

March 4, 2025

VIA MyMGA.gov

Re: HB 1187 - Scalp Cooling Device Manufacturer Support to Require Insurance Coverage of Scalp Cooling Devices to Prevent Hair Loss During Cancer Treatment

Dear Members of the Maryland General Assembly Health & Government Committee.

We, the undersigned organizations, are writing to you to respectfully urge you to support HB 1187¹ to require health insurance coverage for scalp cooling systems for the preservation of hair during cancer chemotherapy treatment. The bill is sponsored by Delegates Nkongolo, Buckel, Hornberger, Kaiser, Kaufman, Miller, Patterson, Taylor, and Woorman.

This bill is an acknowledgement of the importance of scalp cooling to prevent chemotherapy-induced alopecia, one of the most difficult and demoralizing side effects of cancer treatment, and an opportunity to provide support and benefit to your Maryland constituents in their cancer treatment journeys.

We, Dignitana and Paxman, each manufacture FDA-approved scalp cooling devices. The DigniCap[®] Scalp Cooling System from Dignitana, received FDA clearance December 8, 2015² to reduce chemotherapy-induced alopecia in breast cancer patients, with FDA clearance expanded to include all solid tumors on July 3, 2017.³ The Paxman Scalp Cooling System was FDA-cleared to reduce alopecia in breast cancer patients on April 20, 2017⁴, and for all solid tumors on June 7, 2018.⁵

Scalp cooling is a standalone mechanized therapy provided before, during and after chemotherapy administration. It has evolved from primitive ice bags placed on the patient's head prompting safety concerns, to the current FDA-cleared machine-based cooling systems that are proven both safe and effective and used in cancer treatment centers at over 850 locations in the United States. There are 43 NCCN and NCI-designated Comprehensive Cancer Centers that offer scalp cooling, including the two NCI-designated locations that are in Maryland (Johns Hopkins and University of Maryland), as well as 21 other cancer centers across the state.

From a clinical perspective, scalp cooling is found in the NCCN Guidelines and Compendium as a Category 2A treatment option.⁶ Scalp cooling reduces the incidence of chemotherapy-induced alopecia for patients receiving neoadjuvant/adjuvant chemotherapy.⁷ Scalp cooling is effective for the majority of patients, across multiple types of solid tumors and chemotherapy regimens.

¹Maryland General Assembly Legislation HB 1187 mgaleg.maryland.gov/mgawebsite/Legislation/Details/hb1187?ys=2025RS

² Food and Drug Administration (FDA) (2015) DigniCap Scalp Cooling System. accessdata.fda.gov/cdrh_docs/pdf15/den150010.pdf

³ U.S. Food and Drug Administration News Release. FDA clears expanded use of cooling cap to reduce hair loss during chemotherapy [fda.gov/news-events/press-announcements/fda-clears-expanded-use-cooling-cap-reduce-hair-loss-during-chemotherapy](https://www.fda.gov/news-events/press-announcements/fda-clears-expanded-use-cooling-cap-reduce-hair-loss-during-chemotherapy)

⁴ Food and Drug Administration (FDA) (2017) Paxman Scalp Cooler (2017). accessdata.fda.gov/cdrh_docs/pdf16/K163484.pdf

⁵ Food and Drug Administration (FDA) (2018) Paxman Scalp Cooler. https://www.accessdata.fda.gov/cdrh_docs/pdf17/k173032.pdf

⁶ NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Breast Cancer V.2.2022. © National Comprehensive Cancer Network, Inc. 2022. All rights reserved. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer V.1.2022. © National Comprehensive Cancer Network, Inc. 2022. All rights reserved.

A 2024 study looked at the incidence of Persistent Chemotherapy Induced Alopecia (PCIA), which is hair loss that lasts more than 6 months after chemotherapy and leads to permanent baldness in some cases. This randomized clinical trial yielded three key findings: scalp cooling reduced the incidence of PCIA by over 70 percent; increased hair density and thickness compared with control; and enhanced the patients' social and psychological quality of life.⁸

It is important that every patient undergoing chemotherapy have access to a scalp cooling device. Scalp cooling does much more than reduce patient hair loss, it in many cases positively impacts patients on a social and emotional level. Specifically, scalp cooling counteracts the negative consequences of chemotherapy-induced alopecia, which are:

- Causes up to 10% of patients to forego chemotherapy or request a less efficacious treatment^{9, 10}
- Is considered the most feared side effect of treatment by >75% of patients¹¹
- Is often the most traumatic side effect of treatment leading to social isolation^{12, 13}
- Can affect self-image more than mastectomy¹⁴

By signing this bill, HB 1187, which requires coverage for scalp cooling across the state of Maryland, you will be sending a clear message to both patients and payers that not only is scalp cooling beneficial but also necessary. Scalp cooling is still not universally covered by payers across the US, and requiring coverage is an important step in addressing financial disparities and working towards Health Equity. By removing the cost barrier to access these effective hair-preserving devices, this bill will ensure that all patients, including underserved populations, have equitable access to scalp cooling, while also supporting patient privacy and choice during a very difficult time as they undergo treatment for cancer.

Thank you for all that you have done and continue to do to champion cancer patient care for the people of Maryland and to provide access to treatment options that will positively impact their quality of life. We respectfully request that you support HB 1187 in furtherance of these significant efforts.

Please do not hesitate to let us know if we may provide you with any additional information.

Sincerely,



Melissa Bourestom, CCO
Dignitana



Richard Paxman, CEO
Paxman Coolers

⁷ NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines[®]) for Breast Cancer V.1.2019/ page BINV-L 1 of 5, footnote F. © National Comprehensive Cancer Network, Inc. 2022. All rights reserved.

⁸ Chemotherapy-Induced Alopecia: A Randomized Controlled Trial. *JCO* **42**, 3115-3122(2024). DOI:[10.1200/JCO.23.02374](https://doi.org/10.1200/JCO.23.02374)

⁹ 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.

¹⁰ Roe, H., (2011). Chemotherapy-induced alopecia: advice and support for hair loss. *British Journal of Nursing*, 20 (10), S4- S11.

¹¹ Kargar, M., Sarvestani, R., Khojasteh, H. & Heidari, M. , (2011). Efficacy of penguin cap as scalp cooling system for prevention of alopecia in patients undergoing chemotherapy. *Journal of Advanced Nursing*, 67, (11), 2473-2477.

¹² Kargar, *Journal of Advanced Nursing*, 67, (11), 2473-2477

¹³ Roe, H., (2011). Chemotherapy-induced alopecia: advice and support for hair loss. *British Journal of Nursing*, 20 (10), S4- S11.

¹⁴ Roe, *British Journal of Nursing* , 20 (10), S4- S11