QBE

Accident & Health Insurance

Market Report

2024

Get the peace of mind and support it takes to self-fund your *healthcare*

Exploring topics like:

- Medical stop loss claims trends
- Specialty pharmacy pricing innovations
- Popular weight loss drugs

Enabling a more *resilient future*

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Table of *contents*

Tara Krauss
Head of Accident & Health • QBE North America

I'm excited to present QBE's annual Accident & Health (A&H) Market Report. Our 2024 report explores the current trends in healthcare spending to provide valuable insights for employers who offer self-funded health plans. We also examine industry insights and developments from our own claims data.

If you turn on the television, read the daily headlines or glance at the advertisements at your wellness center check-in counter, it's no secret that the latest buzz in the healthcare space is around weight loss drugs. In fact, most of us can likely sing the jingle to one such drug that's now being prescribed off label. Thus, we decided to take a serious look at the use and efficacy of this class of drugs, specifically GLP-1 medications. We review the pros and cons of such usage and more specifically, the potential claims impact on self-funded employer-sponsored health plans. This is an important topic to debate given obesity is a precursor to many of the top diagnoses that drive medical stop loss claims. With nearly 40% of the population being obese, the world is on a trajectory where more than half the global population will be classified as either obese or overweight by 2035 if prevention and support doesn't improve.[1]

In addition, we analyze specialty pharmaceuticals' prevailing proliferation and the cost variability, as these drugs continue to account for a growing share of health plan spending. Moreover, we continue the discussion around the expected growth in cell and gene therapies, offering the promise of treatment advances or cures, but at unprecedented expense to plan sponsors.

In today's environment of increasing and uncertain healthcare costs, well-positioned and executed medical stop loss coverage is an effective mechanism to create cost stability for employers. This report further illustrates how our industry-leading claims and clinical risk management teams come into play by helping to minimize financial loss.

Finally, we discuss what's happening here at QBE. We remain steadfast in our commitment to environmental, social and governance (ESG) initiatives. In addition, we continue to enhance how we monitor and analyze the industry to provide meaningful support and recommendations to broker partners and our shared customer community.

We hope this report provides useful information and insights to **help you successfully navigate the shifting healthcare landscape.**

Tara Krauss

[1] Opening Up on Obesity | Leader's Edge Magazine (leadersedge.com)

Executive *Summary*

The QBE 2024 A&H Market Report analyzes major trends and issues affecting the self-funded medical stop loss market over the past year, including:

- **Medical stop loss claims trends**
- **The rise of preterm birth rates**
- **New weight loss drugs: GLP-1 agonists**
- **Specialty pharmacy pricing innovations**
- **Cell and gene therapy advancements**
- **Legislative updates**
- **Medical stop loss captives**

Beginning with a look at **medical stop loss claims**, we review how the mix of claims change by deductible level as well as provide an analysis of stop loss reimbursements by cancer type, deductible and year. Our analysis of stop loss claims by frequency and severity provides further insight into the composition of claims.

Because preterm births often result in difficult birth experiences and high medical costs, we showcase concerns about the **frequency of preterm births rising as full-term declines**. Preterm birth rates increased 12% from 2014 to 2022 while full-term births declined by 6%. Results for each gestational age were similar across maternal age and race cohorts. QBE's stop loss claims analysis shows claims related to preterm births are among the highest average severity, further emphasizing the importance of cost-mitigation strategies.

Are weight loss drugs worth the hype?
Decide for yourself after we look beyond the headlines to see why new weight loss drugs, like Ozempic, Wegovy and Zepbound, have taken the healthcare world by storm and generated controversy. Known as GLP-1 agonists, there is much to be learned about their potential benefits and side effects that has not been widely covered by the media. Due to high demand around the world, these GLP-1 agonist medications are costly and in short supply.

We consider the challenges of **navigating the complexities of specialty pharmacy** and how to effectively implement the use of specialty drugs. Due to rising costs, an annual review of a plan's specialty drug prices under both pharmacy and medical benefits is critical to understanding potential drivers of inflation, so we also review key actions to manage these costs.

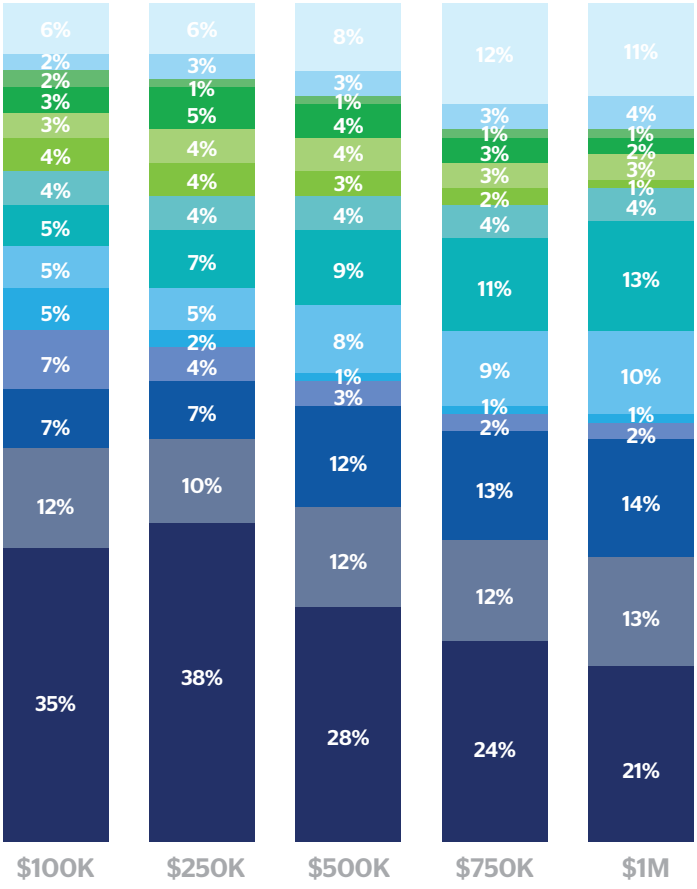
Next, we look at **strides in cell and gene therapy** to provide an update on the recent advancements, including five new gene therapies approved by the FDA in 2023. In the first five months of 2024, three new therapies have also been approved: Amtagvi, Lenmeldy and Breyanzi. Although treating cancer remains the top focus for emerging cell and gene therapies, successful cancer solutions are also inspiring efforts to treat metabolic, genetic and central nervous system disorders. Given the cost of such treatments, we discuss some of the unique drug payment approaches being considered to make future treatments more feasible.

We turn to Capitol Hill for a closer view of **legislative trends – is transparency around the corner?** As medical services and prescription drug prices continue to rise, the House of Representatives and the Senate are proposing reform for price transparency to control costs. Despite both being eager for change, Congress has failed to agree on language to move forward.

We also discuss the importance of connecting healthcare administrators and practitioners with policymakers to build a food as medicine mindset into our nation's healthcare strategy.

In **medical stop loss captives are here to stay,** we examine how they are being used to control costs and add value.

