Treatments for Obesity Management: Final Policy Recommendations

October 20, 2022

Prepared For

NEW ENGLAND CEPAC
COMPARATIVE EFFECTIVENESS PUBLIC ADVISORY COUNCIL
AN ICER PROGRAM

Policy Recommendations

Introduction

The following policy recommendations reflect the main themes and points made during the policy roundtable discussion at the September 16, 2022 New England CEPAC public meeting on treatments for obesity management. At the meeting, ICER presented the findings of its revised report on these treatments and the New England CEPAC voting council deliberated on key questions related to their comparative clinical effectiveness, potential other benefits and contextual considerations, and long-term value for money at current prices. Following the votes, ICER convened a policy roundtable of two patients/advocates, two clinical experts, and two payers to discuss how best to apply the evidence and votes to real-world practice and policy. The manufacturer of the main intervention declined to participate in the policy roundtable. The discussion reflected multiple perspectives and opinions, and therefore, none of the statements below should be taken as a consensus view held by all participants.

A recording of the conversation can be accessed here, and a recording of the voting portion of the meeting can be accessed here. More information on policy roundtable participants, including conflict of interest disclosures, can be found in the appendix of this document. ICER's report on these treatments, which includes the same policy recommendations, can be found here.

The roundtable discussion was facilitated by Dr. Steven Pearson, MD, MSc, President of ICER. The main themes and recommendations from the discussion are organized by audience and summarized below.

All Stakeholders

All stakeholders have an important role to play in ensuring that people living with obesity have access to effective medications as a core benefit of health care insurance coverage.

Though safe and effective medical treatments for obesity are available and more options are in the development pipeline, only a small fraction of individuals who may benefit from such therapy are receiving them. For many individuals, this is because medications for obesity are not covered as part of their health care benefits. In part, this lack of coverage is due to the negative experience with earlier generations of obesity medications. However, given that obesity is a chronic disease with important long-term health consequences, it seems reasonable that newer therapies for obesity such as semaglutide, liraglutide, phentermine/topiramate, and bupropion/naltrexone be covered not as an optional add-on determined by employers but as a core element of health insurance.

To achieve the goal of affordable coverage for obesity medications:

Manufacturers should take the following actions:

- Set the price for new treatments for obesity in proportion to their demonstrated benefit to patients and society, with moderation commensurate with residual uncertainty about long-term benefits and the large size of the potential population of people to be treated.

- Perform long-term comparative studies assessing the benefit of these therapies in improving clinical outcomes such as preventing cardiovascular events among individuals with obesity without pre-existing diabetes or cardiovascular disease.

Payers should take the following actions:

- Ensure that pharmaceutical benefit designs developed in conjunction with employers and other plan sponsors ensure access to approved therapies among individuals with obesity, following the principles in subsequent payer recommendations in this document.

Clinical specialty societies should take the following actions:

- Develop and disseminate educational materials that permit prescribing weight loss medications to eligible patients from a broad range of clinicians, not just weight loss specialists.

Government should take the following actions:

- Enact legislation such as the Treat and Reduce Obesity Act that provides for coverage of weight loss medications under Medicare.

- States should include coverage of weight loss medications under the auspices of the Medicaid program. If narrowing coverage is necessary to ensure affordability within the constraints of state budgets, evidence-based coverage can be framed to ensure access to lower cost and generic drugs for those individuals with clinical characteristics that suggest they have the most to benefit from treatment.

All stakeholders should take steps that make effective treatment options for people living with obesity available in a way that will help reduce health inequities.

Obesity is a growing health problem in the United States that has a particularly large impact on certain racial and ethnic groups. The high cost of some of these treatments makes them unaffordable to many people with fewer economic resources. Limited access to health care clinicians who feel confident in prescribing these therapies is another barrier for these individuals. When combined with variable insurance coverage, this landscape creates a substantial risk that the

introduction of new, more effective treatments will aggravate existing health inequities. Considerable concern was expressed by patient advocates and clinical experts that despite improvements in weight loss with existing medications and those undergoing clinical evaluation that current coverage policies and medication costs are likely to worsen disparities in accessing care unless specific action is taken.

