

# MEDICAL POLICY



MEDICAL POLICY DETAILS	
Medical Policy Title	TRANSCRANIAL MAGNETIC STIMULATION
Policy Number	3.01.09
Category	Technology Assessment
Effective Date	08/20/09
Revised Date	07/15/10, 08/18/11, 11/15/12, 12/19/13, 12/18/14, 10/15/15, 12/15/16, 12/21/17, 12/20/18
Product Disclaimer	<ul style="list-style-type: none"> <li>• If a product excludes coverage for a service, it is not covered, and medical policy criteria do not apply.</li> <li>• If a commercial product (including an Essential Plan product) or a Medicaid product covers a specific service, medical policy criteria apply to the benefit.</li> <li>• If a Medicare product covers a specific service, and there is no national or local Medicare coverage decision for the service, medical policy criteria apply to the benefit.</li> </ul>

## POLICY STATEMENT

- I. Based upon our review and assessment of peer-reviewed literature, transcranial magnetic stimulation has been medically proven to be effective and is be considered **medically appropriate** as a treatment of major depressive disorder when ALL (A, B, and C) of the following conditions have been met:
- A. Confirmed diagnosis of severe major depressive disorder (single or recurrent) documented by standardized rating scales that reliably measure depressive symptoms with the failure of at least one prior antidepressant medication in the current treatment episode; AND
  - B. Any one of the following (1, 2, or 3):
    1. Failure of 4 trials of psychopharmacologic agents including 2 different agent classes and 2 augmentation trials (*please see guidelines section, roman numeral II and III*); OR
    2. Inability to tolerate a therapeutic dose of medications as evidenced by 4 trials of psychopharmacologic agents with distinct side effects; OR
    3. Is a candidate for electroconvulsive therapy (ECT) and ECT would not be clinically superior to repetitive transcranial magnetic stimulation (rTMS) (e.g., in cases with psychosis, acute suicidal risk, catatonia or life-threatening inanition rTMS should NOT be utilized); AND
  - C. Failure of a trial of a psychotherapy known to be effective in the treatment of major depressive disorder of an adequate frequency and duration, without significant improvement in depressive symptoms, as documented by standardized rating scales that reliably measure depressive symptoms.
- II. Based upon our review and assessment of peer-reviewed literature, a request for transcranial magnetic stimulation as a treatment for major depressive disorder that does not meet all the above listed criteria is considered **not medically necessary**.
- III. Based upon our review and assessment of peer-reviewed literature continued treatment with TMS as maintenance therapy has not been medically proven to be effective and is considered **investigational**.
- IV. Based upon our review and assessment of peer-reviewed literature, transcranial magnetic stimulation has not been medically proven to be effective and is considered **investigational** as a treatment of all other psychiatric/neurologic disorders, including but not limited to, bipolar disorder, borderline personality disorder, schizophrenia, obsessive compulsive disorder, or migraine headaches.
- V. Based upon our review and assessment of peer-reviewed literature, retreatment with transcranial magnetic stimulation has been medically proven to be effective and is be considered **medically appropriate** for patients who met the guidelines for initial treatment AND have subsequently developed relapse of depressive symptoms . The patient must have responded to prior treatments as evidenced by a greater than 50% improvement in standard rating scale measurements for depressive symptoms.

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*Refer to Corporate Medical Policy #8.01.07 regarding Tinnitus Treatment.*

