Medical Coverage Policy | Digital Health Technologies - Therapeutic Applications

EFFECTIVE DATE: 10|01|2023
POLICY LAST UPDATED: 06|07|2023

OVERVIEW
Digital health technologies is a broad term that includes categories such as mobile health, health information technology, wearable devices, telehealth and telemedicine, and personalized medicine. These technologies span a wide range of uses, from applications in general wellness to applications as a medical device, and include technologies intended for use as a medical product, in a medical product, as companion diagnostics, or as an adjunct to other medical products (devices, drugs, and biologics).

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
The following services are not covered as the evidence is insufficient to determine the effects of the technology on health outcomes:

- Freespira for all indications including treatment of panic disorder and/or post-traumatic stress disorder
- NightWare for all indications including treatment of nightmare disorder or nightmares from post-traumatic stress disorder

Commercial Products
The following services are not medically necessary as the evidence is insufficient to determine the effects of the technology on health outcomes:

- Freespira for all indications including treatment of panic disorder and/or post-traumatic stress disorder
- NightWare for all indications including treatment of nightmare disorder or nightmares from post-traumatic stress disorder

COVERAGE
Benefits may vary between groups and contracts. Please refer to the appropriate Benefit Booklet, Evidence of Coverage, or Subscriber Agreement for applicable not medically necessary/not covered benefits/coverage.

BACKGROUND
Software has become an important part of product development and is integrated widely into digital platforms that serve both medical and non-medical purposes. The 3 broad categories of software use in medical devices are:

1. Software used in the manufacture or maintenance of a medical device (eg, software that monitors x-ray tube performance to anticipate the need for replacement),
2. Software that is integral to a medical device or software in a medical device (eg, software used to "drive or control" the motors and the pumping of medication in an infusion pump)
3. Software, which on its own is a medical device referred to as "Software as a Medical Device" (SaMD) (eg, software that can track the size of a mole over time and determine the risk of melanoma)

The International Medical Device Regulators Forum, a consortium of medical device regulators from around the world led by the U.S. Food and Drug Administration (FDA) defines SaMD as "software that is intended to be used for one or more medical purposes that perform those purposes without being part of a hardware medical device". Such software was previously referred to by industry, international regulators, and health care providers as "standalone software," "medical device software," and/or "health software," and can sometimes be confused with other types of software.

The scope of this review includes only those digital technologies that are intended to be used for therapeutic application and meet the following 3 criteria:

1. Must meet the definition of "Software as a medical device" (SaMD) which states that software is intended to be used for a medical purpose, without being part of a hardware medical device or software that stores or transmits medical information.
2. Must have received marketing clearance or approval by the U.S. FDA either through the *de novo* premarket process or 510(k) process or pre-market approval and
3. Must be prescribed by a healthcare provider.

Panic Disorder and Post-Traumatic Stress Disorder

Panic disorder is an anxiety disorder associated with marked impairment in social and occupational functioning, significant impact on quality of life, and high utilization of health care services. Fearful interpretation of bodily symptoms such as tachycardia, shortness of breath, chest tightness, and dizziness with catastrophic beliefs is the core of the diagnosis and differentiates it from other anxiety disorders. Many individuals with panic disorder hyperventilate and it has been suggested that respiratory abnormality associated with panic disorder may be due to a hypersensitivity to carbon dioxide (CO 2). Based on the recognition of subtle respiratory irregularities associated with hyperventilation in individuals with panic disorder, and CO2 sensitivity, Meuret et al. (2008) developed a breathing intervention focused on normalizing both exhaled carbon dioxide levels (ETCO2) and respiratory rate. The protocol provided breath-to-breath feedback of ETCO2, while modeling paced breathing at4 different respiratory rates. Administered as twice daily, 17-min sessions over a 4-week period, the authors reported that by study end, 86% of subjects reported zero weekly panic attacks; an improvement that was durable over time, as 73% reported zero weekly attacks 1-year post-treatment. Freespira incorporates this protocol in their approach to managing panic disorder.

Post-traumatic stress disorder (PTSD) is marked by symptoms of hyperarousal, difficulties with emotional regulation, negative affect, and autonomic dysfunction. Carbon dioxide hypersensitivity may be responsible for mediating some PTSD symptoms as CO2 challenge tests in individuals with established PTSD have been shown to provoke a panic attack. Since the characteristic of CO2 hypersensitivity is shared by both PTSD and panic disorder, extending the use of Freespira to a population with PTSD is a logical and potentially valuable clinical tool given the lack of medication-free treatment options for PTSD.

The purpose of prescribed therapeutic digital applications is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals with panic disorder and PTSD. Panic symptoms may be associated with more shallow and rapid breathing. Freespira addresses rapid and shallow breathing that may contribute to panic symptoms through training of respiratory control.

For individuals with panic symptoms who receive Freespira, the evidence includes several single-arm studies. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. Panic symptoms in individuals with panic disorder and post-traumatic stress disorder (PTSD) have been associated with more shallow and rapid breathing, and Freespira is intended to lead to more regular breathing through biofeedback over a 4 week training period. There are 2 single-arm studies in individuals with panic disorder and 1 single-arm pilot study on the use of Freespira in individuals with PTSD. All of the studies report an improvement in symptoms but are limited by loss to follow-up that ranges from 24% to 58% and multiple limitations in the design and conduct. A well-designed blinded randomized controlled study with a clear design for testing a pre-specified hypothesis is needed. Given the high loss to follow-up and lack of a control group in these studies, the benefit of a 4-week program of respiratory biofeedback in individuals with panic

disorder and PTSD is uncertain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Nightmare Disorder and Post-Traumatic Stress Disorder-Associated Nightmares
The purpose of prescribed therapeutic digital applications is to provide a treatment option that is an alternative to or an improvement on existing therapies for individuals with nightmare disorder and PTSD-associated nightmares.

The digital therapy being considered is NightWare. NightWare is intended to reduce nightmares in individuals with nightmare disorder and PTSD-associated nightmares in conjunction with standard therapy. NightWare uses an artificial intelligence algorithm to learn an individual's normal and abnormal sleeping heart rate and motion in conjunction with an Apple Watch, Apple iPhone, and NightWare server. Upon detection of abnormal activity, the watch provides short vibrations to disrupt the nightmare without waking the patient. The watch is intended to be worn only during sleep and is used in addition to usual treatment for PTSD-associated nightmares and nightmare disorder.

For individuals with nightmare disorder or PTSD-associated nightmares who receive NightWare, the evidence includes a single trial. Relevant outcomes are symptoms, functional outcomes, quality of life, and treatment-related morbidity. The single pivotal trial did not meet the primary efficacy endpoint. This trial failed to achieve recruitment goals and was likely underpowered. A well-designed blinded randomized controlled study with a clear design for testing a pre-specified hypothesis is needed. Given these limitations, the benefit of NightWare in individuals with nightmare disorder and post-traumatic stress disorder-associated nightmares is uncertain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products
The following HCPCS code(s) is not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:
A9291 Prescription digital cognitive and/or behavioral therapy, fda cleared, per course of treatment

RELATED POLICIES

Digital Health Technologies - Diagnostic Applications
Digital Health Therapeutics for Substance Abuse Disorders
Digital Health Technologies for Attention Deficit Hyperactivity Disorder

PUBLISHED

Provider Update, August 2023

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