Digital Therapeutic Products for Post-traumatic Stress Disorder and Panic Disorder

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IMPORTANT REMINDER

The Medicare Advantage Medical Policy manual is not intended to override the member Evidence of Coverage (EOC), which defines the insured's benefits, nor is it intended to dictate how providers are to practice medicine. Physicians and other health care providers are expected to exercise their medical judgment in providing the most appropriate care for the individual member, including care that may be both medically reasonable and necessary.

The Medicare Advantage medical policies are designed to provide guidance regarding the decision-making process for the coverage or non-coverage of services or procedures in accordance with the member EOC and Centers of Medicare and Medicaid Services (CMS) policies and manuals, along with general CMS rules and regulations. In the event of a conflict, applicable CMS policy or EOC language will take precedence over the Medicare Advantage Medical Policy. In the absence of a specific CMS coverage determination for a requested service, item or procedure, the health plan may apply CMS regulations, as well as their Medical Policy Manual or other applicable utilization management vendor criteria developed with an objective, evidence-based process using scientific evidence, current generally accepted standards of medical practice, and authoritative clinical practice guidelines.

Some services or items may appear to be medically indicated for an individual, but may be a direct exclusion of Medicare or the member's benefit plan. Medicare and member EOCs exclude from coverage, among other things, services or procedures considered to be investigational (experimental) or cosmetic, as well as services or items considered not medically reasonable and necessary under Title XVIII of the Social Security Act, §1862(a)(1)(A). In some cases, providers may bill members for these non-covered services or procedures. Providers are encouraged to inform members in advance when they may be financially responsible for the cost of non-covered or excluded services. Members, their appointed representative, or a treating provider can request coverage of a service or item by submitting a pre-service organization determination prior to services being rendered.

DESCRIPTION

Digital health products are technologies, platforms, and systems that engage consumers for lifestyle, wellness, and health-related purposes. A digital therapeutic product is a specific type of digital health product that is practitioner-prescribed software that delivers evidence-based therapeutic intervention directly to a patient to prevent, manage, or treat a medical disorder or disease. Digital therapeutic products have been proposed to supplement or replace established treatments for post-traumatic stress disorder, panic disorder, and depression.

MEDICARE ADVANTAGE POLICY CRITERIA

CMS Coverage Manuals*	Medicare Managed Care Manual Chapter 4 - Benefits and Beneficiary Protections, See Section 10.2 in the following link: MCM Chapter 4 Medicare coverage and payment is contingent upon a determination that: a service is in a covered benefit category. Digital therapies or computer software are housed on non-medical devices like smartphones or computers, and the equipment and software as a whole are not durable medical equipment (See Medicare Benefit Policy Manual, Chapter 15, Section 110.8 – Covered Medical and Other Health Services). Therefore, these therapies, including but not limited to the following, do not fall within a DMEPOS benefit category: • Freespira® is a software application used on a tablet that connects to a capnometry-assisted breathing device. • NightWare™ is an AppleWatch®-based software application that analyzes heart rate and motion during sleep and provides vibrotactile feedback.

NOTE: If a procedure or device lacks scientific evidence regarding safety and efficacy because it is investigational or experimental, the service is noncovered as not reasonable and necessary to treat illness or injury. (*Medicare IOM Pub. No. 100-04, Ch. 23, §30 A*). According to Title XVIII of the Social Security Act, §1862(a)(1)(A), only medically reasonable and necessary services are covered by Medicare. In the absence of a NCD, LCD, or other coverage guideline, CMS guidelines allow a Medicare Advantage Organization (MAO) to make coverage determinations, applying an ***objective, evidence-based process, based on authoritative evidence***. (*Medicare IOM Pub. No. 100-16, Ch. 4, §90.5*). The Medicare Advantage Medical Policy - Medicine Policy No. M-149 - provides further details regarding the plan's evidence-assessment process (see Cross References).

POLICY GUIDELINES

REQUIRED DOCUMENTATION

According to Medicare guidelines, Medicare coverage is contingent upon the services meeting certain requirements to determine medical necessity. In order to be considered a covered service, Medicare requires that the service in question:

- Fall within a defined medicare benefit category
- Not be excluded from coverage by statute, regulation, national coverage determination, (NCD), or local coverage determination (LCD)
- Be considered medically necessary, as required per the social security act, §1862(a)(1)(a). This means the service must be considered reasonable and necessary in the diagnosis or treatment of an illness or injury, or to rule out or confirm a suspected

diagnosis because the patient has a sign and/or symptoms. This also means services that are determined to be not medically necessary for any reason (including lack of safety and efficacy because it is an investigational service) are non-covered.
• Be ordered by a physician who is treating the beneficiary,
• Provide data that would be directly used in the management of a beneficiary's specific medical problem.

