APPENDIX to Transcranial Magnetic Stimulation Policy

Prior Authorization Requirements

This service (or procedure) is considered **medically necessary** in certain instances and **investigational** in others (refer to policy for details).

For instances when the indication is **medically necessary**, clinical evidence is required to determine **medical necessity**.

For instances when the indication is **investigational**, you may submit additional information to the Prior Authorization Department.

Within five days before the actual date of service, the Provider MUST confirm with Blue Shield of California / Blue Shield of California Life & Health Insurance Company (Blue Shield) that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should also be directed to the Prior Authorization Department. Please call 1-800-541-6652 or visit the Provider Portal www.blueshieldca.com/provider.

Evidence Basis for the Policy

Rationale

According to the National Institute of Mental Health (NIMH, 2010) an estimated 26.2 % of Americans ages 18 and older (about 1 in 4 adults) suffer from a diagnosable mental disorder in a given year. The occurrence of mood disorders, including major depressive disorder (MDD), dysthymic disorder, and bipolar disorder, affects approximately 20.9 million American adults, or about 9.5 % of the U.S. population age 18 and older in a given year. Other conditions such as anxiety disorders, including generalized anxiety disorder, obsessive compulsive disorder (OCD), panic disorder, phobias, and post-traumatic stress disorder (PTSD) affect approximately 40 million U.S. adults ages 18 and older, or about 18% in this age group in a given year. Individuals who suffer from depression may experience functional impairment, increased risk of suicide, higher health care expenses and losses in productivity. Complaints of sleep disturbance, fatigue and pain are the most common presentations of depression. Treatment in the acute phase of a major depressive episode may include pharmacotherapy, depression-focused psychotherapy (e.g., "talk therapy"), and the combination of medications and psychotherapy, or other somatic

therapies such as electric convulsive therapy (ECT). Electric convulsive therapy is recommended as the treatment of choice for individuals with severe major depression not responsive to psychotherapeutic and/or pharmacological interventions.

Transcranial magnetic stimulation (TMS) was first introduced in 1985 as a new method of non-invasive stimulation of the brain. It was initially used to investigate nerve conduction by applying magnetic stimulation over the motor cortex to produce a contralateral muscular evoked potential. Use as a treatment for depression was proposed when imaging studies showed that the left dorsolateral prefrontal cortex (DLPFC), an area known to contribute to mood, of depressed patients was underactive. Investigators began to study whether the stimulation that occurs with TMS could affect this under activity. It was theorized that when electrical stimulation was applied to the left DLPFC, neurotransmitters such as serotonin, norepinephrine and dopamine, that play a role in the symptoms of depression, would be activated resulting in relief of depressive symptoms.

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 cranium and scalp. In contrast to ECT, TMS does not require anesthesia, and does not induce a convulsion. Early studies suggested that TMS of the left prefrontal cortex was associated with antidepressant properties. Transcranial magnetic stimulation as a treatment for depression was prompted by the development of a device that could deliver rapid, repetitive stimulation (i.e. rTMS). The device utilized for this procedure has been studied as a treatment for other behavioral health and neuropsychiatric disorders including auditory hallucinations in schizophrenia, obsessive compulsive disorder OCD, and PTSD.

The NeuroStar TMS Therapy® System (Neuronetics, Malvern, PA) received clearance from the U.S. Food and Drug Administration (FDA) in December, 2008. The NeuroStar TMS therapy is indicated for the “treatment of adults with major depressive disorder who have failed to achieve satisfactory improvement from prior trials of antidepressant medications at or above the minimal effective dose and duration in the episode" (FDA, October 2008).

Transcranial magnetic stimulation may be performed as an outpatient procedure but must be repeated several times per week over the course of 4 to 6 weeks to achieve maximum response. It may be used alone or as an adjunct to antidepressant medication. An acute treatment course of TMS consists of 30 treatments for 30 minute to 60 minute sessions, usually delivered daily for 5 days a week with treatment taper of 3 weeks duration. Each session consists of rTMS to the left DLPFC area at around 120% of the individual's observed motor threshold (10Hz, 4-second train duration, 26 second inter-train interval, at 3000 pulses per session), using a figure-eight solid core coil.

