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New LCD Request: Scalp Cooling for the Treatment of Chemotherapy-Induced Alopecia

February 1, 2023

**RE: Formal Request for Local Coverage Determination – Scalp Cooling for the Treatment of Chemotherapy-Induced Alopecia**

To Whom It May Concern,

Due to the evolving standard of care and accumulated evidence of scalp cooling efficacy in the reduction of chemotherapy-induced alopecia, Dignitana and Paxman respectfully request development of a Local Coverage Determination (LCD) within Palmetto for Scalp Cooling for the Treatment of Chemotherapy-Induced Alopecia. In conjunction, we request that Palmetto establish a physician fee schedule for CPT codes 0662T and 0663T.

**I. Background**

This formal request is submitted on behalf of a small but underserved sub-population of Medicare beneficiaries who are undergoing chemotherapy treatment for various cancers.

By adopting this LCD, Palmetto can greatly improve patient access to technology that is both FDA cleared and recommended by the National Comprehensive Cancer Network (NCCN).

Scalp cooling is a standalone 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 used in cancer treatment centers at over 700 locations in the United States, including 43 NCCN and NCI-designated Comprehensive Cancer Centers. The mechanized treatment to address chemotherapy-induced alopecia is now referred to as "scalp cooling."

The DigniCap<sup>®</sup> Scalp Cooling System from Dignitana, received FDA clearance December 8, 2015<sup>1</sup> to reduce chemotherapy-induced alopecia in breast cancer patients, with FDA clearance expanded to include all solid tumors on July 3, 2017.<sup>2</sup> The Paxman Scalp Cooling System was FDA cleared to reduce alopecia in breast cancer patients on April 20, 2017<sup>3</sup>, and for all solid tumors on June 7, 2018<sup>4</sup>

This LCD would allow the Palmetto Medicare Administrative Contractors (MACs) to make coverage decisions that more accurately address the standard of care for Medicare cancer patients."

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<sup>1</sup> Food and Drug Administration (FDA) (2015) DigniCap Scalp Cooling System. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf15/den150010.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf15/den150010.pdf) Accessed January 30<sup>th</sup> 2023.

<sup>2</sup> U.S. Food and Drug Administration News Release. FDA clears expanded use of cooling cap to reduce hair loss during chemotherapy <https://www.fda.gov/news-events/press-announcements/fda-clears-expanded-use-cooling-cap-reduce-hair-loss-during-chemotherapy>. Accessed January 3<sup>rd</sup> 2023.

<sup>3</sup> Food and Drug Administration (FDA) (2017) Paxman Scalp Cooler (2017). [https://www.accessdata.fda.gov/cdrh\\_docs/pdf16/K163484.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf16/K163484.pdf). Accessed Jan 3, 2023.

<sup>4</sup> Food and Drug Administration (FDA) (2018) Paxman Scalp Cooler. [https://www.accessdata.fda.gov/cdrh\\_docs/pdf17/k173032.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf17/k173032.pdf). Accessed Jan 30, 2023.

## II. **Decision to Use Scalp Cooling**

Physicians play an important role in the decision to offer scalp cooling to patients and in the education that must be provided to patients regarding scalp cooling. Proper communication between physicians and patients can help the patient decide whether to consider using the scalp cooling intervention. When the physician discusses the cancer treatment plan (choice of regimen, frequency of administration, dose of drug(s), number of dosing cycles, possible therapeutic outcome, and adverse events), they can also share information and respond to patient queries regarding supportive care for chemotherapy-induced alopecia. Patients may want more information on the benefits and risks of scalp cooling, anticipated outcomes, factors that might influence outcomes, and amount of experience that the treatment center has with the scalp cooling procedure.

Together with nurse practitioners (NPs) and physician assistants (PAs), physicians must be aware of these factors and be able to discuss them with patients during a visit or after the patient returns home and has additional concerns. Some institutions have created internal references for nurses and doctors with a checklist that serves as a guide for patient education and information on cap sizing.<sup>5</sup>

If the patient wishes to pursue scalp cooling, the physician must prescribe the scalp cooling, similar to orders and prescriptions for chemotherapy. The patient's decision can have implications on the sequence in which physicians order multi-agent chemotherapy.

