EMPLOYERS WEIGH COVERAGE OPTIONS FOR OBESITY DRUGS

Written By Laura Carabello

At the nexus of obesity and diabetes comes a new genre of blockbuster weight loss medications, which the media characterizes as the "Hollywood diet drugs." While these medications are designed for people with Type 2 diabetes, they quickly reached stardom when socialites and celebrities began using them to help lose weight -- despite some alarming potential side effects.

These red-hot commodities have entered mainstream USA, as people throughout the country aim to arm themselves with a new weapon for losing unwanted pounds.

For employers unfamiliar with the names of these drugs – Ozempic, Wegovy, Mounjaro, Saxenda and potentially more – it's time for a crash course in obesity and the science behind these formulations.

It's because of their growing popularity and price tags of as much as $13,600 or as high as $17,000 per patient per year, an amount which could possibly continue for the rest of an individual's life as indications expand to patients with obesity.

These drugs have skyrocketed in popularity this year. In fact, the demand for Wegovy has prompted its manufacturer Novo Nordisk to pause its advertising campaign and limit its starting doses for new patients as it struggles to meet demand. Telehealth company Ro also reversed aggressive promotional efforts for Wegovy that involved splashy ads in subway stations.

Most recently, it has been reported that some dosages of Eli Lilly's Mounjaro are also in shortage, the latest in a line of recurring supply issues caused by patients using the diabetes medication as a weight loss treatment.

The latest shortage will result in "intermittent backorders" for three of six doses through July 2023, with the manufacturer attributing this situation to continued dynamic patient demand and prompting the company to expand its manufacturing capacity.

These shortages also spurred many desperate patients to seek specially compounded versions of the drugs which contain semaglutide/GLP1s. Following reports of adverse events, the FDA issued a sharp warning that these compounded products have not been shown to be safe or effective.

In fact, legal teams from one manufacturer have filed lawsuits alleging several medical spas, wellness clinics, and weight loss clinics around the U.S. are illegally selling compounded versions of its medicines.

GROWING PREVALENCE

Approximately 142 million adults nationwide meet the Food and Drug Administration's prescription criteria, according to the Institute for Clinical and Economic Review, a nonprofit that reviews the cost-effectiveness of medical treatments. These individuals either are obese with a body mass index (BMI) of at least 30 or have a BMI of at least 27 and a pre-existing condition, such as diabetes.

According to the Centers for Disease Control, roughly 40% of American adults are obese, and studies estimate that the 2019 annual medical cost of obesity was nearly $173 billion. Per person, medical costs are nearly $1,900 higher per year for obese adults as compared to their non-obese peers.

While there is inconsistent insurance plan coverage for these drugs, weight-loss medications are likely to hit drug formularies and pharmacy benefit plans in the next year as health plan sponsors are pressured to cover and grapple with this staggering expense.

Jennifer Perlitch

Jennifer Perlitch, RPh, assistant vice president, Pharmacy, Spring Group, shares this perspective, "Yes, these drugs have created a lot of buzz among our employer client base. There are various factors for employers to consider when evaluating adding weight loss drug coverage into their plan, as they are not typically covered."

She says that it is important to note that Ozempic and Mounjaro are not currently approved to treat weight loss, only type 2 diabetes, adding, "Despite the approved indications, Ozempic appears to have high utilization for weight management in people without diabetes, hence the "Hollywood Diet" term, something employers should keep

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in mind. "These drugs all retail for around $1,300 per month and if not covered, employees can search for copay assistance programs to assist with costs. Lastly, studies suggest that patients may need to stay on the drugs for life, as research shows that most patients gain weight back after stopping medication."

Perlitch advises employers to think about long-term costs and health outcomes: "On their own, it is unlikely that the short-term costs of these drugs will be a wise investment for employers. However, if they are one part of a comprehensive wellness plan focused on sustainable lifestyle changes, the results could be significant."

