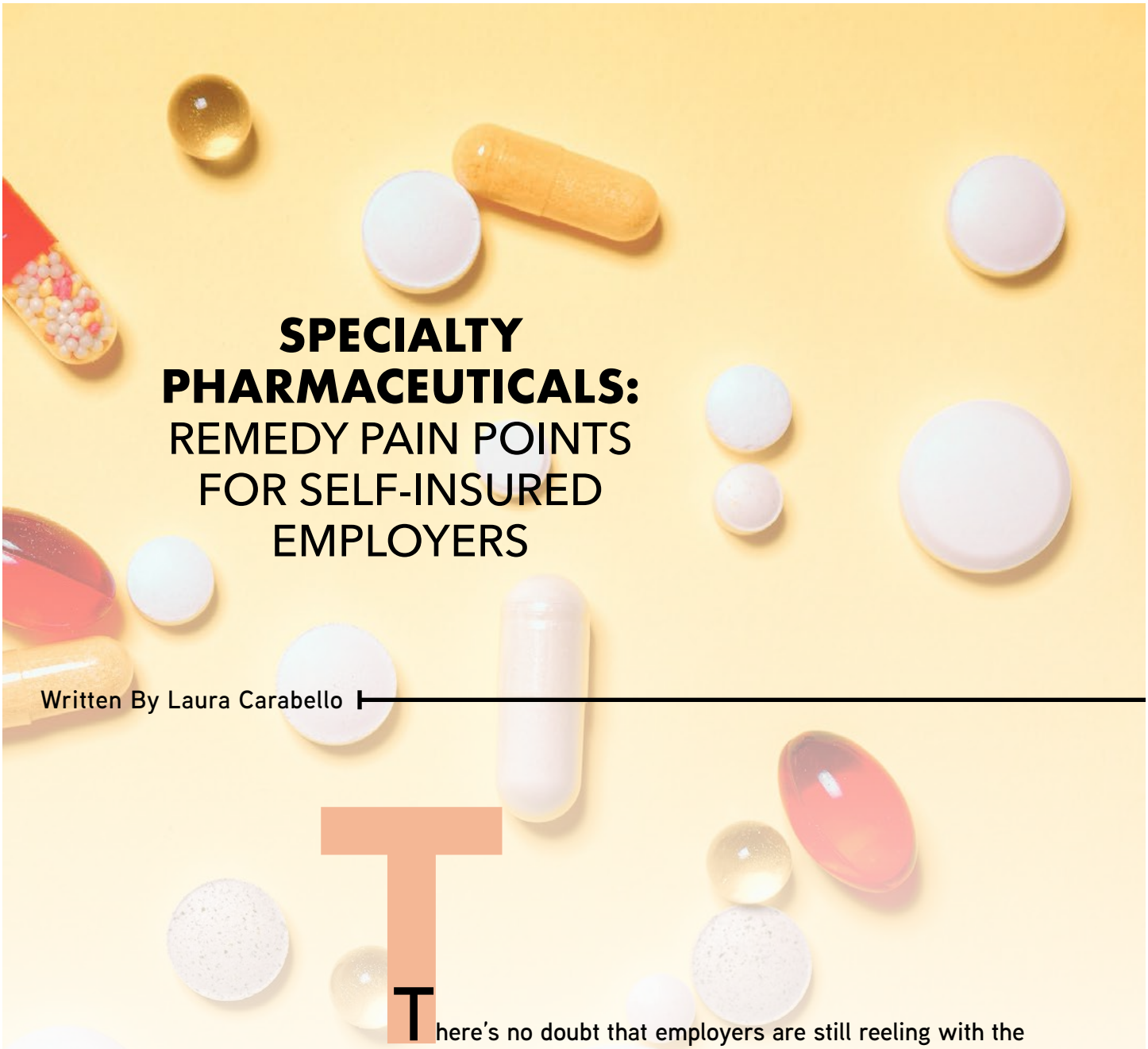


SPECIALTY PHARMACEUTICALS: REMEDY PAIN POINTS FOR SELF-INSURED EMPLOYERS

Written By Laura Carabello

There's no doubt that employers are still reeling with the introduction of novel, expensive and potentially lifesaving cell and gene therapies, but they must also prepare themselves for the relentless launch of specialty medications and infusion therapies that are on the horizon.

The significant impact of the drugs on budgets and benefits planning cannot be underestimated, and while new weight loss drugs are not typically classified as specialty drugs, they are already adding yet another layer of cost.

