Updated Labeling Supports Quality of Life Improvements for Patients Treated with Medtronic DBS Therapy for Advanced Parkinson’s Disease

Positive News for People with Parkinson’s disease: Medtronic, Inc. has received U.S. Food and Drug Administration (FDA) approval of updated labeling for its deep brain stimulation (DBS) Therapy systems for advanced Parkinson’s disease.

Why is this Important?
The labeling update supports the growing evidence that Medtronic DBS Therapy, in addition to medication, is associated with benefits over time, including:

**Quality of Life/Motor Function Improvements**¹
- Five additional hours of good movement control each day compared to medication alone
- 21 percent improvement in Parkinson’s disease related quality of life compared to medication alone at six months
- 28 percent improvement in the activities of daily living at six months compared to medication alone. These include bathing, dressing, writing clearly and drinking from a glass.
- Improvement in total motor function, including shaking, stiffness and movement difficulties from Parkinson’s disease (15 percent with Medtronic DBS Therapy vs. 2 percent with medication alone)

**Significantly Reduced Medication Use**¹
- Significant reduction in the amount of medication needed to treat Parkinson’s disease
- By reducing the need for levodopa, DBS Therapy simplifies a patient’s medication schedule

**Long-Term Safety and Effectiveness**¹
- Established long-term safety and effectiveness of Medtronic DBS Therapy for advanced Parkinson’s disease through 36 months
- The long-term data will further support the already extensive access and insurance coverage for the therapy

**Risks**
DBS Therapy requires brain surgery. Risks of brain surgery may include serious complications such as coma, bleeding inside the brain, seizures and infection. Some of these may be fatal. Once implanted, the system may become infected, parts may wear
through skin, and the lead or lead/extension connector may move. Medtronic DBS Therapy could stop suddenly because of mechanical or electrical problems. Any of these situations may require additional surgery or cause symptoms to return.

Medtronic DBS Therapy may cause worsening of some motor symptoms associated with movement disorders, and may cause speech and language impairments. Stimulation parameters may be adjusted to minimize side effects and attain maximum symptom control. In patients receiving Medtronic DBS Therapy, depression, suicidal thoughts and suicide have been reported. Occurrence of “fall” has also been reported in patients with Parkinson’s disease.

About Parkinson’s and Medtronic DBS Therapy
Parkinson’s disease is a progressive, degenerative neurological movement disorder that affects more than 1.5 million Americans¹ (a subset of whom is approved to receive Medtronic DBS Therapy in the United States). Approximately 60,000 Americans are diagnosed with Parkinson’s disease each year².

Although Parkinson’s disease ordinarily begins in middle or late life and risk continues to increase with age³, the number of people diagnosed with Parkinson’s disease before age 60 is rising at an alarming rate³. About 10-20 percent of those diagnosed with Parkinson’s disease are under the age of 50, about half of whom are diagnosed before age 40⁴.

Developed by Medtronic in collaboration with clinicians and researchers from around the world starting in the 1980s, the therapy was approved by the FDA for the treatment of advanced Parkinson’s disease in 2002. Medtronic DBS Therapy has benefited more than 100,000 patients worldwide.

Medtronic DBS Therapy uses a surgically implanted medical device, similar to a cardiac pacemaker, to deliver electrical stimulation to precisely targeted areas of the brain to reduce some of the most disabling motor symptoms associated with Parkinson’s disease, including shaking, stiffness and movement difficulties. The stimulation can be programmed and adjusted by a clinician to maximize treatment benefits.

Interested in Learning More?
The therapy is not for everyone. Not everyone will receive the same results. For further information, call Medtronic at (800) 328-0810 or visit Medtronic’s website at http://www.medtronic.com/patients/parkinsons-disease/index.htm.

References:
1 Medtronic DBS Therapy for Parkinson Disease and Essential Tremor Clinical Summary, 2013

Important Safety Information

Medtronic DBS Therapy for Parkinson’s Disease: Patients should always discuss the potential risks and benefits with a physician.

**Indications:** Bilateral stimulation of the internal globus pallidus (GPi) or the subthalamic nucleus (STN) using Medtronic DBS Therapy for Parkinson’s Disease is indicated for adjunctive therapy in reducing some of the symptoms of advanced, levodopa-responsive Parkinson’s disease that are not adequately controlled with medication.

**Contraindications:** Contraindications include patients who will be exposed to MRI using a full body transmit radio-frequency (RF) coil, a receive-only head coil, or a head transmit coil that extends over the chest area, patients who are unable to properly operate the neurostimulator, or for patients for whom test stimulation is unsuccessful. Diathermy (e.g., shortwave diathermy, microwave diathermy or therapeutic ultrasound diathermy) is contraindicated because diathermy’s energy can be transferred through the implanted system (or any of the separate implanted components), which can cause neurostimulation system or tissue damage and can result in severe injury or death. Transcranial Magnetic Stimulation (TMS) is contraindicated for patients with an implanted DBS System.

**Warnings/Precautions/Adverse Events:** There is a potential risk of tissue damage using stimulation parameter settings of high amplitudes and wide pulse widths. Extreme care should be used with lead implantation in patients with a heightened risk of intracranial hemorrhage. The lead-extension connector should not be placed in the soft tissues of the neck due to an increased incidence of lead fracture. Theft detectors and security screening devices may cause stimulation to switch ON or OFF, and may cause some patients to experience a momentary increase in perceived stimulation. Although some MRI procedures can be performed safely with an implanted DBS System, clinicians should carefully weigh the decision to use MRI in patients with an implanted DBS System. MRI can cause induced voltages in the neurostimulator and/or lead possibly causing uncomfortable, jolting, or shocking levels of stimulation. MRI image quality may be reduced for patients who require the neurostimulator to control tremor, because the tremor may return when the neurostimulator is turned off.

The DBS System may be affected by or adversely affect medical equipment such as cardiac pacemakers or therapies, cardioverter/defibrillators, external defibrillators, ultrasonic equipment, electrocautery, or radiation therapy. Safety and effectiveness has not been established for patients with neurological disease other than Parkinson’s disease, previous surgical ablation procedures, dementia, coagulopathies, or moderate to severe depression; patients who are pregnant; and patients under 18 years. Depression, suicidal ideations and suicide have been reported in patients receiving Medtronic DBS Therapy for Movement Disorders, although no direct cause and effect relationship has been established.

Abrupt cessation of stimulation may cause a return of disease symptoms in some cases with intensity greater than was experienced prior to system implant ("rebound" effect). Adverse events related to the therapy, device, or procedure can include: stimulation not effective, cognitive disorders, pain, dyskinesia, dystonia, speech disorders including dysarthria, infection, paresthesia, intracranial hemorrhage, electromagnetic interference, cardiovascular events, visual disturbances, sensory disturbances, device migration, paresis/asthenia, abnormal gait, incoordination, headaches, lead repositioning, thinking abnormal, device explant, hemiplegia, lead fracture, seizures, respiratory events, and shocking or jolting stimulation. Patients using a rechargeable neurostimulator should check for skin irritation or redness near the neurostimulator during or after recharging, and contact their physician if symptoms persist.

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