FOCUS: HOSPITAL AND HEALTH LAW

Health Insurers—Making Consumers Wait for Weight-Loss Drugs

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Sweet tooth. The "Freshman 15." Packing on a few extra pounds during the holidays. For years, most people have considered these items as innocuous indulgences. But in America, as in much of the world, weight is an increasingly dangerous problem.

According to the Centers for Disease Control and Prevention ("CDC"), nearly three-quarters of American adults are overweight or obese.[1] The CDC defines "overweight" as having a body mass index ("BMI") of 25 to 29.9 and "obese" as having a BMI over 30.[2] As early as 2013, the American Medical Association ("AMA") defined obesity as a disease,[3] and the CDC and the World Health Organization likewise classify obesity as a disease.[4]

Obesity is dangerous, and the AMA notes that obesity is "associated with more than 200 comorbidities, such as diabetes, high blood pressure, heart disease and multiple types of cancer."[5] In addition to the dangers associated directly and indirectly with obesity, there is a huge financial cost as well, with the CDC estimating that obesity accounted for $173 billion in medical expenditures in 2019.[6] Furthermore, in many communities there is a negative stigma associated with obesity, enough of a stigma that New York City's Human Rights Law considers weight to be a "protected class," namely, it is illegal to discriminate in employment, housing and public accommodations based on a person's weight.[7]

People have started to take notice and are responding in a variety of ways. Restaurants and coffee shops will routinely list the caloric content of food. New diet crazes seem to crop up each day, be it intermittent fasting, the South Beach diet, the Mediterranean diet, the Atkins diet, the Paleo diet and countless others. Exercise trends are also multiplying in number as people try the gym, Peloton, commuting by bike, boot camps, CrossFit, marathons (and similar long-distance endurance challenges), counting steps, rowing machines and even goat yoga (yes, goat yoga is a real thing). At the same time, clothing companies are reacting to a new normal of heavier people by attempting to shift body-image perceptions by producing and selling clothing designed for larger people.

Among people who have tried at least one of the above diets or exercise routines, there is one example that, anecdotally at least, works wonders: weight-loss drugs. Without going too much into the science behind these medicines, weight-loss drugs generally make a person feel less hungry, fuller or both.[8] The Food and Drug Administration ("FDA") has approved eight drugs for weight loss, the most famous of which is a semaglutide known by its brand name Wegovy.[9] Diabetes drugs such as Ozempic or Mounjaro have yet to be approved specifically for weight loss by the FDA.

Health Insurance and Weight-Loss Drugs

A collection of federal and state bodies regulate health insurance in the United States. Much of nongovernmental federal health insurance is governed by the provisions of the Employee Retirement Income Security Act of 1974 (as may be amended and in effect from time to time, "ERISA") and regulations thereunder.[10] ERISA has been amended several times to include various provisions from other sources (*e.g.*, the Patient Protection and Affordable Care Act, the "ACA") and in some regards works in tandem with other laws such as the Internal Revenue Code of 1986, (as may be amended and in effect from time to time). While ERISA generally preempts state law, each state also has its own rules relating to health insurance coverage.

Under ERISA, a "group health plan" is "an employee welfare benefit plan to the extent that the plan provides medical care to employees or their dependents."[11] Group health plans are important benefits that employers provide to their employees. These plans come in different shapes and sizes with a main difference being the funding—either "self-funded" or "fully insured." In a self-funded plan, an employer will pay, from the employer's general assets, for medical claims as they arise (in essence, the *employer itself* serves as the insurance company). By contrast, in a fully insured plan, an employer has segregated assets to pay a pre-determined premium to the insurance company irrespective of the amount of medical claims. ERISA defines "medical care" as:

- Amounts paid for the diagnosis, cure, mitigation, treatment or prevention of a disease or amounts paid for the purpose of affecting any structure or function of the body.
- Amounts paid for transportation primarily for and essential to medical care.
- Amounts paid for insurance covering medical care.[12]

Nothing in ERISA expressly forbids health insurance from covering weight-loss drugs. Indeed, as obesity is widely recognized as a disease, insurance covering weight-loss drugs fits squarely within the definition of medical care, namely the mitigation and treatment of a disease (in this case obesity). Given the rather broad definitions of group health plan and medical care, plans, especially self-funded plans, have a fairly wide latitude in deciding which health treatments to cover and which not to cover. Just as there is no rule in ERISA forbidding coverage of weight-loss drugs, there is similarly no requirement for health insurance to cover weight-loss drugs.