## III. **NCCN Supports the Utilization of Scalp Cooling**

The 2019 NCCN Guidelines and Compendium introduced a recommendation for scalp cooling as a Category 2A treatment option for patients with invasive breast cancer, and since then have recommended scalp cooling treatment as a Category 2A treatment option for patients with ovarian cancer, fallopian tube cancer, and primary peritoneal cancer.<sup>6</sup> Over 43 NCCN and NCI-designated Comprehensive Cancer Centers are among the 700 health care providers in the US offering scalp cooling.

## IV. **The Benefits of Using Scalp Cooling in the Treatment of Cancer for Medicare Beneficiaries**

The treatment of 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 the willingness of some patients to receive recommended chemotherapy regimens. Specifically, chemotherapy-induced alopecia:

- Causes up to 10% of patients to forego chemotherapy or request a less efficacious treatment<sup>7 8</sup>
- Is considered the most feared side effect of treatment by >75% of patients<sup>9</sup>

<sup>5</sup> Fischer-Carlidge E, Ross M, Hernandez K, Featherstone A, Haase C. Scalp cooling. Implementation of a program at a multisite organization. Clin J Oncol Nurs. 2018;22(5):534–41

<sup>6</sup> Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Breast Cancer V.2.2022. © National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed March 2, 2022. Referenced with permission from the 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. Accessed March 2, 2022.

<sup>7</sup> 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.

<sup>8</sup> Roe, H., (2011). Chemotherapy-induced alopecia: advice and support for hair loss. British Journal of Nursing, 20 (10), S4- S11.

<sup>9</sup> 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.

- Is often the most traumatic side effect of treatment leading to social isolation<sup>10 11</sup>
- Can affect self-image more than mastectomy<sup>12</sup>

Chemotherapy-induced alopecia 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.<sup>13</sup> Historically, scalp cooling to reduce chemotherapy-induced alopecia has been limited in the United States. However, with the FDA clearance of two systems,<sup>14 15</sup> its adoption has been swift with machine-based scalp cooling currently available at over 700 locations in the United States.

The rate of successful hair preservation with scalp cooling is variable with outcomes dependent on chemotherapeutic agent, dose, dosing interval, and patient variables. Lifestyle (smoking, alcohol consumption), anthropometric factors (BMI) and hair characteristics (density, thickness, use of hair dye) are not associated with scalp cooling device efficacy.<sup>16</sup> Recent data from prospective trials provides information to guide patient education and practice.<sup>17</sup> A Dean score of  $\leq 2$  was observed in 83.3% of patients receiving a regimen of docetaxel and carboplatin, 83.3% of patients receiving paclitaxel, and 60.5% of patients receiving docetaxel and cyclophosphamide versus 0% of control patients who did not have scalp cooling.<sup>18</sup> In a single center prospective study involving 163 early breast cancer patients eligible for adjuvant chemotherapy, overall, 57% of patients experienced hair preservation and 81% of the subgroup treated with paclitaxel and trastuzumab found DigniCap effective in preventing alopecia.<sup>19</sup> The Paxman SCALP Trial reported an overall success rate of 50.5% (48/95) for cooled subjects versus 0% (0/47) for controls. A subset analysis based on the type of <sup>20</sup>success rate with anthracycline-based regimens. Another prospective study with the Paxman system evaluated scalp cooling in 72 patients undergoing alopecia-inducing chemotherapy that was anthracycline-based, taxane-based, or anthracycline and taxane-based for breast cancer or genital tract malignancies. A total of 63.9% of patients<sup>21</sup> who completed the treatment had a Dean score of  $\leq 2$  and 52.8% of

<sup>10</sup> Kargar, Journal of Advanced Nursing, 67, (11), 2473-2477

<sup>11</sup> Roe, H., (2011). Chemotherapy-induced alopecia: advice and support for hair loss. British Journal of Nursing, 20 (10), S4- S11.

