Clinical Policy Bulletin:
Cryoanalgesia and Therapeutic Cold

Number: 0297

Policy

I. Aetna considers the use of cryoanalgesia medically necessary for the temporary relief of pain due to chronic refractory trigeminal neuralgia (see Appendix for selection criteria).

II. Aetna considers intra-operative and post-operative cryoanalgesia of the intercostal nerves experimental and investigational for the management of post-thoracotomy pain and other types of chronic pain.

III. Aetna considers the passive cold compression therapy units (e.g., AirCast Cryo Cuff, AirCast Cryo Strap, the Polar Care Cub unit, and the Polar Pack) medically necessary DME to control swelling, edema, hematoma, hemarthrosis and pain. Aetna considers the passive cold compression therapy units experimental and investigational for all other indications because their effectiveness for indications other than the ones listed above has not been established.

IV. Aetna considers active cold compression therapy units with mechanical pumps and portable refrigerators (e.g., AutoChill, Game Ready, IceMan, NanoTherm, Prothermo, and Vascutherm) experimental and investigational because they have not been proven to offer clinically significant benefits over passive cold compression therapy units.
V. Aetna considers the use of the Hot/Ice Machine and similar devices (e.g., the Hot/Ice Thermal Blanket, the Kinex ThermoComp Device, the TEC Thermoelectric Cooling System (an iceless cold compression device), the VascuTherm2, the VitalWear Cold/Hot Wrap, and the VitalWrap) experimental and investigational for reducing pain and swelling after surgery or injury. Studies in the published literature have been poorly designed and have failed to show that the Hot/Ice Machine offers any benefit over standard cryotherapy with ice bags/packs; and there are no studies evaluating its use as a heat source.

Note: Aetna considers passive hot and cold therapy medically necessary. Mechanical circulating units with pumps have not been proven to be more effective than passive hot and cold therapy.

Background

Cryoanalgesia for Trigeminal Neuralgia:

Trigeminal neuralgia (TN), also known as tic douloureux, is a disorder characterized by excruciating episodic pain in the areas innervated by one or more divisions (usually the mandibular and maxillary, rarely the ophthalmic divisions) of the trigeminal nerve. The anti-epileptic drug carbamazepine (Tegretol) is the drug most frequently used for the management of TN. For patients who cannot tolerate carbamazepine because of its adverse side effects (poor liver function, confusion, ataxia, drowsiness, and allergic responses), the literature indicates baclofen and other anticonvulsant drugs such as clonazepam (Klonopin) may be useful.

Cryoanalgesia, cryotherapy, or cryoneurotomy has also been used in the treatment of TN. It entails the use of high pressure (approximately 600 pounds per square inch) gas (nitrous oxide or carbon dioxide) administered by a 12- to 14-G needle-shaped cryoprobe. Studies have shown that cryoanalgesia provides temporary pain relief or cure with minimal morbidity (e.g., no permanent sensory loss) in patients with refractory TN.

Intra-Operative and Post-Operative Cryoanalgesia for the Management of Post-Thoracotomy Pain:

Thoracotomy, the establishment of an opening into the chest cavity for the management of various cardiopulmonary disorders/diseases, is one of the most painful surgical incisions. Post-thoracotomy pain impairs patients' ability to breathe deeply and cough frequently to prevent atelectasis. Pain relief medication may decrease the coughing reflex as well as depress respiratory functions when the dosage is high enough to achieve analgesia. On the other hand, if the dosage of analgesics is too low to relieve pain, it may render patients with shallow breathing and inadequate coughing reflex. Epidural anesthesia or analgesia may produce some pain relief, but the side effects of severe hypotension, nausea, and urinary retention, as well as the variability of effect limit the usefulness of this approach. Intercostal or paravertebral nerve blocks by means of local anesthetics and severing of the intercostal nerves have also been used to reduce incisional
pain following thoracotomy. However, the duration of relief for neural blockade is only a few hours and the procedure is painful, while severing of the intercostal nerves during thoracotomy may result in neuromas, which cause late post-operative pain.

Cryoanalgesia has been used on the intercostal nerves to reduce post-thoracotomy pain. Although the procedure is generally performed prior to closure of the chest at the completion of thoracotomy and may add 10 to 15 mins to the total operating time, it can also be carried out percutaneously in a clinical setting.

Cryoanalgesia of the intercostal nerves circumvents the need for repetitive injections of nerve blocks and avoids the toxicity of long acting agents, which may lead to chemically induced intercostal neuritis.

