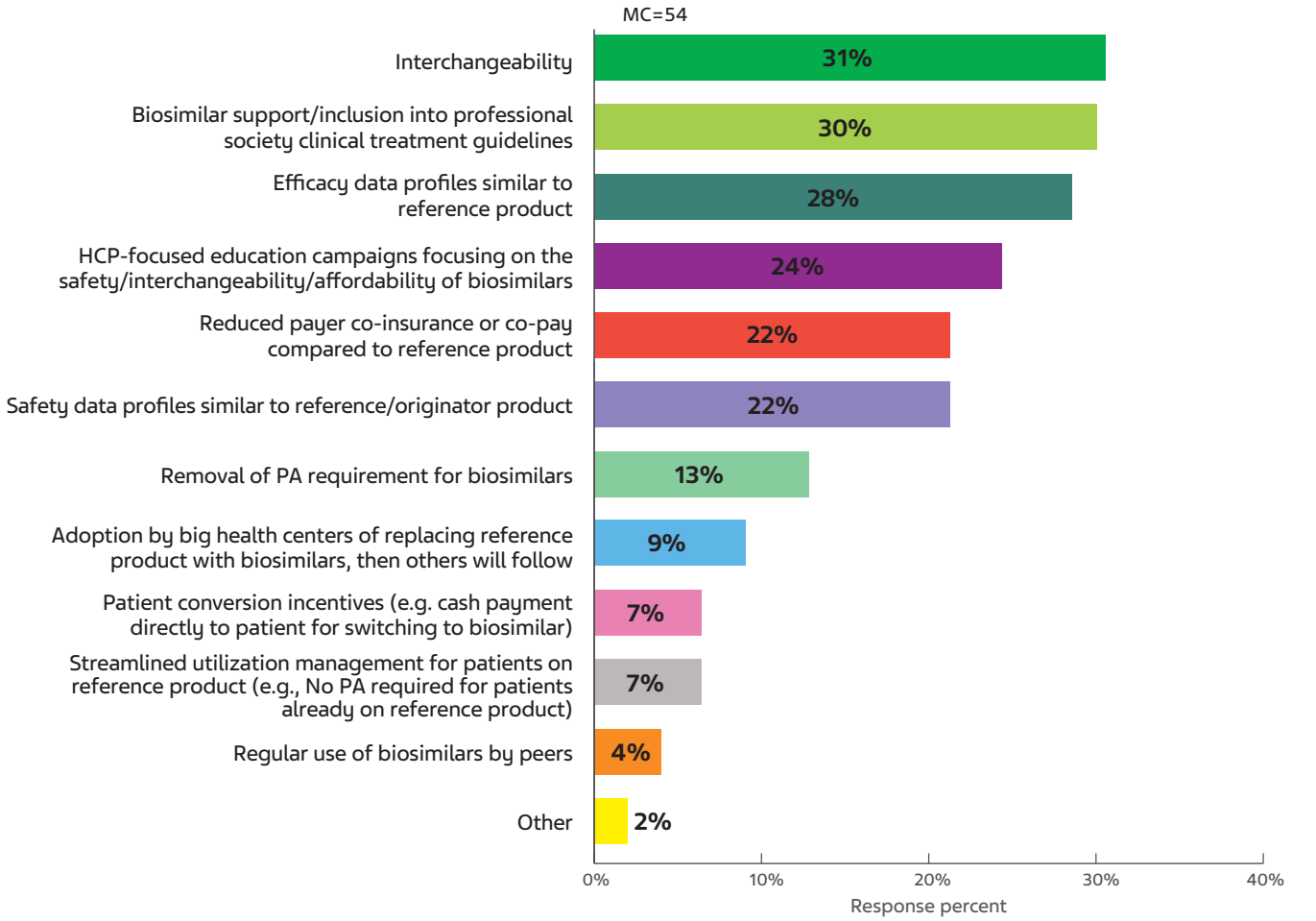


Figure 10

For self-administered biosimilars, what strategies will have the best chance of overcoming Healthcare Provider (HCP) resistance to biosimilar adoption?



Top Concerns about Adding a Biosimilar to Formulary. The switching of patients who are stabilized on a biologic reference drug to a biosimilar has been one of the most difficult challenges. When asked what their top concern is about including a biosimilar on formulary, managed care executives selected this to be most-mentioned issue (24%) **(Figure 11)**.

Dr. Evans stated, "It is really difficult to switch therapies for patients with stable disease. The real question is going to be, are you going to "grandfather" these reference drugs? We decided to not allow established patients to continue on the reference product—they have to switch. Typically, when we make a move to a biosimilar, we do not grandfather. But it is still a problem, because patients complain about it."

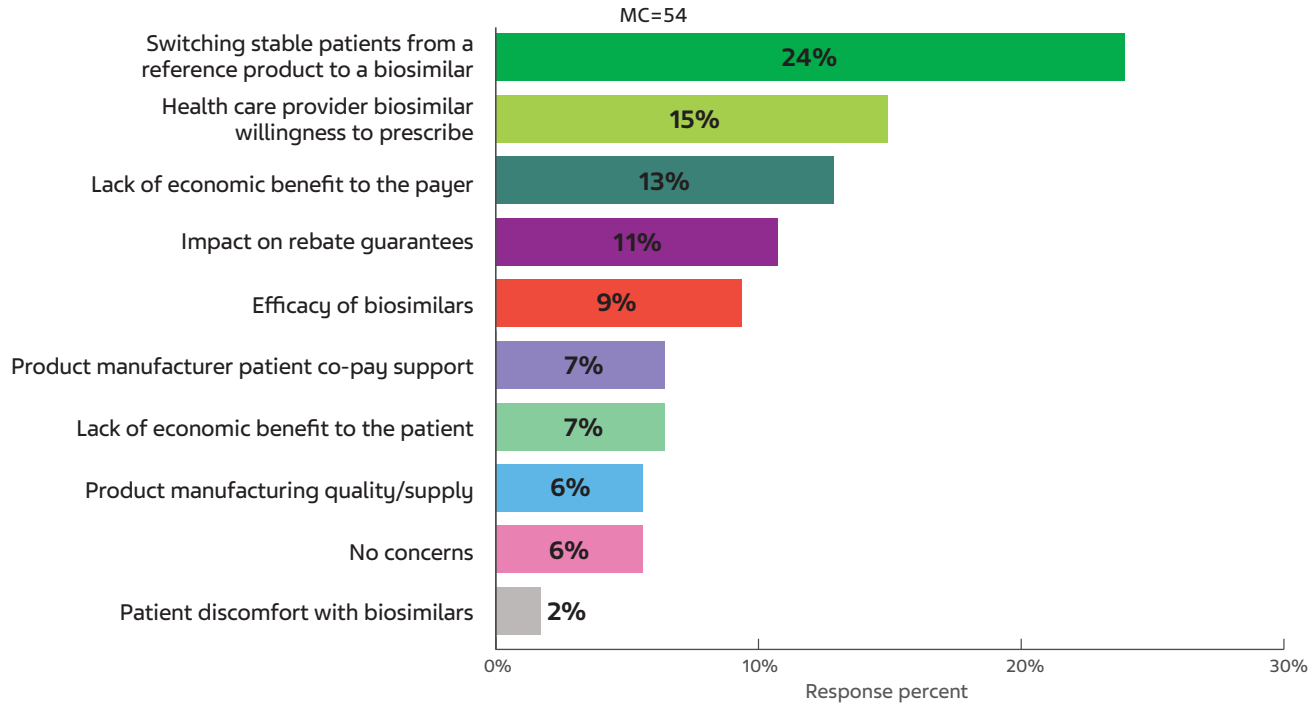
Dr. Lopes pointed out that this is likely the result of providers and patients needing more information: "There is always this fear that the efficacy will not be the same, even though that is not what the published literature demonstrates."

The second most-cited concern is likely related to the first—a clinician's willingness to prescribe the biosimilar (15%). This was followed by lack of economic benefit to the payer (13%). The latter may indicate a disconnect of sorts, because the very existence of biosimilar competition substantially lowers cost in the drug category, even that of the reference product. However, it may threaten rebate guarantees (11%) to the specific plan.[12]

The Most Important Nonprice Attributes of Self-Administered Biosimilars. Overwhelmingly, price is considered the number 1 priority in making decisions about pharmacy benefit–covered biosimilars. With price taken out of the question, other specific drug (and drug maker) characteristics could be ranked and evaluated. For these points,

Figure 11

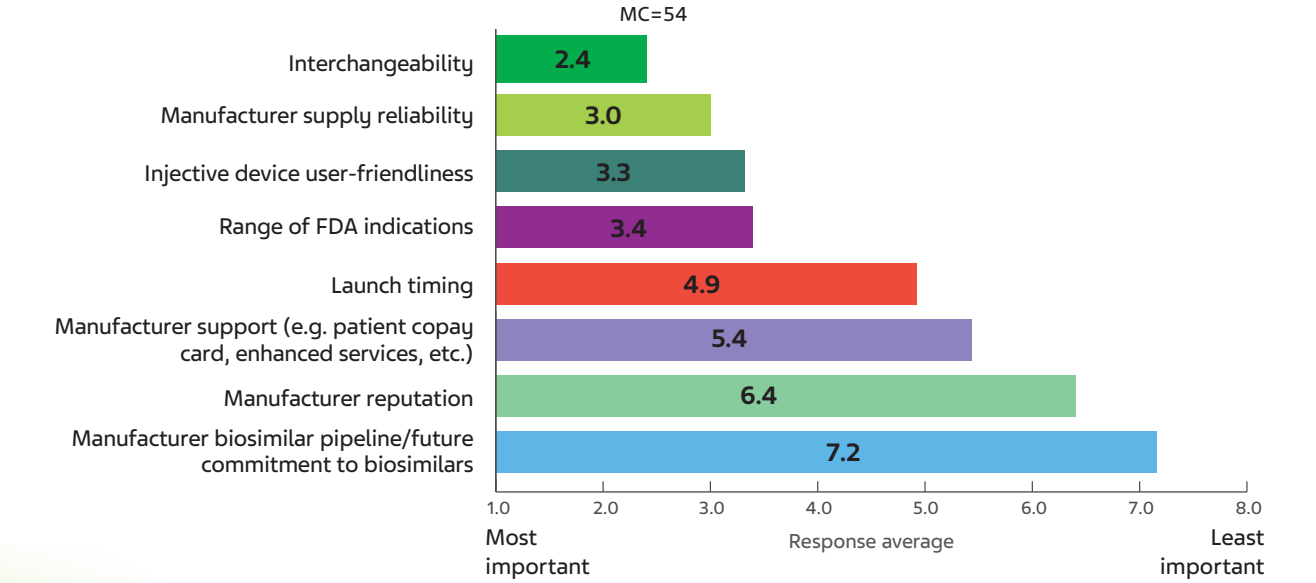
What is your top concern about including a biosimilar on formulary as an alternative for the branded reference product?[1]



payers were asked to rank each of eight specified characteristics. Interchangeability was at the top of the pack (with a mean of 2.4 on an 8-point scale; a lower score means a higher ranking). Occupying the bottom spots were manufacturer attributes, such as manufacturer's pipeline or future biosimilar commitment (7.2), manufacturer reputation (6.4), and manufacturer's patient support (5.4). However, the reliability of supply from the manufacturer was a strong number 2 (3.0) **(Figure 12)**.

Figure 12

What are the most important non-price attributes of self-administered biosimilars?[1]



Dr. Lopes remarked, "I am surprised the patient co-pay assistance is fairly down the list. But the supply chain reliability is a big one. The launch timing is really critical as well: Will all three biosimilars launch at once or will their launches be spread over years? This will impact decision-making." Indeed, a staggered launch timing will play a role with the ustekinumab biosimilars, as it had with the adalimumab launches in 2023.[26]

In a separate survey question, the payers were asked to choose their two most important factors, outside of safety and efficacy, for deciding on biosimilar coverage. In this case, 83% chose net cost or WAC, and 54% named interchangeability. Other factors were far behind, with full list of approved indications leading the way at 20%. Notably, supply chain reliability, patient services, and prior payer experience with the manufacturer were far down the list **(Figure 13)**.

Interchangeability is a complex subject, as the requirements for the designation are changing and the very need for the designation is being reconsidered on several fronts.[27]

When considering the question of interchangeability and its beneficial aspects, the payer respondents focused on the ability to automatically substitute the biosimilar for the reference product at the pharmacy (ranked most important, at 2.6 on a 6-point scale; the lower the number, the greater the importance). This was followed by reduced member disruption and lower pharmaceutical costs. The latter is likely related to moving as many patients as possible away from a higher-cost reference biologic. Reduced member disruption rounded out the top 3 responses. They did not value as highly the additional switching study that most manufacturers had to conduct in order to obtain the interchangeability designation (4.4) **(Figure 14)**.

Dr. Evans emphasized that interchangeability means "simpler, faster, non-medical conversions—if it is interchangeable, you do not have to go through and discuss with the patient why the medication is being changed to a biosimilar. The provider can prescribe the biosimilar and the patient goes to the pharmacy, where the prescription is dispensed as

Figure 13

Other than safety and efficacy, what are the most important factors when evaluating recently FDA-approved biosimilars?[1]

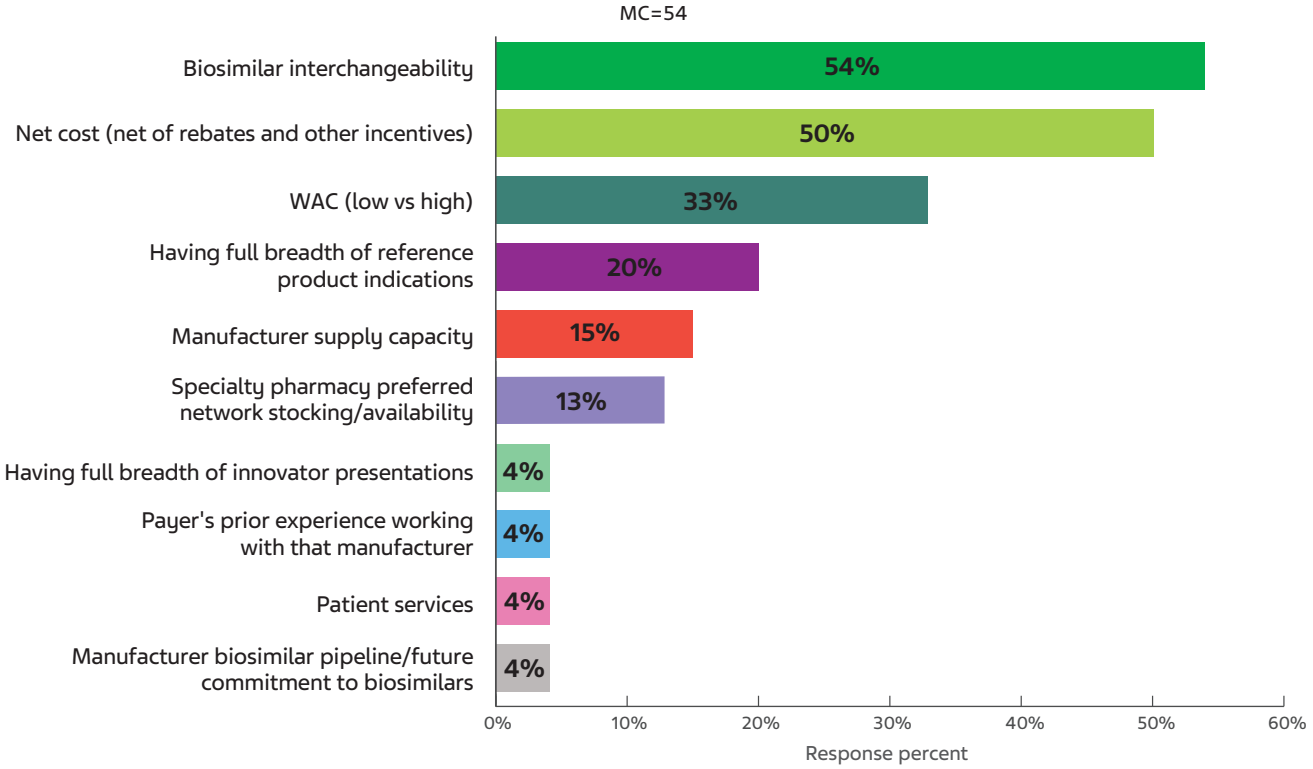
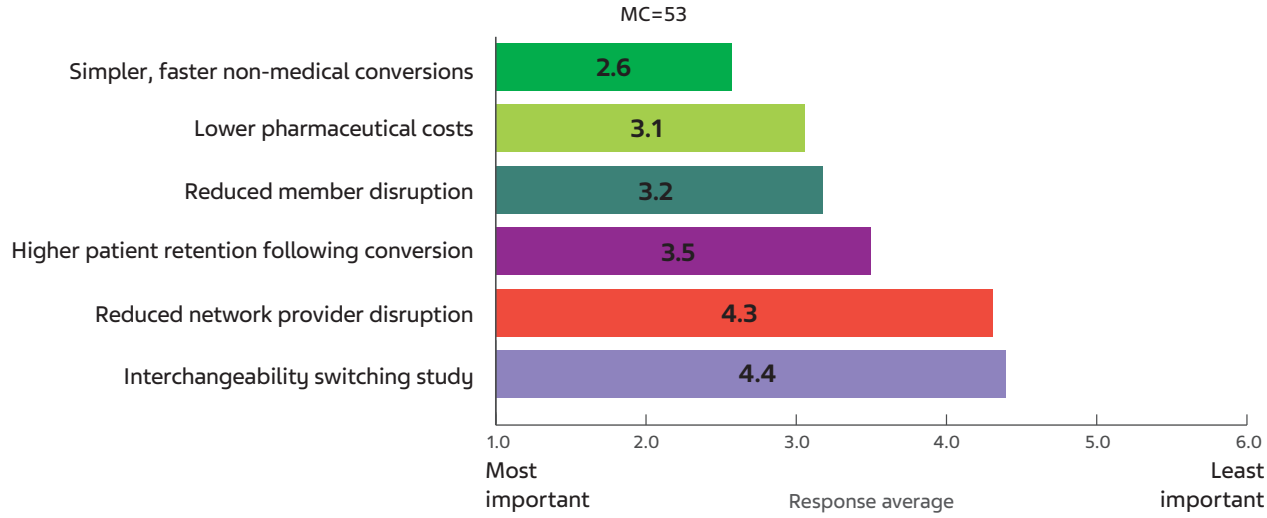


Figure 14

What are the most important benefits of interchangeable biosmiliars to your plan?[1]



the biosimilar. If it is interchangeable, the patient can get the biosimilar the next day."

