Automated scalp cooling

Clinical Policy ID: CCP.1500

Recent review date: 11/2025

Next review date: 3/2027

Policy contains: Amma; chemotherapy-induced alopecia; DigniCap; Paxman; scalp cooling; scalp cryotherapy.

First Choice VIP Care has developed clinical policies to assist with making coverage determinations. First Choice VIP Care's 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 First Choice VIP Care, 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. First Choice VIP Care's 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. First Choice VIP Care's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, First Choice VIP Care will update its clinical policies as necessary. First Choice VIP Care's 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 are undergoing 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 (InformedHealth.org, 2023), 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).

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. The U.S. Food and Drug Administration does not regulate manual scalp cooling devices. Compared to automated systems, manual scalp cooling systems are less expensive but can be more labor intensive (American Cancer Society, 2025).

Automated (mechanical) scalp cooling systems

Automated scalp cooling systems are mechanical devices that provide continuous, regulated cooling to the scalp during chemotherapy infusion.

As of this writing, the U.S. Food and Drug Administration (2025) has issued 510(k) clearance to the following automated scalp cooling systems as Class II devices to reduce the likelihood of chemotherapy-induced alopecia in adult patients with solid tumors:

- Paxman Scalp Cooler (Paxman Coolers Limited, Huddersfield, United Kingdom).
- DigniCap® Cooling System (Dignitana AB, Lund, Sweden) and DigniCap® Delta (Dignitana, Inc., Dallas, Texas).
- Amma™ Portable Scalp Cooling System (Cooler Heads Care, Inc., San Diego, California).

Manufacturers cite the following contraindications for automated scalp cooling: cold sensitivity, cold-related disorders (e.g., cold agglutinin disease), central nervous system malignancies, squamous cell and small cell lung cancers, existing or suspected scalp metastases, hematologic malignancies, skin malignancies; severe liver or renal disease; and patients undergoing bone marrow-ablative chemotherapy or skull irradiation (Cooler Heads Care, Inc., 2023; Dignicap, 2024; Paxman, 2022).

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 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 Network 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, 2025a, 2025b). However, these guidelines do not specifically mention automated scalp cooling.

Evidence review

Recent systematic reviews are beginning to differentiate between automated and non-automated scalp cooling approaches and their potential use beyond patients with breast cancer. Both types of scalp cooling devices can prevent some degree of hair loss in patients with breast cancer, particularly those on taxane-based therapy. Limited data suggest similar results can be extended to some with gynecological cancers on taxane-based treatment. There is no obvious advantage to using one device over another.

Efficacy of automated vs. non-automated systems

In a systematic review of 31 studies enrolling patients on taxane-based chemotherapy, including a subset of those with gynecologic cancers, 2,179 participants received scalp cooling and 141 received no scalp cooling. The primary outcome was defined as less than 50% hair loss. The primary outcome was achieved in 60.7% of participants who used scalp cooling. In seven studies comparing outcomes of those who did (n = 335) and did not (n = 141) receive scalp cooling during chemotherapy, scalp cooling was associated with significantly higher odds of achieving less than 50% hair loss (49.3% versus 0%, odds ratio 40.30, 95% confidence interval 10.49 to 154.75, *P* = .00), particularly among those with breast and gynecological cancers receiving paclitaxel. Meta-analyses showed similar outcomes for manual and automated types and high patient satisfaction. Nonetheless, a significant percentage of patients do not achieve even 50% of hair retention through scalp cooling, regardless of device and chemotherapy regimen (Lambert, 2024).

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, 2023).

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).

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* = .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).

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

In 2025, we updated the references and made no policy changes.

References

On September 23, 2025, 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 “scalp” (MeSH), “cryotherapy” (MeSH),” “cold cap,” “DigniCap,” “Paxman,” and “scalp cooling.” 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.

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Policy updates

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11/2022: Policy references updated.

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11/2024: Policy references updated.

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