Prior Authorization Review Panel
MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: Keystone First Community HealthChoices	**Submission Date**: 1/2/2025
Policy Number: ccp.1500	**Effective Date:** 12/2021 **Revision Date:** November 1, 2024
Policy Name: Automated scalp cooling	

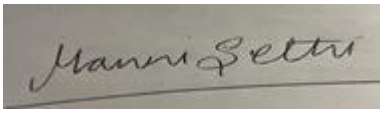
Type of Submission – Check all that apply:

- ☐ **New Policy**
- ☒ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Statewide PDL**

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any clarifying information for the policy below:

See tracked changes below.

Name of Authorized Individual (Please type or print): Manni Sethi, MD, MBA, CHCQM	**Signature of Authorized Individual:** 

Keystone First
Community HealthChoices

Automated scalp cooling

Clinical Policy ID: CCP.1500

Recent review date: 11/2024

Next review date: 3/2026

Policy contains: cancer, chemotherapy, DigniCap, Paxman, scalp cooling, scalp hypothermia

Keystone First Community HealthChoices has developed clinical policies to assist with making coverage determinations. Keystone First Community HealthChoices' clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First Community HealthChoices, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First Community HealthChoices' clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First Community HealthChoices' clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First Community HealthChoices will update its clinical policies as necessary. Keystone First Community HealthChoices' clinical policies are not guarantees of payment.

Coverage policy

Automated scalp cooling is investigational/not clinically proven and, therefore, not medically necessary for members who have undergone chemotherapy for solid cancers.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

No alternative covered services were identified during the writing of this policy.

Background

Chemotherapy causes hair loss on the scalp and body in about 65% of patients undergoing cancer treatment (Rossi, 2020). Hair can become thinner or fall out completely, either gradually or in clumps, often starting days or weeks after chemotherapy begins. Hair loss is a traumatic experience for many cancer patients, affecting their self-image and quality of life. Although hair typically begins to regrow after chemotherapy ends, no medications effectively prevent hair loss during treatment (Institute for Quality and Efficiency in Health Care, 2019), although some have been able to stimulate hair regrowth afterward (de Barros Silva, 2020).

The risk of hair loss from chemotherapy varies by the drugs used. Rates of alopecia range from 60% to 100% with topoisomerase inhibitors, over 80% with taxanes, over 60% with alkylating agents, and are lower with antimetabolites. Other risk factors for hair loss include dosage, pharmacokinetic profiles, combination regimens with various agents, older age (menopause/andropause), comorbidities, poor nutrition, hormonal imbalances, diabetes, lupus, and emotional stress (de Barros Silva, 2020; Haque, 2020).

Scalp cooling is a method used to reduce chemotherapy-induced alopecia by narrowing the blood vessels in the scalp, thereby limiting the amount of chemotherapy drugs that reach the hair follicles. This can reduce hair loss during treatment. There are two main types of scalp cooling methods: manual scalp cooling and automated (mechanical) scalp cooling.

Manual Scalp Cooling

Manual scalp cooling involves the use of frozen gel caps or ice packs that are manually applied to the scalp. The most commonly used method is to wear a cold cap during chemotherapy, which is changed every 20 to 30 minutes to maintain the desired low temperature. These caps can reduce hair loss by 50% to 80% and can be used by patients with any solid tumor cancer (Peethambaram, 2019; Shin, 2015).

Scalp hypothermia was first introduced in the late 1970s in the form of ice caps to reduce alopecia after chemotherapy. Although the U.S. Food and Drug Administration (FDA) banned sales of ice caps in 1990 due to a lack of efficacy and safety data (Shah, 2018), non-FDA-approved cold caps have remained on the market for over 20 years. A popular model is the Penguin Cold Cap. Patients using these devices must rent a kit that includes gel-containing caps, headbands, and coolers with dry ice (Brody, 2019). The process requires patients or their caregivers to manually change the caps at regular intervals and ensure they are properly cooled, which can be labor-intensive.