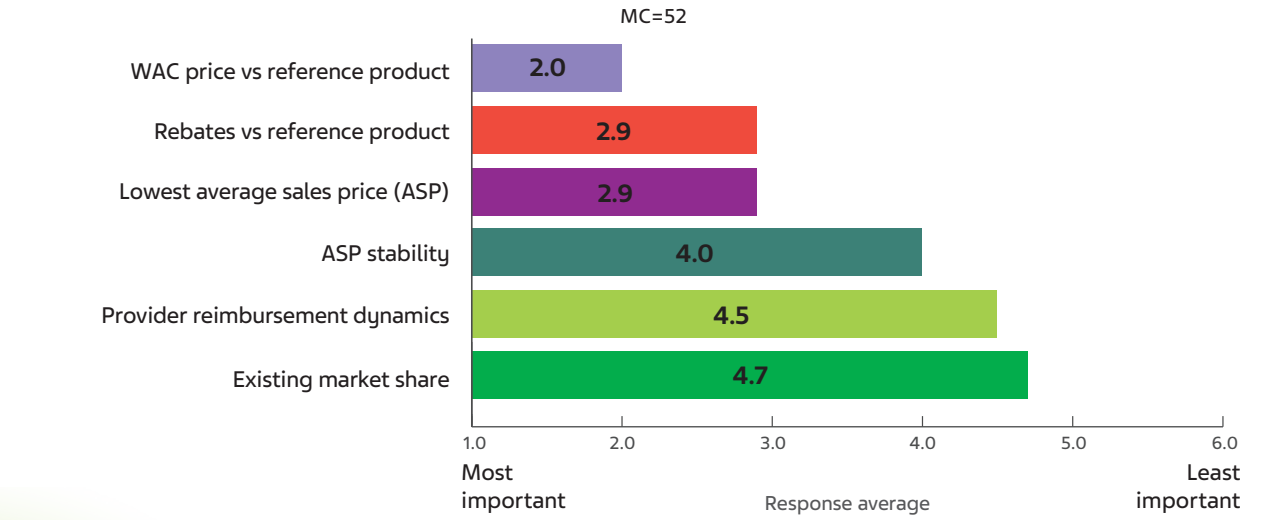
With multiple adalimumab biosimilars designated interchangeable for the low-concentration version, and many others positioned to gain the designation for the high-concentration formulation once exclusivity expires for SIMLANDI® in 2025, this attribute will confer limited benefit in this drug category. It may have some value for the ustekinumab class once launched, but if the efforts to remove the designation are successful, the value of biosimilar interchangeability will likely be limited.[17]

Most Important Factors for a Medical Benefit Biosimilar. In contrast with self-administered medications, which are generally covered under the pharmacy benefit, office-infused biosimilars are covered under the medical benefit. This invokes a somewhat different set of preferences and priorities.

The respondents indicated their most important ranked concerns for biosimilars covered under the medical benefit were purely economic: WAC price was number 1 (mean ranking, 2.0 on a 6-point scale), followed by rebates (2.9), and lowest average sales price (ASP) (3.1) **(Figure 15)**.

Figure 15

What are the most important factors when selecting a medical benefit biosimilar?[1]



According to Dr. Evans, "Low cost is always the number 1 concern. After that, we see other related cost issues, like rebates and lower ASP. It all gets back to pricing."

Dr. Lopes explained, "When you're reimbursing on the medical side, you look at ASP, not just WAC. The stability of the ASP will determine whether the providers will be enthusiastic about the product, assuming a buy-and-bill reimbursement. If they're losing money on a biosimilar versus a brand, they will not be very enthusiastic about adoption. If you increase the ASP-based reimbursement, then that may allow providers to make the same margin, depending on the acquisition price, gross to net spread." (Note: the increase in provider payment from ASP + 6% to ASP + 8% is an attempt by the Centers for Medicare & Medicaid Services to address this issue.[28])

Medical Benefit Sustainability. The payer respondents did not express strong concern for the sustainability of the biosimilars covered under the medical benefit. The mean score of 3.7 (on the 1 to 7 scale, 7 = substantial concern) may be reflective of specific factors. One being that 75% of survey respondents were pharmacy professionals (pharmacy directors, clinical pharmacists, or more senior pharmacy executives). Another factor is the dominance of the pharmacy benefit–covered biosimilars in the news currently, both in terms of recent launches (adalimumab) and upcoming biosimilar introductions (ustekinumab, tocilizumab). Yet, the established medical benefit–covered biosimilars (e.g., trastuzumab, bevacizumab, pegfilgrastim, infliximab) and upcoming launches (e.g., aflibercept, denosumab) pose important questions regarding adequate provider reimbursement **(Figure 16)**.

"The question of sustainability for office-administered drugs hints at the issue of reimbursement," affirmed Dr. Lopes. "What does the provider see? With shrinking margins, you have to understand the dynamics at the provider level. The lower the price, the lower the profit margin and reimbursement dynamics. Pharmacy directors or PBMs answering this question need to consider the ASP—not just WAC on the medical benefit."

Prescribing Adalimumab Biosimilars Over Humira®. In 2023, even though the vast majority of plans and PBMs covered adalimumab biosimilars at parity with the reference product Humira®, biosimilar uptake was limited to only 2% of total adalimumab utilization. The first major PBM to exclude Humira® from formulary was CVS Caremark, which changed its policies on April 1, 2024, causing a spike in biosimilar uptake among covered adalimumab products.[29,30]

As opposed to excluding the reference product on a closed formulary, payers can also enact policies preferring adalimumab biosimilars on an open drug formulary. This also implies placing the preferred biosimilar(s) on a different cost-sharing tier, stepping through the biosimilar to reach the reference agent, or the removal of specific prior authorization criteria for biosimilars but not Humira®. The respondents overall indicated that this is already the case for 48% of the plans and PBMs represented in the survey (specifically, 47% of health plans vs 38% of PBMs), with 72% of the total saying this will be the case through the first half of 2025. The survey respondents may have included exclusions of Humira® in their answers; very few (if any) managed care organizations have a separate biosimilar cost-sharing tier at this time **(Figure 17)**.

"At the point where the discount is greater than the rebate, then people switch over. It does take some time, but it looks like half the people have already switched over," said Dr. Evans. "And by 2025, if you

Figure 16

What is your level of concern around sustainability of medical benefit biosimilars?[1]

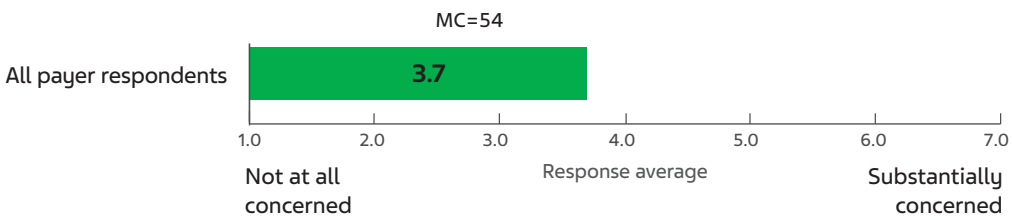
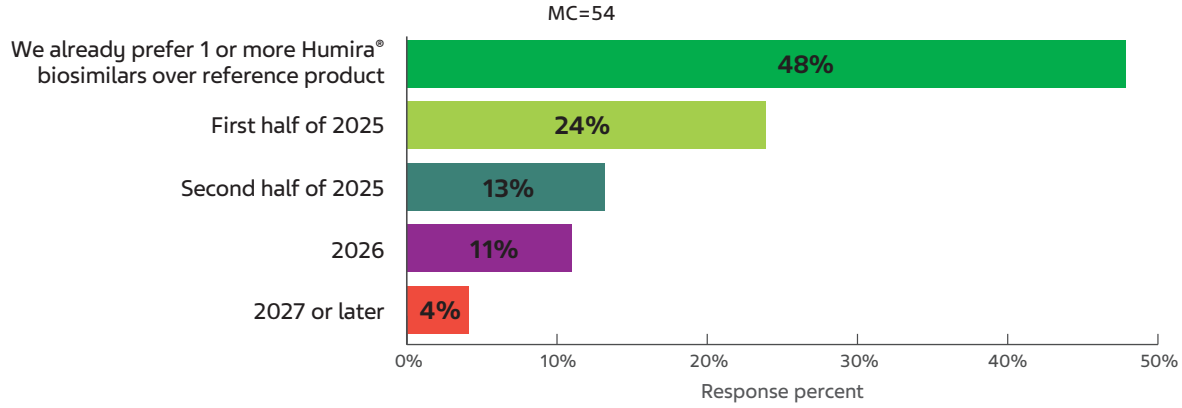


Figure 17

At what point do you anticipate preferring 1 or more adalimumab (Humira®) biosimilars over reference product?[1]



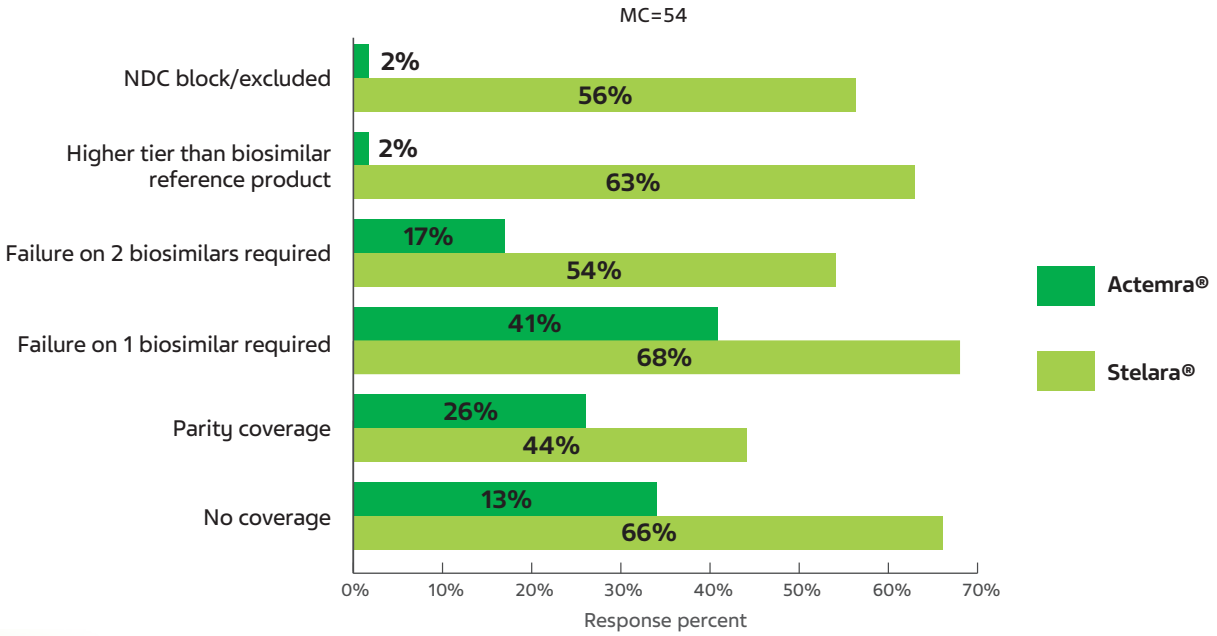
haven't switched over, you're either getting a huge rebate that nobody else is getting or you're just lazy."

Dr. Lopes pointed out that "there are still plans that are not preferring biosimilars over the brand. They may also be providing access to some biosimilars, without excluding the innovator yet."

How Will Organizations Manage the Stelara® and Actemra® Biosimilars? Perhaps ruminating on their experience with the adalimumab biosimilar introductions in 2023, the payers anticipated moving more quickly to exclude the reference product Stelara®, according to two-thirds of those surveyed, as early as in 2025. Actemra® (tocilizumab) is another autoimmune reference product that may face biosimilar competition in 2025. Two tocilizumab biosimilars have received approval, and a third was approved in January 2025. Surveyed payers commonly responded that their initial postlaunch moves will likely be

Figure 18

How will your organization manage the use of Actemra® and Stelara® biosimilars in 2025?[1]



to require patients to step through a biosimilar before accessing the reference product for new prescriptions (41%) and offer parity coverage (26%). Only 13% indicated that Actemra® would be excluded from coverage **(Figure 18)**.[2]

Dr. Evans commented, "That is basically saying they will use a prior authorization to create biosimilar uptake. Very few people, if anyone, fails therapy with a biosimilar. So, if that prior authorization is in place, they will just use the biosimilar. The quarter of respondents who will employ parity coverage believe there will be no effective differential in price between the reference drug with rebate and the biosimilar drug. They will let the market determine what happens in year 1. In the following year, they will make their move."

Dr. Lopes pointed out, "Some PBMs may still be holding on to Actemra® with sufficient rebates. Some may start to add biosimilars at parity to the brand or add steps that require use of preferred biosimilars. Fifty-eight percent said they would require a step through biosimilars."

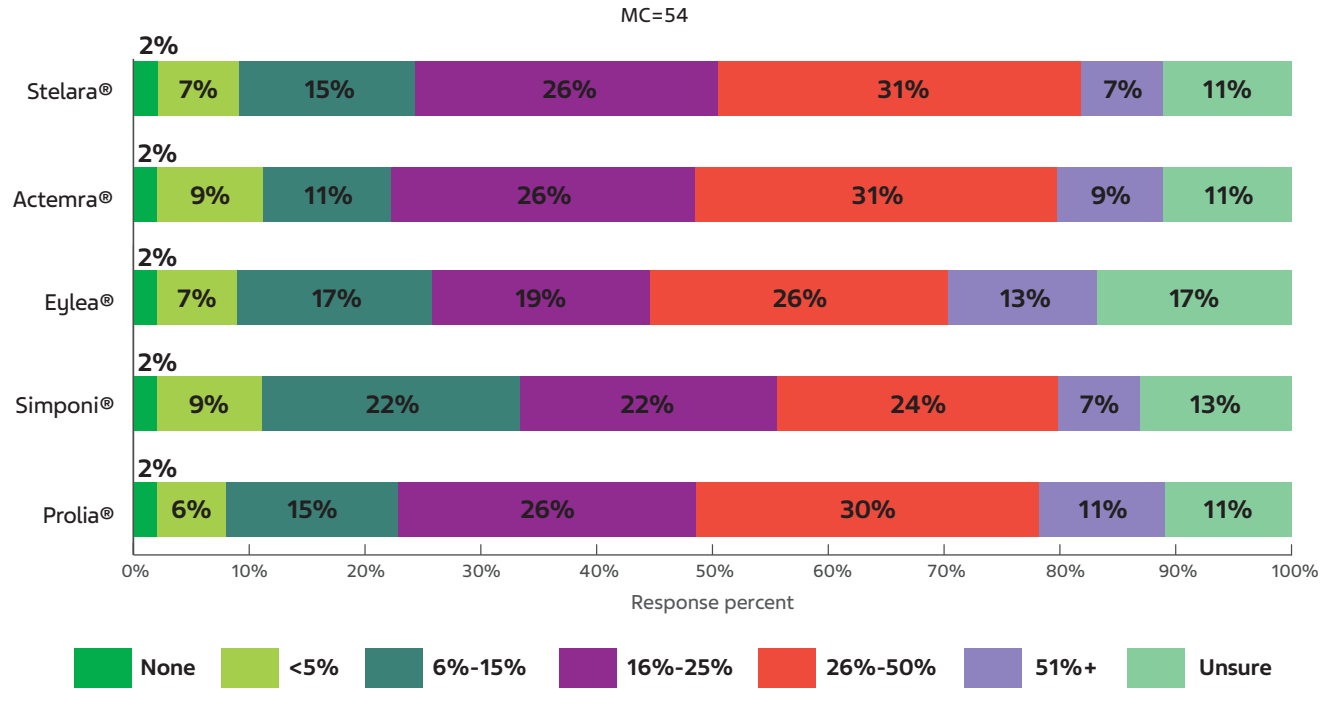
Net Cost Differentials for Stelara® Biosimilars. In the 2023 Teva survey, responding PBMs and health plan payers differed significantly in their preferences between low-WAC/low-rebate and high-WAC/high-rebate pricing approaches for biosimilars, with 83% of health plan and insurer respondents preferring low-WAC pricing and 54% of PBM respondents preferring high-WAC pricing. Although unsurprising, this assumes that the same net price is reached in either case. That may not necessarily be the case for plans and plan sponsors, however, especially if rebates are shared with the PBM.[16,31]

In the summer of 2024, the current survey asked payers what the net cost differential must be before they would prefer a ustekinumab biosimilar, which will become available in the first quarter of 2025, over the reference product Stelara®. Of 46 answering the question, the average responses were 30% or 35%. One-third of responses fell into the 26% to 50% savings range. Of note, the median response for PBM executives was 40%, whereas that for health plan executives was 25%. Three PBM representatives answered only 5% or below, whereas none of the health plan or insurer executives went that low (data not shown).

"It has to be worth it to convert patients, because there's work and disruption in the conversion,"

Figure 19

What level of savings does your organization expect to realize resulting from the adoption of the following biosimilars vs the reference product?[1]



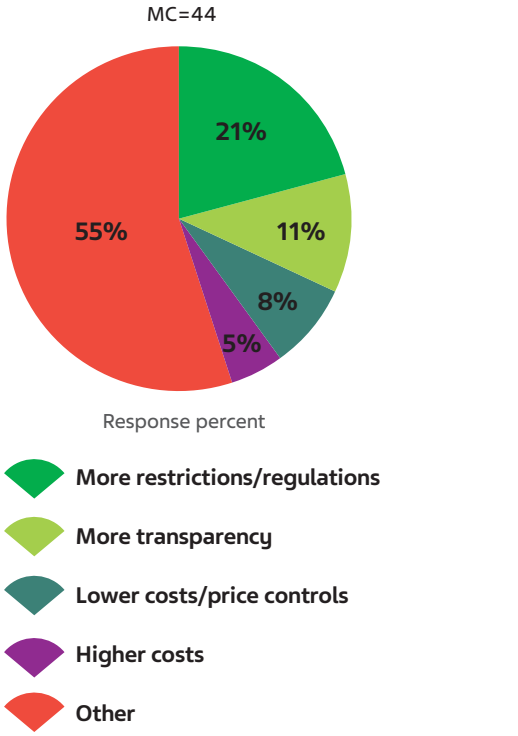
according to Dr. Lopes. "There's also risk when you move away from the branded originator, with the high market share the immediate loss of rebates may overshadow savings unless there is rapid conversion."

The average discount required for Stelara® biosimilar coverage corresponds with that cited for other upcoming biosimilars. "It is not dependent on the drug. It is the same for all drugs," confirmed Dr. Evans. "Most payers don't really know how many biosimilars are being developed for each of the reference products."

Discounts for ustekinumab biosimilars could potentially reflect the deep WAC discounts seen for adalimumab. However, the managed care executives' expectations for other upcoming biosimilars covered under the pharmacy benefit were fairly consistent. For three-quarters of the respondents, savings were expected to be no greater than 50% in these drug categories: Actemra®, Simponi®, or Prolia®/Xgeva®. About equal proportions predicted savings of 26% to 50% versus 16% to 25%. For the medical benefit–covered aflibercept biosimilars, there was no broad consensus; approximately one-quarter expected a savings of 26% to 50%, but most of the other choices received similar votes **(Figure 19)**.

Figure 20

What do you think will happen with future PBM legislation?[1]



"Once we have two or three biosimilars over a certain period of time, we expect at least a 30% discount," said Dr. Evans. "If we don't get that 30% discount, we may not adopt it."

