LCD Reconsideration Request

Dear FCSO Policy-

We are requesting a LCD coverage reconsideration to include OCD as a covered indication for the above mentioned policy. Attached/included please find the proposed policy language, supporting data including peer reviewed published journal article, additional citations for TMS, FDA clearance etc.

Attached copies of published evidence:

· FDA De Novo Approval Letter:

DEN170078

Trade/Device Name: Brainsway Deep Transcranial Magnetic Stimulation System (rTMS)

Regulation Number: 21 CFR 882.5802

Regulation Name: Transcranial magnetic stimulation system for neurological and psychiatric disorders and conditions

Regulatory Class: Class II

Product Code: QCI

Dated: September 26, 2017

Received: September 29, 2017


· Final Patient Labeling 081718. Brainsway Deep Transcranial Magnetic Stimulation (Deep TMS) System for Treatment of Obsessive Compulsive Disorder (OCD)

· Final Physician Labeling 081718. Brainsway Deep Transcranial Magnetic Stimulation (Deep TMS) System for Treatment of Obsessive Compulsive Disorder (OCD)


Proposed Local Coverage Determination (LCD) for Repetitive Transcranial Magnetic Stimulation (rTMS) (L32228).

If you have any questions please don’t hesitate to contact me. Thank you,

Scott Taylor  
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