Cranial Electrotherapy Stimulation and Auricular Electrostimulation

Medicare Advantage Medical Policy #MA-205
Original Effective Date: 05/01/2026
Current Effective Date: 05/01/2026

Applies to all products administered or underwritten by the Health Plan, unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Blue Advantage does not cover investigational or experimental services, including any drug, device, procedure, or service provided under the investigational arm of a clinical trial or study unless mandated by the Centers for Medicare and Medicaid Services. Coverage is limited to routine services for Category A IDE studies and to devices and related services for Category B IDE studies when not supplied by the trial sponsor. Approved IDE studies are posted on www.cms.gov/medicare/coverage/evidence.

Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Health Plan considers cranial electrotherapy stimulation (also known as cranial electrostimulation therapy) in all situations to be **investigational.***

Based on review of the available data, the use of electrical stimulation of auricular acupuncture points in all situations is considered to be **investigational.***

Background/Overview

Cranial electrotherapy stimulation (CES), also known as cranial electrical stimulation, transcranial electrical stimulation, or electrical stimulation therapy, delivers weak pulses of electrical current to the earlobes, mastoid processes, or scalp with devices such as the Alpha-Stim. Auricular electrostimulation involves the stimulation of acupuncture points on the ear. Devices, including the P-Stim and e-pulse, provide ambulatory auricular electrical stimulation over a period of several days. Cranial electrotherapy stimulation and auricular electrostimulation are being evaluated for a variety of conditions, including pain, insomnia, depression, anxiety, weight loss, and opioid withdrawal.

Interest in CES began in the early 1900s on the theory that weak pulses of electrical current have a calming effect on the central nervous system. The technique was further developed in the U.S.S.R. and Eastern Europe in the 1950s as a treatment for anxiety and depression and use of CES later spread to Western Europe and the United States as a treatment for various psychological and physiological conditions. Presently, the mechanism of action is thought to be the modulation of activity in brain networks by direct action in the hypothalamus, limbic system, and/or the reticular activating system. One device used in the United States is the Alpha-Stim CES, which provides pulsed, low-intensity current via clip electrodes that attach to the earlobes. Other devices place the electrodes on the eyelids, frontal scalp, mastoid processes, or behind the ears. Treatments may be administered once or twice daily for several days to several weeks.

Other devices provide electrical stimulation to auricular acupuncture sites over several days. One device, the P-Stim, is a single-use miniature electrical stimulator for auricular acupuncture points that is worn behind the ear with a self-adhesive electrode patch. A selection stylus that measures electrical resistance is used to identify 3 auricular acupuncture points. The P-Stim device connects to 3 inserted acupuncture needles with caps and wires. The device is preprogrammed to be on for 180 minutes, then off for 180 minutes. The maximum battery life of this single-use device is 96 hours.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

A number of devices for CES have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process. In 1992, the Alpha-Stim CES device (Electromedical Products International) received marketing clearance for the treatment of anxiety, insomnia, and depression. Devices cleared since 2000 are summarized in Table 1.

FDA product code: QJQ.

Table 1. Cranial Electrotherapy Stimulation Devices Cleared by the U.S. Food and Drug Administration

Device Name	Manufacturer	Date Cleared	510(k) No.	Indications
Modius Stress	Neurovalens Limited	03/27/2024	K232253	Generalized anxiety disorder
Modius Sleep	Neurovalens Limited	10/27/2023	K230826	Insomnia
Cervella™‡	Innovative Neurological Devices	03/07/2019	K182311	Insomnia, depression, anxiety
Cranial Electrical Nerve Stimulator	Johari Digital Healthcare	05/29/2009	K090052	Insomnia, depression, anxiety
Elexoma Medic™‡	Redplane AG	05/21/2008	K070412	Insomnia, depression, anxiety
CES Ultra™‡	Neuro-Fitness	04/05/2007	K062284	Insomnia, depression, anxiety

Net-2000 Microcurrent Stimulator	Auri-Stim Medical	10/13/2006	K060158	Insomnia, depression, anxiety
Transcranial Electrotherapy Stimulator-A, Model TESA-1	Kalaco Scientific	07/21/2003	K024377	Insomnia, depression, anxiety

Several devices for electroacupuncture designed to stimulate auricular acupuncture points have been cleared for marketing by the FDA through the 510(k) process. Devices cleared since 2000 are summarized in Table 2.