Medical stop loss claims: *observations and trends*



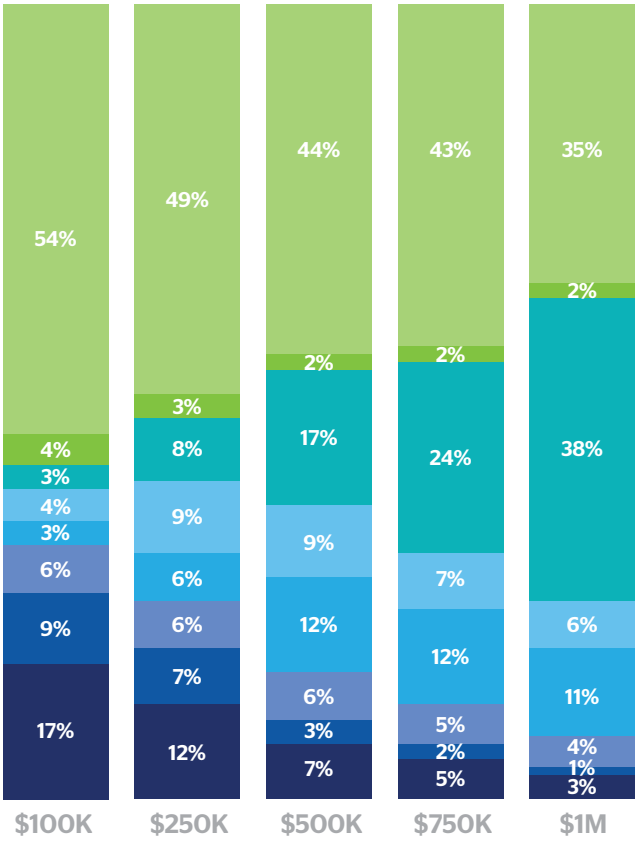
Stop loss claim reimbursements by primary diagnosis and deductible

- All other
- Diseases of the blood and blood-forming organs
- Mental illness
- Endocrine
- Infectious and parasitic diseases
- Diseases of the genitourinary system
- Diseases of the nervous system and sense organs
- Diseases of the respiratory system
- Injury and poisoning
- Diseases of the musculoskeletal system and connective tissue
- Diseases of the digestive system
- Certain conditions originating in the perinatal period
- Diseases of the circulatory system
- Neoplasms

QBE's analysis of stop loss claims (2019 – Q1 2023) by primary diagnosis illustrates how the mix of claims change for different deductible levels.

- Consistent with previous trends, neoplasms remain the top diagnosis for all deductible levels, with a smaller impact at higher deductibles.
- Preterm birth, respiratory diseases, and injury and poisoning related claims become larger drivers of overall claim costs as deductibles increase.
- For higher deductibles ($500K and above), fluctuations are expected due to the impact of large claims.

Stop loss claims include both medical and drug claims based on the member's primary diagnosis (inclusive of comorbidities).

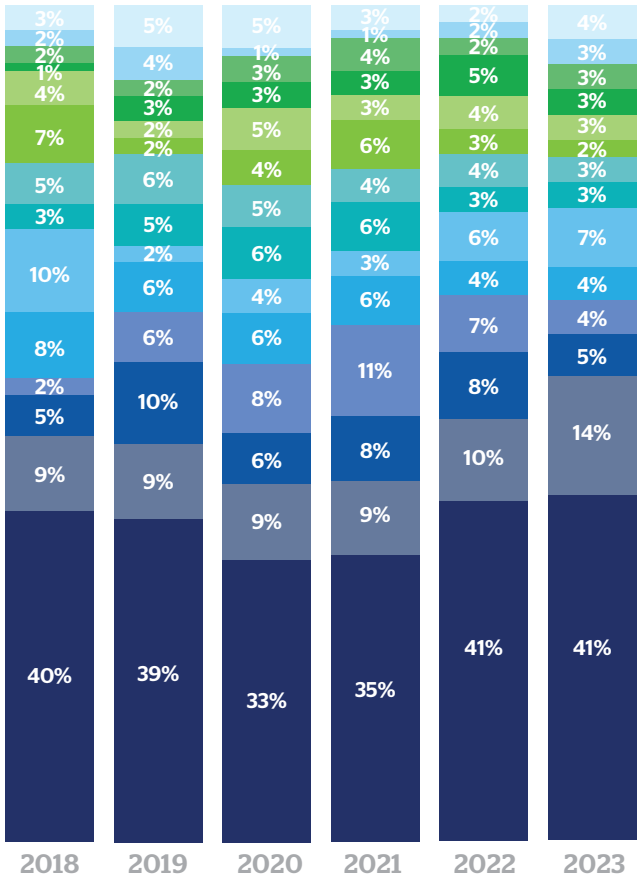


Stop loss claim reimbursements by cancer type and deductible

- All other
- Malignant neoplasm of brain
- Lymphoid leukemia
- Multiple myeloma
- Myeloid leukemia
- Lymphosarcoma and reticulosarcoma
- Malignant neoplasm of trachea bronchus and lung
- Malignant neoplasm of breast

As detailed in the above chart, types of cancer claims vary by deductible size. For example:

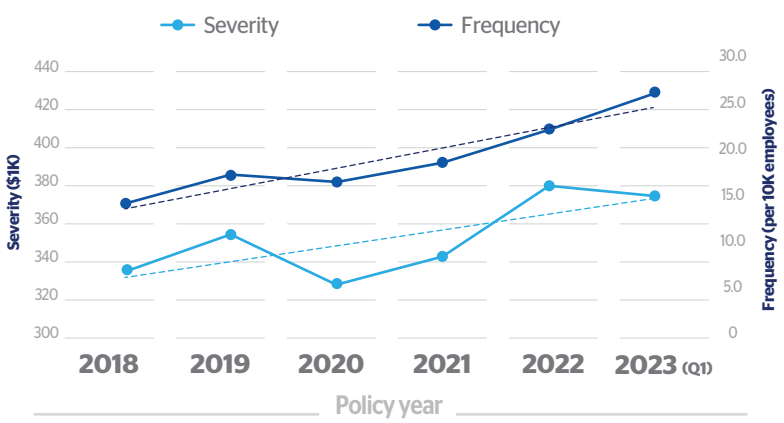
- Breast cancer accounts for about 17% of cancer related claims with a $100K deductible, but only 7% for a $500K deductible, and 3% for a $1M deductible.
- Lymphoid leukemia accounts for only 3% at a $100K deductible, yet 17% of cancer claims at a $500K deductible, and 38% for a $1M deductible.
- Specialty drugs have significantly driven up the treatment costs for lymphoid leukemia and multiple myeloma patients. According to a recent study conducted by Berkeley Public Health, many specialty cancer drug treatments, such as CAR-T therapies, multi-medication protocols and targeted therapies specifically contribute to the rising costs.[1]



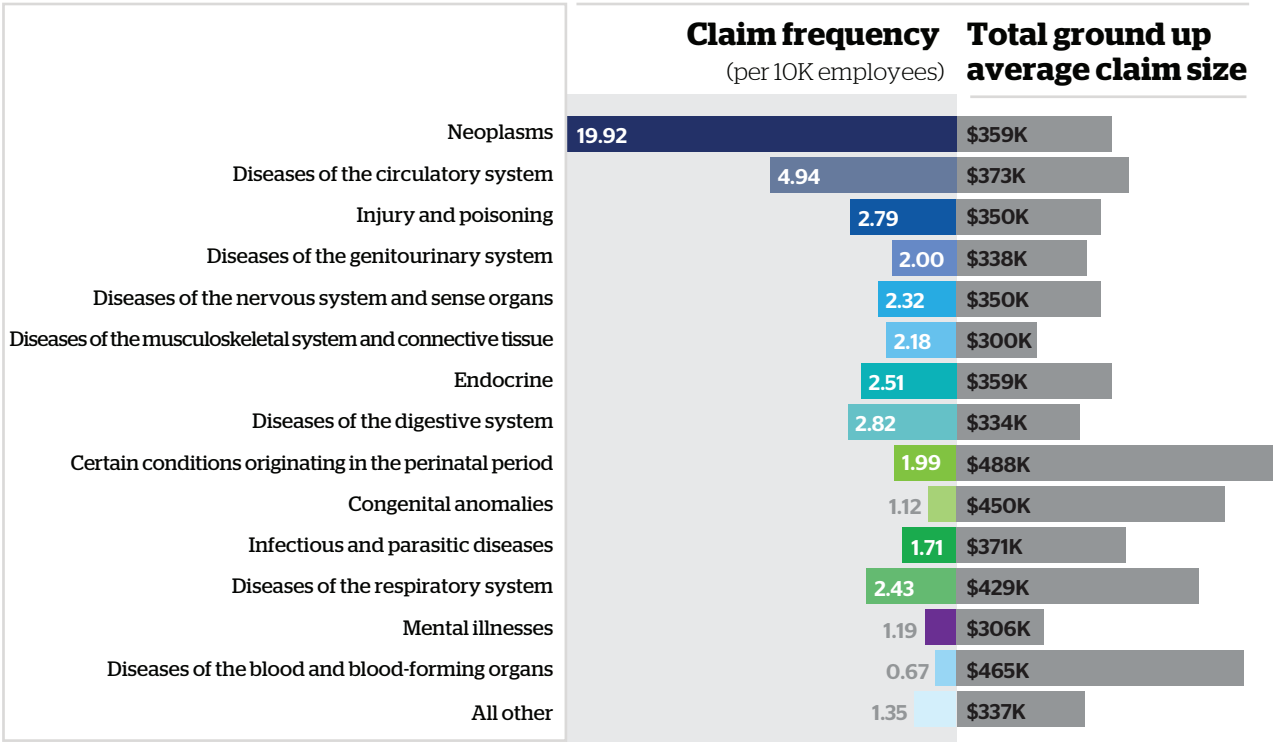
Stop loss claim reimbursements by year *($200K deductible)*

