News From the Food and Drug Administration

Device for Improving Heart Failure Symptoms

An implantable neuromodulation device was approved for symptom improvement in patients with advanced heart failure who aren't eligible for cardiac resynchronization therapy. Heart failure is the fourth leading cause of death attributable to cardiovascular disease, affecting 5.7 million people in the United States.

"Patients with advanced heart failure have limitations of physical activity, experiencing fatigue, palpitation, or shortness of breath with activity and may not benefit from standard treatments, including currently marketed drugs and devices. This approval provides patients with a new treatment option for the symptoms associated with advanced heart failure," said Bram Zuckerman, MD, director of the FDA's Office of Cardiovascular Devices.

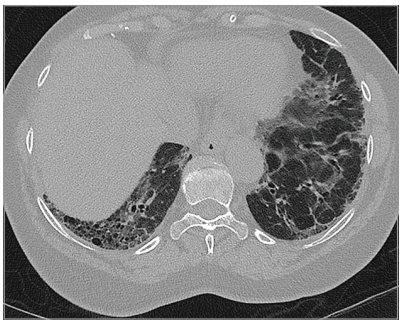
The Barostim Neo System improves heart failure symptoms by restoring autonomic cardiovascular balance. The device is implanted under the collarbone and delivers electrical stimulation to carotid artery baroreceptors. Baroreceptor activation sends signals to the brain, which in turn signals the heart, vessels, and kidneys to relax blood vessels, slow heart rate, and reduce fluid buildup in the body. The device previously received approval for resistant hypertension.

According to the FDA, the most recent approval was based on a clinical trial involving 408 patients with advanced heart failure who were receiving guideline-directed medical therapy. The 125 randomized patients implanted with the device showed significant improvements in a 6-minute walking test and in quality of life compared with those who received medical therapy only. Potential complications include infection, low blood pressure, nerve or arterial damage, stroke, and death.

The device is intended for patients with a regular heart rhythm, a left ejection fraction of ≤35%, and NT-proBNP levels less than 1600 pg/mL despite appropriate treatment. Contraindications include certain nervous system disorders, anatomy impairing device implantation, uncontrolled and symptomatic slow heart rate, atherosclerosis near the implant site, or known allergy to silicone or titanium.

First Treatment for Lung Disease Related to Scleroderma

Nintedanib has received an expanded indication to include interstitial lung disease (ILD) that's associated with scleroderma—a rare autoimmune disorder that causes abnormal connective tissue growth throughout the body. Nintedanib is the first therapy approved for adults with this rare lung condition. It was approved in 2014 to treat idiopathic pulmonary fibrosis, another interstitial lung disease.



Interstitial lung disease results in a progressive loss of pulmonary function, which is the primary cause of death in patients with scleroderma. Nearly half of the 100 000 scleroderma patients in the United States have ILD. Nintedanib, an intracellular tyrosine kinase inhibitor marketed as Ofev, slows the decline in pulmonary function.

The approval was based on a clinical trial involving 576 adults with scleroderma-associated ILD. Patients were randomized to receive twice-daily nintedanib or placebo for 52 to 100 weeks. Nearly half of the patients also received immunosuppressive therapy. During the treatment period, the annual rate of decrease in forcibly exhaled air after a single deep breath—a measure of lung function—was significantly lower in the nintedanib group compared with the placebo group. The most common nintedanib-related adverse event was diarrhea, followed by nausea, vomiting, and weight loss.

Nintedanib may also cause fetal harm, blood clots, bleeding, and gastrointestinal perforation. The drug is contraindicated for patients who are pregnant or have moderate to severe liver impairment, elevated liver enzymes, gastrointestinal disorders, or drug-induced liver injury.

Tether Device for Treating Pediatric Idiopathic Scoliosis

The FDA recently approved the first spinal tether device for children and adolescents with idiopathic scoliosis—the most common form of this spinal deformity.

The device is intended for patients who could opt for surgery because their spinal curvature hasn't responded to conservative treatments such as external bracing. Nearly 7000 patients in the United States develop these progressive spinal curvatures annually. Although spinal fusion surgery is often successful, it permanently limits its spinal range of motion and may result in long-term complications such as arthritis.

Marketed as the Tether-Vertebral Body Tethering System, the device corrects spinal curvature while preserving greater range of motion compared with spinal fusion. The system consists of anchors and screws that are surgically placed into vertebra on the curved section of the spine. A flexible tether attached to the screws is used to compress the curved side of the spine during surgery. As the child grows, tension in the tether increases to further correct spinal alignment.

The approval was based on clinical data from 57 patients who received the device. After 2 years, 43 patients had enough improvement in spinal curvature to avoid spinal fusion surgery. Serious adverse events included overcorrection of spinal curvature, tether breakage, and pneumothorax. Other complications common in any surgical procedure such as pain, respiratory problems, nerve injuries, and bleeding also were reported.

The manufacturer will partner with the Harm Study Group to collect postmarketing data to help assess the device's long-term performance, according to the FDA. –**Feyza Sancar, PhD**

Note: Source references are available through embedded hyperlinks in the article text online.

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