To achieve the goal of equitable availability for obesity medications:

Manufacturers should take the following actions:

- Develop patient assistance programs at a level commensurate with other chronic disease conditions to support access to medications among racial and ethnic groups where the burden of obesity is particularly large, payer coverage is low, and inability to afford out-of-pocket payments is common.

- Take steps necessary to include a more diverse patient population in clinical trials, including an adequate number of patients with ethnic and racial backgrounds who are most likely to be affected by obesity and its consequences.

Payers should take the following actions:

- Design coverage criteria that are sensitive to racial and ethnic variability in the clinical applicability of BMI thresholds to ensure that eligible beneficiaries from racial and ethnic groups particularly affected by obesity have access to effective therapeutic options.

Clinical specialty societies should take the following actions:

- Develop and disseminate guideline recommendations that provide support to clinicians in a manner that equitably identifies individuals who may benefit from therapy across a range of racial and ethnic backgrounds and addresses medication affordability.

Manufacturers

Manufacturers should take the following actions:

Set prices that will foster affordability and good access for all patients by aligning prices with the patient-centered therapeutic value of their treatments. Medication pricing at launch should also be moderated until additional evidence is generated to demonstrate long-term safety and reductions in adverse cardiovascular outcomes.

Prices of drugs for weight loss that are set well beyond the cost-effective range and are often not covered by payers cause not only financial hardship for individuals and exacerbate disparities in access to treatment, but also contribute to general health care cost growth that push individuals

and families out of the insurance pool, and that cause others to ration their own care in ways that can be harmful.

Manufacturers should therefore price new treatments in accordance with the demonstrated benefits to individuals. In settings of substantial uncertainty, initial pricing should err on the side of being more affordable. This would allow more patient access, something critical given the number of individuals with obesity who may be eligible for these drugs. It would also generate additional data on real-world effectiveness that could be used in future assessment updates. With the accumulation of evidence of substantial patient benefit in a broader range of individuals, manufacturers would have expanded access to a growing patient population who would benefit from their drugs.

Accept their responsibility to participate in public dialogue exploring the evidence on the comparative clinical effectiveness and value of their products. Abstaining from participating in dialogue with patients and other stakeholders is a sign of poor corporate citizenship.

The manufacturer of semaglutide chose to make public comments criticizing the ICER Report but justified their non-appearance on the Policy Roundtable as a "business decision." Choosing not to participate in a broader dialogue with patients, clinical experts, and payers on key elements of how to get value and access "right" going forward is a failure of the company to meet their social responsibility, particularly when they receive societal benefits in the form of tax support for research and exclusivity rights for marketing their products.

Establish patient assistance programs for people living with obesity at a level commensurate with other chronic diseases.

According to the US Agency for Healthcare Research and Quality from Medical Expenditure Survey pooled data, out-of-pocket payments from individuals made up two-thirds of the amounts paid for obesity drugs from 2012-2016. Currently, semaglutide (Wegovy®) costs around $1,300 for a month's supply. Manufacturers of phentermine/topiramate (Qsymia®) and bupropion/naltrexone (Contrave®) have assistance programs but even with subsidies, the cost of these drugs is substantially higher than traditionally seen with assistance programs for other chronic conditions. There are no patient-assistance programs for Wegovy, but there are resources available from Novo Nordisk for Ozempic®, which is semaglutide indicated for diabetes.

Initiate long-term studies that can be used to assess the benefits and harms of chronic use of medications for people living with obesity.

Though cardiovascular benefits have been shown for the use of GLP-1 agonists in individuals with diabetes, studies are needed to demonstrate similar benefits in individuals with obesity without pre-existing diabetes mellitus. Similarly, for drugs with other mechanisms of action such as phentermine/topiramate and bupropion/naltrexone, long-term registries are needed to assess for

benefits and harms of chronic use. Ideally, the FDA would permit approval of a new drug from a class without long-term outcomes demonstrated for the drug's mechanism of action in a new population by requiring post-marketing studies. Given the demonstrated long-term risks of obesity on a range of comorbid conditions and even mortality, comparative studies of approved medications for weight loss should also assess a range of clinical outcomes that have been shown to be impacted by obesity.