FDA product codes: BWK, PZR.

Table 2. Auricular Electrostimulation Devices Cleared by the U.S. Food and Drug Administration

Device Name	Manufacturer	Date Cleared	510(k) No.	Indication
NET Device™‡	Net Recovery	05/29/2024	K233166	Reduce symptoms of opioid withdrawal
Sparrow Ascent®‡	Spark Biomedical, Inc.	06/20/2023	K230796	Reduce symptoms of opioid withdrawal
Needle Stimulator	Wuxi Jiajian Medical Instrument	08/27/2021	K202861	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
AXUS ES-5 Electro-Acupuncture Device	Lhasa OMS, INC.	02/03/2021	K200636	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
Drug Relief V1®‡	DyAnsys Inc	11/05/2021	K211971	Reduce symptoms of opioid withdrawal
Sparrow Therapy System	Spark Biomedical, Inc.	01/02/2021	K201873	Reduce symptoms of opioid withdrawal

Drug Relief	DyAnsys Inc	05/02/2018	K173861	Reduce symptoms of opioid withdrawal
Ansistem-Pp	DyAnsys Inc	03/09/2017	K170391	Practice of acupuncture by qualified practitioners of acupuncture as determined by the states
NSS-2 Bridge	Innovative Health Solutions	2017	N/A[a]	Substance use disorders
Stivax System	Biegler Gmbh	05/26/2016	K152571	Practice of acupuncture by qualified practitioners as determined by the states
ANSiStim®‡	DyAnsys Inc	05/15/2015	K141168	Practice of acupuncture by qualified practitioners as determined by the states
Pantheon Electrostimulator	Pantheon Research	11/07/2014	K133980	Practice of acupuncture by qualified practitioners as determined by the states
Electro Auricular Device	Navigant Consulting, Inc.	10/02/2014	K140530	Practice of acupuncture by qualified practitioners as determined by the states
P-Stim	Biegler GMBH	06/27/2014	K140788	Practice of acupuncture by qualified

				practitioners as determined by the states
Jiajian Cmn Stimulator	Wuxi Jiajian Medical Instrument Co., Ltd.	08/16/2013	K130768	Practice of acupuncture by qualified practitioners as determined by the states
JiaJian Electro-Acupuncture Stimulators	Wuxi Jiajian Medical Instrument Co., Ltd.	04/11/2013	K122812	Practice of acupuncture by qualified practitioners as determined by the states
Multi-Purpose Health Device	UPC Medical Supplies, Inc. DBA United Pacific Co.	08/05/2010	K093322	Unknown - Summary not provided
Electro-Acupuncture: Aculife/Model ADOC-01	Inno-Health Technology, Inc.	04/02/2010	K091933	Practice of acupuncture by qualified practitioners as determined by the states
e-Pulse	Medevice Corporation	12/07/2009	K091875	Practice of acupuncture by qualified practitioners as determined by the states
Model ES-130	Ito Co., Ltd.	11/24/2008	K081943	Practice of acupuncture by qualified practitioners as determined by the states

P-Stim	Neuroscience Therapy Corp.	03/30/2006	K050123	Practice of acupuncture by qualified practitioners as determined by the states
Aculife	Inno-Health Technology, Inc.	03/28/2006	K051197	Practice of acupuncture by qualified practitioners as determined by the states
AcuStim	S.H.P. Intl. Pty., Ltd.	06/12/2002	K014273	As an electroacupuncture device

[a] "FDA cleared the NSS-2 Bridge Device for Substance Use Disorders through the de novo premarket review pathway, a regulatory pathway for some low- to moderate-risk devices that are novel and for which there is no legally marketed predicate device to which the device can claim substantial equivalence"
N/A: Not applicable

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

Description

Cranial electrotherapy stimulation (CES), also known as cranial electrical stimulation, transcranial electrical stimulation, or electrical stimulation therapy, delivers weak pulses of electrical current to the earlobes, mastoid processes, or scalp with devices such as the Alpha-Stim. Auricular electrostimulation involves the stimulation of acupuncture points on the ear. Devices, including the P-Stim and e-pulse, provide ambulatory auricular electrical stimulation over a period of several days. Cranial electrotherapy stimulation is being evaluated for a variety of conditions, including pain, insomnia, depression, anxiety, and functional constipation. Auricular electrical stimulation is being evaluated for pain, weight loss, and opioid withdrawal.

