



Harmony Behavioral Health, Inc.

Harmony Behavioral Health of Florida, Inc.

Harmony Health Plan of Illinois, Inc.

HealthEase of Florida, Inc.

*'Ohana Health Plan, a plan offered by
WellCare Health Insurance of Arizona, Inc.*

WellCare Health Insurance of Illinois, Inc.

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WellCare of Texas, Inc.

WellCare Prescription Insurance, Inc.

Therapeutic Cooling Devices

Policy Number: HS-139

Original Effective Date: 10/15/2009

Revised Date(s): 10/29/2010; 9/15/2011

DISCLAIMER

The Clinical Coverage Guideline is intended to supplement certain standard WellCare benefit plans. The terms of a member's particular Benefit Plan, Evidence of Coverage, Certificate of Coverage, etc., may differ significantly from this Coverage Position. For example, a member's benefit plan may contain specific exclusions related to the topic addressed in this Clinical Coverage Guideline. When a conflict exists between the two documents, the Member's Benefit Plan always supersedes the information contained in the Clinical Coverage Guideline. Additionally, Clinical Coverage Guidelines relate exclusively to the administration of health benefit plans and are NOT recommendations for treatment, nor should they be used as treatment guidelines. The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

APPLICATION STATEMENT

The application of the Clinical Coverage Guideline is subject to the benefit determinations set forth by the Centers for Medicare and Medicaid Services (CMS) National and Local Coverage Determinations and state-specific Medicaid mandates, if any.

BACKGROUND

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:

- Game Ready™ Active Cooling Vest (Game Ready, Inc., Berkeley, CA): This system contains a vest and control unit that allows setting of treatment time, level of compression, temperature and circulates the fluid through the vest.
- 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 Cooling, Arlington Heights, IL): This device includes a t-shirt, cooler, pump system and hoses.

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.

There is insufficient evidence in the published, peer-reviewed scientific literature to conclude that the use of cooling systems/cooling devices/cooling garments in members 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 or any other potential therapeutic use.

POSITION STATEMENT

The use of cooling devices, including both passive and active pump-controlled devices, **is considered NOT medically necessary.**

The use of cooling devices for the treatment of multiple sclerosis (340) **is considered NOT medically necessary.**

There is insufficient evidence to conclude that cooling devices have additional clinical efficacy or impact on health outcomes when compared to the use of ice or standard compression devices.

CODING

CPT® Codes - No applicable codes

ICD-9-CM Procedure Codes - No applicable codes

Non-Covered HCPCS Level II ® Codes

E0218 Water Circulating Cold Pad with Pump

E0236 Pump for Water Circulating Pad

Non-Covered Diagnosis

340 Multiple Sclerosis

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REFERENCES

Peer Reviewed

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2. Calabresi, P.A. (2004). Diagnosis and management of multiple sclerosis. *American Family Physician, 70*(10), 1935-44.
3. Meyer-Heim, A., Rothmaier, M., Weder, M., Kool, J., Schenk, P., & Kesselring, J. (2007). Advanced lightweight cooling-garment technology: functional improvements in thermosensitive patients with multiple sclerosis. *Multiple Sclerosis, 13*(2), 232-7.
4. Schwid, S.R., Petrie, Murray, R., Leitch, J., Bowen, J., Alquist, A., & et al. (2003). A randomized controlled study of the acute and chronic effects of cooling therapy for MS. *Neurology, 60*(12), 1955-60.

Government Agencies, Professional and Medical Organizations

1. Multiple Sclerosis Association of America. (2004). Multiple sclerosis and cooling (3rd ed.). Retrieved from <http://www.msassociation.org/publications/cooling/>
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HISTORY AND REVISIONS

Date	Action
12/1/2011	• New template design approved by MPC.
9/15/2011	• Approved by MPC. No changes.