Digital Health Technologies as an Adjunct to Medication Assisted Therapy for Opioid Use Disorder:

Final Policy Recommendations

December 11, 2020

Policy Recommendations

Introduction

The following policy recommendations reflect main themes in the report and those discussed during the Policy Roundtable discussion at the November 18, 2020 Midwest CEPAC public meeting on the use of digital health technologies (DHTs) as an adjunct to medication assisted treatment for opioid use disorder. At the meeting, ICER presented the findings of its revised report on these treatments and the Midwest 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 representatives from the patient community, two clinical experts, two payers, and two representatives from pharmaceutical manufacturers to discuss how best to apply the evidence and votes to real-world practice and policy. The roundtable discussion was facilitated by Steven Pearson, MD, MSc, President of ICER. 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 full report on these treatments, which includes the same policy recommendations, can be found here.

The policy perspectives and recommendations are summarized below.

General

1. **Medication-assisted treatment (MAT) saves lives and money, both inside the health system and outside of it. New interventions should be developed, tested, and implemented that can augment the number of individuals who can access MAT, reduce stigma, and ensure that individuals receive care in a format that helps them achieve their goals. DHTs may be important aids in improving care for many individuals, but it is vital that adequate evidence be generated to evaluate the relative effectiveness of different options so that each person can receive effective treatment tailored to maximize their health. Poor evidence that leads to ineffective use of DHTs represents a health risk to individuals, a financial risk to the health system, and a moral risk for us all that society will fail in its responsibility to use its resources to the greatest effect in combatting an ongoing national epidemic.**

Researchers / Manufacturers

2. **Manufacturers should provide robust evidence of the clinical effectiveness and broader impact of new DHTs. For DHTs like those featured in this report that have a function of guiding or enhancing treatment outcomes, a minimum evidence requirement is high-quality observational or quasi-experimental studies with an appropriate comparator and relevant patient outcomes. However, many DHTs should undergo formal evaluation through randomized controlled trials to minimize the risk of bias in trial results.**

   Some DHTs, such as those with purely administrative or simple health management functions, pose no clinical risk to patients nor a significant financial risk to health systems. But for DHTs that inform clinicians or that seek to augment existing care, a basic minimum requirement for adequate evidence should include multiple high-quality observational or quasi-experimental studies. These studies should always include an appropriate control arm, such as "usual care" among patients who are waitlisted for a new intervention. Historical controls or pre-post evaluations are frequently vulnerable to confounders, such as regression to the mean, or selection bias, that greatly limits the confidence that can be ascribed to research results. And thus, for many DHTs, it will ultimately be impossible to reach a reasonable judgment without high-quality randomized trial evidence.

   For the DHTs in this report, the current evidence comes from older randomized trials of psychosocial interventions (TES, CBT4CBT, A CHESS, peer support, contingency management), but not the actual implementation of one or more of these interventions on a smart phone. The trials should be sham controlled (another DHT providing informational modules alone for example) and of sufficient duration (minimum six months, one to two years preferred) to assess not only ongoing retention in MAT treatment and abstinence from illicit use of opioids, but also outcomes that matter to patients such as ER visits, hospitalizations, obtaining housing and/or employment, and quality of life.

3. **In addition to evidence on relative safety and effectiveness in the short term, manufacturers should be prepared to provide a full dossier of evidence to payers and providers that includes robust information on 1) the durability of beneficial clinical effects; 2) the impact on health care utilization; 3) the impact on clinician productivity; 4) the usability as measured by clinician and patient experience; 5) the security of IT components; 6) the generalizability of results to diverse patient populations and health systems; and 7) the scalability to larger populations.**

   The evidentiary requirements for FDA approval of DHTs are not well established. When regulatory pathways such as 510k are used, a new DHT may be approved with very little evidence of comparative clinical effectiveness. But even if manufacturers produce more robust

evidence on clinical effectiveness, the broader impact of DHTs cannot be assessed without information and evidence on a wide range of factors, as listed above. Manufacturers seeking success in the marketplace should be aware that payers and providers are inundated with requests to consider new DHTs, and that those with a robust evidence package are far more likely to be adopted. To get this evidence, it is often necessary to pilot test a DHT with one or more provider groups. Surveys of patients and clinicians will be needed to assess usability. And clinical trials will need to be designed to last long enough to demonstrate stability of clinical benefit over an intermediate to long term, and they must capture important potential health care utilization effects. Only with a well-developed evidence dossier including all these components will a payer or health system have the information needed to make a prudent judgement about adoption.

4. **Manufacturers and researchers should design trials of DHTs to be able to identify potential subgroups of patients who benefit most from a DHT and those who are less likely to benefit. Existing evidence may also be reanalyzed for this purpose.**

   For example, in Christensen 2014, the subgroup of patients who had previously undergone MAT treatment seemed to derive a large benefit from TES, while treatment-naïve patients experienced minimal benefit. There is significant heterogeneity in the characteristics of patients suffering from OUD (age, sex, route of administration, treatment setting, housing, employment, urban/rural, co-existing mental health disease, multiple substance use disorders, etc.) that could be explored to identify those patients most likely to benefit from a DHT. This information could then be tested in future studies and allow for more efficient use of DHTs in clinical practice.

Payers

5. **Given the limited evidence supporting the efficacy of DHTs for OUD, alternative payment models may be appropriate if coverage is provided. For instance:**

   - Guaranteed outcomes: payment only if certain metrics are obtained, that could include rates of engagement with the DHT or retention rates in MAT at three, six, and/or twelve months.