Dr. Lewis agreed, "For Actemra®, Humira®, Stelara®, and the other biosimilars, payers have a philosophy. They have a number in mind and will stick to that number and philosophy regardless of the drug."

"It has to be worth it to convert patients," said Dr. Lopes, "because there's risk when you move away from the branded originator—with high rebates and market share."

The Future of PBM Legislation. Despite the intense scrutiny of the PBM industry from several fronts, survey respondents are cynical about any results. Forty-four executives responded to the question, "What do you think will happen with future PBM legislation?" Their predictions covered a broad range. Common threads were "more restrictions/regulations" (21%), "more transparency" (11%), "lower costs/price controls" (8%), and "higher costs" (5%). Several were unsure if anything would change related to these efforts (the fact that 14% did not respond may be testament to their uncertainty) **(Figure 20)**.

"Right now, Congress is debating whether PBMs should be transparent regarding the rebates that they are receiving and then choosing which drugs to have on the formulary for their health plans. It is a big deal," said Dr. Evans. He believes that increased transparency will be the major driver (and perhaps outcome).

Dr. Lewis, the former pharmacy director from the Mid-West plan, ventured a stronger opinion: "I think it is fair to say that people think the legislation will lead to important changes with the PBMs."

According to Lisa Le Gette, RPh, MBA, Senior Director, Federal Government Affairs, Evernorth Health Services, the prospects for PBM legislation are dim. At a recent conference, she stated that "in the current Congress, as many as 40 bills offering PBM regulation have been introduced, but only one bill has actually made it out of committee (The Lower Costs, More Transparency Act [H.R. 5378]). Federally, nothing has passed."[32,33]

Conclusions

Multiple forces are influencing both the benefits biosimilars afford the US health system and how those benefits are perceived by payers. The value of the interchangeability designation is a prime example.

As of October 2024, approximately 20% of launched biosimilars have an interchangeability designation. The proposed changes to the interchangeability designation will lower the cost of biosimilar development overall by reducing the need for clinical trials to earn the designation. If fully implemented, it will simplify the competitive playing field and significantly reduce confusion among payers, providers, and patients.[2]

A focus on the pharmacy benefit–covered, self-administered biosimilars and their WAC pricing options has illustrated the complexity of coverage decision-making today. The payers expect that these considerations will likely affect coverage and uptake for future self-administered biosimilars.

The introduction of a paradigm-shifting model of private-labeling and co-labeling of biosimilars have rapidly increased adalimumab biosimilar uptake. This will no doubt impact the ustekinumab market in 2025 and other future biosimilars covered under the pharmacy benefit. However, scrutiny of this new arrangement is just underway.[14,34]

Another new model, where a health plan directly contracts with a drug manufacturer, bypasses the PBM arrangement. In this case, Blue Shield of California, which had already eschewed the traditional PBM relationship, announced an arrangement where it is contracting with Fresenius Kabi for a monthly dose net price of $525 for its members directly who are prescribed adalimumab. This may well represent a new route to market share for biosimilar makers as well.[35]

The 25% to 30% net cost differentials generally expected by payers on new biosimilars will continue to challenge biosimilar makers. This will likely pressure manufacturers to introduce their biosimilar products at WAC discounts of 80% or more (and thus limit profit margins) in order to optimize coverage by managed care plans and PBMs.

The Sustainability and Uptake of Pharmacy Benefit–Covered Biosimilars Will Be Dictated by PBM Policies and Business Models

When the first adalimumab biosimilar (Amjevita®) was launched in January 2023, followed by several competitors in July of that year, manufacturers had reason to expect that their products would gain some of Humira®'s market share, if not quickly, but steadily.[36]

To achieve this, several biosimilar manufacturers introduced their products with a choice of contracting options, based on the drug's wholesale acquisition cost (WAC). Termed high-WAC or low-WAC options, the manufacturers sought to cater to PBMs and plans who wanted a low net cost achieved with or without rebates. For the low-WAC option, biosimilar manufacturers provided discounts of up to 85% (relative to the reference product's list price) to entice PBMs and health plans to add their adalimumab biosimilars to their formularies. These low-WAC options offered payers a low net cost without a rebate contract.[37]

Historically, however, PBMs had relied on AbbVie's rebates for Humira®, which were a significant revenue source for the major PBMs that they were reluctant to give up. Additionally, AbbVie cautioned the PBMs that the rebates for other expensive biologics by the drug maker (i.e., Skyrizi® and Rinvoq®), would be at risk if action was taken to disadvantage Humira® in favor of the biosimilars. Although some payers may opt for a low-WAC option, health plan financial executives had also come to expect a share of those rebates as well. With AbbVie offering to provide a low net cost that matched those of the biosimilar makers, payers had little impetus to move away from Humira®.[38]

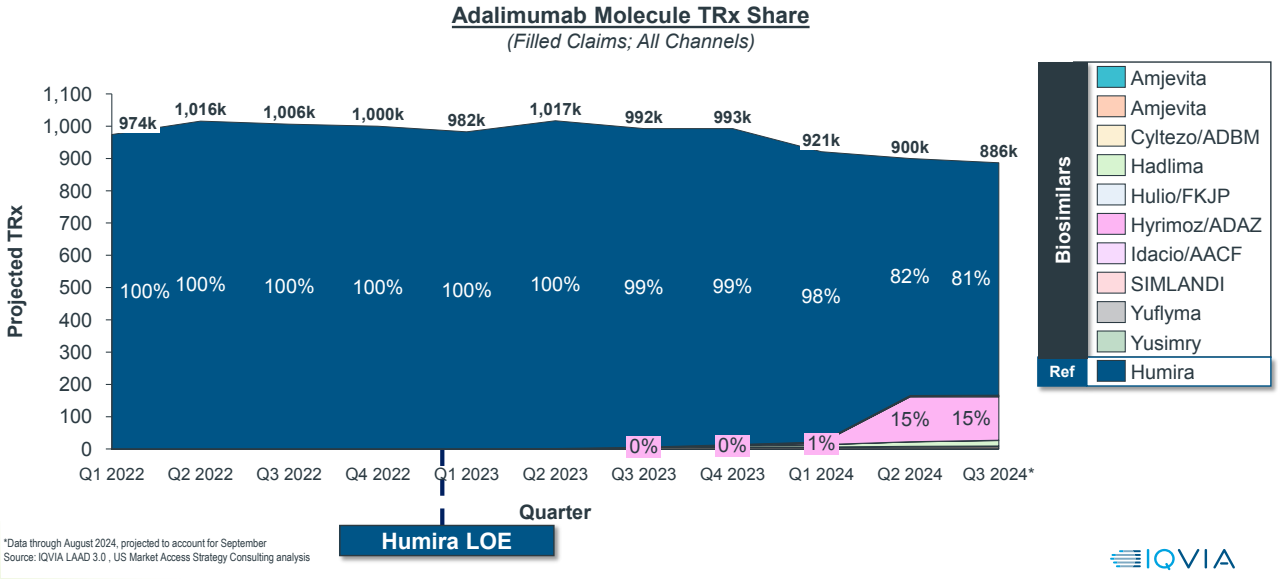
In 2023, very few organizations had excluded the reference product from the formulary. The big 3 PBMs (i.e., CVS Caremark, OptumRx, and Express Scripts) individually announced they would add at least one biosimilar to their formularies at parity to Humira®. With the notable exception of Kaiser Permanente, no other major payer in 2023 had excluded Humira® from its formulary.[39]

Parity Coverage Resulted in Marginal Uptake

According to data from IQVIA, adalimumab biosimilars had gained an overall total of 1% market share by March 2024 **(Figure 1)**.[13]

This was despite an impressive array of biosimilars that included interchangeable agents and formulations that closely matched those available for Humira®.[36]

Figure 1



Still, the very existence of biosimilar competition had created substantial savings. AbbVie reported a drop in net earnings on US sales of Humira® of approximately $6.5 billion in 2023 compared with the previous year (before the launch of biosimilars). AbbVie attributed this decrease almost entirely to lower net prices required to compete with biosimilars.[40]

At parity coverage, there is little to no incentive for physicians or patients to switch to biosimilars. The out-of-pocket costs to patients are the same for the reference product and the biosimilars, and the prescribing physicians would rather continue their patients on their existing therapy if not compelled to switch. Therefore, unless a formulary policy changed, adalimumab biosimilar uptake would remain stagnant, which would also negatively impact the bottom lines of competing manufacturers.[5]

This situation poses a threat to the biosimilar industry. Payers and their PBMs, who control access to adalimumab biosimilars, bear responsibility for the lack of biosimilar uptake in a market offering the greatest potential savings of any biologic currently facing patent expiration. As stated, through 2023, the savings achieved through biosimilar competition was about $6.5 billion; through the first 18 months of biosimilar competition, this figure is $11 billion. However, this was attained without virtually any biosimilar utilization, i.e., none of the benefit (or profits) accrued to the biosimilar manufacturer. The resulting situation can be expected to discourage future biosimilar development if not rectified by those governing formulary access—PBMs and their payer clients.[4,41]

According to IQVIA data, individual prior authorization requests for adalimumab biosimilars are approved significantly less often within the big 3 PBMs compared with other smaller PBMs.[42]

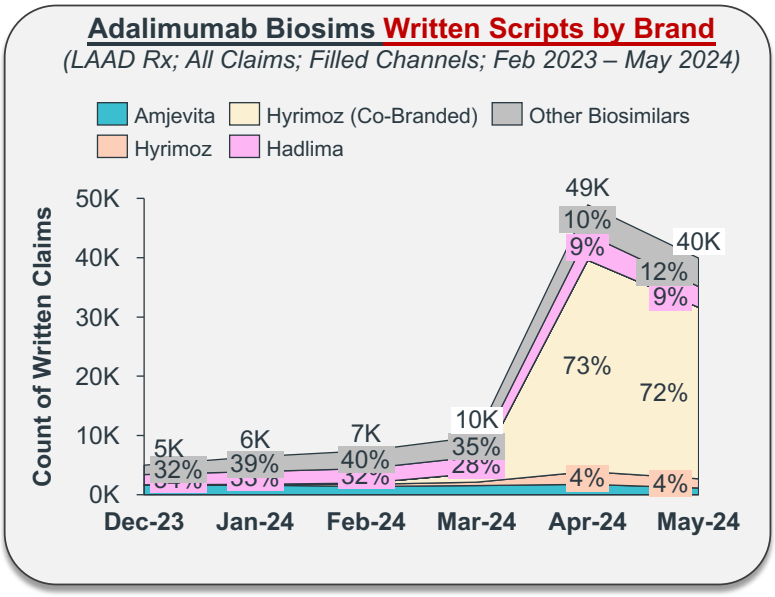
A Crack in the Humira® Dam

Facing congressional scrutiny for their business practices, including their reliance on rebates, the PBM industry has sought a different tactic. In April 2024, CVS Health introduced a new mechanism for earning revenues from biosimilars that does not rely on rebate contracting. Using a new distributor subsidiary (called Cordavis), CVS came to an agreement with Sandoz to market the pharmaceutical company's highly discounted adalimumab biosimilar as a co-branded product that is distributed through Cordavis. In essence, Sandoz supplies an unbranded version of its Hyrimoz® biosimilar and shares the profits with Cordavis.[41,43]

With this agreement in place, CVS Health excluded Humira® from its formulary and within a short period, switched its adalimumab prescriptions to the unbranded Cordavis version. This resulted in approximately 49,000 new prescriptions for biosimilars in April 2024 alone, a fivefold increase

Figure 2

Co-branded Hyrimoz® is driving increased biosimilar utilization.[42]



IQVIA

compared with the previous month, according to IQVIA data. Over 70% of this new volume is a result of Cordavis co-branded adalimumab **(Figure 2)** (both from the unbranded version of Hyrimoz® and AbbVie's unbranded version of Humira®, which is also covered by CVS Health's PBM).[42]

As of October 2024, CVS Health reported that 97% of their adalimumab prescriptions are filled with a preferred biosimilar.[14]

The CVS Health approach is also being implemented by Evernorth's PBM Express Scripts, which announced that it would be co-branding two biosimilars (from Boehringer Ingelheim and Alvotech/Teva) and distributing it through its Quallent Pharmaceuticals subsidiary.[44]

OptumRx, the last of the big 3 PBMs, has announced that it will take a similar private-labeling tact with its own distributor-subsidiary, Nuvaila, for the launch of Amgen's Wezlana™ (ustekinumab-auub).[25]

Evernorth has also announced that it will launch a private-labeled version of a Stelara® biosimilar, with a price at least 80% below that of the reference product.[15]

In conclusion, it may be difficult for biosimilar manufacturers today and in the future to attain significant revenue unless it can partner with the PBMs in similar private-label and cobranding arrangements. These arrangements call for sharing of the sales revenues remaining after 80% or more discounts (along with any rebates) have been applied.

The brief experience of adalimumab biosimilar makers shows that attaining parity coverage with the reference product does not result in significant utilization. For those who cannot obtain preferred or exclusive coverage through the PBM, achieving profitability for a pharmacy benefit–covered biosimilar may be extremely difficult or even impossible. This trend will certainly be considered in companies' drug pipeline decision-making.

Part II. The Healthcare Provider Perspective

For biosimilars covered under the pharmacy benefit, physicians' influence over which specific biologics are prescribed may diminish over time. Coverage decisions by PBMs and their payer and employer clients are the primary drivers of prescribing choice on these self-administered drugs.[5,12]

This chapter reports the responses to an online survey conducted in 2024 of US-based specialist physicians who treat patients with autoimmune disorders and are experienced in prescribing biologics for their patients.

A total of 73 physicians completed the survey. The respondents comprised 30 rheumatologists (41%), 23 dermatologists (32%), and 20 gastroenterologists (27%). Twenty-seven percent worked in small single-specialty practices (≤ 4 physicians), 15% worked in larger single-specialty practices (> 4 physicians), and 26% were part of multispecialty groups. Sixty percent of the respondents were in independently owned group practices, 12% of their practices were owned by an integrated health system, 12% were in solo practice, and an equal percentage (8%) had a hospital-or academic-based practice.

Their patient populations were most often covered by commercial insurance (47%), followed by traditional Medicare (21%), Medicare Advantage (16%), Medicaid (11%), and self-pay or other (5%).

The survey was fielded from July to August 2024, and all respondents received an honorarium for completing the survey.

Expert Commentary

- **Neal Bhatia, MD,** Director of Clinical Dermatology, Therapeutics Clinical Research, San Diego, California
- **David S. Batt, MD,** Rheumatologist, Indiana University Health, Carmel, Indiana
- **Robert J. Tierney, MD,** HealthPartners Medical Group, St. Louis Park, Minnesota
- **Fred C. Fowler, MD,** Carolina Digestive Health Associates, Concord, North Carolina

Survey Questions

Healthcare providers' comfort level with biosimilars has clearly increased over time. Since their introduction in 2015, biosimilars have been used in approximately 2.7 billion days of patient therapy.[9]

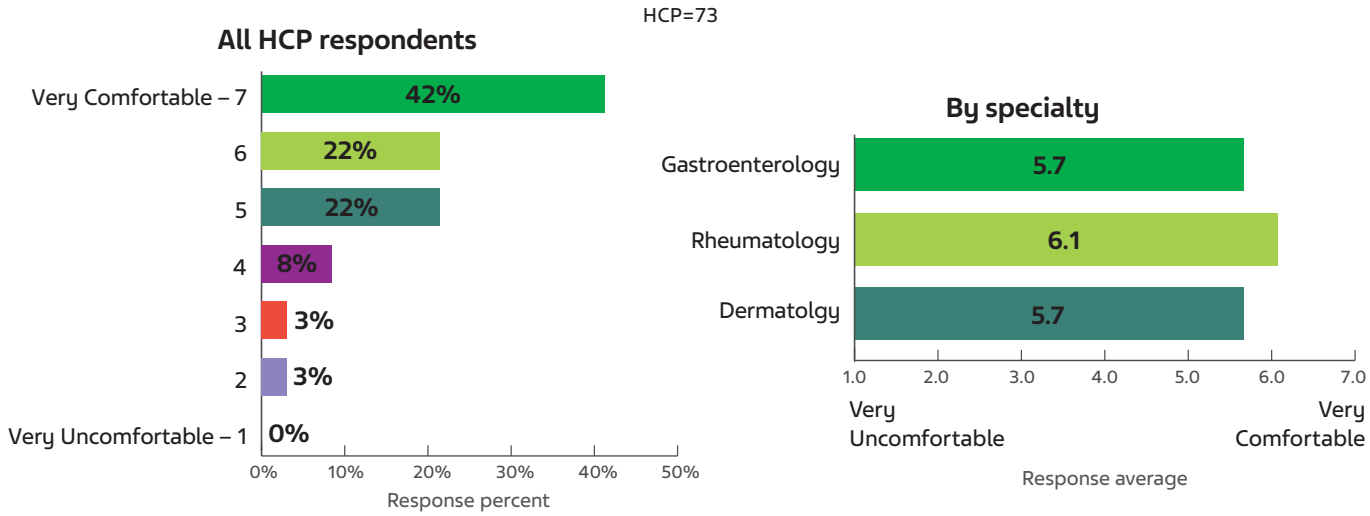
The physician panel responding to the survey indicated a high level of comfort with biosimilar prescribing, with 86% of respondents reporting comfort ratings of 5 or above on a 7-point scale (7 = very comfortable). Rheumatologists indicated a slightly higher mean rating (6.1) than gastroenterologists (5.7) and dermatologists (5.7) **(Figure 1)**.

Dr. Fowler, a gastroenterologist, pointed to experience being the main factor: "Because the infliximab biosimilars have been out for years now, we have a great amount of data" that supports this comfort level. He said that the adalimumab biosimilars could accumulate similar comfort over time with more data.

Dr. Batt, a rheumatologist, added, "Rheumatology is probably a little more comfortable than anybody else overall, but I do not think there is that great a difference, because all three disciplines have been exposed to biosimilars in the intravenous realm. I think we have all found that they work just as well as reference drugs, and they are just as safe. In fact, I am surprised that the comfort level among those three specialty groups isn't greater than what it is."

Figure 1

How comfortable are you with prescribing biosimilars?[1]



It should be noted that more safety and efficacy data on adalimumab biosimilars are available in Europe where they launched in 2018, which was not mentioned by physician commentators. They did specifically mention their desire for more accumulated US real-world evidence.[4,5]

Biosimilars Improving Patient Care. When asked if biosimilars contribute to improved patient care, 85% of the physicians surveyed gave a positive response and 15% negative **(Figure 2)**.

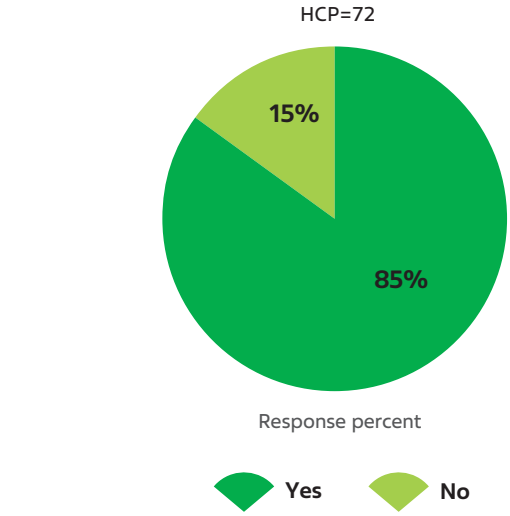
Dr. Fowler believes that some of the resistance to prescribing biosimilars stems from "the idea that biosimilars are copies of drugs that are already out there, so they're not adding anything clinically. And in many situations, it does not directly save money for the patient. It just increases the profit for the insurance company."