COVERAGE DECISIONS FOR GAME-CHANGING OBESITY DRUGS

Peter Weissberg, managing director, head of commercial strategy, Policy Reporter, the industry leading provider of payer coverage policy data to pharmaceutical manufacturers and national payers, says that employers and unions, in collaboration with their health plan administrators, have adopted a variety of utilization management controls designed to ensure appropriate use of treatments for weight-loss:

Peter Weissberg

1. **Limited distribution:** 1199SEIU Plans require that members obtain Mounjaro exclusively from Accredo Specialty Pharmacy which is owned by its PBM vendor Express Scripts.
2. **Step Therapy for OTC and Prescription Drugs:** United Healthcare will only approve use of Wegovy or Saxenda after "Failure to lose greater than or equal to 5% of body weight after six months of treatment with OTC orlistat (Alli)" and "Contraindication, intolerance or failure to lose and maintain greater than or equal to 5% body weight following 3 month trial EACH of two of the following medications (document date of trial of each medication and total body weight lost): • Prescription Xenical • Qsymia • Contrave «"
3. **Clinical Rationale via Physician Attestation:** Blue Cross Blue Shield of North Carolina requires its physicians who want to prescribe Wegovy or Saxenda to document that patients have tried another weight loss medication in the previous 12 months and to provide the clinical rationale for why they believe the patients will be more successful on Mounjaro than the previous treatment.
4. **Prior Authorization:** Caterpillar in collaboration with MagellanRx requires documentation of a diagnosis of Type 2 Diabetes for members seeking coverage for Ozempic. As Ozempic is not specifically FDA approved for weight loss, it is possible (and highly likely) that any patient who is seeking coverage for Ozempic specifically for weight loss and not for the treatment of diabetes will not be approved.

5. **Quantity Limits:** Blue Cross of Michigan limits Mounjaro to "4 pens per 28 days".

"While employers and their health plan administrators are acutely aware of the potential health benefits and financial savings which can be achieved through weight loss, they are have demonstrated a clear willingness to restrict access and reimbursement for these new weight loss drugs," says Weissberg.

As employers already face the highest medical inflation rate in decades, Jeff Levin-Scherz, M.D., managing director and population health leader at insurance services company Willis Towers Watson (WTW), offers a different opinion, saying, "Among our clients, about two-thirds of them are covering GLP-1 drugs for obesity, however, what we're seeing is rapid uptake and costs that are unsustainable. Coverage right now is pretty good, but if these drugs continue to be as expensive as they are now, I don't know if we could project that they will continue to be covered this way."

Employers may want to examine their policies given a recent survey which found that 44% of people with obesity would change jobs to gain coverage for treatment. And more than half of workers would stay at a job they didn't like to retain that coverage, according to the survey from the Obesity Action Coalition.

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So how much would people pay out-of-pocket for these drugs?

According to a STAT-Harris Poll, nearly half of U.S. adults would pay $100 a month for Wegovy, Ozempic or Mounjaro, and one-third say they would pay whatever they can afford indefinitely to get the injectable medicines.

Nearly half the respondents are willing to spend that amount only until they'd reached a goal, while one-quarter said they'd pay $250 a month and 17% said they would spend $500 a month.

Still, the majority (84%) believe their insurance should cover the price and there are still a lot of questions on long-term effects.

Comparing Weight- Loss Drugs

	OZEMPIC	WEGOVY	MOUNJARO
AVG PERCENTAGE BODY WEIGHT LOSS	Studies not designed to assess weight loss	Up to 17%	Up to 22.5%
APPROVED USE	Type 2 diabetes	Obesity	Type 2 diabetes
YEAR INTRODUCED IN U.S.	2017	2021	2022
MOST COMMON SIDE EFFECTS	Nausea, vomiting, diarrhea, abdominal pain	Nausea, diarrhea, vomiting, constipation	Nausea, diarrhea, decreased appetite, vomiting
GENERIC NAME	semaglutide	semaglutide	tirzepatide
MANUFACTURER	Novo Nordisk	Novo Nordisk	Eli Lilly

Figures are from separate studies that tested different dose levels for varying durations.

