Point32Health, parent company of
Harvard Pilgrim Health Care & Tufts Health Plan
ETHICS ADVISORY GROUP (EAG)

Deliberation Report
Medications for Weight Management – Considerations for Payers
December 13, 2023

Purpose
To seek input from the multi-stakeholder Ethics Advisory Group (EAG) on health plan considerations for coverage of weight management medications.

Customers for the Ethics Advisory Group and Expert Guests
The Point32Health customers for the EAG deliberation were Susan Downard, BA, BS, Director of Clinical Pharmacy and David Dohan, MD, Medical Director of Pharmacy. Two obesity physician scientists offered clinical practice and research perspectives: Fatima Cody Stanford, MD, MPH, MPA, MBA, Associate Professor of Medicine and Pediatrics at Harvard Medical School and obesity medicine physician scientist at Massachusetts General Hospital and David S. Ludwig, MD, PhD, Professor of Pediatrics at Harvard Medical School, Professor of Nutrition at Harvard School of Public Health and endocrinologist and researcher at Boston Children's Hospital. Inmaculada Hernandez, PharmD, PhD, Professor, Division of Clinical Pharmacy, Skaggs School of Pharmacy and Pharmaceutical Sciences, UC San Diego offered pharmaceutical policy perspectives.

Background
Overview
Glucagon-like peptide-1 (GLP-1) receptor agonists (also known as incretin mimetics or GLP-1 analogs) have changed the discussion and treatment of obesity.[1] The drugs offer benefits and present challenges. We seek to discuss ethical dilemmas for payers in the US posed by these highly priced, possibly life-long treatments of a chronic disease that is highly prevalent, is caused by complex interactions of individual, environmental, and societal factors, and that has important long-term health consequences.

Obesity
Obesity is a complex, multifactorial, chronic, progressive disease which often leads to poor health, unwarranted stigma, and increased mortality. According to the CDC, "[w]eight that is higher than what is considered healthy for a given height is described as overweight or obesity."[2] Body Mass Index (BMI, weight in kilograms divided by the square of height in meters) is used to screen for overweight and obesity, with BMI 25.0 to <30 considered in the overweight range and BMI 30.0 or higher in the obesity range.[2] The US Centers for Disease Control (CDC) estimate that obesity affected 41.9% of adults in the US (data from 2017-March 2020).[3] Obesity affects populations differently: Non-Hispanic Black adults (49.9%) had the highest age-adjusted prevalence of obesity, followed by Hispanic adults (45.6%), non-Hispanic White adults (41.4%) and non-Hispanic Asian adults (16.1%). The obesity prevalence was 39.8% among adults aged 20 to 39 years, 44.3% among adults aged 40 to 59 years, and 41.5% among adults aged 60 and older.[3]

