

December 14, 2021

Contractor Medical Directors  
C/o Krista Babbitt, Medical Policy Specialist  
Noridian Healthcare Services- Attention JE and JF Medical Affairs  
900 42nd Street S  
PO Box 6781  
Fargo, ND 58108

BY ELECTRONIC MAIL

RE: Reconsideration of Noridian Healthcare Services LCD (L37738) MAGNETIC RESONANCE IMAGE GUIDED HIGH INTENSITY FOCUSED ULTRASOUND (MRGFUS), STEREOTACTIC ABLATION LESION, INTRACRANIAL FOR MOVEMENT DISORDER (CPT 0398T); expanding indications to include Tremor Dominant Parkinson's Disease.

Dear Contractor Medical Directors,

InSightec, manufacturer of ExAblate® Neuro, the device utilized for treating patients who suffer from essential tremor using Magnetic Resonance guided Focused Ultrasound (MRGFUS) writes this letter to formally request a reconsideration of the LCD for L37738, with additional literature not previously submitted/considered. We are specifically requesting consideration to expand and include the indication Tremor Dominant Parkinson's Disease (TDPD) under "Coverage Guidance" section to include the following language:

MRGFUS unilateral thalamotomy is considered medically reasonable and necessary in patients who have Tremor-Dominant Parkinson's disease and all of the following:

1. Medication refractory Tremor-dominant Parkinson's disease, defined as refractory (or intolerant) to levodopa or levodopa equivalent medications (LEDD)  $\geq$  900 mg
  2. Parkinson's disease with tremor dominant subtype. This should generally be reflected by administering the UPDRS in the on-medication state using the ratio of the mean score for tremor items (items 16, 20, and 21) to the mean postural instability/gait disorder score (items 13-15,29, and 30). A ratio of  $\geq$  1.5 indicates tremor dominant Parkinson's Disease
  3. Severe and disabling tremor as indicated by documentation of specific activities in daily life that the patient is unable to perform or has substantial difficulty performing secondary to the tremor
- Not able to tolerate the procedure

Following the FDA approval of MRGFUS for Essential Tremor, MRGFUS was approved by the FDA in December 2019 for Unilateral Thalamotomy (ventralis intermedius) treatment of Tremor-dominant Parkinson's Disease with medication-refractory tremor. Research shows that the pathophysiology of TDPD is different from the pathophysiology of Parkinson's disease in patients affected primarily by rigidity and bradykinesia.

For approximately 10-20% of Parkinson's patients, tremor is the primary disability, and while MRGFUS is not curative for Parkinson's disease, it can provide significant quality of life benefits for those whose primary disability is tremor. The current standard of care treatment for tremor as the target symptom is the highly invasive Deep Brain Stimulation, with less than 1,000 procedures performed annually. Additionally, a unique medication strategy is often indicated for TDPD, but for refractory patients, surgery may be considered. 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. MRGFUS is a single session, non-invasive, real-time monitored and controlled surgical procedure that uses continuous diagnostic-quality magnetic resonance imaging (MRI) with high-power, focused ultrasound (acoustic) energy (non-ionizing radiation) to provide an efficient, single day treatment.

In October 2017, JAMA Neurology published results of a randomized clinical trial (RCT), indicating that Focused ultrasound thalamotomy for patients with TDPD demonstrated improvements in medication-refractory tremor by CRST assessments. Since that time, there have been additional peer reviewed publications that we believe clearly supports the request to include TDPD as a covered indication using MRgFUS thalamotomy.

1. **Bond et al JAMA Neurology 2017:** randomized-pivotal trial demonstrating the safety and efficacy of MRgFUS for the established anatomic target of known clinical benefit in the standard-of-care treatment of Parkinson's disease.
2. **Meng et al Journal of Neurosurgery 2020:** cost-effectiveness analysis favors MRgFUS in the treatment of PD. The authors found that "MRgFUS thalamotomy is a cost-effective treatment for patients with TDPD, particularly over continued medical therapy, "and key results included "Adding MRgFUS to continued medical therapy resulted in an incremental cost-effectiveness ratio of \$30,078 per quality-adjusted life year (QALY)." Of note, in comparing DBS to MRgFUS, DBS did not achieve the willingness-to-pay threshold (\$56,503 per QALY). These findings favor the cost-effectiveness of including MRgFUS coverage in the treatment of Parkinson's Disease.
3. **Sinai et al Journal of Parkinson's Disease 2021:** single institution post-market series demonstrating safety and efficacy of MRgFUS in continued standard-of-care clinical practice. Key findings include: "FUS VIM thalamotomy in TDPD patients was effective and safe and provided long-term tremor relief in most patients. FUS thalamotomy for tremor may delay initiation of levodopa treatment"
4. **Lin et al J Neurol Neurosurg Psychiatry 2021:** comparative meta-analysis of MRgFUS and DBS in Parkinsonian tremor finding that "MRgFUS is an efficacious intervention for improving parkinsonian tremor" and non-inferiority analysis to DBS confirmed no significant difference with equivalent efficacy in the treatment of parkinsonian tremor.

Additionally, the following Local Medicare Administrative Contractors; Palmetto GBA, NGS Medicare and CGS Medicare reviewed and expanded their LCDs to include Tremor Dominant Parkinson's Disease, effective dates were 8/13/20, 4/15/21, and 3/8/21. After expanding their coverage language, the MAC's updated their Billing and Coding articles to include ICD-10 diagnosis code G20 to support the expansion.

Given the information provided in addition to this request, we respectfully request that Noridian Healthcare Services review the information, agreeing that MRgFUS for treating TDPD should be included.

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 Reimbursement, InSightec