

NO. 91002-R11

BIOFEEDBACK

Effective date: 12/01/2025 Last reviewed: 11/2025

Instruction for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion. Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

I. MEDICAL NECESSITY CRITERIA

Biofeedback may be considered medically necessary when indicated for the short-term rehabilitation of a medical diagnosis.

- A. Biofeedback is considered medically necessary for the following:
 - 1. Migraine or tension headaches
 - 2. Urinary incontinence
 - 3. Constipation in adults
- B. Biofeedback is considered NOT medically necessary for all other indications including, but not limited to:
 - 1. Mental health diagnoses, including ADHD
 - 2. Vulvodynia
 - 3. Hypertension
- C. The following are considered experimental, investigational or unproven:
 - 1. Electroencephalography (EEG) biofeedback or neurofeedback for any diagnosis, including ADHD.
 - 2. In-home biofeedback devices (e.g. RESPeRATE®, Innosense®)
 - 3. Prescription digital therapeutic devices (e.g., Freespira)

- D. Biofeedback services must be obtained from a provider who has been credentialed specifically for these services.
- E. Medicaid: For Medicaid/Healthy Michigan Plan members, consult the current Michigan Department of Health and Human Services (MDHHS) Medicaid Provider Manual.

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the <u>CMS Online Manual System (IOMs)</u> and Transmittals. For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to <u>CMS Medicare Coverage Database</u>.

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare Coverage Database website for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

National Coverage Determinations (NCDs)		
Biofeedback Therapy 30.1		
Biofeedback Therapy for the Treatment of Urinary Incontinence 30.1.1		
Local Coverage Determinations (LCDs)		
CGS Administrators, LLC	Outpatient Physical and Occupational Therapy Services <u>L34049</u> <u>A57067</u>	
First Coast Service Options, Inc.	None identified.	
National Government Services, Inc.	Outpatient Physical and Occupational Therapy Services <u>L33631</u> <u>A56566</u> Psychiatry and Psychology Services <u>L33632</u> <u>A56937</u>	
Noridian Healthcare Solutions	None identified.	
Novitas Solutions, Inc.	None identified.	
Palmetto GBA	Home Health Occupational Therapy <u>L34560</u> <u>A53057</u> Home Health Physical Therapy <u>L34564</u> <u>A53058</u> Outpatient Occupational Therapy <u>L34427</u> <u>A53064</u> Outpatient Occupational Physical <u>L34428</u> A53065	

	Partial Hospitalization Programs <u>L37633</u>	
	A56685	
WPS Insurance Corporation	None identified.	

III. BACKGROUND

Biofeedback is a training technique that utilizes monitoring instruments to detect and amplify internal physiological processes. The information is presented by audio and/or visual means to patients to learn specific tasks.

Freespira (Freespira Inc.)

Freespira (<u>Freespira Inc.</u>) is a digital therapeutic device available by prescription only and indicated as adjunctive treatment for panic disorder and/or posttraumatic stress disorder (PTSD) (<u>K180173</u>). It is a biofeedback device, which according to its regulatory guidance is an "instrument that provides a visual or auditory signal corresponding to the status of one or more of a patient's physiological parameters ... so that the patient can control voluntarily these physiological parameters" (<u>21CFR882.5050</u>).

Under the direction of a licensed healthcare provider, patients are trained to use the Freespira sensor and the Freespira mobile application to participate in breathing exercises with the intent of normalizing their respiratory rate and exhaled carbon dioxide levels. Sessions of breathing exercises are conducted twice daily, 17 minutes each for 4 weeks at home (K180173). The Freespira website contends that the device thereby "normalizes CO₂ and respiratory rates in a single 28-day treatment for adults and adolescents" with the intent of preventing panic attacks (Freespira Inc., 2022).

The Freespira device attained 510(k) clearance under applicant Palo Alto Health Sciences Inc. Freespira Inc. became the new name of Palo Alto Health Sciences according to a December 28, 2020, press release. The class II biofeedback device is subject to product codes HCC and CCK, per the Code of Federal Regulations 21
882.5050. Freespira was cleared as substantially equivalent to the Canary Breathing System (Palo Alto Health Sciences Inc.), which first received FDA 510(k) clearance on December 10, 2013 (K131586). According to the summary submitted for Freespira's marketing notification (available through K180173">K180173), the differences between the Freespira and Canary devices are that Freespira can be used while plugged into a power adapter and the indications are expanded to include PTSD.

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
Association for Applied Psychophysiology	Standards for Performing BioFeedback
and Biofeedback (AAPB)	(2013)

American College of Obstetricians &	Practice Bulletin: Urinary Incontinence in
Gynecologists (ACOG)	Women (November 2015; Reaffirmed
	2025)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See <u>U.S. Food & Drug Administration (FDA) Medical Device Databases</u> for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Notice date
Freespira Breathing System	K233337	April 4, 2025
(Freespira, Inc.)		
Freespira (Freespira, Inc.)	K180173	August 28, 2018
Canary Breathing™ System	K131586	December 10, 2013
(Palo Alto Health Sciences Inc.)		
RESPERATE® (InterCure, Inc.)	K020399	July 2, 2002
Innosense® pelvic floor	K971527	June 30, 1997
stimulation and		
electromyography system		

VI. CODING

CPT/HCPCS Codes

- 90901 Biofeedback training by any modality
- 90912 Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; initial 15 minutes of one-on-one physician or other qualified health care professional contact with the patient
- 90913 Biofeedback training, perineal muscles, anorectal or urethral sphincter, including EMG and/or manometry, when performed; each additional 15 minutes of one-on-one physician or other qualified health care professional contact with the patient (List separately in addition to code for primary procedure)

