BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 06/20/23**
SECTION: MEDICINE	**LAST REVIEW DATE: 08/06/24**
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	LAST CRITERIA REVISION DATE:
NEXT ANNUAL REVIEW DATE: 3RD QTR 2025	**ARCHIVE DATE:**

DIGITAL HEALTH TECHNOLOGIES: THERAPEUTIC APPLICATIONS

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 06/20/23**
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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 policy 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.

Freespira® (Canary Breathing System) 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. Freespira was cleared by the FDA 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 post-traumatic stress disorder (PTSD), to be used under the direction of a healthcare professional, together with other pharmacological and/or non-pharmacological interventions.

NightWare(TM) 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. The NightWare digital therapeutic was cleared by the FDA with a breakthrough device designation and 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.

EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 06/20/23**
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DIGITAL HEALTH TECHNOLOGIES: THERAPEUTIC APPLICATIONS

Criteria:

- Freespira for the treatment of all indications is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

  These indications include, *but are not limited to:*

  - Panic disorder
  - Post-traumatic stress disorder (PTSD)

- NightWare for the treatment of all indications is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

  These indications include, *but are not limited to:*

  - Nightmare disorder
  - Nightmares from PTSD

DIGITAL HEALTH TECHNOLOGIES: THERAPEUTIC APPLICATIONS

Resources:

Literature reviewed 08/06/24. We do not include marketing materials, poster boards and non-published literature in our review.

1. American Psychiatric Association. Trauma- and stressor related disorders. *In Diagnostic and statistical manual of psychiatric disorders*. 5th ed. 2013.

2. Davenport ND, Werner JK. A randomized sham-controlled clinical trial of a novel wearable intervention for trauma-related nightmares in military veterans. *J Clin Sleep Med*. Feb 1 2023;19(2):361-369. doi:10.5664/jcsm.10338

3. Deacon B, Lickel J, Abramowitz JS. Medical utilization across the anxiety disorders. *J Anxiety Disord*. 2008;22(2):344-50. doi:10.1016/j.janxdis.2007.03.004

4. Evidence standards framework for digital health technologies. National Institute for Health and Care Excellence (NICE). 2021. Accessed March 10, 2024. https://www.nice.org.uk/about/what-we-do/our-programmes/evidence-standards-framework-for-digital-health-technologies

5. International Medical Device Regulators Forum (IMDRF) Software as a Medical Device (SaMD) Working Group. Software as a Medical Device (SaMD): Key Definitions. International Medical Device Regulators Forum (IMDRF). 2013. Accessed March 10, 2024. http://www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-131209-samd-key-definitions-140901.pdf

6. Kaplan A, Mannarino AP, Nickell PV. Evaluating the Impact of Freespira on Panic Disorder Patients' Health Outcomes and Healthcare Costs within the Allegheny Health Network. *Appl Psychophysiol Biofeedback*. Sep 2020;45(3):175-181. doi:10.1007/s10484-020-09465-0

7. Kellner M, Muhtz C, Nowack S, Leichsenring I, Wiedemann K, Yassouridis A. Effects of 35% carbon dioxide (CO(2)) inhalation in patients with post-traumatic stress disorder (PTSD): A double-blind, randomized, placebo-controlled, cross-over trial. *J Psychiatr Res*. Jan 2018;96:260-264. doi:10.1016/j.jpsychires.2017.10.019

8. Meuret AE, Wilhelm FH, Ritz T, Roth WT. Feedback of end-tidal pCO2 as a therapeutic approach for panic disorder. *J Psychiatr Res*. Jun 2008;42(7):560-8. doi:10.1016/j.jpsychires.2007.06.005

9. Morgenthaler TI, Auerbach S, Casey KR, et al. Position Paper for the Treatment of Nightmare Disorder in Adults: An American Academy of Sleep Medicine Position Paper. *J Clin Sleep Med*. Jun 15 2018;14(6):1041-1055. doi:10.5664/jcsm.7178

10. Muhtz C, Yassouridis A, Daneshi J, Braun M, Kellner M. Acute panicogenic, anxiogenic and dissociative effects of carbon dioxide inhalation in patients with post-traumatic stress disorder (PTSD). *J Psychiatr Res*. Jul 2011;45(7):989-93. doi:10.1016/j.jpsychires.2011.01.009

11. NightWare, Inc. De Novo Classification Request for NightWare Kit (Apple iPhone, Apple Watch, Apple iPhone Charging Cable, Apple Watch Charging Cable). U.S. Food and Drug Administration. 2020. Accessed March 10, 2024. https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN200033.pdf

12. Ostacher MJ, Fischer E, Bowen ER, Lyu J, Robbins DJ, Suppes T. Investigation of a Capnometry Guided Respiratory Intervention in the Treatment of Posttraumatic Stress Disorder. *Appl Psychophysiol Biofeedback*. Dec 2021;46(4):367-376. doi:10.1007/s10484-021-09521-3

13. Tolin DF, McGrath PB, Hale LR, Weiner DN, Gueorguieva R. A Multisite Benchmarking Trial of Capnometry Guided Respiratory Intervention for Panic Disorder in Naturalistic Treatment Settings. *Appl Psychophysiol Biofeedback*. Mar 2017;42(1):51-58. doi:10.1007/s10484-017-9354-4

Coding:

HCPCS: A9291

History:	**Date:**	**Activity:**
Medical Policy Panel	08/06/24	Review with revisions
Medical Policy Panel	06/04/24	Review with no revisions
Pediatric Subspecialty Advisory Sub-Committee	02/15/24	Review with no revisions
Medical Policy Panel	06/20/23	Approved guideline
Pediatric Subspecialty Advisory Sub-Committee	05/18/23	Review with no revisions
Medical Director (Dr. Deering)	04/13/23	Development

Policy Revisions:

08/06/24 Updated: Resource section

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DIGITAL HEALTH TECHNOLOGIES: THERAPEUTIC APPLICATIONS

Non-Discrimination Statement:

Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nílínigíí Blue Cross Blue Shield of Arizona haada yit'éego bína'ídíłkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'ídíłkidgo beehaz'áanii hóló díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh íłínígóó. Ata' halne'ígíí kojį' bich'į' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

Arabic:
إن كان لديك أو لدى شخص تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة. للتحدث مع مترجم اتصل ب 877-475-4799.

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Multi-Language Interpreter Services:

Tagalog: Kung ikaw, o ang iyong tinutulangan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:
اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799
.]تماس حاصل نمایید.

Assyrian:
Blue Cross Blue Shield of Arizona، ...877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคณ หรอคนทคณกาลงชวยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona คณมสทธทจะไดรบความชวยเหลอและขอมลในภาษา ของคณไดโดยไมมคาใชจาย พดคยกบลาม โทร 877-475-4799