03/01/2012
Comments on Local Coverage Determination L32220
Transcranial Magnetic Stimulation (TMS) (NEURO-010)

Note:
While a number of studies have shown a short-term treatment benefit for patients with a major depressive disorder receiving active versus sham rTMS. "Treatment benefit" has been defined by response or remission rates using depression rating scales. Wisconsin Physicians Service (WPS) has found no published literature that shows this therapy has long term results.

The FDS has published that NeuroStar TMS Therapy is indicated for the treatment of Major Depressive Disorder in adult patients who have failed to achieve satisfactory improvement from one prior antidepressant medication at or above the minimal effective dose and duration in the current episode. FDA approval does not always result in coverage under Medicare.

(WPS received comments from beneficiaries giving details of their health history which was not included in these comments. In addition all patient information was removed from the physician's comments.)

Comment:
The purpose of this letter is to request to you to kindly consider Transcranial Magnetic Stimulation (TMS) as a covered treatment option for some of our patients suffering from treatment resistant depression. As you are well aware TMS has shown to be effective treatment for depression in trials and real world clinical outcomes are confirming that it is a proven and established treatment. (detail of beneficiary treatment) In conclusion I would again humbly request you and urge you to please consider TMS as a covered benefit under Medicare plans as this is a much needed service for some of my patients who are being declined this proven and established treatment.

Response:
Thank you for your comments. WPS has reviewed the published information and found that while there is some evidence that TMS may assist patients suffering from treatment resistant depression there is not significant evidence showing that there is long term effect of this treatment or even that there is a predictable outcome. WPS will continue to review literature and if published information changes will reconsider this decision. WPS always accepts requests for reconsideration of local coverage determination (LCD) that follows the required regulations found at http://www.wpsmedicare.com/part_b/policy/active/local/lcd_reconsideration.shtml and http://www.wpsmedicare.com/j5macpartb/policy/active/local/lcd_recon_process.shtml

Comment:
While there are ongoing studies to see if this helps recovery from head injury or stroke and please note there is nothing published yet.

Response:
Thank you for your comments.

Comment:
A commented was received that there is a lot of ambiguous research because TMS is being used for treatment resistant depression and psychiatrists can't even agree on the definition of treatment

resistant depression. One of the things to be aware of is this may be useful in the elderly even those without treatment resistant depression because the treatment options for the elderly are limited. Electroconvulsive therapy (ECT) can be useful but with significant side effects. Often times the elderly patients are already on a number of prescription medications and adding an antidepressant may be problematic. TMS works surprisingly well in some patients and the LCD should be re-looked at when additional literature becomes available.

Response:
Thank you for your comments.

Comment:
This is new technology for depression, a coil is placed on the surface of the skull and stimulation is given the coil is usually placed on the left pre frontal area of the skull. The literature is problematic as the studies are all manufacturer funded. The studies are not well done; they are not quite sure where to put the coil or how strong the stimulation should be or how many treatments should be done. There are too many unknowns. This is not ready for prime time. There are ongoing studies that may prove to be beneficial. We do know that if there is any improvement as soon as the therapy is stopped that improvement goes away so the treatment would have to continue for the life of the patient as far as we can tell.

Response:
Thank you for your comments.

Comment:
In an effort to improve patient outcomes in the area of Major Depression 2 ½ years ago we decided to purchase and start a NeuroStar rTMS program. Since then we have treated over 25 patients with better clinical outcomes then the Neuronetics trials have indicated! We utilize the HAMD 24 depression rating scale and a typical patient has a starting score in the 40's which is considered severely depressed. After TMS therapy a typical HAMD 24 score decrease is below 20 and some single digit scores. Additionally, to TMS therapy it's not uncommon for these patients to also take 3-5 anti-depressants/anti-psychotics without any real improvement . STARD, one of the largest anti-depressant trials ever completed was very clear that anti-depressants aren't that effective and the more anti-depressant attempts a patient has the less likely they are to achieve remission and the more likely the patient is to discontinue their medications.

A few significant positive points we want to highlight are the following.
1. We have not seen any side effects other then mild headache in the first week! There is nothing safer we can offer our patients to treat their Major Depression.
2. We know when a patient is or isn't compliant with TMS as they have to be there for treatment, we can follow, track and help encourage them much more effectively with TMS vs. any anti-depressant therapy.

Our patients need Medicare to cover TMS therapy, we have phone calls and patient consults regularly with patients who are good indicated candidates but can't afford to pay 100% out of pocket.

