

Scalp Cooling During Chemotherapy

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Effective Date 10/2023

Next Review Date 08/2024

Coverage Policy DME 249

Version 1

All requests for authorization for the services described by this medical policy will be reviewed per Early and Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to be medically necessary to correct or ameliorate the member's condition. Department of Medical Assistance Services (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.*.

Purpose:

This policy addresses Scalp Cooling During Chemotherapy.

Description & Definitions:

Scalp cooling device to reduce the temperature of the scalp while the individual is receiving chemotherapy treatments. The cap reduces blood flow to the hair follicles reducing chemotherapeutic agents from the same area of vasoconstriction.

Other common names: Cold cap therapy, Hypothermia hair loss prevention, Cryounits, Cooling Device, Scalp Hypothermia, DigniCap Cooling System

Criteria:

Scalp Cooling is medically necessary for ALL of the following:

- Individual is 18 years or older
- Currently receiving chemotherapy for solid tumors

Scalp Cooling does not meet the definition of medical necessity, to include but not limited to:

- Central nervous system malignancies (either primary or metastatic)
- Squamous cell carcinoma and small cell carcinoma of the lung
- Skin cancers including melanoma, squamous cell carcinoma, and Merkel cell carcinoma
- Patients who are scheduled for bone marrow ablation chemotherapy
- Patients who are scheduled to undergo skull irradiation or have previously received skull irradiation
- · Patients with a history of scalp metastases, or in whom scalp metastases are suspected
- Patients with cold sensitivity, cold agglutinin disease, cryoglobulinemia, cryofibrinogenemia, and posttraumatic cold dystrophy

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- Patients with severe liver or renal disease from any etiology who may not be able to metabolize or clear the metabolites of the chemotherapeutic agent
- Patients with hematologic malignancies (leukemia, non-Hodgkin and other generalized lymphomas)

Coding:

Medically necessary with criteria:

Coding	Description
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)

Considered Not Medically Necessary:

Coding	Description
	None

Document History:

Revised Dates:

Reviewed Dates:

Effective Date: October 2023

References:

Including but not limited to: Specialty Association Guidelines; Government Regulations; Winifred S. Hayes, Inc; UpToDate; Literature Review; Specialty Advisors; National Coverage Determination (NCD); Local Coverage Determination (LCD).

(2022, Aug 18). Retrieved Nov 18, 2022, from MCG: https://careweb.careguidelines.com/ed26/index.html

(2022). Retrieved Nov 18, 2022, from Centers for Medicare and Medicaid Services: https://www.cms.gov/medicare-coverage-database/search-

results.aspx?keyword=cooling&keywordType=starts&areald=s53&docType=NCA,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all

(2022). Retrieved Nov 18, 2022, from Department of Medical Assistance Services:

https://vamedicaid.dmas.virginia.gov/global-search?keys=scalp+cooling

(2022). Retrieved Nov 18, 2022, from AIM Specialty Health:

https://guidelines.aimspecialtyhealth.com/?s=scalp+cooling&et_pb_searchform_submit=et_search_proccess&et_pb_search_cat=11%2C1%2C96&et_pb_include_posts=yes

(2022). Retrieved Nov 18, 2022, from Virginia Premier: https://www.virginiapremier.com/wp-content/uploads/virginia-premier-medicaid-provider-manual-en.pdf

(2022). Retrieved Nov 18, 2022, from UHC: https://www.uhcprovider.com/en/searchresult.htmlAlopecia related to systemic cancer therapy. (2022, Feb 01). Retrieved Nov 18, 2022, from UpToDate: https://www.uptodate.com/contents/alopecia-related-to-systemic-cancer-

 $the rapy? search = scalp \% 20 cooling \& source = search_result \& selected Title = 1 \sim 13 \& usage_type = default \& display_rank = 1 \# H7 + 12 \& usage_type = default \& display_rank = 1 \# H7 + 12 \& usage_type = default \& display_rank = 1 \# H7 + 12 \& usage_type = default \& display_rank = 1 \# H7 + 12 \& usage_type = default \& display_rank = 1 \# H7 + 12 \& usage_type = default \& display_rank = 1 \# H7 + 12 \& usage_type = default \& display_type = def$

Dignicap. (2022). Retrieved Nov 18, 2022, from Dignicap: https://dignicap.com/

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FDA clears expanded use of cooling cap to reduce hair loss during chemotherapy. (2018, Mar 28). Retrieved Nov 18, 2022, from Food and Drug Administration: https://www.fda.gov/news-events/press-announcements/fda-clears-expanded-use-cooling-cap-reduce-hair-loss-during-chemotherapy

NCD Scalp Hypothermia During Chemotherapy to Prevent Hair Loss (110.6). (N.D.). Retrieved Nov 18, 2022, from Centers for Medicare and Medicaid Services: https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=147&ncdver=1&

Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer. (2022, Sep 16). Retrieved Nov 18, 2022, from National Comprehensive Cancer Network:

https://www.nccn.org/professionals/physician_gls/pdf/ovarian_blocks.pdf

Prevention and management of dermatological toxicities related to anticancer agents: ESMO Clinical Practice Guidelines. (2020, Nov 25). Retrieved Nov 18, 2022, from European Society for Medical Oncology: https://www.annalsofoncology.org/article/S0923-7534(20)43157-6/fulltext

Scalp Cooling Devices For The Prevention Of Chemotherapy-Induced Alopecia: A Review Of Reviews. (2021, Dec 03). Retrieved Nov 18, 2022, from Hayes, Inc:

https://evidence.hayesinc.com/search?q=%257B%2522text%2522:%2522transanal%2520endoscopic%2520microsurger y%2522,%2522title%2522:null,%2522termsource%2522:%2522searchbar%2522,%2522page%2522:%257B%2522page%2522:0,%2522size%2522:50%257D,%2522type%2522:%2522al

Scalp cooling therapy prevents hair loss during chemotherapy. (2019, Jun 26). Retrieved Nov 18, 2022, from Mayo Clinic: https://www.mayoclinichealthsystem.org/hometown-health/speaking-of-health/scalp-cooling-therapy-prevents-hair-loss-during-chemotherapy

Rugo, H., & Lacouture, M. (2022, Feb 01). Alopecia related to systemic cancer therapy. Retrieved Nov 18, 2022, from UpToDate: https://www.uptodate.com/contents/alopecia-related-to-systemic-cancer-therapy?search=scalp%20cooling&source=search_result&selectedTitle=1~13&usage_type=default&display_rank=1

PROPOSED LCD: Scalp Cooling for the Prevention of Chemotherapy-Induced Alopecia (DL39573). (2023). Retrieved Jul 26, 2023, from Centers for Medicare and Medicaid Services: https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39572&ver=3&keyword=scalp%20cooling&keywordType=starts&areald=s53&docType=NC A,CAL,NCD,MEDCAC,TA,MCD,6,3,5,1,F,P&contractOption=all&sortBy=relevance&bc=1

Special Notes: *

This medical policy express Sentara Health Plan's determination of medically necessity of services, and they are based upon a review of currently available clinical information. These policies are used when no specific guidelines for coverage are provided by the Department of Medical Assistance Services of Virginia (DMAS). Medical Policies may be superseded by state Medicaid Plan guidelines. Medical policies are not a substitute for clinical judgment or for any prior authorization requirements of the health plan. These policies are not an explanation of benefits.

Medical policies can be highly technical and complex and are provided here for informational purposes. These medical policies are intended for use by health care professionals. The medical policies do not constitute medical advice or medical care. Treating health care professionals are solely responsible for diagnosis, treatment and medical advice. Sentara Health Plan members should discuss the information in the medical policies with their treating health care professionals. Medical technology is constantly evolving and these medical policies are subject to change without notice, although Sentara Health Plan will notify providers as required in advance of changes that could have a negative impact on benefits.

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) covers services, products, or procedures for children, if those items are determined to be medically necessary to "correct or ameliorate" (make better) a defect, physical or mental illness, or condition (health problem) identified through routine medical screening or examination, regardless of whether coverage for the same service or support is an optional or limited service under the state plan.

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Children enrolled in the FAMIS Program are not eligible for all EPSDT treatment services. All requests for authorization for the services described by this medical policy will be reviewed per EPSDT guidelines. These services may be authorized under individual consideration for Medicaid members under the age of 21-years if the services are judged to by medically necessary to correct or ameliorate the member's condition. *Department of Medical Assistance Services* (DMAS), Supplement B - EPSDT (Early and Periodic Screening, Diagnosis and Treatment) Manual.

All medically necessary medical equipment and supplies under the Virginia Administrative Code (12VAC30-50-165) may be covered only if they are necessary to carry out a treatment prescribed by a practitioner. Only supplies, equipment, and appliances that are determined medically necessary may be covered for reimbursement by DMAS. (12VAC30-50-165) The following criteria must be satisfied through the submission of adequate and verifiable documentation satisfactory to DMAS, or its contractor. Medically necessary DME and supplies shall be:

- Ordered by the practitioner on the CMN/DMAS-352;
- A reasonable and medically necessary part of the individual's treatment plan;
- Consistent with the individual's diagnosis and medical condition, particularly the functional limitations and symptoms exhibited by the individual; Not furnished for the safety or restraint of the individual, or solely for the convenience of the family, attending practitioner, or other practitioner or supplier;
- Consistent with generally accepted professional medical standards (i.e., not experimental or investigational);
- Furnished at a safe, effective, and cost-effective level; and
- Suitable for use, and consistent with 42 CFR 440.70(b)(3), that treats a diagnosed condition or assists the individual with functional limitations.

Keywords:

Dignicap, scalp cooling, chemotherapy alopecia

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