FDA Approves Cooling Cap for Hair Loss

Scalp cooling system that reduces hair loss due to chemotherapy can now be used by people with all solid tumor types.

July 10, 2017 By Liz Highleyman

The Food and Drug Administration (FDA) this week announced expanded approval of a cooling device that helps prevent hair loss in patients receiving chemotherapy for many types of cancer.

The DigniCap, manufactured by Dignitana AB in Lund, Sweden, was previously approved in 2015 only for women with breast cancer. The expanded approval makes it available for all adults with solid tumors, such as lung, ovarian or prostate cancer. Nearly 800,000 new cases of solid tumors are diagnosed in the United States each year, according to a Dignitana ABp press release.

“We are pleased to expand the use of this product for cancer patients with solid tumors to potentially minimize chemotherapy-induced hair loss,” Binita Ashar, MD, of the FDA’s Center for Devices and Radiological Health said in an FDA press release. “Managing the side effects of chemotherapy is a critical component to overall health and quality of life.”

Hair loss, or alopecia, can be one of the most distressing side effects of chemotherapy. Traditional chemotherapy stops multiplication of cancer cells, but it also damages rapidly dividing healthy cells throughout the body, including cells in the hair follicles. This can lead to side effects such as hair loss, nausea and low blood cell counts.

The DigniCap scalp cooling system, used at available at more than 80 medical facilities in the United States where patients receive chemotherapy, circulates a cooling liquid through a silicone cap. It works by lowering the temperature of the scalp to near freezing, which constricts blood vessels, reduces the amount of chemotherapy drugs reaching the hair follicles and slows down cell division in the follicles.

A recently published study showed that two thirds of breast cancer patients who used the DigniCap 30 minutes before chemotherapy lost less than half their hair, compared with none of those who did not use the cap.

“With breast cancer patients, we have seen positive results with scalp cooling treatments, although success is dependent on the type and dose of chemotherapy,” Hope Rugo, MD, of the

UCSF Helen Diller Family Comprehensive Cancer Center and principal investigator for the this trial said in the Dignitana AB press release. “Patients with other cancers using similar chemotherapy treatments may also benefit from scalp cooling to preserve their hair, and scalp cooling is used worldwide to prevent hair loss for a number of cancers, including gynecologic cancers and cancer of the prostate as well as others.”

Another scalp cooling system, the Paxman Hair Loss Prevention System from Paxman Coolers Limited, is currently FDA-approved only for patients with breast cancer.

To read an FDA press release about the expanded DigniCap approval, click here.

To read a Dignitana AB press release about the approval, click here.

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