Tirzepatide for Type 2 Diabetes: Final Policy Recommendations

February 15, 2022

Prepared for

©Institute for Clinical and Economic Review, 2022

Policy Recommendations

Introduction

The following policy recommendations reflect the main themes and points made during the Policy Roundtable discussion at the January 20, 2022 New England CEPAC public meeting on the use of tirzepatide for the treatment of type 2 diabetes. 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 patient advocates, two clinical experts, one payer, and two representatives from a pharmaceutical manufacturer to discuss how best to apply the evidence and votes to real-world practice and policy. 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

Recommendation 1

All stakeholders have a responsibility and an important role to play in ensuring that effective new treatment options for patients with type 2 diabetes mellitus (T2DM) are introduced in a way that will help reduce health inequities.

Despite the multitude of treatments available for T2DM, almost half of patients have not met their glycemic target. There are racial and ethnic disparities in both prevalence and treatment in the US, with minorities both more likely to have T2DM and have higher average HbA1c than non-Hispanic whites.[1,2] Therefore, additional treatment options, particularly those that are effective in lowering glucose, promoting weight loss, and decreasing cardiovascular and renal complications, have the

potential to have a greater impact in minority communities. However, efforts are needed to ensure that new therapies for T2DM, such as tirzepatide, improve the health of patients and families and do not aggravate existing health inequities.

Clinical experts and patients highlighted that the high cost of new therapies may worsen disparities in accessing care. This may be due to lack of health insurance that limits access to physicians and the new therapies that they prescribe, or high deductible payments even for those with insurance may result in steep out of pocket costs. Cost of care is not the only factor that may contribute to health inequities. Lack of culturally appropriate information to educate patients with T2DM and their families about lifestyle changes and treatments, as well as inequities in offering new technologies and treatments to minority populations may also play significant roles in existing health disparities relative to T2DM treatment.

To address these concerns:

<u>Manufacturers should take the following actions:</u>

- Do not assume that coupon programs for some eligible patients are sufficient to address affordability more broadly; instead, ensure that the set price for new treatments for T2DM is in fair alignment with added benefits for patients.

- Partner with patient groups, clinicians, and researchers to develop strategies to recruit a more diverse patient population in clinical trials reflective of the broader T2DM population.

<u>Payers should take the following actions:</u>

- Ensure that benefit designs developed in conjunction with employers and other plan sponsors do not create requirements for out-of-pocket spending that create major barriers to appropriate access for vulnerable patients.

- Consider developing quality measures to incentivize clinicians to ensure fair distribution of treatments (e.g., a measure reporting the percentage of patients with ASCVD or CKD who are on a GLP-1 RA or SGLT-2 inhibitor).

<u>Health systems should take the following actions:</u>

- Consider developing programs tailored to their health system needs to identify patients who are eligible for, and who would benefit from, newer therapies with cardiovascular or renal benefit such as GLP-1 RAs or SGLT-2 inhibitors.

- Support primary care physicians and endocrinologists, who care for the majority of patients with T2DM, in developing programs to ensure equal prescribing of appropriate therapies.

For example, supporting e-consults to specialists, developing order sets, and delivering culturally appropriate care. Examples of resources that may assist health systems in implementing programs include: the e-consult Workgroup (https://econsultworkgroup.com/); e-consults in the safety-net setting from San Francisco General Hospital (https://www.careinnovations.org/resources/facilitating-care-integrationintegrating-primary-care-and-specialty-careinnovator-highlight-san-francisco-general-hospitals-ereferral-system/); and protocols and order sets compiled by the American Association of Clinical Endocrinologists (https://pro.aace.com/disease-state-resources/diabetes/depth-information/protocols-and-order-sets).

Clinicians should take the following actions:

- Clinicians caring for T2DM patients should consider organizing team-based care that prioritizes decreasing health inequities in the delivery of diabetes care, including ensuring that guideline-based treatment is offered to all patients and delivering culturally appropriate diabetes education. Examples of programs to emulate include the Latinx and Asian American Diabetes Initiatives at Joslin Diabetes Center (https://www.joslin.org/patient-care/multicultural-programs); the Centers for Disease Control Native Diabetes Wellness Program (https://www.cdc.gov/diabetes/ndwp/index.html); and Diabetes Education Online from the UCSF Diabetes Teaching Center (https://dtc.ucsf.edu/, website and materials available in English, Spanish, and Chinese).

