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## Medical Policy



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**\*Current Policy Effective Date: 11/1/24**  
(See policy history boxes for previous effective dates)

### **Title: Phonophoresis**

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#### **Description/Background**

Phonophoresis is the use of ultrasound to enhance the transdermal delivery of medications. This procedure is most often used in physical therapy and can be traced back to the late 1950's. Medications applied include anti-inflammatories, corticosteroids and analgesics. In early studies, high-frequency ultrasound (0.7 to 16 MHz) was used. In the mid-1990's, it was shown that low-frequency ultrasound (20-100 kHz) was more effective in enhancing skin permeability; research for the past 20 years has focused primarily on low frequency ultrasound for transdermal drug delivery.<sup>1</sup>

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#### **Regulatory Status:**

The U.S. Food and Drug Administration has approved devices for phonophoresis. The SonoPrep® (Sontra Medical Corporation) phonophoresis is one such device. SonoPrep® uses low frequency ultrasound (55kHz) to enhance skin permeability (K040525) 510(k) Premarket Notification 03/01/2004

Classification Product Code NRJ.

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#### **Medical Policy Statement**

Phonophoresis is considered experimental/investigational for all medical indications. Clinical studies have not demonstrated that phonophoresis increases the rate or extent of absorption of topically applied medications over placebo.

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## Inclusionary and Exclusionary Guidelines

N/A

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**CPT/HCPCS Level II Codes** *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

**Established codes:**

N/A

**Other codes (investigational, not medically necessary, etc.):**

97039

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## Rationale

Kozanoglu et al (2003) compared the effectiveness of ibuprofen phonophoresis (PH) with conventional ultrasound (US) therapy in knee osteoarthritis.<sup>2</sup> Sixty patients with a mean age of  $59.8 \pm 9.0$  years were randomly assigned to PH or US groups. Continuous ultrasonic waves of 1 MHz frequency and 1 watt/cm<sup>2</sup> power were applied for 5 minutes to the target knee joint. Acoustic gel without any active pharmacological agent was applied in the US group, versus cream containing 5% ibuprofen was applied in the PH group for a total treatment period of 10 sessions. The Western Ontario and McMaster Universities Osteoarthritis Index (WOMAC) scores, pain on passive and active motion, 20 metres walking time, knee range of motion (ROM), and global assessments of disease activity and treatment efficacy by the investigator and by the patients were evaluated before and after therapy. The primary outcome measure of the study was a 30% improvement in total WOMAC scores at the end of the study when compared to baseline. At the end of two weeks, 30% improvement in total WOMAC score was observed in 12 (40%) and 14 (46.6%) of patients in the PH and US groups respectively, indicating no significant difference in improvement rates. Pain scores, knee ROM degrees, 20 metres walking time measurements and all global assessment scores also improved significantly in both groups, yet these variables showed no significant differences between the two groups. The authors concluded that both therapeutic modalities were effective; and, ibuprofen phonophoresis was not superior to conventional ultrasound.

Gurney et al (2011) proposed that phonophoresis would facilitate the transmission of hydrocortisone acetate (HA) in human connective tissue.<sup>3</sup> Twenty-one patients undergoing anterior cruciate ligament reconstruction surgery were randomly assigned to either a sham or true phonophoresis treatment group. The latter group received 6 minutes of 10% HA ultrasound at a point consistent with the gastrocnemius slip of the semitendinosus tendon (treatment site). The sham group received 6 minutes of 10% HA ultrasound to the same area, but the ultrasound was not turned on. The slip and a sample of the distal attachment of the tendon (control) were removed. Samples were analyzed for HA levels. Although the mean and median levels of HA found at the treatment site were greater than those of the control site

(means, 34.1 vs 22.9 parts per billion; medians, 7 vs 0 parts per billion), the levels of HA found at the treatment site were not significantly greater than those at the control site ( $p=.15$ ). There were no statistically significant differences between the true and sham phonophoresis groups in HA levels ( $p=.80$ ) nor in age, sex, or skin thickness. The authors concluded that phonophoresis does not appear to facilitate the absorption of HA in connective tissue when compared with simple absorption; and, cautioned that use of phonophoresis should be reconsidered in inflammatory conditions.

The effectiveness of phonophoresis to enhance absorption of medications has not been substantiated.