### **POLICY GUIDELINES**

- I. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.
- II. An adequate trial of medication is based on a combination of duration, dosage, tolerance and efficacy of medication. Duration is usually 4-6 weeks (as evidenced by the STAR\*D trial); dosing is dependent on the medication as some medications have a single strength only while others have a minimally effective- maximum effective range. Patients may have more side effect issues or poor tolerance when medications are given at the higher dose ranges. The severity of initial depression and /or the amount of comorbid illness can slow the time to improvement utilizing medication. Providers are required to document medication trials, including the duration, dosing, and side effects when submitting requests for transcranial magnetic stimulation.
- III. The medication regimen can also include use of evidenced-based augmenters or adjunct medications that are not antidepressants themselves; or use of combination therapy when 2 antidepressants are used together. Examples include fluoxetine with bupropion added as combination therapy-augmentation or citalopram and buspirone as adjunctive augmentation.
- IV. Transcranial magnetic stimulation should be performed by physicians who are adequately trained and experienced in the specific techniques used. A treatment course should not exceed 5 days a week for 6 weeks (total of 30 sessions), followed by a 3-week taper of 3 transcranial magnetic stimulation (TMS) treatments in week 1, 2 TMS treatments the next week, and 1 TMS treatment in the last week.
- V. Standardized Rating Scale reliable in rating depressive symptoms include validated depression monitoring scales such as: Geriatric Depression Scale (GDS); Personal Health Questionnaire Depression Scale (PHQ-9); Beck Depression Scale (BDI) Hamilton Rating Scale for Depression (HAM-D) Montgomery Asberg Depression Rating Scale (MADRS); Quick Inventory of Depressive Symptomatology (QIDS); or Inventory for Depressive Symptomatology Systems Review (IDS-SR).
- VI. There are many complementary/ancillary therapies that are not evidence based, or have only low quality evidence that they help in the treatment of depression. There is no evidence that vitamins, supplements, hypnosis, genetic testing, massage are required to make a course of TMS more effective. If there is a particular activity that a provider is adding to TMS, please refer to the member contract or specific medical policy to determine coverage requirements.
- VII. Motor threshold is initially assessed during the first treatment session. Measurement of the motor threshold varies from individual to individual and determines the amount of energy required to stimulate brain cells. This allows for individualization of the intensity of stimulation. It is not medically necessary to check motor threshold at every treatment but motor threshold may be reassessed if there is concern that it may have changed, for example, because of a change in medication. The psychiatric provider should be encouraged to keep medications stable during the rTMS course of treatment and to inform the rTMS clinical staff of any changes in medication use. Requests for multiple motor thresholds during the course of rTMS treatment will require documentation to prove medical necessity.

### **DESCRIPTION**

The majority of individuals treated for depression respond to standard treatments for depression (e.g., psychotherapy, pharmacotherapy, or electroconvulsive therapy [ECT]). One of the alternative treatments being investigated for those patients who do not benefit or cannot tolerate these standard therapies is transcranial magnetic stimulation.

Transcranial magnetic stimulation was initially used to investigate nerve conduction; for example, transcranial magnetic stimulation over the motor cortex will produce a contralateral muscular-evoked potential. The technique involves placement of a small coil over the scalp; a rapidly alternating current is passed through the coil wire, producing a magnetic field that passes unimpeded through the scalp and bone, resulting in electrical stimulation of the cortex. In the course of its use, mood effects have been observed, and interest in developing TMS as a treatment for depression followed. Imaging studies had showed a decrease in activity of the left dorsolateral prefrontal cortex (DLPFC) in

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depressed patients, and early studies suggested that high frequency (e.g., 5–10 Hz) TMS of the left DLPFC had antidepressant effects. Investigation into the use of transcranial magnetic stimulation as a treatment for depression was augmented by the development of a device that could deliver rapid, repetitive stimulation, known as rTMS. Over time, improvements in coil design have allowed more focal stimulation, and the prefrontal cortex has been the region of interest in many recent studies in which rTMS was used in the treatment of depression. In contrast to electroconvulsive therapy, transcranial magnetic stimulation can be performed in an office setting as it does not require anesthesia and does not induce a convulsion. TMS is also being tested as a treatment for other disorders including, but not limited to, schizophrenia, obsessive-compulsive disorder, bulimia, Parkinson's disease, Tourette's syndrome, migraines, chronic pain syndromes, and fibromyalgia.

