

09-E0000-53

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Subject: Cooling and Heating Devices Used in the Outpatient Setting

THIS MEDICAL COVERAGE GUIDELINE IS NOT AN AUTHORIZATION, CERTIFICATION, EXPLANATION OF BENEFITS, OR A GUARANTEE OF PAYMENT, NOR DOES IT SUBSTITUTE FOR OR CONSTITUTE MEDICAL ADVICE. ALL MEDICAL DECISIONS ARE SOLELY THE RESPONSIBILITY OF THE PATIENT AND PHYSICIAN. BENEFITS ARE DETERMINED BY THE GROUP CONTRACT, MEMBER BENEFIT BOOKLET, AND/OR INDIVIDUAL SUBSCRIBER CERTIFICATE IN EFFECT AT THE TIME SERVICES WERE RENDERED. THIS MEDICAL COVERAGE GUIDELINE APPLIES TO ALL LINES OF BUSINESS UNLESS OTHERWISE NOTED IN THE PROGRAM EXCEPTIONS SECTION.

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DESCRIPTION:

Heat, cold and/or compression therapy following surgery or musculoskeletal and soft tissue injury has long been accepted in the medical field as an effective tool for reducing inflammation, pain, and swelling. Ice packs and various bandages and wraps are commonly used. In addition, a variety of continuous cooling and heating devices are commercially available and can be broadly subdivided into those providing passive cold or heat therapy and those providing active cold or heat therapy using a mechanical device.

Passive devices generally operate using gravity or a hand pump, and do not use a battery or electricity. Passive devices usually consist of a cuff or wrap and a cooler. Examples of passive devices include, but are not limited to, the AirCast Cryo/Cuff System and the Polar Care (PC) Cub Unit.

In active devices, a motorized pump both circulates water and may also provide pneumatic compression. Examples of active devices include, but are not limited to, the Auto Chill Device, Bio-Cryo System, Cothera VPulse, Kinex ThermoComp Device, Game Ready Accelerated Recovery System, Hot/Ice Thermal Blanket, JetStream Hot/Cold Therapy Unit, IceMan Cryotherapy Unit, VascuTherm, and the VitalWrap System.

Hybrid active/passive devices include, but are not limited to, the VibraCool Massaging Ice Therapy system, which uses a high frequency vibration unit and specially designed ice packs secured with a neoprene strap.

Scalp hypothermia using a cooling cap has been proposed for preventing alopecia (hair loss) for individuals undergoing chemotherapy. The rationale is that scalp hypothermia causes cutaneous vasoconstriction which thereby reduces the amount of chemotherapeutic agent delivered to the hair follicles. Cellular uptake by the hair follicle would also be reduced since this occurs more readily at warmer temperatures. It is thought that scalp hypothermia lowers the metabolic rate of the hair follicles and thereby further reduce chemotherapy-induced hair loss.

Scalp hypothermia may be accomplished manually, or using a machine-based device. Manual caps include, but are not limited to, the Arctic Cold Cap, Chemo Cold Cap, Penguin Cold Cap Therapy System, Warrior Caps and Wishcaps. Machine-based devices include, but are not limited to the the DigniCap Cooling System and Paxman Scalp Cooling System.

POSITION STATEMENT:

Active or passive heating or cooling devices, with or without pneumatic compression, **do not meet the definition of medical necessity**, as there is insufficient scientific evidence published to conclude that these therapy devices provide any additional therapeutic effect over conventional ice or heat application.

Combination active heating, cooling and compression (cryopneumatic) devices are considered **experimental or investigational**, as there is a lack of clinical scientific evidence published in peer-reviewed literature to permit conclusions on clinical outcomes.

Scalp hypothermia devices used for prevention of hair loss in chemotherapy treatment is considered **experimental or investigational**. Data in published medical literature are inadequate to permit scientific conclusions on long-term and net health outcomes.

BILLING/CODING INFORMATION:

The following codes may be used to describe passive or active cooling devices:

HCPSC Coding:

E0217	Water circulating heat pad with pump (non-covered)
E0218	Fluid circulating cold pad with pump, any type (non-covered)
E0236	Pump for water circulating pad (non-covered)

REIMBURSEMENT INFORMATION:

Refer to section entitled [POSITION STATEMENT](#).

PROGRAM EXCEPTIONS:

Federal Employee Program (FEP): Follow FEP guidelines.

State Account Organization (SAO): Follow SAO guidelines.

Medicare Advantage products:

The following National Coverage Determination (NCD) was reviewed on the last guideline review date: National Coverage Determination (NCD) for SCALP HYPOTHERMIA During Chemotherapy to Prevent Hair Loss (110.6), located at cms.gov.

The following Durable Medical Equipment Regional Carrier (DMERC) Local Coverage Determinations (LCDs) were reviewed on the last guideline reviewed date: Cold Therapy (L33735), and Heating Pads and Heat Lamps (L33784), located at cgsmedicare.com.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

[Durable Medical Equipment \(DME\), 09-E0000-01 and attached DME Table](#)

OTHER:

None applicable.