REGULATORY STATUS

The Freespira® Canary Breathing System (Freespira, previously PaloAlto Health Sciences) received United States (US) Food and Drug Administration (FDA) 510(k) premarket approval on July 23, 2018 and was previously approved as the Canary Breathing™ System in 2013 (K131586, K180173).[5, 6] Freespira capnometry-assisted respiratory therapy 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 that is used with the Freespira® application on a tablet and is to be used twice a day for 17 minutes. Individuals are trained to use the sensor with the mobile application to measure and display their end-tidal carbon dioxide ($EtCO_2$) level, respiratory rate, and how different breathing habits affect $EtCO_2$ levels. Product code: HCC, CCK.

The NightWare™ Kit (NightWare, Inc.) received US FDA breakthrough device designation on May 27, 2023 (DEN200033).[7] The NightWare™ digital therapeutic is a software application that provides vibrotactile feedback on an AppleWatch® based on an analysis of heart rate and motion during sleep. NightWare™ is indicated 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™ therapeutic platform uses a proprietary AppleWatch® and Apple iPhone application. The application learns the wearer's sleep patterns and customizes treatment to the individual. The application monitors the wearer's heart rate and movement during sleep and provides a vibration alert when a stress threshold is reached, intended to interrupt the nightmare but not awaken the patient. Users wear the watch only while sleeping and not during the day. Product code: QMZ.

Note, the fact a new service or procedure has been issued a CPT/HCPCS code or is FDA approved for a specific indication does not, in itself, make the procedure medically reasonable and necessary. The FDA determines safety and effectiveness of a device or drug, but does not establish medical necessity. While Medicare may adopt FDA determinations regarding safety and effectiveness, Medicare or Medicare contractors evaluate whether or not the drug or device is reasonable and necessary for the Medicare population under §1862(a)(1)(A).

CROSS REFERENCES

Investigational (Experimental) Services, New and Emerging Medical Technologies and Procedures, and Other Non-Covered Services, Medicine, Policy No. M-149

REFERENCES

1. Social Security Act §1862 (ssa.gov)
2. Medicare Managed Care Manual, Chapter 4, §10.2
3. Medicare Benefit Policy Manual, Ch. 15 – Covered Medical and Other Health Services Using the following link: Medicare Benefit Policy Manual
4. Medicare Benefit Policy Manual, Chapter 16 - General Exclusions from Coverage, See Section §20 - Services Not Reasonable and Necessary in the following link: Medicare Benefit Policy Manual
5. Medicare Coverage Determination Process
6. Medicare Claims Processing Manual, Chapter 23 - Fee Schedule Administration and Coding Requirements, §30 - Services Paid Under the Medicare Physician's Fee Schedule, Subsection A
7. 42 CFR § 410.32(a) 8. Medicare Benefit Policy Manual, Ch. 15 – Covered Medical and Other Health Services, §80.1 - Clinical Laboratory Services

CODING

NOTE: Not all digital health products will have a specific code. These are examples of codes that may be relevant.

Codes	Number	Description
CPT	None	
HCPCS	A9291	Prescription digital cognitive and/or behavioral therapy, FDA cleared, per course of treatment
	G0552	Supply of digital mental health treatment device and initial education and onboarding, per course of treatment that augments a behavioral therapy plan
	G0553	First 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (dmht) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing information related to the use of the dmht device, including patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month
	G0554	Each additional 20 minutes of monthly treatment management services directly related to the patient's therapeutic use of the digital mental health treatment (dmht) device that augments a behavioral therapy plan, physician/other qualified health care professional time reviewing data generated from the dmht device from patient observations and patient specific inputs in a calendar month and requiring at least one interactive communication with the patient/caregiver during the calendar month

***IMPORTANT NOTE:** Medicare Advantage medical policies use the most current Medicare references available at the time the policy was developed. Links to Medicare references will take viewers to external websites outside of the health plan's web control as these sites are not maintained by the health plan.*