Source: The companies and the *New England Journal of Medicine*

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SCIENCE BEHIND WEIGHT-LOSS DRUGS

Weight loss drugs work by mimicking a hormone called glucagon-like peptide 1 (GLP-1), which regulates blood sugar levels and slows down the rate at which food leaves the stomach, making people fuller for longer. Some people lose 15 percent of their body weight or more after 68 weeks on semaglutide, which is approved in the US for weight loss as Wegovy and for type 2 diabetes under the brand name Ozempic.

Collectively, these drugs sold under the brand names Ozempic, Wegovy and Rybelsus, semaglutide accounted for $10.7 billion in drug spending in 2021, up 90% over the year before, which ranked it fourth among drug expenditures, according to a study published last year in the American Journal of Health-System Pharmacy.

Mary Ann Carlisle, executive VP of ELMC Risk Solutions, LLC, offers this perspective, "Injectables referred to as GLP1s, like semaglutide (Ozempic, Wegovy), have been emerging as safe, effective, and generally well-tolerated options for chronic weight management in addition to their initial indication, T2DM."

She says that while GLP1s are often restricted for use in diabetics, their role will likely continue expanding as further studies are completed and the potential to improve other chronic diseases is quantified.

"Expect tirzepatide (Mounjaro), a novel dual GIP/GLP1 agonist, to experience an increase in utilization if also approved for weight management," she continues. "Early comparative studies have suggested tirzepatide is at least as effective, and potentially superior to semaglutide, for weight management. At this time, many employers are closely monitoring their use as the number of scripts for these medications have exploded. We recommend finding the right balance for each plan sponsor."

Another caveat: amid rising demand for these drugs, some obesity experts are concerned about the drugs' impact on patient health.

One expert cites a large clinical trial for Wegovy that showed that about 40% of the weight participants lost was lean mass. Side effects like nausea, vomiting, and a possible link to rare cases of pancreatitis also still plague this newest class of drugs, which imitate the effects of a hormone called glucagon-like peptide 1 (GLP) that helps people feel full.

CHANGING THE CONVERSATION ABOUT OBESITY TREATMENT

More than a third of adults in the United States are now classified as obese, with some ethnic groups approaching a 50% obesity rate, according to the Centers for Disease Control and Prevention. George J. Huntley, CEO, Diabetes Leadership Council stresses that obesity should be on every employer's radar across the country.

George J. Huntley, CEO

DIABETES PATIENT ADVOCACY COALITION

"We are nearing the point where half of the adult population of the US has the disease making it a major but not well recognized driver of health care costs," says Huntley, citing these facts:

- A person with obesity has on average 50% higher health care costs than a normal weight person.
- Obesity is second only to smoking as a preventable cause of death in the US.
- A person with obesity has an 80-85% risk of developing type 2 diabetes.
- Cancers associated with excess weight contribute to 40% of all cancers.
- Every 5 point increase in BMI results in a 32% increase in heart failure risk.