However, the Association for Accessible Medicines (AAM, and its Biosimilars Council) have found that the availability of biosimilar competition in the United States has resulted in a significant increase in patient days of therapy with biosimilars that would not have occurred otherwise. The conclusion of the AAM report based on this increase is that biosimilars are leading to great health equity through increased access to biologic alternative medications.[9]

Patient Acceptance of Biosimilars. Providers' view of patient acceptance of biosimilars from the front lines also reflects a higher comfort level. As a whole, the mean rating of their concern over

Figure 2

Can biosimilars contribute to improving patient care?[1]

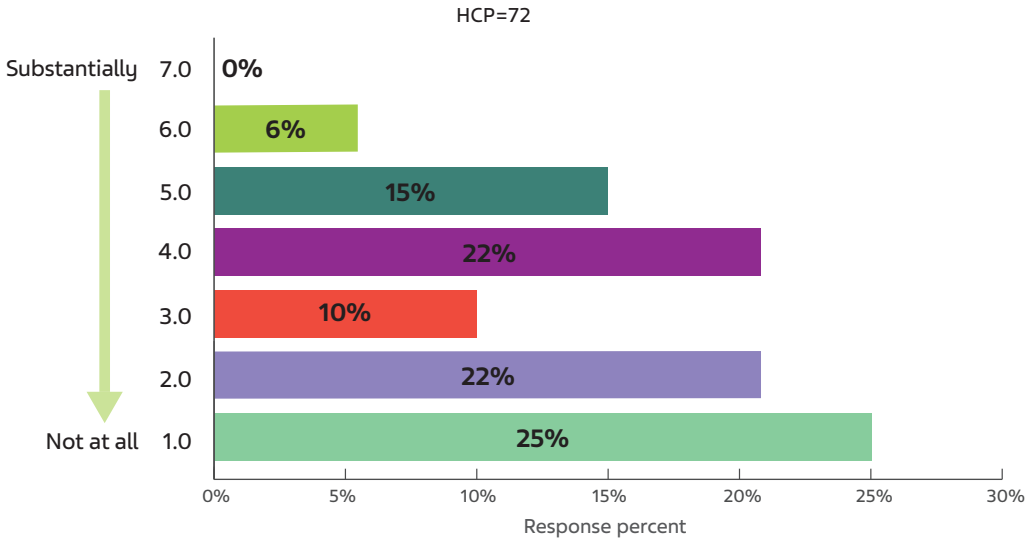


patient acceptance was a 3.0 on a 7-point scale (7 = substantially concerned). This held true across specialties, with approximately 60% rating their level of concern as 3 or below. Importantly, one-quarter of the total were "not at all" concerned about patient acceptance of biosimilars **(Figure 3)**.

This represents a significant shift from the 2023 survey numbers when no more than 9% of gastroenterologists, rheumatologists, or

Figure 3

How concerned are you about patient acceptance of biosimilars?[1]



dermatologists indicated a similar comfort level around patient acceptance.[16]

"I am not terribly concerned about patient acceptance of biosimilars," Dr. Fowler agreed, "and I say that because I don't think most patients are particularly well informed about them. Most patients are accepting of generics. Even though a biosimilar is not a generic, patients mostly care about whether it works, is safe, and is affordable."

Patient acceptance can be a result of how the physician poses the choice to the patient, according to Dr. Batt. "Although biosimilars are not generic drugs, patients understand generics more than they understand biosimilars. For instance, if you said, 'We've been using generics for many of your prescriptions for the last 30 or 40 years, and the FDA basically says that they're equal in terms of efficacy and side effects, and for many of these drugs, the price will be lower for you,' then patient acceptance will be pretty good. On the other hand, if you say, 'Well, this is a new drug I don't have much familiarity with, it's sort of like a generic, but I don't know if it's as good as your Humira® or as safe as your Humira®,' then patient acceptance will be abysmal."

Dr. Tierney added, "I have very few patients who switched from biosimilar back to the reference product. I explain to patients why biosimilars are important and they are less expensive because the manufacturer doesn't have to do two clinical studies with 1,500 patients for each indication. They should be of equal safety, efficacy, pH, immunogenicity—everything else being equal priced at lower cost."

Biosimilar Brand Awareness. Beyond their growing comfort level with biosimilars overall, commentating clinicians feel that they know very little about the individual adalimumab biosimilar brands. With 10 or more adalimumab products (depending on whether private- or co-labeled products are counted), the physicians indicated limited awareness of many of the brands. Only three biosimilar brands registered greater than 70% name recognition by the physicians surveyed (data not shown).

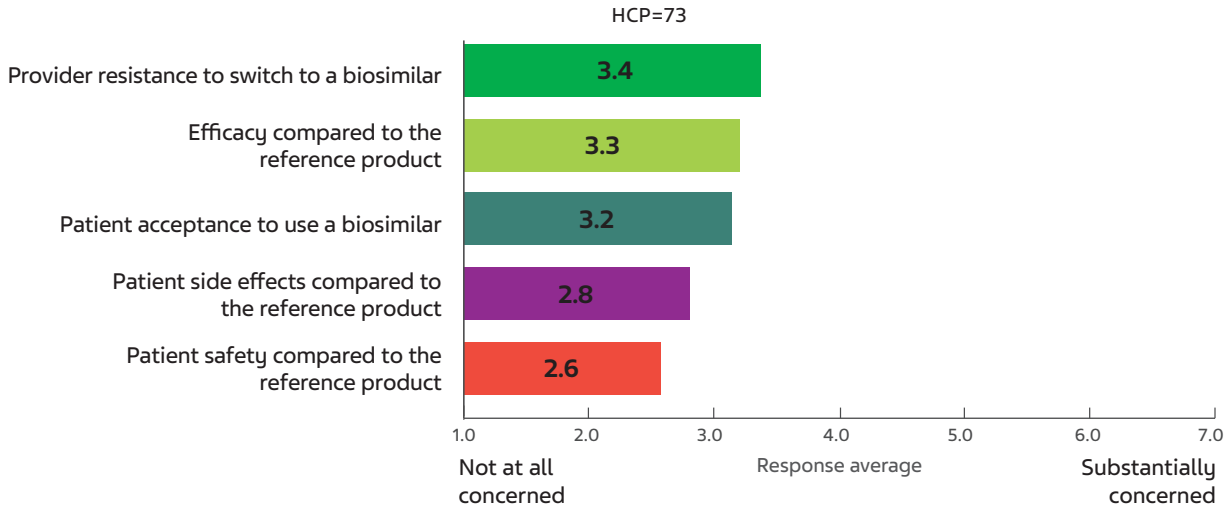
Dr. Batt suggested that this lack of brand awareness was related to product promotion and manufacturers' contact with the practices. "I am not even aware of the names of the companies that make them, because their names are foreign to the rheumatology sphere," he said.

Dr. Tierney added that there may be some differences in specialists' recognition of the adalimumab brands, based on their clinical trials: Most of these agents were studied in rheumatoid arthritis or psoriasis, but fewer were studied in Crohn's disease or ulcerative colitis.

Dr. Fowler said that he was aware of just one or two, but "there are no other biosimilars that come to mind for Humira®, although so many have come

Figure 4

How concerned are you about the following biosimilar medication issues?[1]



out at the same time. I really only memorized a couple of names, because I am inclined to think that insurance plans will specify which ones they want. My prescribing choice is not going to matter very much."

Dr. Bhatia added that these products are not marketed as heavily as branded reference products: "They don't market them by name, and they don't have a sales force, so we end up having to hear about them either at conferences or in literature."

Dr. Tierney admitted that he was familiar with only four adalimumab biosimilar brands. "At our clinic, I write adalimumab and what comes up in the order is whatever the insurance company covers," he said. "I don't actually order a specific biosimilar. The patient's payer dictates which biosimilar agent automatically appears in the orders on the electronic medical record."

Other Biosimilar Adoption and Comparability Issues. In parallel with the increased comfort level in biosimilars that prescribers express over time, potential concerns over biosimilar safety and efficacy also seem to be fading, according to the physician survey results.

About one-third of physicians responding have minimal to no concerns about biosimilar safety or side effects relative to the reference product, with average ratings of 2.6 and 2.8, respectively, on a 7-point scale (7 = substantial concern). In terms of biosimilar efficacy, physicians were slightly more concerned, with an average rating of 3.3 (16% indicating a rating of 6) **(Figure 4)**.

Interestingly, when physicians were asked to list any concerns they have about prescribing a biosimilar to their patients, their most common concern was regarding efficacy (45%), and safety placed fifth (30%). Filling out the physicians' top 5 concerns were a patient's resistance to switching therapies (42%), lack of patient support by biosimilar manufacturer (42%), and consistency of supply (30%) **(Figure 5)**.

"I think most of it comes back to, again, efficacy and safety, whether it has been demonstrated to be safe in trials," said Dr. Bhatia. "If you look at availability of office support, that's also a major issue for many because the support that a company lends to the biologics, whether it be demonstration of injection technique, coverage paperwork for the authorization, or adverse event reporting, that's a big asset to the clinic."

The theme of limited patient support services was also highlighted in another question, when 87% stated that it was one of their two barriers to adoption of patient-administered biosimilars (only exceeded by absence of patient savings and payer coverage) **(Figure 6A)**.

Dr. Fowler explained, "The companies that make the [reference] biologics that we use do a very good job of providing programs to help support the patients both financially and clinically. And that's one of the reasons that I tend to prefer them over the biosimilars, in that we have a representative from the company that we have a relationship with, that if there's any sort of a problem, we call and they

Figure 5

What are your concerns about prescribing a biosimilar to your patients?[1]

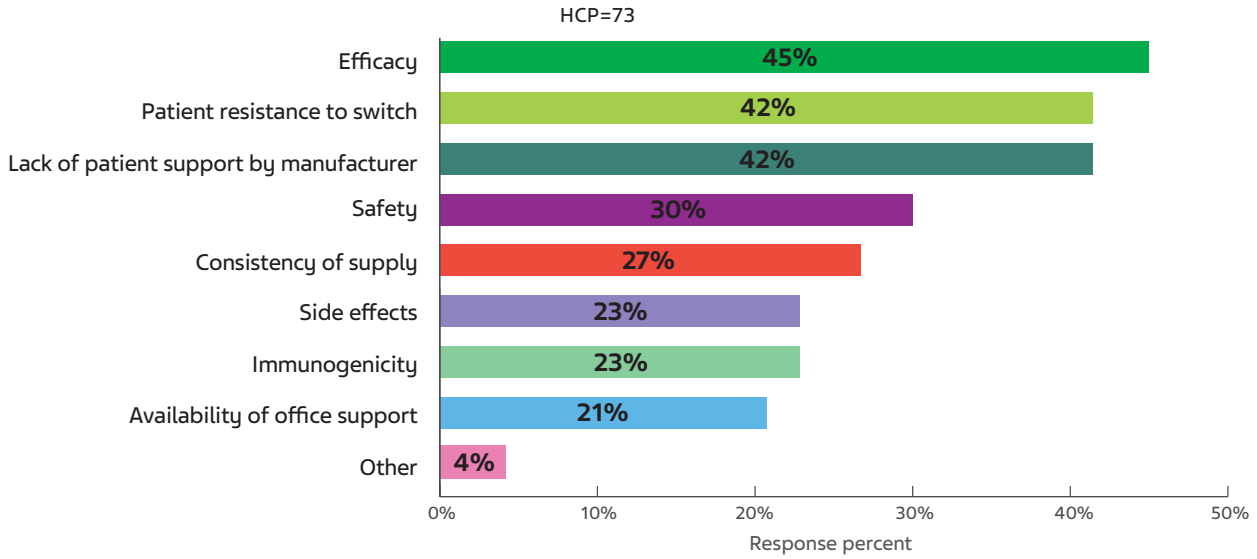


Figure 6A

Which are the greatest barriers to biosimilar adoption by physicians, nurses, and patients?[1]

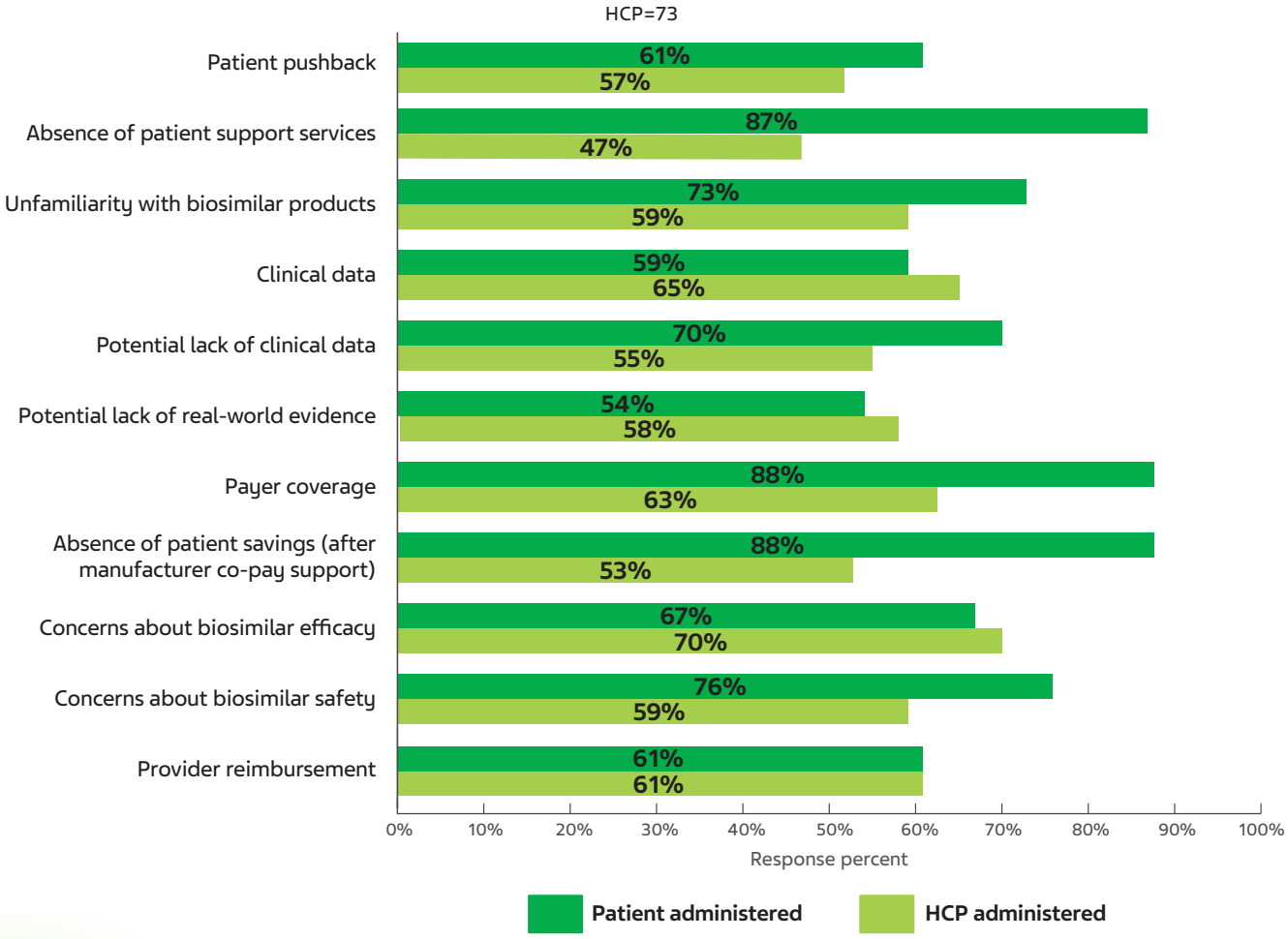
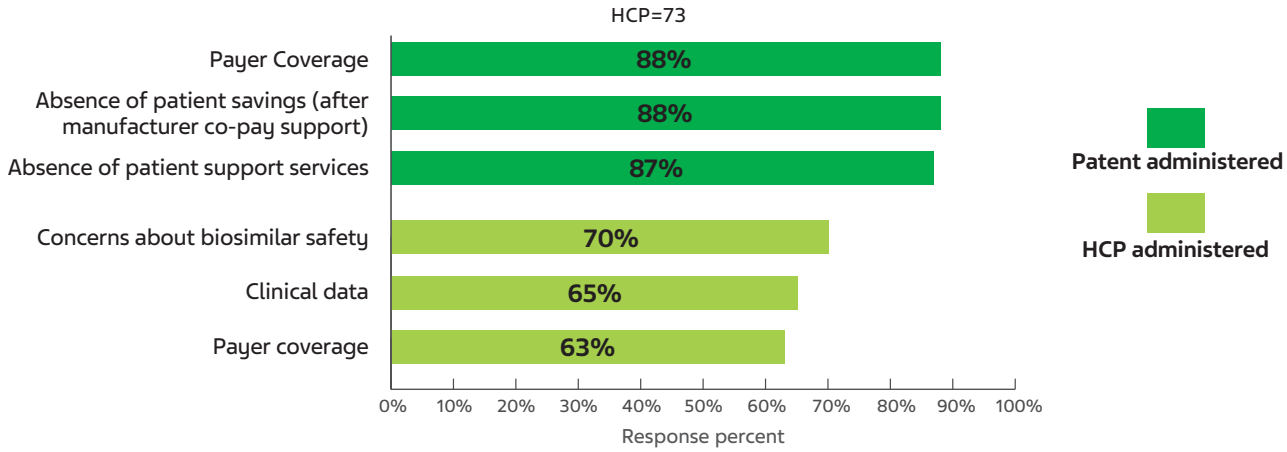


Figure 6B

Top 3 barriers to adoption of patient administered and HCP administered biosimilars.[1]



take care of it, or they help us take care of it. And that's really quite helpful."