- All other
- Diseases of the blood and blood-forming organs
- Diseases of the musculoskeletal system and connective tissue
- Infections and parasitic diseases
- Congenital anomalies
- Diseases of the genitourinary system
- Diseases of the nervous system and sense organs
- Diseases of the digestive system
- Endocrine
- Injury and poisoning
- Diseases of the respiratory system
- Certain conditions originating in the perinatal period
- Diseases of the circulatory system
- Neoplasms

Neoplasms stop loss claim frequency/severity
($200K deductible)



QBE's analysis of stop loss claims over the last six years by primary diagnosis illustrates the mix of claims for $200K deductibles. While the mix of neoplasms remain consistent with 2022, claim frequency has increased significantly, with an offsetting reduction in severity.



*Claim frequency based on underwriting years 2019 – Q1 2023 for a $200K deductible size; claims include employees and dependents.

Analyzing stop loss claims by frequency and severity provides further insight into the composition of claims. For a $200K deductible, the number of members with stop loss claims per 10K employees (inclusive of dependents) and average associated ground-up claims are provided above. Consistent with prior observations,

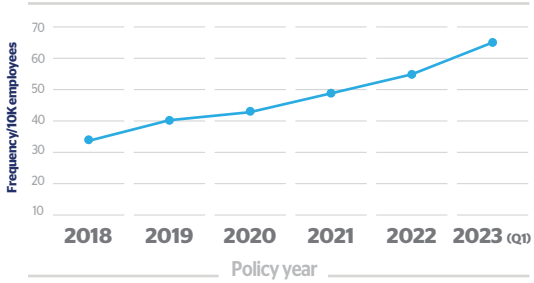
neoplasms continue to have the highest frequency, whereas premature births exhibit the highest severity.

The charts below plot the number of stop loss claimants exceeding $200K, per 10K employees (inclusive of dependents). Data reflects payments through February 2024. Key observations:

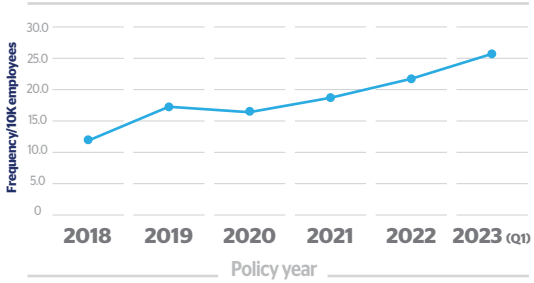
- The total frequency of claims continues to rise at an alarming rate for 2023.
- Neoplasm claim frequency continues to rise at greater speed for 2023.
- Mental illness claim frequency increased sharply in 2020, dropped in 2021 and rose in both 2022 and 2023, with substance abuse being the main driver. Depression and anxiety have also notably increased.

Claim frequency for members exceeding $200K in annual claims
(per 10K employees)

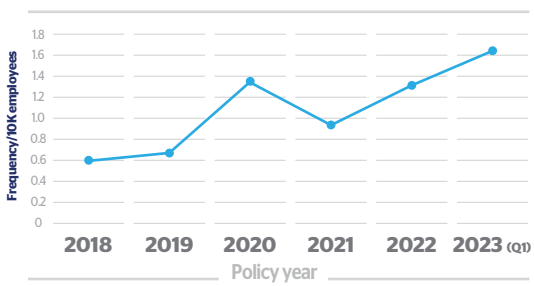
All conditions



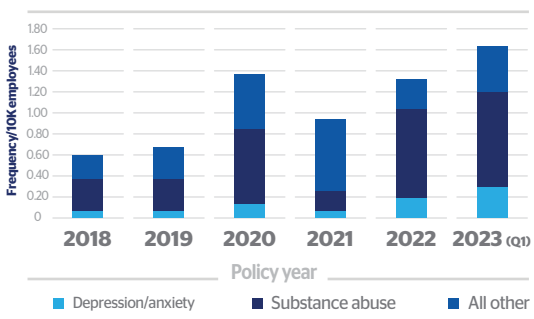
Neoplasms



Mental illness

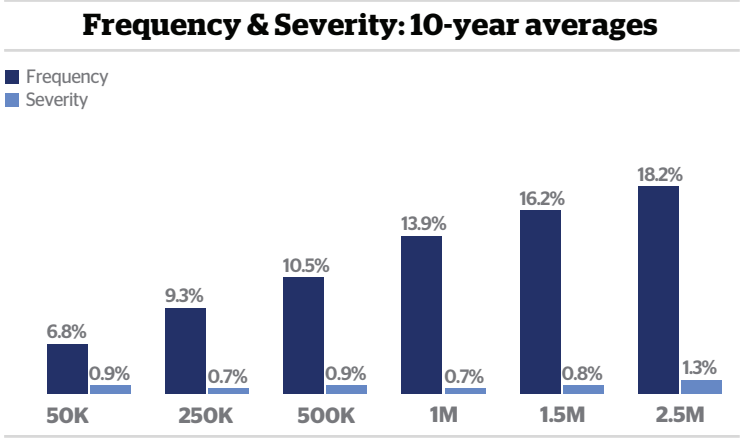


Mental illness by condition



The data from Aon Re's 2023 Market Report aligns with QBE claim trends showing a higher frequency of claims as deductible levels increase. As illustrated in the Aon Re chart below:

- **Claims frequency is the primary driver of medical excess trend**
- **Average severity trend is typically in the +/-2%**
- **While large claims continue to grow, the rising number of claims piercing into higher thresholds moderate the increases in average severity**



Frequency & Severity chart: Marketscan Commercial Claims Database provided by Aon Re in their "2023 Employer Stop Loss Market Report"

[1] https://vcresearch.berkeley.edu/news/study-shows-hospitals-impose-major-price-markups-cancer-and-other-specialty-drugs

Frequency of *preterm births* rise as full-term declines

Gestational age (period between conception and birth) is a strong predictor of morbidity and mortality among infants, with preterm (less than 37 weeks) births being the greatest risk for unfavorable outcomes.