Response:
Thank you for your comments. Your experiences should be submitted for publication in a peer-reviewed journal so that others can see and evaluate them.

Comment:
The federally-funded Effective Health Care Program of the Agency for Healthcare Research and Quality (AHRQ), recently published a Comparative Effectiveness Review (Number 33), entitled, "Nonpharmacologic Interventions for Treatment-Resistant Depression in Adults". http://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=787

> ***"Specifically, rTMS averaged a decrease in depressive severity measured by the Hamilton Rating Scale for Depression (HAM-D) of more than 5 points relative to sham control, and this change meets the minimum threshold of the 3-point HAM-D difference that is considered clinically meaningful. Response rates were greater with rTMS than sham (also high strength of evidence); those receiving rTMS were more than three times as likely to achieve a depressive response as patients receiving sham procedure. Finally, rTMS was also more likely to produce remission than the control procedure (moderate strength of evidence); patients receiving rTMS were more than 6 times as likely to achieve remission as those receiving the sham."***

I hope you find this summary of the AHRQ Panel report of interest. I believe they are among the most scientifically important conclusions regarding the strong evidence base of safety and efficacy of TMS yet reported.

Response:
Thank you for your comments.

Comment:
In an effort to improve, and offer patients all possible options in the area of Major Depressive Disorder I decided to purchase a NeuroStar TMS machine. We started our TMS program 18mths ago. Since that time I have treated over 30 patients, with a more positive outcome than could have ever been projected. Unfortunately because WPS Medicare lacks coverage for TMS therapy, patients who are disabled due to their severe major depressive illness are unable to have access to a treatment that could provide them relief from their debilitating depression.

Response:
Thank you for your comments. The included beneficiary information that was included was reviewed. Again, you should publish your results in a peer-reviewed medical journal so that others can see them and evaluate them.

Comment:
I have been a TMS provider since the spring of 2010. I have treated patients with TMS during that time. Of those patients, six have reached complete remission, seven have reached partial remission and three discontinued treatment due to lack of response and financial considerations. Our overall remission rate is over 37%, which is slightly higher than what is reported in the literature. In our experience, remission has been sustained in all of these patients. In addition to symptom relief, these individuals have experienced significant improvement in their interpersonal relationships and psychosocial functioning.

Response:
Thank you for your comments. Again, you should publish your results in a peer-reviewed medical journal so that others can see them and evaluate them.

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In an effort to improve, and offer patients all possible options in the area of Major Depressive Disorder I decided to purchase a NeuroStar TMS machine. We started our TMS program 18mths ago. Since that time I have treated over 30 patients, with a more positive outcome than could have ever been projected. Unfortunately because WPS Medicare lacks coverage for TMS therapy, patients who are disabled due to their severe major depressive illness are unable to have access to a treatment that could provide them relief from their debilitating depression.

Response:
Thank you for your comments. Again, you should publish your results in a peer-reviewed medical journal so that others can see them and evaluate them.

Comment:
I have had a good amount of experience treating treatment-resistant depression and have used all available mainstream ways of treating this particularly challenging sub-group of depressed patients, including ECTs. I also know that no one modality, or even a combination of treatments, works for all. It is also true that with enough perseverance it is possible to get most patients better. This also requires that a variety of modes of treatment modalities be available to try in those that are resistant, or for one reason or another, poorly tolerant or accepting of pharmacological ways of treating depression. The only other available treatment is ECT, which for reasons I am sure you are well aware, is not for everyone.

I have been a provider of TMS for about a year and have treated about 10 patients so far.
All patients carried a diagnosis of Major Depressive Disorder of many years, and were "resistant" to many different treatments, which in one case, numbered 40 different meds and combinations! They were rated and followed on one or more of the following instruments: QID-SR, IDS-SR, Zung SDS. All of those that showed improvement were with remarkable and robust reduction in their scores. None bar one (scalp discomfort) had any notable side effects, including cognitive.

I urge you to strongly consider approving TMS as an available alternative for treatment of selected patients (and not just treatment-resistant patients) with Major Depression: I have found it effective and without the side effects of functional and other limiting impairments that mainstream psychopharmacology often can bring to these patients.

Response:
Thank you for your comments. Again, you should publish your results in a peer-reviewed medical journal so that others can see them and evaluate them.

