Re: First Coast Service Options LCD for TMS for Major Depressive Disorder L34522

The current LCD for TMS therapy was implemented in 2013 and needs to be reconsidered with attention to the requirement for medication trials. Specifically, the current requirement is for lack of clinically significant response or intolerance to four trials of psychopharmacologic agents from at least two different classes in the current episode.

Trials have demonstrated the efficacy of TMS for Major Depressive Disorder in individuals who have failed one or several antidepressant medication trials. Based on this evidence, some professional medical organizations have now incorporated TMS into their practice guidelines. In the Clinical TMS Society’s review, TMS is indicated for moderate to severe treatment resistant disease, and found that trials included individuals with one to four antidepressant medication failures. (Tarique Perera 2006) They further emphasize that the labeled indication is for “patients who have failed to receive satisfactory improvement from prior antidepressant medication (emphasis added) in the current episode”. In the O’Reardon trial, an analysis of a subsample of persons with one prior antidepressant failure revealed a robust benefit for TMS versus sham procedure with p<0.001. (John P. O’Reardon 2007)

Another review article was published on behalf of the American Psychiatric Association Council on Research Task Force on Novel Biomarkers and Treatment and the National Network of Depression Centers rTMS Task Group in 2017. (Shawn McClintock 2017) In their review, the RCT study using the H1-coil had 71% of their sample pharmaco-resistant to one or two antidepressant medications. Also, they noted that the study samples were generally equivalent to the group treated with next-step pharmacotherapy in level 2 of the Sequenced Treatment Alternatives to Relieve Depression (STAR*D) study. This meta-analysis of 29 randomized, controlled trials yielded pooled odds ratios for response and remission of 3.3 each, and number needed to treat (NNT) of 6 and 8 respectively. According to a meta-analysis of augmentation with atypical antipsychotic medications published in the American Journal of Psychiatry in 2009, the odds ratio for remission was 2.0, and the NNT was 9. (J. Craig Nelson 2009)

According to a 2012 article which appeared in Depression and Anxiety, in a large clinical trial with 307 subjects undergoing TMS, the average number of antidepressant treatments of adequate dose and duration without satisfactory improvement in the current Major Depressive
episode was 2.5. (Linda L. Carpenter 2012) In this study, the response and remission rates were 56.4% and 28.7% respectively.

In a 2014 meta-analysis of TMS therapy authored by Liu et. al., they defined “treatment-resistant” as failing to respond to at least one adequate antidepressant treatment, and adequate treatment was defined as a trial duration of four weeks and dosed to specific levels. (Bangshan Liu 2014) The pooled response and remission rates were 46.6% and 22.1% respectively with an associated number needed to treat (NNT) of 3.4.

In comparison, according to the STAR*D trial, the remission rates for the antidepressant trials in the first, second, third, and fourth acute treatment steps were 36.8%, 30.6%, 13.7%, and 13.0% respectively. (A. John Rush 2006) This demonstrates that a third or fourth medication trial, whether it is an antidepressant switch or an augmentation, is inferior to TMS. Further, in some studies, TMS is equivalent to or superior to two medication trials (antidepressant switch or augmentation).

Thus, the current FCSO LCD is contrary to good medical practice and should be revised. In its current rendition, it requires that physicians attempt inferior treatments before TMS can be offered for the treatment of Severe Major Depressive Disorder. It is also inconsistent with the labeled indication and practice guidelines. The LCD should be revised to trials of at least two antidepressant medications from different classes (such as SSRI vs SNRI) which either fail due to lack of clinically significant effect or intolerance. This revised language would be consistent with the FDA labeling, the evidence presented here, two other Medicare jurisdictions (Novitas and Noridian), and ethical proper medical practice.

Sincerely,

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Works Cited


