Clinical Review Criteria
ReliefBand® Device
To Treat:
- Morning Sickness
- Chemotherapy Nausea
- Post-Operative Nausea

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Criteria
There is insufficient evidence in the published medical literature to show that this service/therapy is as safe as standard services/therapies (and/or) provides better long-term outcomes than current standard services/therapies.

The following information was used in the development of this document and is provided as background only. It is not to be used as coverage criteria. Please only refer to the criteria listed above for coverage determinations.

Background
The Relief Band (Woodside Biomedical, Inc, Carlsbad, CA) is a non-invasive nerve stimulation device that resembles a wristwatch. The battery-powered device emits an electrical stimulus, similar to a TENS unit, and is adjustable for pulse frequency and intensity. The electrical stimulation is targeted to the Nei-Guan P6 acupoint on the underside of the wrist which in traditional Chinese medicine is believed to relieve nausea and vomiting. There are other techniques for stimulating the P6 point including acupuncture (needling) and acupressure (e.g. elasticized wrist bands with a protruding button centered over the P6 point).

The Relief Band (Woodside Biomedical, Inc) received initial FDA approval in February, 1999 as a Class II device to relieve nausea and vomiting due to motion sickness. In March, 2000 newer Relief Band models received FDA approval for the treatment of nausea and vomiting associated with motion sickness, pregnancy and chemotherapy, as an adjunct to antiemetics for post-operative nausea. Over-the-counter Relief Band models were approved in March, 2002 for nausea and vomiting due to motion sickness and for mild to moderate nausea and vomiting during pregnancy.

Medical Technology Assessment Committee (MTAC)
ReliefBand® Device
10/10/2003: MTAC REVIEW

Evidence Conclusion: Pregnancy-related nausea and vomiting: The single RCT on the use of the Relief Band to relieve morning sickness found significantly greater improvement in nausea and vomiting symptoms among women who used the Relief Band for 21 days in early pregnancy compared to those who used a sham device. The primary outcome was the Rhodes Index of Nausea and Vomiting. The Relief Band group had a mean score at follow-up that was 1.83 points lower on the Rhodes Index (out of a total of 32 possible points); the clinical significance of this degree of difference is unclear. The study had some methodological limitations including lack of intention to treat analysis with a 80% study completion rate. Chemotherapy-induced nausea and vomiting: The single RCT on the use of the Relief Band to relieve chemotherapy-induced nausea and vomiting did not find any statistically significant differences in nausea and vomiting outcomes among patients who used a Relief Band compared to an acupressure band or no band following chemotherapy. Post-operative nausea and vomiting (PONV): There were 3 RCTs on this topic, one addressed prevention of PONV following plastic surgery, one addressed prevention of PONV following laparoscopic surgery and one addressed treatment of established PONV...
after laparoscopic surgery. Of the two studies on prophylactic use of the Relief Band, the plastic surgery study found significant reduction of PONV with the relief band plus ondansetron compared to ondansetron alone at 24 hours post-discharge (but not 72 hours discharge). The laparoscopy study found significantly less PONV with the Relief Band compared to an inactive device at most time points during the 9 hour post-operative observation period. In the study of treatment of patients with PONV, there was less use of rescue medication prior to discharge among patients who received the Relief Band plus ondansetron compared to ondansetron alone (but not at the 24 and 72 hour follow-ups). The two studies that included a group that received treatment with ondansetron only found benefit with a combination of the Relief Band and ondansetron compared to ondansetron alone: there was no head-to-head comparison the Relief Band and ondansetron. Studies were limited by multiple statistical comparisons without adjustment of the p-value and unclear specification of the primary outcomes. In addition, all three PONV studies included the same corresponding author (PF White) who was a paid consultant to Woodside Biomedical, the manufacturer of the Relief Band.

**Articles:** The search yielded 14 articles including review articles, opinion pieces and empirical studies. The following randomized controlled trials were identified: 1 RCT on the use of Relief Bands during pregnancy. This study was critically appraised: Rosen T, deVeciana M, Miller HS et al. A randomized controlled trial of nerve stimulation for relief of nausea and vomiting in pregnancy. *Obstet Gynecol* 2003; 102: 129-135. See Evidence Table.

The use of ReliefBand® Device in the treatment of morning sickness, chemotherapy nausea and post-operative nausea does not meet the Kaiser Permanente Medical Technology Assessment Criteria.

### Date Created | Date Reviewed | Date Last Revised
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12/10/2003 | 12/10/2003<sup>MPC</sup>, 07/07/2015<sup>MPC</sup>, 05/03/2016<sup>MPC</sup>, 02/07/2017<sup>MPC</sup> | 07/07/2015

<sup>MDCRPC</sup> Medical Director Clinical Review and Policy Committee

<sup>MPC</sup> Medical Policy Committee

### Revision History

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### Codes

E0765 - FDA approved nerve stimulator, with replaceable batteries, for treatment of nausea and vomiting