Khanbhai et al (2014) examined if cryoanalgesia improves post-thoracotomy pain and recovery. A total of 12 articles were identified that provided the best evidence to answer the question. The authors, date, journal, study type, population, main outcome measures and results were tabulated. Reported measures were pain scores, additional opiate requirements, incidence of hypoesthesia and change in lung function. Half of the articles reviewed failed to demonstrate superiority of cryoanalgesia over other pain relief methods; however, additional opiate requirements were reduced in patients receiving cryoanalgesia. Change in lung function post-operatively was equivocal. Cryoanalgesia potentiated the incidence of post-operative neuropathic pain. Further analysis of the source of cryoanalgesia, duration, temperature obtained and extent of blockade revealed numerous discrepancies; 3 studies utilized CO² as the source of cryoanalgesia, and 4 used nitrous oxide but at differing temperatures and duration; 5 studies did not reveal the source of cryoanalgesia. The number of intercostal nerves anesthetized in each study varied; 7 articles anesthetized 3 intercostal nerves, 3 articles used 5 intercostal nerves, 1 article used 4 intercostal nerves and 1 used 1 intercostal nerve at the thoracotomy site. Thoracotomy closure and site of area of chest drain insertion may have a role in post-operative pain; but only 1 article explained method of closure, and 2 articles mentioned placement of chest drain through blocked dermatomes. No causal inferences can be made by the above results as they are not directly comparable due to confounding variables between studies. The authors concluded that currently, the evidence does not support the use of cryoanalgesia alone as an effective method for relieving post-thoracotomy pain.

Humble et al (2014) noted that peri-operative neuropathic pain is under-recognized and often undertreated. Chronic pain may develop after any routine surgery, but it can have a far greater incidence after amputation, thoracotomy or mastectomy. The peak noxious barrage due to the neural trauma associated with these operations may be reduced in the peri-operative period with the potential to reduce the risk of chronic pain. These investigators performed a systematic review of the evidence for peri-operative interventions reducing acute and chronic pain associated with amputation, mastectomy or thoracotomy. A total of 32 randomized controlled trials (RCTs) met the inclusion criteria. Gabapentinoids reduced pain after mastectomy, but a single dose was ineffective for thoracotomy patients who had an epidural. Gabapentinoids were ineffective for vascular amputees with pre-existing chronic pain. Venlafaxine was associated with less

http://qawww.aetna.com/cpb/medical/data/200_299/0297_draft.html

05/06/2015
Chronic pain after mastectomy. Intravenous and topical lidocaine and peri-operative EMLA (eutectic mixture of local anesthetic) cream reduced the incidence of chronic pain after mastectomy, whereas local anesthetic infiltration appeared ineffective. The majority of the trials investigating regional analgesia found it to be beneficial for chronic symptoms. Ketamine and intercostal cryoanalgesia offered no reduction in chronic pain. Total intravenous anesthesia (TIVA) reduced the incidence of post-thoracotomy pain in 1 study, whereas high-dose remifentanil exacerbated chronic pain in another. The authors concluded that (i) appropriate dose regimes of gabapentinoids, anti-depressants, local anesthetics and regional anesthesia may potentially reduce the severity of both acute and chronic pain for patients; (ii) ketamine was not effective at reducing chronic pain; (iii) intercostal cryoanalgesia was not effective and has the potential to increase the risk of chronic pain; and (iv) TIVA may be beneficial but the effects of opioids are unclear.

Cold Therapy Units and Hot/Ice Machine:

Cold therapy units are devices in which fluid flows through a blanket or cuff, providing immediate cooling to an affected area. The AirCast Cryo/Cuff uses an insulated jug filled with cold water attached to a cuff. Elevating the jug fills and pressurizes the cuff. Compression is controlled by gravity, and is proportional to the elevation of the cooler. When body heat warms the water, it is re-chilled simply by lowering the cooler. Another passive cold compression therapy unit is the Polar Care Cub unit.

More complicated cold therapy units may employ mechanical pumps and refrigerators that are powered by battery or electricity (e.g., IceMan). The Game Ready system is an example of an active cooling device that combines cold and intermittent pneumatic compression therapies. The system consists of a wrap, a connector hose, and a control unit. The wrap contains two internal chambers, one for air and the other for cooling water. The microprocessor control unit features various adjustable compression cycles and temperature controls. However, there is no evidence that these more complicated cold therapy units provide any additional benefit over the CryoCuff or conventional ice bags or packs. Aetna's current policy on mechanical cold therapy pumps is consistent with Medicare DME MAC policy.