Summary of Evidence

Cranial Electrotherapy Stimulation

For individuals who have acute or chronic pain who receive cranial electrotherapy stimulation (CES), the evidence includes a number of small sham-controlled randomized trials and pooled analyses. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Systematic reviews of randomized trials evaluated CES for headache and chronic pain. Pooled analyses found marginal benefits for headache with CES and no benefits for chronic pain with CES. A subsequent sham-controlled trial of remotely supervised CES via secure videoconferencing found a significant benefit with CES for pain reduction, but it had important relevance and conduct and design limitations. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have psychiatric, behavioral, or neurologic conditions (eg, depression and anxiety, Parkinson disease, addiction) who receive CES, the evidence includes a number of small sham-controlled randomized trials and systematic reviews. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Four randomized controlled trials (RCTs) evaluated CES for depression and anxiety. One RCT each found a significant benefit with CES for anxiety or depression, but both had important relevance limitations. Comparisons between these trials cannot be made due to the heterogeneity in study populations and treatment protocols. Studies evaluating CES for Parkinson disease, smoking cessation, and tic disorders do not support the use of CES for these conditions. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have functional constipation who receive CES, the evidence includes an RCT. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. The single RCT reported positive results for the treatment of constipation with CES. However, the trial was unblinded and most outcomes were self-reported. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Auricular Electrostimulation

For individuals who have acute or chronic pain (eg, acute pain from surgical procedures, chronic back pain, chronic pain from osteoarthritis or rheumatoid arthritis) who receive auricular electrostimulation, the evidence includes a limited number of trials. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Studies evaluating the effect of electrostimulation technology on acute pain are inconsistent, and the small amount of evidence on chronic pain has methodologic limitations. For example, a comparison of auricular electrostimulation with manual acupuncture for chronic low back pain did not include a sham control group, and, in a study of rheumatoid arthritis, auricular electrostimulation was compared with autogenic training and resulted in a small improvement in visual analog scale pain scores of unclear clinical significance. Overall, the few published studies have small sample sizes and methodologic limitations. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have obesity who receive auricular electrostimulation, the evidence includes small RCTs and systematic reviews. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. The RCTs reported inconsistent results and used different treatment protocols. The systematic reviews are limited by high heterogeneity with respect to the interventions used, participants included, treatment period, and outcome measures. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have opioid withdrawal symptoms who receive auricular electrostimulation, the evidence includes 2 observational studies. Relevant outcomes are symptoms, morbid events, functional outcomes, and treatment-related morbidity. Both studies report positive outcomes for the use of CES to treat opioid withdrawal symptoms. The studies used different treatment protocols and no comparators, limiting conclusions drawn from the results. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Clinical Input From Physician Specialty Societies and Academic Medical Centers

While the various physician specialty societies and academic medical centers may collaborate with and make recommendations during this process, through the provision of appropriate reviewers, input received does not represent an endorsement or position statement by the physician specialty societies or academic medical centers, unless otherwise noted.

2011 Input

In response to requests, input on auricular electrostimulation was received from 3 physician specialty societies and 5 academic medical centers while this policy was under review in 2011. There was a consensus that auricular electrostimulation is investigational.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

No guidelines or statements were identified.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Table 3 provides a summary of ongoing and unpublished trials that may influence this review.

