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Promoting Pharmaceutical Value through Biosimilar Adoption

Self-Insured Employer Experience

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Executive Summary

A qualitative analysis of interviews with 21 benefit managers from large self-insured employers across the United States conducted in early 2021 revealed a wide spectrum of understanding regarding biologic drugs and their biosimilars. The quantitative synopsis of the interviews revealed that variance in benefit managers' understanding of biosimilars is not related to employer size, but rather to turn-over of staff responsible for managing medical channel and PBM channel drugs, and access to in-house clinical expertise.

Member experience and misaligned incentives emerged as key areas of concern, along with questions about rebates and completeness of medical channel claims data. Plan sponsors need to better understand the impact of rebates on their drug spend and should demand comprehensive reporting of drug specific rebate attribution as well as rebate retention by the health plan or PBM.

Benefit managers are eager for more education on this topic. They are aware that the pipeline of drugs under development is growing and that their ability to manage these expensive drugs will become increasingly important as more come on the market. However, their current willingness and/or ability to be proactive is limited by two factors:

1. Total expenditures on biologic drugs are not yet large enough to capture their attention, and
2. Other priorities such as COVID and spending areas with greater immediate cost savings potential are consuming all their time and energy.

Background

The Purchaser Business Group on Health (PBGH) received a grant to conduct a qualitative analysis of jumbo self-insured employers' understanding, attitudes and activity regarding biosimilars. PBGH developed and deployed a standardized survey instrument used during one-on-one interviews. Each interview took about an hour. Over 50 self-insured organizations were approached with 21 agreeing to participate.

The survey instrument used is attached at the end of this report.

Respondent Demographics

All but two participant organizations provide benefits for more than 10,000 employees and nine purchase benefits for over 100,000 employees. The level of knowledge about biosimilars and the economics surrounding them does not appear to be closely tied to employer size. Rather, because of job turnover and job experience, some newer benefit managers of larger organizations were less knowledgeable than their counterparts at smaller organizations.

Size (Number of employees)	**Number**
under 10,000	2
10,001 – 100,000	10
100,000 and over	9

Eleven of the participating organizations are headquartered in California, Oregon and Washington (Western U.S.). Another 5 are headquartered in Texas or in the greater Chicago area

(Central U.S.). The East Coast, from Florida to New York serves as headquarters for the remaining five employers surveyed.

Headquarters Geography	Number
Eastern US	5
Central US	5
Western US	11

The Third-Party Administrators (TPAs) used by study participants varied, and several employers used multiple TPAs. Regional "Blues" plans serve 7 of the 21 participants in the study. The "national plans," which include Aetna, Anthem, Cigna and UnitedHealthcare (UHC/UMR) serve 13 participants. Collective Health provides TPA services to 2 participants. HealthComp and WebTPA are also among the TPAs used by organizations surveyed.

TPA Name	Number
Aetna	2
Anthem	4
Regional Blue Shield and/or Blue Cross	7
Cigna	3
Collective Health	2
HealthComp	1
UCH/UMR	4
WebTPA	1

Note, some companies use multiple TPAs so total will exceed 21

ESI and CVS/Caremark were the two dominant Pharmacy Benefit Management (PBM) organizations serving the participants in this study. Others involved were Costco Health Solutions, Magellan Rx, MedImpact, Optum, Prime Therapeutics and Rx Benefits. It is important to note that some organizations use more than one PBM.

PBM Name	Number
Costco Health Solutions	1
CVS/Caremark	7
ESI	8
Magellan Rx	1
MedImpact	1
Optum	2
Prime Therapeutics	1
Rx Benefits	1

Note, some companies use multiple PBMs so total will exceed 21

Of the 21 organizations interviewed, only eight had access to an in-house medical director or other clinical expertise. Two organizations had access to Pharm. D.s who were actively involved in the management of the employee drug benefit, including specialty/biologic drugs. The sophistication of these two organizations was very high, to the point that they are also managing the site of care as well as the drug cost. The remaining 13 relied on clinical advice from their TPA, PBM or another outside consultant.

In-House Medical Director or other Clinical/Pharmacy Expertise	Number
Yes	8
No	13

Employers often access information through membership organizations where they network with other benefit managers and convene to hear from vendors and subject matter experts. There are numerous organizations in the US recognized as forums for information sharing among large self-insured employers. Fourteen employers that participated in the research are members of the Purchaser Business Group on Health. The American Benefits Council (ABC) and the ERISA Industry Committee (ERIC) were also frequently mentioned as organizations the research subjects belong to and rely upon for information and education. Several other business coalitions from around the country were also mentioned. A special thank you to the Florida Alliance for Healthcare Value, the Kentuckiana Health Collaborative, the Economic Alliance of Michigan, and the Midwest Business Group on Health for introductions to with some of their highly engaged member organizations.