<sup>12</sup> Roe, British Journal of Nursing, 20 (10), S4- S11

<sup>13</sup> Van den Hurk CJ, Mols F, Vingerhoets AJ, Breed WP. Impact of alopecia and scalp cooling on the well-being of breast cancer patients. Psycho Oncol. 2010;19:701–9. <https://doi.org/10.1002/pon.1615>.

<sup>14</sup> Food and Drug Administration (FDA) (2015) DigniCap Scalp Cooling System.

[https://www.accessdata.fda.gov/cdrh\\_docs/pdf15/den150010.pdf](https://www.accessdata.fda.gov/cdrh_docs/pdf15/den150010.pdf)

<sup>15</sup> Food and Drug Administration (FDA) (2017b) Paxman Scalp Cooler K163484

<sup>16</sup> Pedersini R, Fornaro C, di Mauro P, et al. Efficacy of the DigniCap System in preventing chemotherapy-induced alopecia in breast cancer patients is not related to patient characteristics or side effects of the device. Int J Nurs Pract. 2021 Jun;27(3):e12888. doi: 10.1111/ijn.12888.

<sup>17</sup> Rugo, H., Klein, P., Melin, S., Hurvitz, S., Melisko, M., Moore, A., Park, G., Mitchel, J., Bageman, E., D'Agostino, R., Ver Hoeve, E., Esserman, L., Cigler, T. (2017a). Association Between use of a Scalp Cooling Device and Alopecia After Chemotherapy for Breast Cancer. Journal of the American Medical Association, 317(6) DOI: 10.1001/jama.2016.21038.

<sup>18</sup> Mustoe MM, Lee CM, Melisko ME, Esserman LJ, Rugo HS. The DigniCap Scalp Cooling System and its use in the treatment of chemotherapy-induced alopecia. Future Oncol. 2018 Oct;14(24):2461-2469. doi: 10.2217/fon-2018-0178.

<sup>19</sup> Pedersini R, Fornaro C, di Mauro P, et al. Efficacy of the DigniCap System in preventing chemotherapy-induced alopecia in breast cancer patients is not related to patient characteristics or side effects of the device. Int J Nurs Pract. 2021 Jun;27(3):e12888. doi: 10.1111/ijn.12888.

<sup>20</sup> Nangia, J., Wang, T., Osborne, C., Niravath, P., Otte, K., Papish, S., Holmes, F., Abraham, J., Lacouture, M., Courtright, J., Paxman, R. Rude, M., Hilsenback, S., Osborne, K., Rimawi, M. (2017). Effect of a Scalp Cooling Device on Alopecia in Women Undergoing Chemotherapy for Breast Cancer The SCALP Randomized Clinical Trial. Journal of the American Medical Association, 317(6) DOI: 10.1001/jama.2016.20939.

<sup>21</sup> Ross, M. & Fischer-Carlidge, E. (2017). Scalp Cooling: A literature review of efficacy, safety, and tolerability for chemotherapy-induced alopecia. Clinical Journal of Oncology Nursing, 21(2) DOI: 10.1188/17.CJON.226-233.

patients experienced complete hair preservation with a Dean score of 0<sup>22</sup>. Similar efficacy results with scalp cooling during chemotherapy infusion have been observed in breast cancer patients from Japan,<sup>23</sup> Italy,<sup>24</sup> The Netherlands<sup>25</sup>, and Germany<sup>26</sup>, as has been observed in US patients. Of note, the DigniCap and Paxman clinical trials referenced above<sup>27</sup><sup>28</sup> both included a substantial number of Medicare-eligible patients; 22.6% of patients in the Pivotal Trial,<sup>29</sup> and 10.4% of patients in the Paxman SCALP Randomized Clinical Trial, were over age 65.

