



## Mobile Device-Based Health Management Applications

**Policy #** 00756

**Original Effective Date:** 12/13/2021

**Current Effective Date:** 08/14/2023

*Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.*

*Note: Drug Testing in Pain Management and Substance Use Disorder Treatments addressed separately in medical policy 00387.*

### When Services May Be Eligible for Coverage

*Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:*

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider mobile-based health management applications to be **eligible for coverage**.\*\*

#### Patient Selection Criteria

Coverage eligibility will be considered when **all** of the following criteria are met (see Policy Guidelines):

- Criteria to evaluate the mobile software application (MSA):
    - The MSA has been approved or cleared by the Food and Drug Administration (FDA); **and**
    - There is credible scientific evidence which permits reasonable conclusions regarding the impact of the MSA on health outcomes; **and**
    - The MSA has been proven materially to improve the net health outcome or be as beneficial as any established alternative;
- AND**
- Criteria to evaluate the appropriateness of the MSA for the individual:
    - The MSA has been prescribed by a healthcare practitioner; **and**
    - There is documentation supporting that the MSA was ordered for a covered purpose such as preventing, evaluating, diagnosing or treating an illness, injury, disease or its

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- symptoms, and in accordance with generally accepted standards of medical practice;<sup>1</sup>  
**and**
- The requested MSA is not primarily for the convenience of the individual, prescribing clinician, caregiver, or other healthcare provider.

<sup>1</sup>Generally accepted standards of medical practice means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, physician specialty society recommendations and the views of physicians practicing in relevant clinical areas, and any other relevant factors.

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers mobile-based health management applications when the coverage eligibility criteria have not been met to be **investigational**.\*

Policy Guidelines

Table 1. Examples of Practitioner-prescribed, FDA cleared or approved, MSAs (not an all-inclusive list)

| Device Name                                 | Software Developer    | May Be Considered Medically Necessary |
|---|-----------------------|---------------------------------------|
| See Rationale section for more information  |                       |                                       |
| BlueStar <sup>®†</sup> Rx                   | WellDoc <sup>®†</sup> | No                                    |
| Canvas Dx <sup>™†</sup>                     | Cognoa, Inc           | No                                    |
| d-Nav Insulin Guidance System <sup>®†</sup> | Hygieia               | No                                    |
| Drowzle <sup>™†</sup>                       | Resonea               | No                                    |



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|   |                               |    |
|---|-------------------------------|----|
| EndeavorRx <sup>TM†</sup>                     | Akili Interactive             | No |
| Freespira <sup>®†</sup>                       | PaloAlto Health Sciences, Inc | No |
| Halo <sup>TM†</sup> AF Detection System       | LIVMOR, Inc                   | No |
| Home Vision Monitor <sup>®†</sup> (HVM),      | Vital Art and Science, LLC    | No |
| Insulia <sup>®†</sup>                         | Voluntis, Inc                 | No |
| iSageRx                                       | <u>Amalgam Rx, Inc.</u>       | No |
| Mobile Insulin Dosing System                  | Glooko, Inc.                  | No |
| My Dose Coach                                 | Sanofi, Inc                   | No |
| NightWare <sup>TM†</sup>                      | Apple Watch <sup>®†</sup>     | No |
| Oleena <sup>®†</sup>                          | Voluntis, Inc                 | No |
| Parallel <sup>TM†</sup>                       | Mahana Therapeutics, Inc      | No |
| Regulora <sup>®†</sup>                        | metaMe Health Inc             | No |
| reSET <sup>®†</sup> and reSET-O <sup>®†</sup> | Pear Therapeutics, Inc        | No |
| SleepCheckRx                                  | ResApp Health, Inc            | No |
| Somryst <sup>®†</sup>                         | Pear Therapeutics, Inc        | No |

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### **Background/Overview**

This document addresses the use of practitioner-prescribed software applications for health management purposes when used on a mobile device (e.g., mobile phone, laptop, smartwatch, or tablet) with the intent to evaluate, diagnose or treat an illness, injury, disease or its symptoms. This document does not address mobile-based software applications (MSAs) that are used in the function or control of another FDA-cleared or approved stand-alone hardware medical device. This document also does not address MSAs accessible to the general public for download (including direct-to-consumer [DTC] or “over the counter” applications), applications that promote general wellness, or applications operated by a healthcare practitioner in a clinical setting for remote health monitoring.

**Note:** Some benefit plans may exclude coverage of consumer wearable or personal mobile devices (such as a smart phone, smart watch, or other personal tracking devices), including any software or applications. DTC applications are generally excluded from benefit plan coverage.