Organization Memberships	Number	Board Member
American Benefits Council (ABC)	6	
Catalyst for Payment Reform (CPR)	1	
Certified Employee Benefits Specialist (CEBS)	2	
Conference Board	1	
Dallas-Fort Worth Business Group on Health (DFWBGH)	1	
Economic Alliance of Michigan (EAM)	1	
Employer Health Innovation Roundtable (EHIR)	2	
ERISA Industry Committee (ERIC)	6	
Florida Alliance for Healthcare Value	2	2
Greater Philadelphia Business Group on Health (GPBGH)	1	
Houston Business Group on Health	1	
HR Policy Association	2	
Health Transformation Alliance (HTA)	2	
Integrated Benefits Institute (IBI)	1	1
Kentuckiana Health Collaborative	1	1
Midwest Business Group on Health (MBGH)	3	2
National Association of Worksite Health Centers	1	
New England Business Group on Health (NEBGH)	1	
Pharmacy Benefit Management Institute (PBMI)	1	
Purchaser Business Group on Health (PBGH)	14	3
Silicon Valley Employers Forum (SVEF)	4	
The Business Group on Health (BGH)	3	
Washington Health Alliance. (WHA)	1	

Findings

The majority of those interviewed had a reasonable if not high level of knowledge about biosimilars, how they fit into the drug ecosystem and some of the financial forces working against biosimilars. They understood the potential of biosimilars to provide costs savings, but frequently shared disappointment that the savings opportunity was not as great as anticipated.

"I was expecting the price difference from the biosimilars to be much higher," said one participant. "We were looking for 30% savings, but instead find it to be more like 10% - 20%. That is disappointing to me."

Knowledge Level re: Biosimilars	Number
High	8
Medium	9
Low	4

It is worth noting that four benefit managers interviewed had little or no knowledge of biologic drugs and biosimilars. This was primarily because the individuals involved were new to their position or responsibility for specialty pharmacy was recently added to their job description. Of the four, one worked for an organization with over 100,000 employees, two worked for organizations with between 10,000 and 100,000, and one worked for an organization with under 10,000 employees.

Those in the "Low" category could describe what a biosimilar drug is but had little additional knowledge and had not engaged in conversations about the cost of biologic drugs with their TPA, PBM or employees. Those in the "High" category are actively engaged in conversations with their TPA, PBM and/or beneficiaries regarding the management of their biologic drug spend. Those in the "Medium" category are somewhere between those two ends of the spectrum.

Rebates and Data

Rebates and the lack of data transparency were the two topics that generated the liveliest reactions.

Rebates paid by the reference drug manufacturers were universally understood to have made it challenging for employers to evaluate the real value proposition of biosimilars. While TPAs claim that rebates make the reference product the lowest net cost option, they have not, thus far, provided any evidence to support that assertion. Given that most TPAs do not pass on medical channel rebates to the employer, and if they do there is no clarity about how much each drug contributed to the rebate check, employers have every right to be highly skeptical of this contention.

The carrier's allowance of J code billing in the medical channel makes it more difficult for employers to track biologic spend. It is worth noting that some carriers are making a concerted effort to require use of NDC codes (which is already common for Medicaid managed care plans). Employers have an opportunity to help themselves by calling on more TPAs to do the same to improve cost tracking.

Recent studies released by PBGH based on the data of two very large public purchasers has shown the savings opportunity to be between 17% and 23% if reference drugs are switched to biosimilars. The criteria impacting savings potential included rebates, biosimilar uptake, and biosimilar pricing (discounts for biosimilars as compared to reference drug prices). The work also included observations about cost differentials based on site of care.[1]

Several organizations indicated a willingness to support biosimilars even if they were not the lowest net cost drug in the short term. They understand that the reference drug manufacturers are providing deep discounts in the form of rebates in order to undercut biosimilars and eliminate the competition. Still, a few, particularly those using tax dollars to purchase benefits and those in very low margin businesses, felt they did not have that luxury. If their health plan or PBM asserts the reference drug has the lowest net cost, they will use it, despite the detriment to their long-term self-interest.

