

Dignitana announces proposal for Local Coverage Determination of scalp cooling therapy

Dignitana announces that the Palmetto Medicare Administrative Contractor (MAC) has issued a <u>Proposed Local Coverage Determination (LCD)</u> to provide coverage guidance for Scalp Cooling for the Prevention of Chemotherapy-Induced Alopecia. The draft policy recommends coverage be considered reasonable and necessary for FDA cleared devices as long as the patient does not have any of the listed contraindications. This is the first LCD that has been proposed for scalp cooling.

A MAC is a private health care insurer that has been awarded a geographic jurisdiction to process claims for Medicare beneficiaries. The Palmetto MAC services two jurisdictions in the US Medicare system covering seven states in the southern US: Alabama, Georgia, North Carolina, South Carolina, Tennessee, Virginia, and West Virginia.

The Centers for Medicare and Medicaid Services (CMS) assigns MACs the task of developing coverage articles that give direction on how to bill or code for a service or to provide education on a specific topic. The Draft Article - Billing and Coding: Scalp Cooling for the Prevention of Chemotherapy-Induced Alopecia will be updated at the close of the review process.

This action proposing localized coverage further advances support for health care providers to receive reimbursement from Medicare to administer FDA-cleared scalp cooling therapy, such as The DigniCap Scalp Cooling System.® Two separate CPT® Category III Codes for "mechanical scalp cooling," 0662T and 0663T, were issued by the AMA with an effective date of July 1, 2021. The CPT® codes, coupled with coverage determinations such as the proposed LCD, will expand patient access to scalp cooling and enable oncology providers to appropriately offer the service and bill for the resources required to administer scalp cooling therapy.

CMS assigns Medicare Administrative Contractors (MACs) the task of developing Local Coverage Determinations (LCDs) to describe reasonable and necessary services within the Medicare program. The Cms.gov) is now under public review. Working in collaboration, Dignitana and Paxman submitted the original request letter to Palmetto GBA in February 2023.

The proposed scalp cooling LCD will be discussed at two <u>Open Meetings of the Palmetto GBA on July 17, 2023</u> via webinar. Palmetto GBA is soliciting comments on these proposed LCDs from physicians, manufacturers, suppliers and other professionals involved in the ordering and/or provisioning of these items. Other stakeholder comments are also welcomed and comments regarding the proposed LCD can be submitted with a deadline of July 22, 2023.

If approved, the Palmetto LCD would provide a pathway for successful reimbursement of Medicare scalp cooling claims for patients in the seven-state service area early in 2024.

For More Information Contact

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About Dignitana

Dignitana AB is the world leader in clinically superior scalp cooling technology. The company produces The DigniCap® Scalp Cooling System, a patented medical cooling device that offers

cancer patients the ability to minimize hair loss during chemotherapy. FDA cleared since 2015, DigniCap provides continuous cooling with high efficacy, safety and patient comfort. Hailed internationally as a life-changing medical advancement for cancer patients, The DigniCap Scalp Cooling System was invented in 1999 by a Swedish Oncology nurse and has been available in Europe since 2001. Dignitana AB is listed on Nasdaq First North Growth Market in Sweden with headquarters in Lund, Sweden and US operations based in Dallas, Texas in the United States. Company subsidiaries are Dignitana, Inc. in the United States and Dignitana S.r.l. in Italy. Certified Adviser is Redeye AB. Learn more at www.dignitana.com or www.dignitana.com or www.dignitana.com or www.dignitana.com or www.dignitana.com or