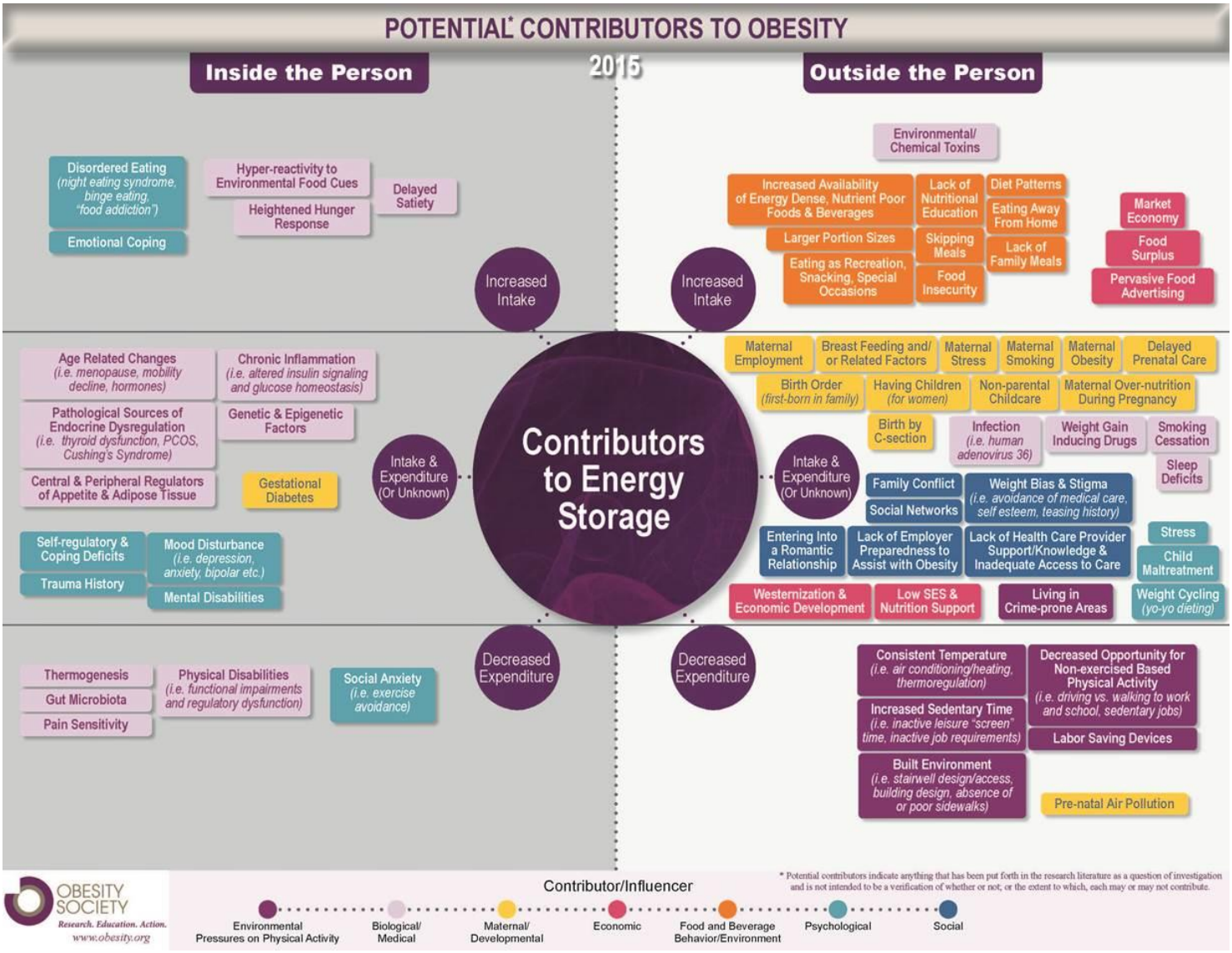
Obesity affects individuals and society. Individuals can suffer severely from obesity in many ways.[4]

> *"I grew up with obesity and I felt like I was diagnosed twice –once in a doctor's office, and again as schoolyard bullies identified me as the fat kid. On a day-to-day basis, I wasn't as concerned about the number on the scale, more so how I was perceived by others. Teachers assumed I was lazy; doctors reduced any issue I faced to my weight. I experienced these feelings in professional settings as well, during job interviews when it was questioned whether I could keep up with my peers."* (Person with obesity, as cited in reference[5])

Unacceptable stigmatization, profound mental, and serious physical impacts of obesity can result in adverse health consequences, including heart disease, stroke, type 2 diabetes, hypertension, hyperlipidemia, certain cancers, sleep apnea, arthritis, mental health conditions, and premature and preventable death.[6]

Excess body weight is associated with higher health care costs.[3,7] A recent study (funded by and conducted in collaboration with Novo Nordisk) estimated that aggregate national medical costs due to obesity more than doubled from 2001 to 2016 and were $260.6 billion in 2016.[8] Compared with adults with normal weight, annual medical care costs for adults with obesity in the United States were $2,505 or 100% higher, with costs increasing with more severe obesity. Obesity effects increased inpatient, outpatient, and prescription drug costs, and obesity-related estimated medical expenditures were higher for adults covered by public health insurance programs ($2,868) than for those with private health insurance ($2,058). The authors estimated that in 2016, private health insurance paid $139.4 billion, public health insurance paid $57.9 billion, and patients paid $20.0 billion out of pocket for obesity-related care and called for interventions to prevent and reduce obesity.[8]

