PAXMAN
PIONEERS IN SCALP COOLING

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NCCN Guidelines Panel: Ovarian Cancer

On behalf of Paxman Coolers Limited, I respectfully request the NCCN Ovarian Cancer Panel consider the enclosed data as support for the inclusion of the Paxman Scalp Cooling System as a supportive care treatment for the reduction and prevention of chemotherapy-induced alopecia (CIA).

Rationale:
Scalp cooling was recently added as a category 2A recommendation in NCCN Guidelines Version 1.2019 Breast Cancer for adjuvant and metastatic cancers. The Paxman Scalp Cooling System is FDA cleared to reduce the likelihood of chemotherapy-induced alopecia in all solid tumors.

The treatment of Ovarian Cancer with chemotherapy is associated with demonstrated reductions in disease recurrence and mortality. However, it is also associated with significant side effects affecting quality of life, and some patients' willingness to receive recommended chemotherapy regimens. Specifically, chemotherapy-induced alopecia:

- Is considered the most feared side effect of treatment >75% of patients [4]
- Is the often the most traumatic side effect of treatment leading to social isolation [4,7]
- Causes up to 10% of patients to forego chemotherapy, or request a less efficacious treatment [3,7]

CIA is a common and significant side effect of cytotoxic chemotherapy. It can result in both physical and psychological distress significantly impacting patient well-being and potentially affecting outcomes. Historically, scalp cooling to limit CIA has been limited in the United States; however, with the Food and Drug Administration (FDA) clearance of two machines—Dignicap® in 2015 and Paxman in 2017—scalp cooling has gained broader acceptance. [1,2] its adoption has been swift with machine-based scalp cooling currently available at over 200 locations in the United States, including thirteen NCCN and NCI designated Comprehensive Cancer Centers.

- The rate of successful hair preservation is variable with outcomes dependent on chemotherapeutic agent, dose, dosing interval and patient variables. Recent data from prospective trials provides data to guide patient education and practice. The DigniCap® study reported an overall success rate of 66.3% (67/101) for cooled subjects vs. 0% (0/16) for controls in a cohort treated predominantly with docetaxel and cyclophosphamide. [9] The Paxman SCALP Trial reported an overall success rate of 50.5% (48/95) for cooled subjects vs. 0% (0/47) for controls. A subset analysis based on the type of treatment reported a 65% (41/63) success rate for taxane-based regimens and a 22% (7/32) success rate with anthracycline-based regimens. [6]
- Historically, safety concerns have limited scalp cooling for CIA. The main concerns have been the potential for increased rates of scalp metastases, as well as the potential for distant organ seeding. A recent systematic review of data including over 50,000 subjects reported relatively low and comparable rates of scalp metastases between cooled (0.04% to 1.1%) and non-cooled (0.3% to 3%) cohorts. [8] These findings are consistent with a meta-analysis reporting scalp metastases rates of 0.61% in cooled patients and 0.41% in non-cooled patients which was not statistically significant (p=0.43). [10] Finally, a published retrospective analysis showed no difference in overall survival between cooled and not-cooled cohorts. [5]
- Based on these data, and considering the rapid transformation of practice along with patient demand, the NCCN panel recommends a discussion of scalp cooling to limit CIA be included in the pre-treatment consultation for patients receiving alopecia-inducing chemotherapy.

FDA Status:
The Paxman Scalp Cooling System is FDA cleared to reduce the likelihood of chemotherapy-induced alopecia in solid tumors.

While scalp cooling is widely incorporated into clinical practice in other parts of the world, scalp cooling to limit CIA is relatively new and inconsistently offered to patients in the United States. Inclusion of this supportive care intervention into the clinical workup of the Ovarian Cancer treatment guidelines would help ensure all patients have equal opportunity to benefit from the intervention.

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Specific changes requested: Please consider the following:

- Addition of a paragraph discussing the efficacy and safety of scalp cooling to limit CIA in the Ovarian Cancer Guidelines discussion section with a Category 2A listing.

Supporting Literature:

A reference list and associated publications are attached below.

Thank you for kind consideration. Please see my contact information should you need to contact me for additional information.

Yours sincerely

Richard J Paxman BSc
CEO

References

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