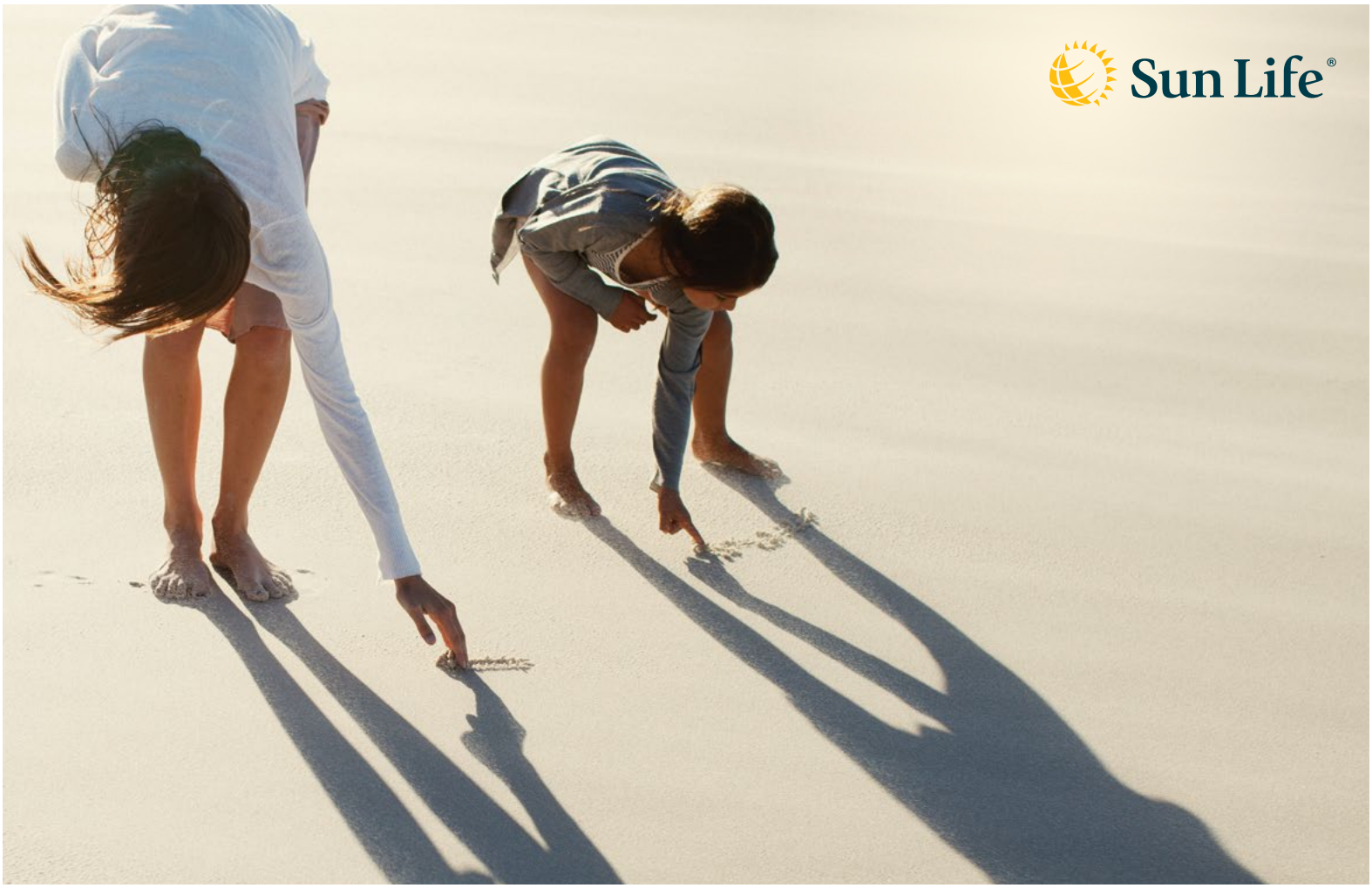
But he states that employers have been slow to make the connection between obesity and pre-diabetes from a coverage perspective, even though it is well known that losing weight during prediabetes can prevent a patient from ever developing diabetes.

"Most of the medical care is not provided until the diagnosis of diabetes is already there," he cautions. "We encourage employers to cover intensive behavioral therapy (IBT), medical nutrition therapy (MNT), anti-obesity medications and as a last resort, bariatric surgery. IBT and MNT are inexpensive and should be covered as broadly as an employer would cover smoking cessation programs. There should be few barriers or limits and strong encouragement by employers to participate in these therapies. Medical experts indicate that the anti-obesity medicines are more effective when combined with IBT and MNT."

He counters media characterization of the medications as Hollywood diet drugs, emphasizing, "They are drugs approved to treat diabetes and obesity. Note that Mounjaro's application for obesity coverage was just recently submitted to the FDA. Calling them "Hollywood Diet" drugs reinforces the unhealthy paradigm that it's the patient's fault that they can't lose weight. It's not their fault."