Easing the strain and impact of these specialty pharmaceuticals requires thoughtful strategies as their sheer number and scope challenge even the most astute employers to improve patient

access to treatment while ensuring affordability. In the year ahead, targeted programs, financial solutions, and other initiatives to relieve these stinging issues necessitate the guidance of professionals.

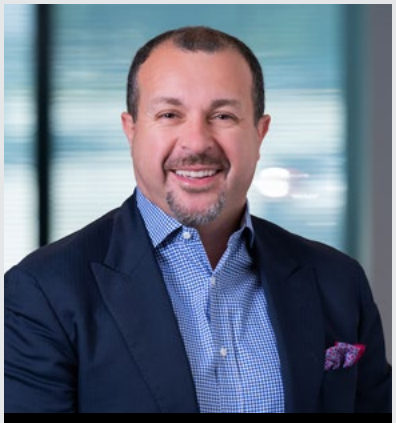

Corey Belken

Thanks to SIIA, attendees at the 2023 National Conference will get this much needed direction from three highly credible industry thought leaders, Monday, October 9, 2023, 3:15 to 4:30 PM.

- Dea Belazi, CEO, Ascella Health
- Corey Belken, Senior Employer Account Executive, Genentech, Inc.
- Dr. Brenda Motheral, CEO & Co-Founder. Archimedes.

ISSUES, TRENDS AND SOLUTIONS WORTH WATCHING IN 2023-2024

Dea Belazi says, "Emerging and continuing issues are being seen with specialty drugs in the year ahead. While specialty drugs are costly, they also can provide life-changing options to physicians and patients. A key issue is the continuing affordability of these products and employers will need to balance cost and access to ensure optimal patient outcomes. In 2022, the median annual cost for newly approved drugs was greater than $222,000 and high cost will continue to be a significant barrier to access."


Dea Belazi

He points to reports that almost half of specialty pharmacy patients have experienced challenges in receiving specialty medications, with nearly a quarter of these patients stating high medication costs as the top challenge in gaining access.

"A shift toward Value-Based (VB) and Outcome-Based contracts promote greater patient access to new biopharmaceutical treatments by linking reimbursement, coverage or payment to a treatment's real-world performance and patient outcomes,"

says Belazi. "Innovative financial solutions for CGT are now available amid continued increases in CGT costs that are putting pressures on employers and others. This will drive innovative approaches for absorbing these costs, which can exceed multi-million-dollar price tags for payers and individual patients. Unique financial solutions, such as loan-based programs for payers, significantly offset the cost of expensive and potentially curative CGTs."

He asserts that another issue will be the evolving role of specialty pharmacies in the management of the specialty medications for the medical benefit, adding, "Payers have typically managed specialty medications on the pharmacy benefit and medical benefit separately, making it challenging to see the full effect of their specialty strategies and where there may be opportunities to improve the patient experience and health outcomes. Specialty pharmacies have the opportunity to manage these benefits seamlessly and assist both the patient and payer in enhancing the quality and cost of the specialty drug therapy regardless of the benefit."

Belazi points out that specialty pharmacies have the additional opportunity to direct patient care and specialty drug administration sites of care.

"Hospitals typically charge more for specialty drugs and their administration than independent administration sites and physician offices, whether treatment occurs in a hospital or a hospital-owned physician practice," he explains. "Administering drugs in physician offices and patients' homes -- instead of hospital outpatient settings -- can significantly reduce costs and provide savings opportunities for both the payer and patient. This approach helps to eliminate hospital stays, decreases hospital utilization, hospital resources and subsequent cost."

Finally, he emphasizes that self-funded employers, plan sponsors and other payers are contracting directly with an SP provider in designing their benefit packages.

"This enables payers to gain better control over SP costs, have greater transparency into their benefit claims and strengthen their negotiating power."

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All panelists cite the emerging role of value-based or outcomes-based contracting as a topic for discussion. Value-based contracts, sometimes called risk-sharing agreements, are innovative payment models used by payers and biopharmaceutical innovators to link reimbursement, coverage, or payment to a treatment's real-world performance.

In an outcomes-based contract, payment is wholly or partly dependent on outcomes being achieved. Service providers are therefore directly incentivized to deliver outcomes with service users.

Additionally, they anticipate that employers will be forced to address the new, popular weight loss drugs, as many cut off or restrict access as a way to save money. These cuts and restrictions signal the financial downside of the drugs' medical success, but people are taking them as a first step to losing significant weight.