### **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Current estimates report over 85% of adults living in the United States (US) own a smartphone (Pew Research Center, 2021). “Health-related mobile applications available to consumers on top app stores worldwide now surpass 350,000, with more than 90,000 digital health apps added in 2020 — an average of more than 250 apps per day.” (Institute for Human Data Science [IQVIA], 2021). Examples of medical mobile device software applications (MSAs) currently available include applications that purport to perform cognitive behavior therapy, augment weight loss goals, identify a suspicious nevi (mole), or even distinguish between normal cardiac sinus rhythm and potentially dangerous arrhythmias. Transforming a personal mobile device, such as a smartphone, into a medical device has the potential for far-reaching implications on the diagnosis and management of many diseases and disorders in addition to promoting general health and wellness. Despite the enormous effort to develop and disseminate digital health innovations, evidence of efficacy, or even a widely

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accepted framework for evaluation of efficacy, currently remains lacking. According to IQVIA (2021),

...independent organizations continue to highlight the need for larger and more robust randomized controlled trials (RCTs) that follow individuals for longer times and report between-group differences in benefit, assessments of usability, and user-retention to determine the durability of their clinical effect, and evidence of cost-effectiveness that can be analyzed versus standard of care.

The US Food and Drug Administration (FDA) Center for Devices and Radiologic Health (CDRH), is among one of several groups leading development of a framework for evaluating the burgeoning number of MSAs anticipated to reach market as part of the expanding digital health innovation arena. The framework is detailed in their guideline entitled, “Policy for device software functions and mobile medical applications” (FDA, 2019).

A number of additional MSA’s are in the developmental pipeline for FDA approval, including Click Therapeutics, Inc., a company developing and seeking FDA approval for several digital software solutions to aid in the management of diverse conditions including but not limited to insomnia, acute coronary syndrome, migraine and overactive bladder.

The FDA’s regulatory oversight of software functions includes the following subsets:

1. **Software functions that are an extension of one or more medical devices by connecting to such device(s) for purposes of controlling the device(s) or analyzing medical device data.**

Examples of software functions that control medical devices include: software that provides the ability to control inflation and deflation of a blood pressure cuff through a mobile platform and mobile apps that control the delivery of insulin on an insulin pump by transmitting control signals to the pumps from the mobile platform.

Device software functions of these types are considered accessories to the connected device and not addressed by this document.

2. **Software functions (typically, mobile apps) that transform the mobile platform into a regulated medical device by using attachments, display screens, or sensors or by including functionalities similar to those of currently regulated medical devices.**

Examples of these types of software functions include: a software function that uses a

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mobile platform for medical device functions, such as attachment of a blood glucose strip reader to a mobile platform to function as a glucose meter; or attachment of electrocardiograph (ECG) electrodes to a mobile platform to measure, store, and display ECG signals; a software function that uses the built-in accelerometer on a mobile platform to collect motion information for monitoring sleep apnea; a software function that uses sensors (internal or external) on a mobile platform for creating electronic stethoscope function is considered to transform the mobile platform into an electronic stethoscope.

Mobile software functions of this type are addressed by this document when the ancillary hardware device is intended to function solely in conjunction with the mobile device application.

3. **Software functions that become a regulated medical device by performing patient-specific analysis and providing patient-specific diagnosis, or treatment recommendations. These types of functions are similar to or perform the same function as those types of software devices that have been previously cleared or approved.**

Examples of software functions that perform sophisticated analysis or interpret data (electronically collected or manually entered) from another medical device include: software functions that use patient-specific parameters and calculate dosage or create a dosage plan for radiation therapy; Computer Aided Detection software (CAD) image processing software; and radiation therapy treatment planning software.

These types of software are addressed by this document when they operate on a mobile device, have received FDA clearance or approval, are clinician-prescribed, and when the intent of the MSA is to evaluate, diagnose or treat an illness, injury, disease or its symptoms.

In January 2019, the FDA released its publication, “Developing a Software Precertification Program.” In it, an innovative plan is described, to reimagine the way the government administers oversight and approval in the digital device arena that is more efficient than the traditional device approval pathway. The FDA is basing the Pre-Cert pilot program's criteria on five principles of excellence: safety, quality, clinical responsibility, cybersecurity responsibility, and proactive culture. The paradigm shift in the FDA approval process for digital innovation lies in the focus on the manufacturer rather than on the device itself, when a product meets the definition of *software as a medical device*. The current Pre-Cert pilot program, has enrolled nine companies, out of over 100

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applicants, to test the novel approval pathway (Apple, Fitbit, Johnson & Johnson, Pear Therapeutics, Phosphorus, Roche, Samsung, Tidepool and Verily). The FDA is currently considering two levels of precertification based on how a company meets the excellence principles and whether it has demonstrated a track record in delivering safe and effective software products. Currently, the FDA is continuing to test the Pre-Cert program to determine whether the results align with the results of the traditional approval pathway and satisfy the FDA's established regulatory requirements for safety and effectiveness.

