STOP LOSING SLEEP

Stop Loss companies and reinsurers help employers tackle key market challenges

Written By Laura Carabello

Sticker-Shock is the best way to describe employer reactions to the high cost of healthcare products and services, with many losing sleep wondering how they are going to maintain a robust menu of healthcare benefits within budget.

This situation is now heightened by the general malaise over inflation and supply chain problems. Collectively, these issues and current market forces now account in large part for the accelerated adoption of self-funded health benefits to address the volatility of health care costs.

As escalating high-cost claims of $1 million or more show no signs of abating, this environment creates an even greater reliance upon stop loss coverage.

A recent report from The Kaiser Family Foundation states that in 2021, sixty-four percent of covered workers were in a plan that is self-funded.

Today, most self-insured companies purchase reinsurance to protect against unexpectedly high claims and protect themselves in the event of a single very large claim or total costs that exceed their actuarial projections.

Ongoing challenges to meet client expectations persist. Thanks to the feedback from member companies of SIIA that provide stop loss or reinsurance coverage, we have a bird's eye view of the types of claims and other issues that lead to these cost over-runs and payouts by the stop-loss carriers or reinsurers.

These companies have an overarching goal to enhance sustainability by controlling costs, ensuring the financial well-being of a self-insured plan by paying constant attention to controlling costs without sacrificing service quality.

Jay Ritchie

CLOSER LOOK AT CATASTROPHIC CLAIMS

While catastrophic claims have always existed from either injury, accident, or a major medical condition, Jay Ritchie, president & CEO, Tokio Marine HCC – Stop Loss Group, says, "What has changed is our perspective on what is catastrophic. There was a time where $500K in annual spend on an individual was considered catastrophic, then it was $1M. Now the frequency of $1M claims has become fairly consistent over a large book of medical stop loss (MSL) and $2M seems to be the new catastrophic point. This is not to say that any of these are insignificant, but that the definition of catastrophic has to trend along with claim costs."

The use of technology is evident across-the-board, as automated systems and experienced stop loss analysts utilize the latest automated technologies and algorithms to flag potential catastrophic claims, allowing for early interventions to mitigate negative impacts on the self-funded plan.

This is critical since industry observers affirm that 0.6% of a clients' claims drive 35% of their self-insured medical and pharmacy spend each year.

So what are the most painful claim conditions? See the chart below:

Top 10 High-Cost Claim Conditions for Stop-Loss Insurance in 2020 and Their Annual Cost

1. Malignant neoplasm (solid tumors): **$744 million** (between 2016 and 2019)
2. Leukemia, lymphoma and/or multiple myeloma: **$276 million**
3. Chronic/end-stage renal disease: **$165 million**
4. Congenital anomalies: **$161 million**
5. Septicemia: **$120 million**
6. Liveborn with secondary complications: **$119 million**
7. Transplants including blood and stem cells: **$118 million**
8. Complications due to surgical and medical care: **$109 million**
9. Unspecified procedures and aftercare: **$83 million**
10. Hemophilia/bleeding disorders: **$82 million**

Source: Sun Life Assurance Company

Source: https://www.leadersedge.com/healthcare/headed-for-catastrophe

Jakki Lynch

Jakki Lynch RN, CCM, CMAS CCFA, director cost containment. Sequoia Reinsurance Services points out that admission to the hospital usually means someone is trying to recover from illness and no one ever expects to get sicker as a result of their stay.

"Preventable hospital-acquired conditions continue to have a high financial burden on the health care system and contribute significantly to inpatient morbidity and mortality," she explains. "Sepsis -- a life-threatening organ dysfunction caused by a dysregulated host response to infection -- is a leading cause of in-hospital mortality and one of the most expensive preventable conditions treated in hospitals. According to the Joint Commission Center for Transforming Healthcare, sepsis treatment costs approximately $17 billion dollars each year."

Lynch makes it clear that treatment for sepsis often involves a prolonged stay in the intensive care unit and costly complex therapies, adding, "Although health plans may have payment policies that address these issues, many do not have processes to identify them and adjust claim payments. Charges incurred for sepsis should not be paid and hospitals will remove them if presented with adequate clinical record support by payment integrity specialists."

She describes a recent high dollar sepsis case reviewed by their payment integrity team which identified $255K (26%) of overall contract payable charges of $984K incurred from preventable sepsis after cardiac surgery. Based upon the claim payment integrity review, the facility agreed these charges are not payable.