Huntley affirms that obesity is a chronic disease recognized by the AMA, WHO and other medical boards as such for over a decade, adding, "Obesity is a metabolic condition where the body stores too much energy in the form of fatty tissue and then fights to maintain that level making it difficult and, in many cases, impossible to lose weight despite herculean efforts by many patients. Well over 90% of dieters regain their lost weight within 3 years. That is too high a statistic for it to be the patient's fault."

These drugs replace a hormone in the gut that is released in response to food intake but a person with obesity doesn't make the hormone in adequate quantities.



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"The medications have been shown to reduce body weight by over 14%," he adds. "More and more employees will be asking for these medications. The demand level is just starting as the drugs are relatively new on the market and awareness of their efficacy is growing."

He recommends that employers cover these drugs for people with a BMI over 27 per the FDA guidelines. "Coverage will improve the health and productivity of the workforce," he advises.

Perlitch notes that while her company, Spring Group, is not a healthcare provider, they do consult with employer organizations looking to control costs and improve health outcomes for a range of conditions, including diabetes.

She points to this example, "We have assisted in selecting vendors for diabetes management point solutions, which take a targeted approach toward this particular demographic. We also assess strategies like self-funding and medical stop-loss coverage that protect against unprecedented claims costs that can result from a high prevalence of chronic conditions. Further, we advise on and build wellness programs for companies that are comprehensive, accounting not just for chronic conditions and weight loss, but also for behavioral health, smoking cessation, financial wellness and more."

She says that there is absolutely a proven link between obesity and diabetes, although not all diabetics struggle with obesity.

"Obesity can put diabetics at high risk for disease progression and other conditions that negatively impact overall wellbeing," says Perlitch. "We are fortunate to have a clinical pharmacist on our team who runs point with our PBMs to ensure their prior authorization policies are in line with what employers need: a comprehensive solution. We also monitor utilization to ensure drug use aligns with the approved indications."

EVIDENCE AND DATA: OBESITY IS A DISEASE

Perlitch concurs that obesity is and has been a growing concern for employers, citing a statistic from the National Institute of Diabetes and Digestive and Kidney Diseases that reports more than 42% of American adults are obese or severely obese, a rate that has almost doubled since 1980. Not only does the weight itself impact health, it also adds to the risk of developing chronic diseases that come with their own set of challenges.

She also refers to the World Health Organization (WHO) reports that four million people die each year from underlying conditions related to obesity.

"Obesity has been known to increase a person's risk of developing type 2 diabetes, hypertension, cardiovascular disease, kidney disease, stroke, sleep apnea, osteoarthritis, and certain types of cancer, and can extend beyond the physical realm to negatively impact mental health, as well," she says. "As employers and the nation work to combat soaring healthcare costs, obesity is a critical piece of the puzzle, especially given that medical costs for the obese tend to be 30%-40% higher than those with a healthy weight."

Reporting on this issue, MEDSCAPE cites industry experts who explain that for some people, obesity as a disease invalidates the importance of discipline, proper nutrition, and exercise and enables individuals with obesity to escape responsibility.

For others, obesity as a disease is a bridge to additional research, coordination of effective treatment and increased resources for weight loss.

In defining obesity specifically, one of the most comprehensive definitions is provided by the Obesity Medicine Association (OMA) in the Obesity Algorithm which states that obesity is

defined as a "chronic, relapsing, multi-factorial, neurobehavioral disease, wherein an increase in body fat promotes adipose tissue dysfunction and abnormal fat mass physical forces, resulting in adverse metabolic, biomechanical, and psychosocial health consequences."