According to the prescribing information, the NeuroStar TMS System is contraindicated for use in some individuals; e.g., those having conductive, ferromagnetic, or other magnetic-sensitive metals in the head or within 30 centimeters (cm) of the treatment coil. Examples include cochlear implants, implanted electrodes and stimulators such as pacemakers, implanted cardiac defibrillators (ICD)s, or vagus nerve stimulator (VNS) devices, and aneurysm clips or coils, stents, and bullet fragments. These individuals should not be treated with the system or will need to take special precautions before treatment. Failure to follow this restriction could result in

serious injury or death. The TMS system is also contraindicated for use in an individual with a wearable cardioverter defibrillator (WCD), even if the device is removed, due to the potentially unstable cardiac condition of such a person. Caution should be used in individuals with other implanted devices or metallic objects that are not controlled by physiologic signals including sutures and implanted insulin pumps located in areas outside the 30 cm distance from the coil during TMS therapy, otherwise serious injury could result.

Safe operation of the NeuroStar TMS System is based on treatment parameters to reduce the potential risk of seizure. These treatment parameters, established by the 1998 National Institute of Neurological Disorders and Stroke (NINDS) Workshop, provide guidelines outlined in the NeuroStar TMS System user manual. These guidelines are also available on the FDA Advisory Committee web site. Treatment outside of these guidelines is not recommended. Additional warnings and precautions associated with the operation of the NeuroStar TMS System are also included in the user manual (FDA, 2007). The major adverse effects of TMS therapy are headache and pain or discomfort at the site of application of the device.

In a study reported by Janicak and colleagues (2008), aggregate safety data were obtained from a comprehensive clinical development program examining the use of TMS in the treatment of MDD. There were 3 separate clinical protocols, including 325 individuals from 23 clinical sites in the U.S., Australia, and Canada. The authors reported that TMS was associated with a low incidence of adverse events that were mild to moderate in intensity and demonstrated a largely predictable time course of resolution.

Transcranial Magnetic Stimulation for Treatment-Resistant Depression

According to Gaynes and colleagues (2011), major depressive disorder (MDD) is a common condition experienced by more than 13 million people over the course of a year. Treatment choices are wide ranging, including both pharmacologic and non-pharmacologic therapies. Each of the numerous antidepressant drugs available are categorized by class according to the neurotransmitter system with which it mostly interacts. If an antidepressant drug in one class does not relieve symptoms or causes intolerable side effects, an antidepressant drug in another class may be prescribed. The rate of remission, or complete symptom relief, has been reported to be approximately 33% for monotherapy with the first prescribed antidepressant drug and lessens with each successive antidepressant drug trial. Individuals with 2 or more prior treatment failures are considered to have treatment-resistant depression (TRD). These individuals represent a complex population with a disease that is difficult to manage. This data and the increasing prevalence of MDD and drug-resistant MDD suggest a need for alternative treatments for TRD.

Repetitive transcranial magnetic stimulation has been studied as a non-pharmacologic treatment option for individuals with TRD. The peer-reviewed medical literature focusing on the use of rTMS for TRD (variably defined), includes a number of double-blind randomized sham-controlled short-term trials. Trial results show statistically significant improvement with active treatment, suggesting a response rate 2 to 3 times that of sham controls. Approximately 15% to 25% of the active treatment population in these trials showed a clinical response to rTMS despite the existence of differences in study definitions for trial inclusion and prior treatment heterogeneity within each study.