Automated (Mechanical) Scalp Cooling Systems

Automated scalp cooling systems are mechanical devices that provide continuous, regulated cooling to the scalp during chemotherapy infusion. The first FDA-approved mechanical cooling cap was the DigniCap Cooling System, approved for adults undergoing specific chemotherapy treatments for solid tumors and who are not susceptible to cold-related injuries. DigniCap is a computer-controlled system that circulates liquid coolant through a cap worn on the scalp, with a second neoprene cap worn over it to maintain contact (U.S. Food and Drug Administration, 2017).

The FDA also granted market approval for the Paxman Scalp Cooling System for adults with solid tumors undergoing chemotherapy. Paxman uses an electrically powered refrigeration unit to circulate liquid coolant through a cap, with a touch screen providing operational information to the user (U.S. Food and Drug Administration, 2018). These systems are contraindicated for cancers of the central nervous system, head and neck, lung, and hematological cancers.

Scalp cooling offers potential reduction in hair loss from chemotherapy, although concerns remain because cooling is usually performed only during treatment, while the half-life of toxic chemotherapy agents may be longer (Rossi, 2020). A number of federally sponsored clinical trials are currently being conducted on scalp cooling methods. Some trials are testing conventional manual cold caps, while others are evaluating mechanical systems, primarily Paxman (Wikramanayake, 2023). As of now, there are 366 chemotherapy infusion centers in the United States offering scalp cooling services (Singer, 2021).

In summary, both manual and automated scalp cooling methods aim to reduce chemotherapy-induced hair loss by cooling the scalp, but they differ in operation and patient experience. Manual methods require frequent cap changes and active participation from patients or caregivers, while automated systems provide continuous cooling with less hands-on involvement during treatment sessions.

Findings

Guidelines

The National Comprehensive Cancer Network (NCCN) recommends considering scalp cooling for breast cancer patients undergoing adjuvant or neoadjuvant chemotherapy, while noting that its effectiveness may be reduced with anthracycline-containing regimens. Additionally, the NCCN endorses scalp cooling for patients with ovarian, fallopian tube, and primary peritoneum cancers who are receiving chemotherapy with high rates of alopecia (National Comprehensive Cancer Network, 2024a, 2023b). However, these guidelines do not specifically mention automated scalp cooling.

Similarly, NHS England was the first British organization to include scalp cooling in a professional guideline by endorsing its use for cancer patients (excluding hematological types) after providing verbal and written information to patients (NHS England, 2017). The European Society for Medical Oncology has also recommended scalp cooling to prevent alopecia (Lacouture, 2021), and Cancer Australia recommends it for breast cancer patients (Hospital and Health Care, 2021), without specifically addressing automated scalp cooling.

Efficacy of Automated vs. Non-Automated Systems

Historically, most studies on scalp cooling did not distinguish between automated and non-automated systems. However, there is a growing trend in recent research to specify and compare these two approaches. For instance, a study involving 238 patients with solid cancers treated with docetaxel three times per week found that those using the Paxman automated cooling system or a cold cap had alopecia rates of 23% and 27%, respectively, compared to 74% in patients with no cooling (Betticher, 2013). This indicates that both the Paxman system and cold caps are similarly effective.

Additionally, a review of eight randomized trials revealed that Paxman demonstrated superior hair retention in one study (51% vs. 0% in controls), while seven other studies showed that non-automated caps achieved similar hair retention rates (61% vs. 14% in controls) (Nangia, 2017; Shah, 2018). The overall hair retention percentages for automated and non-automated caps did not differ significantly.

Safety and Risk of Scalp Metastases

A systematic review and meta-analysis of ten studies involving 3,197 breast cancer patients evaluated the risk of scalp metastases associated with scalp cooling during chemotherapy (Rugo, 2017). Among these patients, 1,959 used scalp cooling devices and 1,238 did not. The incidence of scalp metastases was low and not significantly different between the two groups (0.61% vs. 0.41%, $p = 0.43$), suggesting that scalp cooling does not increase the risk of scalp metastases and supports its safety for hair preservation in breast cancer patients.

