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Stop-Loss State of the Market Report

May 2024

More than 153M individuals and families rely on employer-sponsored benefits plans to partially shoulder the burden of rising healthcare costs. Employer groups of all sizes and funding structures must balance care, risks and costs despite external factors far outside their control.

Medical inflation, novel and high-cost therapies, increases in million-dollar claims and an increasingly competitive market are a few topics we will explore in this year's report.

Fiduciaries are taking a more consumeristic approach, asking informed questions about existing plans and per member spend, aiming to mitigate healthcare costs and seeking more flexible plan design. The transparency that comes with self-funding illuminates important claims trends and offers insights for informed decision-making. A thoughtfully designed self-funded plan paired with stop-loss insurance and innovative cost-containment strategies can become a lucrative talent attraction tool and proactive health investment into employee health. However, such choice and control will carry inherent risks. Brokers and consultants are bound by fiduciary duties that dictate extreme levels of professional and personal responsibility. Staying abreast of market trends to advise clients appropriately is critical.

The notable cost of medical innovation — including emerging specialty drugs and cell and gene therapies — has come center stage again this year. While theories vary widely on treatment efficacy, durability and health outcomes of novel biologics, most agree that the health and insurance industries are navigating extreme pressure in parallel. In the absence of comprehensive manufacturer warranties, stakeholders are charged with deciphering publicly accessible clinical data when making decisions about plan design.

Outside of navigating implications of new and novel therapies, one or two "shock" claims of any type — a premature infant, cancer diagnosis, in-patient stay or infection/sepsis condition — will mark significant issues for groups without proper contract protections and a thorough cost-containment strategy.

While widespread and long-term use of glucagon-like peptide-1 (GLP-1) weight loss drugs will not materially impact stop-loss coverage, the sharp uptick in the frequency of GLP-1 drug claims and lucrative anti-obesity drug market (predicted to reach $100B by 2030 and raise GDP levels by 0.4% in the coming years[1]) are worth noting. All prescription drug spending, clinical efficacy of therapies and medical necessity of medications covered by a self-funded or fully insured plan must be evaluated closely by fiduciaries.

This annual state of the market report is a tool for employee benefits brokers and consultants to stay abreast of market trends. It blends Stealth Partner Group benchmarking data with insights from stop-loss experts, actuaries and partners. Innovative programs, models of care and cost-containment strategies are evolving to challenge the status quo, address systemic deficiencies and bring value to employer groups.

Brokers should leverage the information in this report — along with independent, specialized subject-matter experts and the extensive database of Stealth — to stay properly informed and advocate for their clients in the year ahead.

This year's report highlights:

Economic Conditions

Inflation

Inflation continues to affect nearly every person and market sector in the country. While J.P. Morgan Research reports inflation has "cooled significantly relative to earlier boomy highs from the past few years," inflation remains above target.

Medical cost inflation has run higher than general inflation for the last 15+ years. In 2024, medical cost inflation is projected to hit 7%, even as broader inflation metrics decline. Pressures within the healthcare industry — including an aging physician workforce, primary care and pharmacy "deserts," nursing shortages and pervasive socioeconomic challenges — naturally converge to drive increased costs. Clinical research and expenses associated with bringing innovative treatments to market will continue to amplify prices across the board.

When inflation and capitalism intersect with healthcare, increases will naturally drive higher claims expenditures for fully insured and self-funded plan sponsors. These same market forces can also limit access to care, services, therapies (including emerging and groundbreaking new treatment regimens) and prescription drugs.

Employee healthcare is typically one of an organization's most significant expenses. While healthcare inflation disproportionately impacts small to midsize employers, benefits and costs remain top of mind for groups of all sizes. Given this complex landscape, health plan costs will continue to rise for the foreseeable future. However, with the right cost controls in place, the impact can be less severe.

Mergers and Acquisitions

While it appears to have hit its peak in 2021, with 1,156 acquisitions, yearly broker consolidations have now settled in closer to the 10-year average of 671.[2] In 2023, the industry saw 631 acquisitions, with almost 80% of regional consolidations backed by private equity.[3] More limited M&A opportunities have fueled a noticeable emphasis on organic growth, and many brokers are now offering broader, more diverse services and packages. This shift illuminates the need for strong carrier relationships and access to specific capabilities that address niche concerns and properly mitigate risk. Winning and retaining clients will require specialized expertise, custom solutions and efficient usage of technology.

Workforce and Talent Pipeline

The talent gap between seasoned insurance professionals and new hires is widening, particularly in underwriting roles. Traditionally, skilled individuals would be nurtured and mentored, advancing into new roles in an organization. Brokers and carriers report difficulty finding new, qualified employees to grow their teams.

On a positive note, the labor market has stabilized compared to the volatility of the past few years. Brokers grow their business through hiring and retaining great team members, and most are doubling down on efforts to acquire and retain top talent. Most of the U.S. workforce (in all sectors) cites competitive benefits as a significant factor in evaluating a new employment opportunity.

Government Policies or Interventions

In this year's State of the Union address, healthcare priorities included enacting permanent tax credits to reduce healthcare premiums and capping the cost of insulin. President Biden also referenced the Inflation Reduction Act of 2022. The Act empowers Medicare to negotiate drug pricing and caps total prescription drug costs for seniors at $2,000 per year. The process began in 2023, and the first negotiated prices should go into effect in 2026.

Cancer is omnipresent in the stop-loss world, and more than two million new cancer diagnoses are expected in 2024. Although the federally funded "Cancer Moonshot" initiative in partnership with the National Cancer Institute was not mentioned in the March 2024 State of the Union address, accelerating scientific discovery in cancer and fostering greater collaboration between the federal government, healthcare providers, patients, advocates and the public and private sectors still appear to be active areas of focus within this administration.[4]

Government interventions related to cell and gene therapies are unlikely until Medicare and Medicaid become meaningfully impacted.

High-Level Market Outlook

Stealth
By The Numbers

#1
Largest Stop-Loss Wholesale Broker

2,500
Groups

2M
Insureds

Self Funded Market Growth

Groups that no longer wish to bear the rate increases and limitations of fully-insured plans are attracted to self-funding and alternative risk offerings. According to Milliman's research released in May 2023, the U.S. stop-loss market reached $31B in annual premiums.[5]

At the time of this report's release, Stealth managed $1.85B in premiums; by mid-summer 2025, Stealth's book is projected to hit $2.3B.

According to the Kaiser Family Foundation's (KFF) 2023 Employer Health Benefits Survey, 65% of U.S. workers are enrolled in a self-funded plan — the same percentage as in 2022. Sixty one percent of organizations employing 200-999 workers, 81% employing 1,000-4,999 and 93% employing 5,000 or more opt for a self-funding structure. As expected, the majority of self-funded organizations are larger in size, but in a five-year period from 2018 to 2023, the percentage of groups with 200-999 workers jumped by 11% — currently hovering around the 61% mentioned above.[6]

Employers reporting at least one member claim of more than $1M has jumped from 3.5% in 2018 to 12.4% in 2022.*

* QBE® Accident & Health Market Report 2023

Ninety one percent of self-funded plans covering between 200-4,999 lives had secured stop-loss insurance. For larger groups (5,000 lives or more), stop-loss coverage hovers around 60%.[6]

Self-insurance utilization varies substantially by state. For example, 70% of private-sector enrollees in Ohio are covered through self-insured plans, compared to 33% in Hawaii.[6]

Reference-based Pricing

Reference-based Pricing (RBP) operates within self-funding structures by setting a benchmark price for certain medical procedures or services. Instead of relying solely on network discounts negotiated by insurance companies, RBP plans leverage publicly available pricing and claims data to set reimbursements for employees' medical procedures. Medicare-based reimbursement levels and provider costs are two of the more common benchmarks utilized in these arrangements. RBP encourages cost transparency and can help employers offer employees higher levels of benefits at a lower cost point.