Obesity and its causes need to be viewed in a systems context.[9] Many individual and external factors contribute to obesity (Figure). Individual factors include genetics, diet, physical activity level, sleep, medications, and physical and mental health conditions. External factors include socioeconomic stressors, the built environment, and the market economy with its contributions to an unhealthy, inequitable, unaffordable, and unsustainable food system.[10,11,12] Obesity is one of the three co-occurring pandemics (with undernutrition and climate change) that have been termed "The Global Syndemic" and affect most people across the world.[13] A syndemic is the "presence of two or more disease states that adversely interact with each other, negatively affecting the mutual course of each disease trajectory, enhancing vulnerability, and which are made more deleterious by experienced inequities."[9] Analyses show that obesity, nutrient-deficiency malnutrition, and climate change are caused by deep systemic problems. "Prominent among them is a global industrial system that spurs homogeneity in production and consumption, externalises harms to health, social cohesion, and environment, and prizes cheap food, among other […] negatives.[14] To address underlying causes of obesity, broad policy changes are necessary,[13] requiring "a radical rethink of how we eat, live, consume, and move." Policy suggestions include "measures to influence food retail and provisioning, catalyse food reformulation, amend the built environment, influence behaviour change, and apply economic pressure through fiscal policies."[14]



<u>Benefits and risks of GLP-1 receptor agonists</u>

GLP-1 receptor agonists (and dual gastric inhibitory polypeptide (GIP) and GLP-1 receptor agonists) are used to treat type 2 diabetes mellitus and obesity (Table).[15,16,17] Depending on the product, the agent is FDA-approved and marketed for its specific indication: type 2 diabetes or obesity (Table 1). GLP-1 receptor agonists promote weight loss through multiple mechanisms including slowing gastric emptying, thereby increasing fullness, reducing appetite and energy intake, in addition to direct anorexigenic effects on the brain leading to increased satiety. Saxenda, Wegovy and Zepbound are FDA-approved as adjuncts to a reduced calorie diet and increased physical activity for chronic weight management in adult patients with an initial BMI of 30 kg/m^2 or greater (obesity) or 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes mellitus, or dyslipidemia). Saxenda and Wegovy are also FDA-approved as adjuncts to a reduced calorie diet and increased physical activity for chronic weight management in pediatric patients aged 12 years and older with obesity. Compared to older obesity treatments (orlistat, phentermine/ topiramate, and naltrexone/bupropion), GLP-1 receptor agonists result in higher average weight loss (not-placebo adjusted, 14.9% to 20.9% weight loss over 12 months vs 6.1% to 10.5%[17]) and are better tolerated. GLP-

1 receptor agonists can help control blood sugar among patient with diabetes and reduce cardiovascular events. The most frequent side effects of GLP-1 receptor agonists are gastrointestinal (nausea, vomiting, and diarrhea). Serious rare side effects include an increased risk of certain thyroid cancers, pancreatitis, gallstones, and hypoglycemia. The European Medicines Agency is investigating a potential risk of suicidal thoughts. When stopped, patients regain weight and cardiometabolic health benefits are lost over time, suggesting that continued treatment is required to maintain weight loss and cardiometabolic health.[18]

Economics of GLP-1 receptor agonists

In the US, newer obesity medications are expensive (about 4-10 times more expensive than in Europe).[19] Table 1 lists FDA approved indications and list prices.

Table 1. FDA approved indications and list prices of GLP-1 receptor agonists

Brand Name	Generic Name	Manufacturer	FDA-approved Indication (Date)	Administration	Average Wholesale Price (AWP)* per Month
Bydureon BCise	exenatide extended-release	AstraZeneca	Diabetes	injection	$ 964
Byetta	exenatide	AstraZeneca	Diabetes	injection	$ 990
Mounjaro	tirzepatide	Eli Lilly	Diabetes	injection	$ 1,227
Ozempic	semaglutide	Novo Nordisk	Diabetes	injection	$ 1,122
Rybelsus	semaglutide	Novo Nordisk	Diabetes	oral	$ 1,122
Trulicity	dulaglutide	Eli Lilly	Diabetes	injection	$ 1,117
Victoza	liraglutide	Novo Nordisk	Diabetes	injection	$ 893 (2-pen pack) $ 1,340 (3-pen pack)
Saxenda	liraglutide	Novo Nordisk	Obesity	injection	$ 1,618
Wegovy	semaglutide	Novo Nordisk	Obesity	injection	$ 1,618
Zepbound	tirzepatide	Eli Lilly	Obesity	injection	$ 1,271

* Average wholesale price (AWP) as of November 30, 2023. Note price differences by indication.