Employers that are covering the costs may not be able to afford them. At $1350.00 or more as the monthly cost, employers are having to grapple with the expense despite the fact that their employees are anxious to take these medicines.

They also anticipate a discussion involving greater reliance on co-pay assistance programs and alternative funding. Copay cards are intended to reduce the total out-of-pocket expense for the patient who may be under-insured and unable to afford the expense. The benefits payer pays some of the cost and then the manufacturer pays part or all of the cost that the patient is responsible for through copay or coinsurance.

Panelists also foresee an important role for Foundations that are established to help offset these costs, including CancerCare, HealthWell Foundation, Leukemia & Lymphoma Society, National Organization For Rare Disorders (NORD) and others.

These resources are helping people to overcome financial access and treatment barriers by assisting them with co-payments for their prescribed treatments. Many offer easy-to-access, same-day approval over the phone and online.

An additional topic which is making headlines will focus on prior authorizations (PA), sometimes referred to as a "pre-authorization." This is a requirement from the payer that the doctor obtain approval from the plan before it will cover the costs of a specific medicine, medical device or procedure. Most recently, the insurance carrier Cigna announced it would be removing close to 25% of medical services from PA requirements – although not specifically drugs.

In fact, a letter to CMS was recently issued by the American Hospital Association, the American Medical Association, the Blue Cross Blue Shield Association and America's Health Insurance Plans which united to make the case against proposed prior authorization standards. The groups stated that the provisions of the December 2022 Notice of Proposed Rule Making would create two sets of standards that would slow implementation and add unnecessary costs. The extent to which self-insured employers follow this trend is to be determined.

Dr. Brenda Motheral

Dr. Motheral foresees challenges with the emergence of biosimilars, simply defined as a biological medicine highly similar to another already approved biological medicine, referred to as the 'reference medicine'. Biosimilars are approved according to the same standards of pharmaceutical quality, safety

and efficacy that apply to all biological medicines.

She highlights the entry of several biosimilars to the Humira brand and questions whether this preferred status of the biosimilar should extend beyond Humira to other drugs in the class. The drug suppresses the immune system by blocking the activity of TNF: a protein produced naturally by the body's immune system. Some people with certain autoimmune diseases produce too much TNF. Humira is designed to stop tumor necrosis factor-a, or TNF, from attacking healthy cells.

"The best-selling drug Humira (adalimumab) now faces competition in the United States after a 20-year monopoly," says Dr. Motheral. "Eight different biosimilars have launched this year with discounts as large as 85% from Humira's list price of $6922. A few companies also offer two price points."

She also forecasts that managing the extremely high cost of cell and gene therapies will require employers to have well defined strategies for addressing these expenses. By the end of 2022, 13 cell and gene therapies were on the US market. In 2023, expectations are that up to 12 new cell and gene therapies will be approved in the US.

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"These treatments typically range from $250,000 to $3.5 million per individual," she explains. "While these novel therapies serve only small patient populations, employers may be forced to contend with extreme and, in some cases, unsustainable drug costs. With increased pharmaceutical company investment in regenerative medicine and growing interest in rare disease, it is likely that more companies will face these expenditures for these potentially lifesaving treatments."

Dr. Motheral also believes there will be increased focus upon the best practices for managing specialty drugs under the medical benefit, where many of the gene therapies are covered.

Specialty drugs can be covered insurance based on type of administration, and an estimated 30-50% of specialty drugs are covered under medical benefits, being administered in outpatient facilities, physician offices, or outpatient/ambulatory infusion centers.

She explains that drugs covered under pharmacy benefits are most often self-administered, such as oral medications, self-injectables, or medicines delivered via other methods that patients can manage at home. Drugs that must be administered by a health care provider, which includes many cancer medications, are typically covered by medical benefits.

"There can also be key differences in coverage, depending on whether the drugs are paid for under the medical benefits or pharmacy benefit," she adds. "The member copays, formularies, and clinical prior authorization programs can vary significantly across the two benefits, resulting in benefit shopping and suboptimal sites of care."

COSTS CONTINUE TO RISE

The specialty drug trend continues to be driven primarily by claim utilization, accounting for nearly three-quarters of the overall 14.1% gross trend, according to the Walmart report.

It appears that the cost per claim plays a larger role in specialty trend, with the number of members taking specialty drugs continuing to rise: 4% of members took at least one specialty drug in 2022, while the average number of claims per person remained steady. On the surface, this increase may appear minimal, but even a slight increase in the percentage of members taking specialty drugs can have substantial cost implications on a per member per year basis.