Preterm infants continue to drive stop loss reimbursement claims across all deductibles. QBE's 2019 – Q1 2023 claims data found the primary diagnosis category of conditions originating in the perinatal period to be our third largest contributing disease category. Furthermore, the preterm birth group becomes our second largest cost category when the specific deductible reaches $750K and $1M. From 2014 to 2022, preterm and early term (37 – 40 weeks) birth rates have increased by 12% and 20% respectively, while full-term and late- and post-term

births declined by 6% and 28%, respectively.[1] The CDC reports that these shifts for each gestational age were similar across maternal age and race cohorts. This study showed that the most significant changes occurred in births at 37 weeks (about 8 and a half months) of gestation, which increased by 42% in this period.

Preterm births often result in difficult birth experiences and high medical costs. There are several factors that may contribute to preterm births, including maternal age, smoking, multi-gestation pregnancy, birth spacing, obesity, infection, comorbidities, chronic stress, lack of social support and socioeconomic status.[2] According to the March of Dimes, 35.8% of infant deaths in the U.S. are related to preterm births. Additionally, $25.2B in annual societal economic cost (medical, educational and lost productivity) can be associated with preterm births.[2]

Further, preterm birth can lead to short- and long-term difficulties with birthweight and gestational age contributing to both brief and prolonged complications. According to the Mayo Clinic, short-term complications can include difficulty breathing, heart problems, temperature control issues, digestive problems, anemia, newborn jaundice, metabolism problems and sepsis. Long-term complications can include cerebral palsy, difficulty learning, vision issues, hearing problems, asthma, behavioral and mental health issues, and feeding problems.[3]

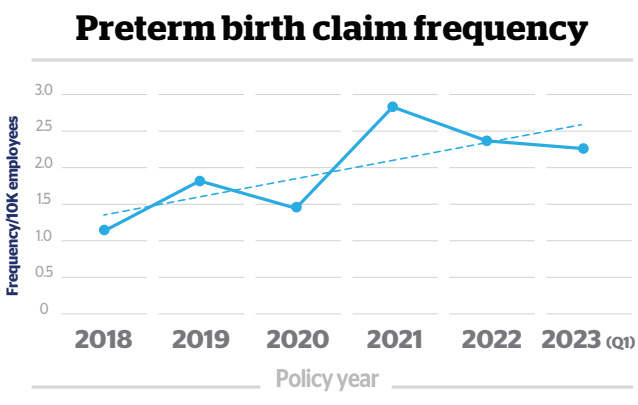
The chart below shows QBE's preterm birth data of claim frequency for members exceeding $200K in annual claims, per 10K employees from 2018 – Q1 2023. While preterm birth claim frequency fell on our block of business, as seen in the graphic, the overall frequency continues to climb. Our preterm frequency rates concur with the nation's higher percentage of preterm births. As reflected in the stop loss claims analysis, claims related to preterm births are among the highest average severity. This further emphasizes the importance of implementing cost mitigation strategies, such as the use of point solutions with a focus on high-risk pregnancies and leveraging medical stop loss coverage over a self-insured employer health plan.

Contributing factors to preterm births:

maternal age, smoking, multi-gestation pregnancy, birth spacing, obesity, infection, comorbidities, chronic stress, lack of social support and socioeconomic status

$25.2B

in annual societal economic cost *(medical, educational and lost productivity)* can be associated with preterm births.[2]



[1] https://www.cdc.gov/nchs/data/nvsr/nvsr73/nvsr73-01.pdf

[2] https://www.marchofdimes.org/peristats/reports/united-states/prematurity-profile

[3] https://www.mayoclinic.org/diseases-conditions/premature-birth/symptoms-causes/syc-20376730#:~:text=Premature%20babies%20are%20more%20likely%20to%20have%20long%2Dterm%20health,unclear%20reasons%2C%20often%20while%20asleep.

Are *weight loss drugs* worth the hype?

With more than 1B adults and children around the world now classified as obese, weight loss drugs have taken the healthcare world by storm and continue to generate attention. They've also created controversy since they're commonly prescribed off label and the impact of long-term side effects is still unknown.

The new drugs are in a class known as glucagon-like peptide-1 agonists (GLP-1 agonists). Originally developed to help manage blood sugar levels in patients with type 2 diabetes, an additional weight loss effect was discovered that had never been seen before with other diabetes medications. In fact, these drugs have demonstrated an average weight loss for patients of up to 15% when used in conjunction with proper diet and exercise.

As a result, GLP-1 agonists are now commonly prescribed for weight loss, and the market has become inundated with numerous types from which to choose, with several others in development. Ozempic, Wegovy and Zepbound are all examples of GLP-1 agonist medications. Prescriptions for these drugs skyrocketed 300% from 2020 – 2022[2] and sales of these drugs have exploded in North America alone, reaching $5B in the first half of 2023.[3,4]

Benefit consulting firms report exponential growth in claims and health plan costs related to GLP-1 agonist medications. The cost of GLP-1 agonist drugs can amount to an estimated $15K per year for each member receiving them. Some companies anticipate as much as a 55% increase in health plan costs per member from 2023 to 2025.[5]

Since 2021, the number of patients being prescribed this class of medications has grown exponentially and today they are highly sought after as a weight loss tool worldwide.

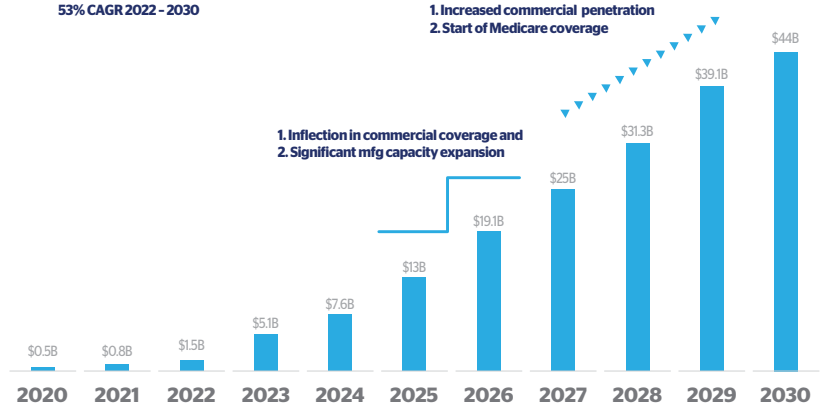
As shown in the chart below, JP Morgan research forecasts the obesity market and the associated appetite for weight loss drugs will be increasing at an alarming rate by 2030. Moreover, the study predicts "total GLP-1 users in the U.S. may number 30M by 2030 – or around 9% of the overall population."[6]

Rising use of novel obesity drugs

As of February 2024, there are nearly 700K GLP-1 agonist new prescriptions across diabetes and obesity, up **181%** compared to two years prior.[1]

A recent JP Morgan research study predicts "total GLP-1 users in the U.S. may number 30M by 2030 – or around 9% of the overall population."[6]

The U.S. obesity market is expanding rapidly



Courtesy J.P. Morgan Chase & Co., Copyright 2024. https://www.jpmorgan.com/insights/global-research/current-events/obesity-drugs

As a biproduct, there are economic factors that expand well beyond the healthcare market at play. Global snack food companies, such as the makers of Cheez-It and Pringles, are studying the potential dietary behavior changes these drugs could have on their business to "mitigate" a financial hit.[7] A potential positive outcome of this analysis would be changes to the formulations of snack food for the better. Furthermore, makers of medical devices used in weight loss surgeries and glucose monitoring are also studying the short-term and long-term impact on their sales projections.

GLP-1 agonist medications are also, in many cases, helping patients and their providers get additional comorbid conditions related to being overweight or obese under control. For example, Wegovy helps reduce cardiovascular events (like heart attacks and strokes), lower A1C levels (through the stabilization of blood sugar) and lower blood pressure and cholesterol levels. Following these findings, Wegovy received an expanded indication approval from the FDA for use in lowering the risk of heart attack, stroke and cardiovascular-related deaths in overweight or obese adults with heart disease.

