

# SCALP COOLING

CMS Advisory Panel on Hospital Outpatient Payment  
August 23, 2021

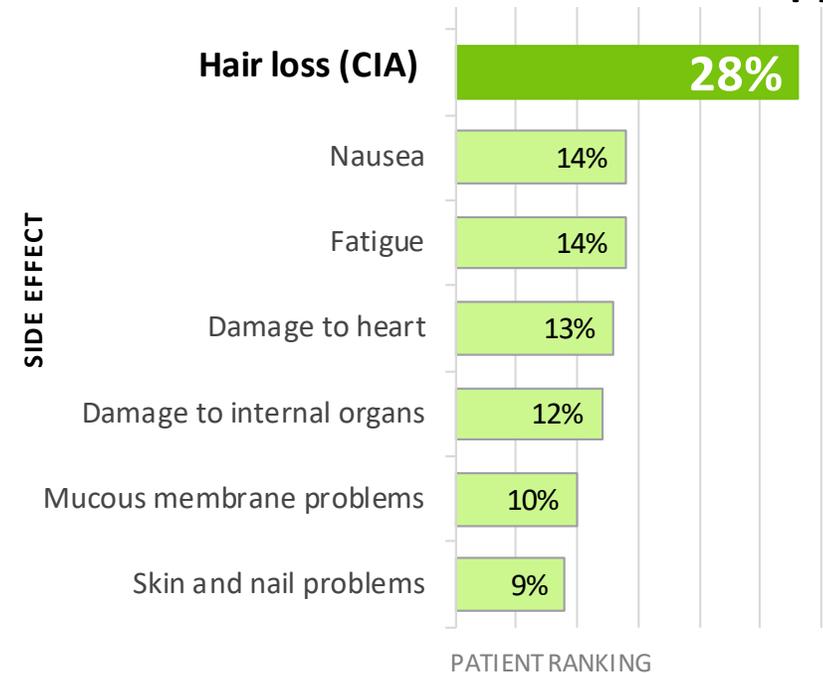
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# Hair loss impacts QoL

- 8-10% of female patients refuse chemotherapy due to concern over hair loss<sup>1</sup>
- CIA impacts quality of life, decreasing self-esteem, social functioning, and overall wellness.<sup>2</sup>

Hair loss is consistently ranked as the most troublesome side effect of chemotherapy<sup>3</sup>



Scalp cooling devices are currently available at 580 cancer centers in 45 of the 50 states in the US

<sup>1</sup> Psychological sequelae and alopecia among women with cancer., McGarvey EL, Baum LD, Pinkerton RC, Rogers LM, Cancer Pract. 2001;9(6):283

<sup>2</sup> Body image in women with breast cancer using a scalp cooling system to reduce chemotherapy induced alopecia, Cigler T, Melin SA, Klein P, et al. Cancer Research,, V 77 Iss 4, February 2017

<sup>3</sup> Online consumer survey March 2015 - 400 females surveyed, All ethnicities, All states in the U.S., Wide range of household incomes, No knowledge of medical history. Age distribution: 40-49 125, 50-59 175, 60 and older 100

FDA cleared  
scalp cooling

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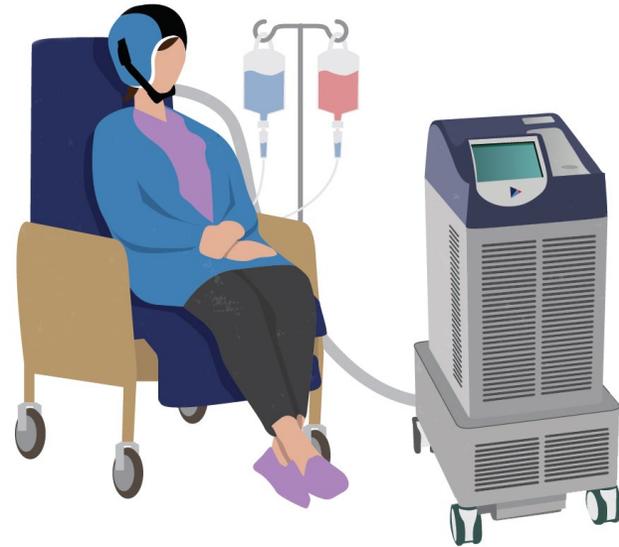
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### **Indication for Use**

Indicated to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors.

