UnitedHealthcare®

MEDICAL POLICY

TRANSCUTANEOUS ELECTRICAL NERVE STIMULATION (TENS) FOR THE TREATMENT OF NAUSEA AND VOMITING

Policy Number: 2013T0240K
Effective Date: November 1, 2013

Table of Contents

Related Medical Policies:
Gastrointestinal Motility Disorders, Diagnosis and Treatment

Related Coverage Determination Guidelines:
None

INSTRUCTIONS FOR USE
This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD)) may differ greatly. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

COVERAGE RATIONALE

Transcutaneous electrical nerve stimulation (TENS) including electrical acupoint stimulation devices is unproven for the treatment of nausea and vomiting of any etiology. There is insufficient evidence to conclude that TENS decreases post-operative nausea and vomiting (PONV), chemotherapy-induced nausea, and the nausea and vomiting of pregnancy and motion sickness. Clinical evidence regarding the efficacy of TENS for treating nausea and vomiting is conflicting and further research is warranted.

BACKGROUND

Nausea and vomiting may be caused by a variety of conditions including pregnancy, motion sickness, post-operative nausea and vomiting (PONV), and chemotherapy-induced nausea and vomiting.

There are many medications currently available to treat nausea and vomiting. Unfortunately, these medications are not always successful at treating postoperative and chemotherapy-induced nausea and vomiting. Most of these drugs are contraindicated in pregnancy. In addition, these medications are associated with adverse side effects that include drowsiness and tremor. These concerns have led researchers to investigate alternative approaches to the treatment of nausea and vomiting, such as transcutaneous electrical nerve stimulation (TENS), which has anecdotally been reported to decrease nausea and vomiting caused by a variety of conditions.

A TENS device consists of an electrical signal generator that transmits pulses of electrical current to electrodes on the skin. The TENS unit is programmable, and the generators are capable of delivering stimulation in different rates and intensities. Conventional TENS has a high stimulation frequency and low intensity. Pulsed (burst) TENS uses low-intensity stimulation firing in high-frequency bursts.

TENS is closely related to the techniques of acupressure and acupuncture since some of the TENS devices are designed to stimulate the area of the wrist that corresponds to the suspected acupuncture point that may prevent nausea and vomiting. This form of TENS may also be referred to as electroacupoint stimulation or acustimulation. The ReliefBand® was marketed as an electrical acupoint stimulation device; however, this product name has been discontinued. Other versions of this product are available by prescription and over the counter in pharmacies for use with motion sickness, chemotherapy, and pregnancy. PrimaBella® is a device that uses the same technology as the ReliefBand. It is intended for treatment of nausea and vomiting due to pregnancy. Reletex® is being marketed for postoperative nausea and vomiting. Acupressure wristbands (bands that apply pressure, but not electrical stimulation) are not addressed in this policy.

CLINICAL EVIDENCE

Chemotherapy-Induced Nausea and Vomiting
The clinical evidence was reviewed on September 13, 2013 with no additional information identified that would change the unproven conclusion for transcutaneous electrical nerve stimulation (TENS) used for chemotherapy-induced nausea and vomiting.

In a meta-analysis, Ezzo et al. (2006) assessed the effectiveness of acupuncture-point stimulation on acute and delayed chemotherapy-induced nausea and vomiting in cancer patients. Randomized trials of acupuncture-point stimulation by any method (needles, electrical stimulation, magnets, or acupressure) for chemotherapy-induced nausea or vomiting, or both was reviewed. Eleven trials (N = 1247) were pooled. Overall, acupuncture-point stimulation of all methods combined reduced the incidence of acute vomiting, but not acute or delayed nausea severity compared to control. By modality, stimulation with needles reduced proportion of acute vomiting but not acute nausea severity. Electroacupuncture reduced the proportion of acute vomiting, but manual acupuncture did not; delayed symptoms for acupuncture were not reported. Noninvasive electrostimulation showed no benefit for any outcome. All trials used concomitant pharmacologic antiemetics, and all, except electroacupuncture trials, used state-of-the-art antiemetics. It was therefore concluded that electroacupuncture demonstrated benefit for chemotherapy-induced acute vomiting, but studies combining electroacupuncture with state-of-the-art antiemetics and in patients with refractory symptoms are needed to determine clinical relevance. Noninvasive electrostimulation appears unlikely to have a clinically relevant impact when patients are given state-of-the-art pharmacologic antiemetic therapy.

Chao et al. (2009) assessed the application of acupoint stimulation on six conditions related to anticancer therapies including vasomotor syndrome, chemotherapy-induced nausea and vomiting, lymphedema, post-operation pain, aromatase inhibitors-related joint pain and leukopenia. Twenty-six papers, 18 in English and eight in Chinese, satisfied the inclusion criteria. Modalities of acupoint stimulation used included traditional acupuncture, acupressure, electroacupuncture, and the use of magnetic device on acupuncture points. Overall, 23 trials (88%) reported positive outcomes on at least one of the conditions examined. However, only nine trials (35%) were of high quality. Three high quality trials revealed that acupoint stimulation on P6 (NeiGuang) was beneficial to chemotherapy-induced nausea and vomiting. For other adverse events, the quality of many of the trials identified was poor; no conclusive remarks can be made. Very few minor adverse events were observed, and only in five trials. Acupoint stimulation (APS), in particular acupressure on the P6 acupoint, appears beneficial in the management of chemotherapy-induced nausea and vomiting, especially in the acute phase. According to the authors, more well-designed trials using rigorous methodology are required to evaluate the effectiveness of acupoint stimulation interventions on managing other distress symptoms.

