Treatments for Obesity Management: Effectiveness and Value

Public Meeting — September 16, 2022

Meeting materials available at: <u>https://icer.org/assessment/obesity-management-2022/</u>



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Clinical and Patient Experts

Scott Kahan, MD, MPH, Director, National Center for Weight and Wellness

• Dr. Kahan has received consulting fees from Eli Lilly.

Lee Kaplan, MD, PhD, Director, The Obesity and Metabolism Institute

• Dr. Kaplan has received consulting fees and/or honoraria from Boehringer Ingelheim, Eli Lilly, Novo Nordisk, and Pfizer.

Nikki Massie, MA, Obesity Advocate

• Nikki Massie serves as a board member of the Obesity Action Coalition, which receives funding from Currax Pharmaceuticals, Eli Lilly and Company, and Novo Nordisk.

Joseph 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.



Why Are We Here Today?

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

Why Are We Here Today?

- What happens the day these treatments receive FDA approval?
- Questions about:
 - What are the risks and benefits?
 - How do new treatments fit into the evolving landscape?
 - What are reasonable prices and costs to patients, the health system, and the government?
 - What lessons are being learned to guide our actions in the future?



The Impact on Rising Health Care Costs for Everyone



https://khn.org/news/article/diagnosis-debt-investigation-100-million-americans-hidden-medical-debt/

ICER

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Organizational Overview

- New England Comparative Effectiveness Public Advisory Council (CEPAC)
- Institute for Clinical and Economic Review (ICER)



Sources of Funding, 2022

https://icer.org/who-we-are/independent-funding/





How Was the ICER Report Developed?

- Scoping with guidance from patients, clinical experts, manufacturers, and other stakeholders
- Internal ICER staff evidence analysis and UIC cost-effectiveness modeling
- Public comment and revision
- Expert reviewers
 - Harold Bays, MD, Medical Director and President, Louisville Metabolic and Atherosclerosis Research Center; Associate Professor, University of Louisville School of Medicine
 - Joseph Nadglowski, Jr., President and CEO, Obesity Action Coalition
 - Fatima Cody Stanford, MD, MPH, MPA, MBA, Associate Professor of Medicine and Pediatrics, Obesity Medicine Physician Scientist, Massachusetts General Hospital and Harvard Medical School
- How is the evidence report structured to support CEPAC voting and policy discussion?

Value Assessment Framework: Long-Term Value for Money

Special Social/Ethical Priorities

Benefits Beyond "Health"

Total Cost Overall Including Cost Offsets

Health Benefits: Return of Function, Fewer Side Effects

> Health Benefits: Longer Life



Agenda

10:00 AM	Meeting Convened and Opening Remarks
10:20 AM	Presentation of the Evidence
11:40 AM	Public Comments and Discussion
12:00 PM	Lunch
12:45 PM	New England CEPAC Panel Deliberation and Vote
1:45 PM	Break
2:00 PM	Policy Roundtable
3:30 PM	Reflections from New England CEPAC
4:00 PM	Meeting Adjourned



Presentation of the Clinical Evidence

Steven J. Atlas, MD, MPH

Associate Professor of Medicine, Harvard Medical School

Director of Practice-Based Research and Quality Improvement

Massachusetts General Hospital



Key Collaborators

- Emily Nhan, Research Assistant, ICER
- Molly Beinfeld, MPH, (Former) Senior Research Lead, Evidence Synthesis, ICER
- Victoria Lancaster, (Former) PharmD, MSc, MBA, HTA Fellow, ICER

Disclosures:

Financial support provided to Dr. Atlas from ICER through Massachusetts General Hospital

Dr. Atlas has no conflicts to disclose defined as more than \$10,000 in health care company stock or more than \$5,000 in honoraria or consultancies relevant to this Report during the previous year from health care manufacturers or insurer.