Patient groups should take the following actions:

- Ensure that their leadership is representative of and informed with input from diverse T2DM patients.

- Partner with other stakeholders to develop and disseminate educational materials and programs about prevention and management of T2DM that are culturally sensitive and language-concordant with the target population(s).

- Continue to advocate for greater diversity in clinical trial populations, reflective of the T2DM population in the US, and work with manufacturers and researchers to develop effective strategies for the recruitment and retention of minority participants in clinical trials of T2DM therapies.

Recommendation 2

Federal and state policymakers, payers, and health systems should work together to ensure that prior authorization processes are transparent and do not place undue burdens on clinicians and patients to ensure timely and equitable access to therapies for T2DM.

During the policy roundtable, patients and clinicians described the burden of unknown out-of-pocket requirements and burdensome prior authorization and the resulting impact of both on patients. Patients described feeling exhausted and humiliated to be prescribed drugs that they discover at the pharmacy to be beyond their ability to afford. Clinical experts gave examples of onerous prior authorization criteria and/or processes that discourage clinicians from offering newer, more expensive, but potentially more beneficial drugs (e.g., drugs with cardiovascular benefit) equitably to all patients. This causes unacceptable harm to patients. This is a problem that is fixable but requires the full commitment of multiple stakeholders working together to achieve more timely, equitable, and affordable drug access.

Federal and state policymakers should take the following actions:

- Work with payers to develop policies around interchangeability that allow pharmacists to exchange rejected drugs for covered drugs in the same class without having to go back to the prescribing clinician for approval, similar to substituting generic drugs for brand name drugs. This would potentially decrease the number of times a patient needs to go to the pharmacy, improve access and affordability of drugs, and decrease paperwork burden for clinicians.

Payers and health systems should take the following actions:

- Work with federal and state policymakers on interchangeability rules as described above.
- Work together to develop technologies to assist clinicians at the point of care know which drugs are covered and at what out-of-pocket cost for individual patients. These "cheat sheets" for clinicians could be electronic or paper but should be easily accessible at the point of care, e.g., deployed within the electronic medical record. An example of a web- and paper-based resource to improve prescriber knowledge about insurance coverage of common drugs is The Prescribing Guide for Hawaii (https://www.prescribingguide.com/).[3]

Payers

Recommendation 1

For coverage purposes, it is not unreasonable for payers to consider tirzepatide as a separate class of T2DM therapy or as part of the GLP-1 RA class.

Based on the 2022 American Diabetes Association (ADA) Standards of Medical Care for Diabetes, GLP-1 RAs with proven cardiovascular benefit (e.g., injectable semaglutide) are the recommended first- or second-line agent for patients with T2DM and at high risk for or with established ASCVD.[4] Although tirzepatide offers the additional GIP receptor agonist mechanism of action, which may have synergistic effects with GLP-1, clinical experts stated that it was not unreasonable to consider tirzepatide as part of the GLP-1 RA class, particularly before confirmation of cardiovascular benefit. However, clinical experts and patients value the apparent greater glucose lowering and weight loss potential of tirzepatide, and expect that cardiovascular benefit is likely to be confirmed based on data from tirzepatide's cardiovascular safety trial and its inclusion of GLP-1 receptor agonism as part of its mechanism of action. Thus, tirzepatide may also be considered separately from other GLP-1 RAs in terms of coverage criteria, access, and formulary tier placement.

Recommendation 2

Payers should consider broadening criteria for coverage of both GLP-1 RAs and SGLT-2 inhibitors since, based on the most current clinical guidelines, these drugs may be considered first-line therapy in T2DM patients with cardiovascular or renal disease, and wider use should be encouraged in these specific populations.

