

SCALP COOLING

CMS Advisory Panel on Hospital Outpatient Payment
August 23, 2021

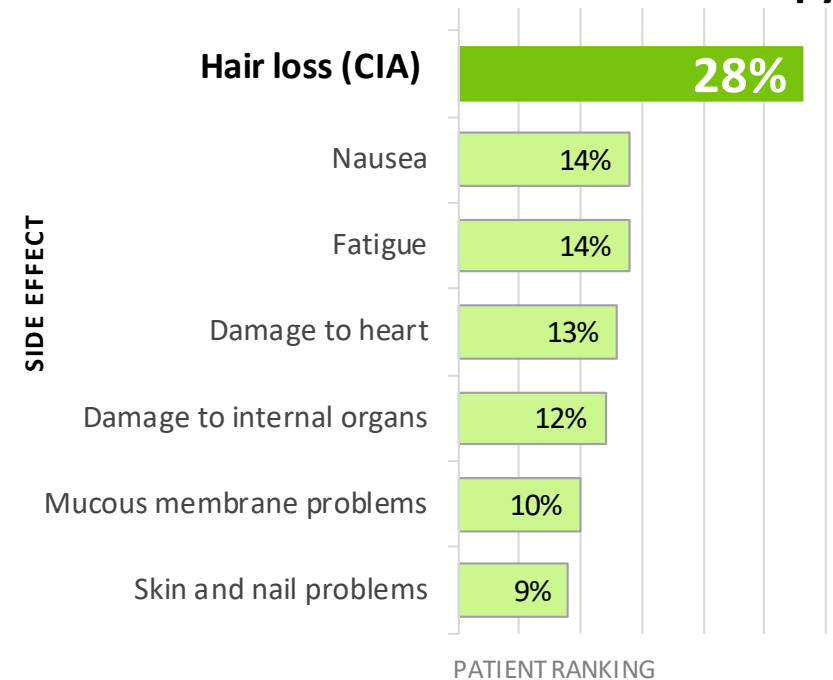
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Hair loss impacts QoL

- 8-10% of female patients refuse chemotherapy due to concern over hair loss¹
- CIA impacts quality of life, decreasing self-esteem, social functioning, and overall wellness.²

Hair loss is consistently ranked as the most troublesome side effect of chemotherapy³



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

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

² *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

³ 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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Indication for Use

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

Intended Use

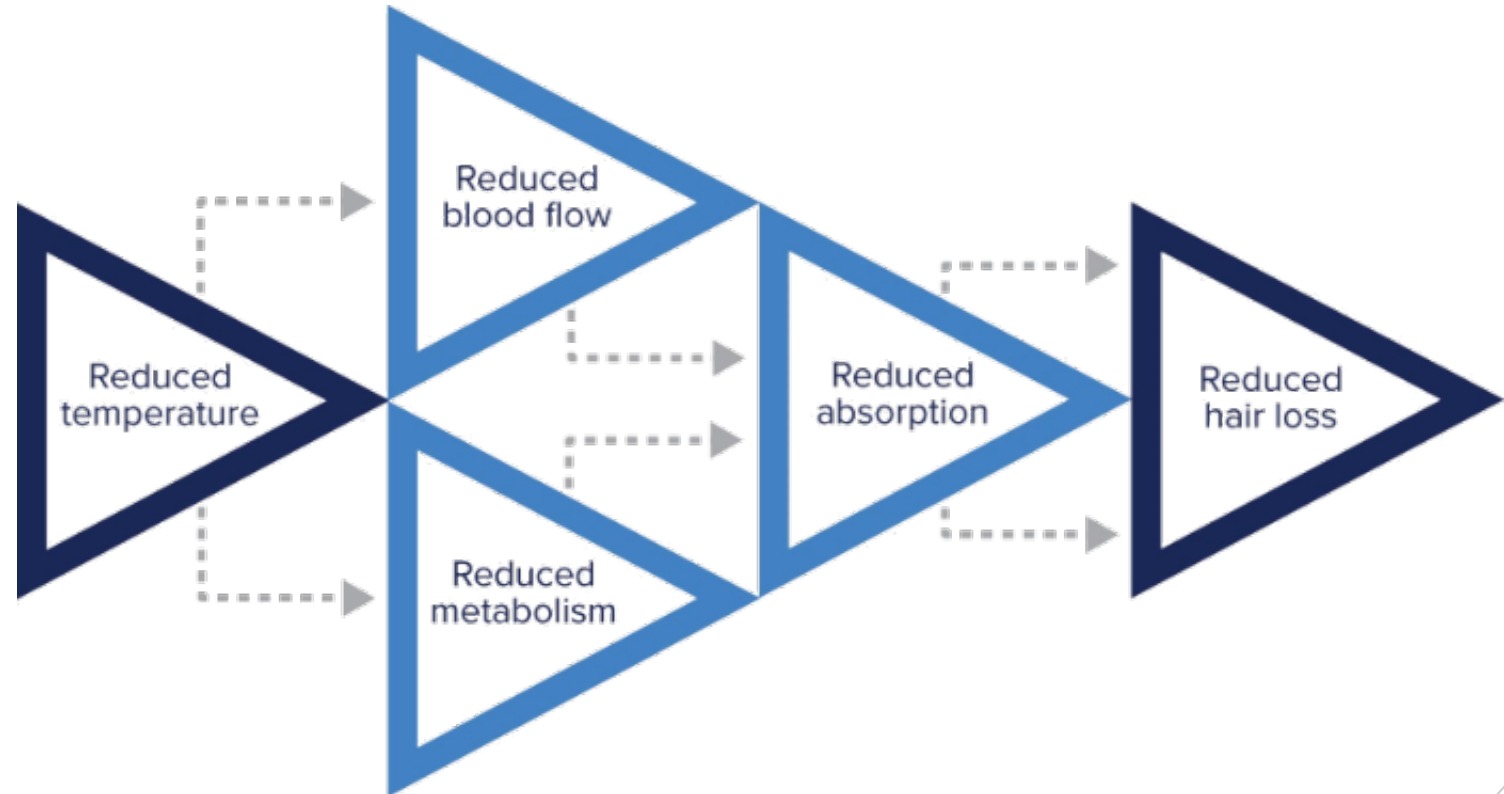
A cooling device intended to reduce or prevent the frequency and severity of alopecia during chemotherapy in which alopecia inducing chemotherapy agents are used.



