

WellCare Health Plans, Inc.

The WellCare Group of Companies

Clinical Coverage Guideline



WellCare Prescription Insurance, Inc.

*'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.*

WellCare Health Insurance of Illinois, Inc.

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Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

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WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

Harmony Health Plan of Illinois, Inc.

WellCare of Ohio, Inc.



Biofeedback to Lower Blood Pressure Using the RESPeRATE® Device

Guideline Number: HS-103

Original Effective Date: 5/7/2009

Revision Date: n/a

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.

Clinical Coverage Guideline HS-103

Biofeedback to Lower Blood Pressure Using the RESPeRATE® Device

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Revised Date(s): n/a

DISCLAIMER

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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.

CLINICAL COVERAGE GUIDELINE

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

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).

CODING

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

Non-Covered CPT®* Codes

90901 Biofeedback training by any modality

Non-Covered ICD-9-CM Procedure Codes

No applicable code

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) 2009 American Medical Association: Chicago, IL.®©

REFERENCES

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