Dorji et al (2022)<sup>4</sup> Six studies involving 249 participants were included. The QoE was very low GRADE. Phonophoresis with capsaicin plus exercise improved pain at immediate post-treatment (MD: -3.30 [-4.05, -2.55]) but not with diclofenac sodium plus exercise as compared to exercise. Continuous ultrasound (CUS) plus exercise improved pain and pressure pain threshold (PPT) at immediate post-treatment (pain: MD: -3.42 [-4.08, -2.7]); (PPT: MD: 0.91 [0.68, 1.14]) and at intermediate-term as compared to exercise. CUS or high-power pain threshold (HPPT) ultrasound plus manual therapy and exercise showed no benefit for pain reduction (MD: -0.75 [-2.08, 0.58]) did not improve function/disability (MD: -1.05 [-4.27, 2.17]) at immediate or short-term as compared to manual therapy and exercise.

Conclusions: Due to high risk of bias, inconsistency, and indirectness the QoE is very low in support of benefit of ultrasound/phonophoresis as an adjuvant treatment for NSNP. Implication for rehabilitation due to high risk of bias, inconsistency, and indirectness the quality of evidence (QoE) is very low in support of benefit of adding ultrasound or phonophoresis to exercise or manual therapy for pain reduction or improvement in function/disability for those with sub-acute and chronic myofascial associated neck pain. However, our confidence in the findings is very low and conclusions are likely to change as more evidence emerges. Clinicians using ultrasound therapy as an adjuvant intervention for management of chronic myofascial associated neck pain should carefully consider the available evidence on ultrasound, including the benefits and costs involved.

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## **Government Regulations**

### **National/Local:**

There is no NCD or LCD related to phonophoresis.

The 2024 CMS Physician Fee Schedule does not have a fee for code 97039.

*(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)*

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## Related Policies

N/A

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## References

1. Polat BE, et al. Ultrasound-mediated transdermal drug delivery: mechanisms, scope and emerging trends. J Control Release. 2011 Jun 30;152(3):330-348. PMID 21238514
2. Kozanoglu E, Basaran S, Guzel R, et al. Short term efficacy of ibuprofen phonophoresis versus continuous ultrasound therapy in knee osteoarthritis. Swiss Med Wkly. 2003;133:3333-3338. PMID 12923684
3. Gurney AB, Wascher D, Schneck R, et al. Absorption of hydrocortisone acetate in human connective tissue using phonophoresis. Sports Health. Jul-Aug 2011;3(4): 346-351. PMID 23016027
4. Dorji K, Graham N, Macedo L, Gravesande J, Goldsmith CH, Gelley G, Rice M, Solomon P. The effect of ultrasound or phonophoresis as an adjuvant treatment for non-specific neck pain: systematic review of randomised controlled trials. Disabil Rehabil. 2022 Jun;44(13):2968-2974. doi: 10.1080/09638288.2020.1851785. Epub 2020 Nov 30. PMID: 33253599.

*The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 5/31/24, the date the research was completed.*

### Joint BCBSM/BCN Medical Policy History

<b>Policy Effective Date</b>	<b>BCBSM Signature Date</b>	<b>BCN Signature Date</b>	<b>Comments</b>
11/1/06	8/30/06	9/18/06	Joint policy established
11/1/08	8/19/08	10/30/08	Updated policy
1/1/12	10/11/11	11/9/11	Routine maintenance
5/1/13	2/19/13	3/4/13	Routine maintenance
3/1/15	12/12/14	12/29/14	Routine maintenance
7/1/16	4/19/16	4/19/16	Routine maintenance
5/1/17	2/21/17	2/21/17	Routine maintenance Updated policy statement to reflect that phonophoresis is experimental/investigational for all indications.
1/1/18	10/19/17	10/19/17	Routine maintenance
1/1/19	10/16/18	10/16/18	Routine maintenance
1/1/20	10/15/19		Routine maintenance
1/1/21	10/20/20		Routine maintenance Ref 1 added
1/1/22	10/19/21		Routine maintenance Ref 2,3 added
1/1/23	10/18/22		Routine maintenance (ls)
11/1/23	8/15/23		Routine maintenance (jf) Vendor Managed: NA Added ref 4
11/1/24	8/20/24		Routine maintenance (jf) Vendor Managed: NA

Next Review Date: 3rd Qtr, 2025

**BLUE CARE NETWORK BENEFIT COVERAGE  
POLICY: PHONOPHORESIS**

**I. Coverage Determination:**

<b>Commercial HMO (includes Self-Funded groups unless otherwise specified)</b>	Not covered.
<b>BCNA (Medicare Advantage)</b>	See Government Regulations Section.
<b>BCN65 (Medicare Complementary)</b>	Coinsurance covered if primary Medicare covers the service.

**II. Administrative Guidelines:**

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.