Medicare now covers Wegovy under Medicare Part D, when prescribed to prevent heart attacks and strokes in patients with obesity and heart disease.[8]

Currently, it is uncertain how long a patient will need to stay on a GLP-1 agonist medication for long-term results, but it is believed to be several years, possibly for life, to avoid regaining most or all of the lost weight within a year of stopping the drug.[9,10] An important component to success is the drug being prescribed in conjunction with behavioral changes including eating a nutrient-rich diet, high in protein combined with an exercise regimen.

Because these are relatively new drugs, many benefits and side effects still remain unknown. 94% of the population is currently considered metabolically unhealthy and 2 out of 3 adults are classified as overweight, 42% of whom are considered obese. Further, 20 – 25% of young adults now have fatty liver disease, 50% are classified as overweight and 33% are considered pre-diabetic.[11] Given these grave statistics, it does present a case for the use of GLP-1 drugs. There are a multitude of advantages, especially for someone classified as obese with comorbidities.

94%

of the population is currently considered metabolically unhealthy and 2 out of 3 adults are classified as overweight,

42%

of whom are considered obese.

Potential advantages:

- Control blood glucose
- Lower blood pressure and cholesterol
- Facilitate weight loss
- Improve cardiovascular outcomes
- Reduce stroke risk
- Beneficial effects on the kidney and liver

There are also benefits related to reducing the risk of heart disease, heart failure, stroke and kidney disease.[6] As such, there is potential to significantly reduce the use of the many other lifestyle drugs we see overly prescribed today, such as statins and beta blockers.

It's important to note that the drug should be prescribed responsibly with doctor oversight. It should be combined with behavioral changes, including a shift away from ultra-processed food to a nutrient-rich diet, combined with an exercise plan, most specifically strength training since those losing weight are at particular risk of losing muscle mass. Moreover, given GLP-1s are comprised of peptide signaling hormones that are otherwise naturally produced in the body, there is evidence that at low dose, they can have a healing component that inhibits appetite.[11]

Potential disadvantages

Patients should be made aware of all potential side effects prior to prescribing or taking these medications. A benefit versus risk analysis needs to be completed, unique to each patient's profile. Serious side effects or complications are possible for many patients at today's therapeutic dose.

Potential side effects:

- Nausea (up to 80% of users)[11]
- Vomiting (up to 30% of users)[11]
- Abdominal pain
- Diarrhea
- Pancreatitis
- Gastroparesis
- Medullary thyroid cancer (black box warning)
- Altered fertility/unplanned pregnancy
- Fetal risk

Other factors contributing to long-term compliance:

- Short supply due to high demand
- High cost ($15K+ per patient annually)
- Interruptions to treatment based on side effects
- High likelihood of weight gain when discontinued[12]

Side effects like nausea, vomiting, abdominal pain and diarrhea can cause patients to stop therapy due to the inability to tolerate it. More severe, and potentially life-threatening side effects, such as pancreatitis (inflammation of the pancreas) and gastroparesis (a slowing/paralysis of the gastrointestinal tract) can also be experienced.

Recently, class-action lawsuits have been filed against some drug makers on behalf of patients who suffered severe and ongoing complications, such as gastroparesis, despite discontinuing the medication.[12] There is also a possible link to the development of medullary thyroid cancer. All such conditions can lead to life-threatening complications which can result in hospitalization and the need for costly ongoing care.

GLP-1 use has also been shown to alter fertility. There are several reports of women becoming pregnant while using GLP-1 medications, despite being on birth control.[13] Currently, women are advised to stop treatment with these medications two months prior to planning to become pregnant. If a patient becomes pregnant while on the drug, it should be discontinued, and the patient should be advised of the risks to the fetus.[14,15,16]

Because of high demand around the world, GLP-1 medications are costly and in short supply. Consequently, patients often must interrupt treatment and go without them until supplies are replenished.[17]

Research to date reveals the medications' benefits such as reduced blood sugars, hypertension and cholesterol levels begin to reverse when the drug is discontinued. Additionally, most patients that stop taking the medication regain more than half and up to as much as three-fourths or more of the weight they lost while using the medication.[18]

Challenges to employer plans

The surge in use of GLP-1 drugs has created a major obstacle for employers: how to curb the cost impact to health plans. The cost to plans related to the drugs is rising exponentially, yet many employers indicate they will continue to cover the medications, as a robust benefit plan helps to attract and retain talent.

Tips for cost savings

Work with Pharmacy Benefit Managers (PBMs) or other vendors to implement any combination of the following:

- Develop a formulary of weight loss drugs that your plan will cover at optimal pricing.
- Perform step therapy solutions aimed at requiring participants to try alternative lower cost medications and treatments, such as a weight management program, prior to dispensing GLP-1 medications.
- Implement a comprehensive prior authorization program to ensure patients are medically approved for and meet criteria to be treated by these medications. This will also ensure the participant is well-supported in choosing the most appropriate treatment path.
- Require periodic re-evaluation to measure compliance with, and response to treatment as part of a prior authorization program, and consider discontinuing coverage for non-compliance or lack of response to treatment.

- **Consider accessing a limited network of providers or a center of excellence that specializes in weight loss treatments and gives oversight to participants receiving GLP-1 medications.**
- **Provide access to educational information around the benefits and risks of GLP-1 medications to ensure participants are well-informed about their treatment choices and the associated benefits and side effects.**
- **Consider limiting the dollar amount allowed for coverage of weight loss medications or increasing the participant's co-pay responsibility.**[19]

While new GLP-1 agonist medications offer potential weight loss benefits to users, which in turn help improve or prevent comorbid conditions, the prescriptions come at a high monetary cost and, for some, may result in severe side effects.

On the other hand, providers are reporting that while treatments may be costly, there's also a reduction in diabetes, heart attack and stroke, cancer, obesity and other serious conditions. A September 2023 National Institutes of Health (NIH) publication noted GLP-1 medications showed a significant reduction of 12% – 14% in cardiovascular mortality, non-fatal myocardial infarction (MI) and non-fatal stroke compared to placebo in patients with type 2 diabetes. The medications were also found to significantly reduce the risk of ischemic stroke in type 2 diabetes patients that also had cardiovascular risk factors.[20]

Illustrated by the obesity statistics provided below, we are amid a metabolic health crisis like never before seen. Furthermore, as previously shown in our claims trend analysis, frequency and severity of catastrophic claims continue to climb.

The 5 most expensive diseases to treat in the U.S. and the annual cost of treatment

https://healthadministrationdegree.usc.edu/blog/most-expensive-disease-to-treat-infographic

There are social, political and economic factors that drive expenses through our country's healthcare system, projected to hit $4.7T in 2023[21] and rising. According to a 2021 report from The Commonwealth Fund, the United States was ranked highest in medical care spend per capita, yet last overall across more than 70 categories, including access to care, equity and outcomes.[21]

