

From: [Angela Cummings](#)
To: A.POLICY
Cc: [Jeff Pilato](#); [Ronda Mahnar](#); [Joanna Kiones](#)
Subject: [EXTERNAL] MRI Guided Intensity Focused Ultrasound LCD Clarification
Date: Monday, May 15, 2023 10:22:10 PM
Attachments: [image005.png](#)
[image017.png](#)
[image005.png](#)
[image009.png](#)
[image010.jpg](#)
[image011.jpg](#)
[image015.png](#)
[L37761_20230310_Palmetto_GBA_JM_HIFU.pdf](#)
[L37738_20230515_Nevrilson_MAF_HIFU.pdf](#)
[MRgFUS FDA Summary of Safety and Effectiveness Data P150038S014B.pdf](#)
[FDA Approval Order MRgFUS P150038S014A.pdf](#)

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Greetings from Duke University Health System,

NPI 1992703540
PTAN 340030

I'm writing to ask for Palmetto's medical policy consideration in changing one of the [limitations of coverage](#) for the MRgFUS procedure from a skull density ration (SDR) of < 0.45 to an SDR of < 0.40 to align with FDA recommendations for treatment of Essential Tremor with the MRgFUS procedure and LCD guidance by other MACs.

Please ask Dr. Banker to review this email and documentation.

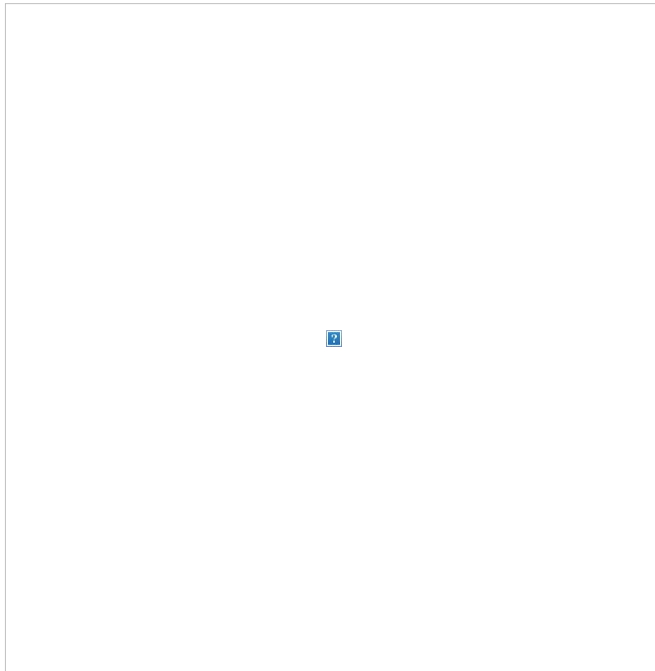
Below is a review of attachments with the addition of relevant screenshots of evidence to support our request.

FDA Documentation

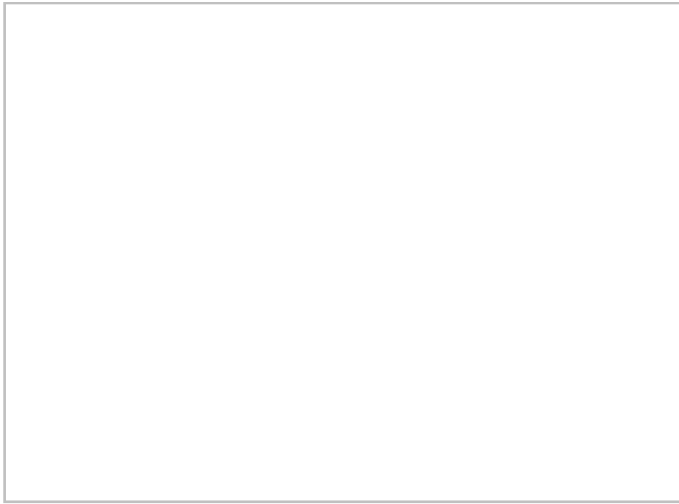
I. Please refer to the below and attached FDA documentation links:

- a. MRgFUS FDA link: [Exablate Model 4000 Type 1.0 and 1.1 System \("Exablate Neuro"\) – P150038/S014 | FDA \[fda.gov\]](#)
- b. FDA Approval Order: [P150038S014A.pdf \[accessdata.fda.gov\]](#)
- c. FDA Summary of Safety and Effectiveness Data

- i. The FDA's formal Exablate directives about when MRgFUS should not be used. The FDA specifically states it should not be used in patient's with an SDR of < 0.45 **+/ - 0.05**. Screenshot below of MRgFUS FDA Link noted above and again here - [Exablate Model 4000 Type 1.0 and 1.1 System \("Exablate Neuro"\) – P150038/S014 | FDA \[fda.gov\]](#).

