Optune device approved for newly diagnosed brain cancer

October 6 2015

(HealthDay)—The U.S. Food and Drug Administration on Monday expanded its approval for the Optune device to include newly diagnosed glioblastoma multiforme, an aggressive brain cancer.

Optune involves placing electrodes on the surface of the scalp to deliver low-intensity pulses called "tumor treatment fields," which are designed to damage growing tumor cells, the agency said in a news release. The portable device, powered by battery or plugged into a common electric outlet, can be used at home or work.

It's been newly sanctioned to treat just-diagnosed patients, in combination with the chemotherapy drug temozolomide. Clinical studies of the device for this purpose showed people treated with the Optune/drug combination lived an average of three months longer than those treated with the drug alone.

"Patients newly diagnosed with this challenging and aggressive form of brain cancer now have another treatment option available," said Dr. William Maisel, acting director of the Office of Device Evaluation in the FDA's Center for Devices and Radiological Health. "While the treatment is not a cure, it can increase survival by several months."

Brain and nervous system cancers will be diagnosed in an estimated 23,000 Americans this year, killing more than 15,000, the FDA said, citing the U.S. National Cancer Institute. Glioblastoma multiforme accounts for some 15 percent of brain tumors, and it is most often

diagnosed among people aged 45 to 70.

Optune was first approved in 2011 to treat this type of brain cancer once it had progressed despite chemotherapy. It should not be used without a doctor's supervision, the agency warned.

Skin irritation is the most common side effect, and users also have a slightly greater-than-average risk of neurologic adverse reactions, including convulsions or headaches, the FDA said.

People with an implanted medical device, skull abnormality or skin sensitivity should not use Optune, the agency said.

The device is manufactured by Portsmouth, N.H.-based Novocure Inc.

More information: Visit the FDA to learn more.