

## Transcutaneous or Peripheral Magnetic Stimulation (TCMS/PMS)

**Policy MP-077**

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### **Disclaimer:**

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, CHIP and Healthy U (Medicaid) plans. Refer to the "Policy" section for more information.
3. Services requiring prior-authorization may not be covered, if prior-authorization is not obtained
4. **This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.**

### **Description:**

In the peripheral nervous system, afferent nerve fibers are part of the sensory nervous system and arise from outside of the central nervous system.

Transcutaneous Magnetic Stimulation (TCMS) also called peripheral magnetic stimulation (PMS) is a non-invasive method of delivering a rapidly pulsed, high-intensity magnetic field to the periphery other than the brain. TCMS/PMS is thought to be another useful method to induce proprioceptive afferent fibers to increase motor control in stroke patients. When the pulse of the magnetic field passes into the body, it will induce a voltage difference between any two points. This creates an electric field and induces electrons to flow between these two points. Unlike electrical stimulation, magnetic stimulation does not need a traverse of electric current through electrodes, skin, and tissue interface. The magnetic field acts as the vehicle to induce ions to flow, and it does not stimulate the nervous tissue itself. However, once the ion flow is created, the mechanism of both electrical and magnetic stimulation at the neural level is the same. Because of the higher stimulation threshold of the cell bodies, peripheral magnetic stimulation will stimulate axons rather than cell bodies.

### **Policy Statement and Criteria**

#### **1. Commercial Plans/CHIP**

**U of U Health Plans does NOT cover transcutaneous or peripheral magnetic stimulation for any indication as it is considered experimental/investigational.**

## **2. Medicaid Plans**

**Coverage is determined by the State of Utah Medicaid program; if Utah State Medicaid has no published coverage position and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicaid policies and coverage, please visit their website at:**

**<http://health.utah.gov/medicaid/manuals/directory.php> or the [Utah Medicaid code Look-Up tool](#)**

**CPT/HCPCS codes covered by Utah State Medicaid may still require further evaluation to determine medical necessity for coverage.**

## **Clinical Rationale**

In a 2022 systematic review, Hwang et al searched for clinical studies of repetitive peripheral magnetic stimulation (rPMS) applied for rehabilitation of dysphagia between 2010 and 2022. This systematic review performed a literature search of four databases (Medline, Embase, CINAHL, and Web of Science) to identify relevant studies published on the application of repetitive peripheral magnetic stimulation (rPMS) for swallowing-related muscles between 2010 and 2022. Seven studies were found in which rPMS was applied to strengthen the submental suprahyoid muscles. The intervention regime varied. The rPMS was applied at a frequency of 30 Hz for 2 s. Rest time ranged from 8 s to 27-28 s. The number of intervention sessions ranged from 2-3 to 30. The intensity ranged from pain-inducing minimum intensity (90% of maximum stimulus output) to non-painful intensity (70-80% of maximum intensity). The rPMS on the suprahyoid muscles had positive effects on physiological changes in the swallowing function, such as displacement of the hyoid bone, muscle strength (cervical flexor, jaw-opening force), swallowing safety, swallowing performance, and swallowing-related quality of life. Participants also reported little pain and adverse reactions during rPMS. The authors found that although rPMS is a therapeutic option that can help improve the swallowing function as a non-invasive stimulation method in the rehabilitation of dysphagia further clinical evidence is needed for the development of clear stimulation protocols and guidelines.

In a 2023 systematic review, Dana et al conducted a search of the literature from inception to July 2023 on the effects of peripheral magnetic stimulation (PMS) in the treatment of chronic peripheral neuropathic pain. Twenty-three studies were identified which included 15 randomized controlled trials (RCTs), five case series, two case reports, and one non-randomized trial. PMS regimens varied across studies and ranged from 5 to 240 min per session over 1 day to 1 year of treatment. Results across included studies were mixed, with some studies suggesting benefits while others showing no significant differences. Of nine placebo-controlled RCTs, four reported statistically significant findings in favor of PMS use. In the meta-analysis, PMS significantly reduced pain scores compared to control within 0-1 month of use (mean difference -1.64 on a 0-10 numeric rating scale, 95% confidence interval -2.73 to -0.56,  $p = 0.003$ ,  $I(2) = 94%$ , 7 studies [264 participants], very low quality of evidence), but not at the 1-3 months and >3 months of PMS use (very low and low quality of evidence, respectively). Minimal to no adverse effects were reported with PMS use. The authors found limited and low-quality evidence to make definitive recommendations on PMS usage, however, the available data is encouraging, especially

for short-term applications of this novel modality. They recommended larger, more robust, high-quality randomized controlled trials are required to establish definitive efficacy and safety effects of PMS.