(Not covered for Medicaid/Healthy Michigan Plan members; see NCD for Medicare indications)

Not covered:

- 90875 Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); approximately 20-30 minutes
- 90876 Individual psychophysiological therapy incorporating biofeedback training by any modality (face-to-face with the patient), with psychotherapy (e.g., insight oriented, behavior modifying or supportive psychotherapy); approximately 45-50 minutes
- E0746 Electromyography (EMG), biofeedback device

- A9291 Prescription digital cognitive and/or behavioral therapy, FDA-cleared, per course of treatment
- S9002 Intra-vaginal motion sensor system, provides biofeedback for pelvic floor muscle rehabilitation device

Revenue Code

0917 Biofeedback2105 Biofeedback

Diagnosis Codes

Biofeedback is covered only for the following diagnoses for Commercial plans:

ICD-10 Codes that apply to this policy

G43.001 – G43.919	Migraine
G44.201 – G44.229	Tension headache
K59.00 - K59.09	Constipation
N36.42	Intrinsic sphincter deficiency (ISD)
N36.43	Combined hypermobility of urethra and intrinsic sphincter
	deficiency
N36.44	Muscular disorders of urethra
N39.3	Stress incontinence (female) (male)
N39.41	Urge incontinence
N39.42	Incontinence without sensory awareness
N39.45	Continuous leakage
N39.46	Mixed incontinence
N39.498	Other specified urinary incontinence

Diagnosis Codes

Biofeedback is covered only for the following diagnoses for Priority Medicare plans:

ICD-10 Codes that apply to this policy

G83.4	Cauda equina syndrome
K59.01	Slow transit constipation
K59.02	Outlet dysfunction constipation
K59.4	Anal spasm
M62.3	Immobility syndrome (paraplegic)
M62.40 - M62.49	Contracture of muscle
M62.50 - M62.59	Muscle wasting and atrophy, not elsewhere classified
M62.830 - M62.89	Muscle spasm
M62.9	Disorder of muscle, unspecified
M63.80 - M63.89	Disorders of muscle in diseases classified elsewhere
N36.42	Intrinsic sphincter deficiency (ISD)
N36.43	Combined hypermobility of urethra and intrinsic sphincter
	deficiency

N36.44 Muscular disorders of urethra N39.3 Stress incontinence (female) (male)

N39.41 – N39.46 Other incontinence

N39.498 Other specified urinary incontinence

R15.0 – R15.9 Fecal incontinence

R32 Unspecified urinary incontinence R33.9 Retention of urine, unspecified

R35.0 Frequency of micturition

R39.14 Feeling of incomplete bladder emptying

R39.15 Urgency of urination

VII. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service or procedure is medically necessary. For more information, refer to the Priority Health Provider Manual.

VIII. APPLICATION TO PRODUCTS

Coverage is subject to the member's specific benefits. Group-specific policy will supersede this policy when applicable.

- **HMO/EPO**: This policy applies to insured HMO/EPO plans.
- **POS**: This policy applies to insured POS plans.
- **PPO**: This policy applies to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.
- **ASO**: For self-funded plans, consult individual plan documents. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL**: For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **MEDICARE**: Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.
- MEDICAID/HEALTHY MICHIGAN PLAN: For Medicaid/Healthy Michigan Plan members, this policy will apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual, the Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

IX. REFERENCES

1. Hayes Inc. Evolving Evidence Review. Freespira Digital Therapeutic (Freespira Inc.) for Treatment of Panic Disorder. Hayes Inc. May 3, 2022. Annual Review May 29, 2025.

- Hayes Inc. Evolving Evidence Review. Freespira Digital Therapeutic (Freespira Inc.) for Treatment of Posttraumatic Stress Disorder. Hayes, Inc. August 4, 2022. Annual Review August 27, 2025.
- Hayes, Inc. Health Technology Assessment. Biofeedback for Headache and Chronic Musculoskeletal Pain. Hayes, Inc. November 3, 2004. Annual Review December 7, 2008.
- 4. Hayes, Inc. Health Technology Assessment. Biofeedback for the Treatment of Hypertension. Hayes, Inc. February 27, 2006. Annual Review April 20, 2010.
- 5. Hayes, Inc. Health Technology Assessment. Biofeedback Therapy for Vulvodynia. Hayes, Inc. March 18, 2008. Annual Review March 27, 2012.
- 6. Hayes, Inc. Health Technology Assessment. Electroencephalogram (EEG) Biofeedback Therapy. Hayes, Inc. April 11, 2003. Annual Review March 13, 2008.
- 7. Hayes, Inc. Health Technology Assessment. RESPeRATE® (InterCure Ltd.) Device to Lower Blood Pressure. Hayes, Inc. November 25, 2008. Annual Review November 23, 2010.
- 8. Lukacz E. Female urinary incontinence: Treatment. In: UpToDate, connor RF (Ed), Wolters Kluwer. (Accessed on September 29, 2025.)
- 9. Taylor FR. Tension-type headache in adults: Preventive treatment. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on September 29, 2025.)
- 10. Wald A. Management of persistent unresponsive constipation in adults. In: UpToDate, Connor RF (Ed), Wolters Kluwer. (Accessed on September 29, 2025.)

Past review dates: 1/93, 12/94, 10/97, 12/99, 12/01, 2/02, 1/03, 1/04, 1/05, 12/05, 12/06, 12/07, 12/08, 12/09, 12/10, 12/11, 12/12, 12/13, 11/14, 11/15, 11/16, 11/17, 11/18, 11/19, 11/20, 11/21, 11/22, 11/23, 11/24

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