Roscoe et al. (2006) examined the efficacy of acupressure wristbands, compared with standard care alone and acustimulation wristbands, in preventing severe nausea among 86 breast cancer patients receiving doxorubicin-based chemotherapy who were at high risk of experiencing severe nausea. Significant differences in the proportion of patients who reported severe nausea were observed across three conditions (standard care, standard care with acupressure bands, and standard care with an acustimulation band). The proportion of patients in the acupressure band group who reported severe nausea following their chemotherapy treatment (41%) was significantly less than that of the standard care group (68%) and the acustimulation band group (73%).

Following chemotherapy, in a small cohort, there was no demonstrated difference in the frequency of nausea or vomiting for patients using an active TENS device or a sham device (Pearl, 1999). Another study (n=49) evaluated the effectiveness of the ReliefBand as an adjunct to standard antiemetics for the treatment of nausea and vomiting in patients receiving chemotherapy (Treish, 2003). Patients wearing the ReliefBand experienced less vomiting and nausea over a 5-day period than the patients wearing the inactive device. Limitations of this study included differences in risk factors for chemotherapy, emesis, and antiemetic regimens. The authors indicated that a larger, randomized study is needed to define optimal use of the ReliefBand. Acustimulation wrist bands were also studied in 96 women for relief of chemotherapy-induced nausea using a randomized 3-arm clinical trial (active acustimulation, sham acustimulation, and no acustimulation) (Roscoe, 2005). Study results did not support the use of acustimulation bands as an adjunct to antiemetics because there were no significant differences in the 3 treatment conditions. Another randomized study of 739 patients with chemotherapy-induced nausea and vomiting concluded that there were no significant differences in women among 3 treatment conditions (acupressure band, acustimulation band, or no band) (Roscoe, 2003). Men using the acustimulation device, but not the acupressure device, had less nausea and vomiting compared to controls.

Post-Operative Nausea and Vomiting

The clinical evidence was reviewed on September 13, 2013 with no additional information identified that would change the unproven conclusion for transcutaneous electrical nerve stimulation (TENS) used for postoperative nausea and vomiting.

In a clinical single-masked randomized study, Silva et al. (2012) assessed the effect of transcutaneous electrical nerve stimulation (TENS) on pain, nausea, and emesis in 42 patients who had surgery for laparoscopic cholecystectomy. The patients were divided into two groups: placebo TENS (n=21 patients) and active TENS (n=21 patients). The relative risk of nausea and/or emesis was 2.17 times greater for patients from the placebo group. The authors concluded that active TENS promoted fewer complaints of nausea and emesis in patients who underwent

laparoscopic cholecystectomy surgery. The small study population limits the validity of the conclusion of this study.

Ng et al. (2011) investigated the effect of transcutaneous electrical nervous stimulation applied over acupuncture points (Acu-TENS) on heart rate (HR), blood pressure (BP), rate pressure product (RPP) and nausea and vomiting score after open-heart surgery. Forty patients were randomly allocated to either an Acu-TENS group, which received a 40-min session of TENS applied bilaterally over the acupuncture point PC6 on postoperative days 1-5, or a Placebo-TENS group, which received identical electrode placement but with no electrical output from the TENS unit, despite an output indicator light appearing activated. Daily HR, BP and antiemetic administration data were recorded from 20 consecutive subjects who received no intervention and formed the control group. The dose of Maxolon required was lowest in the Acu-TENS group. According to the authors, the small number of patients in each group suffering nausea and vomiting limits the power of statistical analysis for this study.

In a prospective, blind, and randomized study, Xu et al. (2012) evaluated the effectiveness of transcutaneous electrical acupoint stimulation (TEAS) at P6 for the prophylaxis of postoperative nausea and vomiting (PONV) in patients undergoing infratentorial craniotomy. Patients received TEAS at P6 on the dominant side starting 30 minutes before the induction of anesthesia and up to 24 hours after surgery or sham acustimulation at P6. Antiemetics with 4 mg ondansetron and 10 mg dexamethasone were administered intraoperatively. Of the 130 patients enrolled, 119 patients completed the study. The 24-hour cumulative incidence of vomiting was significantly lower in the TEAS group than in the control group (22% vs. 41%). The cumulative incidences of nausea at 6 hours (27% vs. 47%) and 24 hours (33% vs. 58%) after surgery were also significantly lower in the TEAS group compared with the control group. The overall requirements of rescue antiemetics were similar between the groups. The authors concluded that perioperative TEAS at P6 may be an effective adjunct to the standard antiemetic drug therapy for the prevention of PONV after infratentorial craniotomy. According to the authors, this study has several limitations. PON is a subjective endpoint, and patients receiving active stimulation were more likely to detect a tingling sensation and deduce which group they belonged to. The study could not be strictly blinded for evaluating reductions in nausea because patient bias might have contributed to the greater antinausea efficacy of acustimulation. Because of the limited observation period, the authors were not able to investigate the prolonged effects of acustimulation after 24 hours. According to the authors, opioids are often used for postoperative analgesia in craniotomy patients. Whether TEAS also has the same effects when opioids are used needs to be confirmed.