Leutz and Harris (1995) described a retrospective study that assessed 52 consecutive patients who underwent total knee arthroplasty (TKA). A total of 33 patients underwent TKA and received cold therapy pads placed over a thin dressing in the operating room; 19 patients underwent TKA using an identical operative and post-operative procedure, but did not receive continuous cold therapy. Continuous cold therapy consisted of 2 sterile plastic pads connected by rubber hoses containing cool water from an electric main unit that maintained a constant temperature of 42 degrees F for the immediate post-operative period. Cold therapy pads were used an average of 3 days and removed with the first dressing change. Patients who had continuous cold therapy averaged a 200 ml decrease in post-operative blood loss. There was no significant difference in the amount of narcotic use, transfusion requirements, or hospital stay between the two groups. Post-operative swelling and range of motion were not consistently recorded. Twenty-eight other variables were also examined, but no significant differences were found between groups. Based on these results, the authors stated that they cannot recommend continuous cold therapy or justify the extra expense for all patients who undergo TKA.
A Hot/Ice Machine consists of 2 rubber pads connected by a rubber hose to a unit that circulates hot or cold fluid through the pads. Studies in the published literature have been poorly designed and have failed to show that the Hot/Ice Machine offers any benefit over standard cryotherapy with ice packs, and there are no studies evaluating the use of this device as a heat source.

The VitalWrap (VitalWear Inc. South San Francisco, CA) is an active heating/cooling device that allows the user to circulate either hot or cold fluid through the system. The VitalWrap system consists of a bladder filled body wrap/pad, tubing, and a reservoir/pump device. Cooled or heated water may be added to the pump reservoir and then circulated through the tubing to the body wrap/pad and then back to the reservoir. The benefits of this type of device above other cooling or heating methods have not been established at this time.

Vascutherm (ThermoTek, Carrollton, TX) is an active cold compression therapy unit with a pneumatic pump. It provides heating, cooling and compression therapies. The device also includes a deep vein thrombosis (DVT) mode -- this is a compression (or air) only mode, that is intended to prevent DVT. However, it provides no additional clinical utility or impact on health outcomes than the use of ice or compression wraps.

The TEC Thermoelectric Cooling System (Maldonado Medical, Phoenix, AZ) is marketed to reduce post-operative pain and edema. It is an iceless cold therapy compression/DVT prophylaxis machine that can also provide heat. It is limited to a cold temperature of 49 degrees F to minimize the potential for frostbite. However, it provides no additional clinical utility or impact on health outcomes than the use of ice or compression wraps.

According to the manufacturer, the Kinex ThermoComp™ Device provides 3 separate pre-programmed therapies that are activated by a push of a button: (i) cold-compression, (ii) contrast-compression, and (iii) intermittent pneumatic compression for DVT prophylaxis. Continuous cold is delivered by a solid-state system without ice. Cold temperature is microprocessor-controlled within 1° making this one of the safest devices for unsupervised use in a patient's home. Contrast therapy cycles every 30 mins with cold at 49° for 20 mins followed by heat at 105° for 10 mins. Intermittent compression is delivered distal-to-proximal through a segmented pad. Deep vein thrombosis prophylaxis is delivered from a rapid inflation pump at 50 mm Hg through a calf pad or 100 mm Hg through a foot pad. All 3 therapies are delivered separately, however cold-compression and DVT compression can run at the same time with the device cycling DVT compression separate from limb compression. The Kinex ThermoComp™ Device is intended to treat post-operative injuries in the home, to reduce edema and pain, to improve blood flow to the surgical site, and to provide DVT prophylaxis therapy for high-risk patients. http://www.kinexmedical.com/thermocomp.html. However, there is a lack of evidence regarding the safety and effectiveness of this device.

According to the manufacturer, the VascuTherm2 solid state device provides heat, cold (without ice), compression, and/or DVT prophylaxis therapy. The system is pre-programmed per written physician's instructions for fully automatic, safe, trouble-free use in the patient's home. It is indicated for pain, edema, and DVT prophylaxis for the post-operative orthopedic patient. The precisely controlled temperature range of 43 degrees F to 105 degrees F insures against frost-bite or
burns. Therapy times are also pre-programmed to insure maximum patient compliance. It is extremely easy for patients to set up and use. http://www.calamarimedical.com/VascuTherm2.html. However, there is a lack of evidence regarding the safety and effectiveness of this device.

