

DigniCap Hub Resources

The following documentation to support reimbursement claims are available from the DigniCap Hub:

- Sample Letter of Medical Necessity for provider to place on their letterhead and personalize for each patient
- Published clinical literature supporting DigniCap use
- FDA clearance letter
- Indications for Use
- Providers should include the treatment order and notes related to DigniCap usage
- NCCN Clinical Practice Guidelines in Oncology listing scalp cooling as a Category 2A recommendation
- ONS Guidelines™ for Cancer Treatment recommendation for scalp cooling

Prior Authorization

Payors may require prior authorization for mechanical scalp cooling. Dignitana recommends that providers preauthorize benefits for scalp cooling at the same time that preauthorization is initiated for the chemotherapy regimen. For assistance with prior authorization letter and medical necessity, contact the DigniCap Hub.

Denied Claim Appeals

For assistance with Denied Claims Appeals contact the DigniCap Hub.

Establishing Payment

Category III CPT® codes are eligible for reimbursement by payors. It is important that the physician document medical necessity for the procedure and that the patient meets the indications for chemotherapy induced alopecia as provided by the payor guidelines. In the absence of specific payor guidelines, the NCCN and ONS guidelines may be referenced.

Patient Support

If the provider is not submitting claims the patient may still be able to file for reimbursement. Detailed claim instructions and codes are available in the Patient Reimbursement Guide, or they may contact the DigniCap Hub for assistance.

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Current Procedural Terminology 2022, American Medical Association. Chicago, IL 2021. CPT is a registered trademark of the American Medical Association. Current Procedural Terminology (CPT®) is copyright 2021 American Medical Association All Rights Reserved. Applicable FARS/DFARS apply.

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The purpose of this document is to provide guidance to physicians and their coding teams on the coding, billing and reimbursement of the Category III CPT Code reporting for the DigniCap Scalp Cooling System. Effective July 1, 2021, DigniCap may be reported using Category III CPT code 0662T and +0663T.

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CMS Final Rule - New Reimbursement Rates from Medicare

November 2021 Update

CMS Final Rule recognizes value of scalp cooling and enables reimbursement for DigniCap to providers

CMS Final Rule for Outpatient Hospital Payment reassigns scalp cooling and increases rate from \$34.72 to \$1,850.50.

CMS Final Rule Nov 2, 2022- CMS-1753FC Addendum B (For scalp cooling, see page 232-233)

Key Actions Supporting this Update

Date	Action
October 2020	Scalp cooling technology recognized by the AMA with two Category III CPT® Codes: 0662T and +0663T
June 2021	CPT 0662T assigned to APC 5732 (Level 2 Minor Procedures) with payment rate \$34.72
July 2021	Dignitana appealed the assignment to the HOP Advisory Panel and initiated contact with CMS to determine an appropriate payment level for Medicare coverage of scalp cooling
September 2021	Dignitana led industry presentations to the HOP Advisory Panel and the CMS Department of Outpatient Care (DOC) outlining hospital cost data and supporting scalp cooling
November 2021	CMS recognized the value of scalp cooling to beneficiaries and reassigned CPT 0662T: APC 1520 (New Technology) with national payment of \$1,850.50 effective January 1, 2022

“The CMS decision ensures that thousands of cancer patients will now have access to life-changing scalp cooling therapy that was previously financially out of reach.

This is a major milestone in supportive care and is significant progress toward the unequivocal establishment of scalp cooling as standard of care.” - William Cronin, Dignitana CEO

Indications for Use

The DigniCap Scalp Cooling System is indicated to reduce the likelihood of chemotherapy-induced alopecia in cancer patients with solid tumors.

For full Intended Use and Contraindications contact the DigniCap Hub or go to dignicap.com/contraindications/

Treatment Description

The DigniCap Scalp Cooling System consists of a computerized cooling unit and an attached cooling cap. Temperature regulated coolant continuously circulates through specially designed channels in the cooling cap. Scalp cooling requires a 30-minute pre-infusion cooling time. Following a patient's infusion, the chemotherapy agent is still active in the patient's bloodstream. Therefore, the scalp cooling treatment continues for a cycle of post-infusion cooling. Depending on drug and dose, this is typically 60 – 180 minutes.

Coding

Effective date: July 1, 2021 • Publication: CPT® 2022

CPT® code 0662T

- Scalp cooling, mechanical; initial measurement and calibration of cap
- Reported once per chemotherapy treatment period for the initial measurement and calibration.

CPT® code +0663T

- Scalp cooling, mechanical; placement of device, monitoring, and removal of device
- List separately in addition to code for primary procedure (e.g., chemotherapy)
- Reported per chemotherapy session

Medicare National Payment of \$1,850.50 under New Technology APC 1520 – effective January 1, 2022

Clinical Guidelines

- NCCN Clinical Practice Guidelines in Oncology 2019 and 2020 list scalp cooling as a Category 2A recommendation to reduce the incidence of chemotherapy-induced alopecia for patients receiving chemotherapy.
- ONS Guidelines™ for Cancer Treatment-related Skin Toxicity 2020 recommends scalp cooling.

Coding and Treatment Verbiage

In introducing CPT® code 0662T, the AMA defined the CPT® codes to be generic and accommodate multiple technologies. The 0662T code descriptor refers to “initial measurement and calibration.” This is the same process as the “initial fitting and adjustment” that is standard when a patient uses DigniCap for the first time.

In the initial treatment DigniCap patients have the Cooling Wrap fitted to their head – at which time the clinician assesses whether the sizing and measurement of the standard Cooling Wrap provides correct coverage. At this time patients with very small heads may need to be switched to the small sized Cooling Wrap. The adjustment of the Cooling Wrap and Thermal Cap include calibration, modification and fine-tuning the Velcro tabs on the Wrap and along the top of the Cap, as well as the proper adjustment of the chin strap to ensure a comfortable but snug fit, with no air pockets.

The fitting and adjustment of the DigniCap requires a trained clinician as well as extensive interaction with the patient.

