

## **Scalp cooling & breast cancer treatment: What providers need to know**

### **Participant questions and speaker responses**

Scalp cooling system and how it works:

*Has it been proven that restricting blood vessels, thereby preventing chemo from getting to the hair follicles, is the mechanism of action? Or is there another mechanism of action?*

1. Vasoconstriction
  - Cooling induces vasoconstriction
  - Reduces cutaneous drug perfusion to 20-40%
  - Therefore, less drug enters into the hair follicle cells
2. Reducing chemo transport into hair follicle cell. Cooling...
  - Reduces active transport/diffusion of drug into cells
  - Lowers hair follicle cellular activity
  - Reduces kinetic energy & membrane fluidity
3. Reducing rate of hair follicle cell division
  - Cell division is an energy dependent process
  - A slower rate of division makes cells less susceptible to chemo
4. Reduces metabolic activity
  - And thereby reduces chemo cytotoxicity in hair follicle cells, as range of processes decelerate

*Do the patients have their own caps, or are they cleaned between patients?*

Each patient has their own, a single patient use cooling cap which is provided in a kit with all the supplies they need, shampoo, conditioner, water spray, tangle teezer brush, etc.

*Is dry ice needed with this device?*

No dry ice needed, it is a mechanical cooling device that connects to a single patient use cooling cap, it is very simple to use. No cap changes are required through the process.

*I am wondering if one is better over the other - Paxman or DigniCap?*

If you look at the data, efficacy is comparable. Service offerings vary. However, both will provide a good solution for a cancer center.

*What logistics are involved for a health system to offer a Paxman scalp cooling system?*

The health system would need to contract with Paxman. This is a basic placement agreement. Once an agreement has been executed, a delivery date for the equipment is provided and implementation planning with Paxman commences. Following implementation, training is provided in-person or virtually at the same time as commissioning of the cooling equipment. In most setups, the physician introduces scalp cooling to the patient. If the patient is interested, further education and cap sizing is carried out by an NP or a Navigator. The patient is then enrolled into the Paxman scalp cooling program. Paxman at present handle payment and further education. The patient receives their cooling cap at home, watches the instructional online videos to practice, and then brings their cooling cap on their first day of treatment. The infusion team supports the patient with the use of the cooling device, as well as fitting and removal of the cooling cap if required. It has been designed to be simple.

***When a patient orders the Paxman caps, are they given a representative that helps them through the process of using the caps?***

The patient first accesses the company's online resources. If the patient needs extra support the patient can connect with a Patient Liaison virtually. Patient Liaisons have first-hand experience of scalp cooling.

***Is scalp cooling available internationally, and if so, where?***

Scalp cooling is available in over 60 countries around the world. Scalp cooling has been available in Europe for many years.

**Costs and billing:**

***What are the costs of scalp cooling for patients? What are the costs for health systems?***

- At present, for the Paxman, the average cost to a patient is \$1,500, but can be as high as \$2,200. The company charge per treatment via the self-pay model.
- The cost to the health system for use of the cooling device can be as much as \$250 per month per scalp cooler.

***Is the system rented by the clinic and then billed through the clinic or directly to the patient?***

The current scenario in most centers is that the patient is billed through the scalp cooling company. This will change in the future where the clinic will bill for the treatment.

***Is there a list of insurances that will cover scalp cooling or provide reimbursement?***

There have been a number of insurance companies that have reimbursed the patient directly for scalp cooling.

As Paxman announced in its recent press release (read press release [here](#)), on November 2, 2021, the Centers for Medicare & Medicaid Services (CMS) issued its Medicare CY 2022 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs Final Rule ("HOPPS Final Rule"). In this HOPPS Final Rule, CMS announced that it was reassigning Current Procedural Terminology (CPT) code 0662T, which is for "Scalp cooling, mechanical; initial measurement and calibration of cap," to a higher reimbursement Ambulatory Payment Classification for hospitals. See HOPPS Final Rule [here](#).

***Background***

In July 2021, the new technology CPT code 0662T was created to describe initial measurement and calibration of a scalp cooling device for use during chemotherapy administration to prevent hair loss. This new technology CPT code is a temporary code which will remain in effect for approximately a three-year period during which time clinical and claims data is collected and the determination is made if the establishment of a permanent CPT code is justified. During this three-year period, the new technology CPT code, and any associated payment rates, are reviewed annually by CMS.

Under Medicare, hospitals are paid based on the assignment of CPT billing codes to Ambulatory Payment Classifications (APCs). Medicare sets the payment rates for each of these APCs. In the HOPPS Proposed Rule (see [Proposed Rule here](#)) which was issued in July 2021, CMS made the initial proposal to assign CPT Code 0662T to APC 5732 (Level 2 Minor Procedures) and solicited comments on the proposed APC. APC 5732 had a Calendar Year (CY) national payment rate of

\$33.84 and a CY 2022 proposed payment rate of \$34.72. See [Proposed Rule here](#). See Addendum B with payment rates [here](#).

***What Happened in the New HOPPS Final Rule regarding Scalp Cooling?***

In its HOPPS Final Rule, which was issued on November 2, 2021, however, CMS reassigned CPT Code 0662T to a different, higher paying APC. Based on comments to the Proposed Rule and information presented at the August 23, 2021 Hospital Outpatient Payment system Panel Meeting, CMS reassigned CPT Code 0662T to New Technology APC 1520 which has a much higher proposed payment rate of \$1,850.50 than the APC to which it was assigned in the Proposed Rule. See Final Rule [here](#). See Addendum B with payment rates [here](#). See addendum [here](#) reflecting the assignment of CPT Code 0662T to APC 1520. CMS said it took into account the substantial hospital resource costs associated with the calibration and fitting of the scalp cooling cap, which a commenter said is between \$1900 and \$2400, in making its determination to assign the CPT code to a higher paying APC.

