Cryounits/Cooling Devices

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Related Coverage Resources

Pneumatic Compression Devices and Compression Garments

INSTRUCTIONS FOR USE

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Overview

This Coverage Policy addresses the use of cold therapy units, cooling devices, and cooling garments.

Coverage Policy

Coverage for cryounits and cryotherapy machines varies across plans. Refer to the customer’s benefit plan document for coverage details. When covered, coverage for cryounits and cryotherapy machines is subject to the terms, conditions and limitations of the applicable benefit plan’s Durable Medical Equipment (DME) benefit and schedule of copayments.

A cold therapy unit or cooling device (HCPCS codes E0218, E0236), including both passive and active pump-controlled cooling and compression devices (HCPCS code E1399), for any indication is considered a convenience item and not medically necessary.

A cooling device/cooling garment (HCPCS code E1399) for the treatment of multiple sclerosis is considered experimental, investigational or unproven.
General Background

Cryotherapy, or cold therapy, is the therapeutic application of cold. It is a widely used modality in the field of physical medicine and rehabilitation, and is often used in conjunction with other rehabilitation treatments to reduce inflammation and relieve pain. Cold therapy has a long history of being used as a standard treatment for soft tissue injury. It is also frequently used as part of postoperative rehabilitation after orthopedic surgery, in particular, knee surgery. The exact mechanism by which cold therapy works is not completely known or understood. It is thought that this modality causes a decrease in temperature, resulting in a reduction of the metabolic rate, thereby decreasing inflammation, edema, muscle spasm and pain. It has also been noted that, after the initial vasoconstriction, there may be an increase in skin blood flow after local ice application, causing a reflex vasodilation. Multiple variables, including room temperature, temperature of ice or cooling agent, thickness of subcutaneous fat, thickness of dressings, method of application, and duration of application, appear to have bearing on the effect of cold therapy.

Cold therapy can be administered using several methods. These include cold immersion, ice massage, application of ice/crushed ice, and use of a gel ice pack, instant ice packs, vapocoolant spray or cooling devices. Compression therapy is generally provided postoperative with compressive wraps such as an Ace bandage or wrap.

Application of ice is often combined with compression and elevation in clinical trials, making it difficult to evaluate the efficacy of this treatment as the sole modality. Few clinical trials have been undertaken to assess the effect of this modality alone in the treatment of specific medical conditions. The mode, frequency, and duration of the ice application vary widely across studies. As with many other rehabilitation interventions, the therapeutic application of cold is based largely on empirical experience.

Cooling Devices

Cooling devices may also be referred to as cold therapy units, cryounits, or cryotherapy machines. Cooling devices may be passive or active and operate by gravity or the use of a mechanical or pneumatic pump. The intended purpose of these devices is to provide a combination of cooling and compression to treat musculoskeletal conditions.

Passive cold therapy devices operate by gravity or a hand pump with no battery or electricity used. Generally they consist of a cuff or wrap and a cooler. Ice water is placed in the reservoir or cooler. The cooler is placed above the body area or joint and then utilizes gravity to fill the cuff and compress the joint. If a hand pump is used the device may be placed closer to or level with the joint or area being treated.

Active cooling devices include pneumatic or mechanical pumps that may be battery or electric operated. The intended function of the pump is to provide cyclical compression and cooling to the affected area. The purpose of the compression is to remove fluid and decrease edema while providing the cooling. The devices generally consist of two basic parts: a wrap or wrap system that is designed to cover specific areas of the body; and a control unit, which is filled with ice and water. The control unit or pump circulates the cooled water through the wraps to the affected area. The devices may also contain a cooler or refrigeration component. Some of these devices are also designed to provide heat therapy.

