



*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.*

## Phonophoresis

Policy Number: HS-089

Original Effective Date: 3/2/2009

Revised Date(s): 3/2/2010; 3/2/2011;  
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

Delivery of medications via the oral or parenteral routes involves challenges such as compliance issues, discomfort (parenteral route), and liver metabolism. As a result, alternatives are being sought, including delivery of medications into the systemic circulation through the skin. The skin has a barrier function, and this essential role renders transdermal drug delivery a challenge, particularly when it comes to molecules that are large and complex. One technology being investigated to enhance transdermal drug delivery is the use of low-frequency ultrasound (US). These US waves, when focused on a small area of the skin, appear to act by temporarily disrupting the skin's outer layer (the stratum corneum) and allowing some types of large molecules to pass through into the dermal layer of the skin to then allow systemic absorption by the capillary network. The combination of low-frequency US and drug delivery is called phonophoresis or sonophoresis.

Overall, the results showed that phonophoresis was associated with a reduction in pain and improvement in function in patients with a variety of musculoskeletal conditions; however, there was a similar improvement in patients who received a placebo drug delivered transcutaneously via low-frequency US. These findings suggest that US alone may have some analgesic or anti-inflammatory effect, or may simply reflect a substantial placebo effect of the treatment. Phonophoresis was not superior to iontophoresis, and two studies reported that it was less effective than local steroid injection. Assessment of phonophoresis was limited by the poor quality of the available studies, which tended to be small, lacked blinding and adequate controls, and provided only short follow-up. Some studies augmented phonophoresis with a number of other rehabilitation interventions, making it impossible to determine whether observed benefits could be attributed to phonophoresis alone (Hayes, 2007).

### *Hayes Statement*

The limited available evidence suggests that phonophoresis may be an effective method of transcutaneous drug delivery. However, results of a few small placebo-controlled studies indicate that US-enhanced drug delivery may not be more effective than US alone, and comparative studies suggest that phonophoresis is not superior to iontophoresis and may be inferior to local injection of steroid. Therefore, phonophoresis as a technology for transcutaneous delivery of anti-inflammatory or analgesic medications is assigned a **Hayes Rating of D**. This Rating reflects the fact that data are sparse, the level of evidence is low, and the available data are inconsistent or conflicting regarding a beneficial treatment effect of this technology.

### *American Academy of Orthopaedic Surgeons Statement*

The following treatments carry no recommendation for or against their use: activity modifications, acupuncture, cognitive behavioral therapy, cold laser, diuretics, exercise, electric stimulation, fitness, Graston instrument, iontophoresis, laser, stretching, massage therapy, magnet therapy, manipulation, medications (including anticonvulsants, antidepressants, and nonsteroidal anti-inflammatory drugs [NSAIDs]), nutritional supplements, phonophoresis, smoking cessation, systemic steroid injection, therapeutic touch, vitamin B6 (pyridoxine), weight reduction, yoga. (Inconclusive, Level II and V). The AAOS issued a 2011 update stating that despite new studies being published they do not change the stance of the association.

### *Ultrasound Devices*

A large number of ultrasound devices are currently available. One system that was specifically developed for transdermal delivery of drugs is the SonoPrep® Ultrasonic Skin Permeation System. This system was developed by Drs. Joseph Kost and Robert Langer from the Chemical and Bioengineering Laboratory at the Massachusetts Institute of Technology and licensed in 1996 by Sontra Medical Corp. The SonoPrep System consists of seven components: control console, hand piece, battery, battery charger, patient reference sensor, AC power adaptor, and decontamination stand. The device is small, battery operated, rechargeable, and readily portable in one hand. To use the system, a 0.8 cm<sup>2</sup> target ring is placed on the skin at the location of interest. The US source is then

placed over the target ring and US waves at 55 kHz are painlessly generated for approximately 5 to 30 seconds (depending on skin condition and location), causing the formation of reversible micro channels approximately 75 microns wide in the skin underneath. Coincident or following this, the drug, generally in combination with a coupling agent, is placed on the skin within the target ring, to be absorbed from there. Treatment can affect skin permeability for up to 24 hours. The device is not designed to be used on injured or otherwise compromised skin.

## POSITION STATEMENT

The ultrasound-enhanced transcutaneous drug delivery method, or phonophoresis, **is considered experimental and investigational and is NOT a covered benefit.**

## CODING

### Non-Covered CPT® Codes

**97035** Application of a modality to one or more areas; ultrasound, each 15 minutes; Constance Attendance

**ICD-9-CM Procedure Codes** - No applicable codes

**HCPCS Codes** - No applicable codes

**ICD-9-CM Diagnosis Codes** - All diagnoses are not covered.

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

## REFERENCES

### Peer Reviewed

1. Hayes Directory. (2007, July 9). Ultrasound-enhanced transcutaneous drug delivery. Retrieved from <http://www.hayesinc.com>
2. Kozanoglu, E., Basaran, S., Guzel, R., & Guler-Uysal, F. (2003). Short term efficacy of ibuprofen phonophoresis versus continuous ultrasound therapy in knee osteoarthritis. *Swiss Medical Weekly*, 133(23-24), 333-338.
3. Rand, S.E., Goerlich, C., Marchand, K., & Jablecki, N. (2007). The physical therapy prescription. *American Family Physician*, 76, 1661-1666.
4. Wong, R.A., Schumann, B., Townsend, R., & Phelps, C.A. (2007). A survey of therapeutic ultrasound use by physical therapists who are orthopaedic certified specialists. *Physical Therapy*, 87, 986-994.

### Government Agencies, Professional and Medical Organizations

1. American Academy of Orthopaedic Surgeons. (2011). AAOS clinical guidelines on the treatment of carpal tunnel syndrome: 2011 report for the re-issue of the original guideline. Retrieved from [http://www.aaos.org/Research/guidelines/CTS\\_Treatment\\_REIssue.pdf](http://www.aaos.org/Research/guidelines/CTS_Treatment_REIssue.pdf)
2. American Academy of Orthopaedic Surgeons. (2008). AAOS clinical guidelines on the treatment of carpal tunnel syndrome. Retrieved from <http://www.aaos.org/Research/guidelines/CTSTreatmentGuideline.pdf>

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**HISTORY AND REVISIONS**

<b>Date</b>	<b>Action</b>
3/1/2012	<ul style="list-style-type: none"><li>• Approved by MPC. New reference pertaining to statement by AAOS (no change from 2008 guideline).</li></ul>
12/1/2011	<ul style="list-style-type: none"><li>• New template design approved by MPC.</li></ul>
3/2/2011	<ul style="list-style-type: none"><li>• Approved by MPC.</li></ul>