Cigna Medical Coverage Policy

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Subject **Cryounits/Cooling Devices**

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Lymphedema Pumps and Compression Garments
Pneumatic Compression Devices in the Home Setting

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Coverage Policy

Cryounits and cryotherapy machines are specifically excluded under many benefit plans. Please refer to the applicable benefit plan language to determine benefit availability and the terms, conditions and limitations of coverage.

Cigna does not cover a cold therapy unit or cooling device (HCPCS codes E0218, E0236), including both passive and active pump-controlled cooling and compression devices for any indication because they are considered convenience items and not medically necessary.

Cigna does not cover a cooling device/cooling garment (HCPCS code E1399) for the treatment of multiple sclerosis because it 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], 2012). 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, 2012). 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, 2012). In addition, it has been theorized that an elevated body temperature further impairs the ability of a demyelinated nerve to conduct electrical impulses (National Multiple Sclerosis Society [NMSS], 2003). 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.
- Silver Eagle Cooling Vest and headwear (Silver Eagle Outfitters, LLC, Huntsville, AL): These items are soaked in water to activate the cooling process, charging the hydrophilic fibers with moisture.
- Chill-Its® cooling vests, hats, headbands (Ergodyne, St. Paul, MN): These are evaporative cooling garments that are chilled in the freezer before use.

U.S. Food and Drug Administration (FDA)

Many cooling devices are described by the U.S. Food and Drug Administration (FDA) as water circulating hot or cold pack. The FDA approves them through 510(k) and has listed them as Class II devices that are in the classification of Medical Devices/Physical Medicine Devices/Physical Medicine Therapeutic Devices. The FDA has determined that a water circulating hot or cold pack is a device intended for medical purposes that operates by pumping heated or chilled water through a plastic bag and that provides hot or cold therapy for body surfaces.

There are some cooling devices that have been classified by the FDA as compressible limb sleeve or intermittent, external pneumatic compression devices (e.g., NanoTherm and Vascutherm systems). The FDA 510(k) summary for these devices includes other intended uses in addition to cooling (e.g., reduction and control of edema including lymphedema and venous stasis ulcers) (FDA, 2006).

Passive cooling devices are described by the FDA as physical medicine devices, for use as daily assist devices. These are modified adaptors or utensils intended for medical purposes to assist a patient to perform a specific function. The FDA has classified these devices as Class I and has noted that they are exempt from the premarket approval notification procedures.

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.

Adie et al (2012) conducted a Cochrane review to evaluate the acute (within 48 hours) 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 very low quality evidence from four trials (322 participants) that cryotherapy improved visual analogue score pain at 48 hours which was considered 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.

Su et al (2012) reported on a prospective, multi-center, randomized trial to evaluate the efficacy of a cryopneumatic device on total knee arthroplasty recovery. Patients were randomized to treatment with a cyropneumatic device (GameReady device) (n=103) or ice with static compression (n=84). Upon discharge from the hospital, cryotherapy treatments were given in an application cycle of one hour on and 30 minutes off. The authors reported finding no significant difference between the groups with regard to visual analog score (VAS) for pain, range of motion, 6-minute walk test, timed up and go test, or knee girth. The cyropneumatic device group reported a significant decrease in narcotic consumption, from 680 mg to 509 mg morphine equivalents, over the first 2 weeks. There was no difference in narcotic consumption in the remainder of the six weeks between the two groups. There was no difference in adverse events or compliance between the two groups.

Waterman et al (2012) reported on a randomized study of 36 patients that compared subjective and objective patient outcomes following anterior cruciate ligament (ACL) reconstruction with combined compression and cryotherapy compared with traditional ice therapy alone. Patients were randomized to cryotherapy/compression device (group 1, n=18) or a standardized ice pack (group 2, n=18). Patient-derived outcome measurements used in this study included visual analog scale (VAS), the Lysholm knee score, Short Form-36 (SF-36), and single assessment numerical evaluation (SANE). Circumferential measurements of the knee were obtained as a measure of postoperative edema. Narcotic medication use was recorded by questionnaire. The primary outcome measure (VAS) was significantly different among groups—baseline VAS for group 1 was 54.9 compared with group 2 at 35.6. By 6 weeks, this had lowered to 28.1 and 40.3, respectively, resulting in a significant 27-point decrease in mean VAS for group 1 ($p < 0.0001$). However, the small increase in VAS for group 2 was not significant ($p=0.34$). No significant differences were noted for the Lysholm, SF-36, or SANE scores either between groups or time points. No significant differences were noted for any of the circumferential measurements either between groups or time points. In group 1, 83% discontinued narcotic use by 6 weeks, compared with only 28% of group 2. Limitations of the study includes small size, patients from multiple operating providers were included in this study and due to the nature of the study, patient blinding was not possible, thus introducing potential responder and treatment bias. Woolf et al. (2008) compared postoperative pain control after knee arthroscopy in 53 patients with use of a continuous temperature-controlled cryotherapy system (Polar Care 500) compared with traditional ice therapy regimen. Pain intensity was found to be similar between groups throughout the course of the study. There were no significant differences found in the groups regarding functional ability. Kullenberg et al. (2006) conducted a randomized study of 86 patients to investigate the effect of long-term postoperative application of combined cooling and compression after total knee arthroplasty (TKA). Patients received either treatment with cold compression applied with the Cryo/Cuff for three days after TKA or were treated according to the normal routine, which included epidural analgesia until the third postoperative day, then intravenous administration with nonsteroidal anti-inflammatory drugs and opioids. Improvement was noted in range of movement at discharge and at three weeks' follow-up in the cooling and compression group. There was a decrease in time of hospitalization in this group. The study did not include a comparison of the Cryo/Cuff to treatment with conventional ice packs.