### **Intended Use**

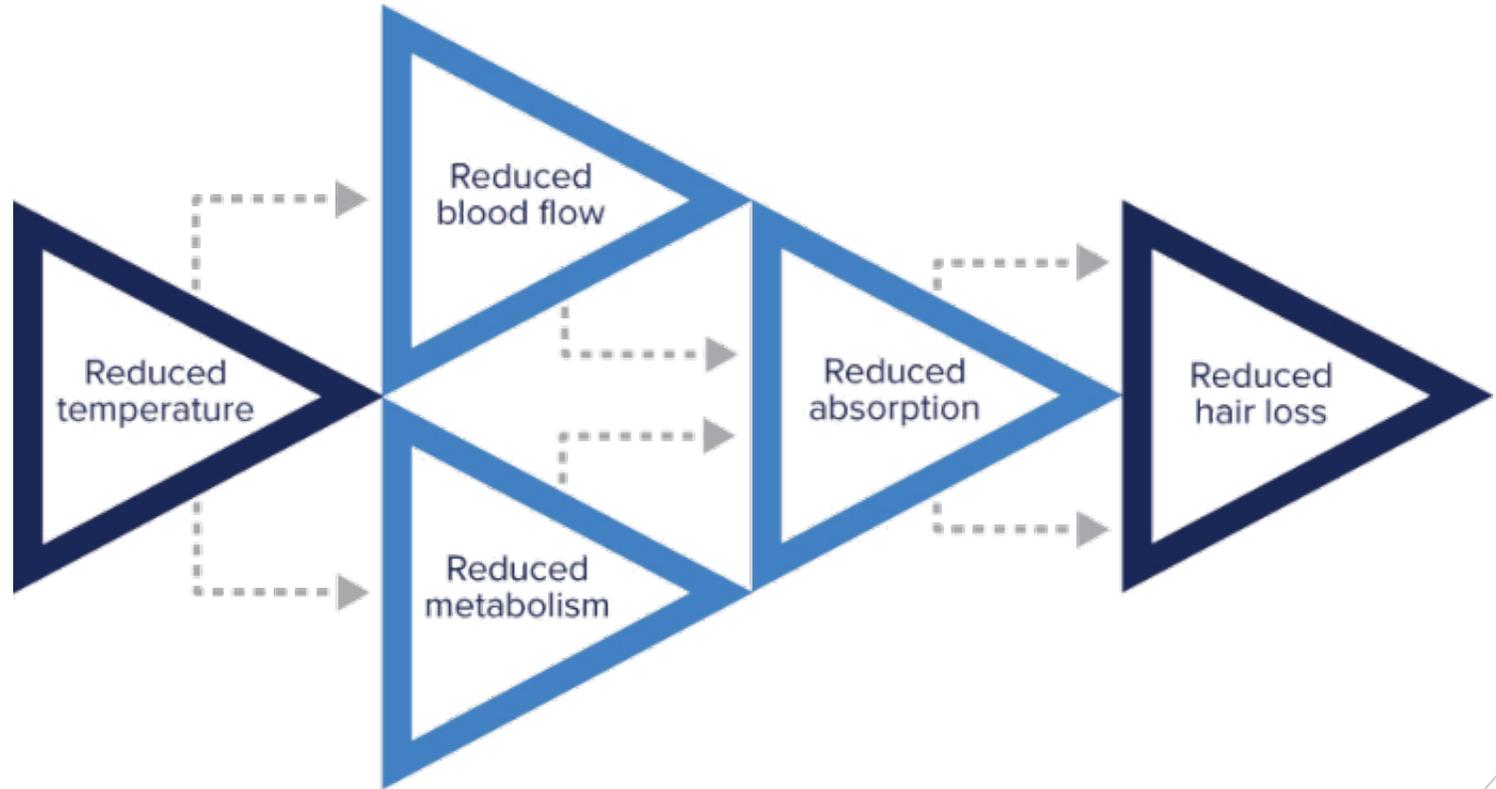
A cooling device intended to reduce or prevent the frequency and severity of alopecia during chemotherapy in which alopecia inducing chemotherapy agents are used.



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# What is needed for scalp cooling?

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- Computerized control unit
- Single-patient cooling cap that connects to the control unit



DigniCap Scalp Cooling System



Paxman Scalp Cooling System

# Standard of Care



National Comprehensive  
Cancer Network®

## **NCCN Clinical Practice Guidelines in oncology**

- Breast cancer (Version 1.2019)
- Ovarian cancer (Version 1.2020)
- Scalp cooling is a Category 2A recommendation to reduce the incidence of chemotherapy-induced alopecia for patients receiving chemo treatments

## **ONS Guidelines™ for Cancer Treatment-related Skin Toxicity 2020**

- Scalp cooling is recommended to minimize chemotherapy-induced alopecia

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# Therapy Resources CPT 0662T