Background: Obesity

- Obesity is a common chronic disease that increases one's risk for diabetes, high blood pressure, arthritis, cancer, heart disease, and death
- More than 40% of adults in the US have obesity; projected to reach 50% by 2030
- Obesity is even more common among certain racial and ethnic groups, such Hispanic adults and non-Hispanic Black women
- Annual medical costs attributable to obesity estimated to be \$260 billion in the US

Standard of Care and Management

- Obesity is most commonly assessed using body mass index (BMI, weight/height²) as it is easy to reliably measure and correlates with total body fat
- Goal of therapy for obesity is to broadly prevent, treat, or reverse its complications, including impact on quality of life
- Initial weight loss treatments focus on lifestyle interventions including healthful nutrition, increased physical activity, and behavioral modification
- Though helpful for some, weight loss is usually modest and weight regain occurs in vast majority of individuals
- For individuals not achieving desired weight loss, medications are often considered before more invasive weight loss techniques are considered



Impact of Obesity from Discussions with Patients

- Highlighted profound physical and mental impact on patients' lives including education, work, and relationships, and social stigma associated with obesity
- This stigma can make individuals feel judged, shamed, and ostracized, and may impact willingness to engage with health care providers around weight loss and consequences of obesity
- Need for new therapeutic options and recognition that no one treatment is a panacea, reflecting various factors causing obesity and side effects of therapies
- Most patients will require chronic medication use to maintain weight loss achieved
- Affordability of increasingly expensive treatments that may not be covered by health insurance



Scope of Review

- Adults actively seeking medical management for weight loss and have:
 - Obesity with a BMI ≥30kg/m² or overweight with BMI ≥27 kg/m² and at least one weight-related comorbid condition (e.g., high blood pressure)
- Assess the clinical effectiveness of semaglutide, liraglutide, phentermine/topiramate, and bupropion/naltrexone
 - Comparing each to usual care (e.g., standard lifestyle management)
 - Comparing semaglutide to the other drugs
 - Focus on those without pre-existing diabetes

Interventions

Intervention	Mechanism of Action	Delivery Route	Prescribing Information	
Semaglutide (Wegovy)	GLP-1 receptor agonist	Subcutaneous injection	2.4 mg once weekly	
Liraglutide (Saxenda)	GLP-1 receptor agonist	Subcutaneous injection	3 mg once daily	
Phentermine/Topiramate (Qsymia)	Sympathomimetic amine/ GABA receptor modulation	Oral	7.5-15 mg/46-92 mg once daily	
Bupropion/Naltrexone (Contrave)	Opioid antagonist/NE and DA inhibitor	Oral	32 mg/360 mg once daily	

Key Clinical Outcomes

- For eligible population at ~1 year
 - Varies based upon titration period for each medication (4 to 16 weeks)
- Primary outcomes from clinical trials
 - Percentage weight loss from baseline to follow-up
 - Categorical weight loss (those achieving 5% or 10% weight loss)
- Secondary outcomes from clinical trials
 - Changes in metabolic and cardiovascular risk factors such as SBP, A1C, and LDL
 - Health-related QoL measures



Clinical Evidence

Key Clinical Trials

- · We conducted systematic review based on PICOTS criteria
- We identified 18 trials to include in NMA
 - Includes trials with usual care comparator (13 without diabetes and 5 with diabetes)*

Interventions	N of Trials	Patients (n)	Age, Years	Female Sex, %	BMI, kg/m²
Semaglutide	5	4,424	49.4	71.5	37.3
Liraglutide	6	6,036	50.2	60.6	37.4
Phentermine/Topiramate	3	2,411	46.5	77.1	37.6
Bupropion/Naltrexone	4	4,455	46.7	79.2	36.3

*Semaglutide, liraglutide, and bupropion/naltrexone each had one trial that used intensive behavioral therapy instead of standard lifestyle modification.



Network Diagram: Medications for Management of Obesity (Trials of Patients without Diabetes)



NMA Results of Medications for the Management of Obesity, Mean Percentage Weight Loss from Baseline at One Year (95% CI)

Semaglutide		_		
-4.6 (-2.4 to -7.2)	Phentermine/ Topiramate*			
-8.7 (-7.3 to -10.4)	-4.1 (-1.9 to -6.3)	Liraglutide		
-9.1 (-7.2 to -11.5)	-4.5 (-2.2 to -6.9)	-0.4 (-2.3 to +1.3)	Bupropion/ Naltrexone	
-13.7 (-12.6 to -15.1)	-9.1 (-7.1 to -11)	-5.0 (-3.9 to -6.1)	-4.6 (-3.0 to -6.0)	Placebo

*High dose.