Metformin is commonly used as first-line therapy based on its inexpensive cost and excellent safety profile. However, the most recent ADA guidelines suggest that use of GLP-1 RAs and SGLT-2 inhibitors with confirmed cardiovascular or renal benefit as initial therapy may be considered in patients at high risk for or with established ASCVD, CKD, or heart failure, regardless of HbA1c or use of metformin.[4] Some clinical experts have interpreted this recommendation to mean that for certain patients, initiation of drug therapy for T2DM can begin with a GLP-1 RA or SGLT-2 inhibitor, without preceding or concomitant use of metformin. Although clinical experts advised that it is not unreasonable to continue to require metformin use as first line and institute a HbA1c threshold for adding further therapy, in light of the new guidelines, health plans may also consider removing metformin as required step therapy, especially for patients at high risk for or with established ASCVD, CKD, or heart failure.

Cost Sharing

- Patient cost sharing should be based on the net price to the plan sponsor, not the unnegotiated list price.
- If all drugs in a drug class are priced so that they represent a fair value, it remains reasonable for payers to use preferential formulary placement with tiered cost sharing to help achieve lower overall costs.

Coverage Criteria: General

- Payers should offer alternatives to prior authorization protocols such as programs that give feedback on prescribing patterns to clinicians or exempt them from prior authorization requirements ("gold carding") if they demonstrate high fidelity to evidence-based prescribing.
- Payers should document at least once annually that clinical eligibility criteria are based on high quality, up-to-date evidence, with input from clinicians with experience in the same or similar clinical specialty.
- Clinical eligibility criteria should be developed with explicit mechanisms that require payer staff to document using an open and transparent process that is readily accessible to the public that they have:
    a) Considered limitations of evidence due to systemic under-representation of minority populations; and
    b) Sought input from clinical experts on whether there are distinctive benefits and harms of treatment that may arise for biological, cultural, or social reasons across different communities; and
    c) Confirmed that clinical eligibility criteria have not gone beyond reasonable use of clinical trial inclusion/exclusion criteria to interpret or narrow the FDA label language in a way that disadvantages patients with underlying disabilities unrelated to the condition being treated.

Drug-Specific Considerations

The large number of patients with T2DM, combined with the high annual prices for newer generation treatments, will lead payers to develop prior authorization criteria for tirzepatide and to consider other limits on utilization. Perspectives on specific elements of cost sharing and coverage criteria within insurance coverage policy are discussed below. Relevant Fair Access Design Criteria set out in ICER's previous work are included.

None of these coverage terms, however, should undermine the tenets of fair access to which all patients have a fundamental right. To explore the appropriate application of evidence to coverage policy, and to reflect the views of patient experts and clinicians 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 tirzepatide.

Coverage Criteria

- **Age:** Tirzepatide will likely be covered for adult patients with T2DM, in line with clinical trial eligibility criteria.

- **Clinical eligibility**: Clinical trials enrolled T2DM patients with HbA1c between 7% and 10.5%. Updated treatment guidelines from the American Diabetes Association emphasize that treatment with GLP-1 RA and SGLT-2 inhibitor class drugs may be considered independent of HbA1c targets and metformin use in patients with cardiovascular disease, chronic kidney disease, and heart failure given the demonstrated benefits of agents in those two classes on cardiovascular and renal outcomes.[4] However, the cardiovascular and renal benefits of GLP-1 RAs may not be a class effect.[5] Thus, because tirzepatide does not yet have confirmed cardiovascular benefit, it is not unreasonable for payers to consider requiring HbA1c to be above 7% on at least metformin therapy for coverage of tirzepatide. On the other hand, clinical experts also advised that given the level of HbA1c lowering and weight loss that tirzepatide provides, payers should also consider broadening eligibility criteria to include patients with HbA1c lower than 7%.

- **Exclusion criteria**: Clinical experts advised that it was not unreasonable to exclude patients who are on concomitant GLP-1 RA therapy, given the overlap in mechanism between GLP-1 RAs and tirzepatide.

- **Duration of coverage and renewal criteria**: Clinical experts advised that it is not unreasonable for payers to consider a limited duration of coverage, after which clinicians would be asked to confirm clinical benefit, particularly prior to confirmation of potential cardiovascular benefits of tirzepatide. However, the mechanism of action of the drug should pose no risk to having uninterrupted coverage.

- **Provider restrictions**: Given the prevalence of T2DM and that much of diabetes care occurs in primary care, there should be no restrictions on type of provider prescribing tirzepatide to help foster equitable access to the drug.