"Plans can successfully implement a comprehensive payment integrity program to mitigate significant charges associated with unexpected hospital acquired conditions," she continues.

While there are many approaches to addressing these types of unexpected costs, here is some overall guidance from Thomas Power, managing member, Phoenix Excess Risk Underwriters, LLC who says, "As a Managing General Underwriter (MGU), it is important to work together with the Third Party Administrator (TPA.) Early notification and involvement by the TPA with the specialty vendors who address large claims and sometimes difficult claims are essential to create the best outcome."

He maintains that transparency and management of large claims by a good administrator in partnership with the employer while keeping the carrier/MGU informed is critical. "While the carrier cannot make plan decisions, there are opportunities available to impact the best possible solution."

COVID AND PANDEMIC ISSUES PERSIST

Stop loss companies are actively monitoring the changing situation related to COVID-19 claims.

Mark Lawrence

According to Mark Lawrence, president, HM Insurance Group, "We've seen numerous claims greater than $1 million where COVID-19 is the primary diagnosis. There's been a higher incidence of aggregate claims, as well. In addition to our "normal" business, where the frequency and severity of high-cost claims continues to rise, we've also seen significant changes in claims development patterns – primarily driven by a lull of claims for most of 2020 and part of 2021, followed by an increase in claims thus far in 2022. This creates challenges in reserve setting."

The post COVID inflationary environment is going to create a period of higher-than-normal medical trend for catastrophic claims defined as those greater than $500K.


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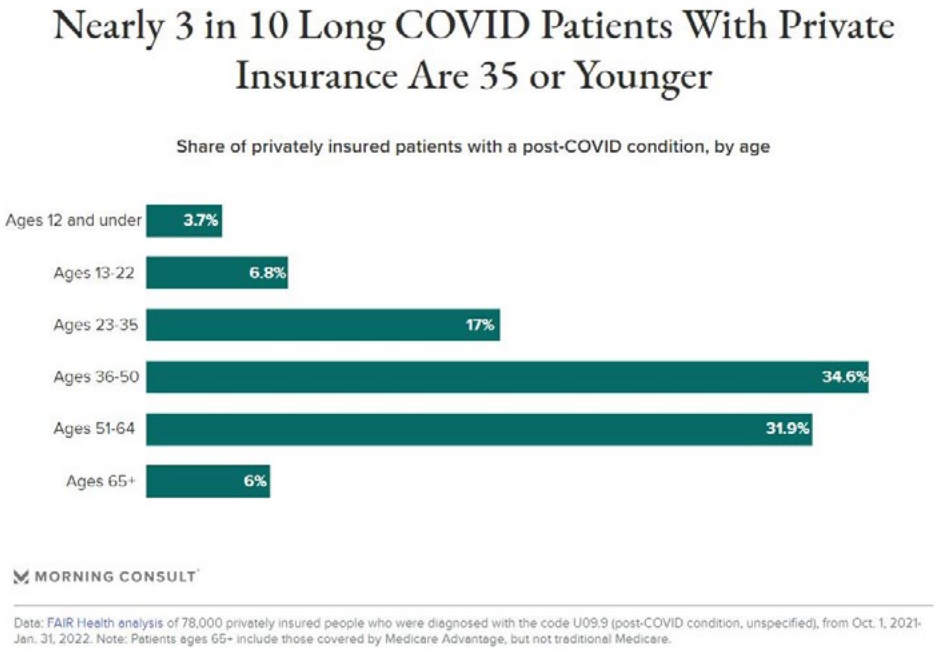
Ritchie says the COVID hush is being following by the COVID crush: "The Crush comes in 3 forms, 1) delayed care, 2) greater severity of the untreated condition and 3) higher costs to provide such care. This will now be combined with other supply and demand inflationary costs."

He states that the medical trend has been consistent for the past decade and while not directly tied to the Consumer Price Index, it will be impacted like every other industry, warning, "Everyone in our industry must be prepared for this rapid increase through effective cost management and a quicker reaction to the overall market conditions."

Observing that initial COVID-19 claims were expected to run either below $50,000 or around $400,000 to $700,000, Don McCully, Medical Captive Underwriters LLC points out, "To date, the largest individual claim exceeds $4 million paid. The initial impact continues to evolve and now includes 'Long Tail' COVID. Reports of indirect side effects such as reduced energy and lung function, as well as seemingly unrelated medical issues are increasing."