Manufacturers provide confidential rebates to insurers (estimated in one study[20] to range from 48% [Wegovy] to 79% [Mounjaro]) and coupons to patients, which may substantially lower costs of the medications.[19,20] Nevertheless, budget impact concerns arise from prices and the estimated number of potential users requiring long-term treatment because more than 53% or 142 million US adults meet the approved indications for the medications (a BMI of more than 27kg/m^2 and 1 obesity-related comorbidity or a BMI above 30 kg/m^2).[21]

Company-provided economic analyses (which do not usually account for costs of the drugs or costs of treating potential long-term side effects) assert that the newer obesity treatments will lead to substantial downstream savings in the health care system by decreasing the rates of obesity-related conditions such as hypertension, type 2 diabetes, and sleep apnea.[22] However, in a 2022 analysis, the independent Institute for Clinical and Economic Review (ICER) found semaglutide not cost-effective at commonly used willingness-to-pay thresholds to treat adults with obesity and estimated an annual health-benefit price benchmark range of $7,500 to $9,800, which would require a manufacturer

discount of 44%-57%.[21] Similarly, another independent economic analysis did find semaglutide not cost-effective for adolescents with severe obesity.[23]

There is uncertainty about the evolution of prices of newer medications for obesity as competition grows. Eli Lilly has priced Zepbound 20% below the list price of Wegovy.[24] However, not all anticipated obesity drugs will prove beneficial.[25] To the extent that current obesity medications, if used long-term, may mitigate costly obesity-related illnesses over time, the economic benefits of commercial insurers' payments for the medications today may translate into slower growth of Medicare spending in the future, as has been estimated for medications that treat cardiovascular diseases and risk factors.[26]

Demand for GLP-1 receptor agonists has led Novo Nordisk to forecast more than $15 billion in sales for semaglutide in 2023.[27] Goldman Sachs Research estimated the global market for anti-obesity medications to grow to $100 billion by 2030.[28] In a so-called "Ozempic panic",[29] shares of food companies, providers of bariatric surgery, glucose-monitoring device makers, and dialysis companies dropped[30] as markets have (over-) reacted under an assumption that millions of Americans would take the medications for life, forego fast food and sugared beverages, lose weight, and not need interventions for obesity-related diseases in the future.

Additional caveats

Not everyone applauds the era of GLP-1 receptor agonists.[31] A focus on decreasing weight and BMI disregards that some obese individuals may be metabolically healthy (between 6% and 75% across heterogenous studies[32]), that is, do not have metabolic diseases, such as hypertension, dyslipidemia and type 2 diabetes and that physical fitness[33] and quality of diet[34] may matter more for cardiovascular health than weight. There are concerns that the drugs may worsen the weight stigma,[31] and that payments for expensive drugs used by many individuals long-term will further displace investments into addressing the systemic causes of obesity. "You can see this ballooning completely out of control," said Walter Willett, professor of nutrition at Harvard T.H. Chan School of Public Health. "Even today, healthcare costs are displacing the true determinants of health, which are education, a safe environment, physical infrastructure to work, play, walk, bike, all of that. Those are being squeezed and displaced by healthcare costs."[35]

There are also concerns about the influence of Novo Nordisk's outsized payments to prescribers.[36,37]

Insurance coverage of GLP-1 receptor agonists

In November 2023, the American Medical Association "urge[d] health insurers to provide coverage of available FDA-approved weight-loss medications, including GLP-1 medications, to demonstrate a commitment to the health and well-being of our patients."[38,39] AMA's press release states that "[t]he cost of medications for weight reduction can be a significant access barrier for people with obesity unless their health plan provides coverage. This policy is an important step towards protecting the patient-physician relationship in determining the best course of treatment without barriers from payers." Some AMA clinicians disagreed with the organization's urge for insurance coverage, suggesting that " [r]ather than advocating for expensive drugs with limited and short-term benefits only, investing the same resources on diet and lifestyle could help far more Americans stay healthy for life."[39]

For legal and budget impact reasons, insurance coverage of GLP-1 receptor agonists varies widely, leading to structural inequities in access to the drugs.[40,41,42]

Medicare

Under current law, Medicare is prohibited from paying for drugs for weight loss. Policy researchers have

outlined options to enable Medicare Part D coverage of GLP-1 receptor agonists.[41] These include legislative change through the passage of the Treat and Reduce Obesity Act[43] and earlier inclusion of the drugs in Medicare price negotiation under the Inflation Reduction Act.