Step Therapy

Payers should only use step therapy when it provides adequate flexibility to meet the needs of diverse patients and when implementation can meet high standards of transparency and efficiency.

Clinical experts and patient representatives stated that delayed and restricted access to treatment due to step therapy requirements for patients with T2DM is common, particularly for newer agents like GLP-1 RAs. 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 patients due to the discontinuation of medicine/missed doses. A particular area of concern raised by patients involved requirements to re-step through previously failed therapies when insurance changed.

New clinical guidelines suggest that metformin may no longer be the preferred first step in therapy for T2DM patients at high risk of or with established ASCVD, chronic kidney disease, or heart failure, and payers should consider access to drugs with proven cardiovascular or renal benefit without requiring a trial of metformin therapy. Payers who do establish step therapy with metformin should allow patients and clinicians to choose from options in both GLP-1 RA and SGLT-2 inhibitor classes as the next step.

As stated above, the most current ADA guidelines state that for patients with T2DM who also have ASCVD, CKD or heart failure, metformin therapy is not necessarily a prerequisite to starting a GLP-1 RA or SGLT-2 inhibitor "with confirmed cardiovascular or renal benefit."[4] The guidelines further subdivide those populations into patients at high risk of or with established ASCVD, where a GLP-1 RA drug is preferred, and patients with CKD or heart failure, where a SGLT-2 inhibitor is preferred, though both classes of agents can be used in all three populations. Thus, clinicians and patients should have the ability to choose the most appropriate drug(s) from these two classes. Furthermore, in many cases, patients will need to be on a drug from both classes in order to reach their glycemic target, and thus access to both classes should be preserved for these populations. Since tirzepatide's cardiovascular outcome data is not mature, health plans may choose to consider tirzepatide as part of the GLP-1 RA class due to its similarity in mechanism or as a separate class.

Manufacturers

Recommendation 1

Manufacturers should seek to set prices that will foster affordability and good access for all patients by aligning prices with the patient-centered therapeutic value of their treatments. In the setting of these new interventions for T2DM, while HbA1c lowering remains an important intermediate outcome, there is increasing emphasis on other potential benefits, including weight loss and prevention of complications such as cardiovascular events and kidney disease. Manufacturer pricing at launch should reflect these considerations and whether longer-term cardiovascular and renal outcomes have been demonstrated.

Drug prices that are set well beyond the cost-effective range cause not only financial toxicity for patients and families using the treatments, but also contribute to general health care cost growth that pushes families out of the insurance pool, and that causes others to ration their own care in ways that can be harmful. This is of particular concern in T2DM, as the financial burden is not only related to drug costs but also costs for glucose monitoring and the costs of managing the micro- and macrovascular complications that result from the disease.

Manufacturers should therefore price novel treatments in accordance with the demonstrated benefits to patients. In settings of substantial uncertainty, initial pricing should err on the side of being more affordable. This would allow more patients access, generating additional data on the real-world effectiveness of novel treatments that could be used in future assessment updates. In the case of tirzepatide, although it has substantial impact on HbA1c and weight, it does not yet have demonstrated cardiovascular or renal benefits that many GLP-1 RAs and SGLT-2 inhibitors have. Thus, launch pricing should reflect this uncertainty; if benefit is shown after the completion of the cardiovascular outcomes trial, the manufacturer should be allowed to adjust pricing in accordance with this benefit.

Recommendation 2

Manufacturers should take steps to increase the diversity of participants in their clinical trials for T2DM. Given the high overall prevalence of T2DM in the US and the higher prevalence in minority populations, it is unacceptable that clinical trials still largely consisted of non-Hispanic white participants.

African Americans, Hispanic Americans, Asian Americans, and Native American/Alaska Natives all have a higher prevalence of T2DM compared with non-Hispanic white Americans.[1] ICER's Health Improvement Distribution Index (HIDI) demonstrates that minority populations may have the opportunity for 10% to 40% more impact from an effective therapy than the general US population. However, the clinical trials for tirzepatide lacked racial and ethnic diversity, and thus any differential impact of tirzepatide – either in efficacy or harms – in these populations is not known.

Manufacturers need to fully commit to increase recruitment of minority populations in clinical trials and should work with patient groups and clinicians to design effective programs for the recruitment and retention of minority participants.