Conduct research that directly compares real-world treatment options and sequential treatment effectiveness.

Multiple stakeholders expressed concerns about the lack of information directly comparing new treatments and the need for active comparator trials. With the potential for having multiple newer therapeutic options that work through different mechanisms for people with obesity, there is a great need for pragmatic research trials that compare different medications as they will be used by patients and clinicians in real-world settings. Appropriate head-to-head trials would inform decision-making by patients and clinicians. Trials that compare multiple treatment options, sequences, and combinations are needed to identify comparative effectiveness, durability of benefit, and adverse effects.

Clinicians and Clinical Societies

Update treatment guidelines for people living with obesity to reflect current treatment options in a form that is easy to interpret and use by clinicians, patients, and payers

Given the social stigma associated with obesity, clinicians and clinical societies have an important role to play in educating the public about the causes of obesity and counteracting the false perception that obesity represents a personal shortcoming that can be managed through individual choice and simple willpower. Clinical societies should update their practice guidelines for managing people with obesity to include newer therapies such as GLP-1 agonists. Payers base their coverage decisions and integration of utilization tools to a great extent on clinical guidelines. The American Heart Association, the American College of Cardiology, and the Obesity Society last provided guidelines for the treatment of obesity in 2013. There is a need to update guideline recommendations to account for newer approved agents for people with obesity as well as agents that are currently undergoing evaluation. Policy round table participants highlighted that guidelines should not only provide information on options to be used by clinicians and patients for shared decision-making but also offer pragmatic advice about how to select specific therapies for specific subgroups. Payers expressed the need for updated guidelines from clinical societies with detailed guidance to permit meaningful stepped therapy approaches that permit reasonable clinical exceptions. For example, guidelines should provide information on the off-label use of medications used alone or in combination, drugs to avoid in specific patient groups, and recommendations for stepped or sequential therapy. Guidelines could also highlight when medication treatment may be

indicated. For example, guidelines for chronic diseases such as hypertension, diabetes, and hyperlipidemia do not require the need for demonstrating inadequate response to lifestyle interventions, and yet guidelines for obesity typically emphasize initial lifestyle interventions that are acknowledged as being of little if any long-term benefit.

Since all stakeholders recognized that given the very large burden of obesity in the United States, primary care practitioners will be needed to treat the growing population of those who may benefit from medications to promote weight loss. Clinical specialty societies are critical to supporting the dissemination of practice guidelines to non-specialists in collaboration with primary care organizations. This need includes not only starting and modifying therapy based upon individual response, but also managing chronic treatment given evidence that weight loss requires long-term medication use for most individuals.

Patient Organizations

Patient organizations have a vital role to play in promoting the dissemination of objective information about new therapies for obesity to individuals and clinicians in order to support shared decision-making. In addition, patient groups have a powerful voice and should apply it to create significant pressure for fair pricing and appropriate payer coverage across all sectors of the health system.

Patient groups should endeavor to educate people living with obesity about the potential benefits and harms of new and existing therapies, particularly given evidence that chronic medication use will be required for most who respond to treatment in order to maintain weight loss. Patient groups can also publicly promote access and fair pricing of new therapies so as to ensure that disparities in access to treatment among diverse individuals with obesity are not worsened. The large and increasing percentage of the population that may be eligible for anti-obesity medications , the small percentage of individuals currently on treatment, and the high cost of new therapies, highlight the need for patient groups to advocate for manufacturers, payers, and government regulators to support efforts to ensure that the uptake of therapy prioritizes those who are most likely to benefit from therapy in a manner that promotes equitable access.

Researchers/Regulators

Support the development of improved measures of disease severity and outcomes that are meaningful to people living with obesity.