Available passive or gravity-controlled cold therapy devices that provide cooling and compression include, but are not limited to:

- ArcticFlow Cold therapy system (dj Orthopedics, Inc., Vista, CA): This device has a gravity-controlled system.
- Cryo/Cuff™ (Aircast®, Summit, NJ): This device has a gravity-controlled system.
- EBI® Gravity Cold Therapy System (Biomet, Inc., Parsippany, NJ): This device has a gravity-driven format.
- Polar Care Cub (BREG, Inc., McKinney, TX): This device includes a pad and hand pump that is used to circulate the water.
Available active cold therapy devices that operate by battery or electric powered pump that provide cooling and compression include, but are not limited to:

- **AutoChill®** system (Aircast®, Summit, NJ): This device is an accessory to the CryoCuff® system that utilizes an electronic pump in order to continuously cycle water between cooler and cuff.
- **BioCryo Cold Compression System** (Bio Compression Systems, Inc., Moonachie, New Jersey): This device includes a gradient, sequential, pneumatic compression pump.
- **Cryotherapy Cold Water Therapy System by Artic® Ice** (Healio Health, Akron, OH): This device includes electric pump and pad.
- **DeRoyal® Cold Therapy Unit** (DeRoyal Industries, Powell, TN): Includes pump motor that circulates water between unit bucket and cooling blanket.
- **EBIce® Cold Therapy System** (Biomet, Inc., Parsippany, NJ): Intermittent pump cycle with adjustable treatment setting controls water temperature and intermittent massage.
- **Game Ready™ Accelerated Recovery System** (CoolSystems, Inc., Berkeley, CA): This device contains an electric or battery-run pump.
- **Iceman Cold Therapy unit** (DJO Incorporated Inc., Vista, CA): This device includes pad and electric pump to circulate the fluid.
- **Nanotherm™** (ThermoTek, Carrollton, TX): This devices includes pneumatic pump and provides heating, cooling and compression therapies.
- **OPTI-ICE™ Cold Therapy System** (Chattanooga Group, Hixson, TN): This device includes an electric pump.
- **Polar Care 500, Polar Care 300** (BREG, Inc., McKinney, TX): This device includes a pad and battery/electric pump that is used to circulate the water.
- **TEC Iceless Cold Therapy/Compression/DVT Prophylaxis** (Maldonado Medical LLC, Phoenix, Arizona): this product provides iceless cold therapy/compression/ deep vein thrombosis (DVT) DVT prophylaxis
- **VitalWrap System®** (VitalWear Inc., South San Francisco, CA): This device provides heating, cooling, and compression therapies. The device includes a control unit, tubing set, and a thermal fabric wrap. The control unit, which includes a fluid reservoir, manages the temperature of water used by the system to supply heat or cold to the fabric wrap that is attached to the body.
- **Vascutherm™** (ThermoTek, Carrollton, TX): Includes pneumatic pump and 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.

### Cooling Garments for Multiple Sclerosis

Multiple sclerosis (MS) is a chronic, progressive, neurologic autoimmune disorder that affects the myelin sheath surrounding the axons in the central nervous system (CNS). The symptoms may be mild or severe, of long or short duration, and appear in different combinations depending on the area of the nervous system that is involved (National Institute of Neurological Disorders and Stroke [NINDS], 2015). The disease course is largely unpredictable. The disease can result in a wide array of symptoms including: muscle weakness, spasticity, impairment of pain, temperature and touch senses, pain (moderate to severe), ataxia, tremor, speech disturbances, vision disturbances, vertigo, bowel, bladder, sexual dysfunction, depression, cognitive abnormalities, and fatigue (NINDS, 2015). Treatment of MS is related to the course of the disease and symptoms that are experienced. The goals of treatment are to improve recovery from attacks; to prevent or lessen the number of relapses; and to halt the disease progression.