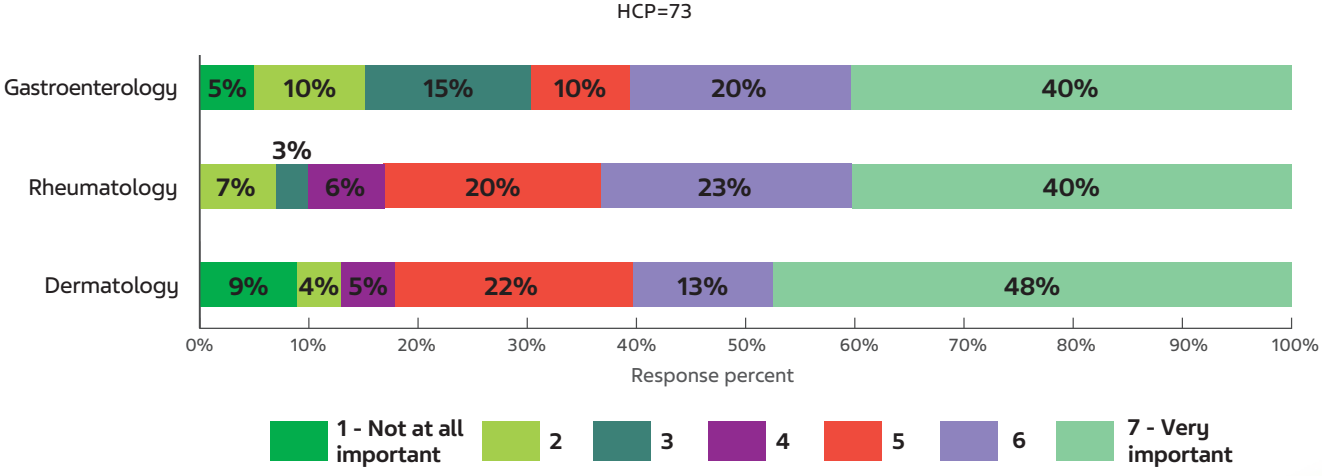
Based on the survey results, this seems to be a greater problem for patient-administered medications, like adalimumab. For example, all of the rheumatologist respondents signaled that lack of patient support services was a concern (along with 90% of dermatologists).

Patient Costs/Cost Savings. When choosing a biologic agent to prescribe, healthcare providers have become accustomed to having conversations with patients regarding out-of-pocket costs. When asked about the role of patient cost savings in the decision to prescribe a biologic or biosimilar, the physicians' mean rating was 5.5 on a 7-point scale (7 = very important). There was little difference across specialties. At least 60% of respondents in each specialty assigned patient costs a 6 or 7 rating **(Figure 7)**.

Dr. Fowler pointed out that "cost savings to the patient is very important," but this is really not an issue for patients with commercial insurance receiving biosimilars. "Virtually all biologic manufacturers have some type of co-pay program that makes those medications inexpensive or affordable for the individual. On the other hand, Medicare patients

Figure 7

When choosing between biosimilars and reference biologics, how important are cost savings to the patient in your prescribing decision?[1]



are not eligible for those programs provided by the drug companies. That's really where cost savings of biosimilars could be important to the patient."

Dr. Tierney agreed, "The cost to the patient must be at least equal to what they're already on. And hopefully, they get some benefit out of switching to a biosimilar, in terms of cost savings." He suggested that offering patients a co-pay card for making the switch to the biosimilar is an effective financial incentive.

Dr. Batt added, "I would assume that some of the cost savings [with the biosimilar] would be passed along to the patient or at the least they would still get the same $5 or $10 co-pay card as they did with the reference compound.

"Without insurance, these drugs can cost over $50,000 a year," Dr. Batt continued. "Patients will not be able to pay this on their own; with a co-pay card, the cost may be only $5 or $10 a month. So, when we prescribe these drugs, it doesn't matter whether it is a great drug. Even for a biosimilar, if it is not covered by their insurance, the cost will not be reasonable for the patient."

Greatest Barriers to Biosimilar Adoption by Providers. For biosimilars administered in a physician's office or clinic, the top three barriers to biosimilar adoption were efficacy concerns (70%), clinical data (65%), and payer coverage (63%). For biosimilars administered by patients, the top barriers listed were absence of patient savings (88%), payer coverage (88%), and absence of patient support services (87%) **(Figure 6B)**.

In some cases, these results are differentiated by specialty. Dr. Bhatia offered that dermatologists administer fewer intravenous medications in the office than do rheumatology and gastroenterology practices, and as such have fewer drug reimbursement issues. He pointed to other differences among specialties as well: "Most of our [dermatology] patients are younger. They usually don't have any other health issues. Whereas most of the rheumatology patients and the GI patients tend to have more health issues and might have other concomitant illnesses."

Dr. Fowler pointed out that concerns over cost do not necessarily apply to patients with commercial and Medicaid coverage. "The drug companies have very generous programs that help the patients with commercial insurance, and they also have very generous programs for patients who have no insurance. The only ones who pay very much out of pocket are the Medicare patients."

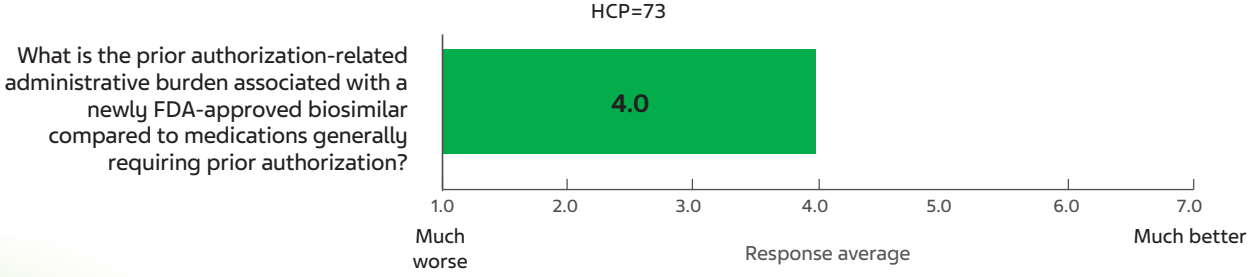
The question regarding clinical data, however, relates back to the extrapolated indications. This is typified by adalimumab biosimilars, which were most often studied in plaque psoriasis or rheumatoid arthritis, and clinical studies were conducted in inflammatory bowel disease by only a couple of manufacturers.[46]

"Everyone is concerned to a degree about payer coverage. That comes from our experience with having to spend a lot of time on the phone, filling out paperwork, and talking to people," explained Dr. Fowler.

The majority of physicians (81%) were neutral on whether the prior authorization–related administrative burden associated with biosimilars was better or worse than that for biologics, with an average rating of 4.0 on a 7-point scale (1 = much worse, 7 = much better). Ten physicians (14%) responded that the prior authorization burden for biosimilars was considerably worse (1-2 rating), whereas only four physicians (5%) indicated that it was much better (6-7 rating) **(Figure 8)**.

Figure 8

What is the prior authorization-related administrative burden associated with a newly FDA-approved biosimilar compared to medications generally requiring prior authorization?[1]



"I've been surprised at the challenges in getting biosimilars approved. I thought that would be one of the advantages to the biosimilars, but I'm finding it just as hard," said Dr. Fowler.

Dr. Tierney had a somewhat different perspective to share even though he agreed that the prior authorization challenges are the same: "We have a biologic coordinator. All she does is handle prior authorizations, so our physicians really don't do any of it themselves."

Greatest Concerns for Your Practice in the Next 12 Months. Despite the perception that the administrative burden of biosimilars was generally similar to that of reference products, prior authorization burden remains one of the greatest concerns over the next 12 months among physicians. For surveyed physicians, the top 2 concerns for their practice were increased prior authorization requirements (62%) and reduced reimbursements (44%), followed by more restricted insurance coverage for treatments (37%) and increased use of step therapy (33%). Somewhat surprisingly, practice overhead costs were indicated by one-fifth of those surveyed, without large variation by specialty (range 15%-27%) **(Figure 9)**.

Rheumatologists agreed that increasing prior authorizations were the number one concern, but only by a small margin over reduced reimbursement (53% vs 47%, respectively). Increased use of step therapy was the number two concern of gastroenterologists (70% for prior authorizations vs 40% for step therapy).

Dr. Batt said, "It looks like the increased prior authorization requirements lead the pack as the major concern. It also seems that for infusible therapies, insurance companies are starting to ratchet down on what they'll pay."

Dr. Bhatia explained, "It's always a burden on the staff and patients to write prior authorizations. It just depends on how many prescriptions are being written and your office staff's capability. It's still bad and it's only getting worse."

Dr. Fowler commented further, "I would have named practice overhead costs number 1, because the increased prior authorization requirements translate into increased practice overhead cost."

Trends/Market Events That Will Impact Your Specialty Over the Next 12 Months. Although the surveyed physicians named increased prior authorization requirements overall as the greatest factor affecting their individual practices in the short term, they reported that additional aspects of working with plans and insurers will dominate their specialties. Changes in formulary exclusions (48%) and alterations in insurance coverage policies and designs (45%) represented the greatest concerns

Figure 9

What are your greatest concerns for your practice during the next 12 months?

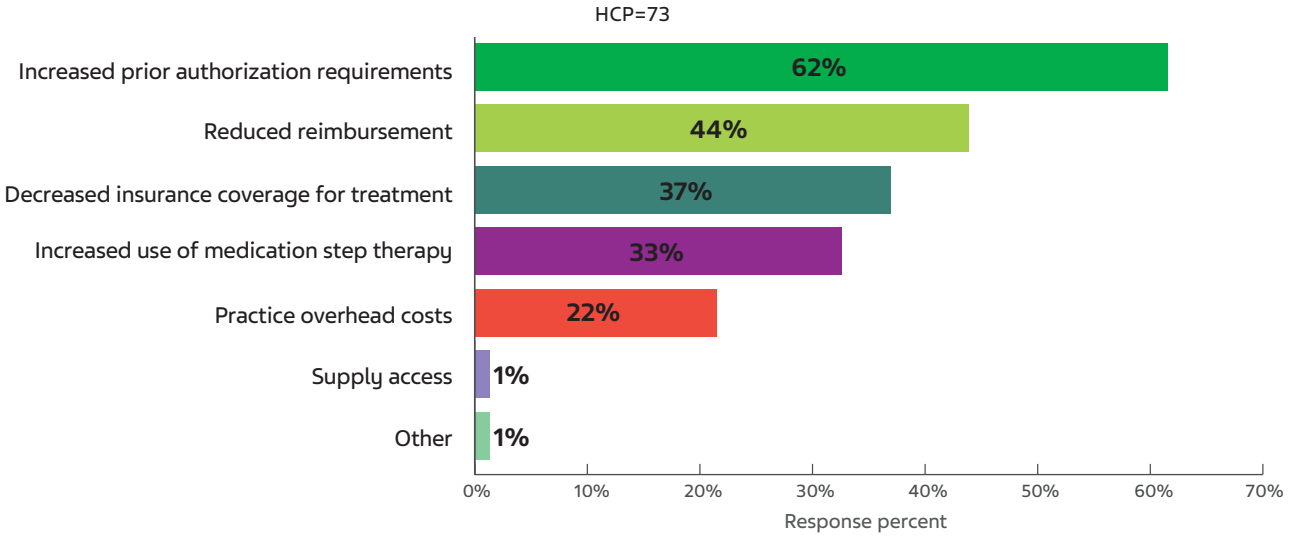
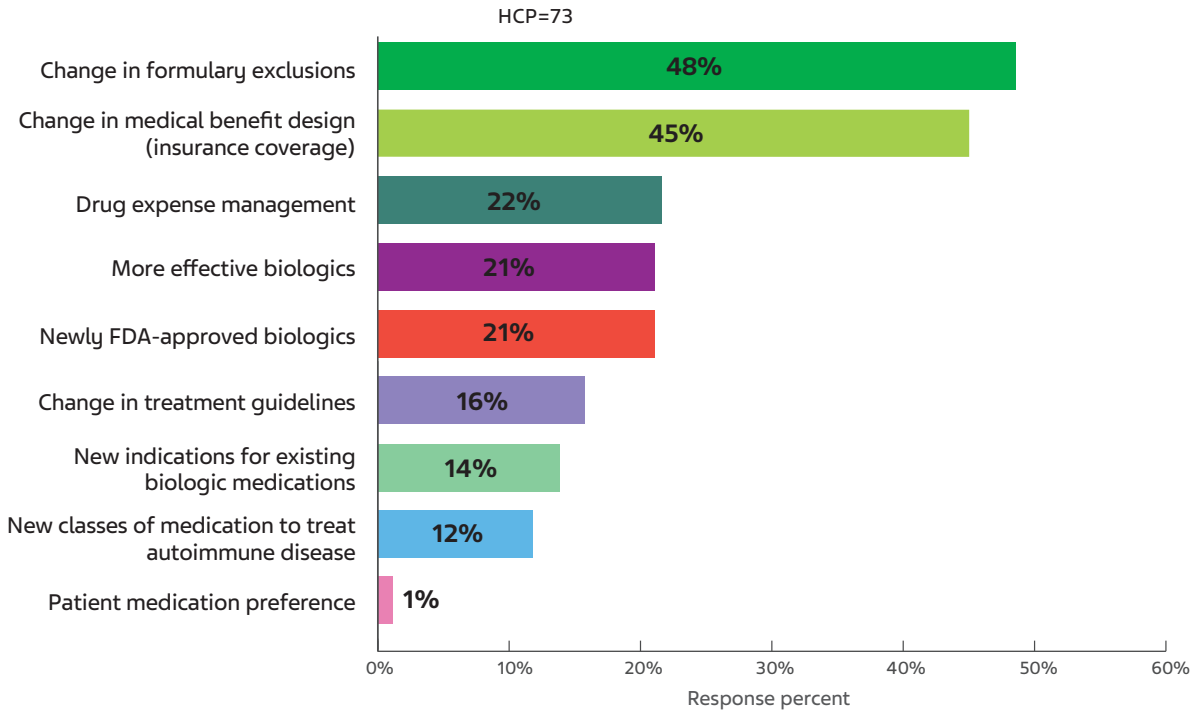


Figure 10

What important trends or market events do you believe may impact your specialty in the next 12 months?



of surveyed physicians, by a considerable margin **(Figure 10)**.

Their responses may have been influenced by the ramifications of recent Humira® exclusions by PBMs. These exclusions in 2024 have highlighted the need for provider and patient education and reconsideration of the doctors' prescribing habits (especially when interchangeability's automatic substitution is not employed).[25]

Other items that were listed as important trends were drug expense management (22%) and the introduction of both new (21%) and more-effective biologics (21%). Drug expense management involves infusible biologics, and this is primarily a concern for specialists who do in-office infusions and buy-and-bill their medications.

The introduction of new FDA-approved biologics may provide valuable treatment alternatives in these autoimmune categories. According to Dr. Fowler, "what has actually happened is that the FDA has made it harder for us to decide which therapies to use before others. We now have multiple classes of medications, and we don't have many head-to-head comparison studies; generally, these studies compare the new treatment to placebo.

"Treatment guideline recommendations can be helpful here," he continued, "but they might not be updated for years before they include the new medications."

Conclusions

Physician comfort levels with biosimilars have been increasing, with 86% of physicians surveyed reporting that they were "comfortable" to "very comfortable" prescribing these biologics. The three physician groups surveyed overwhelmingly agreed (85%) that biosimilars contributed to improved patient care. Yet, there is some evidence that the provider community harbors misperceptions about biosimilar safety and efficacy. More than one-third surveyed still expressed some degree of concern over patient safety, and just over half were not yet convinced of biosimilar efficacy.

The healthcare providers' view of patient comfort levels with biosimilars is also improving. One-quarter of the physicians surveyed in 2024 were

"not at all" concerned about patient acceptance of biosimilars, nearly a threefold improvement from the 2023 survey.[16]

Whereas their comfort level with biosimilars is improving, their prescribing decisions may be becoming more focused on non-clinical factors, such as which product is covered by the patient's insurance and whether there is any cost savings for the patient.

It is unlikely that these specialists will be writing for their prescription choice by adalimumab brand (and potentially others), as they are generally unfamiliar with the broad array of adalimumab biosimilar brands, and they understand that the product dispensed will be highly dependent on the insurance coverage and formulary.

The physicians, wary of increasing administrative burdens on their practices, worry that payers will apply additional prior authorization criteria, particularly in the face of new biosimilars and new biologic categories. The administrative burden translates directly into overhead costs, which impact small practices disproportionately compared to larger groups and those owned by health systems.

What Are the Potential Implications of the Inflation Reduction Act on Biosimilars?

The Inflation Reduction Act (IRA) and its implications for the US healthcare system were being hotly debated in 2024. The announcement of Medicare price negotiation for the first 10 targeted products was followed by analyses from stakeholders and consultants, and points for biosimilar makers and the pharmaceutical industry overall.[47]

The potential effects of the IRA do not seem to be top of mind for managed care. Only half of payers who responded to *The Teva Biosimilar Trend Report, Second Edition*, survey were aware of how the IRA may affect biosimilars **(Figure 1)**.

A Chief Medical Officer of a West Coast plan admitted, "I did not know that [the IRA] had anything to do with biosimilars and did not consider the unintended effects the IRA could have on biosimilars."

Two Biosimilar Journeys

The list of 10 initial Medicare price negotiation targets includes 2 autoimmune medications that will be subject to biosimilar competition. The tumor necrosis factor (TNF) inhibitor Enbrel® and the interleukin (IL)-12/IL-23 inhibitor Stelara® have very different biosimilar journeys.[47]

With regard to Enbrel®, two biosimilars were approved by the FDA in 2016 and 2019, respectively, but biosimilar competition is not expected until 2029 owing to patent litigation. Medicare's negotiated price reduction for Enbrel® of 67% will likely reduce the reference manufacturer's revenues for three years prior to this date. Therefore, the inclusion of Enbrel® on the initial list from the Centers for Medicare & Medicaid Services (CMS) should produce substantial Medicare savings (and perhaps even lower prices for commercial or Medicaid plans).[47,48]

Another consideration may also come into play for Enbrel®. For its major indications (rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, and plaque psoriasis), other anti-TNF products, including adalimumab, are at least as effective. With the deep discounts (81%+) existing for adalimumab products, it would not be unreasonable for Medicare payers to apply a step edit to Enbrel® that requires a trial of adalimumab first.[49]

Stelara® (ustekinumab), on the other hand, will face biosimilar competition as early as January 2025. Based

Figure 1

How aware are you of the potential impact of the Inflation Reduction Act on biosimilars?[1]

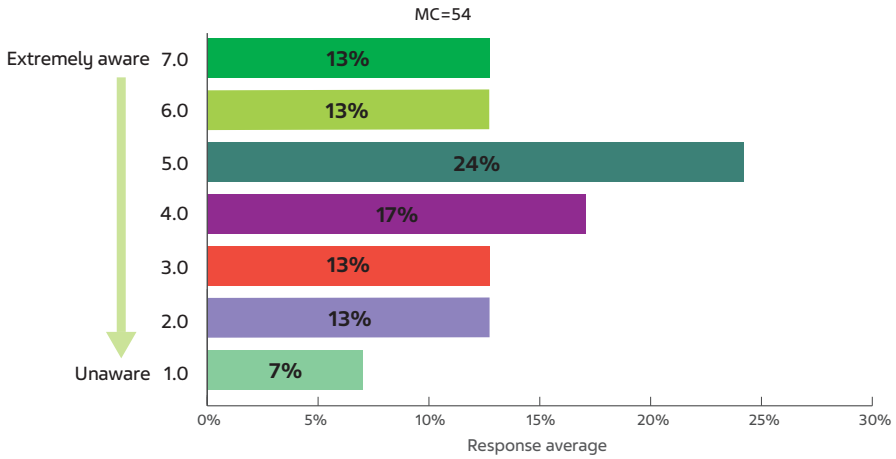


Table 1

Illustrative example of net plan liability impact of Medicare Drug Price Negotiation[11]

	Scenario 1: Traditional rebate (pre-MFP)	Scenario 2: MFP with equivalent net price	Scenario 3: MFP with lower net price	Calculation
Wholesale Acquisition Cost (WAC)	$10,000	$10,000	$10,000	(a)
Gross Part D Cost	$10,000	$5,000	$4,000	(b)
Rebate	50%	0%	0%	(c)
Gross Plan Liability*	$6,000	$3,000	$2,400	(d) = 60% x (b)
Plan Rebates After Reinsurance Sharing**	$4,350	$0	$0	(e) = 87% x (c) x (a)
Net Plan Liability	**$1,650**	**$3,000**	**$2,400**	(f) = (d) – (e)

** Assumes 60% plan liability. Plan liability varies between 60% and 65% following the deductible under the defined standard benefit. Plan liability may be greater for enhanced alternative plans.*

*** Assumes plan must share 13% of rebates to offset federal reinsurance, on average. The percentage of rebates plans must share with the government is determined by the relativity of gross reinsurance to total gross costs.*

on the experience with another pharmacy benefit–covered biosimilar, adalimumab, the price negotiated by CMS for the Medicare population may well be significantly higher than the net price discounts resulting from biosimilar competition (Medicare's 66% discount from the current wholesale acquisition cost vs > 80% discounts through biosimilar competition) one year before Medicare's negotiated discount takes effect.[19]

Plans May Spend More on Biosimilar Than Reference Product Under the IRA

Despite the intention of the IRA's Medicare price negotiation, it may be less biosimilar-friendly than one might expect. In fact, with the current situation for ustekinumab biosimilars, the IRA may actually incentivize health plans to favor the reference product and restrict coverage of biosimilars.