### **RATIONALE**

In October 2008, the NeuroStar TMS device (Neuronetics, Inc.) received FDA marketing clearance utilizing the FDA's "de novo" device clearance classification. TMS therapy is indicated for patients with treatment-resistant depression who have failed one 6-week course of antidepressant medication. The Brainway Company received FDA clearance for its Deep TMS device in January 2013. It 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. On August 16, 2018, the FDA permitted marketing of the Brainsway device to be used as an adjunct for the treatment of adult patients suffering from obsessive compulsive disorder (OCD). On July 31, 2015, the FDA cleared MagVita TMS Therapy System (MegVenture) for the treatment of major depressive disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode. The Rapid Therapy System (Magstim Company, LTD) also received FDA approval in 2015 and is indicated for the treatment of major depressive disorder in adult patients who have failed to achieve satisfactory improvement from prior antidepressant medication in the current episode. Neurosoft TMS (TeleEMG, LLC) received FDA 510(k) clearance in 2016 as a predicate device for the treatment of major depressive disorder in adult patients who have failed to receive satisfactory improvement from prior antidepressant medication in the current episode.

On December 13, 2013, a TMS device, The Cerena Transcranial Magnetic Stimulator (TMS) (eNeura Therapeutics, Sunnyvale, CA) received FDA approval thru the de novo premarket review pathway to market the Cerena TMS device. This is the first device to relieve pain caused by migraine headaches that are preceded by an aura: a visual, sensory or motor disturbance immediately preceding the onset of a migraine attack. In 2014, eNeura Therapeutics received 510(k) marketing clearance for the SpringTMS® for the treatment of migraine headache. The device differs from the predicate Cerena™ TMS device with the addition of an LCD screen, a use authorization feature, lithium battery pack, and smaller size. The stimulation Parameters are unchanged. The sTMS Mini (eNeura Therapeutics) received marketing clearance by the FDA in 2016.

On August 14, 2018, the FDA cleared theta burst stimulation using the MagVita TMS Therapy System based on a study published by Blumberger et al (2018), a multicenter, randomized noninferiority trial (THREE-D) comparing 10-Hz rTMS with intermittent theta burst stimulation (iTBS). Between 2013 and 2016, 414 patients with treatment-resistant major depressive disorder were enrolled and randomized to 4 to 6 weeks of rTMS (n=205) or iTBS (n=209). Treatment resistance was defined as failure to tolerate 2 or more antidepressant trials of inadequate dose and duration or no clinical response to an adequate dose of an antidepressant. Patients who failed more than 3 antidepressant trials of adequate dosage were excluded from the trials. Patients could alter their medication during this trial. Treatment with rTMS (37 minutes) and iTBS (3 minutes) was delivered 5 times a week for 4 to 6 weeks. The primary outcome measure was the 17-item HAM-D, for which scores for patients treated with rTMS improved by 10.1 points and scores for patients treated with iTBS improved by 10.2 points (adjusted difference, 0.103; lower 95% CI, -1.16; p=0.001). Treatment with iTBS resulted in a higher self-rated intensity of pain (mean score, 3.8) than treatment with rTMS (mean score, 3.4; p=0.011). Headache was the most common treatment-related adverse event for both groups (rTMS=64% [131/204]; iTBS=65% [136/208]). Serious adverse events were noted in patients treated with rTMS (1 case of myocardial infarction) and iTBS (1 case each of agitation, worsening suicidal ideation, worsening depression); there was no significant difference in the number of adverse events in the 2 groups. The trial lacked a treatment group with placebo.

Two small (n = 14 and 18) randomized sham-controlled trials found no evidence of efficacy for treatment of bulimia nervosa or obsessive-compulsive disorder (OCD). (Walpoth, et al 2008, Sachdev, et al. 2007, respectively). In 2018,

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Carmi et al published a small pilot study comparing low-frequency deep transcranial magnetic stimulation (LF-DTMS; 1 Hz) to high-frequency deep transcranial magnetic stimulation (HF-DTMS; 20 Hz) to sham deep transcranial magnetic stimulation in patients with obsessive compulsive disorder (OCD). A total of 41 adults with a score of 20 or more on the Yale Brown Obsessive Compulsive Scale (YBOCS) were recruited at the Chaim Sheba Medical Center in Israel. Participants were randomly assigned to receive 1 Hz stimulation (LF), 20 Hz stimulation (HF), or sham stimulation, using a computer program. All groups were treated five times per week for five weeks (for a total of 25 sessions). Final analysis included only the 16 participants in the HF group and 14 participants in the sham group based on a lack of response in the LF group. A significantly higher proportion of participants from the HF group (n=7; 43.75%) compared to the sham group (n=1; 7.14%) reached the predefined response criteria after 5 weeks of treatment. However, at the 1 month follow up, significance was lost with four participants in the HF group and none from the sham group defined as responders. The authors conclude HF DTMS is safe, tolerable and effective in reducing OCD symptoms, but larger studies are needed. Limitations include a small sample size, single center, and short follow-up period. The study was supported by Brainsway.

