

Letter of medical necessity
To be included with claim along with patient records
Place letter on clinician letterhead

Date

Name of insurer

Address

Dear _____:

Patient (Name)_____ has been diagnosed with Diagnosis and ICD10CM_____
and will start chemotherapy treatment on (Date)_____. I am writing on behalf of the patient to document medical necessity for Paxman Scalp cooling therapy for the prevention of chemotherapy-induced hair loss due to Diagnosis and ICD10CM_____. The Paxman Cooling System, is an FDA cleared device (DEN150010) and is used to reduce the likelihood of chemotherapy-induced alopecia. The treatment regimen with the Paxman Cooling system is to use it before (30 minutes prior), during the IV administration of chemotherapy, and after (90-120) minutes after chemotherapy has been discontinued). The Paxman Cooling System requires direct supervision and utilizes a patient-specific cooling cap preloaded with the number of cooling cycles that corresponds to the number of times the patient will receive chemotherapy. Patient (Name)_____ has been prescribed (Number)____ of chemotherapy administrations and will require (Number)____ of preloaded cooling cycles.

Systematic reviews and meta-analyses have demonstrated a statistically significant reduction in hair loss^{1,2}. The studies reviewed and reported on in the medical literature have included randomized controlled trials and; prospective single arm/historical control trials. The vast majority of these peer reviewed articles have demonstrated a positive effect of scalp hypothermia in reducing hair loss; no matter the type of scalp hypothermia system used. When combining these studies for meta-analysis purposes, the effect is statistically significant, favoring scalp hypothermia's ability to minimize hair loss. Reducing the incidence of hair loss during chemotherapy for cancer minimizes hair loss's effect on a patient's anxiety, distress, depression, negative body image, and; lowered self-esteem^{3,4}. Thus minimizing hair loss is an important consideration in light of the patient's condition. Recently there were 2 US prospective studies that also demonstrated the beneficial effects of scalp cooling^{4,5}.

Please contact us with any questions at: _____

Sincerely,

Name of physician

¹ Shin H et al. Efficacy of interventions for prevention of chemotherapy-induced alopecia: A systematic review and meta-analysis. *International Journal of Cancer* 2014;136:E442-E454

² Poder TG et al. Effectiveness of scalp cooling in chemotherapy. *Bulletin du Cancer* 2011;98(9):1119-1129.

³ Hesketh PJ et al. Chemotherapy-induced alopecia: psychosocial impact and therapeutic approaches. *Support Care Cancer* 2004;12:543-549.

⁴ Lemieux J et al Chemotherapy-induced alopecia and effects on quality of life among women with breast cancer: a literature review. *Psycho-Oncology* 2008;17:317-328.

5. Hope S Rugo MD et al: Association between use of Scalp cooling Device and alopecia after chemotherapy for breast cancer. *JAMA*.2017;217(6):606-614.

Name of practice