Claims trends for RBP plans have historically been below 5% whereas PPO plans tend to be above 7%. Some employers enacting RBP have decreased total employee health plan costs by up to 30%. Of Stealth's groups, about 6% select RBP as a primary network alternative, but a much larger percentage leverages RPB as a dual option or secondary network alternative. Assuming the plan is structured appropriately and correctly, Stealth's carrier partners report they will continue to rate groups leveraging RBP favorably.

Balancing the Promise, Risk and Price of Health Innovation

Health care drugs and medical innovations — gene and living cell therapies, specialty drugs and other biologics — are sparking broader conversations about the roles of the insurance sector and employer-sponsored plans.

Gene therapy research and trials have been ongoing since the 1960s, but more recent breakthroughs and Food and Drug Administration (FDA) approvals have brought the techniques to the forefront. Most high-dollar biologics on the market address rare (or very rare) disease states. The power to transform the lives of individuals is incredible, but so are the costs.

Research, clinical trials and approval phases are exceptionally time - and resource-intensive, underscoring the complexity of developing novel therapies. Breakthrough drugs, while promising, can also cause unpleasant side effects, infections, adverse reactions and expensive hospital stays for immune-compromised individuals. Without a well-designed strategy in place, treatment and care can become a significant threat to plan-sponsor finances and stop-loss carriers, highlighting the need for proactive and careful consideration.

The use of biologics also raises interesting and ethical questions about how the insurance sector and employer-sponsored plans impact health equity. Most people agree that access to care and groundbreaking treatments — especially for those within disparate populations, rural locations and disadvantaged socioeconomic classes — is critical. However, perspectives vary widely on which person, entity or industry should be responsible for managing the hefty price tag of health innovation.

Mental Health Parity and Substance Use Disorder Equity

At the intersection of health and social issues — and in the most simplistic terms — people in the U.S. are becoming less healthy physically and mentally. Depression, anxiety and addiction rates, particularly among young adults and women, are rising.

While mental health conditions may not directly result in a stop-loss claim, lost productivity and high prescription drug costs are catching the attention of individuals tasked with designing effective benefit plans. Also of note, mental health issues and substance use disorders are not typically listed as a primary diagnosis, even though those conditions will significantly impact a person's overall health outcomes.

According to the most recent Substance Abuse and Mental Health Services Administration (SAHMSA) National Survey on Drug Use and Health Report, approximately 21.5M people in the U.S. are experiencing a co-occurring disorder. In that same report, 36.2% of adults aged 18 to 25 reported experiencing some type of mental illness.[7]

It is worth reiterating from last year's State of the Market report that the Mental Health Parity and Addiction Equity Act (MHPAEA) of 2008 requires identical health plan coverage for mental health care and substance use disorder treatment as medical and surgical services. While formal audits to demonstrate compliance with mental health parity legislation have been sparse, brokers and plan sponsors should be aware of the online self-assessment tool available from the Department of Labor.

Disruptive Innovation and Emerging Business Models

Widely-deployed wellness initiatives such as gym memberships and preventive care incentives for early disease detection are popular strategies intended to address rising insurance costs. But these tactics are not systemic solutions to mitigate chronic conditions and catastrophic claims. Larger-scale, more forward-thinking solutions are critical.

New business ventures and operational models focused on transparency, clarity and a patient-centric experience are gaining traction with self-funded programs. While longer-term data does not yet exist, initial reports illuminate the merits of Direct Primary Care (DPC) and transparent Pharmacy Benefit Managers (PBMs). Those programs will be explored in more detail throughout this report, along with the more widely used Patient Assistance Programs (PAPs) and Medical Assistance Programs (MAPs). Narrow and direct networks and International drug sourcing can also optimize member care and manage costs.

Direct Primary Care

Establishing relationships with primary care physicians and care teams is essential, but a 2023 National Association of Community Health Centers (NACHC) report highlights a staggering statistic: more than 100M Americans face barriers to accessing primary care. Fee-for-service models, urgent care competition and an aging physician workforce are contributing to a decrease in accessible, community-based primary care practices.

Direct Primary Care (DPC) is emerging as a promising and valuable benefit for self-funded groups. At its heart, DPC is a subscription-based model offering near-unlimited access to primary care services.[8] While most Americans have not heard of DPC, its presence doubled in geographic footprint, from 20 states in 2019 to 48 states today. In a DPC setup, clinicians can focus on the healthcare provided, not the administrative burden entrenching traditional care systems.

An employer's buy-in to DPC reflects a different kind of investment in employee health. Despite its potential, DPC adoption remains most common among small businesses. Independent studies demonstrate the effectiveness of DPC, but limited awareness of the DPC option remains a hurdle.

Direct Contracting and Narrow Networks

Direct contracting — also recognized as a narrow network — allows employers to select and partner with high-value providers or health systems in a given region. In this setup, plans can assert greater control over quality of care and costs. Similar to the DPC arrangement, direct contracting also underpins the crucial nature of advanced primary care (APC) — more widely known as the Patient-Centered Medical Home (PCMH) model. In this setup, localized, comprehensive and proactive value-based health services are intended to divert patients away from the path of developing high-cost, catastrophic or chronic conditions.

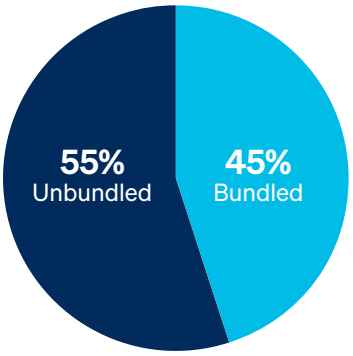
Prescription Drug Programs and Transparent Structures

According to the National Association of Insurance Commissioners (NAIC), the top three PBMs (CVS Caremark, Express Scripts, Inc., OptumRx, Inc.) process approximately 80% of all prescription claims. Furthering their stake in the market, all three have established group purchasing organizations (GPOs) to further consolidate the number of covered lives in rebate negotiations with pharmaceutical manufacturers. Despite the Federal Trade Commission commencing an antitrust investigation into six of the largest GPOs nearly two years ago, results have been delayed due to lackluster compliance with document and data requests.

PBMs are in place to save money for plan sponsors and the 275M Americans who rely on their services, but they have faced criticism by employer groups, industry leaders and independent pharmacy owners. Hidden revenues, lack of transparency and disclosure, conflicts of interest, overlap of ownership and vertical integration between some of the country's largest health plans, providers, health systems and influential PBMs are core points of contention. Outside of the challenges, though, the sheer scale and buying power of the major PBM players can often result in enticing rebates and lowest net costs, often making them the best option and allowing for continued dominance.

When considering the self-funded market, with a heavy concentration in unbundled stop-loss, we still see 51% of business placed with OptumRX, Express Scripts and CVS. It's important to note that this figure only considers the front-end PBM relationship and does not accurately reflect back-end outsourced relationships for rebates, formulary management and other factors.

PBM Bundled and Unbundled



Key Takeaway

A little more than half of the groups in the Stealth portfolio favor unbundled PBM pharmacy arrangements.