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.

Dervin et al. (1998) conducted a study to determine if benefits of the Cryo/Cuff device were due to its compressive effect rather than cold application. Seventy-eight patients were randomized to receive Cryo/Cuff compressive dressings postoperatively or to receive the cuff with room-temperature water. The study failed to show a clinically significant additive effect of cryotherapy to the compressive dressing. It was also noted in conclusion that there are conflicting data as to the benefit of this device for routine use in ACL reconstruction. Edwards et al. (1996) conducted a prospective, randomized study of 71 patients to assess the use of cold therapy after arthroscopic anterior cruciate ligament (ACL) reconstruction. Group I patients had Cryo/Cuffs filled with ice water and drained and filled hourly for the first 36 hours; Group II patients had Cryo/Cuffs filled with room-temperature water; and Group III patients had no Cryo/Cuffs. The study concluded that this trial did not demonstrate beneficial effects of cold therapy in postoperative management of patients undergoing arthroscopic ACL reconstruction. No differences were found in blood loss, analgesic use, pain scores, or range of motion. A randomized study was conducted in 110 patients to assess the effectiveness of postoperative cold therapy in patients who underwent ACL reconstructions (Konrath, et al., 1996). Group I received treatment with the Polar Care device filled with ice water; Group II received the Polar Care device filled with lukewarm tap water; Group III was treated with 1.3–1.5 kg bags of crushed ice, changed every four hours; and Group IV, the control group, received no cold therapy. The authors concluded that ice bags and cooling pads appeared equally effective. There did not appear to be any significant difference in important health outcomes of early range of motion, drain output, length of hospital stay or use of pain medication between the groups.

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, and that cooling therapy could be considered as a potential adjunct to other symptomatic and disease-modifying treatments.

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:
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)

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 (2004). Body cooling is included in section for complementary therapies—two trials found regarding this treatment. The first placebo-controlled trial reported beneficial effects on three out of four of the indices tested, namely visual acuity, timed walk test and muscle strength, but no effect on coordination; however, the length of follow-up was not reported and so it is not possible to determine whether these effects were transitory. The second trial reported no significant effects on either tympanic temperature decreases or on any of twelve performance tests. This treatment is not included in the recommendations.

Summary
There is insufficient evidence in the published, peer-reviewed scientific literature to conclude that cold therapy units or cooling devices, including both passive and active pump-controlled cooling and compression devices, have a clinical benefit over the conventional, intermittent application of ice packs and wraps. Well-designed, randomized, controlled clinical trials are needed to demonstrate that these devices provide additional clinical benefit over and above that achieved with the use of conventional ice pack application and compression wraps.

The studies that have been published regarding the use of cooling therapy for patients with multiple sclerosis (MS) evaluated the use of active cooling devices. Studies evaluating passive devices are lacking. There is insufficient evidence in the published, peer-reviewed scientific literature to conclude that the use of cooling systems/cooling devices/cooling garments in patients with MS provides any additional therapeutic effect over other strategies used to decrease body temperature, such as obtaining adequate rest, and the use of environmental measures such as air conditioning, cool baths and showers, and ingesting cold drinks. Well-designed, randomized, controlled clinical trials are needed to evaluate the clinical benefit of cooling systems/cooling devices/cooling garments for treatment of the symptoms of MS.

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

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

HCPCS Codes	Description
E0218	Water circulating cold pad with pump
E0236	Pump for water circulating pad

Experimental/Unproven/Not Covered when used to report a cooling device/cooling garment for the treatment of multiple sclerosis:

HCPCS Codes	Description
E1399	Durable medical equipment, miscellaneous

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