

# The Skinny on Emerging GLP–1 Exposures for the Healthcare Industry

As the use of glucagon-like peptide-1 receptor agonists (GLP-1) medications explodes, retail insurance agents need to be aware of the emerging exposures associated with them. GLP-1 medications, widely known for their role in managing diabetes and obesity, present unique risks that could impact healthcare providers, including potential liability issues and regulatory challenges that can impact clients' insurance needs.

## WHAT ARE GLP-1 MEDICATIONS?

GLP-1s are a class of medications originally used to treat type 2 diabetes; however, some formulations are also approved to treat obesity. Currently, three peptide medications or incretin mimetics, Wegovy, Saxenda, and Zepbound, have been approved by the U.S. Food and Drug Administration (FDA) specifically for weight loss.<sup>5</sup> GLP-1 receptor agonists mimic the GLP-1 hormone the intestines secrete in response to food, helping to regulate blood glucose levels. The GLP-1 hormone suppresses appetite and slows the process of food leaving the stomach. By taking a GLP-1 receptor agonist, people are able to supplement natural levels of GLP-1, promoting its effects within the body.<sup>4</sup>



The GLP-1 market is estimated to reach a value of \$100B - \$150B or higher by the early 2030s.<sup>1,2,3</sup>

### HOW DO GLP-1S REACH ACROSS HEALTHCARE SPECIALTIES?

GLP-1s are quickly becoming a mainstay of not only weight loss clinics, but also individual providers and digital health companies. In fact, obesity medications from Eli Lilly and Novo Nordisk are poised to become some of the most lucrative pharmaceuticals of all time. Novo's GLP-1 Ozempic was already one of the top-selling drugs of 2023, with the company's GLP-1 drugs bringing in a combined \$18.4 billion in sales, nearly double 2022 sales of \$9.3 billion. Lilly also saw booming demand in 2023 - netting \$2.2 billion in fourth-quarter Mounjaro sales and \$176 million from Zepbound after it was approved in November 2023.<sup>13</sup>

Physicians across the range of specialties, not just clinicians specializing in obesity, are prescribing GLP-1s, including primary care doctors, pediatricians, and endocrinologists. Exploding demand plus the potential for revenue growth for physicians and practices based on the margins and lack of insurance reimbursement remain key factors in whether physicians are jumping into the fray.

## **RISKS FOR HEALTHCARE PROVIDERS CREATED BY GLP-1S**

Even as it's getting easier for patients to obtain GLP-1s, there is still a relatively small number of healthcare providers trained in obesity care. In addition, there is substantial room for error in prescribing GLP-1s, and patients should be regularly monitored to ensure proper dosage, side effect management, and diet/exercise guidance. If an untrained clinician prescribes GLP-1s without appropriate support, an individual could actually become sicker. If patients fail to use the medications properly, it also undermines the case for more broad insurance coverage of the drugs.<sup>8</sup>

The 8,300 physicians certified by the American Board of Obesity Medicine represents less than 1% of U.S. physicians.<sup>8</sup>



## HOW THE GROWING DEMAND FOR GLP-1s IS IMPACTING THE MARKETPLACE & CREATING A COMPOUNDING CRAZE

Recent polling finds that about one in eight adults (12%) report having taken a GLP-1 agonist.<sup>11</sup> The huge demand for these drugs is leading to medication shortages, inconsistent insurance coverage, and dubious counterfeits or compounded versions that create challenges for companies and consumers.<sup>7</sup> Supply shortages are a big hurdle for companies in the GLP-1 market because spiking demand has made it difficult for many patients to access the medication. This is particularly problematic for patients with type 2 diabetes who rely on the medication for disease management.<sup>7</sup>

The demand for Ozempic and similar drugs has pushed compounded medications, once a more niche corner of healthcare, out into the mainstream market.<sup>17</sup> Up to 30% of GLP-1 drugs are acquired by patients through compounding pharmacies rather than large manufacturers like Novo Nordisk or Eli Lilly. There isn't solid data on how many people take compounded GLP-1s, but estimates suggest millions of Americans may be seeking them, often because they are looking for a cheaper option or can't find the brand-name GLP-1 drugs in stock.<sup>17</sup> Many employers have excluded weight loss drugs from their health insurance plans due to the high costs associated with treating large numbers of people.<sup>6,7</sup> Patients typically pay \$100 to \$450 a month for a compounded version, compared with list prices of roughly \$1,000 to \$1,400 monthly for name brand products.<sup>14</sup>

Concerns remain over the quality and safety of compounded versions.<sup>9</sup> Drugmaker giants like Eli Lilly have even filed lawsuits to stop the use of compounded medications.<sup>12</sup> With a complex supply chain and several vendors engaged in making a sterile, injectable medication, there are additional safety risks around compounded drugs. How much risk remains hotly debated.