The environment is ripe for new solutions, and patient focused, clinical PBMs have emerged amidst rapid industry changes. In contrast to traditional PBM structures that deploy convoluted spread pricing, this structure operates using a simple administrative fee. Total rebate dollars are passed to clients and claims data is accessible and usable. One of the clinical PBMs Stealth works with caps shared savings at a modest $2,500 — a strategy typically unheard of since shared savings can generate such juicy revenues for PBMs.

Some innovative, clinical PBMs are leaning into a patient-advocacy role. Integrating precision medicine and pharmacogenomics (the study of an individual's genetic response to prescription drugs) can help ensure that patients are on the appropriate medication, minimize side effects and improve overall patient outcomes.

International Prescription Drug Sourcing

In January of this year, the FDA granted approval for the State of Florida to import drugs from FDA-approved facilities in Canada for a two-year period. International sourcing has long been a gray area for employers, and this notable development has prompted a surge of interest in exploring traditionally inaccessible options. Along with the convenience of direct-to-home shipping, international prescription drug sourcing from Tier 1 countries allows patients to access brand-name medications (in sealed, original manufacturer packaging) at significantly lower costs.

According to KFF, several states, including Colorado, Vermont, Maine, New Mexico, New Hampshire, North Dakota and Texas have enacted laws to establish import programs and are actively pursuing prescription drugs from Canada.[6] Still, while international import of FDA-approved drugs for personal use is illegal in most circumstances, enforcement is minimal.

Litigation to Watch

Industry experts have taken a keen interest in the recently filed class action complaint against Johnson & Johnson Company (J&J) claiming that J&J and its benefits committee members breached Employee Retirement Income Security Act of 1974 (ERISA) fiduciary duties. As the case is in active litigation, we were unable to derive specific insights for what industry experts are calling "the J&J lawsuit" before this report's release.

This case does, however, shine a light on the importance of fully understanding personal and professional fiduciary duties of a self-funded plan. Compared to fully-insured plans, a self-insured plan sponsor assumes a much higher fiduciary duty to administer the plan prudently and in the best interest of participants.

Fiduciary requirements to demonstrate reasonable care and due diligence are core tenets of this litigation.

With this in mind, for an employee benefits broker or consultant, choosing to work with an external unbiased independent expert may not only lead to the most competitive offer for the client, but it may also be the most prudent decision or the employee benefits broker or consultant.

Renewals and Lasers

Stop-loss carriers must keep a close eye on inflation and profitability. The accelerating claim activity within therapeutic service lines (mental health and substance use disorder) and the intricate task of evaluating risk for fresh-to-market rare disease and cancer treatments are challenging existing models and stretching the minds of even the most seasoned actuaries. Ranges in spreads have become so wide, multiple rounds of rate shopping are common, and competing on stop-loss rates alone is becoming increasingly difficult. While cost will always be a significant factor in decision-making, brokers can differentiate themselves by demonstrating knowledge, offering innovative products and delivering unique pricing strategies.

The following data is derived from Stealth's book of business as of Q1 2024.

A few short years ago, as the topic of new therapies was heating up in the stop-loss market, exclusionary language and the deployment of lasers was a generally accepted response. Our most recent data reveals the average number of groups with a contracted laser provision declined by about 18% compared to 2022. The percentage of groups with a laser present held relatively steady into the early part of 2024, with a slight decline of 2% from the year prior.

We believe a few key factors drive this reduction:

- Normal attrition of lasers placed in prior years
- Skilled negotiations by stop-loss experts during the underwriting process
- A shift in how high-dollar claimants are managed through the implementation of well-designed, effective cost-containment solutions

	% of Groups w/ Laser Present		
Group Size	**2022**	**2023**	**2024**
0-100	48%	29%	26%
100-250	46%	30%	30%
250-500	50%	31%	26%
500-1000	37%	28%	26%
1000-1500	52%	23%	19%
1500-2000	31%	12%	20%
2000-5000	32%	17%	19%
5,000+	41%	15%	20%
Total (Avg)	**44%**	**28%**	**26%**

Key Takeaway

We continue to see a decrease in the number of groups with lasers applied to their populations. In 2024, 26% of groups with a stop-loss contract had at least one lasered individual — a decrease of two points from 2023. This trend may be driven by groups electing additional protections, like No New Laser and Rate Cap (NNL/RC) policies.

In Action: Lasers and Strategy

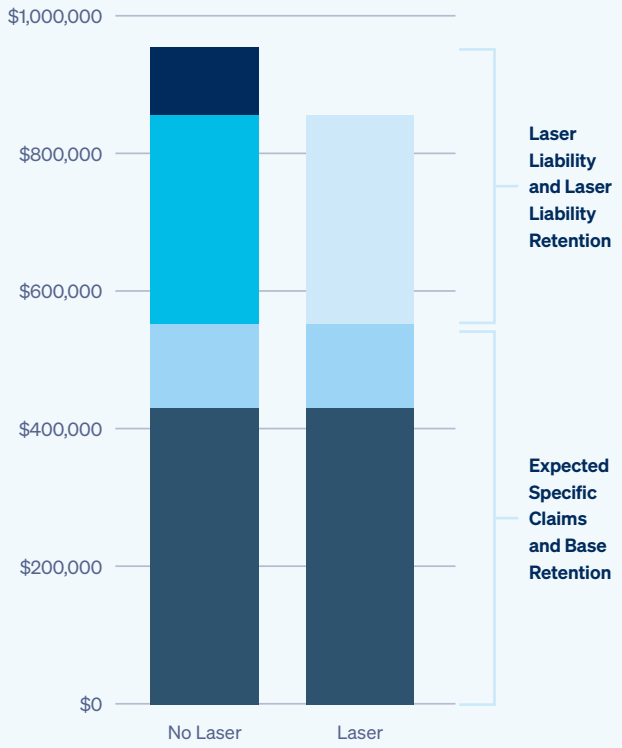
Laser Scenario: In the No Laser option, the laser risk is built into the total cost, which includes additional retention for the laser liability, equating to $960,000. In the Laser option, the minimum cost is $560,000, which is equal to the Expected Specific Claims + Base Retention. Even if the Laser option hits maximum cost, the group would still be better off financially by $100,000.

	No Laser	Laser
Expected Specific Claims	$420,000	$420,000
Assumed Laser Liability (No Laser)	$300,000	$0
Potential Laser Liability (laser)	$0	$300,000*
Base Retention	$140,000	$140,000
Laser Liability Retention	$100,000	$0
Total Maximum Liability	$960,000	$860,000

*Group only pays if claims occur

- **Laser Liability Retention:** Portion of gross stop-loss premium to cover taxes, carrier fees, and risk charge based on any Assumed Laser Liability
- **Assumed Laser Liability (No Laser Option):** Stop-loss carrier determined known risk, full amount of expected risk will be priced into stop-loss premium since no laser can be applied
- **Potential Laser Liability (Laser Option)*:** Stop-loss carrier determined known risk, policyholder will be responsible for this additional laser liability
- **Base Retention:** Portion of gross stop-loss premium to cover taxes, carrier fees and risk charge
- **Expected Specific Claims:** Expected stop-loss claims for specific coverage (excluding any known risk eligible for lasering)

*not a guaranteed cost



While it is advisable to opt for an NNL/RC, in some instances, taking a laser in lieu of a known risk built into premium may be financially advantageous for funding a high-cost claim. The broker's ability to weigh all options and thoughtfully recommend the most prudent path ahead is key.