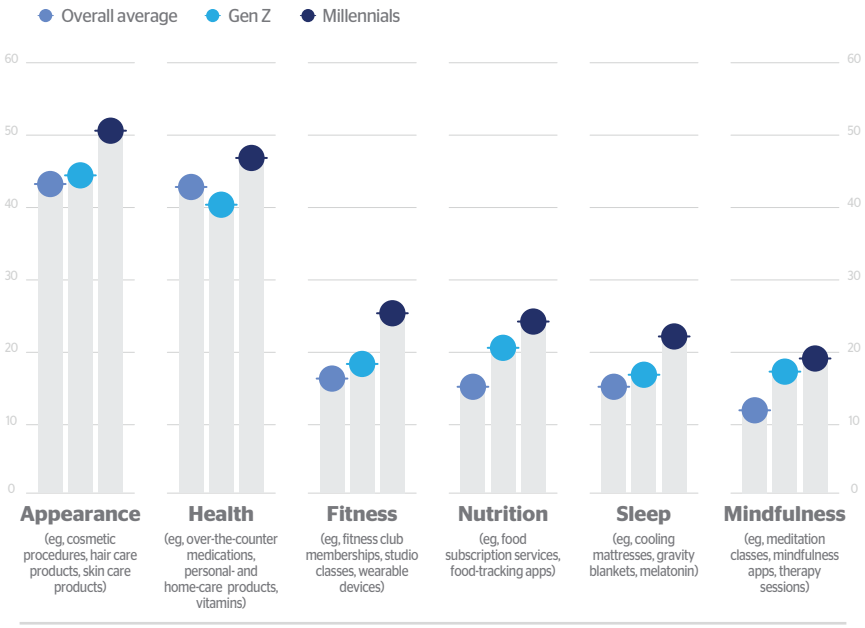
The U.S. will spend a projected **$4.7T** or **18%** of the national economy on healthcare in 2023.[21]

While the effects of long-term GLP-1 use are still unknown, there is a compelling argument for its usage under the right treatment protocol. While pharmaceuticals play a role in healthcare, a shift to holistic health supported by employers and a radical paradigm shift in our healthcare system seems to be the answer. Until then, GLP-1 is one adjunctive tool to what should be a comprehensive provider toolbox. With Millennials and Gen Z consumers spending more on health, is now the time for employer groups to take a hard look at a holistic approach to healthcare? One that's focused on stress reduction, exercise, a nutrient-rich diet, sunlight and proper sleep hygiene.

The increased spending on health and wellness products/services by the younger cohort (see chart below) illustrates a trend toward greater preventive care. In every category, Millennials outspend the overall average on products for beauty, health, nutrition, fitness, sleep and "mindfulness" (meditation, therapy services). Note that for every demographic, appearance products such as cosmetics, hair and skin care, or health products like vitamins and medications account for twice as much spending as fitness or nutrition. The findings indicate further general movement away from the reactive industry model of treating symptoms and illnesses toward a proactive holistic approach rooted in lifestyle changes and preventive care.

Millennial and Gen Z consumers are spending more on health and wellness than older consumers

U.S. health and wellness purchases, by product/service type and generation,[1] | % of respondents (n = 2,007)



[1]Average across all products in each category. Percentage of respondents who purchased at least once in past 12 months.
Source: McKinsey Future of Wellness Survey, Aug 2023

The top wellness trends in 2024 | McKinsey

[1] https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/the-use-of-medicines-in-the-us-2024
[2] https://www.beckershospitalreview.com/pharmacy/more-than-9m-ozempic-glp-1-prescriptions-written-in-q4-2022.html
[3] Popular weight-loss drug Wegovy now approved for heart disease. Here's what we know. | Live Science
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Navigating the complexities of *specialty pharmacy*

Prescription drug costs are the fastest growing expenses to the healthcare system. The median list price of a new drug in 2023 was $300K.[1] Specialty drugs are used to treat complex, rare or chronic conditions like cancer, hemophilia or autoimmune diseases, yet 1 in 3 U.S. adults can't afford them.[2] These higher-cost drugs may require supervision by a qualified healthcare professional in a physician's office, infusion center or other hospital-based setting, or can be self-administered at home. What's more, patients may need education about the administration of their medication and possible side effects, as well as close monitoring during treatment,[3] further adding to the cost.

Roughly half of specialty drugs are billed through the pharmacy benefit and taken orally or self-administered by the patient at home. These drugs can be managed by a PBM and are subject to a plan's drug formulary and prior authorization criteria.

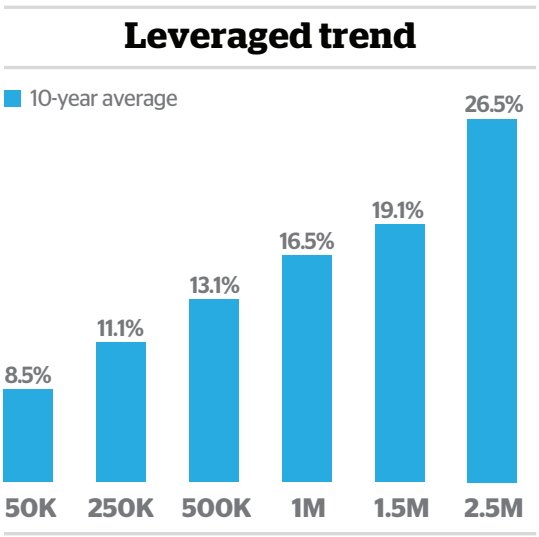
"The median annual list price for a new drug was **$300K** in 2023, according to the Reuters analysis of 47 medicines, up from **$222K** a year earlier."[3]

The remainder of specialty drugs typically fall under a plan's medical benefit and likely require an office or facility setting to administer. Drugs are billed after they are administered to the patient, thus avoiding any PBM formulary restrictions or prior authorization review.

According to a 2024 Reuters article, "Pharmaceutical companies last year launched new U.S. drugs at prices 35% higher than in 2022, reflecting in part the industry's embrace of expensive therapies for rare diseases like muscular dystrophy. The median annual list price for a new drug was $300K in 2023, according to the Reuters analysis of 47 medicines, up from $222K a year earlier."[3]

The PwC Health Research Institute projects a 7% increase in ground up medical costs in 2024 for both individual and group markets. The trend is higher than the projected increase in 2022 and 2023, which was 5.5% and 6%, respectively. Persistent double-digit pharmacy cost trends driven by specialty drugs and the increased use of GLP-1 agonist medications for weight loss and the treatment of type 2 diabetes are heavily influencing the trend.[4]

As it pertains to medical stop loss plans and the rising cost of specialty drugs, it's important for employers to consider the impact of 'leveraged trend,' which refers to the increased risk incurred by stop loss carriers due to inflation in medical costs. To plan for the increased risk and mitigate the impact of the leveraged trend, stop loss carriers often reduce the heightened exposure with self-insured employers by setting premiums yearly based on deductibles remaining unchanged. To offset leveraged trend and the associated higher premium, self-insured employers can choose to increase their specific deductible.



Frequency & Severity chart: Marketscan Commercial Claims Database provided by Aon Re in their "2023 Employer Stop Loss Market Report"

Effectively implementing the use of specialty drugs

Due to rising costs, an annual review of a plan's specialty drug prices under both pharmacy and medical benefits is critical to understanding potential drivers of inflation. Key considerations for cost management should include:

- Ensure formularies address the insured population's use of specialty drugs
- Highlight different drug tier classifications and copay options
- Review rebates and transparency concerns
- Determine the effectiveness of prior authorization for high-dollar drugs
- Encourage low-cost options within changes to benefit language
- Engage a pharmacy cost containment vendor when moving site of care

For optimal results, consider engaging a pharmacy cost containment vendor to help evaluate your specialty drug spend. They can also help develop a comprehensive benefit plan that will provide your insured employees with access to quality, cost-effective specialty prescription treatments.