***How can hospitals best support their patients who are lower-income or underinsured with accessing scalp cooling?***

- There are a number of funds available however the best place to start is through [www.hairtostay.org](http://www.hairtostay.org).
- Patients can also email [patient@paxmanUSA.com](mailto:patient@paxmanUSA.com) and we can provide some level of guidance.
- As cancer centers move to the new buy and bill model with Paxman patients will also potentially be eligible for our patient assistance program.

***Can the cost of scalp cooling (\$1,500 - \$2,200) be broken down into monthly payments?***

Not into monthly payments but into more management payments.

***What other types of financial assistance resources are available to help with the cost of scalp cooling?***

[Sharsheret's](#) Best Face Forward 2.0 provides services and subsidies for eligible individuals for non-medical services that are critical to a woman's quality of life and body image, and that are only partly covered by insurance companies, if at all. Best Face Forward 2.0 services include financial subsidies for wigs (cranial hair prosthesis), cold caps (scalp cooling treatment), and tattooing (three-dimensional micropigmentation of the nipple and areola), and tattooing of the eyebrows (microblading). Additionally, there are complementary and holistic offerings such as meditation and yoga. [sharsheret.org/resource/best-face-forward-2-0](http://sharsheret.org/resource/best-face-forward-2-0)

**Impact of scalp cooling:**

***Is there benefit to starting cooling after chemo treatments have already begun, or after the final dose of chemo?***

We do not have any clinical data supporting the use of scalp cooling after chemo has already begun although there is a view that there would be some protection of the hair follicle and therefore support regrowth. Scalp cooling after the final dose of chemotherapy would not be beneficial.

***What is the percentage of hair that is retained?***

Efficacy in terms of retention is assessed based on a patient losing less than 50% of their hair, but there is a range. Patients consider this successful. We should also think about regrowth.

***Is regrowth more rapid?***

Regrowth is now becoming an important driver too. The clinical data is showing a more rapid regrowth. We are seeing faster and improved hair regrowth for patients who continue to scalp cool. Hair should return to its original texture and thickness over time.

***What are some of the barriers to less data for African Americans and scalp cooling?***

We must do better here. Paxman are committed to collecting further data. See a new study we are hoping to open soon - [Scalp Cooling for Chemotherapy-Induced Alopecia in Patients of Color](#)

***Are you also including Asian American patients in your trial?***

Not in this study however we have a large amount of clinical data from Japan and India, with ongoing clinical trials in South Korea, Singapore, and Hong Kong.

***Any difference in outcome for red-haired patients?***

We have not seen any difference for patients with red hair.

***Do you anticipate use for other cancers (non-hematologic)?***

We hope to extend use beyond, it really is applicable for most solid tumor cancers already.

***Are there differences of success in 2A categories like ovarian, fallopian and others in comparison to breast?***

The key factor to efficacy in these groups is the chemo, not the tumor type. Many Taxanes used in treating gynecological cancers, so results are good.

***Do you have numbers for patients on TCHP?***

In the US study we saw over 50% success with TCHP, I believe closer to 60%. We have a great efficacy calculator on our website [www.scalpcoolingstudies.com](http://www.scalpcoolingstudies.com)

**Patient eligibility and experience:**

***Is this an option for male breast cancer?***

Male breast cancer patients can scalp cool, yes absolutely.

***If a patient has severe eczema on the scalp, would that be an exclusionary criterion?***

It would not be considered an exclusion. The patient may wish to protect using a theatre cap to increase comfort.

***What is the process like for patients? Is there pain/discomfort while wearing the cap?***

Patients who experience pain or discomfort may take mild pain relief or in some cases a sedative. Most of the discomfort is the first 15 minutes due to cold temperature. At times patients complain of mild headache. Patients with known active migraine can experience migraine type headaches although very rare. Supportive care medications such as Tylenol, Ibuprofen and Ativan can improve the side effects and allow for continuation of scalp cooling use.

***How long will headaches/migraine usually last?***

Very individually based. Most patients report having mild headache for that day only.

***What medications are recommended in the PRN treatment plan in addition to Ativan?***

- Tylenol
- Ibuprofen
- Ativan

***Who follows patient care for the 90 minutes following treatment?***

- Limited patient care is needed in the post cooling, but usually a member of the infusion team would support the patient if required.
- The member of the team depends on each institution's guidelines. Examples: Infusion nurses or clinical assistance.

***Should patients be advised to bring liquid meals for nutrition when they are using the scalp cooling, due to the chin strap restricting opening the mouth?***

We would not recommend this. The chin strap should not restrict a patient from drinking and eating.

***How does scalp cooling affect symptoms of chemo brain?***

We do not experience any effect on chemo brain however a group in Israel are looking to study this.

***Are there pros and cons of a patient using cooling mittens and socks to prevent neuropathy, at the same time the patient is using the Paxman scalp cooling unit?***

We have carried out some smaller studies looking at this as Paxman are currently developing a device for CIPN. We have not seen any safety concerns with regards to temperature. It must be noted the studies we carried out were cooling the limbs at higher temperatures than conventional mittens and socks using dry ice.

***How do you document the procedure and outcome in the EMR?***

- At Dana-Farber Cancer Institute we have developed a therapy plan "Scalp cooling machine and supportive care medications" and a smart phrase.
- This order can be placed by MD/APPs.
- The provider will add the smart phrase to the note.