Insurance companies, by and large, are seizing on the lack of formal requirements and are generally not covering weight-loss drugs or significantly limiting such coverage. This coverage gap is driven primarily by cost as U.S. list prices for some of the most common medications used for weight loss range from $900/month to more than $1,300/month, an amount that is often higher than the monthly premium paid by many individuals for insurance coverage.[13] Insurance companies that do cover weight-loss drugs may impose a host of prior authorization requirements to actually qualify for the drug, which may include the following:

- A statement that the drug is "non-experimental" and a determination from a physician that the drug is medically necessary.
- Completing a months-long wellness education program focusing on healthy life choices.
- An attestation that other diets and/or exercise programs have not worked.
- A BMI level that is well into the obese range.

Obese patients may find that weight-loss drugs are out of reach and for those patients that are already taking the drugs, they may face hurdles if insurers and health plans begin to change prior authorization criteria to further limit eligibility for the drugs.

To some, insurance companies and self-funded health plans are being penny wise and pound foolish. As mentioned above, obesity often puts individuals at higher risk for heart disease and cancer. The long-term costs of treating diabetes, heart disease and/or cancer are astronomical and undoubtedly higher than the cost of weight-loss drugs. An insurer or self-funded health plan's coverage of weight loss drugs as a preventive measure likely would reduce instances of chronic diseases associated with obesity for their covered populations, therefore likely reducing costs for insurers and self-funded health plans to treat those populations. Part of insurers' and self-funded health plans' reluctance to uniformly cover weight-loss drugs, however, may be due to the fact that the American health insurance model works on an annual basis, not a lifetime basis, a model that is unlikely to change. The potential cost-saving benefits of an insurer's or self-funded plan's "investment" in weight-loss drug coverage as a preventive measure would be best realized by an insurer or self-funded plan if the individuals who receive the weight-loss drugs remain covered by the same insurer or remain employed by the same employer's self-funded plan for their entire careers.[14]

The tension between cost, social benefit, permissive or prohibitive regulations is borne out in many states,[15] including New York. New York's Medicaid pharmacy program, NYRx, "covers medically necessary FDA-approved prescription and non-prescription drugs for Medicaid members."[16] However, weight-loss drugs are specifically excluded; NYRx goes so far as to state that "weight loss has never been a Medicaid-approved reason for covering a drug."[17] Perhaps even more surprising, NYRx singles out Wegovy, a drug specifically approved by the FDA for weight loss, as not "covered by NYRx when prescribed for weight loss."[18]

On the other end of the spectrum, the New York State Senate is considering a bill with a stated purpose "to provide Medicaid coverage for prescription drugs approved by the FDA for chronic weight to ensure greater healthcare accessibility and address the rising epidemic of obesity in our State."[19] The New York State Assembly proposes an even greater

expansion with a bill that is seeking to write the following into state law: "Every policy which provides medical, major medical, or similar comprehensive-type coverage shall provide comprehensive coverage for treatment of obesity, which shall include coverage for…FDA-approved anti-obesity medication."[20]

Practical Considerations

Moving forward, there is one safe assumption: obesity rates are not going to drop drastically, especially not in the immediate short term. Many other factors are nearly impossible to predict. Will the FDA approve other weight-loss drugs (brand name or generic) and, if so, will that drive down the cost of weight-loss drugs? Will federal and state health insurance regulations mandate coverage of weight-loss drugs, prohibit coverage of weight-loss drugs (if side effects and potential for misuse outweigh the benefits) or retain a middle ground that neither prohibits nor requires coverage? Will the federal and state/local governments offset the cost of weight-loss drugs? Will more/fewer plans cover weight-loss drugs?

Regardless of how the current dynamic changes (if at all), employers have to consider the cost/benefit of healthier employees. As discussed above, obesity leads to an increased risk of other health problems. A healthier workforce means less absenteeism and more productivity in companies of all sizes and across all industries, not just those that require strenuous physical activity. Employers need to determine how the cost of health insurance impacts their bottom lines. In other words, is paying high premiums for expensive weight-loss drugs more or less beneficial than paying high premiums because of a less healthy workforce? For employers who offer self-funded plans, are reserves sufficient to pay the high costs associated with chronic heart disease? For the insurance companies, the calculus is slightly different. Insurance companies need to balance the cost (and conditions) of covering weight-loss drugs with the desire to both offer attractive plans to consumers and remain profitable.