Recommendation 3

Manufacturers should not take steps to delay or deny the role of generic medications in improving the affordability of T2DM drugs.

Because of their superior cardiovascular and renal outcomes, as well as their impact on weight, GLP-1 RAs and SGLT-2 inhibitors have risen to be the preferred first- or second-line drugs for the treatment of T2DM for many patients. Currently none of the GLP-1 RAs and SGLT-2 inhibitors with cardiovascular or renal benefit is available as a generic medication. As the patents expire for these drugs in the coming years, manufacturers should not prevent the timely development and marketing of generic versions of these drugs to improve access and affordability to these important medications.

Clinicians and Clinical Societies

Recommendation 1

Clinical specialty societies should develop and disseminate programs to educate physicians who care for T2DM on the evolving treatment landscape, including the heightened importance of assessing for cardiovascular and renal comorbidities when choosing treatments.

Given the number of comorbidities that T2DM patients have or develop, multiple clinicians – including primary care physicians and specialists – are likely to be involved in the care of T2DM patients. The majority of care for T2DM patients occurs in the primary care setting, with endocrinologists managing less than 15% of T2DM patients nationally.[6] Cardiologists and nephrologists are also likely to be heavily involved in the management T2DM patients with cardiovascular or renal disease given how common these comorbidities are in this population.

Studies show that less than 10% of eligible patients have received treatment with a GLP-1 RA or SGLT-2 inhibitor.[7,8] Thus, there is ample opportunity for all clinicians who care for patients with T2DM with cardiovascular or renal disease to consider recommending initiation of a GLP-1 RA or SGLT-2 inhibitor regardless of HbA1c, in line with the most recent clinical guidelines. However, barriers to prescribing these drugs include unfamiliarity or lack of experience prescribing these drugs, and for specialists, a feeling that management of T2DM is the responsibility of primary care physicians.[9]

Clinical societies should develop and disseminate programs to educate physicians caring for T2DM patients to identify patients who may be candidates for treatment with drugs having cardiovascular

or renal benefit such as GLP-1 RAs and SGLT-2 inhibitors. In particular, such programs should encourage team-based care with primary care physicians and specialists collaborating to ensure that patients are receiving evidence-based care with regard to management of both glucose and cardiometabolic risk factors.

Researchers

Recommendation 1

Clinical trials should be targeted to address gaps in knowledge about the comparative clinical effectiveness of GLP-1 RAs and SGLT-2 inhibitors and their use in patients without established ASCVD, CKD, or heart failure.

Although cardiovascular and renal benefit from treatment with GLP-1 RAs and SGLT-2 inhibitors has been demonstrated in patients at high risk for or with established ASCVD, CKD, or heart failure, independent of their glucose-lowering effect, their impact on cardiovascular and renal outcomes in T2DM patients without those comorbidities is less certain. Furthermore, in patients without a strong indication for either class of medication but who require additional glucose-lowering, the order of stepwise therapy is not readily apparent. We did not find any head-to-head trials of GLP-1 RAs compared with SGLT-2 inhibitors and did not find any cardiovascular outcomes trials in patients without ASCVD. Thus, additional data, either from randomized clinical trials or high-quality observational studies could be useful in further guiding and personalizing therapy.

Recommendation 2

More research is needed to generate quality-of-life data and data for use in economic evaluations regarding the societal costs of diabetes.

Trials of treatments for T2DM should not only include intermediate outcomes such as HbA1c and weight and measures of potential micro- and macrovascular benefit but also collect data on quality of life of patients with T2DM. As the number of treatment choices increase and personalization of therapy is encouraged, the impact of a particular therapy on a patient's quality of life is an important factor to consider. Eli Lilly's inclusion of several validated quality-of-life measures, including versions of the Diabetes Treatment Satisfaction Questionnaire and EQ-5D are to be commended and should be replicated by all manufacturers when designing trials testing new therapies to treat T2DM.

We found there was a lack of comprehensive data to adapt for use in an economic evaluation regarding the societal costs of diabetes. These societal costs generally include costs to the patient and/or their caregivers outside of the health care sector. For example, the societal costs of

diabetes would capture the impact of diabetes on productivity loss (specifically, the average number of hours of presenteeism or absenteeism at work for patients or caregivers), as well as the amount and cost of informal care required for the patient. For use in an economic model, it would be particularly useful if the aforementioned costs were stratified by patient characteristics, such as age, race, and years since diagnosis. Importantly for diabetes, societal costs specific to diabetes-related complications, such as cardiovascular and renal events, are important for accurate economic modeling of the societal perspective.

