DEEP BRAIN STIMULATION FOR TREMOR
SUR712.025

COVERAGE:

Unilateral or bilateral deep brain stimulation of the thalamus, subthalamic nucleus or globus pallidus may be eligible for coverage in patients with disabling, medically unresponsive tremor due to essential tremor or Parkinson's disease.

Disabling, medically unresponsive tremor is defined by the following:

• tremor causes significant limitation in daily activities,
• there has been inadequate control by maximal dosage of medication for at least 3 months before implant.

Deep brain stimulation for other movement disorders, including but not limited to multiple sclerosis and posttraumatic dyskinesia, is considered investigational.

DESCRIPTION:

Deep Brain Stimulation involves the stereotactic placement of an electrode(s) into the brain (i.e., thalamus, globus pallidus, or subthalamic nucleus). The electrode(s) is initially attached to a temporary transcutaneous cable for short-term stimulation to validate treatment effectiveness. Several days later the patient returns to surgery for permanent subcutaneous implantation of the cable and a radiofrequency-coupled or battery-powered programmable stimulator.

After implantation, noninvasive programming of the neurostimulator can be adjusted to the patient's symptoms. This feature may be important for patients with Parkinson's Disease (PD), whose disease may progress over time, requiring different neurostimulation parameters. Setting the optimal neurostimulation parameters may involve the balance between optimal symptom control and appearance of side effects of neurostimulation, such as dysarthria, disequilibrium or involuntary movements.

Contraindications to deep brain stimulation include patients who:

• are not good surgical risks because of unstable medical problems or because of the presence of a cardiac pacemaker,
• have a medical condition that requires repeated magnetic resonance imaging (MRI),
• have dementia that may interfere with the ability to cooperate,
• have had botulinum toxin injections within the last 6 months.

At the present time, only one device has been approved by the U.S. Food and Drug Administration (FDA) for deep brain stimulation: the Activa Tremor Control System manufactured by Medtronic Corp., MN. The System consists of the following components:
the implantable pulse generator,
the deep brain stimulator lead,
an extension that connects the lead to the power source,
a console programmer,
a software cartridge to set electrical parameters for stimulation,
a patient control magnet, which allows the patient to turn the pulse generator on and off or change between high and low settings.

On March 31, 2000, the Neurological Devices Advisory Panel voted unanimously to recommend that the FDA grant Premarket Approval for the Soletra Model 7426 for patients with advanced Parkinson's disease. This device will be used in conjunction with the existing Medtronic Activa Tremor Control System. Final FDA approval is pending.

RATIONAL:

The policy regarding unilateral deep brain stimulation (DBS) as a treatment for tremor is based on a 1997 TEC Assessment, which concluded that tremor suppression was total or clinically significant in 82% to 91% of operated sides in 179 patients who underwent implantation of thalamic stimulation devices. Results were durable for up to 8 years, and the side effects of stimulation were reported as mild and largely reversible. The TEC Assessment concluded that these results are at least as good as those associated with pallidotomy. An additional benefit of deep brain stimulation is that recurrence of tremor may be managed by changes in stimulation parameters.

Unilateral DBS of the thalamus has been widely studied as a treatment of tremor. Preliminary studies of unilateral or bilateral DBS of the globus pallidus or subthalamic nucleus appear encouraging. It is hoped that in the future, patients with refractory Parkinson's disease may be able to select from a variety of neuroablative or neurostimulatory procedures tailored to their specific symptoms. Compared to neurodestructive approaches, advantages of neurostimulation include its reversibility and flexibility in terms of programming. The drawbacks include the potentially time-consuming requirement of periodic reprogramming of the stimulator to find the optimal parameters, and the complications of an implanted device; i.e., risk of infection, electrode migration, or hardware failure.

Even though long term studies are not complete and preliminary studies for the most part are made up of small numbers of patients, the Parkinson's disease patient with disabling, medically unresponsive tremor has limited treatment options. Outcomes so far indicate that there is improved quality of life including improvement in Unified Parkinson's Disease Rating Scale (UPDRS) motor scores for some patients having bilateral brain stimulation. When the levodopa dosage was decreased, the result was a decrease in "on" state drug induced dyskinesias (difficulty in performing voluntary movements).

DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member's contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of
premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically. HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.

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