

Clinical Policy: Scalp Cooling for the Prevention of Chemotherapy-Induced Alopecia

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[Coding Implications](#)

[Revision Log](#)

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Chemotherapy-induced alopecia (CIA) is a common and clinically significant adverse effect of cancer treatment that may substantially affect patient quality of life and psychosocial well-being.^{5,6} Risk varies according to the chemotherapy or targeted therapy regimen used.^{9–12} While most patients experience hair regrowth following treatment completion, recovery may take several months and permanent alopecia has been reported with certain agents.^{11,12} Scalp cooling represents the primary evidence-based strategy for reducing the risk of CIA. Scalp cooling is currently the most established intervention for reducing the incidence and severity of chemotherapy-induced alopecia in selected patients receiving nonmyeloablative chemotherapy regimens.^{2,19,27} Clinical studies have demonstrated that successful scalp cooling may decrease hair loss and improve patient-reported quality of life and body image outcomes.^{2,7}

Policy/Criteria

I. Health Net of California considers the use of an FDA-cleared scalp cooling system medically necessary when all of the following criteria are met:

- A. The scalp cooling system is prescribed by a licensed health care provider for the purpose of reducing the incidence or severity of chemotherapy-induced alopecia; and
- B. The member has a diagnosis of a solid tumor malignancy; and
- C. The scalp cooling system will be used before, during, or after chemotherapy administration; and
- D. None of the following contraindications are present:
 - 1. Pediatric member (under the age of 18);
 - 2. Continuous-infusion chemotherapy administered over one day or longer that is associated with alopecia;
 - 3. Whole-brain radiation therapy or targeted brain irradiation;
 - 4. Cold agglutinin disease, cryoglobulinemia, or post-traumatic cold dystrophy;
 - 5. Small cell lung cancer or squamous cell carcinoma of the lung;
 - 6. Skin cancers, including melanoma, squamous cell carcinoma, or Merkel cell carcinoma;
 - 7. A hematologic malignancy, including leukemia or lymphoma, when chemotherapy is administered with curative intent;
 - 8. A malignancy with a high likelihood of metastases in transit involving the scalp

II. Health Net of California considers scalp cooling not medically necessary when the above criteria are not met.

Background



Chemotherapy-induced alopecia (CIA) is a common adverse effect of systemic anticancer therapy, occurring in approximately 65% of patients receiving chemotherapy.¹⁶ CIA most frequently presents as complete scalp alopecia but may also occur as diffuse or patchy hair loss. Hair loss is typically most pronounced in the scalp, particularly in the crown and frontal regions where hair density is lower and regrowth may be slower. The condition results from the cytotoxic effects of chemotherapy on rapidly dividing hair follicle matrix cells during the anagen (growth) phase of the hair cycle.^{4,9} Although alopecia is generally reversible, it may have significant psychological and social consequences, including diminished quality of life, depression, body image disturbance, and treatment-related distress.^{5,6} Some patients may consider delaying or avoiding cancer treatment because of concerns regarding hair loss.⁵

A prospective, multicenter study evaluating the impact of CIA on quality of life in patients with breast cancer demonstrated that alopecia remained one of the most distressing treatment-related adverse effects throughout chemotherapy and during follow-up. Patients who experienced successful scalp cooling reported improved health-related quality of life and body image compared with patients who experienced unsuccessful scalp cooling.⁷ Hair recovery typically requires several months and may take up to one year, prolonging the psychosocial impact of treatment.^{5,7}

Contraindications and Safety Considerations

The strongest support for the contraindications in this policy comes from FDA-reviewed device labeling and manufacturer safety information rather than from comparative clinical trials designed to evaluate each excluded population.^{31,32} DigniCap labeling identifies pediatric patients and adults with cold sensitivity, cold agglutinin disease, cryoglobulinemia, cryofibrinogenemia, cold urticaria, central nervous system malignancies, certain lung, head and neck, and skin cancers, hematologic malignancies treated with curative-intent chemotherapy, malignancies with a high likelihood of metastases in transit, planned bone marrow ablation, and prior or planned skull irradiation as populations in whom the device should not be used.^{31,32} The biological rationale is that marked cooling may precipitate complications in cold-reactive disorders; reduced scalp blood flow could theoretically protect malignant cells in diseases involving the blood, skin, scalp, or central nervous system; and skull irradiation may narrow cutaneous vessels and reduce cooling effectiveness.^{31,32} Bone marrow-ablative regimens and hematologic malignancies also fall outside the FDA-cleared indication for patients with solid tumors.³¹

Peer-reviewed safety evidence is reassuring for appropriately selected adults with solid tumors but does not establish safety for every excluded population. A systematic review and meta-analysis in breast cancer found scalp metastases in 0.61% of 1,959 scalp-cooled patients and 0.41% of 1,238 patients who did not receive scalp cooling; the difference was not statistically significant ($P = 0.43$).³³ A retrospective cohort study of 1,370 women receiving neoadjuvant or adjuvant chemotherapy for nonmetastatic breast cancer likewise found no adverse effect on overall survival with scalp cooling (adjusted hazard ratio 0.89; 95% confidence interval, 0.68–1.17).³⁴ These studies support the general safety of scalp cooling in nonmetastatic breast cancer,

Clinical Policy

Scalp Cooling for the Prevention of Chemotherapy-Induced Alopecia



but they do not directly evaluate hematologic malignancies, primary or metastatic central nervous system disease, skin cancers, marrow-ablative therapy, or the other tumor-specific exclusions in device labeling.^{31–34}

Evidence supporting pediatric exclusion and continuous-infusion exclusion is limited and evolving. Although current U.S. device information lists pediatric use as contraindicated,^{31,32} a small 2025 nonrandomized study of 22 children with acute lymphoblastic leukemia reported successful hair preservation in 9 of 10 evaluable children receiving scalp cooling versus 2 of 9 controls, without reported headache or dizziness; the study was small, involved one disease and induction regimen, and was not sufficient to establish broad pediatric safety.³⁵ A separate pediatric solid-tumor and nonmalignant-condition study remained ongoing in 2026.³⁶ For prolonged or continuous infusions, available sources indicate that effectiveness varies with drug, dose, infusion duration, metabolism, and required post-infusion cooling time, but they do not provide strong direct evidence for categorically defining all infusions lasting one day or longer as a contraindication.^{22,24} Accordingly, these items are more accurately characterized as device-label restrictions, populations with insufficient evidence, or circumstances of uncertain feasibility and effectiveness unless additional regimen-specific evidence is identified.

Coding Implications

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CPT® Codes	Description
97007	Mechanical scalp cooling, including individual cap supply with head measurement, fitting, and patient education.
97008	Mechanical scalp cooling; including hair preparation, individual cap placement, therapy initiation, and precooling period.
97009	Mechanical scalp cooling provided after discontinuation of chemotherapy, each additional 30 minutes; list separately in addition to the primary procedure.

Reviews, Revisions, and Approvals	Date	Approval Date
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Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

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This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a

Clinical Policy

Scalp Cooling for the Prevention of Chemotherapy-Induced Alopecia



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This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Note: For Medicare members, to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs and LCDs should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at <http://www.cms.gov> for additional information.

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