Source: https://morningconsult.com/2022/04/18/long-covid-data-demographics/

California, for example, classed all COVID claims under Workers Comp initially, prompting McCully to respond, "The question is: in which claim category does Long Tail actually COVID fit? Long Tail COVID is likely to adversely impact health insurance and workers compensation."

The stop loss market hates unpredictability as Mike Schaefer, vice president, Strategic Partnerships, Amalgamated Life Insurance Company, shares, "COVID-19 is the most unpredictable medical condition of our lifetime due to the uncertainties surrounding the actual cost of care and long-term particulars of patient care and associated costs. This disease is masked in many ways; increasing its unpredictability."

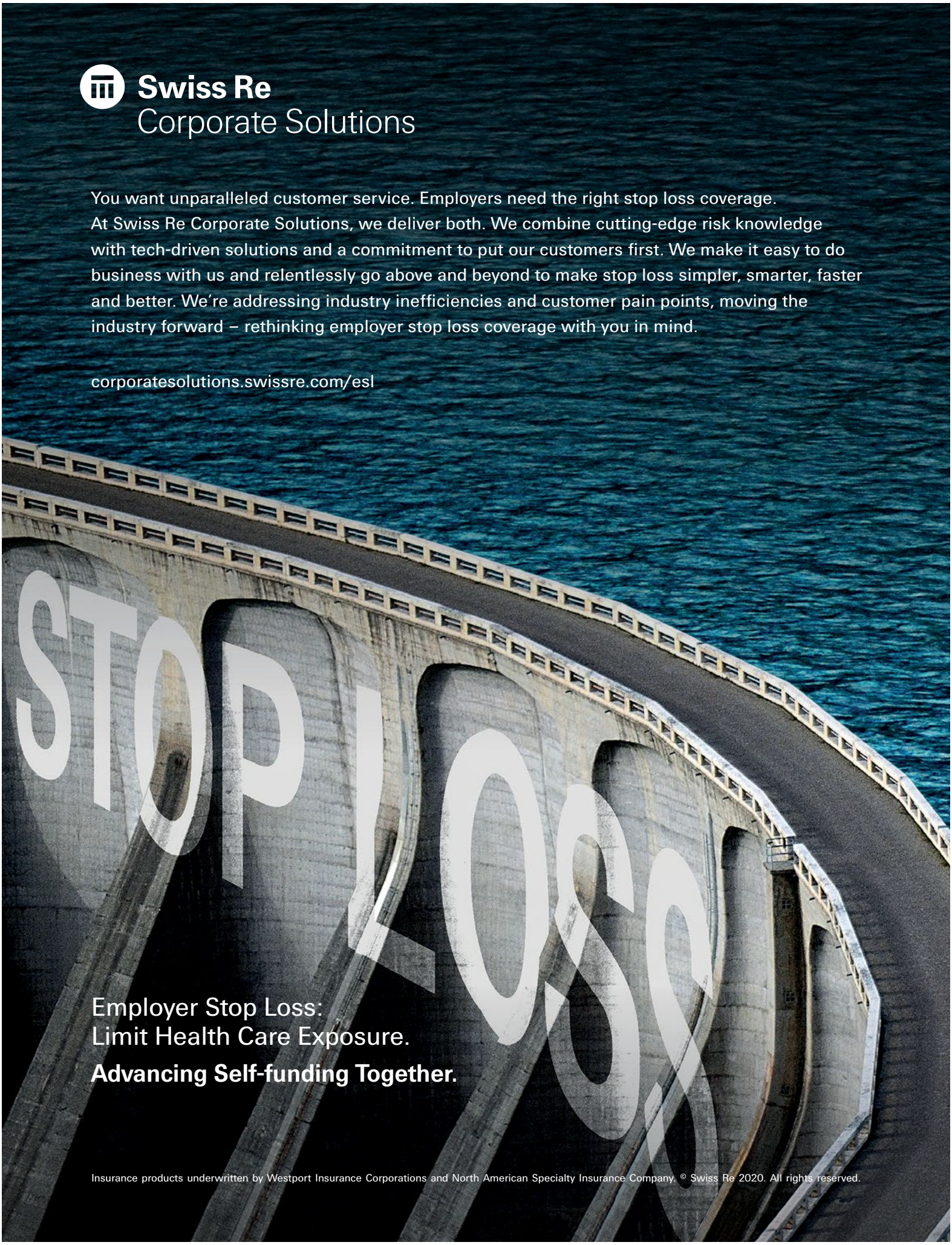

Mark Schaefer

He counsels the industry that what may present as the flu or bronchitis may actually be COVID-19, or vice versa.