It has been reported in the medical literature that heat, whether generated by temperatures outside the body or by exercise, causes temporary worsening of many MS-related symptoms in many patients (NINDS, 2015). In particular, it has been noted that the symptom of fatigue may increase with an elevated body temperature. Fatigue has been noted to be a common and debilitating symptom of MS, affecting many patients (Shapiro, 2005). Various interventions have been proposed for treatment of fatigue, including medication, aerobic exercise, adequate rest, cooling systems and alternative therapies. Various cooling devices or cooling garments have been developed to treat heat sensitivity in a patient with MS. These devices are also used for a variety of industrial, military and recreational applications.
**Active Cooling Devices:** Active cooling devices, also known as cooling suits or liquid-cooled garments, have separate mechanisms (e.g., pumps) that attach to the garments, circulating coolant through tubes in the garments.

Available active cooling devices and garments include, but are not limited to:

- FAST® Personal Medical Cooling Suit System (Fast Race Products, Mount Prospect, IL): This device includes a t-shirt, cooler, pump system and hoses.
- Polar Active Cooling Vest (Polar Products Inc., Akron, OH)

**Passive Cooling Devices:** Passive cooling refers to cooling with no active mechanism such as a separate pump. This type of device is usually a garment such as a vest or collar that works by placing ice or gel packs into the pockets of a vest or by placing the garment in a freezer to pre-cool it. Many of these devices were developed for other uses in industry and recreation to combat heat and are now also marketed for medical purposes.

Available passive cooling garments include but are not limited to:

- Cooltemp Vest (Life Enhancement Technologies, Inc., Santa Clara, CA): This garment consists of a vest with four pockets for ice insertion.
- SteeleVest® Body Cooling Comfort System™ (Kingston, WA): This vest includes frozen Thermo-strips (starch-based gel ice packs that can be frozen in a household freezer) that are inserted into the insulated SteeleVest.
- HeatShield™ (SummitStone Corporation, White Stone, VA): This garment consists of a vest that is placed in the freezer overnight.
- Chill-Its® cooling vests, hats, headbands (Ergodyne, St. Paul, MN): These are evaporative cooling garments that are chilled in the freezer before use.

**Literature Review**

Although cold therapy has a long history as a therapeutic entity in the treatment of soft-tissue injury and in postoperative rehabilitation, the literature is conflicting on the efficacy of this treatment. In addition, there is insufficient evidence in the published, peer-reviewed scientific literature to demonstrate that the use of specialized devices that provide cooling and compression have a clinical benefit over the conventional, intermittent application of ice packs and wraps. Cooling devices, both passive or active pump-controlled devices, that provide cooling and compression have no additional clinical utility or impact on health outcomes than the use of ice or compression wraps. It does appear that such devices may offer ease of application and be more convenient.

Hayes (2019a) conducted a health technology assessment report for the purpose of comparing for cold compression (CC) therapy versus alternative approaches for reducing pain and inflammation following total knee arthroplasty (TKA). The review included 11 randomized controlled trials (RCTs) that met the inclusion criteria, enrolling 60 to 187 patients undergoing TKA with follow-up times ranging from in-hospital to 12-weeks postoperatively. The main outcome measures were hospital length of stay (LOS), pain, medication consumption, swelling, function and range of motion (ROM), blood loss, and patient satisfaction.

Regarding effectiveness the review noted that the 11 RCTs compared CC therapy with an active comparator, such as compression, cryotherapy, epidural analgesia (EDA), or cryotherapy plus static compression. Across studies and comparison types, outcomes were largely similar between CC therapy and alternative treatment groups. The findings included:

- Four of five studies found no differences between CC therapy and active controls in hospital LOS.
- Eight of 11 studies found no differences between CC therapy and active controls on pain measures.
- Five of seven studies found no differences between CC therapy and active controls for medication consumption.
- Eight of ten studies found no differences between CC therapy and active controls in function and ROM.
- Five of six studies found no differences between CC therapy and active controls on swelling.
Three of four studies found no differences between CC therapy and active controls for blood loss. Somewhat in contrast to these findings, two of three studies reported that patient satisfaction was better when comparing CC therapy with active alternatives.

