**(PRACTICE LETTERHEAD)**

**(Variable Field: Date)**

**(Variable Field: Insurance Company)**

**(Variable Field: Address)**

**(Variable Field: Insured)**

**(Variable Field: Policy Number)**

**(Variable Field: Group Number)**

**(Variable Field: *Please insert the information according to the type of appeal:***

 ***Preauthorization Appeal:* Case Reference Number**

***Claims Appeal:* Claims Reference Numbers and Dates of Service)**

**Re: 1st Level Reconsideration Request for NeuroStar (TMS) Therapy®**

**CPT Code(s):**

**90867: Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; initial,**

 **including cortical mapping, motor threshold determination, delivery and management**

**90868: Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent**

 **delivery and management, per session**

**(Variable Field: *Please* *only include the CPT code below when applicable to the patient’s case.*)**

**90869: Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent**

 **motor threshold re-determination with delivery and management**

**Diagnosis Code(s): (Insert applicable ICD-9 Code(s) for Major Depressive Disorder)**

To Whom It May Concern:

I am filing an appeal on behalf of my patient, (Patient Name), who has been denied coverage for NeuroStar Transcranial Magnetic Stimulation (TMS) Therapy. NeuroStar TMS Therapy is a safe

and effective treatment that improves depressive symptoms for those patients diagnosed with

Major Depressive Disorder that have not benefitted from prior antidepressant medication. In the denial dated (Date), it was stated that the request was not authorized for the following reason: Transcranial Magnetic Stimulation (TMS) Therapy is not covered to the extent that it is determined to be

experimental/ investigational and is an excluded benefit on the patient’s plan.

(Insurance)’s decision does not reflect recent medical research, published treatment guidelines, and current psychiatric practice. My patient and I request that this appeal be reviewed in light of these new developments regarding Transcranial Magnetic Stimulation (TMS) Therapy and in the context of this patient’s particular illness and past treatment history. I request that this appeal be reviewed by a Board Certified Psychiatrist, experienced in the management of patients with major depression in patients who have not benefitted from prior antidepressant medication, and who is trained in the clinical use of available FDA-cleared neuromodulation techniques such as Vagus Nerve Stimulation (VNS),

Electro-Convulsive Therapy (ECT) and Transcranial Magnetic Stimulation (TMS) to ensure a fair and clinically appropriate evaluation.

The NeuroStar TMS Therapy system was cleared by the FDA in October 2008. 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. The indicated patients had multiple ineffective treatment attempts (average 4 attempts, range 1-23 attempts) in their current depressive episode (Demitrack and Thase, 2009.)

Transcranial magnetic stimulation is a non-invasive method used to electrically stimulate cortical neurons using rapidly alternating MRI-strength magnetic fields generated by a specially designed magnetic coil placed in contact with the surface of the head over the left dorsolateral prefrontal cortex, an area of the brain known to be involved in mood regulation. These fields are sufficient to produce an action potential across the membranes of the neurons in this targeted region of the brain. TMS differs from other methods of electrical stimulation in that the effects can be directed in a spatially localized manner. TMS directly affects brain function in the area of the induced electric current, as well as indirect effects in areas distant from the site of stimulation.

The evidence for the clinical efficacy of TMS in the treatment of depression is considerable. The most recently published and largest meta-analysis (Slotema, 2010) examines data from 34 studies involving 1,383 patients. They report an effect size of 0.55 (95% confidence interval 0.38 to 0.72) for the use of TMS in the treatment of depression, and conclude that, “…rTMS deserves a place in the standard toolbox of psychiatric treatment methods, as it is effective for depression and has a mild side effect profile...”

The clinical utility of NeuroStar TMS Therapy was established in a large (N=301), multisite, randomized, sham-controlled trial (Janicak, et al, 2008; O’Reardon, et al, 2007). Although head-to-head trials have not been conducted, comparison of TMS treatment effects for mean change from baseline meet or exceed the treatment effects reported for 8 of 11 FDA-approved first-line pharmaceutical antidepressants. It is worth noting that unlike antidepressant drug trials, the NeuroStar TMS Therapy trial patients failed to benefit from prior antidepressant medication and demonstrated a level of treatment resistance similar to patients treated in research studies of ECT. Similarly, NeuroStar TMS Therapy treatment effects for mean change from baseline are well within the range of treatment effects for atypical antipsychotic augmentation medications which provide the only pharmaceutical options that are FDA approved for the treatment of patients with major depression who have not benefitted from prior antidepressant medications (Demitrack and Thase, 2009.)

A second large (N=190) multisite randomized sham-controlled trial, funded by the NIMH, was recently reported in the literature and provides confirmation of the efficacy of TMS in depression patients who have not benefited from prior antidepressant medication (George, et al, 2010.) Using the same TMS device cleared for commercial use by the FDA and the same treatment parameters used in prior studies (Demitrack and Thase, 2009) these authors reported that there was a significant effect of active treatment on the proportion of remitters (15% active TMS vs. 4% sham control group, P=0.015), representing a

4.2 greater odds of reaching remission with active TMS compared to sham control. They conclude that "...daily left prefrontal rTMS as monotherapy produced significant and clinically meaningful antidepressant therapeutic effects greater than sham..." This second study is particularly important since it was NIMH-sponsored and was conducted independent of industry support.

Long-term outcomes following acute treatment with the NeuroStar TMS Therapy system have also been described in the peer-reviewed literature (Janicak, et al, 2010). This report describes the clinical outcome in six months of follow up in a cohort of 99 patients who benefited from acute treatment with to up to six weeks of NeuroStar TMS Therapy, and who then successfully transitioned to maintenance antidepressant medication monotherapy over 3 weeks. Of the patients who met criteria for remission on study entry, 73.2% remained in remission at the six month study completion.