Rebates on biologic drugs are universally reviled. Even among employers who feel they are getting most of the rebates via the PBM channel, the sentiment can be summed up by this quote: "I think rebates are terrible. I'd much prefer to get rid of them because they hide the cost of everything and there is no way to reconcile them – I've tried. I've tried really hard!"

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One particularly knowledgeable participant explained part of the reason they are so pro-biosimilar is that biosimilars, until recently, had not gotten into the rebate game. This participant appreciated the straight-forward pricing offered as biosimilars first appeared on the market. However, now that some drugs have competing biosimilars, those manufacturers are also starting to play the rebate games.

Many benefit managers acknowledge their organization is "addicted to the rebate check," but several indicated a willingness to educate their leaders regarding the challenges of rebates if they could show lower overall cost by eliminating them. The inability to account for rebates is a major pain point for those interviewed. A related pain point is the lack of transparency and a lack of data.

TPAs have convinced several purchasers to stick with reference products when told they provide the lowest net cost. However, none have seen actual accounting, based on their claims, to prove or disprove that assertion. The issue becomes even more complicated by the fact that most rebates in the medical channel, where the majority of these drugs are currently dispensed, are not passed from the TPA to the plan sponsor.

[1] PBGH, "Biosimilar Adoption: Challenges and Opportunities," December 2020 https://www.pbgh.org/initiative/biosimilars/

Plan sponsors need to better understand the impact of rebates on their drug spend and have a right to demand complete reporting of drug specific rebate attribution as well as the rebate and "fees" retained by the health plan or PBM.

Purchasers complain the reporting they get from their TPA regarding medical channel drugs is dismal. PBMs are a bit better, but also not as forthcoming as many would like. Plan sponsors need to better understand the impact of rebates on their drug spend and have a right to demand complete reporting of drug specific rebate attribution as well as the rebate and "fees" retained by the health plan or PBM.

Some purchasers report getting data on the top drug classes used, but for medical channel drugs they don't receive specificity about the drugs used so it is difficult to assess a breakdown of biosimilar vs. reference product utilization. The majority of those with a high level of knowledge regarding biosimilars and some with medium level are using carve out specialty pharmacies or independent consultants to help them sift through their medical and pharmacy claims data for insights on utilization and potential cost savings.

One organization put a hold on health plan coverage of all medical channel drugs in 2013 so that all biologics must be accessed through the pharmacy benefit where they get better information.

Nearly all interviewed indicated they don't get any useful data from their TPA or PBM unless they ask for it. In fact, they often have to insist on it. The problem is, they often don't know what to ask for. In addition, when they get an answer, they don't know what follow-up questions to ask. It is hard for them to know when they are getting told what the TPA or PBM wants them to hear and when they are getting good information.

Every employer not already using an independent consultant to help with the management of specialty drugs, including biologics, expressed interest in having an analysis done to help them identify cost savings. However, a few indicated that the cost of the analysis could be a barrier as is the significant effort required to get a new vendor approved.

Misaligned Financial Incentives

Three benefit managers mentioned physicians using "buy-and-bill" as an anathema to the goal of driving down the cost of health care to those patients needing biologic drugs because it represents a misaligned incentive.

In the commercial fee-for-service world, most oncology and rheumatology physicians are compensated for their services by marking up the cost of the drug they administer. The percentage mark-up can vary widely – from as little as ASP+6% to ASP+ 100% or more. This methodology, known as "buy-and-bill," is pervasive among non-salaried prescribers. It is worth noting that there is variance of opinion about the degree to which "buy-and-bill" impacts physician decision making, however those benefit managers aware of the practice noted that tying physician reimbursement to drug prices is rife with potential for conflict of interest.

The other potential conflict of interest lies with the TPA that both negotiates the rebates it maintains for drugs used in the medical channel and also pre-authorizes the use of those same drugs. This puts the TPA in the position of having its financial interests in conflict with the financial interests of the plan sponsor and/or plan beneficiary.

"White bagging," "brown bagging "and "clear bagging" address both the buy-and-bill issue as well as health plan-related rebate conflicts of interest. A few benefit managers were familiar with these concepts, but most were not.

The practice of white bagging, brown bagging, or clear bagging is presented as a viable mechanism for employers to "take control" of drug prices. Two of the plan sponsors interviewed are engaged in efforts to move the administration of biologic drugs coverage to their PBM and work on a case-by-case basis to move patients to a "white bag" delivery system. This effort has been fairly time and resource intensive as it involves a great deal of communication with the plan, the physician, the patient and the specialty pharmacy. When it works, there is anecdotal information that the cost savings can be significant. However, there are reports of physicians refusing to cooperate. This creates an adverse member experience, and that alone is enough to turn many benefit managers away from this cost-containment strategy.