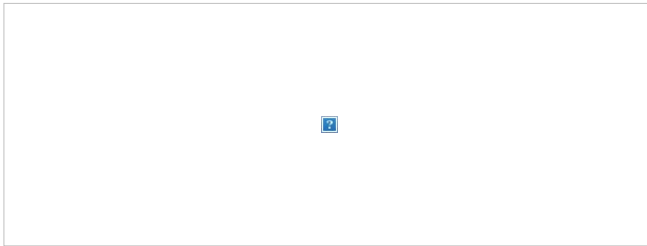


- ii. Screenshot below of the clinical study exclusion criteria noting SDR < 0.40. This is noted in the FDA Summary of Safety and Effectiveness Data pdf.



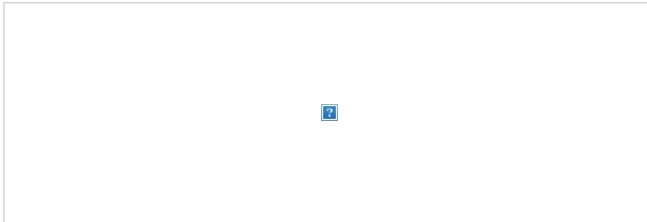
PALMETTO LCD 37761

- II. Excerpt from Palmetto GBA LCD L37761 - Magnetic Resonance Image Guided Intensity Focused Ultrasound (MRgFUS) for Essential Tremor (HIFU)
 - a. Palmetto's LCD states that patients with an SDR of < .45 must be excluded as non-covered. Palmetto's policy is not in line with the FDA's recommendation of < 0.45 +/- 0.05



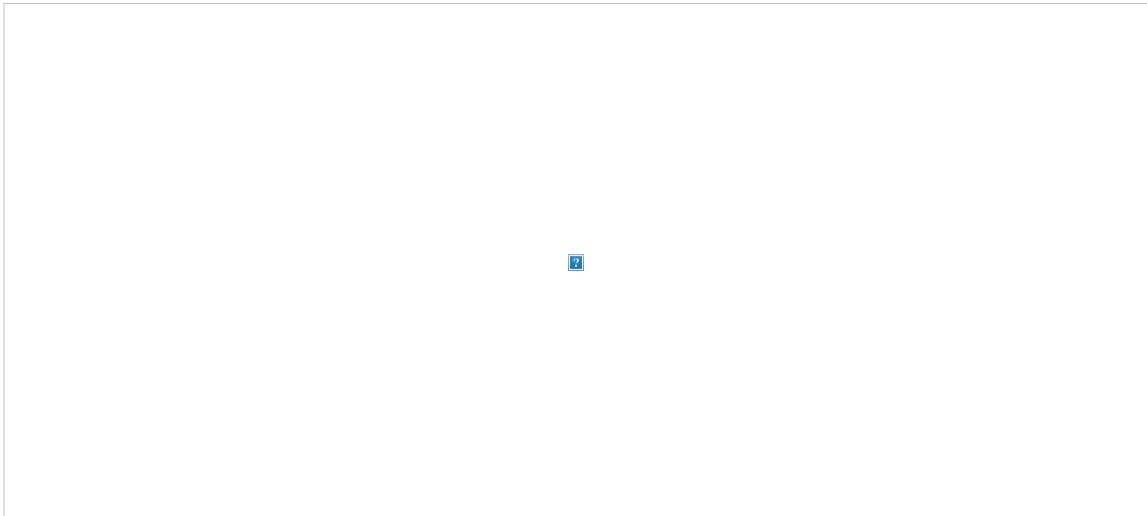
NORIDIAN's LCD 37738

- III. Excerpt from Noridian's LCD 37738 noting exclusion of patients with an SDR of < .40
 - a. See attached MRgFUS Essential Tremor LCD



- b. Noridian also has a proposed LCD - DL37738 for MRgFUS for Essential Tremor and Tremor Dominant Parkinson's Disease. In the proposed LCD, Noridian also excludes patients with an SDR of < .40.

- i. Link to the proposed LCD is found [Proposed LCD - Magnetic-Resonance-Guided Focused Ultrasound Surgery \(MRgFUS\) for Essential Tremor and Tremor Dominant Parkinson's Disease \(DL37738\) \(cms.gov\) \(cms.gov\)](#).



I am respectfully requesting consideration to change Palmetto's LCD 37761 limitations of coverage to exclude patients with an SDR of < 0.40 to align with FDA recommendations, clinical trial exclusion criteria and guidance from other MACs.

All My Best,

Angela

People don't care how much you know until they know how much you care - Theodore Roosevelt

