IEHP UM Subcommittee Approved Authorization Guidelines

**DME-Cold Therapy**

**Policy:**
The use of passive (e.g., AirCast Cryo Cuff, and Polar Care Cub Unit) or active cold therapy devices (therapy units with mechanical pumps or portable refrigerators) is not a covered benefit in postoperative care of patients undergoing musculoskeletal surgery.

All other applications of passive cooling devices are considered not a covered benefit. The use of active or passive devices that combine cooling and heating is not a covered benefit.

Analysis of the medical literature demonstrates variable findings in regards to its usefulness. Alternative forms of cooling modalities exist, such as ice bag or ice packs, which may be employed in the treatment of specific sites.

The following are descriptions of devices that are not covered for indications listed: water circulating heat or cold pad with a pump, pump for water circulating pad, and pad for water circulating heat unit.

**CMS: Local Coverage Determination for Cold therapy (L11567):**
Water circulating cold pad with pump (E0218) will be denied as not reasonable and therefore not covered by Medicare.

**Medi-Cal Determination (E0218):**

<table>
<thead>
<tr>
<th>Procedure Level</th>
<th>Procedure Type</th>
<th>Effective Date</th>
<th>End Date</th>
<th>Follow Up Days</th>
<th>Gender</th>
<th>Min Age</th>
<th>Max Age</th>
<th>Medi-Cal Max Allowable Amount</th>
<th>Split Bill professional percentage</th>
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<td>12/31/2069</td>
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</table>

This procedure is not a covered benefit. No TAR or medi-reservation required.
Medical Review Criteria Guidelines for Managing Care (Apollo):

The application of external sources of cold (e.g., ice packs or water circulating cold pads) to injuries is an accepted treatment to reduce pain and swelling.

Continuous postoperative cryotherapy or continuous-flow cold therapy are systems that automatically provide cryotherapy postoperatively or post-injury. Active circulating cooling and compression devices are commercially available without a prescription.

These devices are not covered by Medicare or the other health plans as DME due to an investigational status.

ECRI’s Health Technology Assessment Information Service:

ECRI conducted a medical literature search for references relevant to the topic from January 1992 to August 2006. Among the 9 randomized controlled trial abstracts (RCT) reviewed:

A. Four studies did not show a significant difference in pain and analgesic use between Cryo Cuff and control (either compression with room temperature or no compression) (Gibbons et al., 2001; Dervin et al., 1998; Edwards et al., 1996; Healy et al., 1994).

B. One showed no significant differences for pain, bleeding, swelling, range of motion or function between groups; but the Cryo Cuff and epidural analgesia groups used significantly less morphine (Holmstrom et al., 2005).

C. Two showed the cold therapy group reported significantly less pain or narcotic use than control (no cold therapy) (Singh et al., 2001; Barber et al., 1998).

D. Two demonstrated that patients who used Cryo Cuff had significantly less pain, swelling or analgesic use than traditional forms of cold therapy (ice bags or ice and elastic bandage) (Whitelaw et al., 1995; Schroder et al., 1994).

Leutz and Harris (1995):

Performed a retrospective study comparing cold therapy to no cold therapy after total knee arthroscopy. 52 patients underwent procedure, 33 received cold therapy and 19 did not.

No significant difference in amount of narcotics used, or length of hospital stay. Twenty-Eight other variables study showed no statistically significant differences.

Authors concluded they could not recommend continuous cold therapy for patients undergoing total knee arthroscopy.

Anthem Medical Policy Number MED.00066:

Not Medically Necessary:

1. The use of active or passive cooling devices is considered not medically necessary in the postoperative care of patients undergoing musculoskeletal surgery.
Investigational and Not Medically Necessary:

All other applications of passive cooling devices, including but not limited to their use for non-operative musculoskeletal injuries, are considered investigational and not medically necessary.

1. The use of active cooling devices with additional pneumatic compression is considered investigational and not medically necessary, for all indications, including, but not limited to the postoperative care of patients.

2. The use of active or passive devices that combine cooling and heating is considered investigational and not medically necessary, for all indications, including, but not limited to the use of the VitalWrap™ system.

Aetna Clinical Policy Bulletin Number 0297:

A. Passive cold compression therapy units such as AirCast Cryo Cuff, and Polar Care Cub are considered medically necessary DME to control swelling, pain, edema, hematoma, and hemarthrosis. They are considered experimental and investigational for all other indications.

B. Cold therapy units with mechanical pumps and portable refrigerators are considered experimental and investigational. Hot/Ice machines, Vital Wear cold/hot wrap, and similar devices are also considered as experimental and investigational. They have not been shown to provide clinically significant benefits over Cryo Cuffs or ice packs.

C. Cold therapy is considered medically necessary in the treatment of the following conditions: (1) temporary relief of pain due to refractory trigeminal neuralgia, and (2) intra-operative cryoanalgesia for the management of post-thoracotomy pain. It is considered experimental and investigational for all other conditions.

Selection Criteria for use of Cryotherapy for Trigeminal Neuralgia (TN):

1. Members with pain from TN for at least six months, and

2. Members have tried and failed medications (e.g. Carbamazepine, Phenytoin, Baclofen), or unable to tolerate side effects.

Repeat cryoanalgesia for TN every six months may be medically necessary.

Background:

Cooling Devices (Cold Therapy/Cryotherapy) are used for the treatment of edema and pain associated with the inflammatory response following musculoskeletal and orthopedic trauma, either from injury or surgery. Cold therapy can be delivered by using either passive or active units. Passive devices include ice bag, ice cups, ice packs, AirCast Cryo Cuff, and Polar Care Cub Unit. Cold therapy units with mechanical pumps and portable refrigerators are considered active units (ECRI, 2008; Aetna, 2008; Apollo, 2008, Anthem 2008).

Cold therapy is contraindicated in the following conditions: Raynaud’s phenomenon, cold allergy, cryoglobulinemia, pheochromocytoma, and unconsciousness (ECRI, 2008).
Effective Date: November 20, 2008  
Reviewed Annually: November 9, 2016

Revised:
March 5, 2014

Bibliography:
5. CMS LCD for Cold therapy (L11567) Revised 07/01/2007. Accessed on 10/31/08 at http://www.cms.hhs.gov/mcd/viewlcd.asp?lcd_id=11567&lcd_version=15&basket=lcd%3A11567%3A15%3ACold+Therapy%3ADME+MAC+ANoridian+Administrative+Services+1%2819003%29%3A
7. ECRI Institute Hotline Response on Gravity-Controlled Cold Therapy Devices for Musculoskeletal, Postoperative and Orthopedic Trauma (2008).
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