In addition to the FDA's innovative program underway to evaluate the safety and effectiveness of digital health applications, a number of other organizations, both global and national, have also initiated tandem efforts to develop a framework for evaluation of products in this burgeoning field (Agency for Healthcare Research and Quality, 2022; American Medical Association, 2018; American Psychiatric Association, 2019; World Health Organization, 2019). At this time, no single framework has been adopted for evaluation of medical mobile applications by medical or regulatory bodies.

Some MSAs, particularly those that operate with an ancillary hardware medical device, may be intended to replace a service rendered in the healthcare setting (for example Freespira). Use of MSAs should not be substantiated primarily for the convenience of the individual, prescribing clinician, caregiver, or other healthcare provider; for example, in cases where appropriate alternatives for the indicated health service(s) are geographically accessible, and/or when the individual has concurrent ambulatory or hospital care needs. However, use of MSAs may be appropriate when they are in accordance with generally accepted standards of medical practice, the MSA has been proven materially to be as beneficial as the established alternative, and credible scientific evidence permits reasonable conclusions regarding the impact of the MSA on health outcomes.

### **Practitioner-prescribed, FDA cleared or approved, MSAs (not an all-inclusive list)**

#### ***BlueStar<sup>®</sup>Rx, WellDoc<sup>®</sup>***

BlueStar is a digital health platform for type 2 diabetes that provides tailored guidance driven by artificial intelligence and is focused on six critical dimensions of chronic disease care, which apply to diabetes as well as many other conditions like blood pressure, pre-diabetes, and heart failure.

BlueStar was evaluated in a randomized controlled trial (RCT) which enrolled 163 individuals with type 2 diabetes whose HbA1c levels were poorly controlled or abnormal at the time of enrollment.

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Enrolled primary care practices (PCP) were randomized to one of four study groups: control-usual care (n=56), coach-only (n=23), coach PCP portal (n=22), and coach PCP portal with decision support (n=62). Participants who were randomized to use an MSA to help manage their diabetes in addition to usual care, improved HbA1c by an average 1.9%, compared with a 0.7% improvement in those randomized to usual care alone, a difference of 1.2% ( $p < 0.001$ ) over the 12-month study period (Quinn, 2011). The study's limitations include a small sample size in the study arms and due to randomization at the clinical level, potential confounding association cannot be ruled out.

Agarwal and colleagues (2020) conducted a multicenter, pragmatic RCT to determine if BlueStar application usage leads to improved HbA1c levels among diverse participants across diverse clinical scenarios. In total, 223 study participants were randomized to either the 'immediate treatment group' (ITG; n=110 [received the BlueStar intervention for 6 months]) or the wait-list control group (WLC; n=113 [received usual care for the first 3 months and then received the intervention for 3 months]). The primary outcome was HbA1c levels at 3-month follow-up. Secondary outcomes assessed disease self-management, experience of care, and self-reported health utilization. At 3 months, the mean difference in HbA1c levels between the ITG and WLC groups was not statistically significant (mean difference = -0.42; 95% confidence interval [CI], -1.05 to 0.21;  $p = 0.19$ ). Similarly, there was no effect on secondary outcomes and BlueStar usage was found to vary significantly across clinical sites (median of 9 versus 36 log-ins over 14 weeks at the lowest, versus highest usage sites, respectively). Evidence of BlueStar's clinical efficacy remains to be established in addition to defining factors that may affect individual and site-specific variations that impact the application's usage as recommended.

### ***Canvas Dx<sup>TM</sup>, Cognoa, Inc***

Canvas Dx is used by healthcare providers as an aid in the diagnosis of Autism Spectrum Disorder (ASD) for individuals ages 18 months through 72 months who are at risk for developmental delay. The device is not intended for use as a stand-alone diagnostic device but as an adjunct to the diagnostic process. In 2022, Megerian and colleagues conducted a double-blinded, cohort study which tested the accuracy of CanvasDx. This study compared the diagnostic agreement of the device to two or more independent specialists in a cohort of 425 children (aged 18-72 months) who had developmental delay concerns (425 study completers, 36% female, 29% ASD prevalence). The PPV was determined to be 80.8% (95% CI, 70.3%-88.8%) and NPV was 98.3% (95% CI, 90.6%-100%). Of those who received a determinate output (ASD positive or negative [31.8%]) sensitivity was 98.4% (95% CI, 91.6%-100%) and specificity was 78.9% (95% CI, 67.6%-87.7%). Of 711 children

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originally consented to participate in the study, 286 (40%) dropped out. There is insufficient data to help us understand whether use of the Canvas Dx application increases time to diagnosis in a real-world setting, in a manner that is likely to improve clinically relevant ASD outcomes.