In 2022 and 2023, **68% of Stealth's groups selected a No New Laser and Rate Cap (NNL/RC) provision.** NNL/RCs are generally more prevalent for groups of more than 250 lives and appear consistent year over year. Self-insured employers, especially smaller ones, are seeking additional protection outside of traditional stop-loss contracts. Despite the increased costs of purchasing NNL/RCs, the benefit of risk transfer and/or avoidance can prove to be financially meaningful.

With the frequency of $1M claims increasing year over year, some carriers have begun to limit NNL/RC provisions to two to three renewal cycles with an option to non-renew thereafter.

Creative mitigation strategies, such as specialty coverage for cell and gene therapy treatments or transplants, provide additional protection for employer groups. As of January 2024, 59.2% of Stealth's clients had added gene therapy coverage to mitigate the high cost of such treatments.

A competitive — perhaps even over-saturated — market has kept hardening at bay. In fighting to retain business, carriers may be challenged in their ability to obtain necessary lasers and rate increases, while carriers seeking to win new business have more flexibility to price aggressively.

Brokers and consultants must be prepared to have educated conversations about lasering with groups that include known high-risk members.

High-Cost Claims Conditions

Detailed research reports from highly referenced sources outline high-cost claims and stop-loss trends each year. While there are slight variances in the exact rankings from carrier to carrier (based on total claims), Malignant Neoplasm, Leukemia, Lymphoma, Multiple Myeloma, Cardiovascular, Orthopedics/Musculoskeletal and Newborn/Infant claims over $1M historically round out the highest cost conditions.

Based on 2022 high-cost claimant data from several of our carrier partners, the highest-cost condition categories included:

	Claim Frequency per 10K Employees	Average First $ Claim Size
Neoplasms	12	$340,000
Circulatory Diseases	5	$280,000
Infectious and Parasitic Diseases	2	$450,000
Conditions Originating in the Perinatal Period	2	$430,000
Injury and Poisoning; Sepsis	2	$380,000
Diseases of the Digestive System	2	$300,000
Congenital Anomalies	1	$450,000
Diseases of the Genitourinary System (Urinary and Renal)	1	$280,000

Data based on information from five of Stealth's largest carrier partners.

The number of large claims over $1M increased from 3.5 per 100K covered lives in 2012 to more than 10 per 100K covered lives in 2021.[9] Sun Life's data shows that 20% of its employer clients covered at least one $1M+ stop-loss claimant between 2019 and 2022, with million-dollar claims rising by 45% across the same four-year period.[10]

In 2021, 10.5% of babies born in the U.S. were considered preterm.[10] Based on the average calculations, newborn/infant care claims averaged around $300K in claims cost, with the highest carrier reporting an average of $718K. While infertility treatments such as in vitro fertilization and intrauterine insemination are associated with preterm birth, these same advances are a coveted and valued benefit for individuals looking for medical support to build their families.

Cancer, another high-claims driver, is not a single disease and does not have a single cause. While promoting healthy lifestyles and encouraging regular primary care visits and screenings are common suggestions to help prevent cancers, according to the National Cancer Institute, almost 40% of Americans will be diagnosed with cancer at some point during their lifetime.

The costs to treat this pervasive disease vary considerably depending on the treatment strategy, health system, provider and facility where the services are delivered. Developing a comprehensive cost-containment solution for cancer is an extreme challenge. However, more innovative disruptors are investing significant resources and aiming to develop responsive programs that mitigate the financial impacts of cancer treatment.

In the interim, designated Centers of Excellence (COEs) have shown promise in delivering cost-effective, comprehensive care within a particular niche area of expertise. Member steerage techniques help patients navigate the myriad in-network and out-of-network options, with the goal of managing costs while choosing high-quality service. COEs are effective in connecting individuals with specific conditions with right-venue access to skilled providers deploying the latest treatments and clinical trials.

High-Cost Biologics and Injectables

Life-changing injectable drugs can drive high-cost claims, and the global injectable drug delivery market is projected to reach $1.3T by 2030. Experts question if and when injectable medications will become the norm, replacing daily doses of pills for chronic conditions like arthritis and diabetes.

In 2019, the $2.2M cost of Zolgensma® (a gene therapy for spinal muscular atrophy) sent shock waves into the market. In March 2024, Lenmeldy™ (a therapy used to treat, not cure, metachromatic leukodystrophy) was released at a $4.25M price point. Expert opinions are mixed on exactly how these groundbreaking drugs will impact the system from a cost and care standpoint. Diverse viewpoints are shaped by questions around durability, efficacy, value, warranties and more, but almost all agree that biological innovation is a trend to watch.

At the opposite end of the severity spectrum, GLP-1 drugs remain in the spotlight due to frequency. Widespread use and demand for injectable medications is a significant area of concern for all employer groups, whether fully-insured or self-funded. Nearly one in three adults in the U.S. are overweight, and injectables like Wegovy®, Rybelsus® and Saxenda® are quicker and simpler drivers of weight loss than the traditional “prescription” of diet and exercise.

The use of Ozempic® — not just to address Type 2 diabetes but now manage obesity — has driven widely-publicized supply chain shortages and pricing issues for independent pharmacies. Consumer desire for weight-loss drugs, including Mounjaro®, dubbed the “King Kong” of weight loss drugs, has been sparked by aggressive marketing campaigns, not directly driven by more diabetes diagnoses.

Understanding Specialty vs Non-Specialty Drugs

The disparity between specialty and generic drugs lies in the availability for replication. Generic drugs can be produced by any manufacturer once the patent expires, leading to increased competition and, typically, lower prices. In contrast, specialty drugs — often used daily for chronic conditions such as Crohn's Disease or Psoriasis — remain under patent protection. Exclusivity allows manufacturers to dictate prices, often resulting in exorbitant costs, month after month, until the patent expires.

Of the new medications expected to hit the market this year, 80% will be designated as specialty drugs with projected costs of hundreds of thousands of dollars annually.

It’s not uncommon for a small number of claimants in a group to utilize a specialty drug and drive a disproportionate amount of spend on the plan. The median price of newly marketed specialty drugs in 2022 is $222K.[11]

Creative ways to mitigate the financial burden of prescription drugs do exist. Brokers must seek out partners with similar cost-conscious goals and structures to best serve their clients.

Cellular, Gene and CAR-T Therapies

According to the FDA, "extremely rare" or "ultra-rare" diseases affect less than 200,000 people — and in some cases, affect only a handful. At the time of this report's release, only 37 therapies — 24 cellular and 13 gene — have received FDA approval. Slightly more than 3,500 additional therapies are nestled in various stages of the clinical approval pipeline, with 200+ in late-phase development. While a chunk of those therapies will not make it to market, more than 30 are expected to earn FDA approval in the next two years.

Notably:

- **Two $3.1M gene therapies for sickle cell disease (impacting almost 100,000 people in the U.S.) came to market weeks apart in December 2023.** Patient adoption of Lyfgenia™ and Casgevy™ has been relatively slow, with experts citing wariness of side effects and potential for cancer risk.

- **In 2023, one gene therapy for Duchenne muscular dystrophy (DMD)** was approved for pediatric patients 4 to 5 years old. About one in every 3,300 boys are affected by this disorder, and experts expect most qualifying patients to receive the treatment.