Key measures employers can take to control pharmaceutical spend include:

- Explore PBMs offering transparent, pass-through pricing, charging a flat fee that eliminates hidden costs
- Seek PBM transparency around rebates and spread pricing – what type of rebates exist, how much and who receives the rebate?
- Meet with your PBM quarterly to review trends/expectations and new drugs hitting the market
- Offer benefits that incentivize addressing the root cause of illness, rather than symptom management

The lion's share of growth for pharmacy services from 2022–2027 is projected in specialty pharmacy and infusion services, accounting for $38B collectively. The category's highest growth subgroups are hospital specialty pharmacy managed services, hospital-owned specialty pharmacy and physician office/ambulatory site infusion, which are anticipated to grow upwards of 10% each. Pharmaceutical distributors/wholesalers are expected to increase by 5% and 10%, or $10B. The PBMs and administrators may rise to 5%, or $12B. The least movement will come from traditional dispensers, using mail and retail outlets, with little to no expected growth, or $10B.[5]

Pharmacy services will continue to see benefits from the growth of specialty pharmacy

Distribution of projected healthcare EBITDA across the pharma value chain (illustrative),[1] 2027, $B

2022 – 2027 growth rate, %
<0 0–5 5–10 >10

[1]Sub-segment numbers may not sum to segment total due to rounding.
[2]Excludes profit earned by PBM-owned specialty pharmacies and mail pharmacies, which is captured under central fill specialty pharmacy and mail respectively.
[3]Excludes specialty pharmacy (specialty dispensed through retail channels is captured under retail-based specialty pharmacy).
[4]Specialty pharmacy services outsourced to vendors such as Sheilds/Trellis.

Source: McKinsey Profit Pools Model

https://www.mckinsey.com/industries/healthcare/our-insights/what-to-expect-in-us-healthcare-in-2024-and-beyond

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[3] https://www.reuters.com/business/healthcare-pharmaceuticals/prices-new-us-drugs-rose-35-2023-more-than-previous-year-2024-02-23/
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Strides in *cell and gene therapy*

The world has seen exponential advancements in cell and gene therapy over the past two years. Five new gene therapies were approved by the FDA in 2023, including Casgevy, a next-generation gene-editing tool to treat those suffering from sickle-cell disease and beta thalassemia. Casgevy is the first-ever therapy to use clustered regulatory interspaced short palindromic repeats (CRISPR, for short). CRISPR allows geneticists and medical researchers to edit parts of the human genome by adding, removing or altering sections of the DNA sequence.

Lantidra, another one of the therapies approved in 2023, provides hope in the form of treatment for adults with type I diabetes who are unable to maintain average blood sugar levels. Lantidra brings the total number of FDA-approved cell and gene therapies to 33,[1] and the approvals don't appear to be slowing.

In the first five months of 2024, three new therapies were approved:

Amtagvi – the first and only single-infusion, individualized T-cell therapy, known as tumor infiltrating lymphocytes (TIL), also referred to as adoptive cell therapy, was approved for treating solid tumors associated with a specific genetic variant of metastatic malignant melanoma.

- Amtagvi has very specific criteria regarding the response to a PD-1 blocking drug and is the first cellular therapy used to treat a form of solid tumor cancer.

Lenmeldy – a new gene therapy recently FDA-approved for treatment of children with pre-symptomatic or early symptomatic metachromatic leukodystrophy, a rare genetic disorder affecting the brain and nervous system resulting in the loss of motor and cognitive function.

- Lenmeldy is used to treat a rare condition that affects roughly 40 children born in the U.S. each year and is expected to have a wholesale price of $4M.

Breyanzi – the expanded application of this CAR T-cell therapy was approved in March 2024 for chronic lymphocytic leukemia and small lymphocytic leukemia. Then expanded again in May 2024 for treatment of relapsed or refractory mantle cell lymphoma and relapsed or refractory follicular lymphoma.

- This treatment is used in patients that have had at least two prior lines of therapy with very specific disease characteristics.

Seventeen additional approvals are anticipated in the U.S. and EU in 2024.[2] Additionally, we may also see the first U.S. approval of an off-the-shelf allogeneic T-cell therapy this year.

More than 600 developers worked on cell and gene therapy initiatives in the U.S. in 2023, with nearly 2K active clinical trials and over $11.7B in total investments between the U.S. and EU. Approximately 10% of these projects are in Phase III, making it likely we will see upwards of 75 therapies approved before 2030.[2] According to GlobalData, the global cell and gene therapy market is projected to reach sales of $80B by 2029.[3]

Treating cancer remains the top focus for emerging cell and gene therapies. Successful solutions for cancer patients have inspired efforts to advance treatment options for metabolic, genetic and central nervous system disorders. As the leading driver of excess loss claims to plans, it's no surprise this is where research dollars are largely being spent.

According to GlobalData, the global cell and gene therapy market is projected to reach sales of $80B by 2029.[3]

While there have been incredible achievements and promising developments in some areas of cell and gene therapy, the field is not without challenges. The explosion of new therapies could create greater competition for manufacturing capacity, which could result in higher costs to patients and even a scarcity of treatments for those in need.

Reasonable access will continue to be a major hurdle, largely due to the astronomical costs of production. Many therapeutics range in price from hundreds of thousands to millions of dollars and can only be delivered by centers of excellence, which can be found very far from patients in need.

To help combat the issue, the Global Gene Therapy Initiative has proposed the idea of place-of-care biomanufacturing to reduce cost and improve accessibility.[5] Beyond that, challenges presented by cell and gene therapies include ensuring product consistency, addressing quality control issues, and reducing delays in FDA approval. For patients, there may be formidable future ramifications from treatment, including life-threatening immune responses and secondary cancers.

The financial impact on healthcare payers is not to be overlooked, as the limited market size for these therapies will ultimately drive up their costs. Many unique payment approaches from traditional drug pricing are being considered to make future treatments more feasible. Risk pools, reinsurance, price-volume agreements and outcome-based contracting, in which reimbursement is tied to the treatment's efficacy, can help with the treatment costs. Another approach is partnering with a specialty pharmacy who can achieve greater savings by purchasing directly from the manufacturer. An added measure is to institute global price regulation, but none comes without administrative, regulatory and logistical hurdles.

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Legislative trends – is transparency around the corner?

As medical services and prescription drug prices continue to rise, both the House of Representatives and the Senate are proposing reform for price transparency to control costs.

The Lower Costs More Transparency Act has been supported and passed by the House of Representatives. This Act would call for the codification of the Hospital Transparency Rule and the requirement to disclose prescription drug prices in a machine-readable file. Price and fee disclosures would also be required of ambulatory surgical centers, imaging centers and medical laboratories. The legislation would also increase the penalties for non-compliance with the Hospital Transparency Rule, which would make it harder for hospitals to choose to stay noncompliant and pay the fee.[1,2]

Currently, there are several different bills aimed at reducing costs and increasing transparency of Pharmacy Benefit Management. The Senate has also recently introduced S.1339, the Pharmacy Benefit Manager Reform Act, which calls for PBMs to disclose detailed information about their pricing practices to plan sponsors, including price differences from any affiliated or nonaffiliated pharmacies. The Act would prohibit PBMs from engaging in "spread pricing," meaning charging more for a drug than what is reimbursed to the pharmacy, thereby creating a profit.[3,4,5]

Should this bill pass, employers would be able to see what discount their PBM is obtaining and thus understand where margin has been built in. Data shows that only 37% of the drug price is from the manufacturer, with the remaining 63% of the cost going to third parties. This variance points to the current system design flaws. Despite both sides of Congress being eager for continued reform, the House of Representatives and the Senate have failed

to agree on language to move forward.[6] One reason for the delay could be concern over the potential implications for privacy rights. In March 2024, The Self-Insurance Institute of America (SIIA) reported that members of Congress are pulling back on their support for increased data sharing. This emerged after hearing from patient advocacy groups who were concerned if a plan sponsor was given access to health claims data, it could result in discrimination against certain employees taking gender affirming drugs or medication to treat HIV or AIDS.[7]

Concerns around potential discrimination could impact future state legislation as well. The Connecticut Commission on Racial Equity and Public Health is working with legislators to further limit stop loss and level funded plans for the small group market due to underwriting practices potentially leading to racial discrimination and gaps in coverage. While proposed legislation has yet to be introduced in Connecticut, SIIA is working on educational materials to provide to policymakers.[1,3]

In addition, there is an uptick in stop loss rate filing objections and both Connecticut and New Jersey continue to limit the practice of "lasering." Furthermore, in Michigan, the Department of Insurance and Financial Services (DIFS) is objecting to small group stop loss rate filings based on previous Bulletins 00-04, 2011-14-INS, and 2013-19-INS, which the DIFS now claims apply to stop loss rates. The DIFS has denied premium adjustments of +/–20% (or +/–25%) as a basis to prevent rate discrimination.[1,3,7]

As it relates to the obesity crisis in the U.S., the White House continues to support programs and initiatives that encourage healthy food choices.