### ***d-Nav Insulin Guidance System<sup>®‡</sup>, Hygieia***

The d-Nav Insulin Guidance System was evaluated in a multicenter RCT of 181 individuals with uncontrolled type 2 diabetes. Participants were randomized to either d-Nav and healthcare professional support (intervention group; n=93) or healthcare professional support alone (control group; n=88). The primary outcome of interest was to compare average change in HbA1c from baseline to 6 months. Safety was assessed by the frequency of hypoglycemic events. The mean decrease in HbA1c from baseline to 6 months was 1.0% in the intervention group, and 0.3% in the control group (p<0.0001). The difference in frequency of hypoglycemic events between the groups was not statistically significant (Bergenstal, 2019). Current data is limited to a single study of small sample size and long-term data of net health outcomes is lacking.

### ***Drowzle<sup>®‡</sup> Pro, Resonea***

Drowzle Pro is a mobile software system that records and analyzes respiratory patterns during sleep to facilitate the in-home screening of obstructive sleep apnea (OSA).

Drowzle was evaluated in a longitudinal cohort study of 59 individuals who were administered a clinically indicated polysomnography (PSG) in a sleep lab where investigators compared the DROWZLE algorithm to PSG results. Investigators found the algorithm provided a sensitivity of 93.7%, specificity of 63.0%, negative predictive value of 89.5%, and positive predictive value of 75.0%, in the detection of moderate and severe OSA among individuals compared to PSG scores (Narayan, 2019). Studies evaluating real-world application are lacking, as is data describing how screening results impact diagnosis and management of OSA as compared to generally accepted standards of medical practice.

### ***EndeavorRx<sup>TM‡</sup>, Akili Interactive***

EndeavorRx is a game-based therapeutic intervention designed to improve cognitive function in children aged 8-12 who have been diagnosed with ADHD through a video game-like interface via at-home play for 25 min per day, 5 days per week for 4 weeks.

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EndeavorRx was evaluated in an RCT which enrolled 348 children (8-12 years old) diagnosed with ADHD to receive treatment with either EndeavorRx (n=108) or a digital control intervention (n=168). Enrolled children were ineligible if they were already receiving medical therapy for ADHD. The mean change from baseline on the Test of Variables of Attention (TOVA) Attention Performance Index (API) was 0.93 in the EndeavorRx group and 0.03 in the control group (Adjusted  $p < 0.050$ ); there were no differences between groups on secondary measures. There were no serious adverse events or discontinuations. Treatment-related adverse events were mild and included frustration (3%) and headache (2%). Compliance averaged 83% of expected sessions played (Kollins, 2020). Study limitations included the enrollment of only children with an objective baseline deficit in attentional function and those not currently receiving medical treatment for ADHD, thus representing a small subset of the ADHD population. In addition, the study-period was limited to 28 days of follow-up. It is unclear whether the treatment resulted in the improvement of clinically meaningful outcomes or benefits commensurate to generally accepted standards of medical practice.

In 2021, Kollins and colleagues conducted a multi-center, open-label study of EndeavorRx as an adjunct to pharmacotherapy in a cohort of 8-14-year-old study participants with ADHD on stimulant medication (n=130) and not on any medication for ADHD (n=76). The enrolled participants used EndeavorRx for 4 weeks, followed by a 4-week pause and another 4-week treatment. The primary outcome of interest was change in ADHD-related impairment after 4 weeks as measured by the Impairment Rating Scale (IRS). IRS significantly improved in both cohorts ( $p < 0.001$ ) after 4 weeks. The study-period was similarly limited to 28 days of follow-up and in both studies, it is unclear whether treatment with EndeavorRx improves clinically meaningful outcomes or provides benefits commensurate to generally accepted standards of medical practice.

### ***Freespira<sup>®</sup>, PaloAlto Health Sciences, Inc***

Freespira is intended for the treatment of post-traumatic stress disorder (PTSD), panic disorder, panic attacks and other panic symptoms. Treatment entails two 17-minute in home sessions daily for 4 weeks under the supervision of a licensed healthcare provider.

Freespira was evaluated in a multicenter, single arm trial of 69 adults with panic disorder who received 4 weeks of Capnometry Guided Respiratory Intervention (CGRI) using Freespira, which provides feedback of end-tidal CO<sub>2</sub> (PETCO<sub>2</sub>) and respiration rate (RR) via a custom sensor device. This intervention is delivered via home use following initial training by a clinician and provides remote monitoring of client adherence and progress by the clinician. Outcomes were assessed

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immediately post-treatment and at 2- and 12-month follow-up. CGRI was associated with a response rate of 83% and a remission rate of 54%, in addition to large decreases in panic severity. Similar decreases were found in functional impairment and in global illness severity. Gains were largely sustained at follow-up. PETCO<sub>2</sub> moved from the slightly hypocapnic range to the normocapnic range (Tolin, 2017).