Table 3. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06212609	Optimized and Personalized Trans-cranial Brain Stimulation in Partial Refractory Epilepsies	20	Jan 2027
NCT06203717	Cranial Electrotherapy Stimulation: Piloting a Road to PTSD Prevention in First Responders	20	Jan 2025
Unpublished			
NCT03896438	Increased Thalamocortical Connectivity in Tdcs-potentiated Generalization of Cognitive Training	85	May 2023

NCT: national clinical trial.
[a] Denotes industry sponsorship.

References

1. U.S. Food & Drug Administration. FDA News Release: FDA grants marketing authorization of the first device for use in helping to reduce the symptoms of opioid withdrawal. https://www.fda.gov/news-events/press-announcements/fda-grants-marketing-authorization-first-device-use-helping-reduce-symptoms-opioid-withdrawal. November 15, 2017.
2. Klawansky S, Yeung A, Berkey C, et al. Meta-analysis of randomized controlled trials of cranial electrostimulation. Efficacy in treating selected psychological and physiological conditions. J Nerv Ment Dis. Jul 1995; 183(7): 478-84. PMID 7623022
3. Bronfort G, Nilsson N, Haas M, et al. Non-invasive physical treatments for chronic/recurrent headache. Cochrane Database Syst Rev. 2004; (3): CD001878. PMID 15266458
4. Brønfort G, Haas M, Evans RL, et al. WITHDRAWN: Non-invasive physical treatments for chronic/recurrent headache. Cochrane Database Syst Rev. Aug 26 2014; 2014(8): CD001878. PMID 25157618
5. O'Connell NE, Wand BM, Marston L, et al. Non-invasive brain stimulation techniques for chronic pain. Cochrane Database Syst Rev. Apr 11 2014; (4): CD008208. PMID 24729198
6. O'Connell NE, Marston L, Spencer S, et al. Non-invasive brain stimulation techniques for chronic pain. Cochrane Database Syst Rev. Mar 16 2018; 3(3): CD008208. PMID 29547226

7. Ahn H, Galle K, Mathis KB, et al. Feasibility and efficacy of remotely supervised cranial electrical stimulation for pain in older adults with knee osteoarthritis: A randomized controlled pilot study. J Clin Neurosci. Jul 2020; 77: 128-133. PMID 32402609
8. Price L, Briley J, Haltiwanger S, et al. A meta-analysis of cranial electrotherapy stimulation in the treatment of depression. J Psychiatr Res. Mar 2021; 135: 119-134. PMID 33477056
9. Ching PY, Hsu TW, Chen GW, et al. Efficacy and Tolerability of Cranial Electrotherapy Stimulation in the Treatment of Anxiety: A Systemic Review and Meta-Analysis. Front Psychiatry. 2022; 13: 899040. PMID 35757229
10. Patel S, Boutry C, Patel P, et al. A randomised controlled trial investigating the clinical and cost-effectiveness of Alpha-Stim AID cranial electrotherapy stimulation (CES) in patients seeking treatment for moderate severity depression in primary care (Alpha-Stim-D Trial). Trials. Apr 04 2022; 23(1): 250. PMID 35379314
11. Morriss R, Patel S, Boutry C, et al. Clinical effectiveness of active Alpha-Stim AID versus sham Alpha-Stim AID in major depression in primary care in England (Alpha-Stim-D): a multicentre, parallel group, double-blind, randomised controlled trial. Lancet Psychiatry. Mar 2023; 10(3): 172-183. PMID 36724796
12. Kim J, Kim H, Kim DH, et al. Effects of cranial electrotherapy stimulation with novel in-ear electrodes on anxiety and resting-state brain activity: A randomized double-blind placebo-controlled trial. J Affect Disord. Dec 01 2021; 295: 856-864. PMID 34706456
13. Barclay TH, Barclay RD. A clinical trial of cranial electrotherapy stimulation for anxiety and comorbid depression. J Affect Disord. Aug 2014; 164: 171-7. PMID 24856571
14. Shekelle PG, Cook IA, Miake-Lye IM, et al. Benefits and Harms of Cranial Electrical Stimulation for Chronic Painful Conditions, Depression, Anxiety, and Insomnia: A Systematic Review. Ann Intern Med. Mar 20 2018; 168(6): 414-421. PMID 29435567
15. Mischoulon D, De Jong MF, Vitolo OV, et al. Efficacy and safety of a form of cranial electrical stimulation (CES) as an add-on intervention for treatment-resistant major depressive disorder: A three week double blind pilot study. J Psychiatr Res. Nov 2015; 70: 98-105. PMID 26424428
16. Lyon D, Kelly D, Walter J, et al. Randomized sham controlled trial of cranial microcurrent stimulation for symptoms of depression, anxiety, pain, fatigue and sleep disturbances in women receiving chemotherapy for early-stage breast cancer. Springerplus. 2015; 4: 369. PMID 26435889
17. Gehrman PR, Bartky EJ, Travers C, et al. A Fully Remote Randomized Trial of Transcranial Alternating Current Stimulation for the Acute Treatment of Major Depressive Disorder. J Clin Psychiatry. Apr 22 2024; 85(2). PMID 38696220
18. Shill HA, Obradov S, Katsnelson Y, et al. A randomized, double-blind trial of transcranial electrostimulation in early Parkinson's disease. Mov Disord. Jul 2011; 26(8): 1477-80. PMID 21538515
19. Pickworth WB, Fant RV, Butschky MF, et al. Evaluation of cranial electrostimulation therapy on short-term smoking cessation. Biol Psychiatry. Jul 15 1997; 42(2): 116-21. PMID 9209728
20. Wu WJ, Wang Y, Cai M, et al. A double-blind, randomized, sham-controlled study of cranial electrotherapy stimulation as an add-on treatment for tic disorders in children and adolescents. Asian J Psychiatr. Jun 2020; 51: 101992. PMID 32145674