Lee and Fan (2009) evaluated the efficacy and safety of P6 acupoint stimulation in preventing postoperative nausea and vomiting (PONV) in a systematic review. The review included 40 randomized controlled trials involving 4858 participants; four trials reported adequate allocation concealment. Twelve trials did not report all outcomes. Techniques intended to stimulate the P6 acupoint included acupuncture, electro-acupuncture, laser acupuncture, transcutaneous electrical stimulation, an acu-stimulation device, acupressure, and capsicum plaster; versus sham treatment or drug therapy for the prevention of PONV. Five of the studies included in the review were for transcutaneous electrical nerve stimulation or an acustimulation device (Fassoulaki 1993; Gan 2004; Habib 2006; Ho 1989; White 2002; Zarate 2001). These diverse techniques were considered as one entity in the main analysis, consistent with the concept that stimulating the correct acupuncture point is more important than the nature of the stimulus. Compared with sham treatment, P6 acupoint stimulation significantly reduced nausea; vomiting, and the need for rescue antiemetics. Heterogeneity among trials was moderate. There was no clear difference in the effectiveness of P6 acupoint stimulation for adults and children; or for invasive and noninvasive acupoint stimulation. There was no evidence of difference between P6 acupoint stimulation and antiemetic drugs in the risk of nausea, vomiting, or the need for rescue antiemetics. The side effects associated with P6 acupoint stimulation were minor. There was no evidence of publication bias from contour-enhanced funnel plots. The authors concluded that P6

acupoint stimulation prevented PONV. There was no reliable evidence for differences in risks of postoperative nausea or vomiting after P6 acupoint stimulation compared to antiemetic drugs.

Allen et al. (2008) performed a systematic review to determine the overall efficacy of P6 stimulation in preventing intraoperative and postoperative nausea and vomiting (IONV and PONV) in women having cesarean delivery under neuraxial anesthesia. Six studies involving 649 patients were included in this review. According to the authors, some studies showed a benefit of P6 stimulation, but this finding was not consistent. The presence of heterogeneity and inconsistent results among the included trials prevents any definitive conclusions on the efficacy of P6 stimulation in reducing IONV and PONV associated with cesarean delivery performed under neuraxial anesthesia.

In a systematic review, Lee and Done (1999) evaluated the effectiveness of non-pharmacologic techniques to prevent post-operative nausea and vomiting (PONV). These studies included acupuncture, electroacupuncture, transcutaneous electrical nerve stimulation, acupoint stimulation, and acupressure. Twenty-six trials (n=3347) were included, none of which reported adequate allocation concealment. There were significant reductions in the risks of nausea, vomiting and the need for rescue antiemetics in the P6 acupoint stimulation group compared with the sham treatment, although many of the trials were heterogeneous. There was no evidence of difference in the risk of nausea and vomiting in the P6 acupoint stimulation group versus individual antiemetic groups. However, when different antiemetics were pooled, there was significant reduction in the risk of nausea but not vomiting in the P6 acupoint stimulation group compared with the antiemetic group. The authors concluded that this systematic review supports the use of P6 acupoint stimulation in patients without antiemetic prophylaxis. Compared with antiemetic prophylaxis, P6 acupoint stimulation seems to reduce the risk of nausea but not vomiting.

A meta-analysis of trials of acustimulation for preventing PONV in children reported the results of twelve trials (Dune and Shiao, 2006). Compared with the control groups, all acustimulation (AS) modalities reduced vomiting and nausea. Acupressure (two trials) and acupuncture (six trials) modalities were effective in reducing vomiting; however, electrical stimulation (ETS) (two trials) did not show significant effects in reducing the vomiting in children. Compared with the controls, medications (three trials) reduced vomiting. There were no differences between the medication and AS treatments (three trials) in reducing vomiting. The authors stated that all acustimulation modalities reduced nausea and vomiting; however, the included trials were highly heterogeneous, and therefore it is difficult to aggregate their collective results. In any event, results were mixed.

Yeh et al. (2010) evaluated the effect of acupoint electrical stimulation with patient-controlled analgesia (PCA) on reducing acute pain, nausea, and vomiting after surgery for nontraumatic spinal cord injury. A randomized, controlled, repeated measures research design was used. Ninety-nine patients undergoing lumbar spinal surgery were randomly assigned to one of three groups. Patients in experimental group 1 (EG1) received true acupoint electrical simulation three times, whereas those in experimental group 2 (EG2) received sham acupoint manually. Patients in the control group (CG) received no acupoint intervention. Significant differences were found in postoperative pain, respiratory rate, blood pressure, and opiate doses across time in the three groups with better outcomes observed in EG1 than in EG2. However, no between-group difference was found in initial demand for PCA or in postoperative nausea and vomiting (PONV). The authors concluded that more studies are needed to evaluate the effects of acupoint electrical stimulation on PONV following other surgical procedures.

El-Deeb and Ahmady (2011) compared the effect of electrical acustimulation with ondansetron for preventing intraoperative and postoperative emetic symptoms. A total of 450 parturients scheduled for elective cesarean delivery were randomly allocated to receive either electrical stimulation using P6 acupoint (pericardium 6) bilaterally for 30 minutes before spinal anesthesia (group III; n=150), or 4 mg ondansetron 30 minutes before spinal anesthesia (group II; n=150), or placebo (group I; n =150). Nausea and vomiting were evaluated and recorded intraoperatively

and postoperative for 24 hours by an independent anesthetist. Nausea and vomiting occurred statistically significantly less often in the active treatment groups (II, III) during operation and for 6 hours postoperatively. Patient satisfaction with PONV control was higher with the active treatment groups compared with group I. The authors concluded that electrical acustimulation is comparable to ondansetron in prevention of PONV during and after cesarean delivery under spinal anesthesia and in improving patient satisfaction. However, there was no statistically significant difference between the groups in the incidence of nausea and vomiting from 6 to 24 hours postoperatively. The authors stated that further studies are needed to define the efficacy of safety of electrical acustimulation plus ondansetron as prophylaxis during and after cesarean delivery.