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What is needed for scalp cooling?

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

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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

Therapy Resources CPT 0662T

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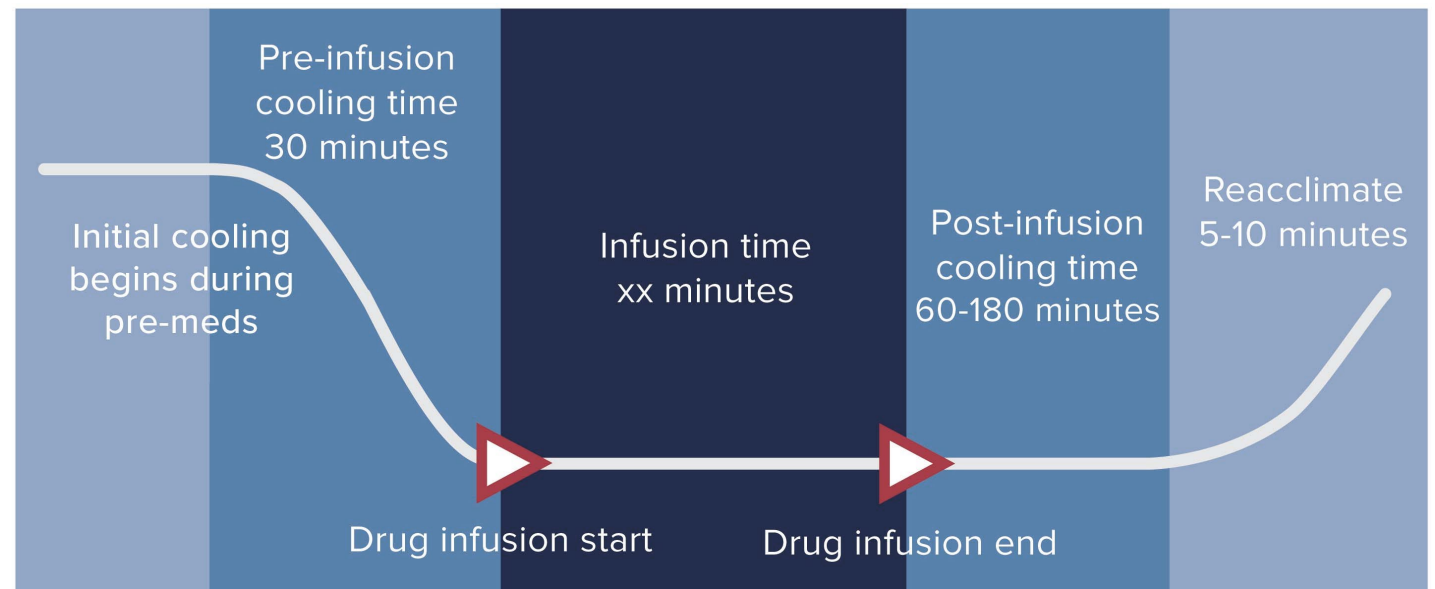
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Cap fitting and patient education

- 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

JAMA[®]

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.”

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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