In 2020, Kaplan and colleagues evaluated the impact of Freespira over a 12-month period in a cohort of 51 individuals enrolled at a single center. In total, 45 (87%) completed the 4-week, twice-daily Freespira home device treatments and at least 15 of the 56 protocol-specified therapy sessions. By study-end (12 months) just 22 participants were available for complete analysis. Overall, the cohort's Panic Disorder Severity Scale (PDSS) score fell from a baseline median of 14.4 (standard deviation [sd]=3.8) to 4.4 (sd=4.5) at 12 months, and 82% of the cohort reported a PDSS decrease of  $\geq 40\%$  (clinically significant) whereas 86% were free from panic attacks.

Currently available evidence evaluation of Freespira lacks comparison to generally accepted standards of medical practice, is limited by small sample sizes despite the prevalence of panic disorder in the general population, and is subject to bias from loss to follow-up.

### ***Halo<sup>TM</sup> AF Detection System, LIVMOR, Inc***

Halo is a wearable smartwatch device for intermittently monitoring pulse rhythms to detect atrial fibrillation (AF).

While there is no published peer-reviewed evidence at this time evaluating the Halo device, a retrospective propensity-matched cohort study was published in 2021 (Wang) which included 125 individuals with AF using wearables to monitor heart rate and rhythm and 500 with AF who did not use wearables. Study participants were followed for 90 days to compare pulse rate and healthcare use between individuals who wore wearables and those who did not. The study found that prior to propensity matching, those who use wearables were, on average, significantly younger ( $p<0.001$ ) and healthier (composite score of congestive heart failure, hypertension, diabetes, prior ischemic event, vascular disease, age, and gender;  $p<0.001$ ). After matching, study participants using wearables were found to have similar pulse rates, to those who did not, but utilized significantly more healthcare. In particular, there was a significant difference in receipt of a cardiac ablation, with 17.6% ( $n=22$ ) in the wearables group compared to 7.4% ( $n=37$ ;  $p=0.001$ ) having received an ablation. The study authors conclude, "Given the increasing use of wearables by individuals with

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AF, prospective, randomized, long-term evaluation of the associations of wearable technology with health outcomes and health care use is needed.”

### ***Home Vision Monitor<sup>®</sup> (HVM), Vital Art and Science, LLC***

Home Vision Monitor is intended for the detection and characterization of central 3 degrees metamorphopsia (visual distortion) in individuals with maculopathy, including age-related macular degeneration and diabetic retinopathy, and as an aid in monitoring progression of disease factors causing metamorphopsia.

Korot and colleagues (2021) studied the Home Vision Monitor in a cohort study of 417 individuals to evaluate uptake and engagement of the application but no published studies have evaluated clinically meaningful outcomes related to use of the software.

### ***Insulia<sup>®</sup>, Voluntis, Inc.***

Insulia is a Software program that recommends basal insulin doses for adults with Type 2 diabetes treated with long-acting insulin analogs as an aid in the management of diabetes based on the treatment plan created by a healthcare provider.

Insulia was evaluated in a 13-month RCT which enrolled a total of 191 participants with inadequately controlled type 2 diabetes who were randomized into three groups: group 1 (standard care, n=63), group 2 (interactive voice response system, n=64) and group 3 (Diabeo-BI app software, n=64). At 4 months follow-up, HbA1c reduction was significantly higher in the telemonitoring groups ( $p<0.002$ ). Fasting blood glucose was reached by twice as many subjects in the telemonitoring groups as in the control group, and insulin doses were also titrated to higher levels. No severe hypoglycaemia was observed in the telemonitoring groups and mild hypoglycaemia frequency was similar in all groups (Franc, 2019). Current data is limited to a short period of evaluation, and the comparison arms sample sizes were limited.

### ***iSageRx, AmalgamRx, Inc.***

iSageRx is indicated for the management of type 2 diabetes by calculating appropriate long-acting basal insulin doses for titrating insulin levels based on a clinician-prescribed, individualized titration plan. Currently, there is no published peer-reviewed evidence evaluating iSageRx which permits reasonable conclusions regarding impact on health outcomes.

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### ***Mobile Insulin Dosing System (MDIS), Glooko, Inc.***

MDIS is indicated for the management of type 2 diabetes by calculating appropriate long-acting basal insulin doses for titrating insulin levels based on a clinician-prescribed, individualized titration plan. Currently, there is no published peer-reviewed evidence evaluating MDIS which permits reasonable conclusions regarding impact on health outcomes.