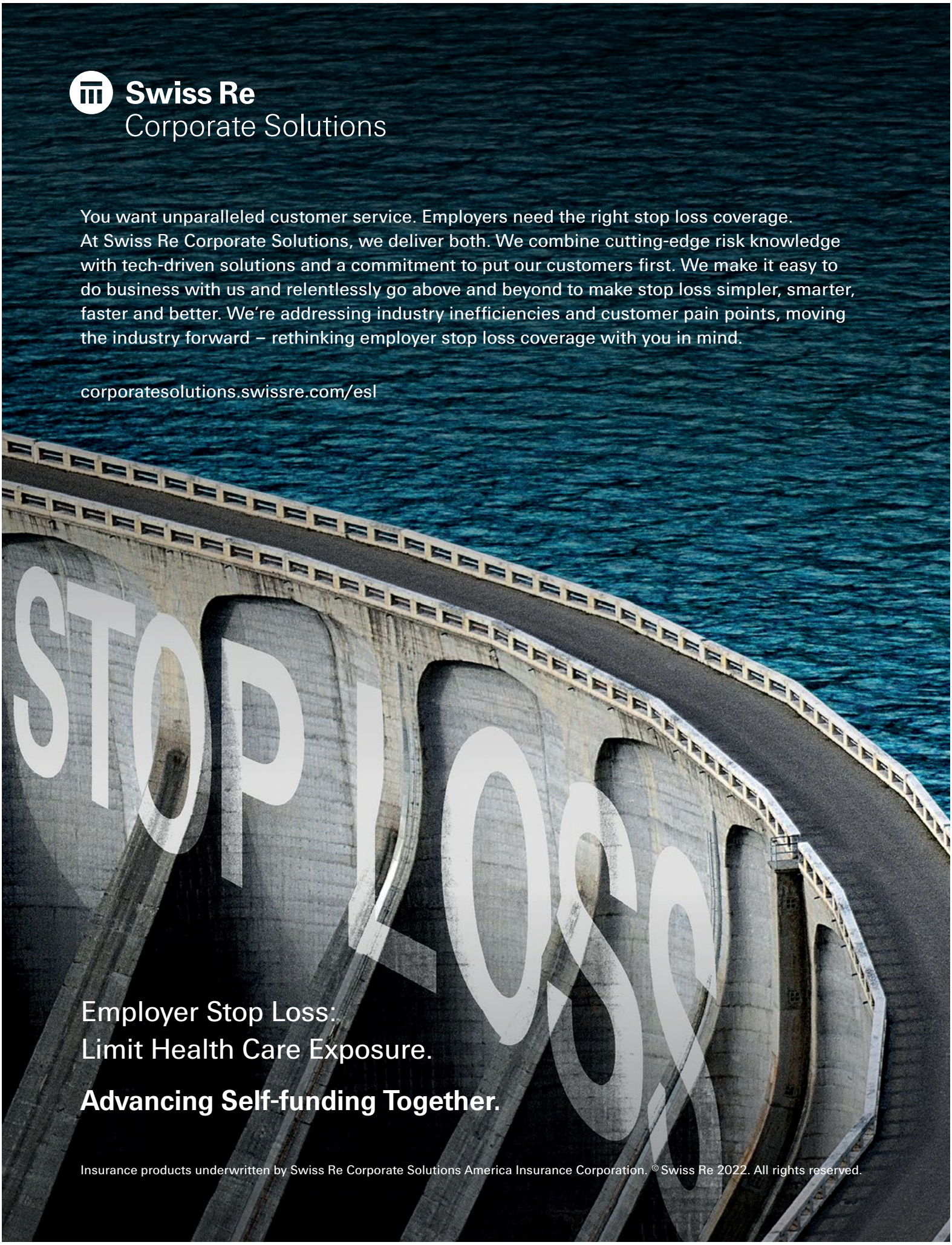
The OMA advises that individuals with obesity have an increased accumulation of fat not always attributable to eating too many calories or lacking physical activity. Individuals with obesity experience impaired metabolic pathways along with disordered signaling for hunger, satiety (the feeling of fullness), and fullness (the state of fullness).

For many, efforts to lose weight are met with unyielding resistance or disappointing weight regain. Many readers may remember the television show, "The Biggest Loser" which demonstrated that as contestants lose even as much as 230 pounds, their body's response is a slower and less efficient basal metabolic rate. Experts say this occurs in an effort to return the body to its previous condition of obesity -- a counter-effort by the body that makes weight gain easier and weight loss harder.