According to Validation Institute, an organization dedicated to providing unbiased, data-driven insights on healthcare solutions and services, the current White House Administration calls for a whole-of-government approach as they implement their strategy to address hunger and reduce diet-related diseases. Validation Institute understands the importance of convening executives from the entire healthcare ecosystem who are spearheading food as medicine programs, as evidenced by a summit they hosted in spring 2024 with this very goal in mind. Connecting healthcare administrators and practitioners with policy makers to build a food as medicine mindset into our nation's healthcare strategy provides a tremendous opportunity to measure the impact of evidenced-based food programs on better health outcomes.[8]

QBE provides industry-leading service to our customers, and we will continue to stay abreast of new legislation that will have an impact on the insurance industry. As a diamond member of SIIA and a member of the Self-Insurance Political Action Committee (SIPAC), QBE is committed to collaborating with other members to advocate for the best interest of our community.

[1] 2/16/2024 SIIA Government Relations Newsletter
[2] February 2024 Advocacy in Action Webinar
[3] March 2024 Advocacy in Action Webinar
[4] https://www.congress.gov/bill/118th-congress/house-bill/5378#:~:text=Shown%20Here%3A,(12%2F11%2F2023)&text=This%20bill%20requires%20health%20care,extends%20several%20public%20health%20programs
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[6] Podcast, PBM Reform Podcast Series, episode 1,449.
[7] 3/15/2024 SIIA Government Relations Newsletter
[8] Validation Institute's Food as Medicine Strategy Summit Announces Federal Agencies' Panel with NIH, CMS, HHS, USDA, and The White House on the U.S Government's National Advancing Food as Medicine Programs and Initiatives (prnewswire.com)

Medical stop loss captives *are here to stay*

Medical stop loss coverage remains an important consideration for risk managers of self-insured health plans. Protecting the solvency of a self-funded employer is imperative given the nature of healthcare economics and evolving healthcare trends.

In the ongoing effort to control costs, medical stop loss captives have been used by many health plan sponsors, creative risk advisors and entrepreneurs to inject value in the marketplace. This strategy has proven to be effective as employers are further incentivized to procure cost containment solutions that manage the higher level of retained risk typically transferred to a stop loss carrier.

AM Best's Market Segment Report states that group captives are proven to aid in self-managing adverse selection in the market, as they often identify misaligned interests and poor risk exposures before agreeing to employer participation in their program.[1]

Single-parent and group captives have demonstrated success in reducing fixed insurance expenses, delivering transparency and capturing underwriting profits and investment returns that would otherwise revert to an insurance company, ultimately reducing the cost of risk.

Since AM Best began reporting on the captive segment more than two decades ago, the operating performance of U.S. captives have readily surpassed that of their commercial market peers.

... the operating performance of U.S. captives have readily surpassed that of their commercial market peers.

[1] Best's Market Segment Report: U.S. Captive Insurance Stepping In Amid Capacity and Pricing Challenges (ambest.com)

Creating strong, resilient and inclusive communities

QBE Foundation

QBE's commitment to enabling a more resilient future doesn't end with our customers; it extends into our communities. Our philanthropic focus includes targeted community investments and impactful volunteer activities. We work in partnership with local organizations on climate resilience and inclusion – two areas we believe we can have a great impact.

The QBE Foundation strives to improve the preparedness of our communities through long-term partnerships designed to help people help themselves. The Foundation's focus is to create strong, resilient and inclusive communities that are better equipped to protect themselves.

FEEDING AMERICA

Nourishing our communities

Food insecurity continues to be a critical concern across the world. In the U.S., approximately 37.8M people face food insecurity.[1] That's one of the many reasons why The QBE Foundation partners with Feeding America as a key charitable beneficiary. Feeding America works to provide food security for the less fortunate by collaborating with grocers, farmers and truckers to do so sustainably.

As a top medical stop loss provider, QBE understands how diet can impact overall wellness. Our Accident & Health practice is passionate about working in our communities to support this worthy cause. Tara Krauss is QBE's executive sponsor of the Feeding America annual food drive. Now in its sixth year, this fundraising initiative is responsible for donating over 2.15M meals to those in need.

In the U.S., approximately **37.8M** people face food insecurity.[1]

Premiums4Good™

Our Premiums4Good initiative

QBE allocates a portion of our customer premiums to impact investments that aim to create positive environmental and/or social change, alongside a financial return. Our impact investments include green, social and sustainability bonds, social impact bonds, and impact investment funds. This program has no bearing on our customer's premium price. Learn more at www.qbe.com/sustainability.

[1] Food for People: How to Combat Food Insecurity [2024 Report] (convoyofhope.org)

Why choose QBE?

QBE North America is a global insurance leader helping customers solve unique risks so they can enable a more resilient future. Based in Sydney, Australia, QBE operates out of 27 countries worldwide with a presence in every key insurance market.

Employers rely on QBE to provide the expertise and resources needed to help manage their self-funded health plans. As a top 10 independent provider of medical stop loss insurance, QBE creates custom solutions that fit the needs of each employer to control the cost and quality of their self-funded plans.

We remain committed to innovation through our focus on continuous improvement and growth. This includes developing modern new products and services, such as Agora, our unique group captive program, all while making working with us easier.

QBE offers its products and services through a network of limited and preferred distribution partners. This allows our brokers direct access to executive leadership, seasoned underwriters and business development leaders, resulting in superior coverage for our policyholders.

When complex claims arise, including those around new treatments and therapies, QBE clinicians are ready to educate and assist producers. Our claims and policy administration teams can customize solutions to facilitate claims on both TPA and ASO-type plans.

After more than 135 years of serving businesses and customers, QBE has become an established top-tier global insurer and reinsurer.

Learn more about how QBE can help

We welcome the opportunity to connect further. Should you have questions about this report, industry insights or how we can work together to manage your customers' risk exposure, please contact one of our team members:

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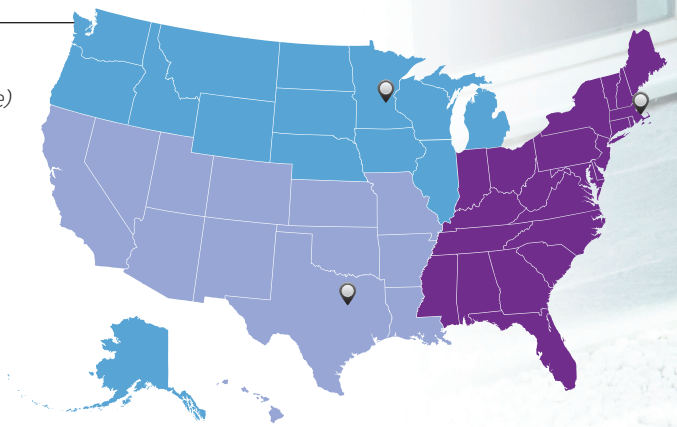

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"Top 10" claim made based on premiums earned, see **2022 NAIC Accident & Health Policy Experience Report**.