"Staying on top of speculative pandemic conditions, new variants and surges in different regions remains a challenge, making it difficult to accurately forecast exposures," says Schaefer.

HIGH-COSTS: EMERGING GENE AND CELL THERAPIES AND SPECIALTY DRUGS

Employers and stop-loss providers are definitely losing sleep about the emerging, super-expensive specialty pharmaceuticals and gene and cell therapies. Toiling away in laboratories worldwide, scientists are drawing on breakthrough research to be able to manipulate the genes of people with certain diseases to significantly improve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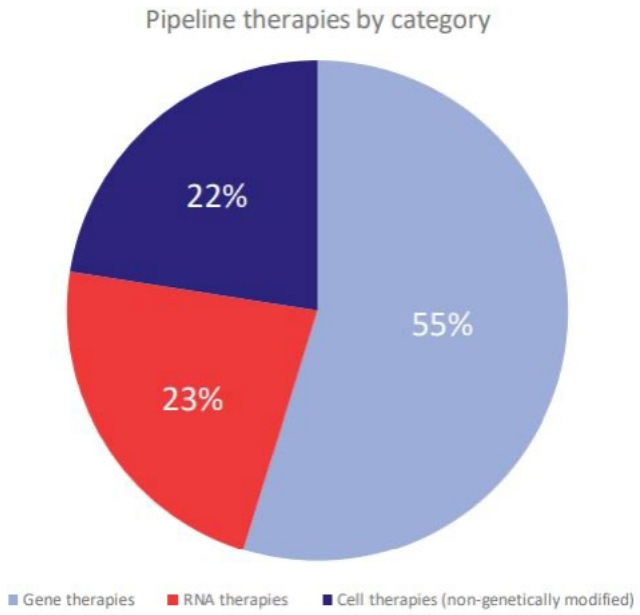
their condition or even cure them.

While this sounds like the basis for a science fiction (or sci-fi) novel or movie, this premise is becoming a reality as pharmaceutical products promise that they can actually accomplish these feats.

Known as gene and cell therapies, these novel products offer new hope for many individuals, representing a potential cure for previously incurable diseases. The caveat: they also carry extraordinarily high price tags.



Source: https://asgct.org/global/documents/asgct-pharma-intelligence-q1-2022-report.aspx

Amanda Christel, Orion navigator nurse consultant, Starline Group, maintains that advancements in genomic medicine remain at the forefront of emerging therapies for a wide range of serious medical conditions, "…offering a glimmer of hope for patients living with these complex diseases."


Amanda Christel

From a payer perspective, she says the sticker shock for many of these therapies presents a new set of challenges in the stop loss space, adding, "What is needed is well-defined policies combined with early identification and triaging of these claims that helps to ensure a smooth process from the time the claim is received until it is paid. Additionally, leveraging vendors, such as Emerging Therapy Solutions, is essential in terms of strategy for cost containment."

Schaefer declares that emerging gene therapies may be the single most challenging cost and care driver facing plan sponsors and stop loss carriers.

"The prevalence of these claims are so infrequent that it is nearly impossible to reserve appropriately," he says. "The costs of these therapies can range from $750,000 to over $4,000,000 and the outcomes are still speculative. Emerging reinsurance and carve-out programs are still in their infancy stage -- which is comparable to Organ and Tissue Transplant programs of the 1980's when they were first launched. Now a mature market, these programs were widely popular at the time for similar reasons -- unpredictable costs and outcomes."

Ritchie advises that if gene therapy becomes what we believe it could be, it will be game changing for the industry, noting, "This is not a negative since the ability to have curative procedures versus our current model of an elongated treatment regimen for a condition is good for our industry. The costs are the real question with value because what are the costs for curative treatments?"

His question points to the issue of whether or not these therapies are actually curative or simply a temporary treatment that has to be re-administered in 3-5 years. "If every 3-5 years, then it is just a modification of our current treatment programs, and the cost is not justified," he argues. "It is difficult to balance costs vs procedure and then measure in 3-5 year returns when the average employee tenure is less than the lifespan of the treatment. How does a self-insured employer who financed the gene therapy deal with this? This becomes even more difficult when existing treatment plans already exist."

