

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.

Position Statement	Billing/Coding	Reimbursement	Program Exceptions	Definitions	Related Guidelines
Other	References	Update			

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 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.

The use of a DigniCap® or Paxman® scalp cooling system **meets the definition of medical necessity** when **ALL** of the following are met:

- The purpose is to reduce or prevent alopecia during chemotherapy, **AND**
- The member has a solid tumor cancer, **AND**
- The scalp cooling system will be used in the chemotherapy infusion suite (not in the home setting), **AND**
- None of the following contraindications are present:
 - Use in a pediatric member
 - Member receiving continuous-infusion chemotherapy regimens over one day or longer that result in alopecia
 - Undergoing whole-brain or targeted brain irradiation
 - The presence of cold agglutinin disease, cryoglobulinemia, or post-traumatic cold dystrophy
 - Member has small cell or squamous lung cancer
 - Member has skin cancer, including melanoma, squamous cell carcinoma, or Merkel cell carcinoma
 - Member has a hematologic malignancy, including leukemia and lymphoma
 - Member is undergoing bone marrow or stem cell transplantation with myeloablative doses of chemotherapy and/or radiation therapy

A cap to be used with the DigniCap® or Paxman® scalp cooling system in the infusion suite **meets the definition of medical necessity**.

The following are considered **experimental or investigational**:

- The use of a scalp cooling device for any indication other than chemotherapy-induced alopecia
- The use of a non-FDA approved or cleared scalp cooling device (e.g., Penguin Cold Caps, Artic Caps, Polar Caps, Chemo Cold Caps, Wishcaps, Warrior Caps, non-automated/manual frozen elastogel, ice-filled bags or bandages, etc.)
- The use of a scalp cooling device in the home setting

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, or scalp cooling systems:

CPT Coding:

0662T	Scalp cooling, mechanical; initial measurement and calibration of cap
0663T	Scalp cooling, mechanical; placement of device, monitoring, and removal of device (List separately in addition to code for primary procedure)
0881T	Cryotherapy of the oral cavity using temperature regulated fluid cooling system, including placement of an oral device, monitoring of patient tolerance to treatment, and removal of the oral device (eg, Cooral Oral Cooling System) (Investigational)

HCPCS 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); Durable Medical Equipment Reference List (280.1), 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); Heating Pads and Heat Lamps (L33784); Infrared HEATING PAD Systems L33825, located at cms.gov.

DEFINITIONS:

No guideline specific definitions apply.

RELATED GUIDELINES:

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

OTHER:

None applicable.

REFERENCES:

1. American Academy of Physical Medicine and Rehabilitation. Treating and Preventing Arthritis.
2. Bajpai J, Kagwade S, Chandrasekharan A, et al. Randomised controlled trial of scalp cooling for the prevention of chemotherapy induced alopecia. *Breast*. 2020 Feb;49:187-193. doi: 10.1016/j.breast.2019.12.004. Epub 2019 Dec 12.
3. Blue Cross Blue Shield Association Evidence Positioning System®. 1.01.26 - Cooling Devices Used in the Outpatient Setting, 04/22.
4. Brosseau L, Judd MG, Marchand S, et al. Thermotherapy for treatment of osteoarthritis. *Cochran Database Systematic Reviews* 2003; (4): CD004522.
5. Centers for Medicare and Medicaid Services (CMS) Region C DMERC Local Coverage Determination (LCD) Cold Therapy (L11152) (Retired 09/30/15).
6. Centers for Medicare and Medicaid Services (CMS) Region C DMERC Local Coverage Determination (LCD). Heating Pads and Heat Lamps (L33784) (10/01/15) (Revised 01/01/20).
7. Centers for Medicare and Medicaid Services (CMS) Region C DMERC Local Coverage Determination (LCD). Cold Therapy (L33735) (10/01/15) (Revised 01/01/20).
8. Centers for Medicare and Medicaid Services (CMS) Region C DMERC Local Coverage Determination (LCD). Infrared Heating Pad Systems (L33825) (10/01/15) (Revised 01/01/20).
9. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) for SCALP HYPOTHERMIA During Chemotherapy to Prevent Hair Loss (110.6) (LONGSTANDING).
10. Centers for Medicare and Medicaid Services (CMS). National Coverage Determination (NCD) Durable Medical Equipment Reference List (280.1) (05/05/05).
11. Dunnill CJ, Al-Tameemi W, Collett A, Haslam IS, Georgopoulos NT. A Clinical and Biological Guide for Understanding Chemotherapy-Induced Alopecia and Its Prevention. *Oncologist*. 2018 Jan;23(1):84-96. doi: 10.1634/theoncologist.2017-0263. Epub 2017 Sep 26.
12. 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.
13. HAYES Alert – Technology Assessment Brief: Gravity-Controlled Cold Therapy Devices for Musculoskeletal and Postoperative Orthopedic Trauma (09/01/04).
14. HAYES Health Technology Brief. “Cold Therapy Device (Cryo/Cuff™; Aircast Inc.) for Treatment of Musculoskeletal and Postoperative Orthopedic Trauma” (05/25/07).
15. HAYES Search & Summary. “Active Cooling Devices with Pneumatic Compression for Treatment of Musculoskeletal Injury” (11/13/06).

