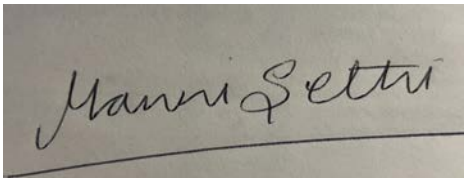
Prior Authorization Review Panel
MCO Policy Submission

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	**Submission Date**: 1/1/2024
Policy Number: ccp.1500	**Effective Date:** 12/2021 **Revision Date:** November 1, 2023
Policy Name: Mechanical scalp cooling	
Type of Submission – Check all that apply: **New Policy** **x 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
Family of Health Plans

Mechanical scalp cooling

Clinical Policy ID: CCP.1500

Recent review date: 11/2023

Next review date: 3/2025

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

Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First'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 Keystone First 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'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. Keystone First's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First's clinical policies are not guarantees of payment.

Coverage policy

Mechanical 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 who undergo chemotherapy for cancer (Rossi, 2020). Hair can become thinner or fall out completely, in clumps or gradually, often starting days or weeks after chemotherapy.

Hair loss is a traumatic experience for many patients suffering from cancer. In most cases, hair begins to grow back in most patients after chemotherapy ends. No medications effectively prevent hair loss from chemotherapy (Institute for Quality and Efficiency in Health Care, 2019), although some have been able to stimulate hair regrowth after chemotherapy (de Barros Silva, 2020).

Risk of hair loss from chemotherapy varies by the drugs used. Rates of alopecia range from 60% to 100% with topoisomerase inhibitors and are > 80% with taxanes, > 60% with alkylating agents, and lower with antimetabolites. Other risk factors for hair loss include dose, pharmacokinetic profile, combination regimens with

various agents, older age (menopause/andropause), comorbidities, poor nutrition, poor hormonal status, diabetes, lupus, and emotional stress (de Barros Silva, 2020; Haque, 2020).

Cooling the scalp can narrow blood vessels, limiting the effect of chemotherapy medicines on hair follicles, and can reduce hair loss. The most commonly used method of scalp cooling is to wear a frozen cap that has been stored in dry ice. The cap is placed on the scalp during chemotherapy and changed every 20 to 30 minutes. The success rate (percent reduction of hair loss) is 50% to 80%. Caps can be used by patients with any solid cancer (Peethambaram, 2019; Shin, 2015).

Scalp hypothermia was first introduced in the late 1970s to reduce alopecia after chemotherapy, in the form of ice caps. The U.S. Food and Drug Administration banned sales of ice caps in 1990 due to a lack of efficacy and safety data (Shah, 2018). Cold caps not approved by the Food and Drug Administration have been on the market for over 20 years. Popular among these models is the Penguin Cold Cap. Patients using these devices must rent a kit from the manufacturer. Kits include gel-containing caps, headbands, and coolers containing dry ice (Brody, 2019).

The first Food and Drug Administration-approved mechanical cooling cap was the DigniCap Cooling System. It was approved for adults who are undergoing specific chemotherapy treatments for solid tumors and are not susceptible to cold-related injuries. DigniCap is a computer-controlled system used during chemotherapy that circulates liquid to a cap; a second cap made of neoprene (a type of rubber) is worn over the cap that touches the skull (U.S. Food and Drug Administration, 2017).

The Food and Drug Administration also granted market approval for the Paxman Scalp Cooling System for adults with solid tumors undergoing chemotherapy. The treatment is contraindicated for cancers of the central nervous system, head and neck, or lung, as well as hematological cancers. Paxman is another mechanical cooling system that uses an electrically powered refrigeration unit that circulates liquid coolant through a cap. A touch screen provides information to the user on the operational status of the unit (U.S. Food and Drug Administration, 2018).

The two systems noted here are the only agents to receive Food and Drug Administration approval for chemotherapy-induced alopecia. Scalp cooling offers potential reduction in hair loss from chemotherapy, although the fact that it is usually performed only during treatment, while the half-life of toxic chemicals involved is often longer, raises concern (Rossi, 2020).

A number of federally sponsored clinical trials are currently being performed on scalp cooling. Some of these are testing conventional cold caps, while others are testing mechanical systems, mostly Paxman (Wikramanayake, 2023).

There are 366 chemotherapy infusion centers in the United States offering scalp cooling services (Singer, 2021).

Findings

The National Comprehensive Cancer Network recommends consideration of scalp cooling for breast cancer patients undergoing adjuvant/neoadjuvant chemotherapy, noting that cooling may be less effective with anthracycline-containing regimens. The group has also endorsed use of scalp cooling for patients with ovarian, fallopian tube, and primary peritoneum cancers who are undergoing chemotherapy with high rates of alopecia (National Comprehensive Cancer Network, 2023a, 2023b). These guidelines do not specifically mention mechanical scalp cooling.

A British organization was the first to include scalp cooling in a professional guideline, by endorsing its use in patients with cancer (other than hematological types) after sharing verbal and written information with 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 (Hospital and Health Care, 2021). Again, no specific notation of mechanical scalp cooling is mentioned.

Most studies use the term “scalp cooling” without clarifying whether they are referring to mechanical or non-mechanical caps. The few articles that make this direct comparison include:

One study of 238 patients with solid cancers treated with docetaxel three times per week showed those using the Paxman mechanical system, cold cap, or no cooling had alopecia rates of 23%, 27%, and 74%. Paxman and cold cap had similar efficacy as 23% and 27% do not differ significantly (Betticher, 2013).

In a review of eight randomized trials, one study showed Paxman had superior hair retention of 51% (48/95) versus 0% (0/47) for controls. However, seven other studies showed non-mechanical caps had similar superiority — 61% (75/122) versus 14% (15/111). The hair retention percentages (61% and 47%) for mechanical and non-mechanical caps do not differ significantly (Nangia, 2017; Shah, 2018).

In a systematic review/meta-analysis of eight studies (n = 832), no significant difference in efficacy of hair retention between mechanical and conventional caps (56% versus 55%, *P* = .967) was found (Trujillo-Martin, 2023).

The Trujillo-Martin systematic review/meta-analysis noted the high number of adverse events in various studies of automated cooling caps. While no event was considered serious, the reported events were: 54 adverse events in 28 patients (Nangia, 2017); 163 adverse events in 31 patients (Smetanay, 2019); and 98 adverse events in 22 patients (Bajpai, 2020).

One of these studies notes that 72% of the adverse events were either grade 1 – 2 headache or grade 1 – 2 feeling of coldness (Bajpai, 2020).

Dropout rates are a concern in chemotherapy patients. One study noted no significant difference in dropout rates (31.7% versus 34.2%) between those receiving scalp cooling using DigniCap and controls (observation). The main reasons for drop out were hair loss, adverse events (from mechanical caps) and randomization to the control arm (Smetanay, 2019).

Other large studies, which all find improvement in alopecia after scalp cooling, do not address whether mechanical and/or non-mechanical approaches are included.

For example, a systematic review/meta-analysis of 27 studies (n = 2,202), only three of which were randomized, revealed that scalp cooling prevented hair loss in 61% of women who received chemotherapy for breast cancer. The article noted side effects such as headache, dizziness, scalp pain, neck pain, feeling cold, heaviness of the head, skin rash, nausea, and overtightened strap are not to be overlooked (Wang, 2021).

References

On August 8, 2023, 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.

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Policy updates

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

11/2022: Policy references updated.

11/2023: Policy references updated.