Furthermore, the pathology of obesity is vast and varies based on the cause of weight gain since there is not just one type or cause for obesity. Obesity sub-types include congenital, stress-induced, menopause-related, and MC4R-deficient, to name a few.

Obesity is related to genetic, psychological, physical, metabolic, neurological, and hormonal impairments. It is intimately linked to heart disease, sleep apnea, and certain cancers. Obesity is one of the few diseases that can negatively influence social and interpersonal relationships.

Last year, the American Gastroenterology Association recommended coverage of weight loss drugs for those with BMI (body mass index) over 30 or BMI over 27 with complications. Currently, about 42% of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people in the U.S. are obese, or have a BMI of 30 or higher, according to CDC data.

Richard Fleder, CEO ELMC Rx Solutions, observes, "For most chronic conditions, obesity is a leading contributor to pathogenesis and a focal point of many holistic treatment plans. Patients with elevated BMIs incur higher total healthcare costs, on average, when compared to counterparts with normal BMIs."

Intuitively, this makes sense, he continues, "…considering obesity is a risk factor for most chronic disorders and successfully addressing elevated BMI is associated with improvements in everything from depression to heart disease."

But even the BMI measure is under scrutiny as the AMA has gone on record with its waning confidence that BMI is a valid measure of health. This time-tested metric is so widely accepted and used throughout medicine – from surgical procedures and fertility treatments to new drug approvals and coverage/ reimbursement decisions – it will not be easy to discard.

In fact, BMI is used extensively in obesity medicine, determining who's eligible for the new weight loss drugs or for more traditional bariatric surgery, based on research gathered using the metric. According to STAT NEWS, AMA's new stance says BMI should be used in conjunction with other inputs to help assess fat mass, such as waist circumference and body composition. It's not simply a measurement for obesity, BMI is used to determine reimbursement for eating disorder treatments.

TEST YOUR KNOWLEDGE

IS OBESITY A DISEASE OR A DISORDER?

Obesity is a chronic disease. According to the Centers for Disease Control and Prevention, obesity affects 42.8% of middle-age adults. Obesity is closely related to several other chronic diseases, including heart disease, hypertension, type 2 diabetes, sleep apnea, certain cancers, joint diseases, and more.

IS OBESITY CONSIDERED A CHRONIC DISEASE?

Yes. Obesity, with its overwhelming prevalence of 1 in 6 adults in the U.S., is now recognized as a chronic disease by several organizations, including the American Medical Association. The Centers for Disease Control and Prevention (CDC) defines chronic disease as conditions that last one year or more and require ongoing medical attention or limit activities of daily living, or both.

Three leading chronic diseases are heart disease, cancer, type 2 diabetes. Obesity is associated with all three of these chronic diseases. CDC also acknowledges widespread consequences of obesity when compared to normal or healthy weight for many serious health conditions, including all causes of death, hypertension, diabetes mellitus, coronary heart disease, stroke and many cancers. Of the $3.3 trillion spent annually on medical care for chronic conditions, obesity alone is associated with $1.4 trillion.

WHAT IS THE LINK BETWEEN OBESITY AND MENTAL HEALTH?

Numerous studies support a strong link between obesity and mental health. This relationship appears to be bi-directional; while mental health disorders increase the risk for obesity, having obesity also increases the risk of mental health disorders, especially in certain populations.

Mental health disorders can increase the risk for obesity for several reasons: 1) Medications used to treat psychiatric illnesses can cause weight gain and insulin resistance, contributing to obesity; 2) Mental illnesses affect behaviors such as decreased sleep, poor eating behaviors, and reduced physical activity, which can contribute to the development of obesity.

Conversely, having obesity increases the risk for depression. This is likely due to numerous complex factors, including poor self-image and depressed mood in response to weight bias and stigma, decreased activity due to joint and back pain associated with excess weight, and biological disruptions caused by chemicals secreted by fat cells when a person has obesity. The link between obesity and mental health is complex and multi-faceted. It is important that patients with mental health disorders are monitored for weight, and that people with obesity are screened for mental health disorders.