### ***My Dose Coach, Sanofi, Inc.***

My Dose Coach is a smartphone application designed to help users diagnosed with type 2 diabetes titrate their basal insulin according to a clinician-prescribed individualized titration plan. Unnikrishnan (2022) and colleagues conducted a retrospective analysis included 2517 active users; 85% of users were from India, none resided in the US. Two weeks of data was analyzed. Just under 50% of users had high MDC usage and 44% (irrespective of usage frequency) achieved their individual fasting blood glucose target. High use was associated with significantly better fasting blood glucose target achievement and less time to achieve that target compared to the moderate- and low-usage groups ( $p < 0.01$  for all). There was no significant difference in hypoglycemia incidence among usage groups. This relatively brief (2 weeks) retrospective trial did not include participants from the US, had limited usage amongst participants and lacked a comparison group. Further study is warranted to permits reasonable conclusions regarding impact on health outcomes.

### ***NightWare<sup>TM</sup>, Apple Watch<sup>®</sup>***

NightWare is a mobile application that exclusively uses Apple's smartwatch motion and heart rate data to detect the occurrence of nightmares and arouses the wearer by vibrating with the intention of interrupting the nightmare without waking the sleeper. Currently, the software is only available for use in the US Military and Veteran population. Davenport and colleagues (2022) conducted a 30-day, RCT to determine the efficacy of NightWare in 65 Veterans ( $n=30$  in active arm;  $n=35$  in control arm) with impaired sleep secondary to trauma-related nightmares. Primary outcomes measures included self-reported sleep quality, PTSD/depression symptoms, and quality of life. Individuals in both the active and control arms demonstrated statistically significant improvement on all measures relative to their own baseline measures. However, none of the comparisons between arms reached a statistically significant difference. A post hoc analysis that excluded participants with low frequency usage ( $< 50\%$  of nights) demonstrated a statistically significant ( $p=0.016$ ) improvement in perceived sleep quality (based on the Pittsburgh Sleep Quality Index) amongst the remaining 21 participants in the control arm. This trial was of short duration, users exhibited low app usage and results did not demonstrate a clinically meaningful difference in the intent-to-treat population.

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### ***Oleena<sup>®</sup>, Voluntas, Inc.***

Oleena received FDA premarketing approval in 2019 as a prescription mobile app designed to help individuals diagnosed with cancer better manage their symptoms as well as enable remote monitoring by care teams. Currently, there is no published peer-reviewed evidence evaluating Canvas Dx which permits reasonable conclusions regarding impact on health outcomes.

### ***Parallel<sup>™</sup>, Mahana Therapeutics, Inc.***

Parallel (formerly known as Regul8) is a Digital program that uses cognitive behavioral therapy (CBT) to reduce the severity of symptoms for irritable bowel syndrome (IBS). It is intended to be used together with other IBS treatments to treat adults, 22 years or older, for up to 3 months.

The premise behind Parallel (web-based CBT) was evaluated in the Assessing Cognitive behavioural Therapy for IBS (ACTIB) trial, a three-arm, RCT in which 558 participants were enrolled into either a telephone-delivered CBT (TCBT; n=186) group, web-based CBT (WCBT; n=185) group with minimal therapist support, or treatment as usual (TAU, n=187) (Everitt 2019a). Both intervention groups continued to also receive treatment as usual. The primary outcomes of interest were IBS Symptom Severity Score (IBS-SSS) and Work and Social Adjustment Scale (WSAS) at 12 months. At study end, 27% of the TCBT arm, 73% of the WCBT arm, and 30% of the TAU group were lost to follow-up. Of the remaining study participants, compared with TAU, IBS-SSS and WSAS scores were significantly lower in the TCBT group (both scores  $p < 0.001$ ) and the WCBT group ( $p = 0.002$  and  $p = 0.001$ , respectively) at 12 months. There were no serious adverse reactions to any interventions. The study was limited by a substantial loss to follow-up and the dissimilarities between the interventions in the study and the Parallel application. Also, comparison to in-person CBT is lacking.

Everitt and colleagues (2019b) conducted a 24-month follow-up to the ACTIB trial, at which time, 58% (n=323 of the original 558 participants remained). At 24 months the IBS-SSS score was significantly lower in the TCBT group ( $p = 0.002$ ) relative to TAU but the differences in the WCBT group were not sustained ( $p = 0.33$ ). Similarly, the mean WSAS score was lower in the TCBT group ( $p < 0.001$ ) but differences in the WCBT group fell to marginal significance ( $p = 0.036$ ) relative to the TAU group. Given the continued substantial loss to follow-up and loss in significance in the WCBT group (more comparable to the Parallel application software design than TCBT), the efficacy of the application as an intervention for refractory IBS, remains to be established.

