



# Rx newsletter

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# Market trends

## The Fluctuating Position of Insulin in America



Diabetes impacts 11% of the US population.<sup>1</sup>

### What is Diabetes?

Diabetes is a chronic health condition where your body does not make enough insulin or can't use it as well as it should. Untreated diabetes can result in conditions such as heart disease, vision loss, and kidney disease.<sup>1</sup>

According to the Centers for Disease Control and Prevention, an estimated 37 million US adults have a type of diabetes, while another 96 million are pre-diabetic.<sup>1</sup> Diabetes related costs total an estimated \$327 billion in medical costs, and lost wages and unfortunately, the rate at which patients are being diagnosed continues to grow.<sup>1</sup>

### Cost Prevention and Legislation

As of 2017, researchers concluded that the average person with diabetes incurs roughly \$16,750 in healthcare costs annually.<sup>2</sup> In 2018, the average list price for one vial of insulin was \$98.70, according to the Rand Corporation.<sup>3</sup>

With no end in sight to these insulin prices and pressure from the general public, the US government took a stand and passed the American Rescue Act, which will take effect on January 1, 2024.

What does the American Rescue Act (ARP) do?

- Caps the insulin price at \$35 for those on Medicaid and Medicare.
- Includes a provision that eliminates the statutory cap on rebates paid to Medicaid. Starting January 1, 2024

this provision will remove the 100% cap for these drugs, which is expected to save the government billions of dollars annually.

With rising public opposition and legislative pressure, insulin manufacturers have begun to preemptively reduce costs on some of their most popular products. Manufacturers like Eli Lilly, Novo Nordisk, and Sanofi have decided to act and reduce these product costs anywhere from 65%-78%. Many welcome this gesture of goodwill from these manufacturers who fully understand that many Americans cannot keep up with the rising costs.

Although future costs and outcomes for patients with diabetes have certainly improved, the need to aggressively and effectively intervene and manage pre-diabetic and diabetic populations has not changed.

### What do these changes mean for employers?

Now that the dust has settled, many have begun to question what type of impact this has on commercial plans and employers.

The medications that have had their costs lowered by Eli Lilly, Novo Nordisk, and Sanofi will no longer receive rebates, which in turn would get passed along to employers on a quarterly and annual basis. Although rebate payouts may be impacted, the point-of-sale cost will be much lower, creating a neutral cost impact or even providing net plan savings to the employer and plan.

In the coming weeks and months, PBMs will begin to shift their rebate guarantee strategies to achieve pharmacy cost neutrality, so it is important to have an open dialogue with your pharmacy insurance provider and be aware of the changes that will be coming for the 2024 plan year.

### Sources:

1. "The Facts, Stats and Impacts of Diabetes" Center for Disease Control, accessed July 26, 2023, <https://www.cdc.gov/diabetes/library/spotlights/diabetes-facts-stats.html>
2. "The Cost of Diabetes" American Diabetes Association, accessed July 26, 2023, <https://diabetes.org/about-us/statistics/cost-diabetes>
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4. "3 big drug companies drastically cut insulin costs for consumers" Deseret News accessed July 26, 2023, <https://www.deseret.com/2023/3/17/23644828/sanofi-eli-lilly-novo-nordisk-drastically-cut-insulin-prices>

# Pharmacy 101

## Alternative Funding Increase in Pharmacy Health Care

As prescription drug costs increase, employer plans look to alternative funding.

Alternative funding is the process in which patient assistance programs are utilized to decrease specialty drug cost spend for employer plans.

### Alternative Funding Trends in Employers Plans

The percentage of employer plans utilizing alternative funding programs (AFPs) has increased to 14% in 2022 compared to 6% in 2021.<sup>1</sup> There are several vendors in the market that promote employer savings by implementing alternative funding.

AFPs provide employers with quick savings on high-cost drugs since they are processed at point of sale compared to the standard process which can take months. The only cost to employers is a small fee from the AFP vendors. If the drug is not AFP eligible, then the plan would need to cover that drug under their health plan.

### Compliance Concerns around AFPs<sup>2</sup>

Employer plans need to consider potential compliance issues when implementing AFPs. In order for AFPs to work, specialty medications are excluded from the plan, which is therefore not within the written plan. These reimbursements are then required to be reported on each employee's W-2 that is filed each year by the employer.