Additional analysis compared CC therapy by type of active treatment groups. Two studies compared CC therapy with compression only:

- There was no difference between treatment groups in hospital LOS, swelling, or function. Limited data from one study favored CC therapy over compression alone for medication consumption in the early postsurgical period, and one study favored CC therapy for blood loss.

Three studies compared CC therapy with cryotherapy only:

- Two studies presented limited data favoring CC therapy for pain and swelling in the early postoperative period. One study reported statistically significant between-group differences, whereas the other study did not perform direct comparisons between groups. The remaining study favored cryotherapy alone for pain and ROM.

Two studies compared CC therapy with EDA:

- Outcomes were largely similar between treatment groups, though one study favored CC therapy over EDA for LOS and ROM outcomes and one study favored CC therapy over no additional therapy for medication consumption.

Three studies compared CC therapy with cryotherapy plus static compression:

- Outcomes related to function and pain were similar between groups across all three studies, though one of three studies reported lower morphine use for CC therapy and two studies reported higher patient satisfaction with CC therapy. One study reported statistically significant differences in pain favoring static compression therapy, though the differences were not likely to be clinically significant.

One study compared CC therapy plus continuous passive motion (CPM) with CPM only. Limited conclusions could be drawn from the findings.

Regarding safety, eight studies found no major complications related to CC therapy; the technology appears to be reasonably safe.

Regarding the quality of evidence, it was noted that the overall body of evidence regarding CC therapy following TKA is moderate. Limitations include variation in the mode, frequency, and duration of CC therapy and variation in comparator therapy, which resulted in sparse evidence per comparison. As a result, a potential relative benefit of CC therapy versus any individual alternative therapy could not be established with confidence.

The report concluded that the available evidence suggests that CC therapy is not associated with any additional overall benefits for reducing pain and inflammation compared with alternative postsurgical therapies in patients who have undergone TKA; rather the benefits were generally similar between CC therapy and alternative therapies. Additional studies are needed to elucidate optimal treatment protocols and provide longer term outcomes.

Hayes (2019b) conducted a health technology assessment report for the purpose of comparing cold compression (CC) therapy with alternative standard therapies in patients undergoing orthopedic procedures on major joints other than the knee and to evaluate whether CC therapy provides additional clinical benefit beyond that of standard interventions. The review included six randomized controlled trials (RCTs), analyzing from 40 to 125 patients undergoing orthopedic procedures to major joints (the wrist, elbow, hip, or shoulder) with postoperative follow-up times ranging from in-hospital to 3 months. The main outcome measures were hospital length of stay (LOS), pain, medication consumption, swelling, function and range of motion (ROM), and patient satisfaction.

The studies compared CC therapy with cryotherapy (4 RCTs) or standard postoperative care (2 RCTs). Across studies and comparison types, the outcomes were largely similar between CC therapy and alternative treatment groups. Specifically, CC therapy offered no consistent additional benefit over alternative treatments. The findings regarding effectiveness included:

- Hospital LOS (two studies): Two studies found no difference between CC therapy and control treatment.
• Pain (six studies): The evidence regarding pain outcomes was presented for several time points after surgery in each study. The majority of findings were not statistically significant between groups. However, results that favored CC therapy over the control were reported in two studies at one or more early postoperative time points but not at later postoperative time points. No results favoring the control group were observed.
• Medication consumption (five studies): One study favored CC therapy over the control treatment. Four studies found no difference between CC therapy and alternative treatment regarding medication consumption.
• Swelling (two studies): Two studies found no difference between CC therapy and alternative treatments for swelling.
• Function and ROM (three studies): Three studies found no difference between CC therapy and comparison treatments for function and/or ROM outcomes.
• Patient satisfaction (two studies): Two studies reported no differences in patient satisfaction between CC therapy versus comparison treatments.

Four studies found no major complications related to CC therapy; this technology appears to be reasonably safe. Only minor complications, such as discomfort and general dissatisfaction, were reported.