TMS is a treatment option in widespread clinical use at major institutions including the Mayo Clinic - Rochester, University of Michigan Depression Center, Walter Reed Army Medical Center, Brown University, UCLA, Harvard medical system (McLean Hospital and Beth Israel Deaconess), Boston University Medical Center, Johns Hopkins University, and Weill Cornell Medical School, Rush University, University of South Florida, as well as being used at freestanding psychiatric hospitals and in private physicians’ offices. TMS Therapy is available only upon the prescription of a psychiatrist.

TMS as a treatment for depression is a proven treatment option and has been incorporated into several treatment guidelines for MDD, including the 2010 American Psychiatric Association “Practice Guideline for the Treatment of Patients with Major Depressive Disorder, 3rd Edition.” The 2010 American Psychiatric Association guideline considers TMS as an appropriate acute phase treatment option for patients who do not respond adequately to initial pharmacotherapy. The guideline states “Acute phase treatment may include pharmacotherapy, depression-focused psychotherapy, the combination of medications and psychotherapy, or other somatic therapies such as electroconvulsive therapy (ECT), transcranial magnetic stimulation (TMS), or light therapy.” TMS is acknowledged to be “safe and

well-tolerated.”

Other published, expert guidelines that report on the evidence for TMS and recommend its use include the Canadian Network for Mood and Anxiety Disorders (CANMAT) 2009 Clinical Guidelines for the Management of Major Depressive Disorder in Adults, and the World Federation of Societies for Biological Psychiatry 2009 Guidelines on Brain Stimulation Treatments in Psychiatry.

The CPT Editorial Research and Development committee of the AMA has granted TMS Therapy Category I CPT codes. The AMA has determined that TMS Therapy is consistent with current medical practice, is widely practiced throughout the country and has the support of the relevant medical societies.

Effective January 1, 2011, the following CPT I codes are to be used for reporting TMS Therapy medical services. according to the two main phases of the treatment. These two codes are CPT 90868 (TMS treatment; initial, including delivery and management) and 90868 (TMS treatment; subsequent delivery and management, per session). Another code, 90869 (TMS treatment; subsequent motor threshold re-determination with delivery and management), has been issued for use only in accordance with the clinical need of re-assessing the motor threshold (MT).

The results from the data presented above provide evidence for the efficacy of a specific TMS treatment protocol (left dorsolateral prefrontal cortex, high frequency TMS), as delivered by a specific FDA-cleared medical device, the NeuroStar TMS Therapy System [Neuronetics, Inc, Malvern, PA] in the treatment of major depression. Your decision to consider NeuroStar TMS Therapy as experimental and investigational is inconsistent with the actions of the FDA, the AMA and the APA. We urge you to approve this patient for treatment and update your medical policy for TMS Therapy by reclassifying it as a proven/established treatment modality given that it is no longer investigational.

*[The following is only applicable if this request is a Claims Appeal. Please add the following only for patients who have received TMS Therapy]:*

Furthermore, I ask that you consider the fact that this patient has not benefitted from multiple exposures to psychopharmacologic agents such as \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. The patient responded well to TMS Therapy with a marked reduction in symptoms and tolerated the treatments well with (no/minimal) side effects. (He/She) experienced additional benefits such as (Include all benefits and results from the treatment i.e., a highly improved level of daily functioning/etc.).

I strongly believe that NeuroStar TMS Therapy is medically necessary and the most effective treatment option at this time based upon this patient’s specific medical history and the clinical data presented.

I appreciate your review of the attached peer-reviewed references that I have included as additional support of this treatment. I am available to discuss this case and TMS Therapy treatment at my practice directly with you. You may contact me at (MD Phone Number). Please notify me in writing of your coverage decision as soon as possible.

Sincerely,

**(Physician’s Name)**

**(Name of Practice)**

**(Address)**

**(Phone Number)**

**(Fax Number)**

*Enclosures:* Corresponding Denial Letter(s)

 Patient’s Clinical Notes

 AMA CPT I Coding Approval Letter

 Bibliography of Publications

 Executive Summary

 FDA Clearance Letter

*References:*

Demitrack, MA, Thase, ME. Clinical Significance of Transcranial Magnetic Stimulation (TMS) in the Treatment of Pharmacoresistant Depression: A Review and Synthesis of Recent Data. Psychopharmacol Bulletin, 2009, 42(2):5-38.

George MS, et al. Daily Left Prefrontal Transcranial Magnetic Stimulation Therapy for Major Depressive Disorder. A Sham Controlled Randomized Trial. Arch Gen Psychiatry, 2010, 67(5): 507-516.

Janicak G, et. al. Transcranial Magnetic Stimulation (TMS) in the Treatment of Major Depression: A Comprehensive Summary of Safety Experience from Acute Exposure, Extended Exposure, and During Reintroduction Treatment. J Clin Psychiatry, 2008, 69:2,222-232.

Janicak G, et. al. Durability of Clinical Benefit with Transcranial Magnetic Stimulation in the Treatment of Pharmacoresistant Major Depression: assessment of relapse during a 6-month, multi-site, open-label study. Brain Stimulation, 2010, 3:187-199.

O’Reardon JP, et. al. Efficacy and Safety of Transcranial Magnetic Stimulation in the Acute Treatment of Major Depression: A Multi-Site Randomized Controlled Trial. Biol Psychiatry, 2007, 62:1208-1216.

Slotema CW, et. al. Should We Expand the Toolbox of Psychiatric Treatment Methods to Include Repetitive Transcranial Magnetic Stimulation (rTMS)? A Meta-Analysis of the Efficacy of rTMS in Psychiatric Disorders. J. Clin Psychiatry, 2010, e1-e13.