FEP Medical Policy Manual

FEP 3.03.02 Digital Health Technologies: Therapeutic Applications

Effective Policy Date: July 1, 2023

Original Policy Date: June 2023

Related Policies:

3.03.03 - Digital Health Therapies for Attention Deficit/Hyperactivity Disorder
1.01.35 - Digital Health Therapies for Substance Use Disorders

Digital Health Technologies: Therapeutic Applications

Description

Description

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). 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" 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. Food and Drug Administration (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.

OBJECTIVE

The objective of this evidence review is to individually assess U.S. Food and Drug Administration-approved prescription digital health technologies to determine whether each therapeutic application improves the net health outcome compared with standard of care.

POLICY STATEMENT

The use of Freespira is considered **investigational** for all indications including treatment of panic disorder and/or post traumatic stress disorder.

The use of NightWare is considered **investigational** for all indications including treatment of nightmare disorder or nightmares from PTSD.

POLICY GUIDELINES

None

BENEFIT APPLICATION

Experimental or investigational procedures, treatments, drugs, or devices are not covered (See General Exclusion Section of brochure).

Non-prescription digital health therapies may be excluded from coverage depending on local contract language.

FDA REGULATORY STATUS

Digital health technologies that meet the current scope of the review are shown in Table 1.

Table 1. Examples of Prescription Digital Health Applications

Application	Manufacturer	FDA Cleared Indication	Description	FDA Product Codes	Clearance	Date
Freespira (Canary Breathing System)	Freespira (previously PaloAlto Health Sciences)	Freespira is intended for use as a relaxation treatment for the reduction of stress by leading the user through guided and monitored breathing exercises. The device is indicated as an adjunctive treatment of symptoms associated with panic disorder and/or PTSD, to be used under the direction of a healthcare professional, together with other pharmacological and/or non-pharmacological interventions.	It is a small breathing sensor with a tablet that is used twice a day for 17 minutes. Individuals are trained to use the Sensor with the Mobile App to measure and display their EtCO2 level and RR and how different breathing habits affect EtCO2 levels.	HCC, CCK	K131586, K180173	2013, 2018
NightWare(TM)	NightWare, Inc	The NightWare digital therapeutic is indicated to provide vibrotactile feedback on an Apple Watch based on an analysis of heart rate and motion during sleep for the temporary reduction of sleep disturbance related to nightmares in adults 22 years or older who suffer from nightmare disorder or have nightmares from PTSD. It is intended for home use.	The NightWare is a therapeutic platform using a proprietary AppleWatch application. The app learns the wearer"s sleep patterns and customizes treatment to the individual. The app monitors the wearer"s heart rate and movement while sleeping and arouses the wearer with a vibration alert when a stress threshold is reached so as not to awaken the individual. Users wear the watch only while sleeping and not during the day.		Breakthrough device designation	2020

EtCO2: exhaled carbon dioxide; FDA: U.S. Food and Drug Administration; PTSD: post-traumatic stress disorder; RR: respiration rate; SaMD: software as a medical device.

RATIONALE

Summary of Evidence

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.

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.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No relevant guidelines that include NightWare or Freespira were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

REFERENCES

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POLICY HISTORY - THIS POLICY WAS APPROVED BY THE FEP® PHARMACY AND MEDICAL POLICY COMMITTEE ACCORDING TO THE HISTORY BELOW:

Date	Action	Description
June 2023	New policy - Add to Digital Health category	Policy created with literature review through February 1, 2023. Prescription digital health technologies for therapeutic application (Freespira and NightWare) that have received clearance for marketing by the U.S. Food and Drug Administration are considered investigational.