White-bagging, brown bagging, and clear-bagging are terms used to describe a process where the typical physician practice of buying, inventorying, and then billing for the drug they administer is intervened upon. It can be a successful strategy if reimbursement methods with physicians include large buy-and-bill profits and/or it is a method that supports better drug management, e.g., site of care management or a biosimilar first policy. It involves removing drug management from the physician and giving it to an intermediary, usually a PBM, that mandates purchase of the drug through a select pharmacy. The operational aspect of getting the drug to the doctor's office for administration has coined the "bagging" terms.

1. White bagging implies that the drug is "drop shipped" for a specific patient from a third party.
2. Brown bagging implies that the patient brings their drug for administration to the doctor's office.
3. Clear bagging implies that the drug will be procured by the integrated health system specialty pharmacy and delivered "just in time" for the appropriate patient.

Critics of the practice indicate that chain of command is threatened and impacts patient safety. They also indicate that waste results when patients' schedules change and drugs pre-delivered can no longer be used.

Member Disruption/Experience

Most benefit managers, particularly those who work in the high-tech industry and other economic sectors where competition for talent is tight, do everything they can to ensure their members experience no friction when accessing or using their health plan benefits. This means that patients and their providers are given as much latitude as possible.

As one benefit manager put it: "Implementing a biosimilar first strategy that is non-disruptive to members is a challenge. We don't want our employees to feel we are being cheap in any way. We want their care to be a premium experience. So, we have to first convince the prescribing physicians that biosimilars are the way to go. We can't have them bad-mouthing these drugs."

Clinical Concern as a Barrier to Biosimilars

Only three benefit managers indicated that they've heard of physicians refusing to use biosimilars based on clinical concerns. "The reference product manufacturers have done a good job of convincing doctors that biosimilars are inferior. The AMA went along with them for a while. Now that there is evidence from Kaiser and Europe to the contrary, that is less of an issue. But we still run up against it in rural areas of the country where there is only one cancer practice in town, and they want to profit off the buy-and bill markup."

Another said she pushed back by asking for the names of the physicians/practices who complained biosimilars were inferior and the TPA has never provided that list. The third indicated they do a great deal of provider outreach and education to ensure their top prescribing physicians are comfortable with biosimilars.

The Role of Employers in Boosting Biosimilar Adoption and Influencing Health Plan Formulary

Every benefit manager interviewed agreed that employers have a responsibility to ensure that the formulary is appropriate and to increase the use of biosimilars in order to preserve competition in the marketplace. However, a few respondents indicated a lack of self-confidence when trying to lead these conversations. As one put it: "I can ask the initial question, but I don't think I can engage in a meaningful way once they give me an answer. I don't know enough to ask the second or third follow-up question."

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Others have been proactive. In addition to pushing their TPA and PBM to use biosimilars, some have implemented a tiered benefit design where biosimilars have a lower co-pay or co-insurance. None have gone to a full-fledged "biosimilar first" program, but two are working on it.

Direct Contracting

Asked if they would ever consider a direct contracting arrangement with a pharmaceutical manufacturer most employers responded with an emphatic, "no." One interviewee literally hit their forehead on their desk and exclaimed, "No! Don't give me more contracts to manage!" Others were more receptive. One said, "Never say never, but there would have to be a really good business model for me to take that on." Another indicated they had actively explored the idea but found they, "got caught up in a bundling approach where we had to buy things we didn't want in order to get what we did, so we dropped the idea."

<u>Recommendations</u>

Based on the interviews conducted we have three recommendations for next steps:

1. Continuous education about the benefits and opportunities of biosimilar adoption
2. A deep dive academy
    a. Include claims data analysis
3. A multi-stakeholder solutions forum to develop action steps

Given the wide variation in the understanding of the economics impacting biosimilars in the US market as well as the differences among distribution channels for biosimilars, continued employer education is needed.

Those with a low level of understanding need to be brought up to speed, and those with a higher level of sophistication and greater experience need to be provided forums in which they can share their knowledge with peers and identify/implement actions to take advantage of the biosimilar opportunity. Even during the short time-frame of this research project, turn-over illuminated the situation. When an educated benefit manager leaves an organization to take a position with another company, the new manager may not understand the issues or programs under development. Lack of comprehensive information about biosimilars is a problem for employers of all sizes.