Adverse Events and Dropout Rates

Adverse events associated with scalp cooling are generally mild. One study reported that 72% of adverse events were either grade 1–2 headaches or grade 1–2 feelings of coldness (Bajpai, 2020). Additionally, dropout rates due to scalp cooling were not significantly different from controls. In one study, dropout rates were 31.7% for those using the DigniCap system compared to 34.2% for controls, with the primary reasons being hair loss, adverse events from automated caps, and randomization to the control arm (Smetanay, 2019).

Recent Trends in Differentiating Scalp Cooling Methods

Recent large-scale studies are beginning to differentiate between automated and non-automated scalp cooling approaches. For example, a systematic review and meta-analysis of 27 studies involving 2,202 women

undergoing chemotherapy for breast cancer found that scalp cooling prevented hair loss in 61% of cases. Specifically, automated devices like the Paxman system demonstrated an effectiveness rate of 59%, and the DigniCap system showed a rate of 55%, compared to 75% effectiveness with manual methods such as the Penguin Cold Cap, although the latter was based on only two studies (Wang, 2021).

Another systematic review of eight randomized controlled trials with 484 breast cancer patients found that automated scalp cooling devices reduced the risk of chemotherapy-induced hair loss by 47%, while non-automated devices achieved a 43% reduction, indicating no significant difference between the two methods (Contreras Molina, 2024). Similarly, a meta-analysis of 13 randomized controlled trials involving 832 patients concluded that automated scalp cooling reduced the risk of severe hair loss by 45%, and manual systems achieved a 44% reduction, with no statistically significant difference in effectiveness between automated and manual methods (Trujillo-Martin MM, 2023).

In 2024, we updated references and added a new systematic review (Contreras Molina, 2024). No policy changes warranted.

References

On October 8, 2024, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were “cancer,” “chemotherapy,” “DigniCap,” “Paxman,” “scalp cooling,” and “scalp chemotherapy.” We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise.

Bajpai J, Kagwade S, Chandrasekharan A, et al. Randomised controlled trial of scalp cooling for the prevention of chemotherapy induced alopecia. *Breast*. 2020;49:187-193. Doi: 10.1016/j.breast.2019.12.004.

Betticher DC, Delmore G, Breitenstein U, et al. Efficacy and tolerability of two scalp cooling systems for the prevention of alopecia associated with docetaxel treatment. *Support Care Cancer*. 2013;21(9):2565-2573. Doi: 10.1007/s00520-013-1804-9.

Brody B. Should you try a cold cap to prevent chemo-related hair loss? Everyday Health. https://www.everydayhealth.com/cancer/treatment/can-cooling-caps-prevent-chemotherapy-hair-loss/. Published September 5, 2019.

De Barros Silva G, Ciccolini K, Donati A, van den Hurk C. Scalp cooling to prevent chemotherapy-induced alopecia. *An Bras Dermatol*. 2020;95(5):631-637. Doi: 10.1016/j.abd.2020.03.005.

Contreras Molina M, Álvarez Bueno C, Cavero Redondo I, Lucerón Lucas-Torres MI, Jiménez López E, García Maestro A. Effectiveness of scalp cooling to prevent chemotherapy-induced alopecia in patients undergoing breast cancer treatment: a systematic review and meta-analysis. *Cancer Nurs*. 2024;47(4):319-326. Doi:10.1097/NCC.0000000000001234.

Hospital and Healthcare (Australia). Scalp cooling lets 1 in 2 women keep hair during chemo. https://www.hospitalhealth.com.au/content/clinical-services/news/scalp-cooling-lets-1-in-2-women-keep-hair-during-chemo-740511520. Published July 22, 2021.

Institute for Quality and Efficiency in Health Care. Hair loss in chemotherapy: Overview. https://www.ncbi.nlm.nih.gov/books/NBK547552/. Published September 12, 2019.