Clinical experts identified a critical need for new measures of disease severity for obesity that better identify those who may most benefit from therapy. All stakeholders recognized that the unmet need for medical therapy far exceeds that which society can afford given the tremendous burden of obesity in the United States. Given that only a fraction of eligible people with obesity have received

treatment, there is a need to develop criteria for how to prioritize treatment among those eligible. Given the fact that few payers cover the use of medications for weight loss as a pharmaceutical benefit and the high current prices of therapy, devising ways to systematically expand coverage are needed. Though obesity is defined and severity is assessed primarily using the BMI, clinical experts highlighted its limitations given the known underlying mechanisms whereby obesity contributes to disease. They highlighted the need to develop measures of disease severity that could be used as part of routine care to identify those individuals who are at greatest risk for the complications of obesity. Implementing such criteria as part of the process payers use to identify individuals for eligibility coverage could help maximize the impact of therapy within the population.

We also heard from patient advocacy groups that endpoints used in clinical trials do not always measure what is most important to people living with obesity. For example, the amount of weight loss that contributes to improved quality of life may vary among individuals. There is also the need for patient-reported quality of life measures that capture the broad range of benefits, both physical and mental health-related, that may be associated with treating obesity. Moreover, such outcomes are rarely translated into utility measures that can be incorporated into cost-effectiveness analyses. Patient groups can take a leading role in collecting real-world data, as well as collaborating with researchers, manufacturers, and regulators to define a core set of severity and outcome measures and then in promoting their use in all future clinical trials.

Payers

The very large number of individuals in the US who may be considered for treatment with more effective and relatively expensive obesity medications creates a justification for payers to develop prior authorization criteria and to consider other limits on utilization that assure appropriate patient selection and treatment.

None of these limits, however, should undermine the tenets of fair access to which all patients have a fundamental right. ICER has previously described general criteria for fair coverage policies that should be considered as cornerstones of any drug coverage policy.

To explore the appropriate application of evidence to coverage policy, and to reflect the views of patients and clinical experts on specific ways that payers might appropriately use coverage policy to manage resources prudently, we present the following perspectives on specific elements of cost sharing and coverage criteria for semaglutide, liraglutide, phentermine/topiramate, and bupropion/naltrexone.

Coverage Criteria: General

- Maintaining coverage across changes in payer: Individuals on treatment with an obesity medication may have achieved success to the extent that if considered as a de novo patient they would no longer meet BMI criteria for coverage. Payers must assure that mechanisms are in place to prevent patients from facing a coverage gap while going through an exceptions process to regain coverage following switching from another insurer.

Coverage Criteria: Drug Specific

- **Age:** Coverage criteria are likely to follow the FDA label on age cutoffs for each drug but for those drugs such as semaglutide not yet approved for adolescents the label is likely to expand in relatively short order to cover earlier age ranges as further evidence is generated. Although there is greater uncertainty in outcomes for younger individuals with obesity, there may be additional benefits for younger women of childbearing age in improving fertility, infant health, and preventing pregnancy-related complications. Therefore, payers should have efficient mechanisms for clinicians to seek coverage exceptions for individuals with severe obesity who are near the cutoff for the age necessary for coverage.
- **Clinical Eligibility**
    - Weight restrictions: Payers are likely to follow the FDA label suggesting eligibility for individuals with BMI ≥30 kg/m^2 or ≥27 kg/m^2 with at least one weight-related comorbid condition. Some international payers (e.g., the National Health System in England) have set a higher threshold for treatment with semaglutide using a BMI of ≥35 kg/m^2 or ≥30 kg/m^2 with a comorbid condition. This higher threshold is due to considerations of cost-effectiveness in the British health system, and may also be supported by considering that the majority of individuals enrolled in the pivotal trials had a BMI ≥35 kg/m^2. US payers seeking to provide affordable coverage for semaglutide and other agents not deemed to be cost effective at current pricing may consider this approach to restricting patient eligibility, but if they do so two important elements would be required. First, payers would need to ensure efficient internal systems to process exceptions based on racial and ethnic groups for whom general BMI thresholds do not accurately reflect their underlying risk for future complications from obesity. For example, BMI among Asian patients may be lower, so strict BMI cut-offs may inadvertently limit access to coverage. Second, coverage that sets a higher BMI threshold should be developed in conjunction with clinical expert input so that additional risk factors may be explicitly included in the policy to identify individuals with lower BMI who have higher risks for complications from obesity, and who therefore should receive coverage without having to go through an exceptions process.