Source: Medscape. https://www.medscape.com/viewarticle/875580?src=wnl_edit_tpal&uac=214004CT

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WHAT'S AHEAD FOR EMPLOYERS

"Everyone wants the same outcomes: a happy and healthy workforce," says Perlitch. "Obesity can profoundly impact your members, whether it be their mental and/or physical health. The short answer is yes, employers should cover these drugs BUT they need to ensure they have comprehensive prior authorization policies and ongoing monitoring in place."

She advises that drug coverage approvals need to be robust, including proof of enrollment and commitment to a weight loss program and physical activity plan. There needs to be frequent check ins and ongoing monitoring to assess continued weight loss, adherence to diet and physical activity, and whether the drug is working as intended.

But having insurance coverage alone doesn't guarantee that people can afford or would be willing to pay continuously for chronic disease medications like Ozempic, according to a new, large-scale study published in JAMA Network Open. For example, people with high copayments, defined as over $50, were about 50% less likely to adhere to drugs such as Ozempic and Trulicity than those with low copayments, defined as less than $10.

Weight-loss drugs may find additional channels for providing health benefits, opening up new avenues for prescription coverage that may be hard to deny. A new small study published in the journal *Obesity* suggests they may also be useful in fighting cancer.

Prior research has shown that people with obesity have deficiencies in their "natural killer" cells, or NK cells — immune cells that help in combating cancer. Researchers found that after a cohort of 20 people with obesity took semaglutide, the underlying ingredient in the

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diabetes drug Ozempic and the weight loss drug Wegovy, they had increased functioning in their NK cells.

A top Eli Lilly executive is quoted in the trade press that the company is aware of and "closely looking into" anecdotes that patients taking GLP-1 drugs seem to have an easier time quitting alcohol or cigarettes—but proving a genuine impact is easier said than done.

Some patients taking GLP-1 agonist meds have had a cessation benefit along with treating diabetes and obesity. Introducing an effective drug for alcohol-use disorder could have a big public-health impact, but more data is needed, and the cost of these drugs may be impractical for broader use.

Healthcare leaders are calling for a consensus on best practices for treating obesity, including the use of anti-obesity medications. Prior to covering the cost of the drugs, employers should seek clinical guidelines that create a body of clinical consensus statements regarding how physicians prescribe medications as well as discouraging providers from prescribing the newest or most expensive medication as first line therapy.

A leading healthcare publication reached out to the Alliance for Community Health Plans and the email response was: "…given some alarming adverse events and the steep price tag, ACHP and our member companies are focused on ensuring prescribing decisions are based on science as well as on providing patients with the best care possible."

A spokesperson for AHIP echoed this position, saying, "…insurers routinely review treatments for obesity, including lifestyle changes and nutrition counseling. Evidence indicates that the GLP-1 drugs do indeed help people lose weight. However, the evidence is still evolving related to how these medications may impact complications related to obesity such as heart disease and diabetes."

Law and lobbying firms are now engaged in the fray to try to convince policymakers to allow Medicare to cover anti-obesity medications, an approval which could set the stage for commercial coverage. Currently, Medicare is banned from covering weight loss drugs as part of the Part D program.

But the summer of 2023 may change the landscape altogether:

- An experimental pill from Eli Lilly – which patients may find more convenient than an injection -- led to 14.7% weight loss on the highest dose in a 36-week trial. Mid-stage results for orforglipron match the estimates of 14-15% weight loss that Lilly reported last year, and full results newly published in the *New England Journal of Medicine* were presented the American Diabetes Association conference.

- Clinical data results from a massive study from Novo Nordisk will disclose whether its in-demand weight-loss treatment Wegovy can prevent cardiovascular problems after years of use. Analysts expect the trial to succeed and the impact on patients and payers will be palpable -- enough to convince public and private insurers, who have been slow to reimburse for the medicine, to change their policies. ■

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