Appendix

Selection Criteria of Cryoanalgesia for Trigeminal Neuralgia:

I. Members have experienced pain for at least 6 months, and

II. Members have tried and failed pharmacotherapies (e.g., baclofen, carbamazepine, phenytoin), or are unable to tolerate the side effects of the medication.

Repeat cryoanalgesia may be medically necessary every 6 months.

CPT Codes / HCPCS Codes / ICD-9 Codes

CPT codes covered if selection criteria are met:

- 64600 Destruction by neurolytic agent, trigeminal nerve; supraorbital, infraorbital, mental, or inferior alveolar branch
- 64620 Destruction by neurolytic agent, intercostal nerve

Other CPT codes related to the CPB:

- 64400 Injection, anesthetic agent; trigeminal nerve, any division or branch
- 64420 intercostal nerve, single
- 64421 intercostal nerves, multiple, regional block
- 64600 Destruction by neurolytic agent, trigeminal nerve; supraorbital, infraorbital, mental, or inferior alveolar branch
- 64620 Destruction by neurolytic agent, intercostal nerve

HCPCS codes not covered for indications listed in the CPB:
<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>A9273</td>
<td>Hot water bottle, ice cap or collar, heat and/or cold wrap, any type</td>
</tr>
<tr>
<td>E0217</td>
<td>Water circulating heat pad with pump</td>
</tr>
<tr>
<td>E0218</td>
<td>Water circulating cold pad with pump</td>
</tr>
<tr>
<td>E0236</td>
<td>Pump for water circulating pad</td>
</tr>
<tr>
<td>E0249</td>
<td>Pad for water circulating heat unit</td>
</tr>
<tr>
<td>E0650 -</td>
<td>Pneumatic compressor; home model [not covered for active cold compression therapy units]</td>
</tr>
<tr>
<td>E0652</td>
<td></td>
</tr>
<tr>
<td>E0660, E0666 - E0667, E0669</td>
<td>Non-segmental and segmental pneumatic appliance for use with pneumatic compressor; leg [not covered for active cold compression therapy units]</td>
</tr>
<tr>
<td>E0671, E0673</td>
<td>Segmental gradient pressure pneumatic appliance, leg [not covered for active cold compression therapy units]</td>
</tr>
</tbody>
</table>

**Other HCPCS codes related to the CPB:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>E0676</td>
<td>Intermittent limb compression device (includes all accessories), not otherwise specified [not covered for active cold compression therapy units]</td>
</tr>
</tbody>
</table>

**ICD-9 codes covered if selection criteria are met (not all-inclusive):**

<table>
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<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>338.0 - 338.4</td>
<td>Pain</td>
</tr>
<tr>
<td>350.1</td>
<td>Trigeminal neuralgia</td>
</tr>
<tr>
<td>611.71</td>
<td>Mastodynia</td>
</tr>
<tr>
<td>719.00 - 719.09</td>
<td>Effusion of joint</td>
</tr>
<tr>
<td>719.10 - 719.19</td>
<td>Hemarthrosis</td>
</tr>
<tr>
<td>719.40 - 719.49</td>
<td>Pain in joint</td>
</tr>
<tr>
<td>724.2</td>
<td>Lumbago</td>
</tr>
<tr>
<td>724.5</td>
<td>Backache, unspecified</td>
</tr>
<tr>
<td>729.0</td>
<td>Rheumatism, unspecified and fibrositis</td>
</tr>
<tr>
<td>729.1</td>
<td>Myalgia and myositis, unspecified</td>
</tr>
<tr>
<td>729.2</td>
<td>Neuralgia, neuritis, and radiculitis, unspecified</td>
</tr>
<tr>
<td>729.5</td>
<td>Pain in limb</td>
</tr>
</tbody>
</table>
The above policy is based on the following references:

**Cryoanalgesia for Trigeminal Neuralgia:**


**Intra-Operative and Post-Operative Cryoanalgesia for the Management of Post-Thoracotomy Pain:**


**Cold Therapy Units and Hot/Ice Machine:**


34. NHIC, Inc. Local Coverage Determination (LCD) for Cold Therapy (L5038). Durable Medical Equipment Medicare Administrative Contractor (DME MAC) Jurisdiction A. Hingham, MA: NHIC; revised January 1, 2011.