O'Reardon and colleagues (2007) conducted an industry-sponsored study under an Investigational Device Exemption (IDE) to determine whether rTMS over the left DLPFC was effective and safe. The trial findings resulted in the FDA clearance of the NeuroStar® TMS Therapy System (Neuronetics, Malvern, PA), for the treatment of adults with MDD without psychosis who "have not adequately responded to appropriate pharmacological treatment intervention" (FDA, 2008). A total of 301 participants enrolled at 23 study sites with antidepressant medication-free major depression were randomly assigned to active (n = 155) or sham (n = 146) rTMS. Participants were required to have failed at least 1, but no more than 4 adequate antidepressant treatments in the current or most recent episode of depression. Treatment and rating personnel were blinded to participant assignments.

The TMS treatment occurred daily, 5 days a week for 6 weeks, followed by a tapering period of 3 additional weeks during which time antidepressant drug therapy was initiated. Participants achieving less than a 25% reduction on the Hamilton Depression Rating Scale-17 (HAMD-17) at 4 weeks could crossover to an open-label, acute treatment extension study. The primary outcome was the difference between active and sham TMS using the last visit Montgomery-Asberg Depression Rating Scale (MADRS). Secondary outcomes included changes on the 17- and 24-item HAMD and response and remission rates using the MADRS and HAMD. At the primary efficacy point of 4 weeks, the baseline to endpoint change on both the HAMD-17 and the HAMD-24 but not the MADRS showed a significant improvement for the active rTMS group. The result was sustained at 6 weeks. Significant response rates (greater than 50% improvement from baseline) were present at 4 and 6 weeks for the active treatment group using each of the 3 scales (HAMD-17, HAMD-24, and MADRS). A significant difference in remission rates did not occur at 4 weeks but was higher for the active group at 6 weeks for the MADRS and HAMD-24. A significant number of participants, 74 (47.7%) in the active group and 92 (63.0%) in the sham group, dropped out after 4 weeks to enter the open-label trial (Avery, 2008), thus, many of the 6 week observation values in the trial reflected 4 week values.

Avery and colleagues (2008) reported on the results of the open-label, crossover extension of participants from the O'Reardon trial (2007) who failed to receive benefit from at least 4 weeks of randomized treatment assignment, either active or sham TMS, in the controlled trial. The first 6 week phase of the study was antidepressant-free followed by a 3 week rTMS taper phase with initiation of 1 of 15 different antidepressants. During the taper phase, rTMS was delivered 3 times in the first week, 2 times in the second week and 1 time in third week. As noted above, 166 participants entered the study but only 158 were present for at least 1 post-baseline observation, 73 of whom had been in the active arm and 85 in the sham. The primary efficacy outcome was the change in total score on the MADRS from the start of the open-label phase to 6 weeks or study endpoint.

Secondary outcome measures included the HAMD-17 and HAMD-24. Remission was defined as a score of less than 10 on the MADRS, less than 8 on the HAMD-17, or less than 11 on the HAMD-24. Improvement was noted in both groups over the 6 week active and the 3 week taper periods. At the conclusion of the taper phase, in the sham-to-TMS group, 44.7% of participants achieved response criteria on the MADRS, and 30.6% achieved remission. In the same group, 45.9% achieved response on the HAMD-24 and 36.5% achieved remission. Similar observations were noted in the extended TMS group; at the end of the taper phase, 34.2% of participants

achieved response criteria on the MADRS, and 17.8% achieved remission. In the same group, 31.5% achieved response on the HAMD-24 and 19.2% achieved remission.