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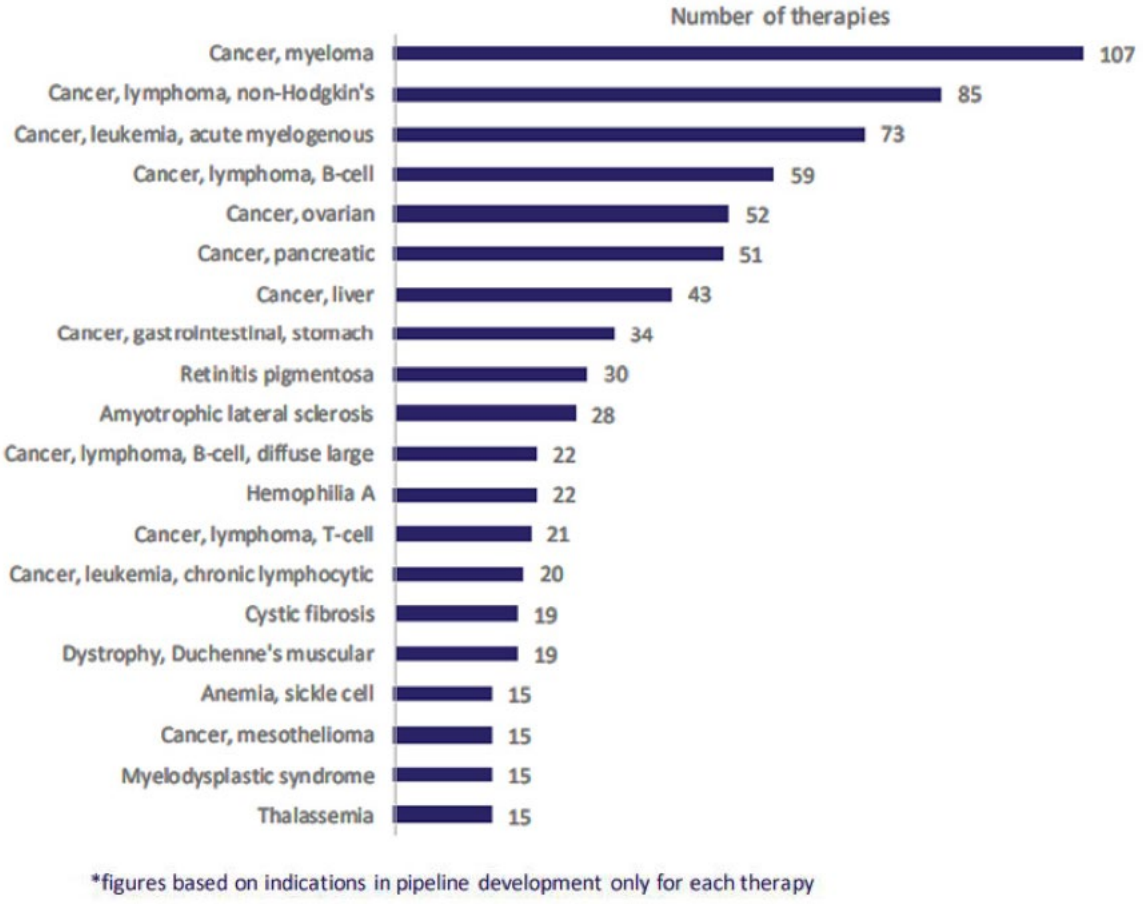
Gene therapy pipeline: Most common rare diseases targeted

- For the 1006 pipeline (preclinical to pre-registration) gene therapies which are being developed for rare diseases, eight out of the top 10 rare diseases are oncological
- In the same order as in Q4 2021, the top five rare diseases for which gene therapies are being developed are:
  1. Myeloma
  2. Non-Hodgkin's lymphoma
  3. Acute myelogenous leukemia
  4. B-cell lymphoma
  5. Ovarian cancer

Despite all questions around these therapies, Mercer reports the gene and cell therapy pipeline is growing rapidly: in 2018 alone, the number of products in development rose by 25%, from 289 to 362. By 2025, the FDA estimates it will be approving 10 to 20 gene and cell therapy products per year.