Summary of Outcome Results

- All drugs improve 1-year weight loss outcomes (% change from baseline and those achieving at least 5% weight loss) compared to standard lifestyle management
 - Magnitude of the weight loss appears to be greater for semaglutide and phentermine/topiramate than for liraglutide and bupropion/naltrexone
- Semaglutide demonstrates greater odds of achieving 5% and 10% weight loss and appears superior to other medications at achieving 15% or 20% weight loss
- Other outcomes show that semaglutide and liraglutide improved SBP and blood sugar compared to usual care
- SBP lower with phentermine/topiramate than usual care; blood sugar not reported in phentermine/topiramate and bupropion/naltrexone trials without diabetes mellitus



Patient-Reported QoL Outcomes

- Interventions used a variety of health-related QoL instruments to assess for improvements in physical and mental function limiting ability to compare outcomes across interventions
- In general, all interventions had a greater impact on physical function than mental health function
- Overall semaglutide, liraglutide, and bupropion/naltrexone resulted in greater improvement in the physical function across all health-related QoL instruments compared to usual care
- Physical function was not assessed in trials of phentermine/topiramate; in general, mental function improved in treatment arms compared to usual care



Harms

- For all interventions, adverse events were commonly reported, but few serious harms were reported in the trials
 - Semaglutide/liraglutide: nausea, constipation, diarrhea
 - Phentermine/topiramate: numbness, nausea, dry mouth, constipation, headache
 - Bupropion/naltrexone: nausea, dry mouth, headache, constipation, respiratory illness
- Discontinuation due to adverse events was higher for each intervention compared to placebo
- Patients taking liraglutide, phentermine/topiramate, and bupropion/naltrexone may have higher discontinuation rates than for semaglutide



NMA Results of Medications for the Management of Obesity, Odds Ratio of Discontinuation Rates Due to AEs (95% CI)

Semaglutide				
0.7 (0.3-1.3)	Liraglutide			
0.8 (0.3-1.5)	1.1 (0.5-2.2)	Bupropion/ Naltrexone		_
0.7 (0.2-1.5)	1.0 (0.4-2.3)	0.9 (0.4-2.1)	Phentermine/ Topiramate*	
1.7 (0.9-2.8)	2.4 (1.4-4.0)	2.2 (1.3-3.7)	2.4 (1.3-5.2)	Placebo



Controversies and Uncertainties

- All drugs lack long-term efficacy and safety data including whether weight regain may occur over time despite continued therapy and if sustained weight loss leads to decreased clinical endpoints
- Differences among medications in their mechanisms of action may lead to differences in clinical endpoints beyond effects on weight loss
 - Unclear if CV benefits of semaglutide and liraglutide for patients with diabetes are seen for those with obesity without diabetes
- Differences in the trials regarding their size, patient characteristics, concomitant lifestyle interventions, outcomes assessed, duration of follow-up, and a lack of trials directly comparing different drugs



Potential Other Benefits and Contextual Considerations

- Semaglutide and liraglutide, GLP-1 receptor agonists, and other therapies under investigation reflect new mechanisms underlying weight regulation
- New medications that lead to sustained weight loss may improve quality of life including social interactions with family and friends, educational achievement, and work performance
- Disproportionate impact of obesity on certain racial and ethnic groups and cost of medications often not covered by health insurance may exacerbate existing health inequities



Public Comments Received

- Though many with obesity are interested in weight loss, some advocated for more efforts focused on managing medical issues associated with obesity, especially those with prior negative weight loss experiences
- For women of childbearing age, weight reduction has potential to improve fertility, maternal morbidity and mortality and infant health
- Existing health inequities may be exacerbated by selectively limiting access of these medications to those patients who are able to afford them and/or have access to health care providers who can prescribe them



Summary

- Results from clinical trials and NMAs demonstrate that semaglutide, liraglutide, phentermine/topiramate, and bupropion/naltrexone improve weight loss outcomes of patients with obesity compared to standard lifestyle management
- Magnitude of weight loss appears to be greater for semaglutide and phentermine/topiramate than for liraglutide and bupropion/naltrexone
- Semaglutide, liraglutide, phentermine/topiramate, and bupropion/naltrexone all had common AEs, higher discontinuation rates than placebo, but few serious harms were reported in the trials
- Semaglutide may have lower discontinuation rates than the other drugs