George and colleagues (2010) published a prospective, multicenter, randomized, sham-controlled trial reporting results using daily DLPFC rTMS on 199 participants with a moderate level of antidepressant drug-free, unipolar MDD (e.g., single episode or recurrent with less than 5 years from onset). The study participants were required to be stable during a 2 week medication-free lead-in period and have a moderate level of treatment resistance defined as insufficient clinical benefit from 1 to 4 adequate medication trials or intolerant to 3 medication trials. The trial used the FDA-cleared NeuroStar TMS device. Magnetic resonance imaging was used to refine the location of the magnetic coil; relocation of the coil occurred in 33.2% of participants. Subjects received treatment for 3 to 6 weeks. Lack of improvement in the first 3 weeks (classified as treatment failures) led to discontinuation from Phase 1 of the clinical trial and crossover to open treatment in Phase 2 of the trial. Partial responders in the first 3 weeks continued with sham or TMS. At the end point of the study, the response rate using an intention-to-treat (ITT) analysis for remitters ($n = 18$) was 14.1% in the active TMS group and 5.1% in the sham group ($p = 0.02$). Most remitters had low antidepressant treatment resistance. Results were similar for response to treatment outcomes, 15.5% in the active TMS group versus 5% in the sham group. Comparing participants receiving active TMS to sham TMS, active TMS participants demonstrated significantly greater improvement in mean scores for the MADRS, Clinical Global Impression Improvement Scale (CGI-S), and the Inventory of Depressive Symptomatology-Symptoms Review/Self Rated (IDS-SR) but not the HAMD-24.

A limitation of this trial was the failure to enroll the projected 240 participants as suggested by the initial power analysis, due in part to the delayed start of the trial as a result of extensive work in designing a sham system. It was also unclear how long participants required treatment. Those who met the 30% improvement criteria continued randomized treatment for an additional 3 weeks or until cessation of meaningful response to treatment; as such, no participant received treatment for a full 6 weeks. Despite more rigorous requirements for progression (30% improvement at 3 weeks compared to 25% improvement at 4 weeks), this study showed a significant improvement in remission at 3 to 5 weeks. The treatment was relatively well tolerated, with no difference in the adverse events between the sham and the active TMS treatment arms. Adverse events included headache (active 29% versus sham 23%), discomfort at the stimulation site (active 17% versus sham 10%), insomnia (active 10% versus sham 7%) and worsening of depression or anxiety (active 6% versus sham 8%). No seizure activity was reported in any of the study participants. The investigators concluded that daily DLPFC 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 (95% confidence interval [CI], 1.21 to 13.24).

Janicak and colleagues (2010) reported that TMS can be an effective acute antidepressant treatment, but noted that few studies systematically examine the persistence of benefit. The investigators assessed the durability of antidepressant treatment after acute response to TMS in individuals with MDD during a longer term observational study of responders in the 2 trials described in an U.S. FDA Executive Summary concerning the NeuroStar TMS Therapy System (FDA, 2007). Participants that ultimately responded to active TMS or sham in the original

randomized controlled trial, or responded to active TMS in the open label extension were followed for recurrence of depression and/or need for reintroduction of active TMS over a 24-week treatment period. The participants who met criteria for partial response (e.g., greater than 25% decrease from the baseline HAMD-17) (n = 142) were tapered off TMS over 3 weeks, while simultaneously starting maintenance antidepressant monotherapy. During this durability study, TMS was re-administered if participants met pre-specified criteria for symptom worsening (e.g., a change of at least 1 point on the CGI-S scale for 2 consecutive weeks). Relapse was the primary outcome measure, defined as a recurrence of the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (DSM-IV) criteria for major depression or failure to achieve symptom improvement upon reintroduction of TMS. Ten of 99 (10%) participants relapsed, 38 (38.4%) participants had worsening symptoms, and 32 of the 38 participants (84%) achieved symptomatic benefit with adjunctive TMS. Safety and tolerability were similar to acute TMS monotherapy.

It is difficult to draw conclusions from this data regarding the treatment effect of TMS. All the study participants had initiated antidepressants, making it difficult to attribute the duration of response to TMS alone. The control group only received sham TMS. Although participants who initially responded to sham had higher relapse and TMS re-treatment rates, the numbers are too small for statistically meaningful comparisons, and the groups may not be comparable. Additional data are needed to determine the durability of the treatment effect, particularly in maintenance phases.

Slotema and colleagues (2010) conducted a meta-analysis evaluating the efficacy of TMS for various psychiatric disorders. Data were obtained from randomized, double-blind, sham-controlled trials of TMS treatment for depression (34 studies, 1383 participants). Studies of TMS versus ECT (6 studies) for depression were meta-analyzed. The 2007 clinical trial by O'Reardon and colleagues is included in this meta-analysis. The analysis had very broad selection criteria for inclusion, allowing any type of TMS treatment and any type of depression experienced by the study participants.