Historically, safety concerns have limited scalp cooling for chemotherapy-induced alopecia. 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 patients reported relatively low and comparable rates of scalp metastases between cooled (0.04% to 1.1%) and non-cooled (0.3% to 3%) cohorts. 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).

In a number of studies, scalp cooling has been shown to not only improve hair retention but also hair regrowth as well as reduce the risk of persistent chemotherapy-induced alopecia, a long term and devastating side effect.<sup>30</sup><sup>31</sup> Scalp cooling resulted in faster recovery of hair volume after chemotherapy, even in patients for whom scalp cooling failed to prevent chemotherapy-induced alopecia.<sup>32</sup>

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<sup>22</sup> Mustoe MM, Lee CM, Melisko ME, Esserman LJ, Rugo HS. The DigniCap Scalp Cooling System and its use in the treatment of chemotherapy-induced alopecia. *Future Oncol*. 2018 Oct;14(24):2461-2469. doi: 10.2217/fon-2018-0178

<sup>23</sup> Ohsumi S, Kiyoto S, Takahashi M, et al. Scalp cooling for hair loss prevention in female Japanese breast cancer patients receiving (neo)adjuvant chemotherapy. *Support Care Cancer*. 2021 Jan;29(1):437-443. doi: 10.1007/s00520-020-05506-w.

<sup>24</sup> Pedersini R, Fornaro C, di Mauro P, et al. Efficacy of the DigniCap System in preventing chemotherapy-induced alopecia in breast cancer patients is not related to patient characteristics or side effects of the device. *Int J Nurs Pract*. 2021 Jun;27(3):e12888. doi: 10.1111/ijn.12888.

<sup>25</sup> Lugtenberg RT, van den Hurk CJG, Smorenburg CH, et al. Comparable effectiveness of 45- and 20-min post-infusion scalp cooling time in preventing paclitaxel-induced alopecia - a randomized controlled trial. *Support Care Cancer*. 2022 Aug;30(8):6641-6648. doi: 10.1007/s00520-022-07090-7.

<sup>26</sup> Smetanay K, Junio P, Feišt M, et al. COOLHAIR: a prospective randomized trial to investigate the efficacy and tolerability of scalp cooling in patients undergoing (neo)adjuvant chemotherapy for early breast cancer. *Breast Cancer Res Treat*. 2019 Jan;173(1):135-143. doi: 10.1007/s10549-018-4983-8.

<sup>27</sup> Rugo, H., Klein, P., Melin, S., Hurvitz, S., Melisko, M., Moore, A., Park, G., Mitchel, J., Bageman, E., D'Agostino, R., Ver Hoeve, E., Esserman, L., Cigler, T. (2017a). Association Between use of a Scalp Cooling Device and Alopecia After Chemotherapy for Breast Cancer. *Journal of the American Medical Association*, 317(6) DOI:10.1001/jama.2016.21038.

<sup>28</sup> Nangia, J., Wang, T., Osborne, C., Niravath, P., Otte, K., Papish, S., Holmes, F., Abraham, J., Lacouture, M., Courtright, J., Paxman, R. Rude, M., Hilsenback, S., Osborne, K., Rimawi, M. (2017). Effect of a Scalp Cooling Device on Alopecia in Women Undergoing Chemotherapy for Breast Cancer The SCALP Randomized Clinical Trial. *Journal of the American Medical Association*, 317(6) DOI: 10.1001/jama.2016.20939.

<sup>29</sup> Rugo, H., Melin, S. & Voigt, J. (2017b). Scalp cooling with adjuvant/neoadjuvant chemotherapy for breast cancer and the risk of scalp metastases: systematic review and meta-analysis. *Breast Cancer Research and Treatment*, 163(119-206) DOI: 10.1007/s10549-017-4185-9.

<sup>30</sup> Prospective study of hair recovery after (neo)adjuvant chemotherapy with scalp cooling in Japanese breast cancer patients. Ohsumi S, Kiyoto S, Takahashi M, Takashima S, Aogi K, Shimizu S, Doi M

<sup>31</sup> Efficacy of Scalp Cooling in Preventing and Recovering From Chemotherapy-Induced Alopecia in Breast Cancer Patients: The HOPE Study. Kinoshita T, Nakayama T, Fukuma E, Inokuchi M, Ishiguro H, Ogo E, Kikuchi M, Jinno H, Yamazaki N, Toi M.