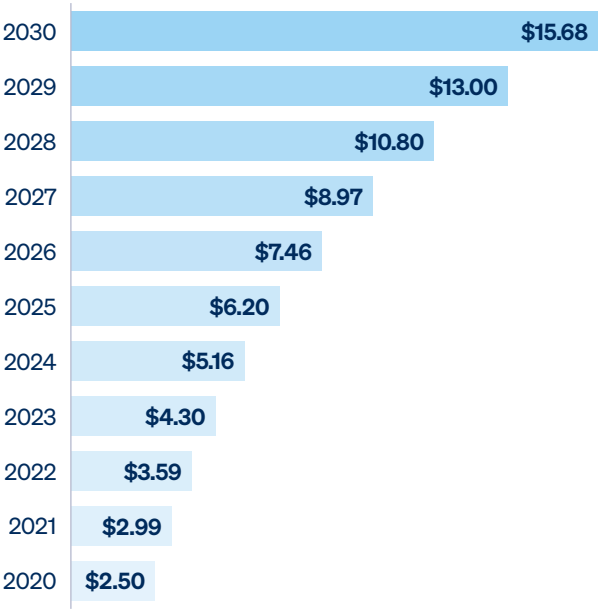
- **One approved CAR-T cell immunotherapy to treat multiple myeloma** moved from a fourth-line treatment to a second-line treatment in mid-March 2024. Another treatment to address the same disease state advanced to a third-line treatment on the same day. Multiple myeloma is a rare (but not extremely rare) cancer. According to the American Cancer Society, the average lifetime risk of developing this disease is 1 in 103 for men and 1 in 131 for women. With these changes, the pool population of candidates for both therapies will naturally increase. First-line treatments are generally accepted as the go-to standard. As a therapy advances it becomes more widely adopted and accepted.

Cell and gene therapy cost-containment solutions are iteratively evolving with new biologic releases. Stealth's program-building strategy centers on covering therapies based on the disease state, with an expected expansion of the program set to launch in the second half of the year. This program will likely include 14 therapies in total after integrating a few cell therapies. The goal is to provide patient choice and comparable options without adding significant expense.

As new gene and cell therapies are released, patients and providers must weigh any uncertainties about risks, side effects and long-term effectiveness against potential benefits. Some may be anxiously awaiting new treatments and options; some may be wary of therapies so new to the market. Racial and ethnic disparities in the U.S. healthcare system have been well-documented, and a sense of trepidation or even mistrust in the medical industry may factor into a decision to incorporate novel therapies or decline certain avenues of care.

While this report will not dig into the efficacy or cost reasoning for specific cell and gene therapies, proprietary cost-containment products alongside stop-loss do provide a way to make treatment accessible to people living with extremely challenging health conditions while protecting the integrity of self-funded plans.

Therapy Revenues



**Data sources: FDA.gov and Precedence Research Gene Therapy Market Size, Growth, Trends Report 2021-2030*

The number of available therapies — and individuals eligible for new biologics — will continue to grow, so this is an important year for brokers to open conversations with clients about thoughtful cost-containment solutions. While brokers do not need to become experts on every new therapy or brand name, they do need to understand that the cost-to-benefit analysis of gene therapy coverage is complex and evolving. Staying informed at a high level and leveraging the deeper insights of stop-loss experts immersed in this field is important.

In Action: Zolgensma® Case Study

In April 2023, a newborn was diagnosed with Type One Spinal Muscular Atrophy within days of birth. The Zolgensma® gene therapy was approved by the health plan and administered within a week of life. An $800,000 specific deductible was in place for the impacted group, and both the plan and stop-loss carrier were made whole through Amwins Gene Therapy Solutions. Aside from the financial benefits realized with a cost-containment program, today, the child is crawling, walking, talking and eating — all of which would have been impossible without access to life-changing therapy.

Gene Therapy Pipeline (2024 Only)

Cell Therapy & Manufacturer	Condition	Current Treatment*	Actual Approval Date**
Amtagvi™ (lifileucel) Iovance Biotherapeutics	Metastatic melanoma	Surgical excision, removal of affected lymph nodes, chemotherapy, radiation, checkpoint inhibitor immunotherapy or targeted therapy drugs, TIL therapy	Approved 2/16/2024 $515,000
Breyanzi (lisocabtagene maraleucel; liso-cel) Bristol Myers Squibb	Chronic lymphocytic leukemia Small lymphocytic lymphoma	Targeted therapy, chemotherapy, HSCT, CAR-T therapy	Approved 3/14/2024 $487,477
Abecma – Third line Bristol Myers Squibb/BBB	Multiple myeloma	Chemotherapy, HSCT, surgery, radiation or combination of these options, CAR-T therapy	Approved 4/4/2024 $498,408
Carvykti – Second line Janssen/Legend Biotech	Multiple myeloma	Chemotherapy, HSCT, surgery, radiation or combination of these options, CAR-T therapy	Approved 4/5/2024 $522,055
Gene Therapy & Manufacturer	**Condition**	**Current Treatment***	**Actual Approval Date****
Casgevy™ *ex-vivo* (exagamglogene autotemcel; exa-cel) CRISPR/Vertex	Transfusion-dependent beta-thalassemia	Chronic blood transfusions, HSCT, chelation therapy, *Ex-vivo* gene therapy	Approved 1/16/2024 $2,200,000
Lenmeldy® *ex-vivo* (atidarsagene autotemcel; OTL-200) Orchard Therapeutics	Metachromatic leukodystrophy	HSCT, *ex-vivo* gene therapy	Approved 3/18/2024 $4,250,000

**Current Treatment here is only a general categorization of generally published and known alternatives and does not reflect every individual situation.*

***Approximate approval dates and cost estimates are based on publicly available data at the time of this publication.*

Carrier Insights

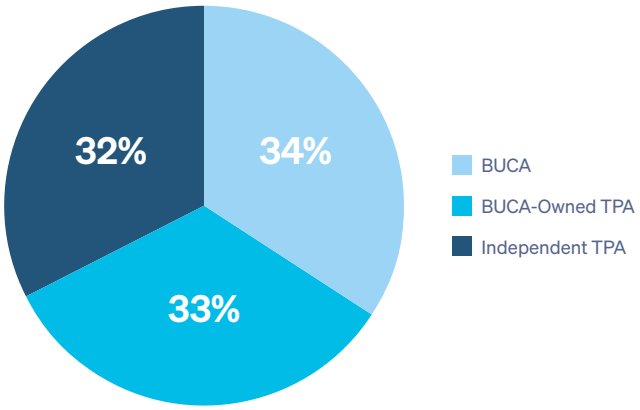
This year, our experts interviewed a group of well-recognized carriers to gather insights for this report. Respondents' blocks of business range from $165M to $660M of written premium with average combined group sizes between 200 and 2,000 lives.

In general, carriers remain highly focused on leveraging data, prescription drug management, cost-containment strategies and alternative self-funding solutions to build appropriate employer programs and address broker priorities. Carriers are also adding features such as step-down deductibles or integrating access to Centers of Excellence to differentiate policy provisions.

Cell and gene therapies pose continued, widespread concern for carriers. While the impact of biologics on rates and groups is not yet completely understood, carriers do know that as more therapies come to market, the pool of eligible patients will grow. Carriers are actively investing in underwriting personnel and tools to be as thorough as possible.