21. Gong BY, Ma HM, Zang XY, et al. Efficacy of Cranial Electrotherapy Stimulation Combined with Biofeedback Therapy in Patients with Functional Constipation. J Neurogastroenterol Motil. Jul 30 2016; 22(3): 497-508. PMID 26932836
22. Sator-Katzenschlager SM, Michalek-Sauberer A. P-Stim auricular electroacupuncture stimulation device for pain relief. Expert Rev Med Devices. Jan 2007; 4(1): 23-32. PMID 17187468
23. Holzer A, Leitgeb U, Spacek A, et al. Auricular acupuncture for postoperative pain after gynecological surgery: a randomized controlled trail. Minerva Anestesiol. Mar 2011; 77(3): 298-304. PMID 21441884
24. Ilfeld BM, Abramson WB, Alexander B, et al. Percutaneous auricular neuromodulation (nerve stimulation) for the treatment of pain following cholecystectomy and hernia repair: a randomized, double-masked, sham-controlled pilot study. Reg Anesth Pain Med. Sep 02 2024; 49(9): 628-634. PMID 38388014
25. Ilfeld BM, Finneran JJ, Alexander B, et al. Percutaneous auricular neuromodulation (nerve stimulation) for the treatment of pain following total knee arthroplasty: a randomized, double-masked, sham-controlled pilot study. Reg Anesth Pain Med. Jan 07 2025; 50(1): 26-35. PMID 38388019
26. Sator-Katzenschlager SM, Scharbert G, Kozek-Langenecker SA, et al. The short- and long-term benefit in chronic low back pain through adjuvant electrical versus manual auricular acupuncture. Anesth Analg. May 2004; 98(5): 1359-64, table of contents. PMID 15105215
27. Sator-Katzenschlager SM, Szeles JC, Scharbert G, et al. Electrical stimulation of auricular acupuncture points is more effective than conventional manual auricular acupuncture in chronic cervical pain: a pilot study. Anesth Analg. Nov 2003; 97(5): 1469-1473. PMID 14570667
28. Bernateck M, Becker M, Schwake C, et al. Adjuvant auricular electroacupuncture and autogenic training in rheumatoid arthritis: a randomized controlled trial. Auricular acupuncture and autogenic training in rheumatoid arthritis. Forsch Komplementmed. Aug 2008; 15(4): 187-93. PMID 18787327
29. Kim SY, Shin IS, Park YJ. Effect of acupuncture and intervention types on weight loss: a systematic review and meta-analysis. Obes Rev. Nov 2018; 19(11): 1585-1596. PMID 30180304
30. Yeh TL, Chen HH, Pai TP, et. al. The Effect of Auricular Acupoint Stimulation in Overweight and Obese Adults: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Evidence-Based Complementary and Alternative Medicine. 2017; vol. 2017, Article ID 3080547, 16 pages, 2017. https://doi.org/10.1155/2017/3080547.
31. Schukro RP, Heiserer C, Michalek-Sauberer A, et al. The effects of auricular electroacupuncture on obesity in female patients--a prospective randomized placebo-controlled pilot study. Complement Ther Med. Feb 2014; 22(1): 21-5. PMID 24559812
32. Yeh ML, Chu NF, Hsu MY, et al. Acupoint Stimulation on Weight Reduction for Obesity: A Randomized Sham-Controlled Study. West J Nurs Res. Dec 2015; 37(12): 1517-30. PMID 25183702
33. Kroening RJ, Oleson TD. Rapid narcotic detoxification in chronic pain patients treated with auricular electroacupuncture and naloxone. Int J Addict. Sep 1985; 20(9): 1347-60. PMID 2867052

