

Dignitana Announces Palmetto GBA Approves First Local Coverage Determination for Scalp Cooling Therapy

Dignitana announces that the Palmetto GBA Medicare Administrative Contractor (MAC) has issued a [Local Coverage Determination \(LCD\)](#) to provide coverage guidance for Scalp Cooling for the Prevention of Chemotherapy-Induced Alopecia. According to the final LCD guidance from Palmetto GBA, “the use of a scalp hypothermia device that has been approved by the United States (U.S.) Food and Drug Administration (FDA) for the prevention of chemotherapy-induced alopecia (CIA) shall be considered reasonable and necessary for patients with solid tumors.” In addition, there were no changes between the Proposed LCD and the Final LCD.

This is the first LCD that has been approved for scalp cooling and is a result of a request made to Palmetto GBA in February 2023 by Dignitana and Paxman. This important Palmetto LCD provides a pathway for successful reimbursement of Medicare scalp cooling claims for patients in the seven-state service area, effective November 12, 2023. Dignitana currently serves 37 locations within the Palmetto GBA jurisdiction.

A MAC is a private healthcare insurer that has been awarded a geographic jurisdiction to process claims for Medicare beneficiaries. The Palmetto GBA 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.

CMS assigns MACs the task of developing LCDs to describe reasonable and necessary services within the Medicare program. CMS also 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. In the [Billing and Coding Guide: Scalp Cooling for the Prevention of Chemotherapy-Induced Alopecia](#), Palmetto GBA reaffirms guidance from CMS, “CMS Internet-Only Manual, Pub. 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1, Part 2, §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).”

This action solidifying localized coverage further advances support for healthcare 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 approved 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.

Dignitana will use the approval of this LCD to form the strategy with other MACS around the country.

For More Information Contact

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About Dignitana

Dignitana AB is the innovation leader in scalp cooling technology. The company produces The DigniCap® Scalp Cooling System, a clinically superior, 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.dignicap.com.