Participants were free of antidepressant agents (e.g., TMS monotherapy) in 7 studies, antidepressants were continued in 17 studies, and antidepressants were initiated along with TMS in 5 studies. The mean weighted effect size of TMS versus sham for depression was 0.55 ($p < 0.001$). ECT therapy was superior to TMS in the treatment of depression (mean weighted effect size of 0.54 ($p < 0.001$). Subgroup analyses comparing TMS as a monotherapy versus continuation or initiation of antidepressants showed that the mean weighted effect size for TMS monotherapy (effect size 0.96, $p < 0.001$), trended toward having a stronger treatment effect than for TMS with continuation of antidepressants (effect size 0.51, $p < 0.001$) or TMS with initiation of antidepressants (effect size 0.37, $p = 0.03$).

This analysis, however, should not be interpreted to mean that TMS monotherapy is possibly more effective than as used with antidepressants, but that the treatment difference between TMS and the corresponding control group for each type of study is larger for TMS monotherapy versus a no-treatment sham-only control group. According to the authors, “although the efficacy of rTMS in the treatment of depression may be considered proven, the duration of the effect is as yet unknown”.

Effect sizes were measured immediately after the cessation of rTMS treatment. There are indications that the effects of rTMS may last for several weeks to months. Further studies should assess symptom relief with longer follow-up periods to assess the cost-effectiveness of rTMS treatment, and to indicate its economic advantages and disadvantages. The authors state: "Although rTMS cannot replace ECT in depressive patients, there may be subgroups in which rTMS can replace antidepressant medication" (Slotema, 2010).

Practice Guidelines and Input from Professional Societies

American Psychiatric Association (APA)

According to the APA Practice Guideline for the Treatment of Patients with Major Depressive Disorder published in 2010:

> A substantial number of studies of TMS have been conducted, but most have had small sample sizes, and the studies overall have yielded heterogeneous results. Further complicating the interpretation of the TMS literature is the variability in stimulation intensities (relative to the motor threshold), stimulus parameters (e.g., pulses/second, pulses/session), anatomical localization of stimulation, and number of TMS sessions in the treatment course (Gelenberg, 2010).

As an initial treatment modality, the guideline recommends that "treatment in the acute phase should be aimed at inducing remission of the major, and competency certification for outcome evaluators".

The guideline summarizes;

> At this time, a number of treatment and protocol variations for rTMS remain, and the optimum treatment protocol and patient characteristics may not yet be identified (Allan, 2011). Nonetheless, rTMS is a low-risk and appealing treatment for treatment-refractory depressed patients for whom it is practical and cost-effective.

Agency for Healthcare Research and Quality (AHRQ)

The AHRQ recently published a comparative effectiveness review of non-pharmacologic interventions for TRD in adults (Gaynes, 2011). Treatment modalities reviewed included ECT, rTMS, VNS and psychotherapy. The review focused on randomized controlled trials comparing 1 intervention with another for efficacy and effectiveness. The authors also evaluated trials using non-pharmacologic interventions versus placebo- or sham-controlled evidence or treatment-as-usual controls. The quality of individual studies was categorized as good, fair, or poor, with only good or fair studies included in the analyses. The strength of the various bodies of evidence used principles in the AHRQ's method guide, grading strength of evidence as high, moderate, low, or insufficient. The greatest volume of evidence found for TRD intervention was for ECT and rTMS; however, the direct comparative evidence about these treatments was limited.