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Many, if not most, of these and other specialty drugs will be delivered in a clinical setting, ranging from hospitals and physician offices to freestanding clinics. This means that employers need to look at their prescription drug benefit on an integrated basis, with strategies focused on medical benefit management as well as the specialty drug pipeline.

Industry observers say these pharmaceuticals are so expensive because of the technology it takes to create them, particularly gene therapies. Also, many of the conditions they treat are relatively rare.


Karen Cunningham

A few of the top prescriptions concerning insurers are Zolgensma, for young children with spinal muscular atrophy, and Luxturna, a gene therapy used for treating vision loss in children. One infusion of Zolgensma costs about $2.1 million. A treatment of Luxturna costs $850,000. Many wonder when and if there will be a tipping point where self-insured employers simply can't afford to include these in a their benefits plans.

Karen Cunningham, director-Clinical Services, Medical Risk Managers, Inc., cites the highly anticipated launch for Roctavian, BioMarin's gene therapy to treat severe hemophilia A, which may come to fruition in 2023 if FDA approval is achieved by the end of 2022.

Cunningham counsels, "Approval delays in the US & Europe occurred as both the FDA & European Medicines Agency (EMA) required additional clinical trial data for an extended time period due to concerns about drug effectiveness noted in earlier trials. Although this therapy is expected to eliminate costly factor replacement as well as prevent common bleeding complications, careful consideration must be maintained since gene therapy is still a relatively new treatment that does involve genetic alteration with no prior or current data can that can predict if unintended consequences may result."

Many employers turn to Pharmacy Benefit Managers (PBMs) that use several tools to help control the crushing cost of specialty medications. Mary Ann Carlisle, Chief Revenue Officer & COO, ELMCRx Solutions, LLC says one of the most common and typically the first line in helping to manage these drugs is the Prior Authorizaton, whereby the PBM reviews specialty medications to ensure they are clinically appropriate (reviewed against the PBM's criteria and FDA approval) and are appropriate for the approved diagnosis.

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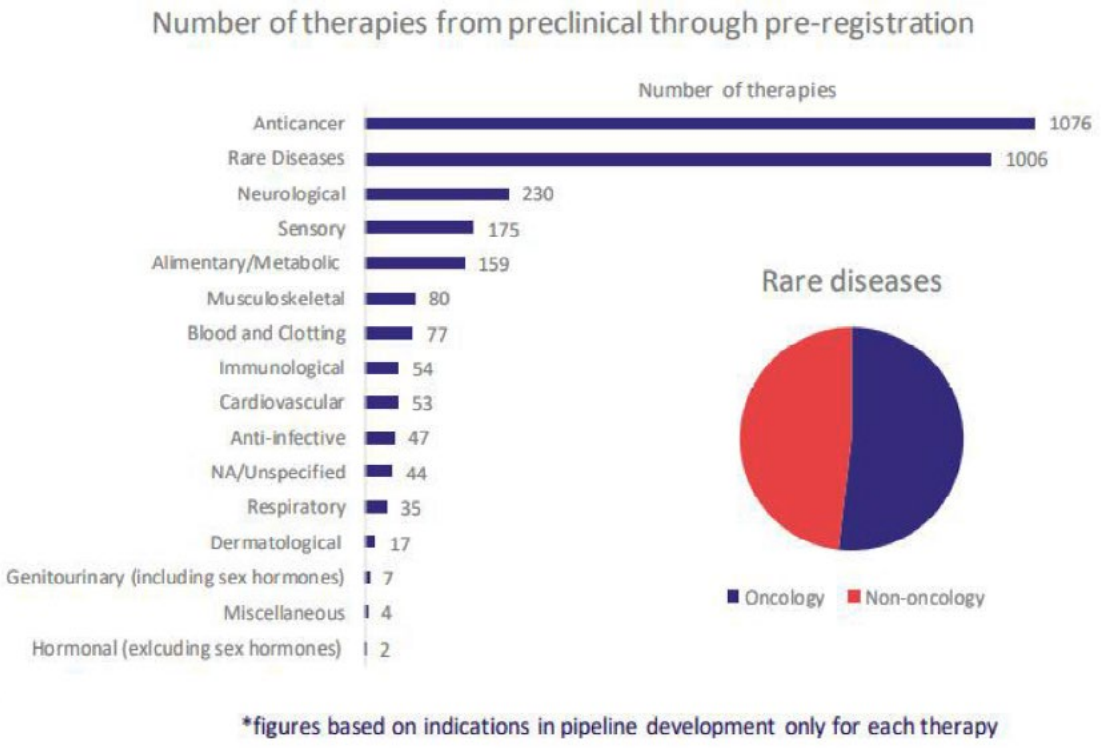
"A PBM's Clinical PA team normally reviews the clinical information provided by the prescriber's office and determines whether the drug is clinically approved or not for a given diagnosis," she explains. "But they do not necessarily review whether the quantity or dosing that the prescriber requests is appropriate for the diagnosis that they approved. As a result, a clinical PA review by the PBM is one part of the process in managing specialty medications."