Medicaid

Medicaid coverage differs by state, and state Medicaid programs are negotiating discounts for the medications to provide obesity treatment for low-income patients and contain costs.[44,45] As of July 2023, 9 states (California, Connecticut, Delaware, Michigan, Minnesota, Pennsylvania, Rhode Island, Virginia, and Wisconsin) had begun coverage via their preferred drug lists.[44] Expectations are that MassHealth will begin coverage of the medications in 2024.

Commercial insurers and self-insured employers

Coverage of newer obesity medications varies across commercial health plans and self-insured employers.[46,47,48] As of April 2023, 7 of 18 of the largest US commercial health plans did not publish a coverage policy for semaglutide. The policies of 11 health plans that did differed in weight restrictions (9 plans requiring FDA-approved label criteria [BMI $\geq$ 30 kg/m^2 or BMI $\geq$ 27 kg/m^2 and at least one weight-related comorbid condition]; 2 had more restrictive BMI criteria); pharmacological step therapy requirements (1 plan required patients to try at least one older medication); diet and exercise requirements (8 plans required use in addition to a reduced calorie diet, increased physical activity and/or other lifestyle modifications); behavioral modification program requirements (7 plans required enrollment to receive the medication, 6 plans required enrollment prior to initiating the medication, 1 plan required enrollment as an adjunct to therapy); approval duration (9 plans, from 12 weeks to 2 years); and continuation criteria (9 plans, documented weight loss of at least 4% or 5% from baseline; 2/9 plans documented BMI no greater than 25 kg/m^2).[46] In efforts to control costs, some large employers have decided to not cover the medications and others have increased copayments. When faced with a coverage decision potentially bankrupting the health plan, the Connecticut state health plan required that members must participate in an online lifestyle management program through which they can meet with providers and receive personalized care plans which may include prescription of the medications, which the state health plan would then cover.[48]

Point32Health coverage

As of December 2023, "[t]he plan does not consider anti-obesity drugs to be medically necessary in the treatment of all patients with obesity, as diet and exercise constitute the mainstay of therapy in most cases." Prior authorization is required for coverage. Consistent with the FDA-labeled indications, for initial coverage of up to 6 months, BMI and lifestyle modification criteria need to be met. For continued coverage for one year, documented weight loss criteria apply.[49]

Ethical issues in insurance coverage of GLP-1 receptor agonists

We can think of ethical questions regarding insurance coverage of expensive weight management medications with respect to responsibilities of payers for a) *individual patient members and their care givers*, b) *member populations*, and c) *society*.

Individual patient members

A health insurer has an obligation to cover medically necessary services consistent with accepted standards of medicine for individual members and seeks to do so without interfering in the patient-clinician relationship. Given the price of newer obesity treatments, continued access for most patients who could benefit from the drugs requires insurance coverage. Broad insurance coverage would allow

providers to prescribe obesity treatments based on clinical criteria alone, without consideration of whether an individual patient can afford the treatment or which utilization management policies a patient's insurer has implemented.[38,46]

Current shortages due to high demand and cost differentials of products with and without an FDA-approved obesity indication complicate payers' coverage policies. Products approved for diabetes only (not obesity) are currently less expensive than products approved for obesity. Their use for obesity by patients without a diagnosis of diabetes constitutes off-label use. Off-label drug prescribing and use are legal in the US. With exceptions (for cancer treatments), off-label drug use is not reimbursed when a safe and effective drug for the indication on label is available. In addition, off-label reimbursement restrictions of GLP-1 receptor agonists are intended to prioritize GLP-1 receptor agonists without an obesity indication for members with diabetes and to mitigate use of compounded versions for which FDA has issued safety concerns.[50]

Member populations

A health insurer must balance its obligation to cover medically necessary services for individual members with its obligation to steward resources for all its members. Given the current price and potential volume of use of newer obesity treatments, payers need to weigh expected costs of coverage of (increasingly more) expensive medications for those who need them against increases in insurance premiums for all insured members. Fully- and self-insured employers need to balance increasing insurance premiums and health care costs against the affordability of providing insurance coverage, the breadth and depth of coverage (e.g., what portion of health care costs is covered and what health care services are covered), wage or salary levels, and non-compensation employee benefits (e.g., retirement plans, paid time off, life insurance, flexible spending accounts). Public payers need to weigh increasing health care expenses against potential depletion of budgets for common goods and/or tax increases.