<sup>32</sup> Kinoshita T, Nakayama T, Fukuma E, et al. Efficacy of Scalp Cooling in Preventing and Recovering From Chemotherapy-Induced Alopecia in Breast Cancer Patients: The HOPE Study. *Front Oncol*. 2019 Aug 6;9:733. doi: 10.3389/fonc.2019.00733.

## V. Scalp cooling treatment procedure

Scalp cooling is a standalone service performed during chemotherapy administration. Using a scalp cooling system will extend the patient's time at the treatment center or clinic. After completion of patient education as detailed in the previous section, time must be allotted for cap fitting prior to initiation of treatment. A patient is measured and fitted with a cap and the cooling unit is calibrated for time and intensity of therapy customized for each patient according to their chemotherapy regimen. The cap is connected to a compact, mobile refrigeration unit which circulates liquid coolant at low pressure through a special cooling cap on the patient's head. The circulation of the refrigerated coolant through the cap extracts heat from the patient's scalp while maintaining temperature.

Scalp cooling treatment starts at least 30 minutes before the infusion of chemotherapy. Cooling continues throughout the infusion of cytotoxic agents (typically one to five hours) and for up to 180 minutes after the infusion is completed, with the post-infusion duration dependent on the chemotherapy regimen.<sup>33,34</sup> During the entire cooling procedure the nursing team must monitor the patient for any clinical issues (e.g., headache, anxiety, discomfort, and poor tolerability of the cold) and manage any technical difficulties with the cooling apparatus.

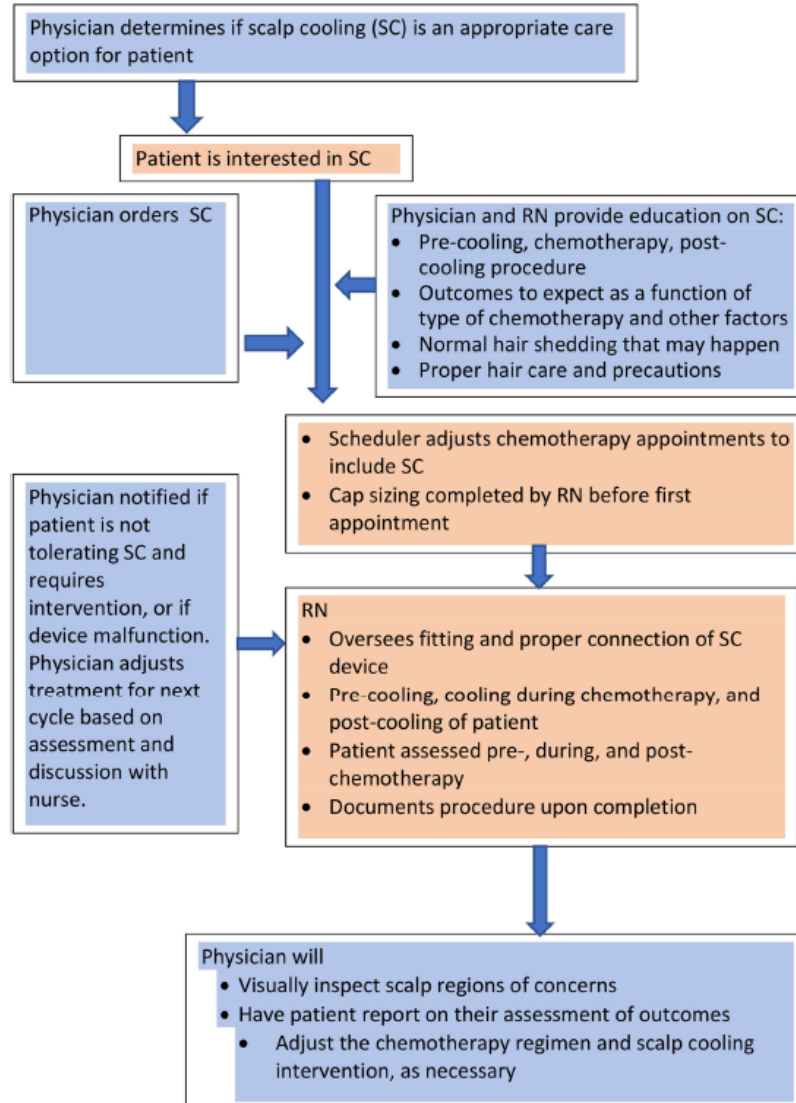
The physician provides direct supervision of scalp cooling for chemotherapy-induced alopecia before, during, and after delivery of chemotherapy and is available by telephone to assist and direct as needed. The hands-on roles of the chemotherapy nurse and nurse manager in the process are also critical. Interaction and proper communication between physicians, PAs, NPs, and allied health professionals are needed to provide this supportive care service to patients at risk for chemotherapy-induced alopecia. As such, scalp cooling is a distinct professional service that should not be considered incident to the chemotherapy service.

