



Following is a sample letter to appeal a Prior Authorization Denial. Items in **red** must be edited to indicate the specifics of the individual patient's case. Please review and understand the specific health plan requirements for appeals and the necessary process (i.e. online vs fax.)

Date

Payer Name

Attn: Name

Address

City, State Zip

Dear [insert contact name],

We have received a claims denial notification from [insert payer name] for scalp cooling.

- Patient Name:
- Policy ID or #:
- Authorization or claim #:
- Date of service:
- Services Denied:
- Rationale for Denial:

We at [insert practice name] are requesting that [insert payer name] reconsider this claim as medically necessary and deserving of payment. In this specific circumstance, [include pertinent details of the patient's history, current treatments, and the chemotherapy regimen that makes scalp cooling necessary].

Rationale for Scalp Cooling

Several cytotoxic drugs are known to cause moderate to severe chemotherapy-induced alopecia (CIA).ⁱ CIA usually occurs 7–14 days after infusion of chemotherapy. The incidence and severity of alopecia depend both on the type and dose of chemotherapy used. CIA can result in both physical and psychological distress. Hair loss impacts self-esteem, is a visible reminder of the disease, affects the patient's privacy, and negatively impacts social and work interactions.ⁱⁱ Some patients will choose to forego chemotherapy, or request a less efficacious treatment to avoid CIA.ⁱⁱⁱ In a patient survey, the impact of CIA on patients ranks highest, ahead of fatigue, nausea, trouble sleeping, and early hot flashes.^{iv}

Scalp cooling (SC) limits CIA in two ways. First, cooling constricts blood vessels in the scalp, thereby decreasing the amount of chemotherapy that reaches the hair follicles. Second, the cold decreases the proliferative activity of hair follicles and makes them less sensitive to cytotoxic drugs, which target rapidly dividing cells.^v

PAXMAN's scalp-cooling cap is made from lightweight, biocompatible silicone that is soft and flexible, providing a snug yet comfortable fit during treatment. The system allows the scalp to be cooled by circulating cold fluid through channels in the inner cap. The temperature of the coolant is kept within 23–25°F

Clinical Data to Support Inclusion of Paxman Scalp Cooling System in the Clinical Pharmacology Gold Standard Library:

The majority of studies have been conducted in patients with early-stage breast cancer receiving neoadjuvant or adjuvant chemotherapy with curative intent.^{vi} The Paxman Phase 3 SCALP Trial reported an overall success rate of 51% for cooled subjects vs. 0% for controls. Rates of oncologist-graded hair preservation were 55.8% for women in the cooling group and 0% of women in the control group (P = 0.0061). Wigs or head wraps were used by 63% of the patients who received scalp cooling and 100 % of those in the control group. A subset analysis based on the type of treatment reported a 59% success rate for taxane-based regimens and a 16% success rate with anthracycline-based regimens.^{vii}

One prospective trial and one large registry analysis performed in patients with breast, lung, prostate, gastrointestinal/ colorectal, and female genital solid tumors demonstrate the potential for broader use, including in the palliative setting.^{11,12} In a direct comparison of cooling vs. no cooling, irrespective of treatment regimen, use of a cooling device reduced hair loss substantially: alopecia (grades III–IV) and/or necessity to wear a wig were 17% and 64 % in patients treated with Paxman SC, or no cooling, respectively.^{viii}

Safety

SC has minimal adverse events, and is generally well tolerated by cancer patients. The most common SC-related adverse events are grade 1 and include Moderate chills, "heavy head", headaches, scalp or forehead pain, nausea, dizziness, and skin ulceration. No serious adverse events have been reported from the device.^{ix}

Although initially, there was concern that SC during chemotherapy could increase the risk of scalp metastases, subsequent studies did not show this to be a significant risk, nor did it affect overall mortality.^x

Thank you for your review of our patient's case and your reconsideration of it in light of the detail we provided. As such, we are requesting these services be covered as medically necessary and clinically appropriate.

Regards,

Name & title

ⁱ Komen MMC, Smorenberg CH, van den Hurk CJG, Norier JWR. Factors influencing the effectiveness of scalp cooling in the prevention of chemotherapy induced alopecia. *Oncologist*. 2013;18:885–891.

ⁱⁱ Lemieux J, Maunsell E, Provencher L. Chemotherapy- induced alopecia and effects on quality of life among women with breast cancer: a literature review. *Psycho Oncol*. 2008;17:317–28. <https://doi.org/10.1002/pon.1245>.

ⁱⁱⁱ Kadakia, K., Rozell, S., Butala, A. & Loprinzi, C. (2014). Supportive Cryotherapy: A Review From Head to Toe. *Journal of Pain and Symptom Management*, 47, (6), 1100–1115.

^{iv} Van den Hurk CJ, Mols F, et al. Impact of alopecia and scalp cooling on the well-being of breast cancer patients. *Psycho Oncol*. 2010;19:701–709. <https://doi.org/10.1002/pon.1615>.

^v American Cancer Society. Cooling caps (scalp hypothermia) to reduce hair loss. <https://www.cancer.org/treatment/treatments-and-side-effects/physical-side-effects/hair-loss/cold-caps.html>. Accessed Jan 08, 2021.

^{vi} Kruse M, Abraham J. Management of chemotherapy-induced alopecia with scalp cooling. *J Oncol Pract*. 2018;14(3):149–154.

^{vii} 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. *J Amer Med Assoc*. 2017; 317(6) DOI: 10.1001/jama.2016.20939.

^{viii} 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 Canc*. 2013; 21:2565–2573

^{ix} Giarratano T, Frezzini S, Zaocco M, et al. Use of scalp cooling device to prevent alopecia for early breast cancer patients receiving chemotherapy: A prospective study. *Breast J*. 2019;00:1–6.