The top categories for specialty drug spend show that inflammatory, oncology and multiple sclerosis lead the way, with about 13 oncology drugs approved each year. In 2023, there are 16 oral drugs and 6

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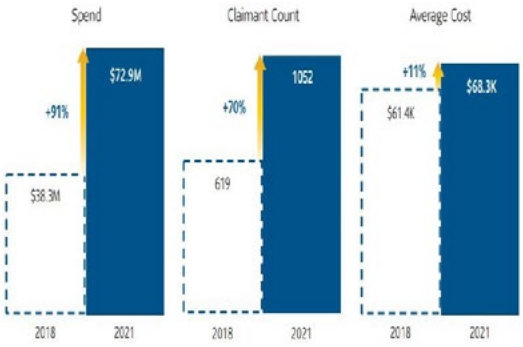
drugs delivered via injection in the pipeline, with 6 drugs in the pipeline for breast cancer and 3 for non-small cell lung cancer (NSCLC).

These findings suggest that the overall increase in spend is now being driven by the introduction of new specialty utilizers rather than by increased claims among those who already take a specialty drug. Biosimilars also have a profound impact on the overall specialty spend, with biosimilar utilization increasing from 20.5% in 2021 to 26.3% in 2022.



Source: 2023 SunLife

SPECIALTY DRUGS TO WATCH

The latest Sun Life Report reveals that cancer categories Malignant Neoplasm and Leukemia, Lymphoma and Multiple Myeloma continue to be top drivers of high-cost claims, making up 29% of total claim reimbursements over the past four years, with cancer drugs comprising over half of the top 20 high-cost injectable drugs for 2022.

Stop-loss claim reimbursements

2021 Rank	4 Year Rank	Condition/Disease/Disorder	2021 Single Year Reimbursements	2018–2021 Reimbursements
1	1	Malignant Neoplasm	$294.9M	$1.03B
2	2	Leukemia, Lymphoma, Multiple Myeloma	$117.0M	$443.1M
3	3	Cardiovascular	$102.3M	$389.4M
4	4	Orthopedics/Musculoskeletal	$89.6M	$297.5M
5	5	Newborn/Infant Care	$82.3M	$287.0M
6	6	Respiratory	$65.0M	$234.1M
11	7	Urinary/Renal	$57.5M	$222.6M
9	8	Neurological	$61.2M	$210.7M
10	9	Gastrointestinal/Abdominal	$59.3M	$200.9M
7	10	Sepsis	$64.2M	$182.4M
13	11	Congenital Anomaly (structural)	$41.9M	$172.0M
12	12	Physician Treatment	$47.1M	$143.1M
17	13	Transplant	$26.7M	$127.8M
14	14	Cerebrovascular	$29.8M	$98.7M
16	15	Hemophilia/Bleeding	$28.4M	$96.3M
19	16	Immune System	$21.2M	$87.5M
15	17	Mental and Behavioral Health	$28.5M	$87.1M
18	18	Malnutrition	$23.1M	$79.8M
8	19	COVID-19	$61.5M	$75.4M
21	20	Blood and Blood Forming Organs	$18.6M	$72.0M

Total payments
38% Top 3 conditions
70% Top 10 conditions

☐ Indicates a change in 3 or more places compared to the single year rank

Stop-loss reimbursements for top 10 conditions	$3.50B
Stop-loss reimbursements for top 20 conditions	$4.54B
Stop-loss reimbursements for all conditions	$4.97B

Source: Sun Life book of business data, stop-loss reimbursements from 2018-2021.

The trend report also states that some of the specific drugs have changed:

- Herceptin and Tecentriq have completely dropped out of the top 20.
- Almita, which is used to treat malignant mesothelioma and other lung cancers, moved up two rungs, at an average cost close to $67,000.
- Leukemia and lymphoma drug Rylaze, at an average cost of over $800,000, make it the most expensive drug in the top 20.

