

Blue Cross Blue Shield of Massachusetts is an Independent Licenses of the Blue Cross and Blue Shield Association

Medical Policy

Electrical Stimulation Devices for Psychiatric and Neurological Conditions

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Policy Number: 157

BCBSA Reference Number: N/A

NCD/LCD: NA

Related Policies

- Cranial Electrotherapy Stimulation CES and Auricular Electrostimulation, #362
- Outpatient Electroconvulsive Therapy, #319
- Percutaneous Electrical nerve Stimulation (PENS) and Percutaneous Neuromodulation Therapy (PNT), #172
- Transcranial Magnetic Stimulation as a Treatment of Depression and Other Psychiatric/Neurologic Disorders, #297
- Transcutaneous Electrical Nerve Stimulation (TENS), #003

Policy¹

Commercial Members: Managed Care (HMO and POS), PPO, and Indemnity Medicare HMO BlueSM and Medicare PPO BlueSM Members

Transcranial direct current stimulation devices (TDCS) are considered <u>INVESTIGATIONAL</u> for the treatment of all conditions including but not limited to brain and spinal cord injury, Parkinson's disease and behavioral health conditions such as major depressive disorder, anxiety, substance use disorders, and post-traumatic stress disorder (PTSD).

Transcranial alternating current stimulation (TACS) devices are considered <u>INVESTIGATIONAL</u> for the treatment of all conditions including Parkinson's disease, Alzheimer's, Seizure disorders, and behavioral health conditions such as major depressive disorder, anxiety, substance use disorders, and post-traumatic stress disorder (PTSD).

External Trigeminal Nerve Stimulation (eTNS) devices are considered <u>INVESTIGATIONAL</u> for the treatment of pediatric attention-deficit/hyperactivity disorder (ADHD).

INVESTIGATIONAL devices include but are not limited to:

• The Brain Stimulator v3.0

- The Brain Driver v2.1
- APEX Type A
- OMNI Stimulator
- TCT TDCS Device
- Soterix 1x1
- Focus V2 (TES)
- Focus V3
- NeuroConn DC Stimulator PLUS
- Activa Dose II Caputron
- Foc.us V2
- Monarch (eTNS).

Note: BCBSMA does not approve any medical devices that have not received FDA approval.

Prior Authorization Information

Inpatient

 For services described in this policy, precertification/preauthorization <u>IS REQUIRED</u> for all products if the procedure is performed <u>inpatient</u>.

Outpatient

• For services described in this policy, see below for products where prior authorization <u>might be</u> required if the procedure is performed outpatient.

| | Outpatient |
|---------------------------------------|---------------------------------------|
| Commercial Managed Care (HMO and POS) | This is not a covered service. |
| Commercial PPO and Indemnity | This is not a covered service. |
| Medicare HMO Blue SM | This is not a covered service. |
| Medicare PPO Blue SM | This is not a covered service. |

CPT Codes / HCPCS Codes / ICD Codes

Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage as it applies to an individual member.

Providers should report all services using the most up-to-date industry-standard procedure, revenue, and diagnosis codes, including modifiers where applicable.

The following codes are included below for informational purposes only; this is not an all-inclusive list.

The following HCPCS code is considered investigational for <u>Commercial Members: Managed Care</u> (HMO and POS), PPO, Indemnity, Medicare HMO Blue and Medicare PPO Blue:

HCPCS Codes

| CPT | |
|--------|---|
| codes: | Code Description |
| E0733 | Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve |
| A4541 | Monthly supplies for use of device coded at E0733 |

Description

Transcranial direct current stimulation (TDCS) devices neurostimulation to specifically targeted areas of the brain through low levels of constant electric currents. TDCS devices deliver cathodal (negative) stimulation or anodal (positive) stimulation via small electrodes placed on different regions of the scalp and are thought to influence the rate of neuronal activity.

Transcranial alternating current stimulation (TACS) devices deliver neurostimulation to specifically targeted areas of the brain with alternating electoral currents. The alternating currents are thought to change the rate of abnormal neuronal activity that may be related to a variety of behavioral and cognitive conditions.

TDCS and TACS are non-invasive, painless treatments that are being evaluated for a variety of conditions including, chronic pain, brain and spinal cord injury, Parkinson's disease, and psychiatric conditions such as major depressive disorder, substance use disorders and anxiety. TDCS and TACS devices can be used in the home setting or in a therapeutic setting under the direction of a physician. TDCS and TACS devices can be manually set to the desired electrical current and length of time. Recommended time for treatment is 20-30 minutes of neurostimulation per session. Results from the treatments depend on how long the neurostimulation is delivered.