These dilemmas require payers to manage utilization of newer obesity medications so that limited resources are used to enable healthier individuals and healthier populations. In this context, payment for temporary GLP-1 receptor agonist treatment after which a patient regains lost weight could be considered wasteful spending. Given that according to one analysis only 27% of patients may stay on the medications for more than one year,[51] questions arise: Which patients will benefit most from the medications, which non-pharmacological interventions would support patients in maintaining weight loss and better metabolic health, and how should payers identify and prioritize patients for whom they cover the drugs and support weight management interventions? Should payers in the US, as some have, implement guidelines like that of the National Institute for Health and Care Excellence (NICE) in the UK which requires that semaglutide is used (for a maximum of 2 years) alongside lifestyle interventions provided by specialist multidisciplinary weight management services in the National Health Service? NICE states that its policy "is in keeping with the clinical trial, and there is no evidence of effectiveness if semaglutide is used as a single stand-alone treatment. Also, the [European Medicines Agency] marketing authorisation [like the FDA-approved label in the US[52]] specifies use as an adjunct to a reduced-calorie diet and increased physical activity."[53] How should potentially mandated multidisciplinary weight management services be implemented, who should pay for those, and how should adherence be monitored?

Society

At the level of society, spending on highly priced, potentially life-long treatments of a prevalent chronic

condition that is in large part caused by market-driven, unhealthy food systems and policies raises bigger picture questions as well: Does broad coverage of medications to treat obesity further misalign incentives[35] to investigate and change the systemic causes of obesity? What, if any, are the responsibilities of payers to try to mitigate system-level factors?

Equity

Disadvantaged populations suffer more from systemic factors causing obesity, have a higher likelihood of obesity, and less access to covered obesity treatments, likely increasing health disparities.[40] ICER recommends that "[a]ll stakeholders should take steps that make effective treatment options for people living with obesity available in a way that will help reduce health inequities."[21] If widespread coverage of GLP-1 receptor agonists leads to higher insurance premiums, stagnating wages, and less access to common goods, poorer populations will also suffer more. In this context, how should payers strive for health equity with respect to individuals, populations, and society?

Selected Related Prior Ethics Advisory Group (EAG) Deliberations

Since 1998, more than 10 EAG deliberations have focused on pharmaceuticals.[a] Until 2017, the deliberations mostly addressed ethical questions around incentives for members and prescribers toward most cost-effective treatment alternatives for the health plan to balance its responsibility to cover costly drugs for individual members against its responsibility to ensure sustainably affordable coverage for all its members.

- In 2017, in a deliberation on the increasing proportion of (specialty) pharmaceutical spending of the health plan,[54] participants discussed, for the first time, questions around not covering a drug based on costs. At that time, the *"EAG recognized that some new agents provide outcomes not achievable by other means. At the extreme, a new drug may cure an otherwise fatal disorder. Patients expect to have access to these life-changing benefits. Saying "no" to a breakthrough drug would be clinically and morally repugnant to a health plan. But the ever-escalating cost of health care creates its own form of harm to the public. Not covering a valuable agent versus contributing to access-preventing health care cost increases is a lose/lose situation*."
- In 2019, the EAG discussed *compassion as a key value* and the default frame for direct and indirect actions of a health plan. Compassionate responses to an individual's suffering must consider a health plan's responsibilities to *fairness, equity, and fiscal stewardship within the complex health system*.
- In 2023, the EAG underscored a need for and responsibility of the health plan to *engage with all its stakeholders proactively and visibly about the trade-offs* that are required, locally and nationally, by increasing spending. Communication should include *a focus on equity* and will require a long-term strategy to be effective.
- In 2023, the EAG suggested that *coverage expansion* should be implemented prudently, in a step-change fashion, and following fair priority-setting processes. *Fair priority setting* requires deliberation by all 'fair-minded' stakeholders (including those affected by the decision), transparency of the decision and reasons behind it, and mechanisms through which stakeholders can appeal a decision and it can be revised.