Regarding quality of evidence the report noted that the overall body of evidence regarding CC therapy following orthopedic procedures to major joints is very low. Limitations of the evidence base included the small overall body of evidence, limited number of studies for each orthopedic indication and comparator intervention, the wide heterogeneity in treatment protocols, and individual study limitations. As a result, a potential relative benefit (or lack of benefit) of CC therapy for any orthopedic indication or any individual alternative therapy could not be established with confidence.

The report concluded that a very-low-quality body of evidence suggests that CC therapy is not associated with any additional overall benefits for reducing pain and inflammation compared with alternative postsurgical therapies in patients who have undergone orthopedic procedures to major joints other than the knee; instead, benefits were generally similar between CC therapy and alternative therapies. Therefore, the evidence is insufficient to conclude that CC therapy does not offer additional benefit compared with alternative interventions. Additional studies are needed to determine whether CC therapy does provide clinical benefit beyond standard interventions, elucidate optimal treatment protocols, establish which patients may benefit from CC therapy, and provide longer-term outcomes.

Adie et al (2012) conducted a Cochrane review to evaluate the acute application of cryotherapy following total knee replacement (TKR) on pain, blood loss and function. The review included 11 randomized trials and one controlled clinical trial with 809 participants. The included studies had clinical heterogeneity in interventions and controls—utilizing cold with compression and no compression and cold therapy applied with devices and with application of ice. The inclusion criteria was randomized controlled trials or controlled clinical trials in which the experimental group received any form of cryotherapy, and was compared to any control group following TKR indicated for osteoarthritis. The authors found very low quality evidence from 10 trials (666 participants) that cryotherapy has a small benefit on blood loss, however, it was noted that this benefit may not be clinically significant. There was no difference between groups in adverse events (RR = 0.98, 95% CI, 0.28 to 3.47). There is low quality evidence from two trials (107 participants) for improved range of motion at discharge, but this benefit may not be clinically significant. There was no difference between groups in transfusion rate and knee function was not measured in any trial. No significant benefits were found for analgesia use, swelling or length of stay. Outcomes measuring quality of life or activity level were not reported. The authors concluded that the potential benefits of cryotherapy on blood loss, postoperative pain, and range of motion may be too small to justify its use, and the quality of the evidence was very low or low for all main outcomes. They noted that these findings need to be balanced against potential inconveniences and expenses of using cryotherapy. Well-designed randomized trials are required to improve the quality of the evidence.

Published randomized trials have not demonstrated the efficacy of a cryotherapy devices compared to the use of ice packs for knee surgery including for total knee arthroplasty (Su, et al., 2012), anterior cruciate ligament (ACL)
reconstruction (Waterman, et al., 2012; Dervin, et al., 1998; Konrath, et al., 1996), and knee arthroscopy (Woolf, et al., 2008). A randomized study of 40 patients undergoing total shoulder arthroplasty (TSA) found no differences in pain control, quality of sleep, patient satisfaction, or narcotic usage were detected between cryotherapy and plain ice following TSA (Noyes, et al., 2018).

Bleakly et al. (2004) performed a systematic review of randomized, controlled trials to assess the evidence base for cryotherapy in the treatment of acute soft-tissue injury. Twenty-two studies of randomized, controlled trials were included in the review. Five different methods of cryotherapy were used in the studies: crushed or chipped ice, Cryo/Cuff or cold compressive devices, commercial ice machines, commercial/gel ice packs and ice submersion. Five of the studies simply stated that an ice bag or pack was applied and eight studies used more than mode of cooling. It was noted that the duration and frequency of the treatments were not consistent across studies and had a wide range. Four studies compared two different methods of applying simultaneous compression and cryotherapy. The authors stated that due to the poor reporting of data, it was difficult to draw conclusions. Two studies did not provide adequate information on mode of cryotherapy, and all studies failed to specify the duration and frequency of ice application. The review concluded that many more high-quality studies are needed on this topic. Studies should focus on developing modes, durations and frequencies of ice application in order to optimize cryotherapy treatment during postoperative and rehabilitative care.