In addition to an "evergreen" Biosimilars 101 course, we recommend the development of an "academy" that provides the opportunity for benefit managers to do a deep dive on biologic and biosimilar drugs. The academy should provide benefit managers with an in-depth understanding of the misaligned financial incentives scattered among the various stakeholders in the supply chain and consulting realm. Preparation for this academy could include an analysis of the employers' claims data do be reviewed as part of the curriculum.

The interviews conducted as part of this research revealed that benefit managers increasingly have a sense they are being bamboozled by their conflicted TPAs, PBMs, consultants, and other intermediaries. However, they lack the knowledge to push back and hold their "partners" accountable.

Topics to be included in the academy sessions could include:

- Highlighting the work of employers who excel at managing both the cost of biologic drugs and site of care.
- A checklist of items to include in an RFP and/or contract with a TPA and/or PBM that, if in place, would reduce the barriers employers face when trying to manage their drug spend.

The interviews conducted as part of this research revealed that benefit managers increasingly have a sense they are being bamboozled by their conflicted TPA's, PBMs, consultants, and other intermediaries. However, they lack the knowledge to push back and hold their "partners" accountable.

One of the most knowledgeable benefit managers interviewed suggested they would appreciate some entity organizing a forum that included all the stakeholders so that difficult, honest conversations could take place. His hope is that solutions to problems which benefit managers feel powerless to address could be debated. His goal would be to walk away from the forum with agreed upon action steps that could solve one or two problems.

Resource Restrictions

Finally, it is essential to note that benefit managers are keenly aware of the growing pipeline of biologic drugs coming to the market. They know their ability to manage this expense will become increasingly important. However, for today, all their energy and resources are consumed with other, more immediate concerns such as COVID, mental health, maternity expenses or musculoskeletal spend. Many see the problem of managing biologic and biosimilar drugs as a "tomorrow" issue. They know it is coming, but it is not currently among the most pressing matters.

Purchaser Business Group on Health

About the Project

PBGH received a grant to support an interview process with the objective of learning about employers' understanding, attitude, and actions towards biosimilar adoption. This interview guide will be the basis of conversations with about 20 employers. No comments will be attributed.

About the Employer

1. Company Name:	
2. Name/Title of Interviewee:	
3. Internal clinical support (Medical Director, etc.)	
4. Partner Coalitions? (*indicate Board seat)	
5. Health Plan	
6. PBM	

Questions

1. Are you familiar with biosimilars, how they fit into the drug eco-system, and the potential for savings?
    a. Has your health plan or PBM discussed biosimilars with you?
    b. If not, how did you learn about them? What other source of information has been helpful to you?
    c. Do you know if your health plan includes biosimilars on the formulary?
    d. Do you know if your PBM includes biosimilars on the formulary?
    e. What role do you think employers can/should play in biosimilar adoption?

2. Are you interested in seeing greater uptake of biosimilars?
    a. Why or why not?

3. Do your PBM and health plan provide you with adequate data about drugs by disease state, by drug class, etc?
    a. What data support do you not get that you would like to get from your PBM? From your health plan?
    b. Has your PBM discussed "white bagging"? What is your perspective or experience with white bagging?
    c. Would you be interested in having an external analysis completed to identify the opportunity for savings if you converted reference drugs to biosimilar drugs?

4. What do you think are the largest barriers to further adoption of biosimilars and reference biologics?
    a. What role do you think rebates play as a barrier?

5. Have you asked your health plan to report on rebates that might be associated with reference drugs?
    a. If so, what was your experience? If not, why not?

6. What is needed to gain more biosimilar traction at your company?
    a. Is there something specific that you think would assist you to promote biosimilar uptake, e.g. guidance, info, data)

7. Have you considered how you could use benefit design as a lever to engage your enrollees in a Biosimilar-First policy?
    a. Why or why not?
    b. Have you discussed this with your health plan? What was their reaction?

8. Define or discuss the inertia and resistance to change.

9. Are you concerned (or has your health plan reported to you) that excluding innovator biologics from a particular manufacturer will result in retaliatory price increases on other drugs from that manufacturer?

10. Has your health plan told you that there is prescriber-resistance?
    a. If so, have you asked your health plan what they are doing to address this?

11. Do you think employers can or should play a larger role in deciding what drugs get preferred on a health plan formulary?
    a. Why or why not?

12. Would you ever consider a direct contracting arrangement with a pharmaceutical manufacturer? Why or why not?