Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

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

WellCare Health Insurance of Illinois, Inc.

WellCare Health Insurance of New York, Inc.

WellCare Health Plans of New Jersey, Inc.

WellCare of Florida, Inc.

WellCare of Connecticut, Inc.

WellCare of Georgia, Inc.

WellCare of Kentucky, Inc.

WellCare of Louisiana, Inc.

WellCare of New York, Inc.

WellCare of Ohio, Inc.

WellCare of Texas, Inc.

WellCare Prescription Insurance, Inc.

Palatal Implant System (Pillar®) for Obstructive Sleep Apnea

Policy Number: HS-193

Original Effective Date: 3/20/2011

Revised Date(s): 3/1/2012

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

Obstructive sleep apnea (OSA) is a disorder in which breathing stops for periods of at least 10 seconds during sleep. Partial or complete collapse of airway at the back of the throat decreases oxygen uptake and carbon dioxide release. Several apneic episodes during a night's sleep disrupt normal sleep patterns, resulting in excessive daytime sleepiness and other symptoms of sleep-disordered breathing. The pauses in breathing can last 30 seconds or longer and lead to blood oxygen levels falling to as low as 40% in severe cases. This lack of oxygen causes the brain to briefly arouse the body from sleep to restore normal breathing, a pattern that can occur many times during a single night leading to fragmented sleep. Symptoms and effects of untreated OSA can include excessive daytime sleepiness, morning headaches, increased heart rate, elevated blood pressure, increased risk of stroke, increased risk of death due to heart disease, impaired glucose tolerance / insulin resistance, impaired concentration, mood changes, and increased risk for motor vehicle accidents. The prevalence of OSA with excessive daytime sleepiness in adults aged 30 to 60 years is 2% in women and 4% in men.

The Pillar® Palatal Implant System consists of three small woven polyester inserts that are placed in the soft palate to stiffen the palate and thereby reduce the number of episodes of partial or complete blockage of breathing during sleep. Each insert is 18 mm in length and 2 mm in diameter and is placed in a parallel fashion in the soft palate at 2-mm intervals with a special tool provided by the implant manufacturer. Insertion can be performed in a physician's office under local anesthetic. The woven consistency of the polyester inserts is designed to facilitate an inflammatory response to the inserts. This response results in formation of a fibrous capsule surrounding each insert. Due to their close positioning, fibrous connections tie the three polyester inserts together making a raft-like structure that is approximately 10 by 18 mm in size.

The literature search identified two randomized controlled trials (RCTs), a nonrandomized controlled study, and four uncontrolled studies that evaluated the Pillar Palatal Implant System for treatment of OSA. Results of these studies provide preliminary but somewhat inconsistent evidence that this procedure benefits patients who have mild-to-moderate OSA. One RCT found that, compared with placebo treatment, palatal implantation provided statistically significant improvements in two measures of sleep quality. Similar results were obtained in the uncontrolled studies of palatal implantation. Although these results are promising, the magnitude of the benefits has not been large, the largest RCT found that average OSA worsened in spite of treatment, the available studies involved ≤ 1 year of patient monitoring after treatment, and the RCTs compared palatal implants with placebo treatment rather than with other minimally invasive techniques for OSA treatment. Additional studies are needed to determine the role of the Pillar implant system in the management of OSA (from Hayes, 2010).

POSITION STATEMENT

The Pillar® Palatal Implant System (Medtronic Xomed Inc.) for the treatment of obstructive sleep apnea **is considered experimental and investigational** and is NOT a covered benefit.

CODING

Non-Covered CPT© Code when billed for Pillar Palatal Implants for OSA.

42299 Unlisted procedure, Palate, Uvula

ICD-9-CM Procedure Code - 27.64 Insertion of palatal implant

Non-Covered HCPCS Level II© Codes

C9727 Insertion of implants into the soft palate; minimum of three implants

Non-Covered ICD-9-CM Diagnosis Codes

327.23 Obstructive Sleep Apnea (OSA)

***Current Procedural Terminology (CPT®) ©2012 American Medical Association: Chicago, IL.**

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5. Walker, R.P., Levine, H.L., Hopp, M.L., Greene, D., & Pang, K. (2006). Palatal implants: a new approach for the treatment of obstructive sleep apnea. *Otolaryngology Head and Neck Surgery*, *135*(4), 549-554.

Government Agencies, Professional and Medical Organizations

1. Restore Medical, Inc. (2005, August). The Pillar® procedure: scientific overview. Retrieved from http://www.pillarprocedure.com

HISTORY AND REVISIONS

Date	Action
3/1/2012	• Approved by MPC. No changes.
12/1/2011	• New template design approved by MPC.
3/20/2011	• Approved by MPC. New guideline.