ICER Evidence Ratings of Medications for Obesity Management

Treatment	Comparator	Evidence Rating
Semaglutide	Lifestyle modification	B+
Liraglutide	Lifestyle modification	В
Phentermine/Topiramate	Lifestyle modification	C++
Bupropion/Naltrexone	Lifestyle modification	C+
	Liraglutide	C+
Semaglutide	Phentermine/topiramate	C+
	Bupropion/naltrexone	C++





Presentation of the Economic Model

Kibum Kim, PhD

Assistant Professor

University of Illinois Chicago



Key Review Team Members

- Pei-Wen (Hilary) Lien, MSc, PhD Candidate, University of Illinois Chicago
- Kanya Shah, PharmD, MS, MBA, PhD Candidate, University of Illinois Chicago
- Daniel R. Touchette, PharmD, MA, Professor, University of Illinois Chicago; Director, Center for Pharmacoepidemiology and Pharmacoeconomics Research

Disclosures:

Financial support was provided to the University of Illinois Chicago from ICER.

Researchers have no conflicts to disclose defined as more than \$10,000 in health care company stock or more than \$5,000 in honoraria or consultancies relevant to this report during the previous year from health care technology manufacturers or insurers.



Objective

To estimate the long-term cost effectiveness of the following treatment strategies for weight management in patients with BMI \geq 27 kg/m² with weight-related comorbidity or BMI \geq 30 kg/m²:

- Semaglutide (Wegovy[®]) + Lifestyle Modification (LSM)
- Liraglutide (Saxenda®) + LSM
- Phentermine/topiramate ER (Qsymia[®]) + LSM
- Bupropion/naltrexone (Contrave[®]) + LSM


Methods in Brief

Methods Overview

- Model: Markov model
- Setting: United States
- **Perspective**: Health care sector perspective
- Time Horizon: Lifetime horizon
- Discount Rate: 3% per year (costs and outcomes)
- Cycle Length: One year
- Outcome(s): Cost per QALY gained; cost per life year gained; cost per evLY gained



Model Schematic



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Cohort Characteristics

- Target population was defined based on review of clinical trials
 - Mean age: 45
 - Mean BMI: 38 kg/m²
 - % female: 80%
 - % smoking: 12.5%
- Treatment duration
 - Lifetime

- % hypertension: 35%
- Mean SBP: 125 mmHg
- Mean HbA1c: 5.7%

Key Model Assumptions

- Costs associated with treatment discontinuation were included in first model cycle; only patients who continued treatment are included in model
- Proportion of actively treated hypertension is a function of BMI without a significant influence on incremental cost-effectiveness ratio
- In patients with hypertension, blood pressure is equally well-managed across all weight loss treatments



Key Model Inputs: Efficacy Outcomes

Parameters	Input value	Source
% Weight Change, LSM	-1.5 %	
Absolute Difference in % Weight Change, SEM vs. LSM	-13.7 %	
Absolute Difference in % Weight Change, LIR vs. LSM	-5.0 %	ICER NMA
Absolute Difference in % Weight Change, P/T vs. LSM	-9.1 %	
Absolute Difference in % Weight Change, B/N vs. LSM	-4.6 %	
HbA1c Change, LSM, P/T and B/N	0.0	CONQUER; EQUIP; COR-I; COR-BMOD
Absolute Difference in HbA1c Change, SEM vs. LSM	-0.3	STEP 1 trial
Absolute Difference in HbA1c Change, LIR vs. LSM	-0.2	SCALE trial



Key Model Inputs: Risk Equations

Onset of Cardiovascular Condition, 10-Year Risk

Non-Laboratory Based CV Disease Risk Prediction Model

Baseline and Beta Coefficient	Women	Men
So(10)	0.94833	0.8843
Log of Age	2.72107	3.113
BMI	0.51125	0.7928
Log of SBP if Not Treated	2.81291	1.8551
Log of SBP if Treated	2.88267	1.9267
Smoking	0.61868	0.7095
Diabetes	0.77763	0.5316

Onset of Diabetes, Annual Risk

Regression of Diabetes Annual Incidence on HbA1C and BMI



Key Model Inputs: Clinical Inputs

Parameters	Input	Source	
Mortality Following Acute Stroke or MI	8%	OECD statistics	
Relative Risk* of Annu	al Mortality		
Post-Stroke	3.1	Majed 2015	
Post-MI	1.6	Majed 2015	
Other CV Disease	1.9	Pande 2011	
Diabetes	1.2	Tancredi 2015	
Heart Failure	1.8	Ødegaard 2020	

*Relative risk was multiplied to the annual mortality rate in a general population.