34. Miranda A, Taca A. Neuromodulation with percutaneous electrical nerve field stimulation is associated with reduction in signs and symptoms of opioid withdrawal: a multisite, retrospective assessment. Am J Drug Alcohol Abuse. 2018; 44(1): 56-63. PMID 28301217

Policy History

Original Effective Date: 05/01/2026
Current Effective Date: 05/01/2026
02/18/2026 Utilization Management Committee review/approval. New policy.
Next Scheduled Review Date: 02/2027

Coding

The five character codes included in the Health Plan Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2025 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

The responsibility for the content of the Health Plan Medical Policy Coverage Guidelines is with the Health Plan and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in the Health Plan Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of the Health Plan Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	0783T, 63650, 64555
HCPCS	A4543, A4596, E0721, E0732, L8680
ICD-10 Diagnosis	All related diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into

standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the Health Plan's Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Health Plan recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

NOTICE: All codes listed on the Medical Policy require prior authorization. This ensures appropriate utilization and alignment with current clinical guidelines.

NOTICE: If an authorization for an ongoing course of treatment has been provided to a member and the member changes from one health plan to another health plan (e.g., a member moves from carrier A to Blue Advantage), Blue Advantage may honor the previous health plan's authorization for the same service under the same type of in-network benefit for a 90-day transition period. Documentation of the authorization for the ongoing course of treatment from the previous health plan must be provided to us by the member or their provider and the services provided for the course of treatment must otherwise be a covered service under the Blue Advantage health plan.

Medicare Advantage Members
Established coverage criteria for Medicare Advantage members can be found in Medicare coverage guidelines in statutes, regulations, National Coverage Determinations (NCD)s, and Local Coverage Determinations (LCD)s. To determine if a National or Local Coverage Determination addresses coverage for a specific service, refer to the Medicare Coverage Database at the following link: https://www.cms.gov/medicare-coverage-database/search.aspx. You may wish to review the Guide to the MCD Search here: https://www.cms.gov/medicare-coverage-database/help/mcd-benehelp.aspx.

When coverage criteria are not fully established in applicable Medicare statutes, regulations, NCDs or LCDs, internal coverage criteria may be developed. This policy is to serve as the summary of evidence, a list of resources and an explanation of the rationale that supports the adoption of this internal coverage criteria.

InterQual®
Interqual® is utilized as a source of medical evidence to support medical necessity and level of care decisions. InterQual® criteria are intended to be used in connection with the independent professional medical judgment of a qualified health care provider. InterQual® criteria are clinically based on best practice, clinical data, and medical literature. The criteria are updated continually and released annually. InterQual® criteria are a first-level screening tool to assist in determining if the proposed services are clinically indicated and provided in the appropriate level or whether further evaluation is required. The utilization review staff does the first-level screening. If the criteria are met, the case is approved; if the criteria are not met, the case is referred to the medical director.