**Figure 1** provides a workflow that defines the role of physicians, PAs, NPs, and nurses, as they work together to deliver scalp cooling to appropriate patients.

<sup>33</sup> Kruse M, Abraham J. Management of chemotherapy-induced alopecia with scalp cooling. *J Oncol Pract.* 2018;14(3):149–54.

<sup>34</sup> Komen M, Breed WPM, Smorenburg CH, et al. Results of 20- versus 45-min post-infusion scalp cooling time in the prevention of docetaxel-induced alopecia. *Support Care Cancer.* 2016;24(6): 2735–42.

**Figure 1. Integrated Scalp Cooling Workflow<sup>35</sup>**



Documentation is provided for all orders, alerts, and tolerability issues and assessments before and after the scalp cooling intervention. The physician assesses the outcomes of scalp cooling on chemotherapy-induced alopecia during an interval follow-up visit with the patient.

Treatment centers must incorporate the logistics of scalp cooling into facility workflows by coordinating the physician's direct supervision of the patient, as defined by the 2020 Hospital Outpatient Prospective Payment System (HOPPS) final rule,<sup>36</sup> scheduling additional chair time, planning for incremental nursing staff effort, and modifying the physical infusion suite to accommodate cooling machines (e.g., space, power requirements).<sup>37</sup>

<sup>35</sup> Peterson LL, Lustberg M, Tolane SM, Ross M, Salehi E, Isakoff SJ. Integration of Physician and Nursing Professional Efforts to Deliver Supportive Scalp Cooling Care to Oncology Patients at Risk for Alopecia. *Oncol Ther*. 2020 Dec;8(2):325-332. doi: 10.1007/s40487-020-00120-6.

<sup>36</sup> Saulet D, Riley A. The 2020 HOPPS final rule brings major changes to physician supervision—and more—for cancer programs. <https://www.advisory.com/research/oncology-roundtable/oncology-rounds/2019/11/hopps-takeaways-cancer-programs>. Accessed June 7, 2020.

<sup>37</sup> Fischer-Carlidge E, Ross M, Hernandez K, Featherstone A, Haase C. Scalp cooling. Implementation of a program at a multisite organization. *Clin J Oncol Nurs*. 2018;22(5):534-41

## VI. **Benefit Category: Physician Service**

The Centers for Medicare & Medicaid Services (CMS) has provided a clear definition of scalp cooling as a standalone physician service. In the OPPS Final Rule released November 1, 2022, "CPT guidance states that CPT code 0662T should be billed once per chemotherapy session, which we interpret to mean once per course of chemotherapy. Therefore, if a course of chemotherapy involves 6 or 18 sessions, HOPDs should report CPT 0662T only once for that 6 or 18 therapy sessions. For CY 2022, CMS assigned CPT code 0662T to APC New Technology 1520 (New Technology - Level 20 (\$1801- \$1900)) with a payment rate of \$1,850.50." The OPPS Final Rule confirmed that for CY 2023 CPT code 0662T will continue to be assigned to the new technology APC 1520.<sup>38</sup>