16. 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.
17. Murgier J, Cailliez J, Wargny M, Chiron P, Cavaignac E, Laffosse JM. Cryotherapy With Dynamic Intermittent Compression Improves Recovery From Revision Total Knee Arthroplasty. *J Arthroplasty.* 2017;32(9):2788–2791. doi:10.1016/j.arth.2017.03.052.
18. Mitric C, How B, Matanes E, et al. Scalp cooling for reducing alopecia in gynecology oncology patients treated with dose-dense chemotherapy: A pilot project. *Gynecol Oncol Rep.* 2021 Jul 27;37:100842. doi: 10.1016/j.gore.2021.100842.
19. National Comprehensive Cancer Network (NCCN). Ovarian Cancer, Fallopian Tube Cancer, Primary Peritoneal Cancers Version 1.2021.
20. Noyes MP, Denard PJ. Continuous Cryotherapy vs Ice Following Total Shoulder Arthroplasty: A Randomized Control Trial. *Am J Orthop (Belle Mead NJ).* 2018;47(6):10.12788/ajo.2018.0045. doi:10.12788/ajo.2018.0045.
21. Robinson VA, Vrosseau L, Casimiro L, et al. Thermotherapy for treating rheumatoid arthritis. *Cochran Database of Systematic Reviews* 2005; (3): CD002826.
22. 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.
23. 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.
24. 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.
25. 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.
26. 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.
27. Shen XF, Ru LX, Yao XB. Efficacy of scalp cooling for prevention of chemotherapy induced alopecia: a systematic review and meta-analysis. *Eur Rev Med Pharmacol Sci.* 2021 Aug;25(16):5090-5103. doi: 10.26355/eurrev_202108_26520.
28. Silva GB, Ciccolini K, Donati A, Hurk CVD. Scalp cooling to prevent chemotherapy-induced alopecia. *An Bras Dermatol.* 2020 Sep-Oct;95(5):631-637. doi: 10.1016/j.abd.2020.03.005. Epub 2020 Jun 16.
29. Thienpont E. Does advanced cryotherapy reduce pain and narcotic consumption after knee arthroplasty?. *Clin Orthop Relat Res.* 2014;472(11):3417–3423. doi:10.1007/s11999-014-3810-8.
30. UpToDate. Alopecia related to systemic cancer therapy. 2022. Accessed at uptodate.com.
31. UpToDate. Musculoskeletal injury in children and skeletally immature adolescents: Overview of rehabilitation for nonoperative injuries. 2021. Accessed at uptodate.com.
32. 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).
33. U.S. Food and Drug Administration (FDA) 510(k) K072620 Summary of Safety and Effectiveness, Game Ready Classic System 550550 (10/31/07).

34. Villarreal-Garza C, Mesa-Chavez F, Garza-Ledezma MR, et al. Impact of chemotherapy regimen and sequence on the effectiveness of scalp cooling for alopecia prevention. *Breast Cancer Res Treat.* 2021 Jan;185(2):453-458. doi: 10.1007/s10549-020-05968-w. Epub 2020 Oct 30.
35. 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 and Coverage Committee on 08/25/22.

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.
03/15/20	Scheduled review. Maintained position statement and updated references.
05/15/21	Scheduled review. Maintained position statement and updated references.
07/01/21	Quarterly CPT/HCPCS coding update. Added 0662T and 0663T.
09/15/22	Scheduled review. Added coverage statement for the use of scalp cooling caps. Updated references.
07/01/24	Quarterly CPT/HCPCS coding update. Added 0881T.