Employers face the potential to be financially penalized by the IRS if the W-2 forms are incorrectly filed.

An employer plan may be penalized under ERISA if there is evidence of a fiduciary breach. Employee financial contributions are to be set within a trust and only utilized for benefits that are covered through the plan. A fiduciary breach can occur if claims are reimbursed that are not technically covered by the plan. This can occur if a specialty drug is not being covered by the AFP and is given an override to be covered by the employer's health plan. Under ERISA, the Department of Labor can impose a financial penalty on the employer.

Outside of potential financial violations, an employer plan may be seen as discriminatory by the Department of Labor if they are covering drugs on the pharmacy plan based on the employee's financial status. An employer plan cannot cover a drug based on the eligibility of an employee being able to utilize AFPs.

### Other Potential Unrelated ERISA Issues<sup>2</sup>

- Misrepresentation may occur as alternative funding depends on receipts having no insurance.
- If an employee's financial information is included in the alternative funding application, it must be accurate when provided by the AFP to other agencies and manufacturers.
- Stop loss insurance is typically used by the employer in relation to amounts covered by the group health plan. Claim reimbursements made outside of the terms of the group health plan and not covered by alternative funding may not apply to the group health plan stop loss insurance.

It is important for any employer considering the use of alternative funding to work with their compliance team to determine the fit. While cost savings are important, it is equally important to substantiate the value these programs bring to employees.

#### Sources:

1. "Employers Expand Use of Alternative Funding Programs," *Drug Channels*, accessed July 24, 2023 <https://www.drugchannels.net/2023/05/employers-expand-use-of-alternative-funding-programs>
2. "ERISA and IRS Compliance Related Issues for Alternative Funding Programs," *Vivio Health*, accessed July 24, 2023 <https://viviohealth.com/wp-content/uploads/2022/06/Compliance-Issues-with-Alternative-Funding-V1.01.pdf>

# Disease Spotlight

## The Effects of Obesity Continue to Be Severe, Complicated, and Costly.

### Obesity can cause risky health conditions to develop

Obesity is a disease characterized by an excessive amount of body fat and is often diagnosed by measuring one's body mass index (BMI). BMI measures weight in relation to height. A BMI equal to or greater than 30 is an indicator of obesity.<sup>1</sup>

According to the Mayo Clinic, "there are genetic, behavioral, metabolic, and hormonal influences on body weight." These influences can include an unhealthy diet, lack of sleep, age, medications, stress, minimal physical activity, and socioeconomic factors.<sup>2</sup>

### Obesity can Cause or Worsen Other Health Conditions

Individuals with obesity are more likely to develop other serious health conditions, and pre-existing conditions can be exacerbated. A few examples are listed below.

- Heart disease and/or strokes: Obesity increases the likelihood of developing high blood pressure and may affect cholesterol and triglyceride levels.<sup>2</sup>
- Diabetes: Obesity can impact how the body processes insulin, which can lead to abnormal blood sugar levels.<sup>2</sup>
- Cancer: Recent studies show that obesity in both men and women increases the risk of developing cancer of the esophagus, colon, rectum, gallbladder, kidney, and more.<sup>3</sup>

### Treatment can be Elaborate and Expensive

The objective of treatment for obesity is to attain and maintain a healthy weight. Obesity is often treated with an array of lifestyle changes, which may be accompanied by medication or procedures. Providers commonly recommend a healthier diet and more exercise, along with therapy or counseling.<sup>4</sup>

More critical cases of obesity may require weight-loss medications, such as GLP-1 drugs like Ozempic and

Wegovy. Wegovy and Mounjaro are two of the newer GLP-1 drugs and the most effective. Wegovy is showing a 16% reduction in weight from the patient's baseline, while Mounjaro is showing a 21% reduction.<sup>5</sup>

These drugs can help people lose weight, but they are expensive, making employers hesitant to cover their costs. Employers are concerned about the expense of the medications, which can exceed \$10,000 per year without insurance.<sup>6</sup>

### Employer Insights and Concerns

According to a survey conducted by the International Foundation of Employee Benefit Plans, 22 percent of employers currently cover weight loss medications for their employees.<sup>7</sup>