Comments:
Our patients that have not responded to traditional antidepressant pharmacotherapy or have not been able to tolerate antidepressant medications due to side effects.
We offer TMS Therapy to patients for several reasons: 1) NeuroStar TMS Therapy system was cleared by the FDA in 2008; 2) The American Psychiatric Association incorporated TMS into its "Practice Guideline for the Treatment of Patients with Major Depressive Disorder"; The AMA is stressing evidenced based treatments. 3) The NIMH sponsored a study (George et al, 2010) in which the authors concluded that "daily left prefrontal rTMS as monotherapy produced statistically significant and clinically meaningful antidepressant therapeutic effects greater than sham". The odds of attaining remission were 4.2 times greater with active rTMS than with sham;

4) In a meta-analysis involving 1,383 patients Slotema (2010) concludes that "rTMS deserves a place in the standard toolbox" of psychiatric care as it was an effective treatment for depression; 5) Demitrack and Thase (2009) conclude "the efficacy of TMS demonstrated in randomized controlled trials was comparable to that of pharmaceutical antidepressants studied in similarly designed registration trails and to the adjunctive use of antipsychotic medications in controlled trials of antidepressant non-responders"; 6) Janicak (2008) writes "It has been estimated that 20% to 40% of patients do not benefit sufficiently from, or are intolerant to existing antidepressant interventions, including trials of medication, psychotherapy, and electroconvulsive therapy," which is consistent with my psychiatric practice covering almost 20 years.

There appears to be an unmet need for evidence based treatments for depression in a significant number of patients that do not respond to or who can not tolerate traditional antidepressant medications. It is for this reason that I urge Medicare to cover TMS as an evidenced based service for patients who have not responded to traditional antidepressant pharmacotherapy.

Response:
Thank you for your comments. Again, you should publish your results in a peer-reviewed medical journal so that others can see them and evaluate them. In 2008 the U.S. Food and Drug Administration (FDA) did grant510(k) marketing clearance as a de novo device (assessed as low risk, no predicate device) for NeuroStar® TMS to be utilized as a Class II rTMS device for the treatment of major depressive disorder in patients who had not responded to one adequate trial of antidepressant medication. A 510(k) designation means a device is the equivalent to something already on the market that was “grandfathered in” by the Federal Drug Administration (FDA). This is not the same as FDA approval. Under section 510(k), a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective: that it is, substantially equivalent, to a legally marketed device (that is not subject to PMA). Such a reference device is a legally marketed device that was legally marketed prior to May 28, 1976 (preamendments device), for which a PMA is not required, or a device which has been reclassified from Class III to Class II or I, or a device which has been found SE through the 510(k) process. The term "preamendments device" refers to devices legally marketed in the U.S. by a firm before May 28, 1976 which are exempted (with some conditions) form marketing clearance. Thus, 510(k) clearance does not mean that a device works: it means that it is just as good (or as bad) as a device that came on to the market before the FDA changed its standards. 510(k) clearance does NOT mean the device is safe, effective, or covered by Medicare.

Comment:
I would like to comment on the actual noncoverage policy and what it states. I carefully read through the noncoverage policy and look at the research cited to support this decision. The research cited actually supports use of transcranial magnetic stimulation and is positive as far as outcomes for patients whereas the coverage policy actually states the opposite and indicates that the science cited does not support it. This is a false representation of the scientific information cited and actually not a summary of what the research cited actually states. The objections stated in the summary for noncoverage of transcranial magnetic stimulation for the most part are not actually addressed within the data cited. It appears that either the reviewers did not understand the data that they were reviewing or chose to ignore the content and referenced it only to appear unbiased. I do not believe that the noncoverage decision is based on current scientific evidence and certainly is not supported by the peer review articles summarized in this policy.
Expert consensus guidelines and the APA practice guidelines have recommended transcranial magnetic stimulation for treatment of major depression. This has achieved either a category I or category II level of support through replicated, scientific evidence that has been published in peer reviewed articles. If our expert consensus and practice guidelines cite this as a valid and

scientifically based treatment, am I to understand that the reviewers from WPS have chosen to override this level of expertise? Have they formulated their own opinion outside of what is published, accepted in the scientific community and thoroughly supported in peer review published data?

It seems quite frivolous to disregard this level of review and scientific rigor or to formulate your own opinion which does not coincide with the scientific data and evidence.

It appears that the decision is not based on scientific evidence but on other criteria that are not mentioned in this noncoverage policy. I recall conversation with a young psychiatrist regarding use of atypical antipsychotics for bipolar patients. She indicated that their hospital did not use atypical antipsychotics because "The standard care is different here." I was initially appalled at that comment and now recognized that it probably is just being honest. If we, as clinicians, are unable to get financial coverage for specific treatments for our patients, then our standard care changes such that it essentially excludes a valuable treatment option because of lack of access for that treatment.

