Clinical Review Criteria

Pulsed Electromagnetic Field (PEMF) for Pain Reduction After Breast Reconstruction Surgery

Group Health Clinical Review Criteria are developed to assist in administering plan benefits. These criteria neither offer medical advice nor guarantee coverage. Group Health reserves the exclusive right to modify, revoke, suspend or change any or all of these Review Criteria, at Group Health's sole discretion, at any time, with or without notice. Member contracts differ in their benefits. Always consult the patient's Medical Coverage Agreement or call Group Health Customer Service to determine coverage for a specific medical service.

Criteria
See breast reconstructive surgery document.

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
Pulsed electromagnetic field (PEMF) therapy, also known as electromagnetic therapy uses an electromagnet to generate electric current, and nonthermal pulsed electromagnetic energy to deliver the current. PEMF utilize generators designed to create radiofrequency signals that are delivered through coils which do not come in direct contact with the skin. The electric current is generated in short bursts into the injured tissue without the production of heat or interfering with nerve or muscle function. Unlike electrical stimulation, FEMF therapy does not involve the use of current, leads, or electrodes. The FEMF devices are noninvasive and can be applied over or as part of the dressing in the wound healing area directly following a procedure for the postoperative management of a surgical wound (Kinney 2005, Gupta 2009, Strauch 2009).

The mechanism of action of PEMF on tissue growth and repair is not completely known. In vitro and animal research showed that PEMF can increase blood flow, enhance circulation, induces collagen synthesis, granulocyte infiltration, and inhibit growth of some wound pathogens. The literature also suggests that this modality of therapy can modify the inflammatory process, reduce edema, and enhance tissue repair. The effects of PEMF are immediate and are not limited by pharmacokinetics because the induced currents are instantaneously present when the coil is transmitting into the affected area (Kinney 2005, Gordon 2007, Strauch 2009).

Electromagnetic therapy is currently being used in physical medicine, orthopedic and sports injuries, and other musculoskeletal conditions. PEMF therapy use is proposed for other conditions as the reduction of pain and edema after facial surgery, breast surgery, and abdominoplasty. Several trials are currently underway or planned to study the use of PEMF in several other fields of medicine (Kinney 2005, Gupta 2009).

Medical Technology Assessment Committee (MTAC)

<table>
<thead>
<tr>
<th>Date</th>
<th>Evidence Conclusion</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>6/18/2012</td>
<td>The two published trials on the use of pulsed electromagnetic field therapy (PEMF) to reduce pain and the use of pain</td>
<td>The use of Pulsed electromagnetic field</td>
</tr>
</tbody>
</table>

© Group Health Cooperative. All Rights Reserved.
medications after breast reconstruction surgery were small pilot studies with valid methodology. Both trials were randomized, blinded, used sham therapy as a control, and had sufficient power to detect statistically significant differences between PEMF and the sham therapy. Hedén and Pilla’s trial randomized 42 women to receive bilateral active PEMF therapy, bilateral breast sham therapy, or one of the two therapies on each breast. The results of the study showed a significant difference between the active and sham therapies in the pain experienced and in the use of postoperative pain medication. Those who received PEMF on one breast and sham therapy on the other breast showed no significant differences between the two breasts or between them and the active treatment. This was attributed to the fact that the breast randomized to sham treatment received 40-60% of signal amplitude delivered to the active treatment breast due to the propagation of PEMF signal from the coil application. Based on this observation, Rohde and colleagues (2009) randomized their study participants to receive either bilateral active therapy or bilateral sham therapy. The trial included 24 patients and reported outcomes for only 48 hours. Similar to Hedén and Pilla’s results, women who received PEMF therapy experienced less pain and used fewer narcotics in the 48 postoperative hours.

Conclusion:
The overall results of the published small pilot studies show that PEMF therapy may reduce pain and use of pain medication after breast reconstruction surgery. Both trials noted that no adverse events were reported, but neither studied the effect of PEMF on the reduction of postoperative edema, or on the speed and quality of wound repair

<table>
<thead>
<tr>
<th>Date of Literature Search</th>
<th>Articles</th>
</tr>
</thead>
</table>