   - Pilot projects/co-development to facilitate outreach and education of providers about the availability of the DHT, helping with implementation in specific clinics, along with measurement of the impact of the availability of the DHT on retention in MAT, ER visits, and hospitalization rates.

- Subscription model where the payer pays a certain amount per month based on the number of identified patients with OUD in their covered lives, but with no limit on the number of prescriptions that their providers can write for the DHT.

Regulators

6. **The FDA should develop a clear taxonomy of DHTs, with different levels of risk and other factors, and clarify evidence requirements that are robust enough to inform patients, clinicians, health systems, and payers regarding the safety and comparative effectiveness of their use in representative patient populations.**

Appendix

Appendix Tables 1 through 3 contain conflict of interest (COI) disclosures for all participants at the November 18, 2020 Public meeting of the Midwest CEPAC.

Appendix Table 1. ICER Staff and Consultants and COI Disclosures

ICER Staff and Consultants	
Pamela Bradt, MD, MPH,* Chief Scientific Officer, ICER	**Maggie O'Grady, BS,*** Program Manager, ICER
Jon Campbell, PhD, MS,* Senior Vice President for Health Economics, ICER	**Steven D. Pearson, MD, MSc,*** President, ICER
Rick Chapman, PhD, MS,* Director of Health Economics, ICER	**Jeffrey A. Tice, MD,*** Professor of Medicine, University of California, San Francisco
Noemi Fluetsch, MPH,* Research Assistant, ICER	**Melanie Whittington, PhD, MS**,* Associate Director of Health Economics, ICER
Maggie Houle, BS,* Program and Event Coordinator, ICER	**Lorenzo Villa Zapata, PhD, PharmD,*** Post-doctoral fellow University of Colorado Anschutz Medical Center
Nicholas Mendola, MPH,* PhD Student University of Colorado Anschutz Medical Center	

*No conflicts of interest to disclose, defined as individual health care stock ownership in any health plan or pharmaceutical, biotechnology, or medical device manufacturers, or any health care consultant income or honoraria from health plans or manufacturers.

Appendix Table 2. Midwest CEPAC Panel Member Participants and COI Disclosures

Participating Members of Midwest CEPAC	
Eric Armbrecht, PhD (Chair),* Associate Professor, Saint Louis Center for Health Outcomes Research, School of Medicine and College for Public Health and Social Justice	**Jill Johnson, PharmD,*** Professor, University of Arkansas for Medical Sciences
Angela Brown, MPH,* Chief Executive Officer, St. Louis Regional Health Commission	**Chris Jones, PhD,ǂ** Network Director, Venture Investments, University of Vermont Health Network
Donald Casey, MD, MPH, MBA,* President, American College of Medical Quality	**Greg Low, RPh, PhD,*** Director, Massachusetts General Physicians Organization Pharmacy Quality and Utilization Program
Greg Curfman, MD,* Deputy Editor, JAMA	**Tim McBride, PhD,*** Co-Director, Center for Health Economics and Policy; Professor, Washington University in St. Louis
Stacie Dusetzina, PhD,* Associate Professor of Health Policy, Vanderbilt University School of Medicine	**Jeanne Ryer, MSc, EdD,*** Director of Delivery System and Payment Reform, University of New Hampshire Institute for Health Policy and Practice
Megan Golden, JD,* Co-Director, Mission: Cure	**Timothy Wilt, MD, MPH*,** Professor of Medicine; Director, Minnesota Evidence-based Synthesis Program, Minneapolis VA Center for Chronic Disease Outcomes Research
Elbert Huang, MD, MPH,* Professor of Medicine; Director, Center for Chronic Disease Research and Policy, University of Chicago	**Stuart Winston, DO,*** Physician Lead, Professional Enhancement Program, Integrated Health Associates

ǂChris Jones is a founder of TRUSX Inc. with clients such as Sanofi, and a founder of ForMyOdds.com. He is a board member of portfolio companies in which UVMHN Ventures is invested, as well as an institutional investor (on behalf of UVM Health Network Ventures) in Aspenti Health, a drug testing facility.

*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 3. Policy Roundtable Participants and COI Disclosures

Policy Roundtable Participant	Conflict of Interest
Kelcey Blair, PharmD, Vice President, Clinical Solutions at Express Scripts	Kelcey is a full-time employee of Express Scripts.
Anita Ju, Innovation Manager, Blue Shield of California	Anita is a full-time employee of Blue Shield of California.
Miriam Komaromy, MD, FACP, DFASAM, Medical Director, Grayken Center for Addiction, Boston Medical Center, Boston University	No financial conflicts of interest to disclose.
Hans Morefield, Chief Executive Officer, CHESS Health	Hans is a full-time employee of CHESS Health.
Jake Nichols, PharmD, MBA, President and Chief Executive Officer, Professional Recovery Associates	Jake Nichols was previously employed by Pear Therapeutics.
Mike Pace, MBA, Vice President and Global Head of Market Access, Value, and Evidence, Pear Therapeutics	Mike is a full-time employee of Pear Therapeutics.
Kevin Roy, MBA, Chief Public Policy Officer, Shatterproof	No financial conflicts of interest to disclose.
Scott Steiger, MD, FACP, FASAM, Associate Clinical Professor of Medicine and Psychiatry, University of California San Francisco	No financial conflicts of interest to disclose.