Lacouture ME, Sibaud V, Gerber PA, et al. Prevention and management of dermatological toxicities related to anticancer agents: EMSO clinical practice guidelines. *Ann Oncol*. 2021;32(2):157-170. Doi: 10.1016/j.annonc.2020.11.005.

Nangia J, Wang T, Osborne C, et al. Effect of a scalp cooling device on alopecia in women undergoing chemotherapy for breast cancer: The SCALP randomized clinical trial. *JAMA*. 2017;317(6):596-605. Doi: 10.1001/jama.2016.20939.

National Comprehensive Cancer Network. Breast Cancer. Version 4.2024. www.nccn.org. Published July 3, 2024. (a)

National Comprehensive Cancer Network. Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer. Version 3.2024. www.nccn.org. Published June 2, 2024. (b)

NHS England. Scalp Cooling Guidelines for Adult Oncology Patients. https://www.england.nhs.uk/mids-east/wp-content/uploads/sites/7/2018/04/scalp-cooling-for-adult-oncology-patients.pdf. Published August 11, 2017.

Peethambaram PP, Loprinzi CL. Can scalp cooling stop hair loss from chemotherapy? American Society of Clinical Oncology. https://www.cancer.net/blog/2019-01/can-scalp-cooling-stop-hair-loss-chemotherapy. Published January 24, 2019.

Rossi A, Caro G, Fortuna MC, Pigliacelli F, D'Arino A, Carlesimo M. Prevention and treatment of chemotherapy-induced alopecia. *Dermatol Pract Concept*. 2020;10(3):e2020074. Doi: 10.5826/dpc.1003a74.

Shin H, Jo SJ, Kim do H, et al. Efficacy of interventions for prevention of chemotherapy-induced alopecia: A systematic review and meta-analysis. *Int J Cancer*. 2015;136(5):E442-E454. Doi: 10.1002/ijc.29115.

Singer S, Tkachenko E, Sharma P, Nelson C, Mostaghimi A, LeBoeuf NR. Geographic disparities in access to scalp cooling for the prevention of chemotherapy-induced alopecia in the United States. *J Am Acad Dermatol*. 2021;85(5):1248-1252. Doi: 10.1016/j.jaad.2020.06.073.

Smetanay K, Junio P, Feißt M, et al. COOLHAIR: A prospective randomized trial to investigate the efficacy and tolerability of scalp cooling in patients undergoing (neo)adjuvant chemotherapy for early breast cancer. *Breast Cancer Res Treat*. 2019;173(1):135-143. Doi: 10.1007/s10549-018-4983-8.

Trujillo-Martin MM, de Armas-Castellano A, Gonzalez-Hernandez Y, et al. Scalp cooling for the prevention of chemotherapy-induced alopecia: Systematic review and meta-analysis. *Rev Esp Salud Publica*. 2023;97e202303024.

U.S. Food and Drug Administration. FDA Clears Expanded Use of Cooling Cap to Reduce Hair Loss During Chemotherapy. https://www.fda.gov/news-events/press-announcements/fda-clears-expanded-use-cooling-cap-reduce-hair-loss-during-chemotherapy. Published July 3, 2017.

U.S. Food and Drug Administration. Letter to Paxman Coolers Limited. https://www.accessdata.fda.gov/cdrh_docs/pdf17/K173032.pdf. Published June 7, 2018.

Wang S, Yang T, Shen A, Qiang W, Zhao Z, Zhang F. The scalp cooling therapy for hair loss in breast cancer patients undergoing chemotherapy: A systematic review and meta-analysis. *Support Care Cancer*. 2021;29(11):6943-6956. Doi: 10.1007/s00520-021-06188-8.

Wikramanayake TC, Haberland NI, Akhundlu A, Nieves AL, Miteva M. Prevention and treatment of chemotherapy-induced alopecia: What is available and what is coming? *Curr Oncol*. 2023;30(4):3609-3626. Doi: 10.3390/curroncol30040275.

Policy updates

11/2021: initial review date and clinical policy effective date: 12/2021.

11/2022: Policy references updated.

11/2023: Policy references updated.

11/2024: Policy references updated.