A recent analysis from Milliman illustrates the problem **(Table 1)**.[11]

The issue is the value of the rebates, according to Milliman. For example, in Scenario 3 by increasing the Part D or Medicare Advantage plans' net plan liability, which somewhat resembles the case of ustekinumab biosimilars, the plan would actually pay less prior to the maximum fair price (MFP) negotiation.

A second factor is the Part D redesign, which increases the manufacturer's portion of drug coverage from 0% to 20% in the catastrophic phase. This could be considered an additional "tax" to the manufacturer, on top of existing discounts. It can have a substantial, detrimental effect on a product later in its life cycle.[20]

It should be noted that an innovator drug that is subject to Medicare price negotiation is not subject to this 20% fee, which may thus give that manufacturer a competitive edge over a biosimilar competitor (assuming the reference drug was not exempted from price negotiation because of existing or upcoming biosimilar competition). For a lower-cost product (as illustrated as Product A) in **Table 2**, the Part D plan actually pays a bit less than before the MFP was initiated. However, in the case of Product B, a more-expensive agent, the costs to the Part D plan multiplied.[20]

If an initial delay request is approved by the CMS, Stelara® could be removed from the list of first 10 products subject to Medicare price negotiations. This will be revealed in a final guidance released on October 27. If there is no approved delay, the Stelara® negotiated Medicare price would be implemented on January 1, 2026, and removed one year later, assuming a January 2025 biosimilar launch date.

The IRA and Patient Cost Sharing in Medicare

In the past, patients were responsible for a portion of cost sharing until reaching the coverage gap, which was solely the responsibility of the patient, after which they paid 5% of any remaining Part D drug costs. With some therapies costing more than $100,000 per

Table 2

Comparison of benefit redesign impact by stakeholder group, a 2025 projection[20]

	Product A: $400/month		Product B: $12,000/month	
	Pre-IRA benefit design	IRA benefit design	Pre-IRA benefit design	IRA benefit design
Beneficiary	$1,616	$1,616	$9,990	$2,000
Part D plan	$3,184	$2,759	$23,575	$86,356
Manufacturer	–	$425	$4,720	$28,111
Government	–	–	$105,715	$27,533

The Product A scenario results in minimal changes, while the Product B scenario significantly shifts costs for all stakeholders. Both beneficiaries and the federal government have much lower costs annually, as Part D plans and drug manufacturer costs significantly increase.

In addition, CMS's new authority to negotiate drug prices has further potential to create unintended access challenges in drug classes with one or more drugs that are subject to negotiation. While Part D plans must include negotiated drugs on formularies, those drugs may still be subject to utilization management restrictions, which can limit beneficiary access. In some instances, drugs not subject to negotiation will be at higher risk for coverage exclusion or utilization management because it is more financially advantageous for plans to prefer the negotiated drug. In other instances, a negotiated drug may be placed in a less favorable position on a formulary if a plan is able to negotiate greater price concessions for a non-negotiated drug.

year, this could represent a large financial burden for patients receiving biologic therapy. The IRA addresses this financial risk by restricting patient out-of-pocket costs on Part D drugs to $2,000 overall.[20]

Dr. Maria Lopes, former Chief Medical Officer of MagellanRx, asserted that the new Part D maximum out-of-pocket cap of $2,000 per year will affect formulary management. "After reaching the $2,000 cap, from the patient's perspective, everything is free. I think you will see more formulary restrictions and exclusions, and more prior authorizations. Biosimilars are definitely part of the thinking, if you can save dollars and go to a lower-cost option," she said.

This can be an important benefit to biosimilar makers, said Dr. Lopes, to the extent that biosimilars provide less-expensive options for Medicare beneficiaries who have not yet reached the cap. For example, if biosimilars were offered at a lower co-payment or co-insurance tier than the reference product, patients receiving Medicare could benefit from the improved value of the biosimilar. However, this is not yet widespread: "biosimilar tiers" have not been implemented.

If the biosimilar offers a lower net price, "there's a good chance that payers will remove innovator products from formulary," Dr. Lopes stated, but she cautioned that this was not automatic. "It really all depends on the net cost."

Another consequence of the IRA could offset some of Medicare patients' lower out-of-pocket costs. With the Part D benefit redesign, a plan's financial responsibility for medication costs in the catastrophic care phase increases sharply, from 20% of costs beyond $7,000 to now 60% to 80% of the costs exceeding $7,000. The expected result is higher premiums that will be paid by Medicare eligibles.[50]

How Might the IRA Reduce Biosimilar Competition?

The IRA contains provisions to avoid interfering with upcoming competition, like biosimilars. However, this provision did not come into play in the case of Stelara®, as discussed earlier. According to the Act, if there is a high likelihood that a biosimilar will enter the market within two years of the published listing of the targeted drug, the reference drug can apply for exemption from Medicare price negotiation. The timing of CMS's announcement of the first 10 drugs subject to price negotiation and the 2025 launch timing of ustekinumab biosimilars did not exempt the reference product. Yet, the first ustekinumab biosimilars were accepted for review prior to FDA's deadline of August 15, 2023.[2]

The basic tenet of the IRA MFP provisions is to reduce the cost to CMS associated with a reference product targeted by the IRA. This in turn reduces the drug maker's revenue, indirectly dissuading a biopharmaceutical company from developing a biosimilar for that reference drug.[21]

Hypothetically, the manufacturer of biologic Product R had been earning $2 billion per year in revenues, making Product R a very attractive target for biosimilar developer B. The IRA, however, now cuts

this revenue by 60% three years before biosimilar competition is to begin. As a result, Product R is not nearly as attractive a biosimilar target, especially if several biosimilar developers were expected to compete for this market.

Dr. Lopes pointed out that "Once you're on the IRA list, that impacts not only the drug, but the entire category. Maybe even [drugs with other mechanisms of action] and new market entrants. The IRA sets the price threshold, which is also a biosimilar price threshold."

Fundamentally, the IRA can affect life cycle management of reference drugs by limiting the drug maker's period for maximizing its profits. Some have argued that this will deter some manufacturers from developing new, innovative drugs.[52]

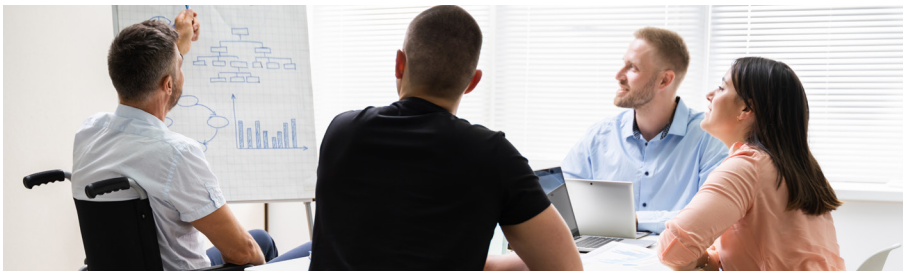
The IRA may compel the pharmaceutical industry to seek higher pricing and market share of a targeted medicine as soon as possible, before CMS negotiates a discounted Medicare price for the product. In that case, costs for the healthcare system will rise (as a result of higher initial drug prices) for reference Product R before it is targeted for Medicare price negotiation or biosimilar competition.

Under the IRA, any biologic approved by the FDA at least 11 years ago can be targeted for Medicare price negotiation unless its sole indication is for an orphan disease or condition. This timeline is dissociated from that for patent expiration—patents can be filed for each (and any) subsequent indication that the manufacturer tests for its product. For a manufacturer, that means new patents for new formulations, indications, or production processes can keep generic or biosimilar competition at bay for decades.[51]

If an initial indication for Product R was approved in 2017, any subsequent indications that are approved by the FDA do not factor into the potential Medicare price negotiation date of 2028. It can be argued that this strategy will stifle a drug manufacturer's desire to seek additional indications for their product (e.g., Keytruda®, which has about 40 indications, accumulated over the course of 10 years).[53]

From Medicare to Commercial Pricing

Despite the CMS's intention for the IRA's direct impact to be restricted to Medicare drug financing, no firewall exists between Medicare and commercial payers. In other words, payers are likely to use the Medicare negotiated prices as a basis for negotiating discounts for drug reimbursement in commercial health plans.



Part III. The Employer Perspective

According to the Kaiser Family Foundation, employers in the United States sponsor health insurance coverage for 60% of the US commercial population under the age of 65. About 86% of employees in the private sector work for organizations that provide health insurance, based on US census figures.[54,55]

Given this role in healthcare, employers are concerned about the rising cost of healthcare, such as the recent trend showing a rapid increase of specialty pharmaceuticals (specialty pharmacy accounts for 51% of the pharmaceutical spend, even though only 6% of the population utilizes them). One might expect that employers, in particular self-funded (or self-insured) employers, possess significant leverage in healthcare coverage and decision-making with their health plan and PBM partners. In addition, employers often rely on health benefits consultants (e.g., AON, Mercer, and several others) to assist in making contracting choices. This would include biosimilar coverage decisions.[56,57]

The chapter reports the 2024 survey responses from 39 employer-based health benefits executives (90%), an employee benefits purchasing group (2%), and benefits consultants or brokers (8%). Of employer respondents, 69% are structured as self-insured companies, assuming the financial risk of providing benefits, and 31% as fully insured, buying health coverage from commercial insurers. Nearly one-third of employers surveyed cover less than 500 workers and dependents, and approximately half cover between 1,001 and 10,000 workers and their dependents **(Figure 1)**.

Figure 1

How many employees/beneficiaries does your organization cover?[1]

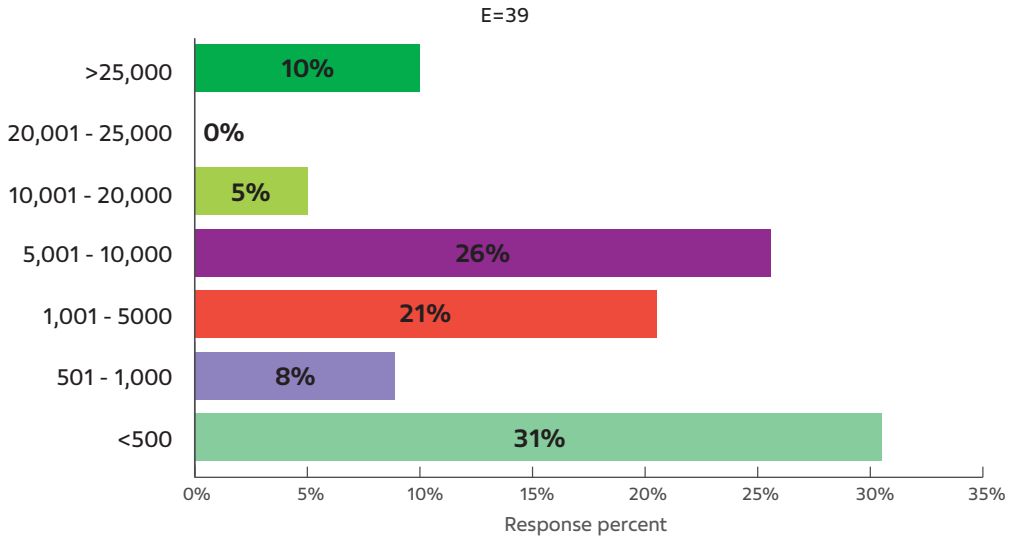
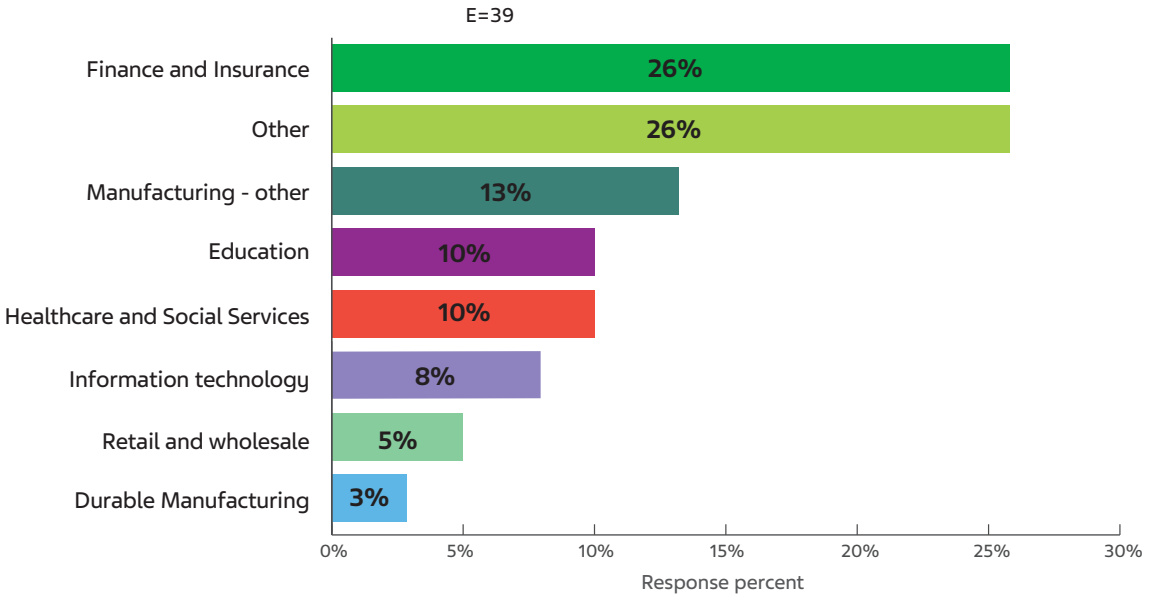


Figure 2

What is your industry type?[1]



The two top types of industries represented by employer respondents were Finance and Insurance and Other (e.g., employee staffing, media, transportation services, nonprofits, manufacturing, and mining companies) **(Figure 2)**.

Of employer respondents, 70% utilize one of the big three PBMs as their pharmacy benefits administrator **(Figure 3)**.

This is comparable with *The Teva Biosimilar Trend Report, First Edition*, survey, in which most employers reported using the same three PBMs: Express Scripts (27%), CVS Caremark (22%), or OptumRx (19%). The other PBMs employers reported using in the 2023 survey included a mix of health benefits consultants or brokers, internal human resources professionals, insurance carriers, and employer coalitions (16%), Magellan Rx (8%), Medimpact (5%), and Humana Pharmacy Solutions (3%).[16]

Commentary is provided from the following employer health benefits professionals:

- **Jerry Suther,** Director, Workers' Comp & Insurance Benefits, Heartland Express, Inc., North Liberty, Iowa
- **Bret Jackson,** President and Chief Executive Officer, Economic Alliance for Michigan, Novi, Michigan
- **Denise Giambalvo,** Director, Member Engagement & Business Strategy, Washington Health Alliance, Seattle, Washington

Survey Results

The majority of employers responded that they have open formularies, which offer coverage for nearly all drugs in each noncosmetic or over-the-counter medication category (72%), 22% have closed formularies, and one respondent choose not to answer (3%) (data not shown).

PBM Influence and Rebates. With medications covered under the pharmacy benefit, employers generally rely on PBM recommendations for coverage and formulary decision-making. Employer respondents indicated that PBMs have moderately high influence, with a mean score of 5.5 on a 7-point scale (7 = very high influence). Significantly more self-insured employers (89%) than fully insured employers (59%) rated PBM influence as high, with a rating of 5 or above **(Figure 4)**.

Bret Jackson, President and Chief Executive Officer, Economic Alliance for Michigan, explained, "I don't think most employers have the capacity or expertise to really make formulary decisions. They have a very small staff, which is spread thinly across many different parts of the health benefits spectrum.