Employers are also weighing the short-term costs of the drugs against their long-term potential savings. Weight loss drugs could lower costs in the long run if they improve an employee's underlying health conditions like hypertension or diabetes.<sup>6</sup>

Private payers have been reluctant to cover the drugs for weight loss only. Currently, Medicare is barred from covering any weight loss drugs. Weight loss drug coverage could be an attractive benefit for employees in a competitive labor market.<sup>6</sup>

### Sources:

1. "Learn About Obesity – About Obesity (Causes and Classifications)," Obesity Action Coalition, accessed July 22, 2023, <https://www.obesityaction.org/education-support/learn-about-obesity/causes/>
2. "Obesity – Symptoms and causes," Mayo Clinic, accessed July 22, 2023, <https://www.mayoclinic.org/diseases-conditions/obesity/symptoms-causes/syc-20375742>
3. "Learn About Obesity – Related Conditions," Obesity Action Coalition, accessed July 25, 2023, <https://www.obesityaction.org/education-support/learn-about-obesity/related-conditions/>
4. "Obesity – Diagnosis and treatment," Mayo Clinic, accessed July 25, 2023, <https://www.mayoclinic.org/diseases-conditions/obesity/diagnosis-treatment/drc-20375749>
5. "Weight Loss Drug Cost and Impact," Optum Rx, accessed July 25, 2023, <https://www.optumrx.com/public/landing>
6. "Employees are asking for this: Will more employers cover weight loss drugs?" Becker's Payer Issues, accessed July 25, 2023, <https://www.beckerspayer.com/payer/employees-are-asking-for-this-will-more-employers-cover-weight-loss-drugs.html>
7. "Employers Covering Prescription Drugs for Weight Loss," International Foundation of Employee Benefit Plans, accessed July 25, 2023, <https://blog.ifebp.org/employers-covering-prescription-drugs-for-weight-loss/>



# Clinical Spotlight

## Polypharmacy and its Impact on Members and Employers



### What is Polypharmacy?

Polypharmacy is when a pharmacy utilizer is taking five or more medications at one time, which can increase the risk of adverse medical outcomes.<sup>1</sup>

### How can Polypharmacy occur?

While it may sound like a rare occurrence, polypharmacy is actually very common. It occurs frequently with seniors or those who suffer from multiple health complications. It is so common that 1 in 5 Americans ages 40-79 use five or more prescription drugs.<sup>2</sup> Although each medication has its benefit, it can become an issue for the patient and doctors who have to keep track of them all and be aware of the drug interactions.

Here are some of the reasons as to why polypharmacy may occur:<sup>3</sup>

- **Prescribing cascades:** This refers to a patient who has multiple health conditions and is prescribed a medication to address the side effects of another medication.
- **Disconnected medical care:** A patient may have multiple healthcare providers with whom they only interact with at certain points in the year. Prescriptions may have multiple refills and interact with newly prescribed medications, and a prescriber may not be aware of this until seeing the patient many months later.

- **Pharmacy changes:** Patients may change pharmacies multiple times throughout the year and have different medications at each. Because of this, it is difficult for pharmacists to flag medications that may interact with one another.

### What can be done to prevent Polypharmacy?

Polypharmacy can be managed, but it requires a team effort between patients, providers, and insurance partners. This is important as polypharmacy not only contributes to patient safety concerns but also financially to the member and insurer.

What you can do as a patient:<sup>3</sup>

- **Pick a point person:** Work with a trusted primary care provider that can help keep track of and review drug utilization. Be honest and open with them about any new medications you are trying or previous medications that you have stopped taking that still have active refills.
- **Keep track of medications:** Log all your current medications and supplements and bring it to your health care providers for review. It is important to make sure that these drugs are not duplicates of one another or interact negatively.
- **Talk to your local pharmacist:** Pharmacists are always available to consult with when picking up your medication. They can also perform a drug utilization review on site and confirm that this medication does not interact with any others.
- **Don't stop your medications without approval from your health care provider.**<sup>3</sup> It is easy to become overwhelmed when researching drug interactions, but it is important to stay on your medications until your doctor can provide a formal review.