She continues, "Pharmacies receive prescriptions for approved medications from a prescriber with instructions to dispense the drug. The pharmacy does not always know the diagnosis to verify that the strength, quantity, and day supply is appropriate for the specific diagnosis. Or the pharmacy system may include the diagnosis but there may not always be a check within the pharmacy's software to see if the dose and quantity are appropriate for that diagnosis."

This can lead to errors in the quantity dispensed of an approved drug submitted. "For example, Stelara is usually billed per mL (milliliter)," she says. "But in a recent case, a quantity of "1" was accidentally entered for one Stelara 45 mg/0.5 mL syringe... instead of 0.5 mL This led to the pharmacy dispensing TWO $12,700 syringes, instead of one. If no one questioned the submitted quantity, the drug would have processed as a paid claim since the drug itself has already been approved through a clinical prior authorization."

EXPENSIVE SPECIALTY DRUGS AND TREATMENTS

Apart from gene therapy, the cost of specialty drugs is also interrupting the sleep patterns of employers. These are defined high-cost prescription medications used to treat complex, chronic conditions like cancer, rheumatoid arthritis, and multiple sclerosis. They sometimes require special handling and administration (typically injection or infusion), and patients using a specialty drug may need careful oversight from a health care provider who can watch for side effects and ensure that the medication is working as intended.



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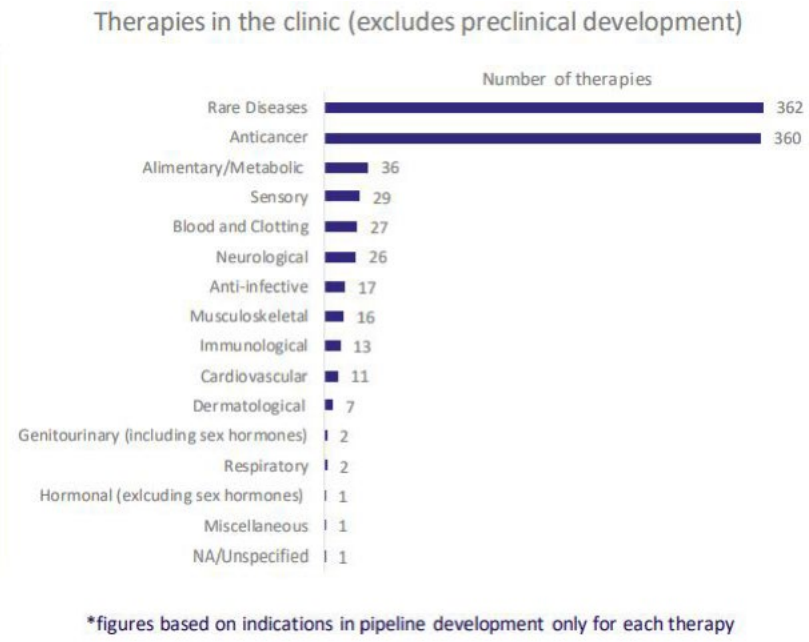
According to Cunningham, specialty drug costs are exorbitant when considering that only 2% of the patient population uses specialty drugs yet these costs account for 51% of total drug spend in the USA.



"Approximately 65% of specialty drugs are available through pharmacy benefit managers (PBMs) and typically covered under the individual's drug benefit," she explains. "These costs can be managed by selection of a formulary of approved drugs and use of biosimilars when available. However, most drugs that require infusion such as chemotherapy, immunotherapy or enzyme replacement therapy are usually covered under medical benefits. In addition, these infusions are typically administered in physician offices, hospital infusion clinics or during inpatient admission."