Key Model Inputs: Therapy Costs

Annual Intervention Cost	Cost Ir	Source	
	Year 1	Year 1 Year 2 or Later	
Semaglutide	\$13,618	Same as year 1	
Liraglutide	\$11,309	\$11,760	ESS Drice
Phentermine/Topiramate	\$1,355	\$1,465	FSS Plice
Bupropion/Naltrexone	\$2,034	\$2,095	
Lifestyle Modification	\$564		Lee R. 2020



Key Model Inputs: Non-Therapy Cost

Cost Parameters	Input Value	Source
Diabetes, Annual Cost	\$11,425	ADA 2018
Other CV Disease, Annual Cost	\$14,279	Scully 2017
Stroke, Acute Care Cost for the Onset and Recurrent Event	\$17,316	HCUP
Post-Stroke, Annual Cost	\$6,500	Kazi 2019
MI, Acute Care Cost for the Onset and Recurrent Event	\$26,034	HCUP
Post-MI, Annual Cost	\$3,117	Kazi 2019
Heart Failure, First Year	\$27,030	Urbich 2020; Patel 2021
Heart Failure, Second Year or Later	\$15,605	Patel 2021



Key Model Inputs: Utilities

Utility Parameters	Input value	Source
General Population Utility	0.9442-0.0007 × Age	Sullivan 2006
Diabetes	0.962	Sullivan 2006
Other CV Disease	0.959	Sullivan 2006
Post-Stroke	0.943	Sullivan 2006
Post-MI	0.955	Sullivan 2006
Heart Failure	0.930	Sullivan 2006
Disutility per BMI Unit Increase	-0.0033	Kim 2022; Pi-Sunyer 2015
Disutility of Acute Stroke	-0.190	Matza 2015
Disutility of Acute MI	-0.150	Matza 2015



Results

Base-Case Results

Drug	Drug Cost	Non-Drug Cost	Total Cost	Life Years	QALYs	evLYs
Semaglutide	\$285,800	\$106,200	\$392,100	21.04	17.85	17.86
Liraglutide	\$241,800	\$135,200	\$377,000	20.86	17.36	17.37
Phentermine/Topiramate	\$39,700	\$142,800	\$182,600	20.85	17.40	17.41
Bupropion/Naltrexone	\$52,200	\$155,100	\$207,300	20.78	17.18	17.19
Lifestyle Modification	\$11,400	\$167,800	\$179,200	20.70	16.95	16.95



Base-Case Incremental Results

Incremental Outcomes Drug	Drug Cost	Non-Drug Cost	Total Cost	Life Years	QALYs	evLYs
Semaglutide	\$274,400	-\$61,600	\$212,900	0.34	0.89	0.91
Liraglutide	\$230,400	-\$32,600	\$197,800	0.16	0.41	0.42
Phentermine/Topiramate	\$28,400	-\$24,900	\$3,400	0.16	0.45	0.46
Bupropion/Naltrexone	\$40,800	-\$12,700	\$28,100	0.08	0.23	0.23

Base-Case Results

Drug	Incremental Cost per QALY gained	Incremental per evLY gained
Semaglutide	\$238,000	\$235,000
Liraglutide	\$485,000	\$475,000
Phentermine/Topiramate	\$8,000	\$7,000
Bupropion/Naltrexone	\$124,000	\$121,000



One Way Sensitivity Analyses



Phentermine/Topiramate vs. Lifestyle Modification





Probabilistic Sensitivity Analysis



Societal Perspective Analyses

Drug	Incremental Cost per QALY Gained	Incremental per evLY Gained
Semaglutide	\$217,000	\$214,000
Liraglutide	\$461,000	\$451,000
Phentermine/Topiramate	Less costly and more effective compar	red to the lifestyle modification
Bupropion/Naltrexone	\$106,000	\$104,000



Comorbidity Effect:

Inclusion of Cancer and Chronic Kidney Disease, Separately, in Model

	Can	cer	Chronic Kidney Disease		
Drug	Incremental Cost per QALY Gained	Incremental per evLY Gained	Incremental Cost per QALY Gained	Incremental per evLY Gained	
Semaglutide	\$215,000	\$211,000	\$213,000	\$209,000	
Liraglutide	\$447,000	\$434,000	\$439,000	\$426,000	
Phentermine/Topiramate	\$6,000	\$6,000	\$4,000	\$3,000	
Bupropion/Naltrexone	\$106,000	\$102,000	\$100,000	\$97,000	



Scenario Analyses

	Baseline BMI 45-50 kg/m ²		Male:Female = 50:50		ale = 50:50
Drug	Incremental Cost per QALY Gained	Incremental per evLY Gained	Incremental Cost per QALY Gained		Incremental per evLY Gained
Semaglutide	\$205,000	\$200,000	\$228,000		\$225,000
Liraglutide	\$501,000	\$486,000	\$466,000		\$455,000
Phentermine/Topiramate	\$3,000	\$3,000	\$7,000		\$6,000
Bupropion/Naltrexone	\$115,000	\$111,000	\$116,000		\$114,000
Drug		Incremental Cost per QALY Gained		Incremental per evLY Gained	
Generic Phentermine/Topira	mate Combination	Le	Less costly, more effective		/e
Generic Bupropion/Naltrex	c Bupropion/Naltrexone Combination \$6,000		,000 \$6,000		\$6,000



Health Benefit Price Benchmarks for Semaglutide

Outcomes for Annual Health Benefit Price Benchmark Calculation	Annual WAC	Annual Price at \$100,000 Threshold	Annual Price at \$150,000 Threshold	Discount from WAC to Reach Threshold Prices
QALYs Gained	\$17,597	\$7,500	\$9,700	45-57%
evLYs Gained	\$17,597	\$7,600	\$9,800	44-57%



Limitations

- A model-based cost-effectiveness assessment may not include full potential impact of weight loss; some conditions were purposely excluded due to a concern over double counting of weight-loss benefits
- Risk equations may have limitations when attempting to predict impact of drug treatments for weight loss
- Outcomes in subpopulations with larger potential benefits (e.g., younger individuals, women of childbearing age, or underserved populations) were not specifically addressed because analysis was limited by available evidence

Comments Received

- Recommended to assess shorter treatment durations of two years to reflect uncertainties around utilization of medications
- Assuming MI as a prerequisite to developing heart failure may underestimate incidence of heart failure
- Treatment benefits associated with other relevant comorbidities (e.g., GERD, back pain, liver disease, reproductive system disorders, sleep apnea) are not captured



Conclusions

- Long-term weight management with semaglutide or liraglutide was not cost effective given commonly accepted willingness-to-pay thresholds
- Phentermine/topiramate in addition to lifestyle modification was cost effective given commonly accepted thresholds owing to its comparatively smaller net acquisition costs
- Bupropion/naltrexone was cost effective at higher thresholds only
- Phentermine/topiramate is cost-saving, and bupropion/naltrexone was cost effective when prescribed generically





Public Comment and Discussion

Jason Brett, MD Executive Director, Medical Affairs, Novo Nordisk Inc.

Conflicts of Interest:

• Dr. Jason Brett is a full-time employee of Novo Nordisk, Inc.





Michele Tedder, MSN,RN Senior Program Manager, Black Women's Health Imperative

Conflicts of Interest:

• No financial conflicts to disclose.





Theodore K. Kyle, RPh, MBA Founder, ConscienHealth

Conflicts of Interest:

• Theodore Kyle receives honoraria from Nutrisystem and Gelesis.





Lunch

Meeting will resume at 12:45 PM ET



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Voting Questions

1. Is the evidence adequate to demonstrate that the net health benefit of <u>semaglutide</u> added to lifestyle modification is superior to that provided by <u>lifestyle modification</u> alone?

A. Yes



2. Is the evidence adequate to demonstrate that the net health benefit of <u>liraglutide</u> added to lifestyle modification is superior to that provided by <u>lifestyle modification</u> alone?

A. Yes



3. Is the evidence adequate to demonstrate that the net health benefit of <u>phentermine/topiramate</u> added to lifestyle modification is superior to that provided by <u>lifestyle modification</u> alone?

A. Yes



4. Is the evidence adequate to demonstrate that the net health benefit of <u>bupropion/naltrexone</u> added to lifestyle modification is superior to that provided by <u>lifestyle modification</u> alone?