Omnipresent data-access challenges exist whether a group is small and fully-insured (with no data) or covered under a large, BUCA (Blue Cross and Blue Shield, United Health Group, Cigna and Aetna) bundled arrangement in which only selected information is shared. The debate of who "owns" the data vs. who "houses" it is ongoing. Brokers should become comfortable applying pressure as needed to get the information required to make sound decisions.

Self-Funded Administration



Key Takeaway

When it comes to choosing self-funded administration, groups tend to be evenly distributed between three categories: BUCA ASO (Administrative Services Only), BUCA-owned TPA (Third Party Administrator) and Independent TPAs. Groups that select BUCA ASO tend to be larger in size — 60%+ of groups are 1,500 employees and larger. Groups selecting an Independent TPA tend to be much smaller in size — nearly 60% are under 100 employees.

Renewals and Retention

Ranges in spreads have become so wide, multiple rounds of rate shopping are common. Competing on stop-loss rates alone is becoming increasingly difficult. While cost will always be a significant factor in decision-making, brokers can differentiate themselves by demonstrating knowledge, offering innovative products and delivering unique pricing strategies.

The combined premium and group renewal retention rates of our carrier partners sits between 70% and 75%. It is important to note that offering a renewal without any rate increase is a common, but short-sighted, tactic to retain business. General costs of doing business in any sector rise, mostly predictably, each year. However, annual rate increases do not solely correlate to a group's claims activity (or lack thereof). This common misconception continues to derail otherwise simple renewal discussions.

Stop-loss carrier growth goals are a bit more varied, ranging between 6% and 10% target year-over-year. Our experts indicate a 6% to 7% growth rate to be most realistic.

Requests for early locks (greater than 90 days) are increasing, and some may be available for up to 150 days. An increase in claim activity at the end of a plan year is almost a guarantee; early locks lessen the risk of large claims impacting renewal negotiations.

Sales and underwriting philosophies — and varying reliance on manual or experience — differ widely from carrier to carrier.

Pricing Strategies

A majority of carriers' business continues to be driven by brokers and general agents while a handful are reporting success with key, strategic TPA partners. Effective cost-containment strategies include reference-based pricing, specialty vendor carve outs, gene and cell therapy solutions and high-cost claims review. Prescription drug-focused solutions have promise but, without true transparency and usable data, quantifying and explaining the overall impact is challenging. In response, vendors are sprouting up to assist with data acquisition.

Regional awareness will continue to set carriers apart. Health systems, member needs and related regional nuances vary widely by geography. For example, a carrier experienced and invested in the Pacific Northwest marketplace can leverage that knowledge and justify its underwriting to be more competitive. A carrier with most of its business on the East Coast will likely struggle to deliver a strong proposal courting that same client.

Integration and Use of Artificial Intelligence

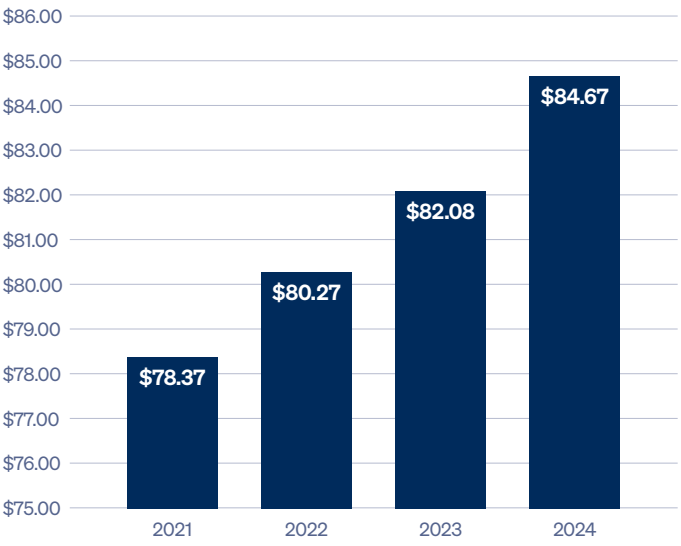
Carrier use of and appetite for Artificial Intelligence (AI) remains mixed. Some are using group-level scoring to vet cases with limited or no data, acknowledging individual-level reporting is still a work in progress. Privacy laws and compliance concerns compound the issue, but AI vendors are investing resources to improve over time. Carriers not actively using AI currently cite either general skepticism of the technology, concerns about bias, lack of trust in AI-generated recommendations or fear of misuse. Like any other technology, AI is a tool, not a silver bullet.

Benchmarking Data Derived from Stealth's Book of Business

45	30	18	300
Carriers/Markets	National Producers	Locations	Employees Nationwide

The following data from Stealth's book of business is provided as a benchmarking tool for brokers to compare similarly situated groups and assist employers in determining which stop-loss solutions will most appropriately balance risk, cost and protection. Stealth's independent nature and depth and breadth of partners — direct writers, BUCAs, niche MGUs and Amwins-owned proprietary markets — allow for a broad and unbiased view of industry trends.

Stop-Loss Premium PEPM Over Time

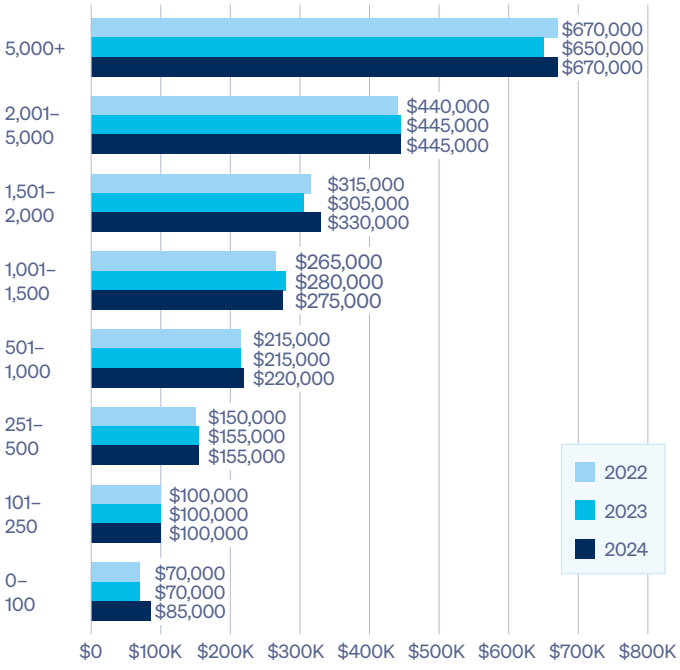


Key Takeaway

The average increase in premium PEPM is about 2%. However, groups of larger size that tend to select higher deductible levels experienced above average increases.

Note: These amounts are not normalized for market and reflect changes in book of business, deductible, and/or lasers, etc. PEPM has been normalized for group size.

Average Specific Deductible by Group Size / 3-Year Look Back



Key Takeaway

Overall, the average specific deductible remained relatively flat year-over-year. This reflects a similar pattern from last year.