2018 Rank		2021 Rank	Injectable drug	Total cost	Average Cost
5	▲ 4	1	Keytruda	$34.7M	$148.3K
6	▲ 4	2	Opdivo	$21.0M	$132.1K
2	▼ -1	3	Neulasta	$16.8M	$37.1K
7	▲ 3	4	Soliris	$14.2M	$526.0K
3	▼ -2	5	Perjeta	$13.9M	$81.2K
N/A	——	6	Tepezza	$9.3M	$373.9K
1	▼ -6	7	Herceptin	$9.0M	$80.0K
25	▲ 17	8	Ocrevus	$8.9M	$110.7K
N/A	——	9	Zolgensma	$8.6M	$2.1M
4	▼ -6	10	Avastin	$8.3M	$54.8K
N/A	——	11	Tecentriq	$8.1M	$126.7K
13	▲ 1	12	Inflectra, Remicade	$8.0M	$82.7K
20	▲ 7	13	Adcetris	$7.0M	$249.7K
17	▲ 3	14	Gammagard	$6.9M	$94.9K
28	▲ 13	15	Kadcyla	$6.7M	$117.5K
8	▼ -8	16	Yervoy	$6.5M	$117.9K
N/A	——	17	Darzalex Faspro	$6.5M	$104.7K
N/A	——	18	Ultomiris	$6.4M	$457.7K
21	▲ 2	19	Gamunex-C, Gammaked	$6.1M	$99.2K
N/A	——	20	Hemlibra	$4.4M	$376.8K

Totals	
Cancer conditions	$138.6M
Blood disorders	$26.6M
Immunodeficiency disorders	$13M
All other conditions	$34.8M
Overall top 20	**$212.9M**
All injectables	**$349.0M**

// To reflect the high average cost of Zolgensma at $2.1M, the line break demonstrates that it is not to scale.

Source: Sun Life book of business data. Top 20 rank order, average paid, total paid and condition category are all based on 2021 book of business data. Four-year comparison view is based on 2018 and 2021 book of business data.

RISING COSTS AHEAD

The outlook for escalating costs is clear: venerable analysts at PwC's Health Research Institute anticipate persistent double-digit pharmacy trends driven by specialty drugs and the increasing use of certain medications used to treat Type 2 Diabetes or weight loss.

In a survey they conducted with US health plans, covering 100 million employer-sponsored large and small group members and 10 million Affordable Care Act (ACA) marketplace members, they report that plans are experiencing inflationary pressure from rising median prices of new drugs as well as increasing prices of existing drugs.

Combine with the accelerated approvals of new CGTs, they don't expect pharmacy trends to slow down in 2024 with the inflationary impact predicted to be in the high single or double digits from 2023-2024.

They do foresee two "deflators":

- The adoption and potential of biosimilars to manage these rising drug costs. With the prices of biosimilars on average more than 50% lower than the reference products for which they can substitute, there is substantial opportunity to manage costs. 65% of health plans surveyed ranked biosimilars coming to market among their top cost deflator.
- Site of care is shifting from expensive hospital settings to less expensive sites, such as independent administration sites, physician offices and patients' homes. In fact, one report said that close to two-thirds of Immune Checkpoint Inhibitors (ICI) also known as immunology treatments are administered by outpatient clinics at hospitals, where it costs $157,000 each year on average to receive care. By comparison, it costs $87,000 on average annually for a patient to receive the infusions in a doctor's office.

Additional reports, such as one survey released from the Pharmaceutical Strategies Group, raises concerns about the lack of uptake in value-based or outcomes-based contracting for specialty drugs.

They polled more than 180 employers, insurers and labor unions and found that just 12% are using value-based models for pricey specialty therapies, with payers citing multiple hurdles to rolling out these models.

Payers are demanding to see more evidence that the models are effective and can't seem to agree on methodologies for tracking outcomes.

What is encouraging is that the survey also found that 14% of employers and 7% of health plans are deploying alternative funding models, while 14% and 33%, respectively, are exploring their use – although a majority of those polled said they don't view these models as sustainable.

While co-pay assistance programs drew positive responses that they are necessary to assist people in affording high-cost medications, there was some respondents who said that at these programs encourage patients to take pricier brand-name drugs rather than select the lower-cost alternative medication.

It appears from this survey that the primary concern in this space is ensuring parity in costs across both the medical benefit and pharmacy benefit. Employers remain challenged on the issue of affordability and cost-sharing for members, with the majority of surveyed payers using PA for these drugs while expressing concerns about the potential for unintended related consequences, such as member dissatisfaction or care delays.

Clearly, these topics and findings reflect and complement the topics that are addressed at the SIIA panel presentation. What is so compelling is that employers will find the panelists' guidance and recommended strategies highly valuable in the year ahead. ■

Laura Carabello holds a degree in Journalism from the Newhouse School of Communications at Syracuse University, is a recognized expert in medical travel, and is a widely published writer on healthcare issues. She is a Principal at CPR Strategic Marketing Communications. www.cpronline.com

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