- Diet and activity programs: Trials of medications for obesity have required that patients have tried, but not had adequate results from, formal programs of diet restriction and increased activity. The label for semaglutide also includes that it "should be used in conjunction with a reduced calorie diet and increased physical activity." Payers are therefore likely to consider requiring both: that patients have tried a formal diet and activity program without success and are continuing to participate in such programs.

  However, obesity is a chronic disease and most individuals with obesity who are seeking medical therapy have already tried multiple times to modify their lifestyle to lose weight. Numerous studies have demonstrated that lifestyle modification does not provide adequate long-term weight management for the vast majority of individuals with obesity. Moreover, trial evidence suggests that the weight loss achieved by individuals on semaglutide were comparable between those receiving intensive diet and activity counselling and those having minimal or no formal guidance. Clinical experts and payer representatives acknowledge that individuals who have never received any professional advice regarding diet and activity should get this information as part of being prescribed a medication, but it does not serve the interests of most individuals who have a long history of attempting to lose weight to require that they enroll in a new weight loss program just to qualify for coverage with an obesity medication. Therefore, best practice in insurance coverage appears to be elimination of any requirement for ongoing enrollment in a lifestyle management program or a history of lack of success with these programs. Physician attestation that individuals are aware of diet and activity guidance should prove adequate to ensure appropriate use with obesity medications.

- **Exclusion Criteria**: Clinical experts suggested that combination therapy with available obesity medications may be necessary for some patients and that there are no safety or other reasons to exclude combination therapy from coverage.
- **Duration of Coverage and Renewal Criteria**: Each of the medications for weight loss have varying titration periods to minimize side effects when starting therapy. Therefore, the initial duration of coverage should permit enough time to allow individuals to demonstrate a response to the recommended dose of medication based on the FDA label. For most individuals, a six-month period should be sufficient to assess response.

  Clinical experts and payers felt that it would be appropriate to require clinician attestation of patient benefit for the continuation of therapy. As noted, the timing of such renewal may depend to some extent upon the specific therapy based upon its titration phase. Most clinical experts suggested a minimum six-month treatment period is appropriate with patients having to demonstrate at least a 5% durable reduction in weight prior to renewal.

- **Provider Restrictions**: Patients and clinical experts agreed that given the large number of individuals potentially eligible for weight loss medications and the limited number of specialists trained in obesity medicine, it is reasonable to approve prescriptions for semaglutide, liraglutide, phentermine/topiramate, and bupropion/naltrexone from a broad range of clinicians including generalist physicians and advanced practice providers. By permitting access to therapy through non-specialists, prior authorization criteria should not be excessively onerous, such as requiring ongoing enrollment in specific lifestyle modification programs prior to approval.

Step Therapy

Payers may consider step therapy, particularly given that the more expensive options are not priced at a cost-effective level, and failure to reach clinical goals with a first-step option should not lead to irremediable harm. However, payers should only use step therapy when they have designed it to provide adequate flexibility to meet the needs of diverse individuals and when implementation can meet high standards of transparency and efficiency.

Step therapy has not been a prominent aspect of the prescribing criteria because most health plans have not covered medications for weight loss. However, with more options now available and more likely to be approved in coming years, step therapy may be a reasonable way for payers to manage access to expensive therapies. Clinical experts and patients stated that delayed and highly restricted access to treatment due to step therapy requirements for patients with obesity should be avoided. While it is possible to tailor step therapy in a clinically responsible fashion, it is often administered with documentation burdens and inadequate procedures for exceptions that make step therapy a source of great frustration and the cause of poor outcomes for some individuals due to the discontinuation of medicine/missed doses. These limitations of step therapy protocols may be avoided by having fewer step through requirements and permitting rapidly moving to restricted medications if initial therapy is not tolerated or does not achieve weight loss goals. A particular area of concern raised by patients involved requirements to re-step through previously failed therapies when the payer changes.

Payers establishing step therapy with less expensive or off-label medications should allow people living with obesity and clinicians to choose from multiple options and permit combination therapy.

Clinical experts at the ICER meeting stated that it may be reasonable for payers to require individuals to step through less expensive or off-label therapies used in combination. For multiple drugs with the same mechanisms of action and similar side effects, payers may be able to have a preferred drug on formulary. Since all therapies have side effects and contraindications for certain populations, individuals should have access to a range of initial therapies if step therapy is required.