This provision for scalp cooling supports the consistent use of the scalp cooling CPT code and APC payment, proposed and finalized within the CY 2022 OPPS. CPT code 0662T (Scalp cooling, mechanical; initial measurement and calibration of cap) was originally granted to scalp cooling services in 2021 and assigned to New Technology APC 1520, with a payment rate of \$1,850.50. Although it is a Category III CPT code and not assigned a federal physician payment rate, it is important to allow physician practices to bill for scalp cooling services and ensure access to scalp cooling for Medicare patients.

As previously issued by the AMA in 2021, an additional scalp cooling CPT code of 0663T ((Placement of device, monitoring, and removal of device (list separately in addition to code for primary procedure) may be reported in conjunction with 96409, 96411, 96413, 96415, 96416, 96417 once per chemotherapy session.

An important distinction to note is that scalp cooling is a standalone service this is administered concurrently with chemotherapy, however the administration of scalp cooling starts well before the infusion and continues for several hours post infusion. Scalp cooling additionally requires direct physician supervision and monitoring, and nurse monitoring throughout the treatment.

In addition, based upon communication from Heather Hostetler, J.D., *Health Insurance Specialist, Division of Policy and Evidence Review, Coverage and Analysis Group, Center for Clinical Standards and Quality, Centers for Medicare & Medicaid Services*, it was noted that the CCSQ CAG has discussed concerns with colleagues in the CMS' Hospital and Ambulatory Policy Group (Division of Outpatient Care and Division of Practitioner Services), and with the MAC Contractor Medical Directors.

Heather Hostetler stated "NCD 110.6 (Scalp Hypothermia During Chemotherapy to Prevent Hair Loss) is not a barrier to coverage or to pricing/payment of the Category III temporary CPT codes for professional/facility services related to scalp cooling (CPT Codes 0662T and 0663T). The NCD, while very old, serves as a benefit category/policy statement. As indicated in the NCD, the cap *itself* is considered a supply. Supplies are coverable "incident to" a physician's professional service and/or hospital outpatient service meaning that payment for supplies is packaged into the payment for professional services and hospital facility service. Therefore, the Category III T-codes for the professional services are coverable by the MACs under local coverage authority for both Medicare Part A (Hospital Outpatient PPS) and Part B (Physician Fee Schedule). The NCD need not be removed."

<sup>38</sup> <https://www.cms.gov/files/document/cy2023-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center-final-rule.pdf> (see pages 212-213)

Local coverage authority means each MAC can choose to cover, process, and pay claims for these T-codes on a claim-by-claim basis, or may develop a local coverage determination.<sup>39</sup>

**VII. Allow Local Medicare Administrative Contractor Discretion to Make a Coverage Decision Better Serves the Needs of the Medicare Program and its Beneficiaries**

Scalp cooling is currently approved by NCCN for patients receiving chemotherapy treatment for breast cancer, ovarian cancer, fallopian tube cancer, and primary peritoneal cancer. The median age at which women contract breast cancer is 62<sup>40</sup>, ovarian cancer is 63<sup>41</sup>, fallopian tube cancer is usually contracted in women ages 60-66<sup>42</sup>, and peritoneal cancer is most commonly diagnosed in those above 60 years of age.<sup>43</sup> These cancers are prevalent in the Medicare patient population, and are also commonly treated with chemotherapy, such that many Medicare beneficiaries will suffer from the side effect of chemotherapy-induced alopecia. As such we encourage Palmetto to exercise its authority to make coverage decisions and issue an LCD to ensure Medicare beneficiaries have access to this standard of care.