The available head-to-head literature concerning the efficacy of these interventions for TRD was limited to 2 trials (both rated as fair) in MDD-only populations. One trial compared ECT and rTMS, and the other compared ECT and ECT plus rTMS. They showed no differences between treatment options for depressive severity, response rates, and remission rates. Indirect evidence that was available to assess the potential benefits of non-pharmacologic interventions versus

controls was also measured by calculating mean changes in depressive severity, relative risks of response, and relative risks of remission. Repetitive TMS was beneficial relative to controls receiving a sham procedure for all 3 outcomes and produced a greater decrease in depressive severity (high strength of evidence). Specifically, rTMS averaged a decrease in depressive severity measured by the HAMD of more than 5 points relative to sham control (a 3 point HAMD difference is considered clinically meaningful). Response rates were greater with rTMS than sham (also high strength of evidence); those receiving rTMS were more than 3 times as likely to achieve a depressive response as persons receiving a sham procedure.

Finally, rTMS was also more likely to produce remission than the control procedure (moderate strength of evidence); persons receiving rTMS were more than 6 times as likely to achieve remission as those receiving the sham procedure. With respect to maintaining remission (or preventing relapse) for TRD, the authors found no direct comparisons involving ECT, rTMS, VNS, or cognitive behavioral therapy (CBT).

Indirect evidence in 3 fair trials compared rTMS with a sham procedure and found no significant differences. However, too few participants were followed during the relapse prevention phases in two of the three studies, and participants in the third received a co-intervention providing insufficient evidence for a conclusion. In the final analysis, the report concludes that when used as an antidepressant therapy, rTMS appears to produce a clinical benefit without the systemic side effects typical with oral medications, has no adverse effects on cognition, and unlike ECT, does not induce amnesia or seizures. Repetitive TMS offers a well-tolerated, non-pharmacologic alternative that does not require attendant anesthesia services and can be administered in an outpatient setting for individuals with MDD who have failed to benefit from initial treatment of their depression. The report suggests that when effective, rTMS may prevent the need to utilize more complex pharmaceutical augmentation strategies (e.g., atypical antipsychotic medication), ECT, and inpatient hospitalization at later stages of the illness.

New England Comparative Effectiveness Public Advisory Council (CEPAC)

In December 2011, the CEPAC, an AHRQ funded, independent body composed of clinician and public representatives and led by a research team at the Institute for Clinical and Economic Review (ICER) at the Massachusetts General Hospital, reviewed the AHRQ comparative effective analysis on rTMS along with consideration of supplemental information. A majority of CEPAC members determined that for individuals with TRD, the evidence is adequate to demonstrate that rTMS provides a net health benefit equivalent or superior to usual care (e.g., general supportive psychotherapy with or without continued use of antidepressant medication) and a net health benefit equivalent to ECT. In a subsequent coverage policy analysis of the CEPAC report, the ICER (2012) recommended the need to further identify:

- The appropriate subpopulations of individuals with TRD to receive treatment with rTMS and ECT
- Treatment duration and frequency for rTMS
- Maintenance therapy requirements for rTMS
- Threshold for previously failed treatments required before considering rTMS (e.g., equal to or greater than 2 failed drug treatments during the most recent episode of depression; a higher threshold than suggested by the FDA)

Transcranial Magnetic Stimulation as Treatment for Other Neuropsychiatric Disorders

A number of studies and meta-analyses explore the efficacy of TMS for the treatment of auditory verbal hallucinations (AVH) in schizophrenia and other conditions (Blumberger et al., 2010; Burt et al., 2002; Cordes et al., 2010; Dlabac-de et al., 2010; Freitas et al., 2009; Hoffman et al., 2000; Hoffman et al., 2002; Hoffman et al., 2003; Klein et al., 1999; Loo et al., 2010; Matheson et al., 2010; Rollnik et al., 2000; Slotema et al., 2010; Slotema et al., 2011; Tranulis et al., 2008).

Other studies have investigated the use of TMS to treat bulimic eating disorders and addictions (Van den Eynde et al., 2010; Walpoth et al., 2008), cravings in alcohol dependence syndrome (Mishra et al., 2010), mood status post stroke (Kim et al., 2010), OCD (Alonso et al., 2001; Greenberg et al., 1997; Kang et al., 2009; Mantovani et al., 2006; Mantovani et al., 2010; Martin et al., 2003; Sachdev et al., 2007; Slotema et al., 2011), panic disorders (Prasko et al., 2007), and PTSD (Boggio et al., 2010; Cohen et al., 2004; Osuch et al., 2009).