REFERENCES:

1. American Academy of Physical Medicine and Rehabilitation. Treating and Preventing Arthritis. Accessed 09/01/09.
2. Blue Cross Blue Shield Association Medical Policy 1.01.26, Cooling Devices Used in the Outpatient Setting (March 2018).
3. Brosseau L, Judd MG, Marchand S, et al. Thermotherapy for treatment of osteoarthritis. Cochran Database Systematic Reviews 2003; (4): CD004522.
4. Centers for Medicare and Medicaid Services (CMS) Region C DMERC Local Coverage Determination (LCD) Medical Policy #L11152, Cold Therapy. Retired 09/30/15.
5. Centers for Medicare and Medicaid Services (CMS) Region C DMERC Local Coverage Determination (LCD). Heating Pads and Heat Lamps (L33784) (10/01/15).
6. Centers for Medicare and Medicaid Services (CMS) Region C DMERC Local Coverage Determination (LCD). Cold Therapy (L33735) (10/01/15).
7. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for SCALP HYPOTHERMIA During Chemotherapy to Prevent Hair Loss (110.6).
8. First Coast Service Options, Inc. (FCSO). Local Coverage Determination (LCD): Cold Therapy (L33735) (01/01/19).
9. First Coast Service Options, Inc. (FCSO). Local Coverage Determination (LCD): Heating Pads and Heat Lamps (L33784) (01/01/17).
10. Gatewood CT, Tran AA, Dragoo JL. The efficacy of post-operative devices following knee arthroscopic surgery: a systematic review. *Knee Surg Sports Traumatol Arthrosc.* 2017 Feb;25(2):501-516. doi: 10.1007/s00167-016-4326-4. Epub 2016 Oct 1. PMID: 27695905.
11. HAYES Alert – Technology Assessment Brief: Gravity-Controlled Cold Therapy Devices for Musculoskeletal and Postoperative Orthopedic Trauma (09/01/04).
12. HAYES Health Technology Brief. “Cold Therapy Device (Cryo/Cuff™; Aircast Inc.) for Treatment of Musculoskeletal and Postoperative Orthopedic Trauma” (05/25/07).
13. HAYES Search & Summary. “Active Cooling Devices with Pneumatic Compression for Treatment of Musculoskeletal Injury” (11/13/06).
14. Kraeutler MJ, Reynolds KA, Long C, McCarty EC. Compressive cryotherapy versus ice-a prospective, randomized study on postoperative pain in patients undergoing arthroscopic rotator cuff repair or subacromial decompression. *J Shoulder Elbow Surg.* 2015 Jun;24(6):854-9. doi: 10.1016/j.jse.2015.02.004. Epub 2015 Mar 29. PMID: 25825138.
15. Robinson VA, Vrosseau L, Casimiro L, et al. Thermotherapy for treating rheumatoid arthritis. Cochran Database of Systematic Reviews 2005; (3): CD002826.

16. Ross M, Fischer-Carlidge E. Scalp Cooling: A Literature Review of Efficacy, Safety, and Tolerability for Chemotherapy-Induced Alopecia. *Clin J Oncol Nurs*. 2017 Apr 1;21(2):226-233. doi: 10.1188/17.CJON.226-233. PMID: 28315539.
17. Rugo HA, Klein P, et al. Association Between Use of a Scalp Cooling Device and Alopecia After Chemotherapy for Breast Cancer. *JAMA*. 2017 Feb 14;317(6):606-614. doi: 10.1001/jama.2016.21038.
18. Rugo HS, Melin SA, Voigt J. Scalp cooling with adjuvant/neoadjuvant chemotherapy for breast cancer and the risk of scalp metastases: systematic review and meta-analysis. *Breast Cancer Res Treat*. 2017 Jun;163(2):199-205. doi: 10.1007/s10549-017-4185-9. Epub 2017 Mar 8.
19. Satterwhite B, Zimm S. The use of scalp hypothermia in the prevention of doxorubicin-induced hair loss. *Cancer*. 1984 Jul 1;54(1):34-7.
20. Shah VV, Wikramanayake TC, et al. Scalp hypothermia as a preventative measure for chemotherapy-induced alopecia: a review of controlled clinical trials. *J Eur Acad Dermatol Venereol*. 2018 May;32(5):720-734. doi: 10.1111/jdv.14612. Epub 2017 Nov 24. PMID: 28976026 DOI: 10.1111/jdv.14612.
21. U.S. Food and Drug Administration (FDA) 510(k) K071050 Summary of Safety and Effectiveness, Game Ready Professional Therapy System, Model 550100, Game Ready Pre-programmed Professional Therapy System (07/29/07).
22. U.S. Food and Drug Administration (FDA) 510(k) K072620 Summary of Safety and Effectiveness, Game Ready Classic System 550550 (10/31/07).
23. VitalWear VitalWrap® System Specifications. Accessed at https://www.ncmedical.com/item_1523.html.

COMMITTEE APPROVAL:

This Medical Coverage Guideline (MCG) was approved by the Florida Blue Medical Policy & Coverage Committee on 03/28/19.

GUIDELINE UPDATE INFORMATION:

10/15/05	New Medical Coverage Guideline.
08/15/07	Scheduled review; reformatted guideline; updated references.
10/15/09	Scheduled review; no change in position statement; updated references.
06/15/13	Revision: Position Statement revised regarding combination active cooling and compression (cryopneumatic) devices; Program Exceptions section updated; references updated.
11/15/15	Revision. Added coverage statement for active/passive heating devices. Revised HCPCS coding section. Updated references.
01/01/19	Annual CPT/HCPCS coding update. Revised descriptor E0218.
04/15/19	Scheduled review. Revised description, index terms, and program exceptions. Added coverage statement for scalp cooling devices. Updated references.