A 2023 meta-analysis by Diao et al investigated the effects of repetitive peripheral magnetic stimulation (rPMS) on pain intensity, functional mobility, and kinesiophobia in individuals with low back pain (LBP) from inception until November 25, 2022. Eligible randomized controlled trials contained information on the population LBP, intervention (rPMS), and outcomes (pain intensity, functional mobility, and kinesiophobia). Participants in the rPMS intervention group were compared with those in sham or other control groups. Two independent researchers searched for, screened, and qualified the articles. Two independent researchers extracted key information from each eligible study. The authors' names, year of publication, setting, total sample size, rPMS parameters, baseline/mean difference (MD), and 95% confidence interval (CI) were extracted using a standardized form, and the methodological quality was assessed using the Physiotherapy Evidence Database score and GRADE (Grading of Recommendations, Assessment, Development, and Evaluation) system. Of 733 studies identified, 6 randomized controlled trials (n = 139) were included for meta-analysis. Compared with sham rPMS or other therapy, rPMS showed significant efficacy in reducing pain intensity (visual analog scale: MD, -1.89; 95% CI, -3.32 to -0.47;  $P < .05$ ; very low-quality evidence). Significant efficacy was also found in terms of functional disability (Oswestry Disability Index: MD, -8.39; 95% CI, -13.65 to -3.12;  $P < .001$ ; low-quality evidence). However, there was no statistically significant between-group difference on the Tampa scale of kinesiophobia (MD, -1.81; 95% CI, -7.60 to 3.98;  $P > .05$ ; very low-quality evidence). The authors found very low- to low-quality evidence that rPMS can be used to reduce pain intensity and improve functional disability in individuals with LBP. However, no significant effect of rPMS on kinesiophobia was found of repetitive peripheral magnetic stimulation (rPMS) on pain intensity, functional mobility, and kinesiophobia in individuals with LBP.

In a 2014 case series, Leung et al noted that peripheral nerve injury can result in the formation of neuroma/nerve entrapment, a persistent peripheral neuropathic pain state that is often refractory to invasive interventions or medications. A new intervention, transcutaneous magnetic stimulation (TCMS), is derived from the use of transcranial magnetic stimulation in which a rapid discharge of electric current is converted into dynamic magnetic flux for modulating neuronal functions. Low-frequency (0.5 Hz) TCMS was developed over the site of neuroma/nerve entrapment in 5 patients who have failed both steroid injection and conventional pain medications; 400 pulses of stimulation were delivered per treatment session. Each patient received 3 to 4 sessions of treatment over a period of 2 months. Pre- and post-intervention spontaneous pain levels were evaluated with NRS; 5 patients with post-traumatic neuroma/nerve entrapment pain received the treatment. Average pre- and post-scores ( $\pm$  SD) on the NRS were 5.00 ( $\pm$  1.41) and 0.80 ( $\pm$  1.10), respectively, with an average pain reduction of 84 ( $\pm$  21.91) % in the NRS after 3 to 4 treatments within 2 months. This analgesic effect appeared to be sustainable with repeated treatment delivered at a 6- to 8-week duration. Pre-treatment tactile allodynia found in 3 patients resolved after the initial 2-month treatment sessions. In conclusion, the authors found that TCMS offered a non-invasive therapeutic option for neuroma-related neuropathic pain conditions. However, further RCTs are needed to validate the efficacy of this treatment modality and additional studies to examine the underlying electrophysiological mechanisms of the observed analgesic benefit.

A pilot study from 2021 (Rao et al) assessed the safety and efficacy of high intensity transcutaneous magnetic stimulation (TCMS) delivered to the feet of 10 participants (only 9 completed the study) with painful diabetic peripheral neuropathy (DPN). Treatment consisted of a single session of 1.2 Tesla magnetic pulses delivered to the plantar and dorsal surfaces of the foot. Each surface received 50 pulses with a 6 second pulse period over 5 minutes. Pain was measured using the Numeric Pain Rating Scale (pain level: 1-10) after 10 steps in stocking feet on a hard floor surface. Pain scores were collected from

each foot and then averaged. Scores were recorded before treatment and followed for 28 days after treatment. The mean duration of diabetes was 24.3 years and the mean duration of neuropathy was 11.7 years. Baseline hemoglobin A1c (HbA1c) was 7.77%, (only available for 7 of the participants). Prior to treatment, baseline pain in each foot was measured. Participants had an average pain score of  $5.72 \pm 0.97$  (mean  $\pm$  SD). Immediately post-treatment, pain decreased to  $1.22 \pm 1.79$ , a 78% improvement, with 5 individuals reporting no pain, i.e., 100% improvement. Reductions in pain were significant up to 7 days post-treatment ( $P = .0295$ ). Treatment success was experienced by 6 participants, which was determined by a 3 point or greater decrease in pain from baseline one day post-treatment. Immediately after TCMS treatment, pain improvement did not correlate with diabetes duration ( $P = .3818$ ), neuropathy duration ( $P = .5704$ ), or HbA1c ( $P = .4409$ ) at 7 days post-treatment, pain improvement correlated with lower HbA1c ( $P = .0297$ ). The authors concluded that with one 20-minute session of high intensity TCMS delivered to the feet provided pain relief lasting up to 7 days in individuals with painful DPN. No adverse events were observed with treatment. Therefore, based on these findings, high intensity TCMS warrants further investigation as a therapy for painful DPN.