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### ***Regulora<sup>®</sup>, metaMe Health Inc.***

Regulora provides gut-directed hypnotherapy for adults 22 years of age and older who have been diagnosed with IBS. Regulora is indicated as a 3-month treatment for individuals with abdominal pain due to IBS and is intended to be used together with other IBS treatments. There is no published peer-reviewed evidence evaluating the efficacy of Regulora.

### ***reSET<sup>®</sup> and reSET-O<sup>®</sup>, Pear Therapeutics, Inc***

reSET<sup>®</sup> and reSET-O are mobile device software applications intended to increase retention of individuals with opioid use disorder (OUD) and substance use disorder in outpatient treatment by providing cognitive behavioral therapy, as an adjunct to outpatient treatment, for individuals 18 years or older who are currently under the supervision of a clinician.

ReSET-O was evaluated in a randomized, unblinded, parallel trial conducted in 170 opioid-dependent adults who received supervised buprenorphine treatment paired with a behavior therapy program, with or without the addition of a desktop-based version of reSET-O, which was accessed at the clinic 3 times a week for 30 minutes per visit. At study-end (12 weeks), participants who used the desktop computer version of reSET-O had an overall retention rate of 80 percent compared with 64 percent overall retention rate for those who did not. Use of reSET-O was not shown to decrease illicit drug use or improve abstinence compared to the control group (Christensen, 2014). A secondary analysis of the pivotal study data reported outcomes of treatment retention and abstinence relative to 'treatment as usual' but was hampered by the same study limitations (Maricich, 2020a).

In 2020, Velez and colleagues reviewed retrospective pharmacy and medical claims data from commercial, Medicare and Medicaid databases (2018-2019). Ultimately, 334 study participants were included who activated reSET-O, and were continuously enrolled in their medical plan for at least 4 weeks of the 6-month pre-activation and post-activation periods. Despite the abundance of clinically significant pre- and post-activation measures reported (including but not limited to, inpatient encounters [45 less;  $p=0.03$ ], emergency department visits [27 less;  $p=0.25$ ] psychiatry encounters [349 less;  $p<0.04$ ], case management encounters [176 additional;  $p=0.59$ ], behavioral health services [111 additional;  $p=0.12$ ], alcohol and substance abuse services [96 less;  $p=0.35$ ], and mental health services [61 additional;  $p=0.10$ ]), some were only marginally statistically significant while most were not significant (i.e.,  $p\text{-value} > 0.05$ ), with the exception of 638 less drug test events recorded post reSET-O activation ( $p<0.001$ ) an outcome that may not be desirable in this clinical scenario. Claims data also revealed of the 240 participants who had pharmacy claims data, pre-/post-

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activation medication possession ratios increased from 0.73 to 0.82, respectively ( $p=0.004$ ); however, possession of buprenorphine is unlikely to be a valid surrogate measure for medication adherence. In this real-world clinical scenario, generalizability is lacking ( $> 80\%$  Medicaid enrollees), mortality data (a crucial outcome in this setting) is not reported and reSET-O's ability to impact health behaviors or clinically relevant outcomes was not demonstrated.

In another pragmatic, retrospective evaluation, Maricich and colleagues (2020b) enrolled 3144 individuals upon their downloading the reSET-O application to their personal device. Engagement and therapeutic use data were collected and analyzed on a population, versus individual, level. Substance use was evaluated using a composite measure of self-reported data collected by reSET-O and urine drug screens which were nonuniformly administered by different clinic sites. When excluding participants with missing data from analysis, the abstinent rate (defined as abstinent in the last 4 weeks of treatment) was observed to be 91%, when missing data was considered 'positive' the abstinence rate was 66%. Just 29% of the study population used reSET-O appropriately and consistently for the first 4 weeks (completed 4 or more modules per week), thus adherence to reSET-O's proper use was low in this very large, real-world cohort. The study outcomes relied on self-report, lacking clinically meaningful measures beyond urine drug screens which were not routinely measured across study sites.

In 2020, the Institute for Clinical and Economic Review (ICER) published an evidence report which included published data, to date, evaluating the reSET-O. ICER concluded, "We found no randomized trials, cohort studies or case series that evaluated the DHTs [digital health technologies] reviewed in this report until after the draft report was released. Recently, two uncontrolled studies suggested potential benefits with reSET-O, but there was a high risk of bias for both studies."

Current data is limited to short-term follow-up, and impact on net health outcomes has not been demonstrated. Few of the published studies assess the use of the reSET-O when used outside of a clinic (for example, when downloaded directly to a personal device such as a mobile phone or tablet).