According to the FDA, compounded medications are generally not considered as safe. Between August 2021 and mid-July 2024, the FDA had reviewed 288 reports of adverse patient reactions to compounded semiglutide and 108 such reports for tirzepatide. Those are only a few of the tens of thousands of adverse-event reports submitted for all types of the drugs, including brand-name versions, which are known to have well-documented side effects. The FDA has received reports of patients erroneously injecting too much or healthcare providers calculating incorrect doses resulting in the need for medical attention or hospitalization.<sup>13</sup>



More than 2.5 million GLP-1 prescriptions were filled in the U.S. by December 2023.<sup>10</sup>

## WHAT ARE THE EMERGING EXPOSURES AROUND GLP-1S FOR HEALTHCARE PROVIDERS?

The increased risks associated with the compounded GLP-1 versions have resulted in an FDA advisory that, accompanied with the higher risk of potential claims, make placement of these risks difficult.<sup>15</sup> As demand is expected to remain high, and the shortage is expected to last into 2025, insureds are likely to continue offering the compounded product and associated services.

The FDA has also advised that some compounders may be using salt forms of the medication, such as semaglutide sodium and semaglutide acetate, which include different active ingredients from approved GLP-1 drugs. The FDA indicated it was not aware of any basis for compounding using salt forms that would meet FD&C requirements, reporting that "products containing these salts, such as semaglutide sodium and semaglutide acetate, have not been shown to be safe and effective."<sup>16</sup>

The risk of overdose is also higher with compounded versions. Medications prescribed through a telehealth service generally come with a vial and syringes to draw the drug out at home. Some patients have been hospitalized, developed pancreatitis or gallstones, or have fainted or become dehydrated after taking five, 10, or even 20 times more than the intended dose. Accidents like this are becoming more common. So far in 2024 there have been 159 calls to national poison control centers involving compounded GLP-1s. In 2023, there were only 32.<sup>17</sup>

It's vital that physicians, other prescribers, and compounding pharmacists ensure that patients are properly counseled about how to administer compounded GLP-1s. Patients report being sent boxes with tons of information and video QR codes. In some cases, patients are skipping provided videos or written instructions in favor of Facebook or Reddit threads.<sup>17</sup> Online, patients also turn to YouTube tutorials and calculators to determine dosage. Some even post about doubling doses, trying to lose weight more quickly. Some who originally took a name brand GLP-1 also find it difficult to transition to a compounded version as label instructions may contradict other advice.<sup>17</sup>

## Global spending on obesity medications totaled \$24B in 2023.<sup>2</sup>



## HOW IS THE INSURANCE MARKETPLACE RESPONDING?

The insurance marketplace has adopted varied strategies in response to the exposures associated with GLP-1 medications. Some insurers are opting out entirely, fearing potential claims and the associated risks. Others are willing to cover only the branded versions of GLP-1s, excluding compounded forms that are not under FDA advisory warnings. A more selective group of insurers is prepared to cover both branded and compounded versions, provided that the compounding is not conducted by the insured party themselves. This nuanced approach highlights the importance of having a knowledgeable wholesale partner who understands the market's appetite and can navigate these complexities effectively.

With the increasing demand for coverage, agents are facing a pressing need to find solutions for this exposure. The standard markets' reluctance to cover compounded versions underscores the necessity for experienced wholesale representation, particularly for excess and surplus (E&S) solutions. The revenue potential from these medications means that insureds are unlikely to accept the inability to secure coverage. Given that the sale of these medications spans various risk types, agents must be prepared to collaborate with wholesalers who can swiftly locate suitable coverage, whether by moving the entire risk or developing a carve-out policy. Additionally, the rise of online companies offering GLP-1s across state lines requires expertise in telemedicine and its associated risks. A proficient wholesaler will efficiently identify and target appropriate markets by asking relevant questions about compounding risks, ensuring a smooth placement process.

### HOW CAN AGENTS HELP?

Agents play a crucial role in managing the coverage for GLP-1 medications by engaging proactively with their insureds. Many insureds may be offering these medications under the assumption that they have adequate coverage, which may not always be the case. Agents should reach out to wholesalers who have access to markets that can write this exposure and possess in-depth knowledge of their appetite and underwriting processes. By doing so, agents can ensure a seamless placement and avoid potential coverage gaps that could jeopardize their clients' operations.

### BOTTOM LINE

As the use of GLP-1 medications continues to rise, retail insurance agents must navigate emerging exposures tied to these treatments. GLP-1s, crucial for managing diabetes and obesity, present unique risks including potential liability issues and regulatory challenges. Despite their growing prominence in digital health and obesity management, insurance coverage remains inconsistent. Some insurers avoid covering GLP-1s due to high risks, while others only cover branded versions or exclude compounded forms not FDA-approved. With demand high, especially for compounded medications, agents must work with knowledgeable wholesalers to secure appropriate coverage.

CRC Group is well-equipped to handle the exposures associated with GLP-1 medications, drawing on extensive experience and expertise within the healthcare space. Our robust healthcare practice, which encompasses a significant portion of our total

premium, uniquely positions us to address the complexities of this exposure effectively. Our team is prepared to provide tailored solutions that align with the evolving needs of the market and our clients. Reach out today!

## CONTRIBUTORS

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#### **END NOTES**

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