Some of the devices used for TDCS include The Brain Stimulator v3.0tm, the APEX type Atm, and the Omni Stimulator. Other devices include the Activa Dose II, The Brain Driver v2.1, and the NeuroConn. Some of the devices come with software that help improve reproducible neurostimulation levels and headbands that hold the electrodes in place during treatment. TACS devices include Soterix 1x1, Starstim, and the Brain Stimulator tm.

External trigeminal nerve stimulation (eTNS) devices (MonarchTM) deliver low levels of electrical stimulation to targeted areas of the brain thought to be associated with ADHD. eTNS devices are a minimally invasive approach that does not require the use of medication for the treatment of ADHD in the pediatric population and can be prescribed by a physician for in home use. Caretakers will apply the stimulation device to the patient while asleep. Current studies are evaluating the use of eTNS to reduce symptoms of ADHD, including hyperactivity, impulsivity, anxiety, affective reactivity and behavioral changes. Studies have also evaluated eTNS as a treatment for facial pain and migraine.

Summary

Transcranial Direct Current Stimulation (TDCS) and Transcranial Alternating Current Stimulation devices are being investigated for a variety of conditions including chronic pain, brain and spinal cord injury, Parkinson's disease and psychiatric conditions including major depressive disorder, anxiety, and post-traumatic stress disorder.

Small randomized controlled trials and multiple case studies have evaluated the use of TDCS and TACS devices in Parkinson's and Alzheimer's disease, major depressive disorder, anxiety and post-traumatic stress disorder (PTSD). While some of the studies showed small improvements in symptom reduction and increased mood, outcomes did not demonstrate clinically significant improvements in symptoms. The study designs and treatment protocols differed significantly and were not reproducible. The evidence is insufficient to determine the effects of this technology on health outcomes.

Policy History

| Date | Action |
|---------|---|
| 1/2024 | Clarified coding information. |
| 9/2023 | Annual policy review. References and policy statements reviewed. No changes made. 9/2023. |
| 5/2022 | Annual policy review. References updated 5/2022. |
| 4/2021 | Clarified coding information. |
| 11/2019 | New investigational indications added. Effective 11/1/2019. |
| 4/2019 | New medical policy describing investigational indications. Effective 4/1/2019. |

Information Pertaining to All Blue Cross Blue Shield Medical Policies

Click on any of the following terms to access the relevant information: Medical Policy Terms of Use

Managed Care Guidelines
Indemnity/PPO Guidelines
Clinical Exception Process
Medical Technology Assessment Guidelines

