INSIGHTEC

March 17, 2023

National Government Services, Inc.
Medical Policy Unit
Contractor Medical Directors
LCD Reconsideration Request
P.O. Box 7108
Indianapolis, IN 46207-7108

BY ELECTRONIC MAIL

RE: Reconsideration of NGS LCD (L37421) Magnetic Resonance Image Guided High Intensity Focused Ultrasound (MRGFUS) for Tremor, requests to expand indications to include Parkinson's Disease, and amend current criteria and limitations related to essential tremor, specifically to remove "dominant hand" and reference to "bilateral".

Dear Contractor Medical Directors,

InSightec, manufacturer of ExAblate® Neuro, the device utilized for treating patients who suffer from movement disorders using Magnetic Resonance guided Focused Ultrasound (MRgFUS) writes this letter to formally request a reconsideration of the LCD for L37421. Since ExAblate was FDA Approved in July 2016 for essential tremor, subsequent FDA approvals have been granted via PMA. These include Tremor Dominant Parkinson's Disease (December 2018), for which NGS currently covers, Parkinson's Disease (October 2021), and most recently, In the staged (by at least 9 months), unilateral thalamotomy of idiopathic Essential tremor patients with medication-refractory tremor of their contralateral side that was not previously treated in the index unilateral thalamotomy. We are respectfully requesting the following items:

I. Consideration to expand and include the indication Parkinson's Disease (PD) under bullet point #1 within the "**Coverage Indications, Limitations, and/or Medical Necessity"** section to include the following language:

> **c. MRgFUS in the unilateral pallidotomy of patients with advanced, idiopathic Parkinson's disease with medication-refractory moderate to severe motor complications as an adjunct to Parkinson's disease medication treatment is considered medically reasonable and necessary in patients who have Tremor-Dominant Parkinson's disease and all of the following:**
>
> 1. **Patients must be at least age 30.**
> 2. **The designated area in the brain responsible for the movement disorder symptoms [globus pallidus (GPi)] must be identified and accessible for targeted thermal ablation by the Exablate device.**

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Nearly one million people in the U.S. are living with Parkinson's disease (PD). This number is expected to rise to 1.2 million by 2030. Parkinson's disease (PD) is the second most common neurodegenerative disorder after Alzheimer's disease, and the fastest-growing neurological disease in terms of prevalence, related disability, and mortality. PD affects 1–2% of individuals above 65 and its prevalence is rapidly increasing as the population ages. Since there are currently no neuroprotective therapies able to prevent or delay disease progression, PD is a major healthcare and societal challenge. Medications alone cost an average of $2,500 a year and therapeutic surgery can cost up to $100,000 per person.[1] Patients with significant disability and refractory to medication therapy are candidates for interventional therapy. The current standard of care treatment is the highly invasive Deep Brain Stimulation. A significant 'treatment gap' exists between medication and open brain surgery with implanted hardware requiring chronic follow up and multiple outpatient procedures. ExAblate® Neuro, using transcranial MRgFUS could potentially fill this gap. Recently (Feb. 23, 2023) the New England Journal of Medicine (NEJM) published results of a randomized clinical trial (RCT), indicating that MRgFUS is safe, efficacious, and durable. This RCT concluded that in patients with medication-refractory Parkinson's disease, those who underwent unilateral focused ultrasound ablation of the globus pallidus internus were significantly more likely to have a reduction in motor symptoms or dyskinesias over a period of 3 months than those who underwent a sham procedure.

We believe the recently published results clearly supports the request to expand indications to include coverage for Parkinson's disease.

AND

II. Amend the following items under "Coverage Guidance"; Item #2 under "MRGFUS unilateral thalamotomy is considered medically reasonable and necessary in patients with all of the following".

2. Moderate to severe postural or intention tremor of the dominant hand (defined by a score of ≥2 on the Clinical Rating Scale for Tremor (CRST)

Insightec respectfully request that NGS remove the verbiage **"dominant hand"** based on the most recent FDA PMA approval attached. The language from the FDA PMA labeling states the following:

[1] [http://doi.org/10.1038/s41531-018-0058-0](https://www.nature.com/articles/s41531-018-0058-0)

"In the unilateral thalamotomy treatment of idiopathic essential tremor patients with medication1refractory tremor. Patients must be at least age 22. The designated area in the brain responsible for the movement disorder symptoms (ventralis intermedius) must be identified and accessible for targeted thermal ablation by the Exablate device".

AND, under "Limitations (Not Covered), Item #2, "Bilateral Thalamotomy", Removal of this limitation in its entirety.

2. Bilateral Thalamotomy

INSIGHTEC respectfully request that NGS remove "bilateral" from the limitations based on the most recent FDA PMA approval attached. Bilateral sides in the sense that MRgFUS would NEVER be performed on the same date of service. The FDA approval was based on a staged procedure by at least 9 months.

Under the most recent Food and Drug Administration (FDA) PMA approval letter P150038/S014 and P1500387/S022 (attached), available via the following link: Premarket Approval (PMA) (fda.gov), The FDA has approved ExAblate using the following approval/labeling language:

"**In the unilateral thalamotomy treatment of idiopathic Essential tremor patients with medication-refractory tremor and in the staged (by at least 9 months from the first thalamotomy), unilateral thalamotomy of idiopathic Essential tremor patients with medication-refractory tremor of their contralateral side that was not previously treated in the index unilateral thalamotomy. Patients must be at least age 22. The designated area in the brain responsible for the movement disorder symptoms (*ventralis intermedius*) must be identified and accessible for targeted thermal ablation by the Exablate device".**

Given the information provided in addition to this request, we respectfully request that NGS review the information, agreeing that MRgFUS for treating Parkinson's disease should be included in the coverage language, and "dominant hand" and 'bilateral" language be removed from the limitations (not covered) section. Expanding coverage for Parkinson's disease for Medicare beneficiaries who suffer from this debilitating disorder is appropriate based on the FDA labeling/approval and the recent peer reviewed clinical publication.

Thank you in advance for the opportunity. I am available should you have any questions. I look forward to your response.

Regards,

Dee Kolanek

VP of Market Access and Reimbursement

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