Appendix 1. Conflict of Interest Disclosures

Tables 1 through 3 contain conflict of interest disclosures for all participants at the September 16, 2022 public meeting of the New England CEPAC.

Table 1. ICER Staff and Consultants*

Steven J. Atlas, MD, MPH, Associate Professor of Medicine, Harvard Medical School; Director of Practice-Based Research and Quality Improvement, Division of General Internal Medicine, Massachusetts General Hospital	**Ashton Moradi, PharmD, MS,** Health Economist, Institute for Clinical and Economic Review
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Monica Frederick, Program Manager, Institute for Clinical and Economic Review	**Kanya Shah, PharmD, MS, MBA,** PhD Candidate**,** University of Illinois at Chicago
Kibum Kim, PhD, Assistant Professor, University of Illinois at Chicago	**Daniel R. Touchette, PharmD, MA,** Professor, University of Illinois at Chicago; Director, Center for Pharmacoepidemiology and Pharmacoeconomic Research
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*No conflicts of interest to disclose, defined as individual health care stock ownership (including anyone in the member's household) in any company with a product under study, including comparators, at the meeting in excess of $10,000 during the previous year, or any health care consultancy income from the manufacturer of the product or comparators being evaluated.

Table 2. New England Panel Member Participants*

Robert H. Aseltine, Jr., PhD, Professor and Chair, Division of Behavioral Sciences and Community Health Director, Center for Population Health, UCONN Health	**Tara Lavelle, PhD,** Assistant Professor, Center for the Evaluation of Value and Risk in Health at Tufts Medical Center
Austin Frakt, PhD, Director, Partnered Evidence-Based Policy Resource Center, VA Boston Healthcare System Professor, Boston University School of Public Health	**Greg Low, RPh, PhD,** Program Director, MGPO Pharmacy Quality and Utilization Program
Marthe Gold, MD, MPH, Logan Professor Emerita, CUNY School of Medicine	**E. Mylonakis, MD,** Chief of the Infectious Diseases Division and Dean's Professor of Medicine, Warren Alpert Medical School of Brown University
Megan Golden, JD, Co-Director, Mission:Cure	**Stephanie Nichols, PharmD, BCPS, BCPP, FCCP,** Associate Professor of Pharmacy Practice, University of New England College of Pharmacy
Rebecca Kirch, JD, Executive Vice President, Health Care Quality and Value for the National Patient Advocate Foundation	**Jason Schwartz, PhD,** Assistant Professor, Department of Health Policy and Management, Yale School of Public Health
Stephen Kogut, PhD, Professor of Pharmacy Practice, University of Rhode Island College of Pharmacy	**Jason Wasfy, MD, MPhil,** New England CEPAC Chair; Director, Quality and Outcomes Research, Massachusetts General Hospital Heart Center
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Table 3. Policy Roundtable Participants and COI Disclosures

David Dohan, MD, Medical Director, Pharmacy at Point32Health	Dr. Dohan is a full-time employee at Point32Health.
Alyssa Guest, PharmD, Clinical Pharmacist, IPD Analytics	Dr. Guest is a full-time employee at IPD Analytics.
Scott Kahan, MD, MPH, Director, National Center for Weight and Wellness; Associate Faculty, Johns Hopkins Bloomberg School of Public Health	Dr. Kahan has received consulting fees from Eli Lilly.
Lee Kaplan, MD, PhD, Director, Obesity and Metabolism Institute	Dr. Lee has received honoraria from Boehringer Ingelheim, Eli Lilly, Novo Nordisk, and Pfizer.
Nikki Massie, MA, Obesity Advocate; Board Member, Obesity Action Coalition	The Obesity Action Coalition has received funding from Currax Pharmaceuticals, Eli Lilly and Company and Novo Nordisk.
Joe Nadglowski, Jr., President and CEO, Obesity Action Coalition	The Obesity Action Coalition has received funding from Currax Pharmaceuticals, Eli Lilly and Company and Novo Nordisk.