Figure 3

Who is your organization's pharmacy benefit administrator?[1]

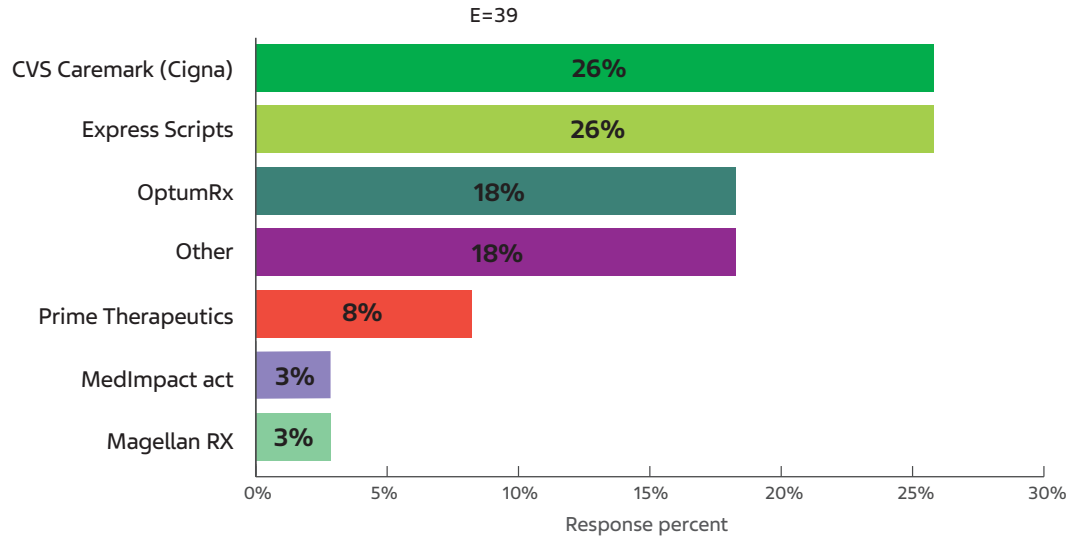
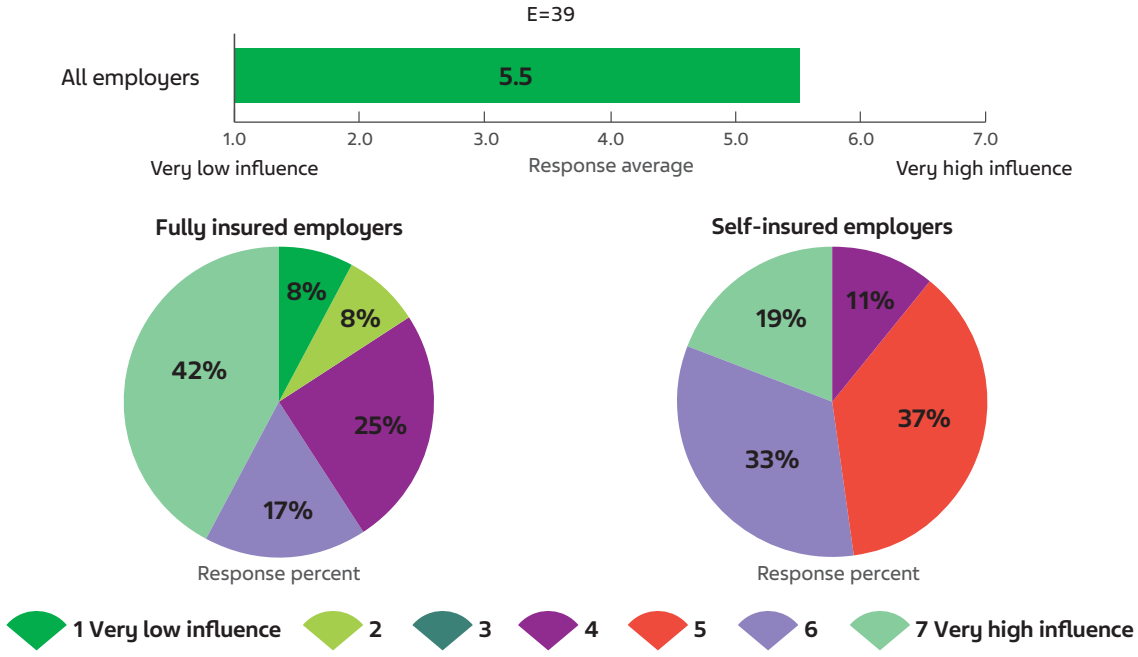


Figure 4

How much influence does your PBM have on your organization's adoption of a formulary?[1]

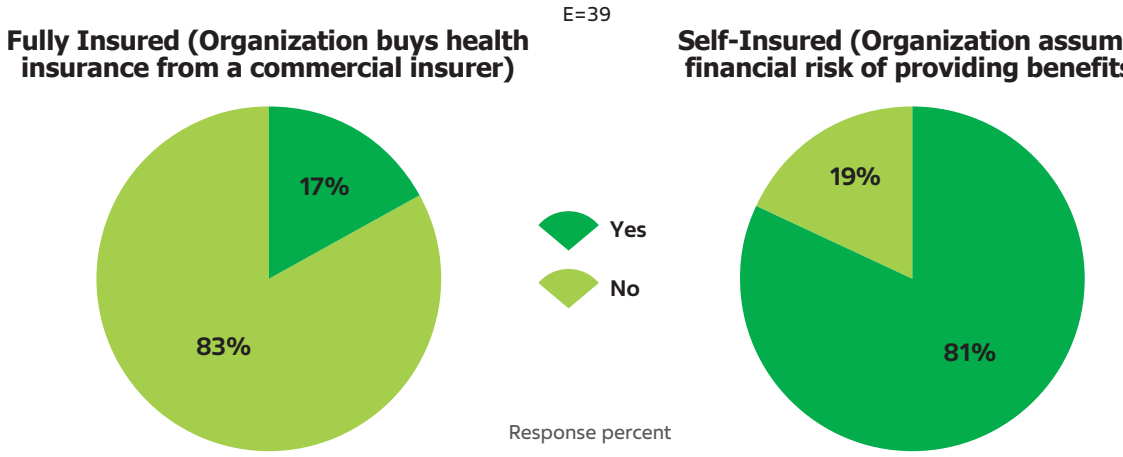


Practically none of these benefits professionals have medical degrees. And so, they do have to rely on a formulary that is brought to them either by their PBM, or by their consultant, or someone who they're trusting."

Jerry Suther, Director, Workers' Comp & Insurance Benefits, Heartland Express, Inc., agreed that the results indicate "most employers don't have the knowledge or skill to know which drugs should be on the formulary. So, they have to rely on the PBM

Figure 5

Does your organization have current rebate guarantees and will your organization move away from them in the next 3 years?[1]



to choose, and the PBM's going to choose drugs for the formulary that are probably in the PBM's own best interest financially."

Mr. Jackson added, "in fact, the PBM pushes strongly for employers to use the PBM's formulary. They use financial disincentives to avoid employers wanting to utilize a custom formulary in many cases (e.g., added fees)."

Denise Giambalvo, Director, Member Engagement & Business Strategy, for the Seattle-based health business coalition Washington Health Alliance, stated, "I'd say there's a conflict because the PBM is also negotiating rebates. They're dictating the formulary plus negotiating rebates. That's a conflict of interest to do what's best for the patient." She continued, "Some members of our business coalition are getting independent consultants to make sure there are no conflicts. And they are writing requests for proposals to change their PBM partners. They're taking more action to reduce our drug trend."

Responding employers' opinions about rebate guarantees are related closely to the question of PBM influence. Almost two-thirds of employers surveyed claimed to have current rebate guarantees and will move away from them in the next three years, the majority of whom are self-insured organizations (81%). In contrast, the majority of fully insured employer organizations denied having current rebate guarantees (83%) **(Figure 5)**.

Within the next three years, employer respondents indicated a low mean likelihood that they would move away from rebate guarantees (with an average rating of 3.0 on a 7-point scale) **(Figure 6)**.

"This is not surprising at all," stated Mr. Jackson. "Most employers expect a rebate guarantee, rightly or wrongly. They just know that they're expecting the check. And so, the PBMs tell the manufacturers, 'Listen, we've got to meet these rebate guarantees.'" Although they believe they are chasing value, in reality, he said, they're just "chasing the rebate."

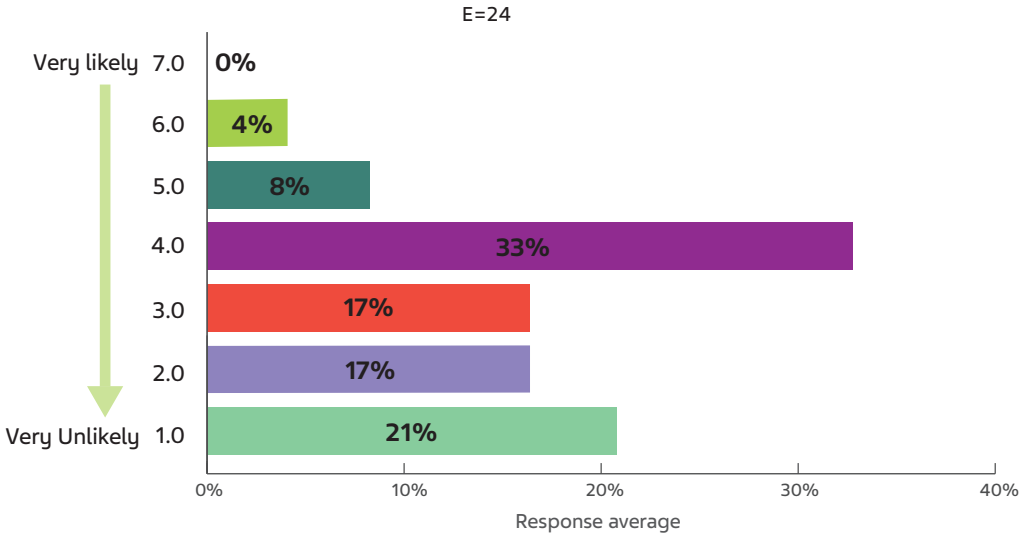
Most of Mr. Jackson's business coalition members use one of the big 3 PBMs, and receive rebate guarantees from them. He noted that several smaller PBMs (e.g., Navitus, Capital Rx, US-Rx, among others) are emphasizing lowest net drug costs with 100% pass-through rebates or without any rebates. Mr. Jackson sees these other PBMs slowly gaining ground on the big 3.

Mr. Suther said, "I would be happy with zero rebates if my net cost was lower. That means we're paying less when we purchase the drug. And if it gets me to the lowest net cost, I'm okay. Forget about the rebates. And I think there are employers out there who are just looking for the highest rebate. In the end, when they calculate their net cost, they may find they are worse off."

According to Ms. Giambalvo, it is more complex than simply whether the contract contains a

Figure 6

In the next three years, how likely is your company to move away from a rebate guarantee model to a net cost model of pharmaceutical benefit administration? [1]



rebate guarantee. "Typically, it's just aggregated guarantee, based on the contract. So, you get $X in rebates for $X in terms of each brand dispensed, with a higher dollar amount for specialty dispensed products. There's no transparency there. Just because you have a rebate guarantee, doesn't mean that you're getting price transparency around the full amount that's due to you."

The demand for rebate-based savings does not necessarily come from the health benefits executives, according to Mr. Jackson. However, this is not always easy to attain because the reliance on rebates may emanate from the C-suite.

The majority of surveyed employers indicated their preference for achieving lowest net cost without a reliance on rebates (82%). This is up significantly from the 2023 survey results (65%) **(Figure 7).**[16]

"The chief financial officer sees the rebate check at the end of the year and may get the impression that the company is saving all kinds of money," he said. "I look at that rebate check, and I say, look at all the extra money you gave the PBM, which they held on to for the year, collecting interest. They want the high rebate check, but what they really want is the lowest net cost."

Figure 7

What is your organization's pricing preference for biosimilars?[1]

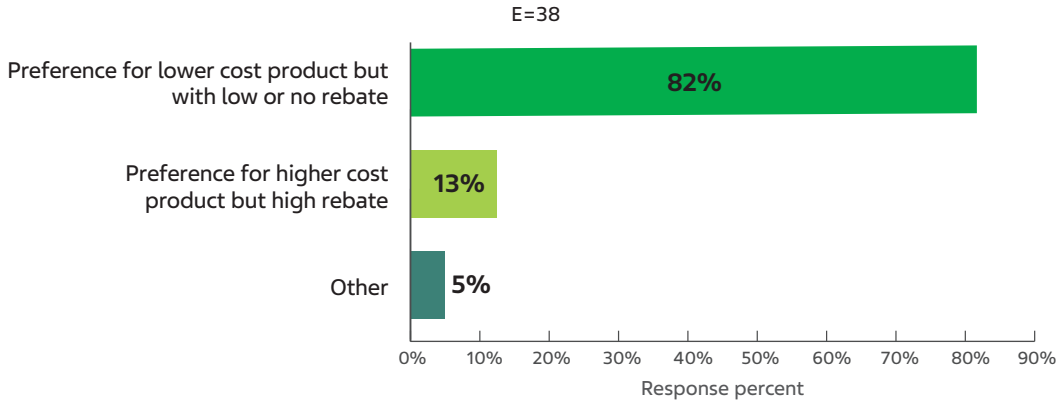
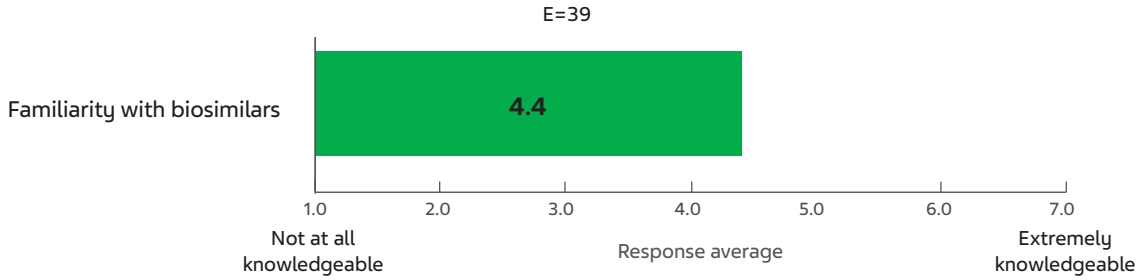


Figure 8

How would you describe your familiarity with biosimilars?[1]



"It's nice to see the numbers saying that they want to move to the lowest cost product, with low or no rebate," commented Ms. Giambalvo, "but I find it hard to believe that 82% are actually contracting for the lower cost product with low or no rebates. It may be their preference, but it's not what they're actually doing."

Familiarity With Biosimilars. In general, the employers surveyed rated their knowledge and familiarity with biosimilars as moderate, mean rating of 4.4 on a 7-point scale (7 = extremely knowledgeable) **(Figure 8)**.

"There's much more work to be done to bring awareness to the fact that there are lower costs or at least competitive alternatives to the biologics in the country," said Mr. Jackson, in light of the fact that the first biosimilar was approved in the United States 10 years ago.[2]

Yet, the employers' overall perception of biosimilars is positive, with a mean rating of 5.4 on a 7-point scale (7 = extremely favorable) (data not shown).

These scores may represent employers' recognition of the importance of biosimilar competition to controlling drug costs, according to Mr. Suther.

"Employers are paying attention," said Ms. Giambalvo. "They are looking for opportunities to save by covering biosimilars and possibly putting them on a lower cost-sharing tier."

The main source of information about newly approved biosimilars seems to be employer benefit consultants, as 56% of health benefits executives noted. The second most-cited source is the PBM (41%), followed by manufacturers (36%). In the 2023 survey, employer benefits consultants were also the most-cited resource **(Figure 9)**.[16]

"This shows that the benefits consultant and the PBM still have a lot of control of information the employers see and how employers are making decisions," asserted Mr. Jackson.

Ms. Giambalvo supported this assessment, saying, "They know about biosimilar availability, and they know about interchangeability, and they know about comparative cost to branded reference and drug management strategies, which is all the things that you would expect a human resources benefits person to know. They're relying on consultants for the rest."

The employers acknowledged only moderate levels of understanding around several biosimilar-related issues. They have the least confidence in understanding the pending legislation on biosimilars and federal rules and regulations involving them; 41% rated themselves at a 1 or 2 on a 7-point scale (7 = extremely knowledgeable) for these two variables. The other attributes earned modestly higher mean ratings (3.8–4.0), including comparative cost to the reference product, which may be biosimilars' most note-worthy characteristic **(Figure 10)**.

The Drug Price Trend. The rising cost of the pharmacy benefit is on everyone's mind. Glucagon-like peptide-1 (GLP-1) agonist coverage for obesity management, although not a biosimilar issue, has raised the stakes for drug prices overall. The employers surveyed gave a mean 6.4 rating on a 7-point scale (7 = very concerned) for this issue. A total of 87% of respondents noted a rating of 6 or 7, reflecting a rising trend from the results of the 2023 survey (< 80%) **(Figure 11)**.[16]

Ms. Giambalvo said, "Well, no surprise there. It's just not affordable for employers to continue to see the rising cost of drugs."

Figure 9

Which of the following would help you achieve a greater understanding of newly FDA approved biosimilars?[1]

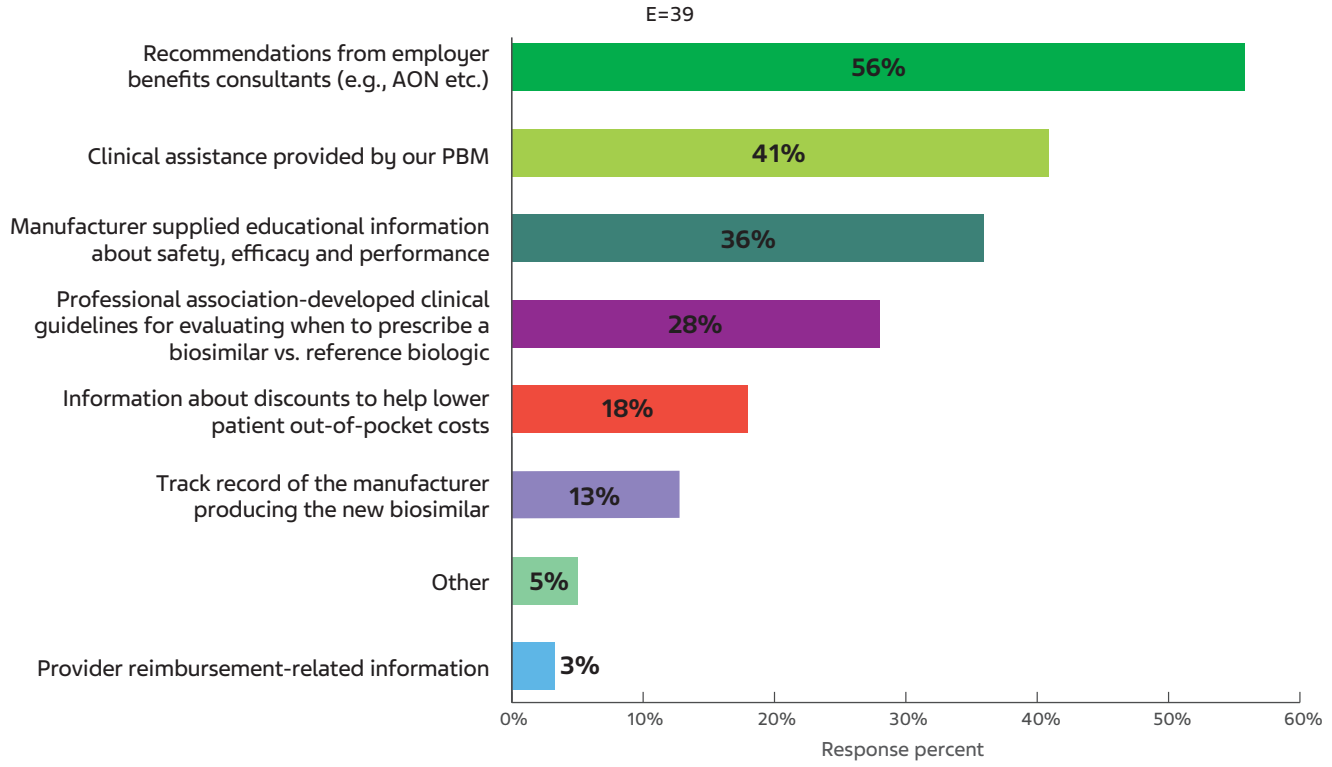


Figure 10

How would you rate your understanding of the following areas related to biosimilars?[1]