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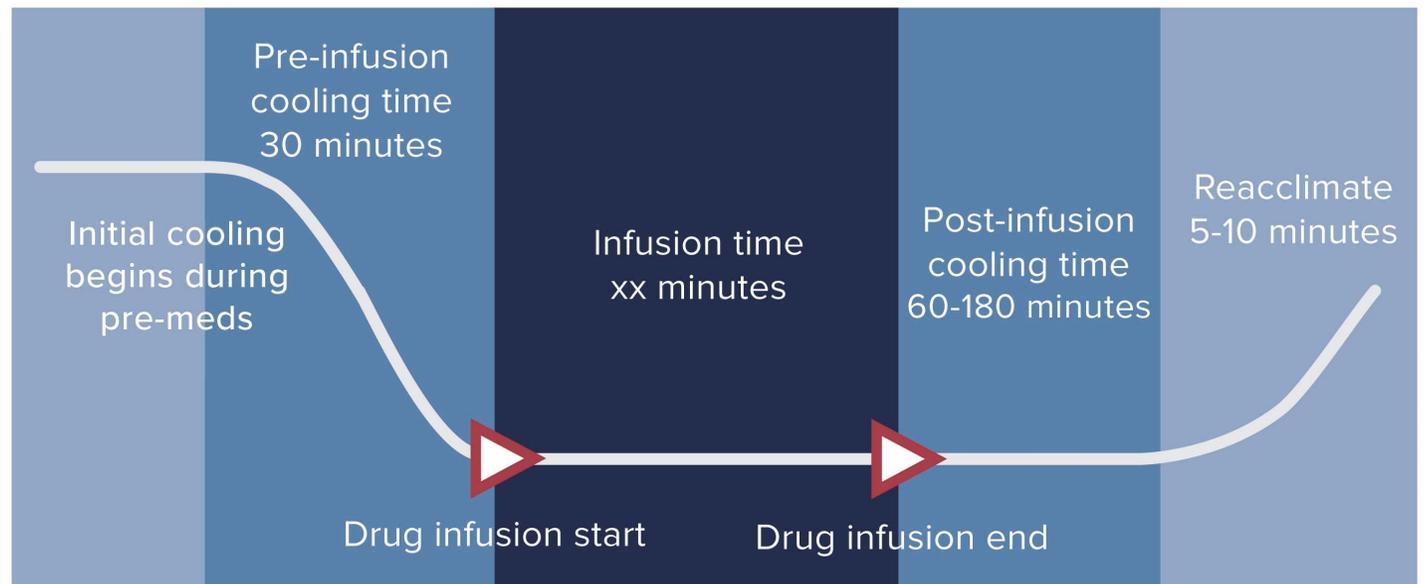
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## Cap fitting and patient education

- 30 – 60 minutes Clinician time prior to starting treatment

## Treatment time:

- 5 minutes Initiate therapy
- 180 - 360 minutes Patient monitoring by clinical personnel during and after chemotherapy infusion



APC  
Reassignment  
Request for 0662T

**Current APC Assignment 5732 (Level 2 Minor Procedures) = \$33.84**

- Does not accurately reflect clinical and resource characteristics of the service

**Request: APC reassignment for CPT code 0662T**

- Rationale: CMS policy of APC assignment of procedures and services based on clinical and resource homogeneity
- Reasonable reassignment is to the family of Skin Procedure APCs:
  - APC 5055 (Level 5 Skin Procedures) = \$3,613
  - This APC would cover technology costs (~ \$2,500 - \$3,000) and hospital overhead expenses for customized cap measurement, fitting, placement, and patient education for scalp cooling therapy during chemo administration and post-administration
- As there are no other clinically similar APC families, the other reasonable option is to place 0662T into a New Technology APC
  - APC 1524 (New Technology) = \$3,250.50
  - APC 1525 (New Technology) = \$3,750.50

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# Clinical acceptance

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# JAMA<sup>®</sup>

The Journal of the American Medical Association

*JAMA February 2017:*

- “DigniCap prevented hair loss in 66.3% of patients with breast cancer receiving adjuvant chemotherapy, compared to a control group where all patients experienced significant hair loss. Scalp cooling treatment was well tolerated, and no scalp metastases have been observed.”
- “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.”

*Studies demonstrating the efficacy of scalp cooling have been published in numerous scientific journals:*

**BJC**  
British Journal of Cancer

**Breast Cancer**  
Research and Treatment

**Oncology  
Research and  
Treatment**

**Supportive Care  
in Cancer**

**Clinical Journal  
of Oncology Nursing**

**Molecular  
and Clinical  
Oncology**



**JAN**  
JOURNAL OF ADVANCED NURSING