As an employer, talk to your Pharmacy Benefit Manager (PBM) and inquire about programs that can help address polypharmacy concerns. More often than not, they will have a polypharmacy program that can help identify and consolidate these medications on behalf of members while saving money for employers.

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1. "Polypharmacy: Evaluating Risks and Deprescribing," *American Family Physician*, accessed July 27, 2023, <https://www.aafp.org/pubs/afp/issues/2019/0701/p32.html>
2. "Prescription Drug Use Among Adults Aged 40-79 in the United States and Canada," *Centers for Disease Control and Prevention*, accessed July 27, 2023, <https://www.cdc.gov/nchs/products/databriefs/db347.htm#:~:text=Nearly%207%20in%2010%20adults,and%2018.8%25%20in%20Canada.>
3. "Polypharmacy Concerns and Risks," *Verywell Health*, accessed July 27, 2023, <https://www.verywellhealth.com/what-is-polypharmacy-2223450>

# Pipeline

## Pending drug approvals

Drug name	Manufacturer	Indication/use	Expected FDA decision date
zuranolone	Sage/Biogen	Major depressive disorder; postpartum depression	8/5/2023
avacincaptad pegol	Iveric Bio	Dry AMD-related geographic atrophy	8/19/2023
lotilaner	Tarsus	Demodex blepharitis	8/25/2023
lebrikizumab	Eli Lilly	Atopic dermatitis	Sept 2023
nedosiran	Novo Nordisk	Hyperoxaluria	Sept 2023
motixafortide	Biolinerx	Stem cell mobilization for multiple myeloma	9/9/2023
atezolizumab SC	Genentech	Hepatocellular carcinoma; Melanoma (BRAF-mutant); NSCLC; SCLC; Soft tissue sarcoma; Urothelial cancer	9/15/2023
meningococcal pentavalent vaccine (PF-06886992)	Pfizer	Meningococcal Immunization	October 2023
tocilizumab (biosimilar to Genentech's Actemra)	Biogen/Bio-Thera Solutions	RA; Polyarticular JIA; Systemic JIA"	10/9/2023
infliximab SC	Celltrion	Inflammatory bowel Disease	10/22/2023
vamorolone	Santhera	DMD	10/26/2023
reproxalap	Aldeyra	DED	11/23/2023
denosumab (biosimilar to Amgen's Prolia/Xgeva)	Sandoz	Osteoporosis/osteopenia	12/6/2023
trastuzumab (biosimilar to Genentech's Herceptin)	Henlius/Accord	Breast cancer; Gastric or gastroesophageal junction adenocarcinoma"	12/15/2023

## Brands Losing Patent

Drug name	Manufacturer	Indication/use	Expected FDA decision date
Humira	adalimumab	Rheumatoid arthritis, psoriatic arthritis, ankylosing spondylitis, Crohn's disease and plaque psoriasis	January 2023
Xyren	Sodium oxybate	Narcolepsy	January 2023
Trokendi XR	Topiramate	Epilepsy, migraine prevention	January 2023
Aubagio	Teriflunomide	Multipole sclerosis	March 2023
Aggrastat	tirofiban	Used during a heart treatment to protect the arteries	March 2023
Gattex	Teduglutide	Short bowel syndrome	March 2023
Corlanor	Lvabradine	Heart failure	April 2023
Edurant	Rilpivirine	HIV	April 2023
Livalo	Pitavastatin	Lowers bad cholesterol and triglycerides and raises good cholesterol	May 2023
Symbicort	Budesonide/formoterol	Asthma and chronic obstructive pulmonary disease	July 2023
Qtern	Dapagliflozin/Saxagliptin	Used to lower blood sugar in patients with high blood suga	July 2023
Mozobil	Plerixafor	Used to raise the number of stem cells	July 2023
Vyvanse	Lisdexamfetamine	Attention-deficit/hyperactivity disorder	August 2023
Victoza	Liraglutide	Used to lower blood sugar in patients with high blood sugar	December 2023
Complera	Emtricitabine, Rilpivirine, Tenofovir	HIV	January 2024
Gralise	Gabapentin	Neuropathic pain	January 2024
Omidria	Ketorolac 0.3%/Phenylephrine 1%	Used during eye surgery & to lower eye pain after eye surgery	January 2024

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