In all deliberations on pharmaceuticals and other highly priced technologies, EAG participants advised the health plan to provide physicians and members with information about drug prices. They also suggested that the health plan work with other stakeholders to promote public understanding of (a) the fact that health care costs trade off against other desirable social goals and (b) the health plan's ethical

[a] EAG deliberation reports are available from anita_wagner@hm.harvard.edu.

imperative to manage care and costs. Provider, member, and public education by the health plan were seen as necessary to support reforms of the pharmaceutical system.

Questions for the Point32Health Ethics Advisory Group Deliberation
On December 13, 2023, the Ethics Advisory Group was asked to reflect on the following questions:

Related to coverage of expensive newer weight management medications,

1. From the perspectives of individual patients and their providers, member populations, and society, which ethical principles should commercial payers consider?
2. How should payers balance competing ethical responsibilities for different constituencies, specifically how should commercial payers balance expanding coverage for individual members with increasing premiums for all members?
3. Given that obesity is caused by unhealthy, inequitable systems, including the food system, what is the role of a commercial payer in mitigating the systemic causes of obesity and other chronic conditions?

Summary of the Point32Health Ethics Advisory Group Deliberation
This section summaries points made during, and suggestions offered by some participants after the discussion. More than 100 individuals joined the meeting. At the outset, the Point32Health customers and invited experts highlighted the following realities:

- Race and weight-based stigmas are ubiquitous in society, including in health care. Obesity and obesity care are evidence of structural biases. Language matters. Individually and collectively, we need to counteract discrimination, by, among other ways, not referring to "obese individuals", but to "individuals with obesity".
- Lack of availability, accessibility, and affordability prevent patients from using the newer weight management medications. Patients from more disadvantaged groups are more likely to encounter barriers than patients from less disadvantaged groups. Insurance coverage can mitigate or augment some of the structural inequities.
- Published cost, cost-effectiveness, and budget impact estimates of newer weight management medications are not based on actual spending data (as those are proprietary), use different assumptions, and do not include long-term health benefits and risks. [41,55] Budget impact may become lower than estimated if competition among more products, including generics, decreases negotiated prices. However, generic products of GLP-1 receptor agonists are not available currently and some new weight management medications in the development pipeline have failed.[25]
- Currently, the health plan faces a dilemma of balancing rising spending on pharmaceuticals with its objectives of covering individual members' medically necessary care, promoting public health, and keeping premiums affordable.
- Using BMI-based criteria, it is estimated that 50% of Point32Health members could qualify for newer weight management medications. The expense of covering newer weight management medications for this number of members (while maintaining other benefits) would result in higher premiums which would be borne by all members. Key questions for the health plan are:
    - Who would benefit most from coverage of weight management medications?
    - Should coverage be tied to behavior modification (e.g., nutrition, exercise) programs?
- A polarized view of addressing obesity with either medications or behavior modification dominates the public discussion of obesity treatment.[56] Advocates for medications highlight data on better effectiveness of pharmacologic treatment than diet and exercise interventions. Advocates for behavior modification highlight that industrial economy and lifestyle changes since the 1960s are

the main causes of obesity, and that much higher investments in research of pharmacologic compared to research of behavioral interventions lead to more and better evidence for GLP-1 receptor agonists. A low-carbohydrate diet shares mechanisms of action of GLP-1 receptor agonists, without the side effects.[56] Life-long pharmacotherapy does not constitute a public health solution of the obesity epidemic, which seeks to achieve the most beneficial outcome most equitably with most wisely spent dollars and least negative effects. A synergistic approach combining pharmacotherapy and behavior modification is needed.

The table below summarizes EAG participants' answers to three poll questions.