In a prospective, double-blind, randomized, controlled trial, Frey et al. (2009a) evaluated the effectiveness of acustimulation in 200 patients undergoing a laparoscopic cholecystectomy. In the acustimulation group (n=101), an active ReliefBand device was placed at the P6 acupoint. In the sham group (n=99), an inactive device was applied. The incidence of early nausea (up to 2 hours) was significantly lower in the acustimulation than in the sham group (29% vs. 42%). No significant effect could be detected for retching/vomiting. Acustimulation showed no effect on PONV after 6 and 24 hours.

One hundred twenty-two patients undergoing surgical procedures at an outpatient surgery center were randomized to 2 treatment arms. The first arm received the standardized pharmacologic postoperative nausea and vomiting prevention typical for patients undergoing outpatient surgery, whereas in the second arm, the ReliefBand and pharmacologic measures were used. The electroacustimulation arm reported statistically significant lower nausea scores at 30 minutes and 120 minutes postoperatively. In addition, subgroup analysis demonstrated significant findings in favor of the experimental group, with anatomical subsets of surgical patients requiring less pain medication and shorter times from surgery to discharge when compared with the standard treatment. However, electroacustimulation did not have a significant effect on the amount of pain experienced by patients in any group. The authors concluded that this study demonstrates that electroacustimulation offers added protection against symptoms of postoperative nausea and vomiting in an outpatient cosmetic surgery population, representing a safe and cost-effective addition to current pharmacologic preventive measures (Larson et al. 2010). A significant limitation of this study is that the surgical procedures included varied considerably and included cosmetic and reconstructive face, breast, and body contouring procedures. Another limitation of the study is that the post-operative survey of nausea and vomiting were subjectively measured.

Frey et al. (2009b) investigated the effectiveness of acustimulation with the ReliefBand in relation to known risk factors for PONV in a prospective, observer-blind, randomized controlled trial of 200 women undergoing vaginal hysterectomy. Patients received randomly for 24 hours acustimulation (n=101), subdivided into groups of pre-induction (n=48) and post-induction (n=53), or sham stimulation (n=99), subdivided into groups of pre-induction (n=49) or post-induction (n=50). Nausea and vomiting/retching was recorded for 24 hours after operation in the whole group. The incidence of PONV and need for rescue therapy was significantly lower in the acustimulation than in the sham group (PONV, 33% vs 63%; rescue therapy, 39% vs 61%. The risk ratio for acustimulation and PONV was 0.29 and for rescue therapy, it was 0.38. The investigators concluded that continuous 24 hour acustimulation with the ReliefBand decreases PONV, particularly in patients at high risk. According to the investigators, due to the limited sample size, they were not able to investigate interactions between risk factors and acustimulation therapy. The investigators recommended that factorial trials of sufficient sample size (where for two interventions participants are allocated to receive neither intervention, one or the other, or both) should be performed.

Wang et al. (2010) evaluated the effectiveness of transcutaneous electrical acupoint stimulation (TEAS) at the P6 acupoint for prevention of postoperative nausea and vomiting in patients undergoing supratentorial craniotomy. The study population was patients aged 20 to 60 years who underwent supratentorial craniotomy under general anesthesia. Patients were randomized

into 2 groups: stimulation and control. In the former, transcutaneous stimulation electrodes were placed at the right P6 acupoint. In controls, electrodes were positioned at a non-acupoint site. Ondansetron was given as a routine antiemetic treatment for each patient before skin closure. Postoperatively, metoclopramide was administered as a rescue antiemetic. Forty patients received TEAS and 40 were controls. In the TEAS group, 18% of patients had nausea compared with 37% of the controls. The cumulative prevalence of vomiting was 12.5% with acustimulation and 32.5% in controls. The prevalence of nausea, vomiting was significantly lower with TEAS at the P6 acupoint. The investigators concluded that TEAS at the P6 meridian points is an effective adjunct to standard antiemetic drug therapy for prevention of nausea and vomiting in patients undergoing supratentorial craniotomy. The small study population limits the validity of the conclusion of this study.

Habib et al. (2006) randomized 94 patients undergoing cesarean delivery with spinal anesthesia to receive the ReliefBand at the P6 point (active group) or an active ReliefBand applied to the dorsum of the wrist (sham control group). The ReliefBand was applied 30 to 60 minutes pre-operatively and left in place for 24 hours. There was no statistically significant difference between the active and sham control groups in the incidence of intra-operative/post-operative nausea (30 % versus 43 %/23 % versus 41 %), vomiting (13 % versus 9 %/26 % versus 37 %), need for rescue anti-emetics (23 % versus 18 %/34 % versus 39 %), or complete response (55 % versus 57 %/51 % versus 34 %). There was also no difference between the two groups in nausea scores, number of vomiting episodes, or patient satisfaction with post-operative nausea and vomiting management.