In 2022, Kanjanapanang et al assessed peripheral magnetic stimulation (PMS) or transcutaneous magnetic stimulation as a non-invasive method of delivering a rapidly pulsed, high-intensity magnetic field to the periphery other than the brain. Interest in the research and clinical applications has increased over the last three decades as it is considered a novel, painless, and easy approach for many neurological and musculoskeletal conditions. The authors found that unlike transcranial magnetic stimulation, the safety data regarding PMS remain insufficient and solid evidence for its efficacy is lacking. Many studies demonstrated peripheral magnetic stimulation to be advantageous in many medical conditions. However, more evidence is needed for validating the effectiveness of PMS in certain clinical settings for any indications.

Two studies in 2023 also explored transcutaneous magnetic stimulation (TCMS) in management of various conditions. In the first, Rao et al evaluated TCMS for decreasing pain in several neurologic conditions. This multicenter parallel double-blind phase II clinical trial is a follow-up to a pilot study that demonstrated pain relief in patients with diabetic peripheral neuropathy (DPN) treated with TCMS. Thirty-four participants with confirmed DPN and baseline pain score  $\geq 5$  were randomized to treatment at two sites. Participants were treated with either TCMS ( $n = 18$ ) or sham ( $n = 16$ ) applied to each foot once a week for four weeks. Pain scores using the Numeric Pain Rating Scale after 10 steps on a hard floor surface and answers to Patient-Reported Outcomes Measurement Information System pain questions were recorded by participants daily for 28 days. Thirty-one participants completed the study and were analyzed. Average pain scores decreased from baseline in both the groups. The difference in pain scores between TCMS and sham treatments was -0.55 for morning, -0.13 for evening, and -0.34 overall, below the pre-determined clinically relevant difference of -2. Moderate adverse events that resolved spontaneously were experienced in both treatment arms. This two-arm trial, failed to demonstrate a significant benefit over sham in patient reported pain suggesting a substantial placebo effect in our previous pilot study.

The second 2023 study (Panathoop et al) compared the effects of rPMS and conventional therapy in the management of carpal tunnel syndrome (CTS). Repetitive peripheral magnetic stimulation (rPMS) is a potential therapeutic option for focal peripheral nerve disease and may be beneficial for CTS treatment. The study compared the effects of rPMS and conventional therapy in the management of CTS. A blinded assessor randomly assigned 24 participants with electrodiagnostically-confirmed mild or moderate CTS to either rPMS or conventional therapy. Both groups were briefed on disease progression and tendon-gliding exercises. In the intervention group, the rPMS protocol, five sessions of rPMS-with a frequency of 10 Hz, 10 pulses/train, and 100 trains/session-were performed over a period of 2 weeks, with three

sessions in the first week and two sessions in the second week. At baseline and the end of the second week, the Boston Carpal Tunnel Questionnaire, pinch strength, and electrodiagnostic results were evaluated. The rPMS group demonstrated significantly greater within-group improvement in symptom severity scores (2.3 vs. 1.6,  $p = 0.009$ ) and pinch strength (10.6 lbs vs. 13.8 lbs,  $p < 0.001$ ). Regarding electrodiagnostic parameters, sensory nerve action potential (SNAP) amplitude was significantly increased (8.7 microV vs. 14.3 microV,  $p = 0.002$ ) within the group treated with rPMS. With conventional therapy, there were no statistically significant within-group differences. Multiple linear regression models showed that there were no significant differences in other outcomes in between-group comparisons. The authors found that five sessions of rPMS resulted in significant reduction in symptom severity, improvement in pinch strength and increase in SNAP amplitude. However, further more robust studies are needed to investigate the clinical utility of rPMS using a larger sample and longer treatment and follow-up durations.

## Applicable Coding

### CPT Codes

#### Non-covered codes

- 0766T** Transcutaneous magnetic stimulation by focused low-frequency electromagnetic pulse, peripheral nerve, initial treatment, with identification and marking of the treatment location, including noninvasive electroneurographic localization (nerve conduction localization), when performed; first nerve
- 0767T** ; each additional nerve (List separately in addition to code for primary procedure)
- 64999** Unlisted procedure, nervous system

### HCPCS Codes

No applicable codes

### References:

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3. Hwang, N. K., J. S. Park, J. B. Choi and Y. J. Jung (2022). "Effect of Peripheral Magnetic Stimulation for Dysphagia Rehabilitation: A Systematic Review." *Nutrients* 14(17).
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