Lam and colleagues (2008) conducted a meta-analysis of 24 randomized controlled trials comparing active versus sham rTMS in patients with treatment-resistant depression, although there were varying definitions of treatment-resistant depression. This analysis calculated a number needed to treat of 6, with a clinical response in 25% of active rTMS and 9% of sham rTMS patients. Remission was reported for 17% of active rTMS and 6% of sham rTMS patients. The largest study (23 study sites) included in the meta-analysis was a double-blind multicenter trial with 325 treatment-resistant depression patients randomized to daily sessions of high frequency active or sham rTMS (Monday to Friday for 6 weeks) of the left dorsolateral prefrontal cortex. Treatment-resistant depression was defined as failure of at least one adequate course of antidepressant treatment. Patients had failed an average of 1.6 treatments in the current episode, with about half of the study population failing to benefit from at least 2 treatments. Loss to follow-up was similar in the 2 groups, with 301 (92.6%) patients completing at least one post-baseline assessment and an additional 8% of patients from both groups dropping out before the 4-week assessment. Intent-to-treat analysis showed a trend favoring the active rTMS group in the primary outcome measure (2 points on the Montgomery-Asberg Depression Rating Scale;  $p = 0.057$ ) and a modest (2-point) but significant improvement over sham treatment on the HAM-D. The authors reported that after 6 weeks of treatment the subjects in the active rTMS group were more likely to have achieved remission than the sham controls (14% vs. 5%), although this finding is limited by loss to follow-up.

Another randomized sham-controlled double-blind trial was conducted in 68 patients who had failed at least 2 courses of antidepressants. (Avery, et al. 2006) Three patients in each group did not complete the 15 treatment sessions or were excluded due to a change in medication during treatment, resulting in 91% follow-up. Independent raters found a clinical response in 31% (11 of 35) of the active rTMS patients and 6% (2 of 33) of the sham group. The average change in HAM-D was 7.8 for the active group and 3.7 for the control group. The BDI decreased by 11.3 points in the active rTMS group and 4.8 points in controls. Remission was observed in 7 patients (20%) in the active rTMS group and 1 patient (3%) in the control group. Regarding effectiveness of blinding; 15% of subjects in each group guessed that they were receiving active TMS after the first session. After the 15<sup>th</sup> session, 58% of the rTMS group and 43% of the sham group guessed that they had received active TMS; responders were more likely than non-responders (85% vs. 42%) to think that they had received the active treatment. The 11 responders were treated with antidepressant medication and followed up for 6 months. Of these, 1 was lost to follow-up, 5 (45%) relapsed, and 5 (45%) did not relapse.

Several studies have compared the outcomes of rTMS with those from electroconvulsive therapy. McLoughlin, et al. (2007) studied forty-six patients who had been referred for electroconvulsive therapy were randomized to either electroconvulsive therapy (average of 6.3 sessions) or a 15-day course (5 treatments per week) of rTMS of the left dorsolateral prefrontal cortex. Electroconvulsive therapy resulted in a 14-point improvement in the HAM-D and a 59% remission rate. rTMS was less effective than electroconvulsive therapy (5-point improvement in HAM-D and a 17% remission rate).