Liu et al. (2008) evaluated the efficacy of transcutaneous electroacupoint stimulation for the prevention of postoperative nausea and vomiting (PONV) in the 96 patients undergoing laparoscopic cholecystectomy. Patients were randomized into Neiguan (P6) electroacupoint stimulation group (treated group) and a placebo control group (placement of electrodes without electroacupoint stimulation). The incidence of nausea and vomiting, the dose of antiemetics and the occurrence of severe nausea were all significantly lower in the treated group compared with the control group and the score for pain was reduced in patients of the treated group at 24 hours post-operation. A limitation of this study is the small sample size.

Zheng et al. (2008) assessed the effect of transcutaneous electrical acupoint stimulation (TEAS) on nausea and vomiting (N&V) induced by patient controlled intravenous analgesia (PCIA) with Tramadol. Sixty patients who underwent operations for tumor in the head-neck region and post-operation PCIA, aged 39-65 years, were randomized into two groups, A and B, 30 in each group. Group A received intermittent transcutaneous electrical acupoint stimulation on bilateral Hegu (LI4) and Neiguan (PC6) points. The same management was applied to patients in Group B, with sham TEAS for control. The incidence and degree of N&V, as well as the number of patients who needed remedial antiemetic in Group A were less than those in Group B. The VAS score and PCIA pressing time were lower in Group A than those in Group B in the corresponding time segments respectively.

Tarcin et al. (2004) reported on a study in which 313 adult patients undergoing gastroscopy were randomized to one of four conditions: active TENS (n=78), TENS device attached but turned off (n=79), TENS device attached at sham acupoint (n=79), and no attachments (n=77). No significant differences were found among the four groups with respect to any parameters measured.

A study by Zarate et al. (2001) looked at the use of the ReliefBand in patients having laparoscopic cholecystectomy to prevent PONV. The study involved 231 patients of whom 110 received the treatment of transcutaneous acupoint electrical stimulation at the P6 acupuncture point. Fifty-six patients received a sham device at the P6 point and 55 people received an inactivated device on the dorsum of the wrist. The study attempted to blind the subjects by telling them there may be a sensation with treatment that they "might or might not feel." The results showed statistically significant decrease in average nausea scores for the treatment group versus

the sham and placebo groups. But as with other studies there was no difference in the incidence of vomiting and the need for rescue medications. This study was partially funded by the manufacturer of the device.

In contrast, a study by Cekman et al. (2007), evaluated the effectiveness of transcutaneous electrical nerve stimulation (TENS) on postoperative nausea and vomiting (PONV) in 40 patients who underwent elective laparoscopic cholecystectomy. Patients were randomly divided into two equal groups. Group I received TENS (stimulation group), whereas group II served as the control group (nonstimulation group. Postoperative nausea and vomiting, frequency of dizziness, additional antiemetic and analgesic need, and PONV scores were lower in group I than group II. Electrical stimulation of the vestibular system may be useful in the prevention of PONV. The value of this study is limited by the small sample size.

A randomized double-blind, sham-controlled trial (n=104) by White et al. (2005) evaluated the antiemetic efficacy of the ReliefBand in combination with ondansetron when applied before, after, or both before and after plastic surgery. Patient satisfaction with antiemetic management was significantly higher in the patients receiving peri- or postoperative acustimulation therapy. The limitations of this study were a relatively small sample size in each group and the study primarily included a female study population.

Coloma et al. (2002) reported on a group of 90 patients complaining of nausea or experiencing vomiting or retching within 2 hours after laparoscopic cholecystectomy. These patients were randomized to receive 4 mg of intravenous ondansetron and a sham ReliefBand, 2 ml of intravenous saline and a ReliefBand, or 4 mg of intravenous ondansetron and a ReliefBand. Although the ondansetron and ReliefBand (combination treatment) group demonstrated slightly better results, there was little evidence for the efficacy of acustimulation.

A single-center randomized double-blind controlled study compared the efficacy of the ReliefBand to ondansetron when used alone or in combination for preventing PONV in 120 patients undergoing plastic surgery (White, 2002). The study results indicated that combining ondansetron and TENS treatment may offer advantages over ondansetron alone in preventing nausea and vomiting. A limitation of the study was that the follow-up was brief, only 24 hours.

Nausea and Vomiting Associated with Motion Sickness
The clinical evidence was reviewed on September 13, 2013 with no additional information identified that would change the unproven conclusion for transcutaneous electrical nerve stimulation (TENS) used for motion sickness.

Chu et al. (2012) investigated the effects of TENS on motion sickness (MS) in a within-subjects crossover study that included 15 healthy young men. Each study participant completed four test sessions (control, rotation, TENS, TENS + rotation) in randomized order. Rotary chair combined with pitch movement of the subject's head was used as a model to provoke MS. The TENS protocol involved simultaneous electrical stimulation of posterior neck and Zusanli acupoint. Severity of MS symptoms significantly decreased with TENS intervention. After TENS treatment, subjects were able to concentrate better and showed fewer errors in a cognitive test. Salivary cortisol concentration significantly decreased after TENS treatment. The authors concluded that TENS was effective in reducing MS symptoms as well as alleviating cognitive impairment. The small study population limits the validity of the conclusion of this study.

The results of a clinical controlled trial (n=77) examining the efficacy of acupressure and acustimulation bands for the prevention of motion sickness indicated that the bands did not prevent the development of motion sickness (Miller, 2004).

