



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.

Subject Cooling Devices for Multiple Sclerosis

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Coverage Policy Number 0375

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Cryounits/Cooling Devices
 Glatiramer Acetate (Copaxone®)
 Multiple Sclerosis Interferon Products

INSTRUCTIONS FOR USE

Coverage Policies are intended to provide guidance in interpreting certain **standard** CIGNA HealthCare benefit plans. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement (GSA), Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document **always supercedes** the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. Proprietary information of CIGNA. Copyright ©2011 CIGNA

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 cooling device/cooling suit for the treatment of multiple sclerosis because each is considered experimental, investigational or unproven.

General Background

Multiple sclerosis (MS) is a chronic, progressive, neurologic autoimmune disorder that affects the myelin sheath surrounding the axons in the central nervous system (CNS). Demyelination of the nerves occurs and may also be accompanied by damage to the axons. 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], 2009). 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,2009). There are four clinical courses of MS, with potential for progression from a less serious course to a more serious course over time. The most common is relapsing-remitting MS, which is manifested by a series of attacks followed by complete or partial remissions MS (National Multiple Sclerosis Society [NMSS], 2005).

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, 2009). In addition, it has been theorized that an elevated body temperature further impairs the ability of a demyelinated nerve to conduct electrical impulses (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 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 include, but are not limited to:

- Flexitherm™ (Life Enhancement Technologies, Inc., Santa Clara, CA): This is an active cooling device which consists of a head-vest garment and can be used with the Isopro™ Portable Personal Cooling System (PCS) or the Isopro Cooling Console to provide circulating cool water.
- 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)

U.S. Food and Drug Administration (FDA): Active cooling devices are described by the FDA as water circulating hot or cold packs. These devices are intended for medical purposes that operate by pumping heated or chilled water through plastic bags and provide hot or cold therapy to body surfaces. The FDA has classified these as class II devices, and has noted that they are exempt from the premarket notification procedures.

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): 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

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) reported on a double blinded, placebo controlled, cross-over study that evaluated the effects of head and neck cooling on six heat-sensitive, stable, ambulatory females with MS. At three visits, participants received 60 minutes of true, sham, or no cooling using a custom head and neck cooling hood, followed by evaluation of ambulation, visual acuity, and muscle strength, along with measurements of rectal and skin temperature, heart rate, and thermal sensation. Both the true and sham cooling resulted in sensations of thermal cooling, but only the true cooling condition decreased core temperature by 0.37°C (36.97 ± 0.21 to $36.60\pm 0.23^{\circ}\text{C}$). Improved performance was seen with true cooling in the six-minute walk test and the timed up-and-go test but not in visual acuity or hand grip strength. Myer-Heim et al. (2007) conducted a single-blinded crossover study of 20 patients that examined the effectiveness of an advanced lightweight cooling-garment technology to improve clinical symptoms of MS. The cooling device utilized was a water-filled, cooling thigh cuff. The results suggested improvement in timed-walking test, leg-strength, fine motor skills and subjective benefits. Preliminary data of heart rate variability suggested that the MS patients showed abnormalities after sham treatment which normalized after cooling. The authors noted that further research should determine the practicability of this device, the efficacy of chronic cooling including assessment of fatigue, activities of daily living and quality of life. Beenakker et al. (2001) conducted a cross-over study involving 10 heat-sensitive patients with MS. In the first session, 10 patients were randomly assigned to wear a cooling garment for 60 minutes, either at 7°C for active cooling or at 26°C for sham cooling, with blinding for the type of cooling. A second session was performed one week later. An active head-vest cooling garment from Lifetime Enhancement Technologies Inc. was used in the study. Neither sham nor active cooling was associated with lowering of tympanic temperature. It appeared that the active cooling resulted in improvement of fatigue, muscle strength in lower limbs, and standing balance with eyes closed. It was also noted that active cooling was associated with a decrease in the mean leukocyte nitrite concentration, while sham cooling did not appear to have a significant effect on this measurement.

Professional Societies/Organizations:

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 was not included in the recommendations.

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)

Summary

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

Experimental/Investigational/Unproven/Not Covered:

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

ICD-9-CM Diagnosis Codes	Description
340	Multiple Sclerosis

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

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Policy History

<u>Pre-Merger Organizations</u>	<u>Last Review Date</u>	<u>Policy Number</u>	<u>Title</u>
CIGNA HealthCare	6/15/2007	0375	Cooling Devices for Multiple Sclerosis

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