i) **[FINAL DRAFT – LOGO TO BE INSERTED UPON FINAL PRODUCTION DATE]**

Clinical UM Guideline

Subject:	**Mobile Device-Based Health Management Applications**		
Guideline #:	**CG-ANC-08**	**Publish Date:**	**04/15/2020**
Status:	**New**	**Last Review Date:**	**02/20/2020**

Description

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.

Clinical Indications

Medically Necessary:

Mobile-based health management applications are considered medically necessary when *all* of the following criteria in I and II have been met:

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I. Criteria to evaluate the mobile software application (MSA):

A. **The MSA has been approved or cleared by the Food and Drug Administration (FDA); and**
B. **There is credible scientific evidence which permits reasonable conclusions regarding the impact of the MSA on health outcomes; and**
C. **The MSA has been proven materially to improve the net health outcome or be as beneficial as any established alternative;**

AND

II. Criteria to evaluate the appropriateness of the MSA for the individual:

A. **The MSA has been prescribed by a healthcare practitioner; and**
B. **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 symptoms, and in accordance with generally accepted standards of medical practice;* and**
C. **The requested MSA is not primarily for the convenience of the individual, prescribing clinician, caregiver, or other health care provider.**

***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.**

Not Medically Necessary:

Mobile-based health management applications are considered not medically necessary when the criteria above have not been met.

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Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT

99199	**Unlisted special service, procedure or report [when specified as a mobile-based health management software application]**

HCPCS

E1399	**Durable medical equipment, miscellaneous [when specified as a mobile-based health management software application]**
T1505	**Electronic medication compliance management device, includes all components and accessories, not otherwise classified [when specified as a mobile-based health management software application]**

ICD-10 Diagnosis

All diagnoses

Discussion/General Information

Current estimates report over 80% of adults living in the United States (US) own a smartphone and in 2017 alone, over 3.4 billion individuals worldwide downloaded health-related applications to their mobile devices (Pew Research Center, 2019; Research2Guidance, 2017). 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

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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 accepted framework for evaluation of efficacy, currently remains lacking.

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 Akili's personalized digital therapeutics, designed to help individuals with cognitive impairment due to a number of diseases and disorders, including attention-deficit/hyperactivity disorder (ADHD), major depressive disorder (MDD), autism spectrum disorder (ASD), and multiple sclerosis (MS).

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.

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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 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.

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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 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 (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 health care 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,

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and credible scientific evidence permits reasonable conclusions regarding the impact of the MSA on health outcomes.

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

Device Name	Software Manufacturer	Software Application Function	Summary of Supporting Evidence	May Be Considered Medically Necessary
BlueStar®Rx	WellDoc®	A digital health platform for type 2 diabetes that provides tailored guidance driven by artificial intelligence and focused on six critical dimensions of chronic disease care, which apply to diabetes as well as many other conditions like	Randomized controlled trial in 163 individuals with type 2 diabetes whose A1C levels were poorly controlled or abnormal at the time of enrollment. 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 A1C by an average 1.9%, compared with 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,	No

		blood pressure, pre-diabetes, and heart failure.	**potential confounding association cannot be ruled out.**	
d-Nav Insulin Guidance System®	**Hygieia**	**Digital support for management of uncontrolled type 2 diabetes through customized insulin dose guidance on a daily basis prior to each insulin injection.**	**Multicenter, randomized, controlled trial in 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).** **Longer-term data on net health outcomes is currently lacking. Current data is limited to a single study of small sample size.**	**No**
Drowzle™	**Resonea**	**Mobile software system that**	**In a longitudinal cohort study, 59 individuals were administered a clinically indicated polysomnography (PSG) in a**	**No**

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		records and analyzes respiratory pattern during sleep to facilitate the in-home screening of obstructive sleep apnea (OSA).	**sleep lab where investigators compared the DROWZLE algorithm to PSG results. They found the algorithm provided a 93.7% sensitivity, 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 standard of care.**	
Freespira®	**PaloAlto Health Sciences, Inc**	**Treatment for post-traumatic stress disorder (PTSD), panic disorder, panic attacks and other panic symptoms. Treatment entails two 17-minute in home sessions daily for 4**	**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_2 ($P_{ET}CO_2$) 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 immediately post-treatment and at 2- and 12-month follow-up. CGRI was associated with a response**	**No**

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		weeks under the supervision of a licensed healthcare provider.	**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. $P_{ET}CO_2$ moved from the slightly hypocapnic range to the normocapnic range (Tolin, 2017).** **Comparison to standard of care is lacking. Current data is limited to a single study of small sample size.**	
Insulia®	**Voluntis**	**Software 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**	**A 13-month randomized controlled trial enrolled 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**	**No**

		healthcare provider.	**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 small.**	
reSET-O™	**Pear Therapeutics, Inc**	**Software intended to increase retention of individuals with opioid use disorder (OUD) in outpatient treatment by providing cognitive behavioral therapy, as an adjunct to outpatient treatment that includes transmucosal buprenorphine and contingency management,**	**A randomized, unblinded, parallel trial in 170 opioid-dependent adults who received an internet-based community reinforcement approach intervention plus contingency management (CRA+) and buprenorphine, or contingency management alone (CM-alone) plus buprenorphine. The primary outcomes were longest continuous abstinence, total abstinence, and days retained in treatment. At study-end (12 weeks), an average of 9.7 days more of abstinence were achieved with the use of reset-O and a statistically significant reduced likelihood of dropping out of treatment (hazard ratio=0.47; 95% confidence interval [CI]; 0.26, 0.85) (Christensen, 2014).** **Current data is limited to short-term follow-up, and impact on net health outcomes are unknown.**	**No**

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		for individuals 18 years or older who are currently under the supervision of a clinician.		

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.

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.

References

Peer Reviewed Publications:

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Websites for Additional Information

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History

Status	Date	Action
New	02/20/2020	Medical Policy & Technology Assessment Committee (MPTAC) review. Initial document development.

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