Nausea and Vomiting Associated with Pregnancy

The clinical evidence was reviewed on September 13, 2013 with no additional information identified that would change the unproven conclusion for transcutaneous electrical nerve stimulation (TENS) used for nausea and vomiting associated with pregnancy.

A study evaluated the effectiveness of electrical nerve stimulation at the P6 point to treat nausea and vomiting in 230 pregnant women (Rosen, 2003). Participants were randomly assigned to receive a device for nerve stimulation therapy or a placebo. A total of 187 women completed the trial. Scores for symptom frequency and distress improved gradually in time in both groups, but to a greater extend in the nerve stimulation group. The investigators concluded that nerve stimulation therapy is effective in reducing nausea and vomiting and promoting weight gain in symptomatic women in the first trimester of pregnancy. This study had a high dropout rate (18%) and was limited by a lack of blinded assessment of the outcomes.

Matthews et al. (2010) assessed the effectiveness and safety of all interventions for nausea, vomiting and retching in early pregnancy, up to 20 weeks' gestation. Randomized controlled trials of any intervention for nausea, vomiting and retching in early pregnancy were included in the review. Twenty-seven trials, with 4041 women, met the inclusion criteria. These trials covered many interventions, including acupressure, acustimulation, acupuncture, ginger, vitamin B6 and several antiemetic drugs. Evidence regarding the effectiveness of P6 acupressure, auricular (ear) acupressure and acustimulation of the P6 point was limited. Acupuncture (P6 or traditional) showed no significant benefit to women in pregnancy. The authors were unable to pool findings from studies for most outcomes due to heterogeneity in study participants, interventions, comparison groups, and outcomes measured or reported. The methodological quality of the included studies was mixed. According to the authors, health professionals need to provide clear guidance to women regarding nausea and vomiting in pregnancy. However, there is a lack of high-quality evidence to support that advice. The authors state that the difficulties in interpreting the results of the studies included in the review highlight the need for specific, consistent and clearly justified outcomes and approaches to measurement in research studies.

Evans et al. (1993) examined the effect of sensory affect stimulation (SAS) delivered through the volar surface of the wrist on pregnancy-induced nausea and vomiting. Twenty-three women with significant nausea and vomiting in the first 14 weeks of pregnancy were enrolled in a randomized, crossover study comparing an active SAS unit and an inactive placebo unit. Twenty-one women experienced improvement in symptoms, 20 (87%) with the SAS unit and 10 (43%) with the placebo device. Nine women had an improvement with both devices. Eleven women reported an improvement with SAS only, while one woman had placebo improvement only. According to the investigators, SAS applied to the wrist can effectively improve pregnancy-induced nausea and vomiting as compared to a placebo device.

Helmreich et al. (2006) conducted a meta-analysis of effects of acustimulation (i.e., acupressure, acupuncture, and electrical stimulation [ETS]) on nausea and vomiting in pregnant women. Fourteen trials, eight random controlled trials (RCTs), with one RCT having two treatment modalities with four groups, and six crossover controlled trials (N = 1655) published over the last 16 years were included in the analysis. Before the treatment, 100% of the women (13 trials, n = 1615 women) were nauseated, and 96.6% reported vomiting. After the treatment, compared with the controls, acustimulation (AS) (all modalities combined) reduced the proportion of nausea and vomiting. Acupressure methods applied by finger pressure or wristband reduced NVP. The ETS method was also effective in reducing NVP. However, the acupuncture method did not show effects on reducing NVP. There was a placebo effect when compared with controls in reducing nausea and vomiting. According to the authors, this meta-analysis demonstrates that acupressure and ETS had greater impact than the acupuncture methods in the treatment of NVP.

Although there is some evidence that TENS may provide nausea and vomiting relief for some patients with postoperative nausea and vomiting, results are conflicting, and the studies have methodological flaws that hamper evaluation of the efficacy of TENS. Studies evaluating the utility of TENS for control of chemotherapy-associated nausea and vomiting also provided conflicting

results and were limited and methodologically flawed. The evidence is too limited to support conclusions regarding efficacy of TENS for control of pregnancy associated nausea and vomiting. Rigorous clinical evaluation will be required to determine whether TENS is effective for control of nausea and vomiting and to define appropriate patient selection criteria, if any.

Professional Societies

The American College of Obstetricians and Gynecologists (ACOG) (2004): According to ACOG's practice bulletin for nausea and vomiting of pregnancy, pressure or electrical stimulation at the P6 point has been studied for nausea and vomiting of pregnancy with conflicting results. ACOG states that the preponderance of the literature does show a benefit, but many of the studies had significant methodologic flaws. A randomized, controlled trial (Rosen, 2003) of acustimulation with a commercial transcutaneous electrical stimulation device for varying degrees of nausea and vomiting of pregnancy found that acustimulation improved nausea and vomiting symptoms in the first trimester (ACOG, 2004).

Society of Obstetricians and Gynecologists of Canada: According to the Society of Obstetricians and Gynecologists of Canada guideline for the management of postoperative nausea and vomiting, acupoint electrical stimulation may be used as an alternative or adjuvant therapy for prevention of PONV (II-1 rating (evidence obtained from well-designed controlled trials without randomization) and grade of A (there is good evidence to recommend the clinical preventive action) (McCracken, 2008).