The delicate interplay of health insurance and weight-loss drugs seems likely to remain a fascinating topic for years to come. In the event federal or state legislation requires insurers or health plans to cover the costs of weight-loss drugs, insurers and employers must effectively use data to develop strategies to ensure coverage of such drugs is financially feasible within their existing models in light of the anticipated need for the drugs in their covered patient populations. They must also control costs through prior authorization requirements that achieve a balance between ensuring adequate patient access to the drugs and ensuring the drugs are used for their intended, approved clinical purpose (and not otherwise abused).

1. Cheryl D. Fryar, Margaret D. Carroll & Joseph Afful, *Prevalence of Overweight, Obesity, and Severe Obesity Among Adults Aged 20 and Over: United States, 1960–1962 Through 2017–2018*, CDC Nat'l Ctr. for Health Stat., https://www.cdc.gov/nchs/data/hestat/obesity-adult-17-18/obesity-adult.htm#Citation (last revised Jan. 29, 2021).
2. *Id.*
3. *Memorial Resolutions, Proceedings of the 2013 Annual Meeting of the House of Delegates*, AMA, ¶ 420 (approved Nov. 17, 2013), https://www.ama-assn.org/sites/ama-assn.org/files/corp/media-browser/public/hod/a13-resolutions_0.pdf.
4. *About Obesity*, CDC (Jan. 23, 2024), https://www.cdc.gov/obesity/php/about/index.html; *Obesity and Overweight*, WHO (Mar. 1, 2024), https://www.who.int/news-room/fact-sheets/detail/obesity-and-overweight.
5. *Obesity*, AMA, https://www.ama-assn.org/topics/obesity (last visited Aug. 29, 2024).
6. *Adult Obesity Facts*, CDC (May 14, 2024), http://bit.ly/4cHdc57.
7. N.Y.C. Admin. Code § 8-107.
8. *Prescription Weight-Loss Drugs*, Mayo Clinic (Oct. 29, 2022), https://www.mayoclinic.org/healthy-lifestyle/weight-loss/in-depth/weight-loss-drugs/art-20044832.
9. Phuoc Anh Nguyen, *8 FDA-Approved Drugs for Weight Management*, Very Well Health (Feb. 15, 2024), https://www.verywellhealth.com/7-fda-approved-drugs-for-weight-management-7568596.
10. 29 USC §§ 1001-1461. Title I, Part 7 of ERISA specifically incorporates provisions of the Patient Protection and Affordable Care Act (ACA), the portability and nondiscrimination provisions of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), the mental health parity provisions of the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPAEA), the Newborns' and Mothers' Health Protection Act of 1996, the Women's Health and Cancer Rights Act of 1998 and the Genetic Information Nondiscrimination Act of 2008.
11. 29 USC § 1191b(a)(1).
12. 29 USC § 1191b(a)(2).
13. Louise Norris, *Does Health Insurance Cover Drugs Used for Weight Loss Such as Ozempic, Wegovy, Mounjaro, and Zepbound?*, Healthinsurance.org (Apr. 26, 2024), https://www.healthinsurance.org/faqs/does-health-insurance-cover-drugs-used-for-weight-loss-such-as-ozempic-wegovy-mounjaro-and-zepbound/.
14. Given employee turnover rates, an employer-sponsored health plan may be reluctant to offer coverage for weight-loss drugs if the health plan will not "realize" the investment in drug coverage if a covered employee leaves employment.
15. A state-by-state survey is beyond the purview of this article.
16. *New York State Medicaid Members Benefits and Coverage*, N.Y. State Dep't of Health, https://member.emedny.org/pharmacy/benefits (last visited Aug. 29, 2024).
17. *Id.*
18. *Id.*
19. 2023 NY Senate Bill S9584, https://www.nysenate.gov/legislation/bills/2023/S9584 (last visited Aug. 30, 2024).
20. 2023 NY Assembly Bill A8045, https://www.nysenate.gov/legislation/bills/2023/A8045 (last visited Aug. 30, 2024).

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