I understand that other areas in the United States have draft policies for coverage of transcranial magnetic stimulation. This indicates to me that we will indeed have a different standard care than the other areas of the United States because of lack of access to an effective, safe and scientifically proven treatment. If the policy of noncoverage stands, I ask that either the true reasons for denial are included in the policy or the policy is edited to read, “The standard care is different here". I believe this statement would much more accurately reflect our societal policy of truth in labeling to indicate your rationale for a noncoverage decision for transcranial magnetic stimulation.

I find it very sad and disheartening that the northern Midwest section of United States will be subjected to a limitation of a valuable, efficacious, cost effective, and scientifically proven treatment for major depression. Major depression is a highly prevalent illness but is now the number one cause of disability in this country. Approval for transcranial magnetic stimulation provides a window of opportunity for individuals or suffering from this illness to make positive changes, potentially even to achieve remission from this illness and have a more realistic chance of overcoming the disabling illness and returning to the work force. It has been my experience that individuals that completed ECT treatment rarely returned to the work force and do so after extended disabilities leave due to cognitive impairment caused by ECT treatments. Emerging data on transcranial magnetic stimulation treatment outcomes shows a substantial likelihood of return to the work force, even when entering treatment already on disability.

It does not appear that the decision to decline coverage is based on science, cost effectiveness, outcomes, or efficacy. What really is the rationale for declining coverage of this treatment?

Over this past year, I have had a very poignant case that brings to light the impact on individuals that these decisions make. I have been treating K for 15 years for recurrent and treatment refractory depression. Last fall, she had a relapse into depression and was able to go through one series of total of 36 treatments of transcranial magnetic stimulation. She was a partial responder but had significant benefits with improved cognition and was able to resume working at her usual job because of these improvements. She was unable to obtain coverage for additional transcranial magnetic stimulation treatments and therefore relapsed within two months of stopping TMS treatments. She strongly preferred to return to TMS treatments because of the tolerability and the benefit she saw in her functional improvement. She had a prior history of going through ECT and had been disabled for a significant time because of cognitive issues from ECT following these treatments in the past. Having exhausted medication options, and having only ECT as a realistic treatment option, she went through another series of ECT. She did not achieve remission after having the maximum of 24 treatments of bilateral ECT. Within one month of completing ECT series, she had relapsed and was more depressed than when she initiated the ECT treatments. Again, she has had significant cognitive impairment with the ECT treatment, resulting in her inability to work in any capacity. She is now on disability and will not be returning to her job

because of both the treat refractory depression and the cognitive limitations that are still residual from ECT treatments. She will now qualify for Medicare not due to her age but her disability from treatment refractory depression. Without further treatment options, she will remain on disability until age 65, an additional 25 years.

The estimated cost of 24 ECT treatments at $5,000 per treatment is $120,000. The estimated cost of transcranial magnetic stimulation for one series is $10-$15,000. The cost of this patient with now having a treat refractory and disabling illness that prevents her from working in any capacity prevents her from participating with her family and in normal daily activities, is priceless. Her comment after going through this process was "Why can't I just have a normal life?" I don't know the answer that question for her, but WPS will now be managing her Medicare benefits and will have a noncoverage policy for TMS, which has been the only effective treatment for her depression, so the answer should be "The standard care is different here"?

As a physician and a provider, I do not agree with this noncoverage decision for transcranial magnetic stimulation. I am unable to accept that because of geographic location, we are subjected to different standards than other parts of our country. I ask that you review this policy with greater level of scrutiny, this time considering the science behind the treatment, the impact this decision will make on individual patients, alternative treatments for this illness, the cost verses benefits of transcranial magnetic stimulation and the impact this treatment can make on a highly disabling illness.

Please reconsider the noncoverage decision, and enter into this discussion based upon real science so that we can access this much-needed treatment for our patients. Our patients need access to every available treatment for this much disabling illness. This treatment has been scientifically proven, is cost effective, and greatly diminishes the disability associated with this prevalent and very costly illness. Rewrite this policy based on the evidence that you site. Give us a policy that includes criteria to allow access to this much needed treatment.

I plan to send portions of this letter for publication as an editorial comment. If you would like to ask me questions, please feel free to contact me.

(From a physician)

Response:

Thank you for your comments. You are incorrect that other areas in the United States have draft policies for coverage of transcranial magnetic stimulation. At the time this policy was drafted, all but one Medicare contractor drafted non-coverage policies. The sole exception allowed coverage only if the patients were enrolled in an evidence collection study. Medicare does not use costs as a method to accept or disallow services.