Additional Search Terms

Antiemetic therapy, alternative medicine, electrostimulation therapy, emesis, transcutaneous electrical acupoint stimulation; electroacupuncture, neuromodulation, P6 acupuncture point

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Transcutaneous electrical nerve stimulation (TENS) units are classified as Class II medical devices. There are currently more than 300 TENS devices approved for marketing within the United States. Additional information may be obtained from the *U.S. Food and Drug Administration* [Web site] - Center for Devices and Radiological Health (CDRH) at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accessed September 2013 (Search by device name or product code GZJ)

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare does not have a National Coverage Determination (NCD) for transcutaneous electrical nerve stimulators (TENS) specific to treatment for nausea and vomiting. Local Coverage Determinations (LCDs) which address treatment for nausea and vomiting with TENS do not exist at this time. (Accessed September 17, 2013)

APPLICABLE CODES

The codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the benefit document. This list of codes may not be all inclusive.

HCPCS Code	Description
E0765	FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting

REFERENCES

Allen, TK, Habib, AS. P6 stimulation for the prevention of nausea and vomiting associated with cesarean delivery under neuraxial anesthesia: a systematic review of randomized controlled trials. Anesth Analg. 2008;107(4):1308-1312.

American College of Obstetrics and Gynecology. ACOG (American College of Obstetrics and Gynecology) Practice Bulletin: nausea and vomiting of pregnancy. Obstet Gynecol. 2004 Apr;103(4):803-14. Reaffirmed 2011.

Cekmen N, Salman B, Keles Z, et al. Transcutaneous electrical nerve stimulation in the prevention of postoperative nausea and vomiting after elective laparoscopic cholecystectomy. J Clin Anesth. 2007 Feb;19(1):49-52.

Chao, LF, Zhang, AL, Liu, HE, et al. The efficacy of acupoint stimulation for the management of therapy-related adverse events in patients with breast cancer: a systematic review. Breast Cancer Res Treat. 2009;118(2):255-267.

Chu H, Li MH, Juan SH, et al. Effects of transcutaneous electrical nerve stimulation on motion sickness induced by rotary chair: a crossover study. J Altern Complement Med. 2012 May;18(5):494-500.

Coloma M, White PF, Ogunnaike BO, et al. Comparison of acustimulation and ondansetron for the treatment of established postoperative nausea and vomiting. Anesthesiology. 2002 Dec;97(6):1387-92.

Dune LS, Shiao SY. Metaanalysis of acustimulation effects on postoperative nausea and vomiting in children. Explore (NY). 2006 Jul-Aug;2(4):314-20.

ECRI Institute. Hotline Response. Acustimulation Wristbands for Nausea and Vomiting. March 2011.

El-Deeb AM, Ahmady MS. Effect of acupuncture on nausea and/or vomiting during and after cesarean section in comparison with ondansetron. J Anesth. 2011 Jul 15.

Evans AT, Samuels SN, Marshall C et al. Suppression of pregnancy-induced nausea and vomiting with sensory afferent stimulation. J Reprod Med. 1993 Aug;38(8):603-6.

Ezzo JM, Richardson MA, Vickers A, et al. Acupuncture-point stimulation for chemotherapy-induced nausea or vomiting. Cochrane Database Syst Rev. 2006 Apr 19;(2):CD002285.

Fassoulaki A, Papilas K, Sarantopoulos C, et al. Transcutaneous electrical nerve stimulation reduces the incidence of vomiting after hysterectomy. Anesthesia and Analgesia 1993;76:1012–4.

Frey UH, Funk M, Löhlein C, Peters J. Effect of P6 acustimulation on post-operative nausea and vomiting in patients undergoing a laparoscopic cholecystectomy. Acta Anaesthesiol Scand. 2009a Nov;53(10):1341-7.

Frey UH, Scharmann P, Löhlein C, et al. P6 acustimulation effectively decreases postoperative nausea and vomiting in high-risk patients. Br J Anaesth. 2009b;102(5):620-625.

Gan TJ, Jiao KR, Zenn M, Georgiade G. A randomized controlled comparison of electro-acupoint stimulation or ondansetron versus placebo for the prevention of postoperative nausea and vomiting. Anesthesia and Analgesia 2004;99:1070–5.

Habib AS, Itchon-Ramos N, Phillips-Bute BG, et al. Transcutaneous acupoint electrical stimulation with the ReliefBand for the prevention of nausea and vomiting during and after cesarean delivery under spinal anesthesia. Anesth Analg. 2006;102(2):581-584.

Hayes, Inc. Medical Technology Directory. Acupuncture and Acupressure for the Treatment of Nausea and Vomiting. May 2011. Update search June 2013.

Hayes, Inc. Medical Technology Directory. Transcutaneous Electrical Nerve Stimulation for the Treatment of Nausea and Vomiting. February 2006. Update search March 2010. Archived March 2011.

Helmreich RJ, Shiao SY, Dune LS. Meta-analysis of acustimulation effects on nausea and vomiting in pregnant women. Explore (NY). 2006 Sep-Oct;2(5):412-21. Erratum in: Explore (NY). 2007 Mar-Apr;3(2):94.

Ho CM, Hseu SS, Tsai SK, Lee TY. Effect of P6 acupressure on prevention of nausea and vomiting after epiduralmorphine for post-Cesarean section pain relief. *Acta* Anaesthesiologica Scandinavica 1996;40:372–5.

Larson JD, Gutowski KA, Marcus BC, Rao et al. The effect of electroacustimulation on postoperative nausea, vomiting, and pain in outpatient plastic surgery patients: a prospective, randomized, blinded, clinical trial. Plast Reconstr Surg. 2010 Mar;125(3):989-94.