Methodological limitations of these studies include small sample size, absence of a placebo control group, presence of concurrent pharmacotherapy, and lack of long-term outcomes. The durability of this treatment and its role in the treatment of other neuropsychiatric disorders is unknown.

Summary

In summary, the studies of rTMS in the peer-reviewed medical literature show a short-term benefit for individuals with treatment resistant MDD who received active versus sham rTMS. Treatment benefit has been defined by response or remission rates using depression rating scales. Most studies have short treatment periods, varying from 1 to 6 weeks and few studies have included long term outcomes. Durability of rTMS response at this time is unclear and the optimal approach to sustaining any benefit achieved is unknown. In addition, the use of rTMS as a maintenance therapy is not supported by a controlled clinical trial. Despite questions that remain about stimulation parameters and the length of optimal treatment, rTMS is well-tolerated. Repetitive TMS is a safe and less invasive alternative treatment option for individuals with TRD.

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program (FEP)) prohibit Plans from denying Food and Drug Administration (FDA) - approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

This Policy relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement.

Type	Number	Description
CPT	90867	Therapeutic repetitive transcranial magnetic stimulation treatment; planning
	90868	Therapeutic repetitive transcranial magnetic stimulation treatment; delivery and management, per session
	90869	Therapeutic repetitive transcranial magnetic stimulation (TMS) treatment; subsequent motor threshold re-determination with delivery and management
HCPC	None	
ICD9 Procedure	None	
ICD9 Diagnosis	All Diagnoses	
Place of Service	All Places of Service	

Tables

N/A

Definitions

Adequate trial of an antidepressant drug - The therapeutic dose range of a drug for a duration of at least 6 weeks at the maximum dose for the specific antidepressant as approved by the FDA, or, documentation exists that higher doses were not tolerated when the dose is less than the FDA-approved maximum.

Augmentation therapy - A drug regimen consisting of one or more drugs, which are not antidepressant drugs, added to increase the efficacy of an antidepressant drug in an adult with MDD. An example would be to add pindolol to fluoxetine.

Depression - A state of depressed mood characterized by feelings of sadness, despair and discouragement.

Depression rating scales - Standardized rating scales to reliably assess the range of symptoms that are most frequently observed in adults with major depression. The following rating scales comprehensively survey the type and magnitude of symptom burden present, and are therefore considered to be measures of illness severity. Examples of depression rating scales are as follows:

- Beck Depression Inventory (BDI)
- Geriatric Depression Scale (GDS)
- Hamilton Depression Rating Scale (HAMD),
- Inventory of Depressive Symptomatology-Systems Review (IDS-SR)
- Montgomery-Asberg Depression Rating Scale (MADRS)
- Personal Health Questionnaire Depression Scale (PHQ-9)
- Quick Inventory of Depressive Symptomatology (QIDS)

Dysthymia - A type of depression involving long-term, chronic symptoms that does not disable a person but inhibits their ability to function at a high level or to feel well.

Major depressive disorder (MDD) - A combination of symptoms (e.g., overwhelming sadness, anxiety, or "empty" feelings, hopelessness and pessimism, trouble making decisions, remembering, and concentrating) that impact daily activities consistently for at least a two week period.

Index / Cross Reference of Related BSC Medical Policies

The following Medical Policies share diagnoses and/or are equivalent BSC Medical Policies:

N/A

Key / Related Searchable Words

- Electroconvulsive therapy (ECT)
- Depression
- NeuroStar
- Repetitive transcranial magnetic stimulation (rTMS)

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Policy History

=This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action	Reason
3/30/2012	BCBSA Medical Policy adoption	Medical Policy Committee
1/11/2013	Policy revision with position change	Medical Policy Committee
7/3/2013	Policy criteria revision	Medical Policy Committee

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