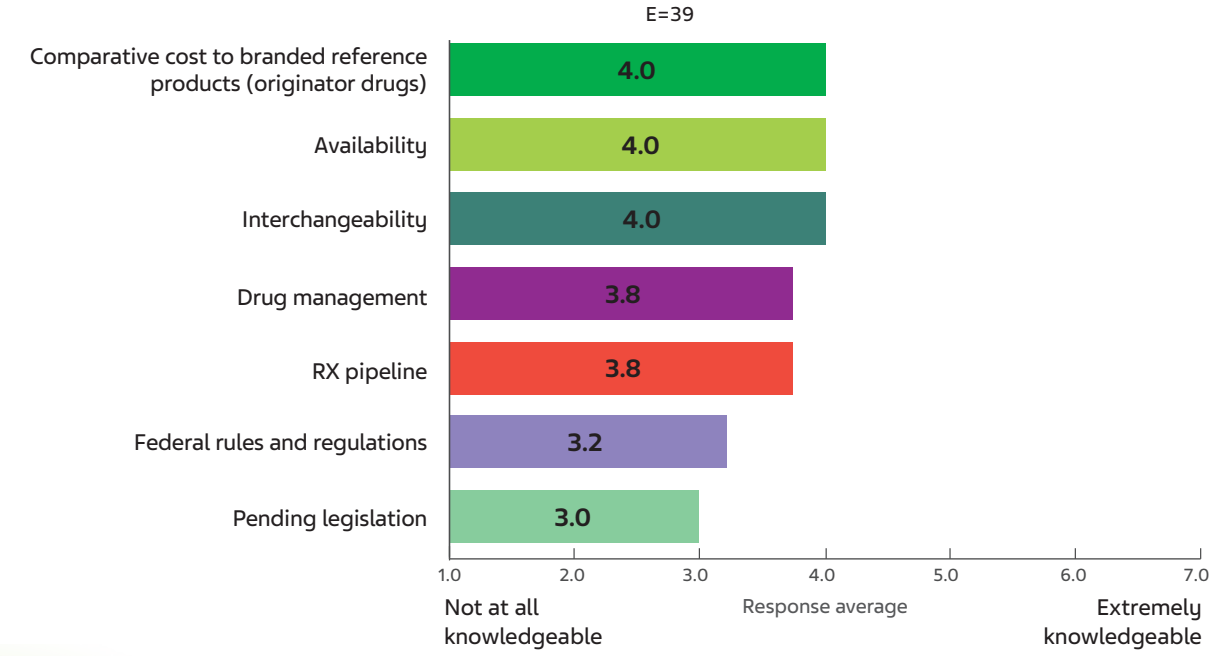
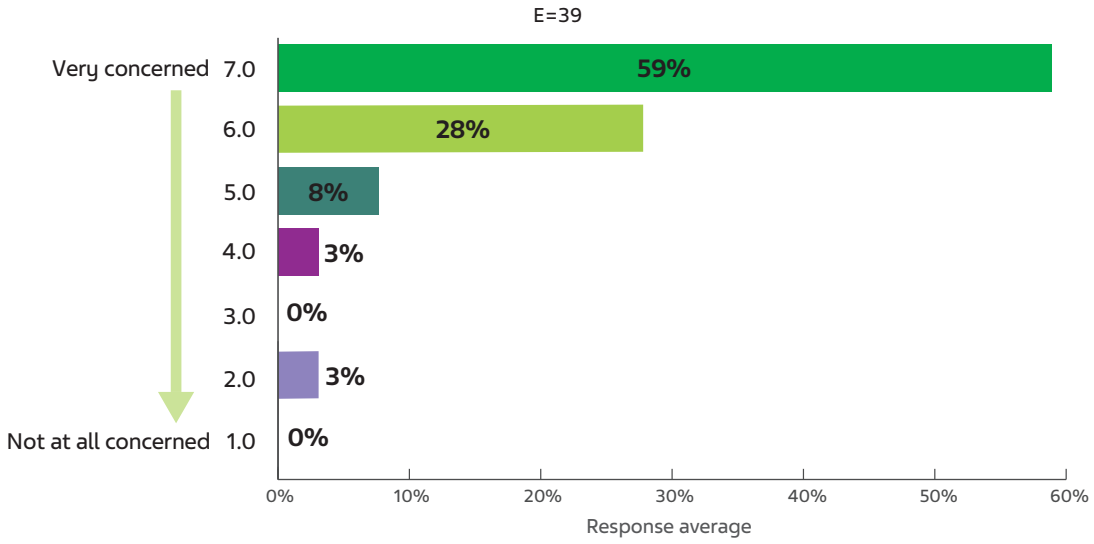


Figure 11

How concerned is your organization about the escalating drug trend?[1]



Percentages may not total 100% due to rounding.

Mr. Suther added, "Costs are going out of the roof, and there are many new, very expensive drugs. Drugs in the pipeline will also be very expensive. I'm fearful it will get much worse than it already is, and it's extremely bad now."

According to Mr. Jackson, the low response rate "reflects the world we live in, with the GLP-1 agonist phenomenon, our members are very concerned about drug prices and escalating drug trends."

The health benefits executives are looking for answers. There are limits to the amounts they may ask their workers to contribute (i.e., greater cost sharing), but there is no consensus on what tools can effectively address the rising cost trends. Of respondents, 30% will be reevaluating plan designs within the next one to two years, and 23% will focus on employing more biosimilars on formulary. Only 13% will consider increasing drug exclusions on the drug formulary **(Table 1)**.

Table 1. What strategies does your organization intend to implement in the next 12 to 24 months to manage the escalating cost of drugs?[1] | E=39

Plan design changes (e.g., patient cost sharing)	30%
Include new biosimilars in formularies when feasible after launch	23%
Implement a custom exclusion (preferred product) in the drug formulary	13%
Carve out specialty pharmacy	10%
Require full pass through of rebates and incentives	7%
Move to a net cost benefit design	6%
Care management & managed sourcing from cost-effective suppliers	5%
Outcomes-based Rx contracting	2%
Direct contracting with pharmaceutical manufacturers	1%
Reference based pricing	1%
Join a purchasing group	0%

Table 2. What are your top concerns with biosimilars and plan design?[1] | E=39	
Uncertainty about biosimilar interchangeability	56%
Employee resistance/ complaints associated with non-medical conversions to biosimilar	36%
Disruption if members switched from reference to biosimilar	33%
Savings resulting from patients switching from reference product to a biosimilar will be less than the rebates from the reference product	31%
The level of savings passed through to the member may be lower for the biosimilar compared to the reference product	23%
Affordability for members	23%
Level of understanding about biosimilar coverage under medical benefit vs, pharmacy benefit	21%
How biosimilar pricing affects patient co-pays and coinsurance	21%
PBM requirements (i.e., formulary block, no clinical exemptions) for switching from a reference product to biosimilar	21%
Physician acceptance	18%
Placement of biosimilars in specialty tier instead of a generic tier	18%

"The number 1 response is to change plan design; they're just looking to increase patient cost sharing," commented Ms. Giambalvo. "That's a disappointing finding, but I don't know if that's what they're actually doing. I expect the majority have an opportunity to better negotiate their contracts or align with different partners who are going to save the plan money and the member."

One of the easiest moves, agreed Mr. Jackson, "is to just shift more costs to people. It's not the smartest thing to do. I think people who are employing custom formularies that include biosimilars and carving out specialty, they're more knowledgeable and they're able to make some strategic decisions that will help them in the long run."

"Plan design changes, in my opinion, will not help much," according to Mr. Suther. "Let's say you change your plan design, and you increase your co-pay. Your workers won't pay that, because of all the co-pay coupons available. That will have minimal impact on your plan." He continued, "I would say most employers don't understand that, and that's why they chose that as number one. The smart benefit managers would want to introduce more biosimilars into the formulary to control costs."

Top Concerns With Biosimilars and Plan Designs. The top 3 concerns listed by employer respondents were uncertainty about biosimilar interchangeability (56%), resistance/pushback to mandated switches to biosimilars (36%), and therapeutic disruption for members switched to a biosimilar (33%). The only other issue that was mentioned by more than one-quarter of the respondents was lower savings than anticipated for biosimilars (31%) **(Table 2)**.

That issues around interchangeability topped the list for employers is a bit surprising. The landscape around interchangeability is shifting, and it has not played a major role to date in improving biosimilar uptake. Perhaps, education about the potential role of interchangeability and how the FDA views the designation may be valuable. On the other hand—the possible resistance to pharmacy policies that mandate a switch to a biosimilar from a reference product—has been a concern of all stakeholders in the healthcare system. As indicated in the payer and physician sections of this report, therapeutic disruption, along with member resistance, are common and well-voiced concerns.

Ms. Giambalvo commented, "These are areas of opportunity to educate employers, because the areas they mention are of greatest concern around biosimilars actually should not be of concern. There is no evidence to support some of these concerns."

In the 2023 survey, affordability for members was the dominant concern, with 41% of employer respondents (tied with resistance and pushback by

Table 3. What is your top concern about including a biosimilar on formulary as an alternative for the reference product?[1] | E=39

Efficacy of biosimilars	23%
Switching stable patients from a reference product to a biosimilar	15%
Lack of economic benefit to the payer	13%
Patient discomfort with biosimilars	10%
Impact on rebate guarantees	10%
Product manufacturing quality/supply	8%
Healthcare provider biosimilar willingness to prescribe	8%
Lack of economic benefit to the patient	5%
No concerns	5%
Product manufacturer patient co-pay support	3%

members). In the current survey, affordability was mentioned by only 23% of these health benefits executives.[16]

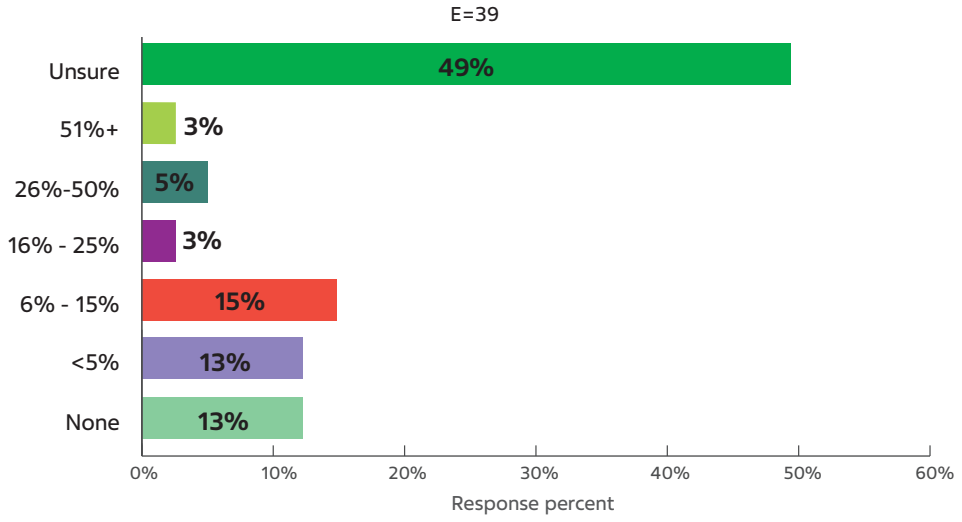
Employers were asked about trepidations around biosimilar prescribing, specifically what was their top concern about including a biosimilar on formulary as an alternative to the reference product. The question of biosimilar efficacy was the top concern, but this was cited by fewer than one-quarter of the employers responding. Switching patients with stable conditions to a biosimilar was second, but capturing only 15% of votes **(Table 3)**.

Mr. Jackson believes that employers' lack of knowledge fueled the somewhat disparate responses to this and the previous survey question. In the previous responses, "the respondents expressed a good deal of worry about biosimilars," he said. "But when you ask them what their concerns are, they actually don't have many. There's no consensus on why they are concerned, either. This is likely a result of their limited understanding of biosimilars."

There are parallels with the introduction of generics versus brands, added Mr. Suther. "Efficacy would be my top concern as well in this situation. Employers

Figure 12

What level of savings did your organization realize resulting from the adoption of adalimumab biosimilars vs. the reference product (Humira®)?[1]



may think that there is a difference in efficacy between a biosimilar and a reference product, just like when the first generics were introduced for branded agents."

Ms. Giambalvo once again emphasized that this is another opportunity for education. "We haven't had any problems with the efficacy of the biosimilars."

Biosimilar Savings. A truly disconcerting finding in this survey was that almost half of employer respondents were unsure of the level of savings they realized from the adoption of adalimumab biosimilars. Approximately one-quarter thought the level of savings to be less than 5% **(Figure 12)**.

Employer responses regarding anticipated savings from ustekinumab biosimilars in 2025 yielded almost identical percentages, with 51% unsure of the level of savings, and 28% responding that their savings will be 0% to 5% (data not shown).

"Forty-nine percent are unsure of the savings they received from adalimumab biosimilar competition," said Ms. Giambalvo. "I think that's very telling. Again, there's no transparency. I doubt they're connecting the rebate money that they received to all the Humira® that was dispensed and getting a true figure as to how much a biosimilar is costing them versus the reference product."

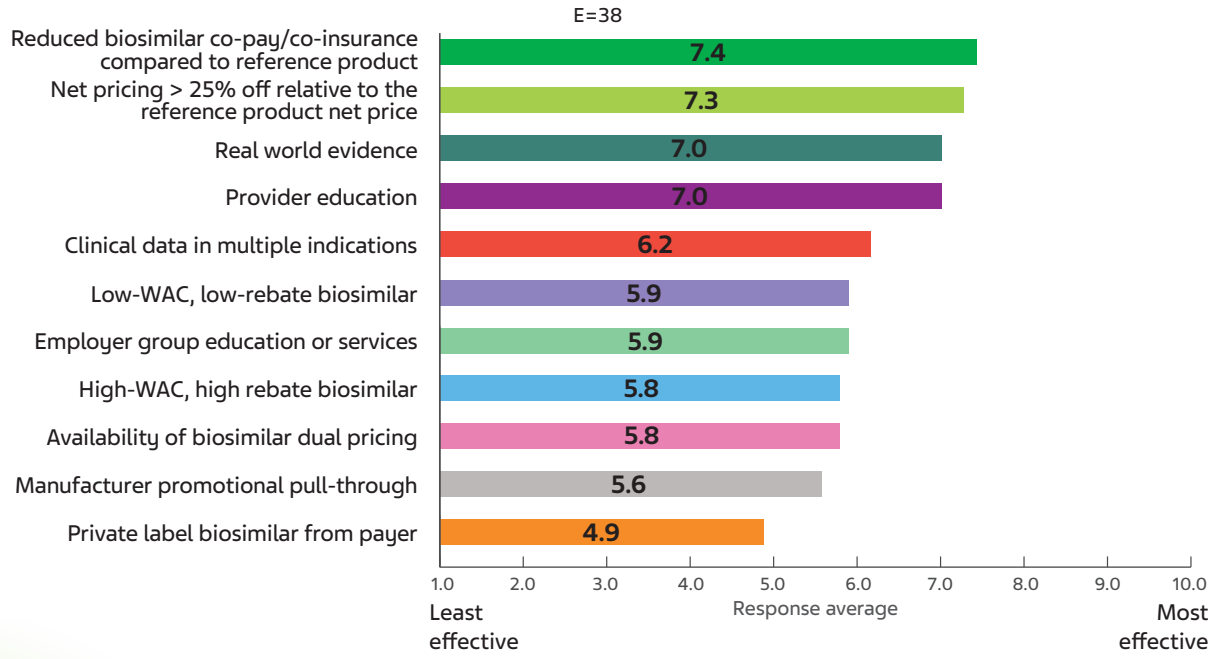
If employers believe that biosimilars don't yield savings greater than 5%, it does raise a couple of other questions, including the foundational one: If not to save money, why do they believe biosimilars exist? And do they realize that the biosimilar competition (if not actual utilization) has driven down the cost of reference products, and thereby, has resulted in small net price differences between reference biologic and its biosimilars?

For adalimumab, the survey asked what their target net cost differential would be in order for them to prefer a biosimilar. The average response was 20% (median 15%), with nearly one-quarter not responding. Yet fully one-third of the employers answered that no discount was necessary to prefer the biosimilar (data not shown).

Overcoming Barriers to Biosimilar Adoption. Despite the variety of responses to the previous question on biosimilar savings, the employers indicated that a net price greater than 25% below the reference product was one of the most effective ways to improve biosimilar adoption in commercial coverage. This tactic was rated just below reduced patient biosimilar co-pay/co-insurance in terms of effectiveness, 7.3 and 7.4, respectively, on a 10-point scale (10 = most effective) **(Figure 13)**.

Figure 13

Which strategies will have the best chance of overcoming barriers to biosimilar adoption in Commercial Plans?[1]



"There are quite a few strategies rated at 7 or more," said Mr. Jackson. "But I think that net pricing 25% off is misleading. Even at a 10% discount, that would rate highly among these options, based on the employers' previous responses." Highlighting the impact of real-world evidence, he added, "there's a ton of real-world evidence already available on biosimilars, and we just have to get it to these people."

Mr. Suther added, "Obviously, the net pricing is important. Clinical data that shows its effectiveness compared with the reference product is also important, and this also affects providers who must be comfortable with prescribing biosimilars. Those three areas are probably the most important."

"Well, the themes are reducing the cost for the member (through reduced co-pay or co-insurance) and seeing a net price greater than 25% off of the reference product," according to Ms. Giambalvo. "The other theme is provider education–related real-world evidence. I'm looking at this as two-pronged: providers need to be writing more prescriptions for biosimilars, and they need to be educated; at the same time, there needs to be a reduction in cost for the patient."

Conclusions

Pharmacy benefits managers have a powerful influence on employers in terms of drug coverage decisions, and this is often communicated through the employer's external health benefit consultant. As pointed out by expert commentators, this may not be in the best interest of the corporate employer, as the incentives of the consultant and PBM may be misaligned with those of the plan sponsor or employer. This misalignment extends to the use of rebate guarantees, which are prevalent, especially for self-insured employers.

Employers' engagement on biosimilars continues to be somewhat limited. Their expectations for savings from biosimilars continue to be modest, but this may be due to a number of reasons. One is their reliance on consultants or PBMs for contracting and coverage decision-making, which has resulted in limited awareness of actual net price, based on the lack of transparency on the part of PBM rebate contracts. Another is the efforts by reference manufacturers to compete with newly launched biosimilars. Finally, is the limited time/availability of employers to focus on this specific area of pharmaceutical care.

Methodology

The Teva Biosimilars Trend Report, Second Edition, brought to you by Teva Pharmaceuticals USA, examines trends in biosimilars from three perspectives: those of healthcare providers, managed care payers, and employers. The report combines quantitative analysis through survey findings with qualitative analysis and expert commentary.

Three surveys were sent by email to healthcare providers, managed care executives, and employers in July and August 2024. The survey featured:

- 73 physicians, comprising 30 rheumatologists (41%), 23 dermatologists (32%), and 20 gastroenterologists (27%)
- 54 managed care executives, of which 65% worked for health plans or administrative-services organizations, 15% worked for pharmacy benefit managers, 13% worked for integrated health networks, and 6% listed miscellaneous other affiliations
- 39 employer-based health benefits executives (90%), an employee benefits purchasing group (2%), and benefits consultants or brokers (8%).

Adding commentary to the findings are 10 independent experts, with three each representing the managed care and employer stakeholder groups, and four representing healthcare providers.

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The Teva Biosimilars Trend Report

Perspectives From Managed Care, Providers, & Employers

SECOND EDITION

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