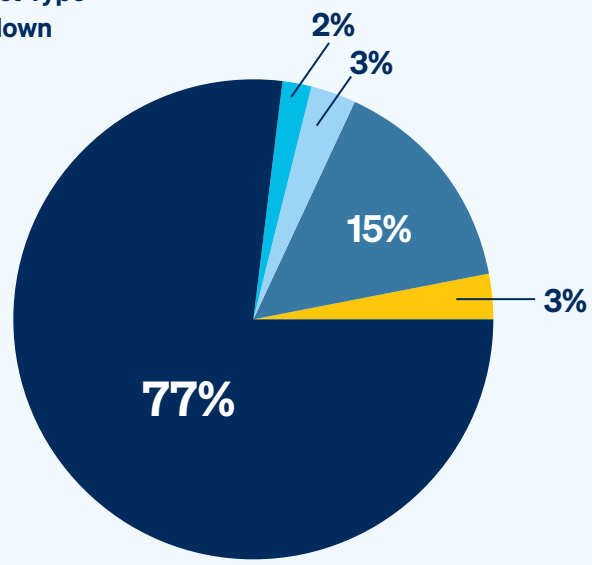
Percent of Cases Electing Aggregating Specific Deductible and Corresponding Premium Decrease

	2023	2024
% Elected Aggregating Specific Deductible	27.9%	27.9%
% Premium Decrease	16.8%	17.2%

Key Takeaway

Overall, similar to last year, a consistent number of groups elected aggregating specific deductible. The prevalence of aggregating specific deductibles is consistent across all levels, indicating it is a risk and cost mitigation solution employed by groups regardless of size or specific deductible.

Contract Type Breakdown



Key Takeaway

Compared to our 2023 State of the Market report, the distribution by contract types remained consistent, with most contracts sold on a paid basis. Paid contracts are typically attributed to more mature groups that require continuation in coverage without gaps.

Percent by Group Size that Purchase Aggregate Coverage

	% of Cases with Aggregate Coverage		
Group (EE) Size	**2022**	**2023**	**2024**
0-100	86%	87%	85%
100-250	86%	86%	87%
250-500	71%	75%	78%
500-1000	64%	65%	66%
1000-1500	45%	44%	44%
1500-2000	44%	52%	46%
2000-5000	15%	12%	18%
5,000+	12%	12%	7%

Key Takeaway

Claims predictability naturally increases as the number of employees in a group increases, so larger groups are more willing to forgo aggregate coverage. Consistent with recent years, the majority of groups with less than 1,000 employees do elect aggregate coverage.

Note: While it may look odd to see any groups of more than 5,000 employees with aggregate coverage, some entities (like school districts or state organizations) are legally required to purchase aggregate coverage. Some states also require entities to elect aggregate coverage. While catastrophic claims risk is an increasing concern even for those large groups, unless legally obligated, very large groups are still not purchasing aggregate coverage.

Strategies to Address Cost

Cost-Containment Solutions

Cost-containment programs fit hand-in-glove with self-funded plans. The challenge with the current cost-containment model is not lack of choice — as offerings have multiplied in recent years — but rather knowing how to separate the signal from the noise.

The amount of information and technology at stakeholders' fingertips is exciting. From a risk management and underwriting perspective, the ability to make shared decisions is as good as it's ever been. Yet, no matter how well anyone may "know" a population base or geographic market, no one can perfectly predict a premature baby, kidney disease or cancer diagnosis.

Condition-specific cost-containment solutions will continue to evolve and expand. Widely adopted dialysis carveout programs are generally understood across the industry, but cell and gene therapy cost-containment programs may require brokers to spend more time becoming educated on risks and costs.

Information-gathering is par for the course in a broker's world, and acting with prudence, diligence and care is an ERISA requirement. But trying to gather a deep, unbiased understanding of many moving parts can quickly become overwhelming. While brokers should do their own research, they can also tap into industry leaders and subject matter experts who know the ins and outs of stop-loss as to not go it alone.

Alternative Risk Programs and Captives

Traditionally, fully-insured plans were believed to be the only manageable option for small to mid-sized groups. Even today, despite countless successful examples of self-funded transitions, perceptions and fears still exist surrounding risk, barriers to change, lack of reporting and more. Savvy consumers understand the benefits of self-funding, though, and are intent on finding a route to get there.

Alternative risk programs and captives both pave an incremental path towards self-funding.

An effective vehicle to obtain new business, captive arrangements allow employer groups to leverage the stability and cashflow protection of stop-loss solutions while protecting against risk. A captive is also built to address minimal visibility into the member utilization and claims data needed to make informed decisions, a typical roadblock.

Captives can provide turn-key strategies and leverage the law of large numbers to gain purchasing power, lower administrative fees, more reliably predict outcomes and diversify risk. When done correctly, captives can outperform commercial markets and produce extremely competitive returns.

While a robust, custom stop-loss captive is not a cost-containment program, it does offer greater access to specialty programs and cost-containment solutions that benefit both the consumer and the broker. However, the captive space is more saturated than ever and not all captives are created equal. Many lack transparency — sliding across the line with hidden fees — and some may lock in groups for longer periods of time. Captives are complex, requiring more time and attention to build. However, the right partner can provide invaluable perspective and deliver an effective, functional and transparent structure. In many cases, the effort pays off.

In Action: More than 30,000 members have benefitted from Stealth's alternative risk programs since 2022. They are a sensible choice for certain industries, and the municipal sector is worth highlighting in this report. One $26M municipal program in a captive structure finished its first year in July 2023. Based on performance, $2.8M in premium was returned to the municipalities.

Level Funding

Level funding is commonly touted as a strategic approach to exiting the fully insured space and as a bridge to self-funding. The percentage of all small firms on level funded health plans rose to 38% in 2023, a slight increase of 3% compared to 2022, but a notable jump from the 6% workers covered by a level funded plan in 2018[6].

Level funding does place some data and claims information into the hands of decision makers. Newly gleaned insights can help stakeholders analyze the conditions prevalent within a group and market and provide a clearer understanding of risks and costs. When claims are lower than expected, surplus claims payments may be refunded at the end of the contract, making level funding an attractive solution for many groups.

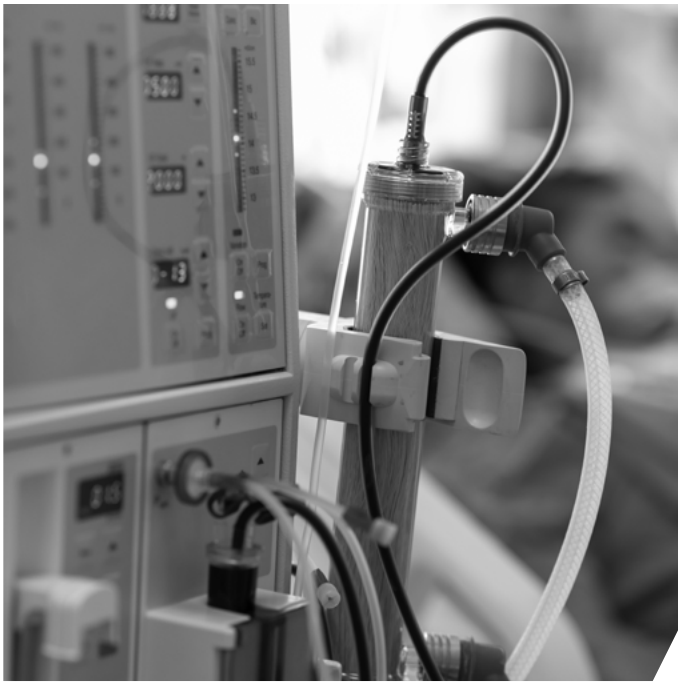
Dialysis Programs

Kidney disease and the long-term medical expenses to treat — not cure — can wreak havoc on an employer's health plan. An estimated 15% of adults in the U.S. are living with some level of chronic kidney disease and more than 800,000 people are coping with end-stage renal disease (ESRD). Dialysis care for an individual on Medicare was last estimated at $82,167 annually[12] — a far cry from the $100,000 per month, or even up to $2M annually, a self-funded plan may be charged for the same dialysis treatment administered by the same provider.