### ***SleepCheckRx***

SleepCheckRx is a mobile software system that screens adults for the risk of moderate to severe OSA by analyzing breathing and snore sounds recorded on an Apple iPhone. Currently there is no peer-reviewed published data on SleepCheckRx which permits reasonable conclusions regarding impact on health outcomes.

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### ***Somryst<sup>®</sup>, Pear Therapeutics, Inc***

Somryst is a digital therapeutic intended to provide 9 weeks of a neurobehavioral intervention (CBT-I) to individuals 22 years of age and older with chronic insomnia.

Somryst's efficacy was evaluated in two RCTs. In the first, Christensen and colleagues (2016) randomized 1149 participants with insomnia and depression symptoms to receive Somryst's predecessor (SHUTi; n=574) or HealthWatch (an interactive, attention-matched, internet-based placebo control program; n=575). The primary outcome of interest was depression symptoms at 6 months. At 6 weeks follow-up, 49% of participants were lost to follow-up and by 6 months this figure grew to 64%. In the remaining study participants, at 6 months, SHUTi lowered depression symptoms compared to the HealthWatch ( $p<0.0001$ ) and no adverse events were reported. Study limitations include a substantial loss to follow-up and a comparator group that is not commensurate to generally accepted standards of medical practice for treatment of insomnia.

In the second RCT, Ritterband and colleagues (2017) enrolled 303 self-diagnosed adults with chronic insomnia and randomized participants to SHUTi (n=151) or an online educational program with fixed (nontailored) information about insomnia (n=152). Results from the 3 primary sleep outcomes (Insomnia Severity Index, Sleep Onset Latency, and Wake After Sleep Onset) at 9 weeks, 6 months and 1 year significantly favored the SHUTi cohort ( $p<0.001$  for all 3 outcomes). All the data collected in this study was self-reported and as such may be subject to bias. Similar to the other published RCT, the comparator group did not receive standard of care medical treatment for insomnia, as such, Somryst's efficacy relative to generally accepted standards of medical practice remains to be established.

Pear Therapeutics has initiated the SLEEP-I study (NCT04909229; estimated enrollment=100) and the DREAM study (NCT04325464; estimated enrollment=1000) to collect real-world evidence for Somryst. The estimated primary completion dates are August 2022 and January 2023, respectively.

## **Supplemental Information/Definitions**

Mobile application (mobile app): Software application that can be executed (run) on a mobile platform (i.e., a handheld commercial off the-shelf computing platform, with or without wireless connectivity), or a web-based software application that is tailored to a mobile platform but is executed on a server.

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Mobile platform: Commercial off-the-shelf (COTS) computing platforms, with or without wireless connectivity, that are handheld in nature (e.g., mobile computers such as smart phones, tablet computers, or other portable computers).

Off-the-self: As purchased or as commonly available, without modification or customization.

Over-the-counter: Non-prescription therapeutic intervention.

Software: A set of instructions, data or programs used to operate a computing device and execute specific tasks; a generic term used to refer to applications, scripts and programs.

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## Mobile Device-Based Health Management Applications

Policy # 00756

Original Effective Date: 12/13/2021

Current Effective Date: 08/14/2023

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## Policy History

Original Effective Date: 12/13/2021

Current Effective Date: 08/14/2023

|            |   |
|------------|---|
| 11/04/2021 | Medical Policy Committee review   |
| 11/10/2021 | Medical Policy Implementation Committee approval. New policy.   |
| 03/21/2022 | Coding update   |
| 11/03/2022 | Medical Policy Committee review   |
| 11/09/2022 | Medical Policy Implementation Committee approval. Title changed to Digital Health Therapies for Substance Use Disorders. No change to coverage.   |
| 07/06/2023 | Medical Policy Committee review   |
| 07/12/2023 | Medical Policy Implementation Committee approval. Title changed from Digital Health Therapies for Substance Use Disorders to Mobile Device-Based Health Management Applications. Coverage changes made to match mobile device applications. |

Next Scheduled Review Date: 07/2024

## Coding

*The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)®, copyright 2022*

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*by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.*

*The responsibility for the content of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines is with Blue Cross and Blue Shield of Louisiana and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.*

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

| Code Type        | Code  |
|------------------|---|
| CPT              | Add code effective 08/01/2023: 99199          |
| HCPSCS           | A9291<br>Add code effective 08/01/2023: T1505 |
| ICD-10 Diagnosis | All related Diagnoses                         |

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and

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whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or

- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
1. Consultation with technology evaluation center(s);
  2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  3. Reference to federal regulations.

**\*\*Medically Necessary (or “Medical Necessity”)** - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, “nationally accepted standards of medical practice” means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient’s health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

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**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

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