With the start of the new year 2022, drug companies raised prices on hundreds of medications with most prices up 5% on average. According to STAT News, prices went up on 460 drugs, which tracks in line with recent years. Several major drugs were included in this batch of 2022 price increases:

- Gilead: 5.6% on HIV drugs named Biktarvy and Descovy
- Pfizer: 6.9% on breast cancer drug Ibrance, 6.9% on the Prevnar vaccine for pneumonia, and 4.4% on the heart drugs Vyndamax and Vyndaqel
- Purdue: 5% on opioid drug OxyContin
- Vertex: 4.9% on Trikafta, a cystic fibrosis medication that has no competitors and already had a list price of more than $311,000 per year

The specialty drug trend has been outpacing medical trend for several years and the issue at hand is not the pure costs but the opaqueness of the actual costs.

Ritchie shares this perspective, saying, "Sure, drug costs from manufacturers are going up, but the increase in the distribution layers and the opaqueness around those layers is causing additional concern.

Distribution between manufacturer and consumer must be lean and clear. As this gets more and more blurry, the ability to disrupt becomes more significant along with the desire of the consumer to seek change."

Industry analysts across the board advise that it may be prudent to consider alternative risk financing strategies, including stop loss or reinsurance solutions, installation payments and outcomes-based reimbursement that soften the impact of these high-priced therapies.

Schaefer observes that with the pharmaceutical industry in lock step with the development of high cost specialty drugs, the burden of financing them has been reverted back to the consumers, more specifically plan sponsors.

"Consequently, all aspects of plan costs have seen an increase disproportionate to normal trends, especially pertaining to stop loss coverage," says Schaefer. "Plan sponsors are exploring creative strategies to finance these drugs and keep their plans solvent. Many pharmaceutical companies support programs and nonprofits offer drug assistance programs (PAPs) which provide free or low-cost medicines. This has created a cottage industry of companies assisting plan sponsors and their members to secure financing for these drugs."

Finally, McCully poses this question: "Should insulin's cost qualify as expensive?"

He describes the situation, explaining that Eli Lilly manufactures its patented brand insulin, Humalog and its generic brand Lispro on the same production line. Patented insulin retails for about $1,470, with an after-rebate net cost of approximately $1,375. Lispro retails for $797, with no rebate. That's a $6,900 higher annual cost overall. Fully Insured carriers buy Humalog.

"Rebates are paid within the same parent company, without violating or impacting the medical loss ratio," says McCully. "Members who choose Lispro are charged more for picking a prescription not on the formulary."

IMPACT OF TRANSPARENCY RULES

Many stop loss carriers now identify transparency rules as one of the largest issues for the industry.

Ritchie says that disclosure of hospital pricing, drug costs and additional data leads to a better-informed consumer, which includes stop loss carriers. "In an age of big data, the smokescreen around expected vs actual costs is as murky as ever. The ability to apply data analytics and logic to transparent data would be a significant benefit to all in the self-insured marketplace. However, we can't be just the ones receiving the data, we need to offer the data on ourselves to impact true change."

McCully clarifies that ERISA empowers employers to own their medical and pharmacy claims information, advising that partial self-funding is the mechanism to obtain this data.

"ERISA's intent and reality are separated by a wide gulf," he cautions. "National carrier networks, non-profit and for-profit hospitals collude to restrict access and hide behind made up rules. Stop-loss group captives are not directly impacted by the transparency rules, but voluntary transparency by publishing sources of revenue streams allows differentiation from fully insured carriers. Fully insured carriers do not publish pharmacy rebate revenue and are now adopting $0 cop-pays in some cases. It's an excellent transparency smoke screen that is good for their stock price."

Throughout the industry, many underwriters rely on historical experience to help predict future expected loss costs. However, Theresa Galizia, SVP and Chief Underwriting Officer, Berkley Accident and Health attests that the health care market is dynamic and changing rapidly.

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Theresa Galizia

"Our recent history is skewed by the impact of COVID-19. And the current inflationary environment, coupled with advancements in cell and gene therapies, is only adding to the uncertainty, making our jobs as underwriters even more challenging. An informed view of how these exposures will impact the rate environment is essential," says Galizia.

She offers praise to SIIA, saying that the organization provides a forum for these thoughtful types of discussions, and she "…is delighted to help facilitate one such discussion on cell and gene therapy at SIIA's National Conference this October." ■

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

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