More than 15% of U.S. adults, over 37 million people, are estimated to have Chronic Kidney Disease (CKD).[12]

Experts do not believe the limited number and highly concentrated regionalization of for-profit dialysis providers will shift anytime soon. And with more than 100,000 new ESRD diagnoses each year, the need and demand for dialysis will continue to grow. However, self-funded employers can deploy programs focused on reducing the frequency of kidney disease and ensure members are aware of all treatment options.

A strong dialysis management program proactively identifies at-risk members and pairs them with a knowledgeable case manager. Together, the case manager and patient can explore safer, better options than initiating dialysis. When dialysis case management is coupled with a robust re-pricing methodology, employers can reduce their costs up to 85% or more on billed charges, including all program fees and costs.



In Action: A large hospital system struggling with escalating dialysis claim costs implemented Amwins Dialysis Management Solutions (DMS). Although the client had nearly 10,000 employees, efforts to negotiate reasonable rates or discounts from the local dialysis provider were not successful. Since implementing the DMS program, the average annual claims cost per patient has decreased from roughly $850,000 per patient, per year to about $133,000, a net cost savings of 84%. To date, the client has saved over $25M off billed charges.

Patient Assistance Programs (PAPs) and Medical Assistance Programs (MAPs)

PAPs and MAPs can enable cost-savings opportunities for some employer groups. These programs are meant to provide financial assistance or free medication to individuals who cannot afford the cost of their prescribed drugs. Eligibility criteria will vary, but factors such as income level, insurance status and specific medical conditions are core considerations. Program administrators typically facilitate the application process, and patients may receive discounted or free medication directly from the program or through a participating pharmacy.

However, the downside of so many options emerges when disparate programs are pieced together. Program overlap, even when unintentional, can result in unnecessary costs, gaps and unexpected exposures. Brokers must review proposals in detail and should lean on independent experts like Stealth to dissect, understand and report on program results.

Best Practices

There is no one-size-fits-all approach when designing a comprehensive and cost-effective employer health plan, and brokers are challenged with becoming a Swiss Army knife of sorts. Stop-loss may be a small part of the larger plan design, but it can deliver a distinctive competitive advantage for U.S. employers when deployed effectively. Here are a few of our most commonly recommended best practices.

Preventing Stop-Loss Claims Denials

Denial of a health claim is incredibly frustrating. Understanding the top reasons for stop-loss claim denial — eligibility issues, unintentional omissions and/or failure to properly administer leave — will help ensure clients are adequately advised.

In the Stealth block of business, less than .01% of stop-loss claims are denied when facilitating claims.

Plan sponsors must properly document member eligibility, continuation of benefits language and leave of absence policies within the plan itself or in an employee handbook. Along with documenting member eligibility, groups should conduct thorough and timely dependent eligibility audits. A robust, technology-driven verification process can eliminate the burden of manual validation and proactively identify ineligible individuals prior to the date coverage is issued.

Integrating cell and gene therapy language into plan document wording is also highly recommended.

Our audits reveal that 3% to 6% of dependents are not eligible for the benefit programs they are enrolled in. When removed, an employer saves an average of $5,000 per dependent per year in fixed costs.

Language must be crystal clear and detail exactly when coverage is and is not available. Documentation must include the dates coverage begins and ends, including specifications for leaves of absences, COBRA, maternity and paternity leave and FMLA to name just a few critical components. Mandated leave policies vary from state to state, and brokers must stay aware of any changes in their region. Stealth provides a high-level eligibility reference guide for brokers to address best practices in full detail.

Requesting Plan Mirroring

Stealth's experts consistently recommend ensuring the stop-loss policy follows the underlining Plan Documents, also known as plan mirroring. Mirroring can resolve conflicts between covered expenses outlined in the health plan document and the limitations/exclusions specified in the stop-loss contract. Ideally, the stop-loss carrier should defer to the plan document and honor eligible claims under its terms. Brokers may need to request plan mirroring.

Ensuring Adequate Run-In and Run-Out Provisions

Complex claims take longer to adjudicate, particularly those from large network providers. Underlying plan documents often stipulate a 12-month submission window and network agreements allow providers up to a year to appeal reimbursement decisions. To avoid gaps in coverage, a 12-month run-in or run-out clause can be put into place and/or paid or gapless coverage can be negotiated.

An appropriate contract will minimize the risk of claims falling through the cracks and align with the trend of industry-wide extended timelines. While some clients may opt for shorter runways of three or six months, the potential pricing implications (ranging from 3% to 6%) are a minimal tradeoff for adequate coverage duration.

Anytime there is a stop-loss carrier change, it opens the potential for a gap in coverage. Brokers have the power to educate through each transaction, and the ideal recommendation will depend on client needs.

Building Effective Plans

Staying informed about stop-loss trends and complementary solutions for the self-insured market — even at a high level — is crucial. Every broker should be thinking about the myriad of solutions they can present to their client this year. Avoiding an increase in premium should not be the goal; the goal should be delivering creative solutions to help a client save money and mitigate risk.

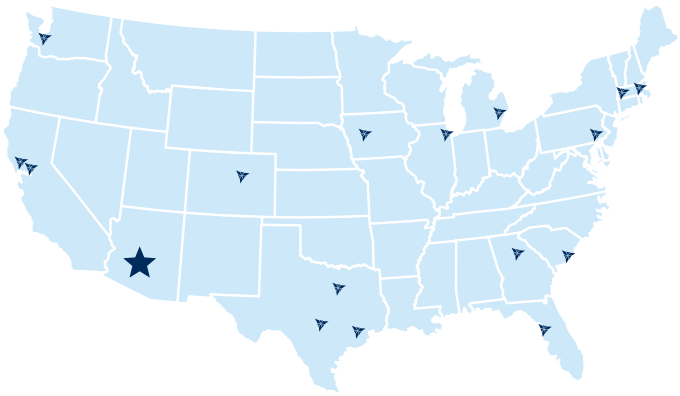
Making time to thoughtfully build tailored, client-focused solutions and structures with innovative, niche partners and forward-thinking stop-loss experts can differentiate a broker in the current cluttered market.

Stealth: Bringing Best-in-Class Expertise to You

Plan design traditionally has been based on historic claims data unique to each employer. While the core health conditions contributing to billions of dollars in stop-loss claims — such as kidney disease and dialysis, hospitalizations, cancers, transplants and premature births — will continue to be consistent drivers of high-cost claims, new and emerging variables in this report (such as widespread challenges in the existing health system, high-cost specialty drugs and novel therapies) will pose challenges for actuaries, carriers, brokers and their clients.

Critical nuances such as geography, culture and expectations of each group also play into developing effective coverage plans. There is much to know, and brokers are obligated to ensure their clients have the guardrails in place now to protect against the myriad of unknown risks ahead.

Stealth's independent, third-party experts bring unmatched knowledge and expertise within the dynamic stop-loss marketplace. We also offer a synergistic suite of group benefits programs and products through our ancillary division. As a company, Stealth is committed to strengthening productive, long-term partnerships with brokers and consultants who are similarly determined to deliver strategic, competitive and valuable solutions to clients at every turn.



#1 Largest Stop-Loss Wholesale Broker	**$1.85B+** Premium Placements	**300** Employees Nationwide	**30** National Producers
2M Lives Covered	**2,500** Groups	**45** Carriers/Markets	**18** Locations

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