References

- Fregni, F., El-Hagrassy, M. M., Pacheco-Barrios, K., et al. Evidenced Based Guidelines and Secondary Meta-Analysis for the Use of Transcranial Direct-Current Stimulation in Neurological and Psychiatric Disorders. Neuropsychopharmacol. 2021 April. 24(4). 256-313.
- De Lima, A. L., Braga, F.M.A., da Costa, R.M.M., et al. Transcranial Direct Current Stimulation for the Treatment of Generalized Anxiety Disorder: A Randomized Clinical Trial. J. Affect Disorder. Dec 2019. 1(259). 31-37.
 - Ahmadizadeh, M.J., Rezaei, M., Fitzgerald, P.B. Transcranial direct current stimulation (tDCS) for post-traumatic stress disorder (PTSD): A Randomized, double-blinded, controlled trial. Brain Res Bull. Nov 2019. 153: 273-278.
- 3. Fregni, F., Nitsche, M.A., Loo, C. K. Regulatory Considerations for the Clinical and Research Use of Transcranial Direct Current Stimulation (tDCS): review and recommendations from an expert panel. Clin Res Regul Aff. 2015 Mar 1; 32(1): 22–35.
- 4. Alonzo, A., Aaronson, S., Bikson, M. Study design and methodology for a multicentre, randomised controlled trial of transcranial direct current stimulation as a treatment for unipolar and bipolar depression.
- Dell'Osso, B., Dobrea, C., Arici, C. Augmentative transcranial direct current stimulation (tDCS) in poor responder depressed patients: a follow-up study. CNS Spectr. 2014 Aug;19(4):347-54. doi: 10.1017/S1092852913000497. Epub 2013 Aug 20.
- Dondé, C., Amad, A., Nieto, I. Transcranial direct-current stimulation (tDCS) for bipolar depression: A systematic review and meta-analysis. Prog Neuropsychopharmacol Biol Psychiatry. 2017 Aug 1;78:123-131. doi: 10.1016/j.pnpbp.2017.05.021. Epub 2017 May 25.
- 7. Benninger, D., Lomarev, M., Lopez, G. Transcranial Direct Current Stimulation for the Treatment of Parkinson's Disease. Journal of Neurosurgical Psychiatry. 2010 October. 81(10):1105-1111.
- 8. Loo, C.K., Husain, M.M., McDonald, W.M. International randomized-controlled trial of transcranial Direct Current Stimulation in depression. Brain Stimul. 2018 Jan Feb;11(1):125-133. doi: 10.1016/j.brs.2017.10.011. Epub 2017 Oct 27.
- 9. Sampaio-Junior, B., Tortella, G., Borrione, L. Efficacy and Safety of Transcranial Direct Current Stimulation as an Add-on Treatment for Bipolar Depression. A Randomized Clinical Trial. *JAMA Psychiatry*. February 2018. 75(2) 158-166. doi:10.1001/jamapsychiatry.2017.4040
- Brunoni, A.R., Moffa, A.H., Fregni, F. Transcranial direct current stimulation for acute major depressive episodes: meta-analysis of individual patient data. <u>Br J Psychiatry.</u> 2016 Jun;208(6):522-31. doi: 10.1192/bjp.bp.115.164715. Epub 2016 Apr 7.
- 11. Shiozawa, P., Fregni, F., Benseñor, I.M. Transcranial direct current stimulation for major depression: an updated systematic review and meta-analysis. Int J Neuropsychopharmacol. 2014 Sep;17(9):1539.
- 12. Meron, D., Hedger, N., Garner, M. Transcranial direct current stimulation (tDCS) in the treatment of depression: Systematic review and meta-analysis of efficacy and tolerability. Neurosci Biobehav Rev. 2015 Oct;57:46-62. doi: 10.1016/j.neubiorev.2015.07.012. Epub 2015 Jul 29.
- 13. Kekic, M., Boysen, E., Campbell, I.C. A systematic review of the clinical efficacy of transcranial direct current stimulation (tDCS) in psychiatric disorders. J Psychiatr Res. 2016 Mar;74:70-86. doi: 10.1016/j.jpsychires.2015.12.018. Epub 2015 Dec 22.
- Brunoni, A.R., Moffa, A.H., Sampaio-Junior, B. Trial of Electrical Direct-Current Therapy versus Escitalopram for Depression. N Engl J Med. 2017 Jun 29;376(26):2523-2533. doi: 10.1056/NEJMoa1612999
- 15. Brunoni, A.R., Valiengo, L., Baccaro, A. The sertraline vs. electrical current therapy for treating depression clinical study: results from a factorial, randomized, controlled trial. JAMA Psychiatry. 2013 Apr;70(4):383-91. doi: 10.1001/2013.jamapsychiatry.32.
- 16. Philip, P., Nelson, B.G., Frohlich, F. Low-Intensity Transcranial Current Stimulation in Psychiatry. American Journal of Psychiatry July 2017. 174(7). 628-639.

- 17. Murphy, D.N., Boggio, P., Fregni, F. Transcranial direct current stimulation as a therapeutic tool for the treatment of major depression: insights from past and recent clinical studies. Curr Opin Psychiatry. 2009 May;22(3):306-11. doi: 10.1097/YCO.0b013e32832a133f.
- 18. Vigod, S., Dennis, C.L., Daskalakis, Z. Transcranial direct current stimulation (tDCS) for treatment of major depression during pregnancy: study protocol for a pilot randomized controlled trial. <u>Trials.</u> 2014 Sep 18;15:366. doi: 10.1186/1745-6215-15-366.
- 19. Lefaucheur, J.P., Antal, A., Ayache, S.S. Evidence-based guidelines on the therapeutic use of transcranial direct current stimulation (tDCS). <u>Clin Neurophysiol.</u> 2017 Jan;128(1):56-92. doi: 10.1016/j.clinph.2016.10.087. Epub 2016 Oct 29.
- 20. Tavakoli, A. V., Yun, K. Transcranial Alternating Current Stimulation (tACS) Mechanisms and Protocols. Front Cell Neurosci. 2017. 11:214. doi: 10.3389/fncel.2017.00214

Endnotes

¹ Based on expert opinion