The evidence for repetitive transcranial magnetic stimulation (rTMS) in patients who have treatment resistant depression (TRD) includes numerous double-blind, randomized sham-controlled short-term trials. Relevant outcomes are symptoms, functional outcomes, and quality of life. Results of these trials show small mean improvements across groups as a whole. The percentage of subjects who show a clinically significant response is reported at approximately 2 to 3 times that of sham controls, with approximately 15% to 25% of patients meeting the definition of clinical response. Based on the short-term

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benefit observed in randomized controlled trials and the lack of alternative treatments, aside from electroconvulsive therapy in patients with TRD, rTMS may be considered a treatment option in patients with TRD who meet specific criteria. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

Contraindications to rTMS include: Seizure disorder or any history of seizure with increased risk of future seizure; presence of acute or chronic psychotic symptoms or disorders (such as schizophrenia, schizophreniform or schizoaffective disorder) in the current depressive episode; neurologic conditions that include epilepsy, cerebrovascular disease, dementia, increased intracranial pressure, having a history of repetitive or severe head trauma, or with primary or secondary tumors in the central nervous system (CNS); presence of an implanted magnetic-sensitive medical device located 30 centimeters or less from the TMS magnetic coil or other implanted metal items, including but not limited to a cochlear implant, implanted cardioverter defibrillator (ICD), pacemaker, vagus nerve stimulator, or metal aneurysm clips or coils, staples, or stents.

A 2015 meta-analysis (Kedzior, et al.) examined durability of the antidepressant effect of high-frequency rTMS of the left DLPFC in the absence of maintenance treatment. Included were double-blind, sham-controlled RCTs with a total of 495 patients. The range of follow-up was 1 to 16 weeks, but most studies only reported follow-up to 2 weeks. The overall effect size was small with a standardized mean difference (SMD; Cohen's  $d$ ) of  $-.48$ , and the effect sizes were lower in RCTs with 8- to 16-week follow-up ( $d = -.42$ ) than with 1- to 4-week follow-up ( $d = -.54$ ). The effect size was higher when antidepressant medication was initiated concurrently with rTMS (5 RCTs,  $d = -.56$ ) than when patients were on a stable dose of medication (9 RCTs,  $d = -.43$ ) or were unmedicated (2 RCTs,  $d = -.26$ ).

In 2014, Dunner and colleagues reported 1-year follow-up with maintenance therapy from a large multicenter observational study (42 sites) of rTMS for patients with TRD. A total of 257 patients agreed to participate in the follow-up study of 307 who were initially treated with rTMS. Of these, 205 completed the 12-month follow-up, and 120 patients had met the Inventory of Depressive Symptoms-Self Report response or remission criteria at the end of treatment. Ninety-three of the 257 patients (36.2%) who enrolled in the follow-up study received additional rTMS (mean, 16.2 sessions). Seventy-five of the 120 patients (62.5%) who met response or remission criteria at the end of the initial treatment phase (including a 2-month taper phase) continued to meet response criteria through follow-up.

Fitzgerald, et al. reported a prospective open-label trial of clustered maintenance rTMS for patients with TRD. All patients had received a second successful course of rTMS following relapse and were then treated with monthly maintenance therapy consisting of 5 rTMS treatments over a 2.5-day period (Friday evening, Saturday, and Sunday). Of 35 patients, 25 (71%) relapsed at a mean of 10.2 months (range, 2- 48 months).

Overall, the outcome data related to maintenance therapy is insufficient to determine the overall benefit on health outcomes. Additional data are needed related to durability of effect and to maintenance therapy.

Consensus recommendations for the application of repetitive transcranial magnetic stimulation (rTMS) were published in 2018 by the National Network of Depression Centers (NNDC) rTMS Task Group and the American Psychiatric Association Council on Research (APA CoR) Task Force on Novel Biomarkers and Treatments. A total of 118 publications, including 3 multicenter RCTs, from 1990 through 2016 were included in the review by 17 expert clinicians and researchers. The authors state rTMS is appropriate for patients with major depressive disorder but found insufficient evidence to support routine clinical rTMS use for other indications. They recommend patients with comorbid psychotic symptoms or acute suicidal ideation should be considered for other established antidepressant treatments such as electroconvulsive therapy. The recommendation for preferred length of acute TMS treatment depends on the risk-benefit ratio for clinical response and remission, with consideration for side effects and measurement-based care, with a likely standard acute course of 20 to 30 treatments over 6 weeks to achieve results consistent with published trials. Motor threshold (MT) determination should occur at baseline and be rechecked when there have been medication changes which could affect the MT. The patient and psychiatric provider should be encouraged to keep medications stable during the rTMS course of treatment and to inform the rTMS clinical staff of any changes in medication use. The authors found limited evidence regarding maintenance strategies following response or remission with acute rTMS. One RCT compared a once monthly scheduled approach with a re-introduction approach and found both approaches were approximately equivalent in prolonging clinical benefits. The study also found that "rescue therapy" (re-introduction of daily rTMS triggered by symptom relapse) was effective in 69% of instances.