EAG poll results

	Question #1 Do you think the health plan should cover newer medications for weight loss of all members who meet FDA-approved package insert criteria? (n=50)	Question #2 Because stopping GLP-1 receptor agonists leads to regain of weight and reversal of metabolic health benefits, do you think the health plan should require members to participate in behavior modification for weight management, as a condition for GLP-1 receptor agonist coverage? (n=51)	Question #3 Given the food system causes of obesity, do you think the health plan has a responsibility in trying to change the local and regional food systems (for example, through advocacy, education, engagement with communities, providing healthy food access)? (n=54)
Yes, n (%)	27 (54)	33 (65)	31 (57)
Not sure, n (%)	13 (26)	10 (19)	11 (21)
No, n (%)	10 (20)	8 (16)	12 (22)

The following additional points were made:

- To date, supply shortage constitutes the main barrier to equitable access to newer weight management medications.
- Supply shortage, coverage restrictions given high prices, short-term inappropriate use of GLP-1 receptor agonists by individuals not meeting BMI criteria for treatment, and lack of clinician guidance may explain reported early discontinuation of the medications which results in weight regain and loss of metabolic benefits.
- Comprehensive treatment planning seems necessary and has worked well with patients offered bariatric surgery. Like patients considering bariatric surgery, patients considering medication treatment require high-quality prescribers who offer health education and supervision, and would likely benefit from accompanying support groups, nutritionists, behavioral health services, and close follow-up with primary care clinicians.
- Most care providers lack education about pharmacologic weight management options and how to choose an appropriate medication for each patient, according to individual causes and severity of obesity.[57,58] Most patients do not have access to specialized, multidisciplinary weight management support. It is likely that some providers, especially non-specialists, prescribe the newer drugs inappropriately.
- Insurance utilization management policies (e.g., requirements of prior authorization and accompanying diet and exercise, in accordance with FDA-approved indications) could guide appropriate use. Although 2 out of 3 respondents to poll question #2 said that the health plan

should require members to participate in a weight management program as a condition for GLP-1 receptor agonist coverage, EAG participants also raised concerns:
    - Patients who seek care from specialist providers likely have tried multiple weight management strategies. A requirement of behavior modification for these patients would seem paternalistic.
    - Lifestyle adjustment is not a precondition for coverage of other chronic disease interventions and could be considered punitive and another form of weight bias.
    - Positive weight loss experience with GLP-1 receptor agonists may help patients feel less stigma and adhere to nutrition counseling and diet changes. If that's the case, a behavior modification-first requirement may constitute a "backwards approach".
    - For these reasons, strong encouragement of behavior modification could be preferred over mandatory behavior modification as a pre-condition for drug coverage.
- Discussion of spending associated with newer weight management medications affirmed that pharmaceutical company pricing creates the economic challenges for individuals, payers, and society. The fragmented US insurance system disincentivizes coverage of expensive interventions that provide downstream health benefits because present costs accrue to the commercial payer and savings from benefits (better cardiovascular health of the population, if realized) to Medicare.[26] On the one side, loss of downstream savings are not an ethical justification for not covering the medications at present. On the other hand, large expenses at present will increase commercial payers' premiums, make commercial insurance less affordable for all, and lead to preventable worse health outcomes downstream, a consequence that is also not ethically justifiable. A suggestion was made for joint multi-payer demonstration projects to identify value-based obesity care approaches and challenge drug manufacturer to prove downstream improved patient health and lower societal obesity-related costs. (Not discussed in this deliberation was the question of whether other, less cost-effective currently covered treatments should not be covered to avoid raising premiums.)
- A recently published stepwise obesity treatment roadmap proposes value-based payments along 4 steps of comprehensive individualized patient care as a sustainable coverage strategy at scale: patient engagement and diagnosis, decision on treatment or specialist referral, treatment to a personal goal (rather than a generic target BMI), and transition to chronic obesity care.[59,60] The Network for Excellence in Health Innovation developed the proposed strategy (with funding by and in collaboration with industry companies that focus on treatment for individuals with obesity).

In summary, effective pharmacologic treatments for patients with obesity and overweight constitute a much-needed advance for a highly prevalent, complex, chronic disease that has serious, long-term consequences and impacts vulnerable populations inequitably. Individual suffering, complexity of the disease, high prices of newer pharmacologic treatments, and unsustainable population health impacts of expenditures associated with both the disease and its treatments require a combined focus on effective, clinically appropriate care for individuals and cost-effective, sustainable population health coverage at scale (in addition to efforts to counteract the underlying systemic causes of obesity).

This report is respectfully submitted, with gratitude to Point32Health leaders, the expert guests, and all who generously shared their perspectives, during and following the meeting, for making this important and timely Point32Health EAG conversation possible. Thanks also go to Alyssa Halbisen, Caitlyn Tabor, and Kristina Larson for supporting this EAG deliberation.

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