Lee A, Done ML. Stimulation of the wrist acupuncture point P6 for preventing postoperative nausea and vomiting. Cochrane Database Syst Rev. 2004; (3):CD003281.

Lee, A, Fan, LT. Stimulation of the wrist acupuncture point P6 for preventing postoperative nausea and vomiting. Cochrane Database Syst Rev. 2009;(2):CD003281.

Liu YY, Duan SE, Cai MX, et al. Evaluation of transcutaneous electroacupoint stimulation with the train-of-four mode for preventing nausea and vomiting after laparoscopic cholecystectomy. Chin J Integr Med. 2008 Jun;14(2):94-7.

Matthews A, Dowswell T, Haas DM, et al. Interventions for nausea and vomiting in early pregnancy. Cochrane Database Syst Rev. 2010 Sep 8;9:CD007575.

McCracken G, Houston P, Lefebvre G; Society of Obstetricians and Gynecologists of Canada. Guideline for the management of postoperative nausea and vomiting. J Obstet Gynaecol Can. 2008 Jul;30(7):600-7, 608-16. English, French. PubMed PMID: 18644183.

Miller KE, Muth ER. Efficacy of acupressure and acustimulation bands for the prevention of motion sickness. Aviat Space Environ Med. 2004 Mar;75(3):227-34.

Ng MC, Jones AY, Cheng LC. The Role of Acu-TENS in Hemodynamic Recovery after Open-Heart Surgery. Evid Based Complement Alternat Med. 2011;2011:301974.

Pearl ML, Fischer M, McCauley DL, et al. Transcutaneous electrical nerve stimulation as an adjunct for controlling chemotherapy-induced nausea and vomiting in gynecologic oncology patients. Cancer Nursing. 1999;22:307-311.

Roscoe JA, Jean-Pierre P, Morrow GR, et al. Exploratory analysis of the usefulness of acupressure bands when severe chemotherapy-related nausea is expected. J Soc Integr Oncol. 2006 Winter;4(1):16-20.

Roscoe JA, Morrow GR, Hickok JT, et al. The efficacy of acupressure and acustimulation wrist bands for the relief of chemotherapy-induced nausea and vomiting. A University of Rochester

Cancer Center Community Clinical Oncology Program multicenter study. J Pain Symptom Manage. 2003 Aug;26(2):731-42.

Roscoe JA, Matteson SE, Morrow GR, et al. Acustimulation wrist bands are not effective for the control of chemotherapy-induced nausea in women with breast cancer. J Pain Symptom Manage. 2005 Apr;29(4):376-84.

Rosen T, de Veciana M, Miller HS, et al. A randomized controlled trial of nerve stimulation for relief of nausea and vomiting in pregnancy. Obstet Gynecol. 2003 Jul;102(1):129-35.

Silva MB, de Melo PR, de Oliveira NM, et al. Analgesic effect of transcutaneous electrical nerve stimulation after laparoscopic cholecystectomy. Am J Phys Med Rehabil. 2012 Aug;91(8):652-7.

Tarcin O, Gurbuz AK, Pocan S, et al. Acustimulation of the Neiguan point during gastroscopy: its effects on nausea and retching. Turk J Gastroenterol. 2004;15(4):258-262.

Treish I, Shord S, Valgus J, et al. Randomized double-blind study of the Reliefband as an adjunct to standard antiemetics in patients receiving moderately-high to highly emetogenic chemotherapy. Support Care Cancer. 2003 Aug;11(8):516-21. Epub 2003 Jun 27.

Wang XQ, Yu JL, Du ZY, Xu R, Jiang CC, Gao X. Electroacupoint stimulation for postoperative nausea and vomiting in patients undergoing supratentorial craniotomy. J Neurosurg Anesthesiol. 2010 Apr;22(2):128-31.

White PF, Hamza MA, Recart A, et al. Optimal timing of acustimulation for antiemetic prophylaxis as an adjunct to ondansetron in patients undergoing plastic surgery. Anesth Analg. 2005 Feb; 100(2):367-72.

White PF, Issioui T, Hu J, et al. Comparative efficacy of acustimulation (ReliefBand) versus ondansetron (Zofran) in combination with droperidol for preventing nausea and vomiting. Anesthesiology. 2002 Nov;97(5):1075-81.

Xu M, Zhou SJ, Jiang CC, et al. The Effects of P6 Electrical Acustimulation on Postoperative Nausea and Vomiting in Patients After Infratentorial Craniotomy. J Neurosurg Anesthesiol. 2012 Jun 22.

Yeh ML, Chung YC, Chen KM, et al. Acupoint electrical stimulation reduces acute postoperative pain in surgical patients with patient-controlled analgesia: a randomized controlled study. Altern Ther Health Med. 2010 Nov-Dec;16(6):10-8.

Zarate E, Mingus M, et al. The Use of Transcutaneous Acupoint Electrical Stimulation for Preventing Nausea and Vomiting After Laparoscopic Surgery. Anesthesia and Analgesia. March 2001; 92(3).

Zheng, LH, Sun, H, Wang, GN, et al. Effect of transcutaneous electrical acupoint stimulation on nausea and vomiting induced by patient controlled intravenous analgesia with tramadol. *Chin J Integr Med*. 2008;14(1):61-64.

POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
11/01/2013	• Updated description of services to reflect most current clinical evidence and references; no change to coverage rationale or list of applicable codes • Archived previous policy version 2013T0240J