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The largest area of TMS research outside of depressive disorders appears to be treatment of auditory hallucinations in schizophrenia resistant to pharmacotherapy. Fitzgerald et al. (2005) conducted a randomized double-blind trial of 33 patients with treatment-resistant auditory hallucinations. rTMS was applied for 10 consecutive days for 15 minutes at 1 Hz and 90% of the resting motor threshold. The investigators found that active treatment did not result in a greater therapeutic effect than sham on any measure except for the loudness of the hallucinations, with a reduction in the active versus the sham group. The authors concluded that the study did not support the effectiveness of rTMS using the stimulation parameters provided.

A meta-analysis (Aleman et al. 2007) was conducted to investigate the efficacy of rTMS treatment of hallucinations. A total of 15 studies were identified that reported empirical data regarding rTMS treatment of auditory hallucinations. Ten of the studies met the inclusion criteria with a total of 212 patients. The authors concluded that rTMS may prove to be a promising method for reducing the frequency and intensity of auditory hallucinations in treatment-resistant patients, but larger clinical trials with follow-up are needed to establish the clinical efficacy of this treatment.

Evidence related to the efficacy of rTMS for other disorders such as ALS, Tourette's, fibromyalgia, Alzheimer's disease, stroke, Parkinson disease, tinnitus, headaches, or chronic pain is limited (e.g., Gou, et al. 2011, Kwon, et al. 2011, Short, et al. 2011, Benninger, et al. 2012, Yang, et al. 2013, Peng, et al. 2012, Ahmed, et al. 2011, O'Connell, et al. 2011, respectively). Studies are plagued by methodological limitations such as small samples sizes and limited follow-up. The role that TMS has in the treatment of these disorders has not been established.

### **CODES**

- Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.
- **CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.**
- Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

#### **CPT Codes**

<b>Code</b>	<b>Description</b>
90867	Therapeutic repetitive transcranial magnetic stimulation treatment; initial, including cortical mapping, motor threshold determination, delivery and management
90868	Therapeutic repetitive transcranial magnetic stimulation; subsequent delivery and management, per session
90869	Therapeutic repetitive transcranial magnetic stimulation; subsequent motor threshold re-determination with delivery and management

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#### **ICD10 Codes**

<b>Code</b>	<b>Description</b>
F32.0-F32.9	Major depressive disorder, single episode (code range)
F33.0-F33.9	Major depressive disorder, recurrent (code range)

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\*Key Article

**KEY WORDS**

Brainsway Deep TMS, MagVita TMS, NeuroStar, rTMS, Transcranial magnetic therapy, TMS.

**CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS**

There is currently a Local Coverage Determination (LCD) for transcranial magnetic stimulation. Please refer to the following LCD (L33398) website for Medicare Members:

[https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33398&ver=14&CntrctrSelected=298\\*1&Cntrctr=298&name=National+Government+Services%2c+Inc.+\(13201%2c+A+and+B+and+HHH+MAC%2c+J++K\)&s=All&DocType=Active&bc=AggAAAQBAAAA&](https://www.cms.gov/medicare-coverage-database/details/lcd-details.aspx?LCDId=33398&ver=14&CntrctrSelected=298*1&Cntrctr=298&name=National+Government+Services%2c+Inc.+(13201%2c+A+and+B+and+HHH+MAC%2c+J++K)&s=All&DocType=Active&bc=AggAAAQBAAAA&)