Recommendation 3

Research in T2DM should focus not only on interventions to treat the disease, but also include testing of upstream interventions to prevent onset of the disease.

Given that some risk factors for developing diabetes, such as obesity, are modifiable with lifestyle interventions, data on the most effective types of structured lifestyle interventions for prevention and/or treatment are needed to help guide patients and clinicians. Such information could also be useful for policymakers in helping to guide funding for scaling up of effective prevention programs such as the Diabetes Prevention Program to ensure a wide reach and potentially decrease health inequities in access to such programs. Currently, we note that no health plans require participation in structured lifestyle intervention programs to treat diabetes prior to and/or concomitant with drug treatment for T2DM, despite clinical guidelines citing this as the backbone of diabetes treatment. With evidence of efficacy, health plans could be encouraged to cover structured lifestyle interventions in addition to drug therapy to ensure that T2DM patients receive comprehensive, evidence-based treatment.

References

1. Centers for Disease Control and Prevention USDoHaHS. *National Diabetes Statistics Report, 2020.* Atlanta, GA: Centers for Disease Control and Prevention, U.S. Dept of Health and Human Services;2020.
2. Smalls BL, Ritchwood TD, Bishu KG, Egede LE. Racial/Ethnic Differences in Glycemic Control in Older Adults with Type 2 Diabetes: United States 2003-2014. *Int J Environ Res Public Health.* 2020;17(3).
3. Tseng CW, Lin GA, Davis J, et al. Giving formulary and drug cost information to providers and impact on medication cost and use: a longitudinal non-randomized study. *BMC Health Serv Res.* 2016;16(1):499.
4. American Diabetes Association Professional Practice C, American Diabetes Association Professional Practice C, Draznin B, et al. 9. Pharmacologic Approaches to Glycemic Treatment: Standards of Medical Care in Diabetes-2022. *Diabetes Care.* 2022;45(Supplement_1):S125-S143.
5. Sheahan KH, Wahlberg EA, Gilbert MP. An overview of GLP-1 agonists and recent cardiovascular outcomes trials. *Postgrad Med J.* 2020;96(1133):156-161.
6. Gunawan F, Nassif ME, Partridge C, Ahmad T, Kosiborod M, Inzucchi SE. Relative frequency of cardiology vs. endocrinology visits by type 2 diabetes patients with cardiovascular disease in the USA: implications for implementing evidence-based use of glucose-lowering medications. *Cardiovasc Endocrinol Metab.* 2020;9(2):56-59.
7. Arnold SV, de Lemos JA, Rosenson RS, et al. Use of Guideline-Recommended Risk Reduction Strategies Among Patients With Diabetes and Atherosclerotic Cardiovascular Disease. *Circulation.* 2019;140(7):618-620.
8. Arnold SV, Inzucchi SE, Tang F, et al. Real-world use and modeled impact of glucose-lowering therapies evaluated in recent cardiovascular outcomes trials: An NCDR(R) Research to Practice project. *Eur J Prev Cardiol.* 2017;24(15):1637-1645.
9. Nelson AJ, Pagidipati NJ, Aroda VR, et al. Incorporating SGLT2i and GLP-1RA for Cardiovascular and Kidney Disease Risk Reduction: Call for Action to the Cardiology Community. *Circulation.* 2021;144(1):74-84.

Appendix

Appendix Tables 1 through 3 contain conflict of interest (COI) disclosures for all participants at the January 20, 2022 public meeting of the New England CEPAC.

