



CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

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Subject Cryounits/Cooling Devices

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Cooling Devices for Multiple Sclerosis
Lymphedema Pumps and Sleeves
Pneumatic Compression Devices for
Vascular Diseases of the Lower
Extremities

INSTRUCTIONS FOR USE

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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 cold therapy units or cooling devices, including both passive and active pump-controlled cooling and compression devices, because they are considered convenience items and not medically necessary.

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.
- Versa-Cool™ Portable Cold Therapy Unit (Pro Orthopedic Devices, Inc., Tucson, AZ): This device includes a battery-operated pump.
- 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.

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 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).

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.

Woolf et al. (2008) examined 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.

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.

Coding/Billing Information

Note: This list of codes may not be all-inclusive.

Not Medically Necessary/Convenience Item/Not Covered:

HCPCS Codes	Description
E0218	Water circulating cold pad with pump

E0236	Pump for water circulating pad
E1399†	Durable medical equipment, miscellaneous

†**Note: Not medically necessary/convenience item/not covered when used to report both passive and active pump-controlled devices that provide cooling and compression.**

ICD-9-CM Diagnosis Codes	Description
	All codes

*Current Procedural Terminology (CPT®) ©2010 American Medical Association: Chicago, IL.

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Policy History

Pre-Merger Organizations	Last Review Date	Policy Number	Title
CIGNA HealthCare	4/15/2008	0314	Cryounits/Cooling Devices

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