**VIII. LCD Language Request**

We request Palmetto adopt an LCD that states that the use of scalp cooling for the prevention of chemotherapy-induced alopecia shall be considered reasonable and necessary as part of the treatment protocol for patients with solid tumors undergoing chemotherapy, and covered as a physician service under Medicare Part B.

In conjunction with LCD development, we request that Palmetto also consider establishing a MAC physician fee schedule for CPT codes 0662T and 0663T. Based on salary and time information provided by Memorial Sloan Kettering, we offer the following information.

CPT code 0662T describes the initial service that occurs in the infusion center or office and requires between 60 to 90 minutes of face-to-face time with the patient, provided by a specialized oncology nurse under direct physician supervision. This includes time for customized cap measurement and fitting, calibration and placement of the cap, patient education regarding therapy and post-treatment hair care. Direct practice expense consists of a single patient use cap and treatment cards, amortized capital expense for the control unit, and overhead expenses for the infusion room with associated specialized nursing staff. We respectfully request a non-facility physician fee schedule be established in the \$4,500-\$6,500 range and a facility physician fee schedule be in the \$350-\$450 range.

CPT code 0663T may be reported once per chemotherapy session and involves fitting and placement of the device as well as patient pre-assessment prior to the chemotherapy service. Continual assessment of the scalp cooling treatment is performed by the nurse under direct supervision by the physician. The monitoring is necessary to evaluate patient tolerability of the scalp cooling and potential device malfunction. The scalp cooling service continues for up to 180 minutes post-chemotherapy administration depending on regimen. Total therapy time ranges from 3 hours to 8 hours per chemotherapy session. A final assessment may be performed by the physician to determine whether any adjustments need to be made in future therapy sessions. As each placement of the device requires the time and effort of the nursing

<sup>39</sup> <https://www.cms.gov/medicare/coverage/determinationprocess/lcds>.

<sup>40</sup> [Breast Cancer Survival Rates: Prognosis by Age, Race & More \(healthline.com\)](https://www.healthline.com/health/breast-cancer-survival-rates)

<sup>41</sup> [Ovarian Cancer Statistics | Ovarian Cancer Research Alliance \(ocrhope.org\)](https://www.ocrhope.org/Ovarian-Cancer-Statistics)

<sup>42</sup> [Fallopian Tube Cancer | MD Anderson Cancer Center](https://www.mdandersoncancercenter.org/fallopian-tube-cancer)

<sup>43</sup> [Peritoneal Cancer: Symptoms, Causes, Diagnosis, and Treatment \(verywellhealth.com\)](https://www.verywellhealth.com/peritoneal-cancer-symptoms-causes-diagnosis-and-treatment)

staff and physician, we believe this code should be paid to reflect the work involved, and that scalp cooling is performed as a standalone service. A reasonable request is that this code should be paid in the range of \$250- \$400 for the non-facility physician fee schedule and \$200- \$300 for the facility physician fee schedule.

In conclusion, the data presented here overwhelmingly shows the benefit of NCCN-approved scalp cooling to patients battling breast, ovarian, fallopian tube, and peritoneal cancer who are being treated with cytotoxic chemotherapy regimens that have alopecia as a common side effect. This adverse event of hair loss is traumatic for patients with cancers frequently observed in the Medicare-age population. It not only has a significant detrimental effect on the patient's self-image and quality of life but leads to social isolation that needs social connection. In addition, patients often choose to not be compliant with necessary, effective cancer treatment to avoid hair loss. Refusing chemotherapy can then reduce patient outcomes. Implementing this LCD would help ensure all beneficiaries have equal opportunity to benefit from the intervention. It is our belief that all patients receiving chemotherapy treatment should have access to scalp cooling.

Based on the evidence presented in this letter, we respectfully request Palmetto implement an LCD for the use of Scalp Cooling for the Treatment of Chemotherapy-Induced Alopecia, and in conjunction establish a MAC physician fee schedule for CPT codes 0662T and 0663T.

Sincerely,



Catarina Löwenadler, CEO  
Dignitana



Richard Paxman, CEO  
Paxman Coolers