DBS Medical Necessity Documentation Requirements for Essential Tremor and Parkinson's Disease

Thalamic VIM DBS

Summary Caption	Condition
Diagnosis of ET	Based on postural or kinetic tremors of hand(s) without other neurologic signs.
Diagnosis of Idiopathic PD	Presence of at least 2 cardinal PD features (tremor, rigidity, or bradykinesia) which is of tremor dominant form.
Disabling Tremor	Tremor of at least 3 or 4 on the Fahn-Taloso-Marin clinical tremor rating scale (or equivalent scale) in the extremity intended for treatment.
Medical Management	Limitation in daily activity despite optimal medical management
Operative Procedure	Willingness and ability to cooperate during conscious operative procedure.
Post-Operative Follow-Up	Ability to participate in post-surgical evaluations, adjustment of medication and stimulator settings.
Limitations (Not Reasonable and Necessary)	Contradictions I. Non-idiopathic Parkinson's or Parkinson's plus syndromes II. Cognitive impairment, dementia or depression that would interfere or worsen from a DBS implant. III. Psychosis, alcohol, or other drug abuse IV. Structural lesions such basal ganglionic stroke, tumor vascular malformation as the cause of the movement disorder V. Previous Movement Disorder surgery within the basal ganglia

	VI. Significant co-morbidities that would contraindicate surgery or stimulation.

STN or GPi DBS

Summary Caption	Condition
Diagnosis of PD	Based on the presence of at least 2 cardinal PD features (tremor, rigidity, or bradykinesia)
Rating Scales/Stage	Advanced idiopathic PD as determined using Hoehn and Yahr stage or Unified Parkinson's Disease Rating Scale (UPDRS) part III motor subscale. A minimal score of 30 points on the motor portion of the United Parkinson's Disease Rating Scale (UPDRS) when the member has been off medication for about 12 hours (scores on this scale range from 0 to 108; higher values indicate greater severity of symptoms)
Medical Management	Optimal Medical Management L-Dopa responsive with clearly defined "on" periods.
Optimal Medical Management	Persistent disabling Parkinson's symptoms or drug side effects (dyskinesias, motor fluctuations or disabling "off" periods despite optimal management
Operative Procedure	Willingness and ability to cooperate during conscious operative procedure.
Post-Operative Follow-Up	Ability to participate in post-surgical evaluations, adjustment of medication and stimulator settings.
Limitations (Not Reasonable and Necessary)	Contraindications I. Non-idiopathic Parkinson's or Parkinson's plus syndromes II. Cognitive impairment, dementia or depression that would interfere or worsen from a DBS implant. III. Psychosis, alcohol, or other drug abuse IV. Structural lesions such basal ganglionic stroke, tumor vascular malformation as the cause of the movement disorder

	V. Previous Movement Disorder surgery within the basal ganglia VI. Significant co-morbidities that would contraindicate surgery or stimulation.

https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=279
https://www.aetna.com/cpb/medical/data/200_299/0208.html

See important notes on the uses and limitations of this information below

Indication for Use: The Boston Scientific Vercise™ PC, Vercise Gevia™, Vercise Genus™ Deep Brain Stimulation Systems are indicated for use in:

-Bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy in reducing some of the symptoms of moderate to advanced levodopa-responsive Parkinson's disease (PD) that are not adequately controlled with medication.

-Bilateral stimulation of the internal globus pallidus (GPi) as an adjunctive therapy in reducing some of the symptoms of advanced levodopa-responsive Parkinson's disease (PD) that are not adequately controlled with medication.

-Unilateral thalamic stimulation of the ventral intermediate nucleus (VIM) is indicated for the suppression of tremor in the upper extremity. The system is intended for use in patients who are diagnosed with essential tremor or parkinsonian tremor not adequately controlled by medications and where the tremor constitutes a significant functional disability.

The Boston Scientific Vercise Deep Brain Stimulation System is indicated for use in:
-Bilateral stimulation of the subthalamic nucleus (STN) as an adjunctive therapy in reducing some of the symptoms of moderate to advanced levodopa-responsive Parkinson's disease (PD) that are not adequately controlled with medication.

Contraindications, warnings, precautions, side effects: The Boston Scientific Deep Brain Stimulation (DBS) Systems or any of its components, are contraindicated for: Diathermy as either a treatment for a medical condition or as part of a surgical procedure, Electroconvulsive Therapy (ECT) and Transcranial Magnetic Stimulation (TMS) as the safety of these therapies in patients implanted with the Boston Scientific DBS System has not been established, patients who are unable to operate the system, patients who are poor surgical candidates or who experience unsuccessful test stimulation. Patients implanted with Boston Scientific DBS System without ImageReady™ MRI Technology should not be exposed to Magnetic Resonance Imaging (MRI). Patients implanted with Vercise Gevia or Vercise Genus or Vercise Genus Mixed System with M8 Adapter or Vercise DBS Lead-Only System (before Stimulator is implanted) with ImageReady MRI Technology are Full Body MR Conditional only when exposed to the MRI environment under the specific conditions defined in ImageReady MRI Guidelines for Boston Scientific DBS Systems. Assess patients for the risks of depression and suicide. This assessment should consider both the risk of depression and suicide as well as the potential clinical benefits of DBS therapy. Monitor patients for new or worsening symptoms of depression, suicidal thoughts or behaviors, or changes in mood or impulse control and manage appropriately. Refer to the Instructions for Use provided with the Boston Scientific DBS Systems or BostonScientific.com for potential adverse effects, warnings, and precautions prior to using this product. Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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