A systematic review of the literature (MacAuley, 2001) examined use of cryotherapy in acute soft tissue injury and attempted to produce evidence-based guidance on treatment. The review examined the effectiveness of ice in reducing tissue temperature, different methods of ice application, differing temperature, and duration to and the depth of the cooling effect. The study’s conclusion noted that the optimal method of ice application is wet ice applied directly to the skin through a wet towel and that the target temperature reduction is to 10–15 °C. While there is no evidence from the literature suggesting an optimal frequency or duration of treatment, it appears that repeated ice applications of 10 minutes each are effective. Most studies are not controlled for area of ice application, mode of application, depth of subcutaneous fat, method of calculating depth, or method of measuring temperature.

**Literature Review—Cooling Devices for Multiple Sclerosis**

The NASA/MS Cooling Study Group (Schwid, et al., 2003) conducted a multicenter, controlled double-blinded study to determine the effects of a single acute dose of cooling therapy and to determine whether effects are sustained during long-term use of a daily cooling garment. The study involved 84 patients with definite MS, mild to moderate deformity, and self-reported heat sensitivity, and used active cooling garments. The active cooling device from Lifetime Enhancement Technologies Inc. was used in this study. It was noted that body temperature declined with both the high dose and the sham, or low dose, cooling. It was also noted that the high dose cooling produced a small improvement, and the low-dose showed a trend toward improvement. The authors concluded that cooling therapy was associated with objectively measurable but modest improvements in motor and visual function, as well as persistent subjective benefits. Limitations of the studies include the small patient populations and lack of a comparator.

Several small cross-over studies evaluated effectiveness of cooling devices on the symptoms of MS (Reynolds, et al., 2011; Myer-Heim, et al., 2007; Beenakker, et al., 2001). These trials were preliminary, included small number or subjects, and noted that further studies were needed to assess the efficacy of cooling of symptoms of multiple sclerosis.

**Professional Societies/Organizations:**

**American Academy of Orthopedic Surgeons (AAOS):** AAOS published a revised clinical practice guideline for Surgical Management of Osteoarthritis of the Knee (Weber, et al., 2016). The guideline largely focused on total knee arthroplasty (TKA). The authors state that there is moderate evidence to support that cryotherapy devices do not improve outcomes following TKA.

**National Multiple Sclerosis Society (NMSS):** NMSS, in a clinical bulletin regarding complementary and alternative medicine in MS, notes that, “Limited studies indicate that several CAM therapies may be beneficial for people with MS. Cooling therapy, which involves the use of cooling suits, may improve some MS symptoms.” (NMSS, 2010)
Centers for Medicare & Medicaid Services (CMS)

- National Coverage Determinations (NCDs): No NCD found
- Local Coverage Determinations (LCDs): Cold Therapy (L33735) (2017). Refer to the CMS LCD table of contents link in the reference section.

Use Outside of the US

National Collaborating Centre for Chronic Conditions (NCC-CC) (United Kingdom): NCC-CC published guidelines for diagnosis and management of MS (2014; 2019). Treatment with body cooling is not included in the recommendations.

Coding/Billing Information

Note: 1) This list of codes may not be all-inclusive.
   2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Considered Not Medically Necessary/Convenience Item when used to report cold therapy units or cooling devices, including both passive and active pump-controlled cooling and compression devices:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>E0218</td>
<td>Fluid circulating cold pad with pump, any type</td>
</tr>
<tr>
<td>E0236</td>
<td>Pump for water circulating pad</td>
</tr>
<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
</tr>
</tbody>
</table>

Considered Experimental/Investigational/Unproven when used to report a cooling device/cooling garment for the treatment of multiple sclerosis:

<table>
<thead>
<tr>
<th>HCPCS Codes</th>
<th>Description</th>
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<tbody>
<tr>
<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
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References


