Priority Health

MEDICAL POLICY
No. 91002-R10

BIOFEEDBACK

Effective Date: November 22, 2023

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

Date Of Origin: June 30, 1988

Status: Current

I. POLICY/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. MEDICAL REVIEW

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

III. APPLICATION TO PRODUCTS

Coverage is subject to 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) and/or the Evidence of Coverage (EOC); 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 located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the Michigan Medicaid Provider Manual will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.***

IV. DESCRIPTION

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 (Freespira Inc.) is a digital therapeutic device available by prescription only and indicated as adjunctive treatment for panic disorder and/or posttraumatic

stress disorder (PTSD) (K180173). 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" (21CFR882.5050).

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 CO_2 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), 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.

V. CODING INFORMATION:

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	Biofeedback
2105	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

VI. REFERENCES

1. Cigna. Biofeedback. Medical Coverage Policy-Therapy Services..
2. Hayes, Inc. Health Technology Assessment. Biofeedback Therapy for Vulvodynia. Hayes, Inc.; March 18, 2008.
3. Hayes, Inc. Health Technology Assessment. Biofeedback for the Treatment of Hypertension. Hayes, Inc.; February 27, 2006.
4. Hayes Inc. Evolving Evidence Review. Freespira Digital Therapeutic (Freespira Inc.) for Treatment of Panic Disorder. Hayes Inc.; May 3, 2022.
5. Hayes Inc. Evolving Evidence Review. Freespira Digital Therapeutic (Freespira Inc.) for Treatment of Posttraumatic Stress Disorder. Hayes, Inc.; August 4, 2022.
6. Hayes, Inc. Health Technology Assessment. RESPeRATE® (InterCure Inc.) Device to Lower Blood Pressure. Hayes, Inc.; November 25, 2008.
7. Hayes, Inc. Health Technology Assessment. Biofeedback for Headache and Chronic Musculoskeletal Pain. Hayes, Inc.; November 3, 2004.