Appendix Table 1. ICER Staff and Consultants and COI Disclosures

ICER Staff and Consultants	
Elizabeth Brouwer, PhD, MPH* Research Scientist, The CHOICE Institute, University of Washington	**Grace A. Lin, MD*** Medical Director for Health Technology Assessment, ICER Associate Professor of Medicine and Health Policy, University of California, San Francisco
Jon D. Campbell, PhD, MS* Senior Vice President for Health Economics, ICER	**Ashton Moradi, PharmD, MS*** Health Economist, ICER
Yilin Chen, MPH, PhD student* PhD Student, The CHOICE Institute, University of Washington	**Dmitriy Nikitin, MSPH*** Research Lead, Evidence Synthesis, ICER
Kelsey Gosselin, MA* Program Manager, ICER	**Steven D. Pearson, MD, MSc*** President, ICER
Ryan N. Hansen, PharmD, PhD* Associate Professor, The CHOICE Institute, University of Washington	**Liis Shea, MA*** Program Director, ICER
Serina Herron-Smith, BA* Senior Research Assistant, Evidence Synthesis, ICER	**Grace Sternklar, BS*** Program Coordinator, ICER

*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.

Appendix Table 2. New England CEPAC Panel Member Participants and COI Disclosures

Participating Members of CEPAC	
Rob Aseltine, PhD* Professor and Chair, Division of Behavioral Sciences and Community Health Director, Center for Population Health, UCONN Health	**Aaron Mitchell, MD, MPH*** Assistant Attending, Memorial Sloan Kettering Cancer Center
Austin Frakt, PhD* Director, Partnered Evidence-Based Policy Resource Center, VA Boston Healthcare System; Professor, Boston University School of Public Health	**Eleftherios Mylonakis, MD, PhD, FIDSA*** Chief of Infectious Diseases Division, Dean Professor of Medicine, Warren Alpert Medical School of Brown University
Marthe Gold, MD, MPH* Logan Professor Emerita, CUNY School of Medicine	**Stephanie Nichols, PharmD, BCPS, BCPP, FCCP*** Associate Professor of Pharmacy Practice, University of New England College of Pharmacy
Megan Golden, JD* Co-Director, Mission:Cure	**Jason L. Schwartz, PhD*** Assistant Professor, Department of Health Policy and Management, Yale School of Public Health
Stephen Kogut, PhD, MBA, RPh* Professor of Pharmacy Practice, University of Rhode Island College of Pharmacy	**Jason Wasfy, MD, MPhil (Chair)*** Director, Quality and Outcomes Research, Massachusetts General Hospital Heart Center; Medical Director, Massachusetts General Physicians Organization
Donald Kreis, JD* Consumer Advocate, New Hampshire Office of the Consumer Advocate	**Rev. Albert Whittaker, MA*** Interim Pastor, St. Mark Congregational Church Consultant, Health Integration and Equity
Greg Low, RPh, PhD* Program Director, MGPO Pharmacy Quality and Utilization Program, Massachusetts General Hospital	

*No relevant conflicts of interest to disclose, defined as more than $10,000 in healthcare company stock or more than $5,000 in honoraria or consultancies during the previous year from health care manufacturers or insurers.

Appendix Table 3. Policy Roundtable Participants and COI Disclosures

Policy Roundtable Participant	Conflict of Interest
Lizzette Cambron, PhD Type 2 Diabetes Patient and Advocate	None.
Mohammad Dar, MD Senior Medical Director, MassHealth	Mohammad Dar practices as an internist in the VA Boston Healthcare system.
Bonnie Donato, PhD Executive Director, HEOR VDT CV-MET & Respiratory, Boehringer Ingelheim	Bonnie Donato is an employee of Boehringer Ingelheim and has had equity interest from Astra Zeneca.
Sarah Kim, MD Associate Clinical Professor, University of California San Francisco	None.
Liz Leff Senior Corporate Relations Director, National Kidney Foundation	The National Kidney Foundation receives less than 25% of its funding from pharmaceutical manufacturers, including from Novo Nordisk and the BI-Lilly Diabetes Alliance.
Joanna Mitri, MD, MS Medical Director, Global Education and Care Division Joslin Diabetes Center, Assistant Professor, Harvard Medical School	Dr. Mitri has received manufacturer support of research in the clinical area of this meeting, and her institution conducts clinical trials and educational programs that may be supported by health care companies. A household member of Dr. Mitri's has received consulting fees from health care companies including AbbVie, Roche, Janssen Pharmaceuticals, Pharmacyclics, and BeiGene.
William Riesner, JD, MBA Director	William Riesner is a full-time employee at Eli Lilly.