



**BIOFEEDBACK TO LOWER BLOOD PRESSURE
USING THE RESPERATE® DEVICE
HS-103**



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Harmony Behavioral Health of Florida, Inc.

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WellCare Prescription Insurance, Inc.

**Biofeedback to Lower Blood
Pressure Using the
RESPeRATE® Device**

Policy Number: HS-103

Original Effective Date: 5/7/2009

Revised Date(s): 5/28/2010; 7/18/2011

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

Hypertension, the elevation of blood pressure (BP), is the most common primary diagnosis in the United States. Because the risk of hypertension increases with age, the prevalence of hypertension is expected to increase further as the population ages. Chronic hypertension may damage arteries, the heart, kidneys, and brain and may result in heart attack, kidney failure, and stroke. Despite the prevalence of hypertension, it is estimated that only 34% of the approximate 50 million hypertensive Americans are receiving adequate therapy. Initial treatments for hypertension typically include lifestyle changes combined with a diuretic that increases the rate of urination. For more advanced or resistant hypertension, other drugs that act on the kidneys and heart are used to reduce BP. Clinical trials have shown that lowering BP with these agents reduces the incidence of cardiovascular complications associated with hypertension.

The RESPeRATE® device relies on biofeedback to attempt to reduce BP. The device consists of a breathing sensor and headphones that are connected to a computerized monitoring and control unit. The breathing sensor is strapped around the user's chest to detect the expansions and contractions that correspond to breaths. At the beginning of each treatment session, a computer program in the monitor assesses the user's breathing rate and creates a program designed to slow the user's breathing. While wearing the headphones, the user hears 2 distinct tones; the higher tone signals when to inhale, and the lower tone signals when to exhale. During the treatment session, the monitor gradually adjusts the timing of these tones to help the device user reach a breathing rate of < 10 breaths per minute. According to the device manufacturer, a reduced breathing rate causes relaxation of blood vessels and a decrease in BP. To help the user keep track of progress, the monitor also displays the current breathing rate. The RESPeRATE device is typically used by patients at home, and the device manufacturer recommends 3 to 4 sessions of treatment per week with 15 minutes of continuous device use per session.

The literature search identified 1 nonrandomized controlled study and 4 randomized controlled trials (RCTs) that evaluated the RESPeRATE device for treatment of hypertension. Results of these studies provide conflicting evidence concerning the RESPeRATE device for treatment of high BP. Although 1 RCT found that this therapy provided statistically significant improvements in diastolic BP both after the initial treatment and 6 months after completion of the treatment, 3 RCTs found that RESPeRATE therapy was no better than placebo treatment. A nonrandomized controlled study reported that RESPeRATE therapy was also beneficial in lowering diastolic BP; however, the results of this study are not reliable, since there were statistically significant pretreatment differences between the Treatment and Control Groups in patient age, use of multiple antihypertensive drugs, and systolic BP measured at home. Additional studies are needed to determine whether RESPeRATE therapy is an effective treatment for hypertension (Hayes, 2008).

POSITION STATEMENT

Using the RESPeRATE® (InterCure Ltd.) biofeedback device to lower high blood pressure **is considered experimental and investigational and is NOT a covered benefit.**

CODING

Non-Covered CPT®* Codes

90901 Biofeedback training by any modality

Non-Covered ICD-9-CM Procedure Codes - No applicable code

Non-Covered HCPCS Codes

E0746 Electromyography (EMG), biofeedback device

Non-Covered ICD-9-CM Diagnosis Codes

- 401.0 - 401.9** Essential Hypertension; Malignant, Benign, Unspecified
- 402.00 - 402.91** Hypertensive heart disease; Malignant, Benign; Unspecified
- 403.00 - 403.91** Hypertensive Chronic Kidney Disease; Malignant, Benign, Unspecified
- 404.00 - 404.93** Hypertensive Heart and Chronic Kidney Disease; Malignant, Benign, Unspecified
- 405.00 - 405.93** Secondary Hypertension; Malignant, Benign, Unspecified

*Current Procedural Terminology (CPT) 2010 American Medical Association: Chicago, IL.®©

REFERENCES

Peer Reviewed

1. Hayes Brief, Technology at a Glance. RESPeRATE® (InterCure Ltd.) Device to Lower Blood Pressure. November 25, 2008.

Government Agencies, Professional and Medical Organizations

1. Centers for Medicare and Medicaid Services (CMS), National Coverage Determination (NCD) for Biofeedback Therapy (30.1).
2. Centers for Medicare and Medicaid Services (CMS), Local Coverage Determination (LCD) for Biofeedback (L29084). First Coast Service Options, Inc. March 2, 2009.

HISTORY AND REVISIONS

Date	Action
12/1/2011	• New template design approved by MPC.
7/18/2011	• Approved by MPC.