A. Yes



5. Is the evidence adequate to demonstrate that the net health benefit of <u>semaglutide</u> added to lifestyle modification is superior to that provided by <u>liraglutide</u> added to lifestyle modification?

A. Yes


Patient Population for all questions: Adults without pre-existing diabetes and either a BMI \geq 30 kg/m² or \geq 27 kg/m² with at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes, or dyslipidemia).

6. Is the evidence adequate to demonstrate that the net health benefit of <u>semaglutide</u> added to lifestyle modification is superior to that provided by <u>phentermine/topiramate</u> added to lifestyle modification?

A. Yes

B. No



Patient Population for all questions: Adults without pre-existing diabetes and either a BMI \geq 30 kg/m² or \geq 27 kg/m² with at least one weight-related comorbid condition (e.g., hypertension, type 2 diabetes, or dyslipidemia).

7. Is the evidence adequate to demonstrate that the net health benefit of <u>semaglutide</u> added to lifestyle modification is superior to that provided by <u>bupropion/naltrexone</u> added to lifestyle modification?

A. Yes

B. No



Contextual Considerations and Potential Other Benefits or Disadvantages Please vote on the following contextual considerations:

When making judgments of overall long-term value for money, what is the relative priority that should be given to any effective treatment for obesity on the basis of the following contextual considerations:

8. Acuity of need for treatment of individual patients based on shortterm risk of death or progression to permanent disability

- A. Very low priority
- B. Low priority
- C. Average priority
- D. High priority
- E. Very high priority



Please vote on the following contextual considerations:

When making judgments of overall long-term value for money, what is the relative priority that should be given to any effective treatment for obesity on the basis of the following contextual considerations:

9. Magnitude of the lifetime impact on individual patients of the condition being treated

- A. Very low priority
- B. Low priority
- C. Average priority
- D. High priority
- E. Very high priority



Please vote on the following potential other benefits or disadvantages:

What are the relative effects of semaglutide versus lifestyle modification on the following outcomes that inform judgment of the overall long-term value for money of semaglutide?

10. Patients' ability to achieve major life goals related to education, work, or family life

- A. Major negative effect
- B. Minor negative effect
- C. No difference
- D. Minor positive effect
- E. Major positive effect



Please vote on the following potential other benefits or disadvantages:

What are the relative effects of semaglutide versus lifestyle modification on the following outcomes that inform judgment of the overall long-term value for money of semaglutide?

11. Caregivers' quality of life and/or ability to achieve major life goals related to education, work, or family life

- A. Major negative effect
- B. Minor negative effect
- C. No difference
- D. Minor positive effect
- E. Major positive effect



Please vote on the following potential other benefits or disadvantages:

What are the relative effects of semaglutide versus lifestyle modification on the following outcomes that inform judgment of the overall long-term value for money of semaglutide?

12. Society's goal of reducing health inequities

- A. Major negative effect
- B. Minor negative effect
- C. No difference
- D. Minor positive effect
- E. Major positive effect



Long-Term Value for Money

15. Given the available evidence on comparative effectiveness and incremental cost effectiveness, and considering other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment at current pricing with <u>semaglutide</u> added to lifestyle modification versus <u>lifestyle</u> <u>modification</u> alone?

- A. Low long-term value for money at current price
- B. Intermediate long-term value for money at current price
- C. High long-term value for money at current price



Long-Term Value for Money

16. Given the available evidence on comparative effectiveness and incremental cost-effectiveness, and considering other benefits, disadvantages, and contextual considerations, what is the long-term value for money of treatment at current pricing with <u>semaglutide</u> added to lifestyle modification versus <u>phentermine/topiramate?</u>

- A. Low long-term value for money at current price
- B. Intermediate long-term value for money at current price
- C. High long-term value for money at current price



Break

Meeting will resume at 2:00 PM ET



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Policy Roundtable

Policy Roundtable

Policy Roundtable Participant	Conflict of Interest
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.



New England CEPAC Reflections



- Meeting recording posted to ICER website next week
- Final Report published on or around October 17
- Includes description of New England CEPAC votes, deliberation, policy roundtable discussion
- Materials available at: <u>https://icer.org/assessment/obesity-management-</u>
 <u>2022/</u>







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