MEDICAL POLICY	Cefaly Device for Treatment of Migraine Headaches
Effective Date: 8/1/2021  8/1/2021 Medical Officer Date	Medical Policy Number: 176 Technology Assessment Committee Approved Date:10/14; 10/15 Medical Policy Committee Approved Date: 10/16; 12/17; 12/18; 12/19; 5/2020; 07/2021

See Policy CPT/HCPCS CODE section below for any prior authorization requirements

SCOPE:

Providence Health Plan, Providence Health Assurance, Providence Plan Partners, and Ayin Health Solutions as applicable (referred to individually as "Company" and collectively as "Companies").

APPLIES TO:

All lines of business

BENEFIT APPLICATION

Medicaid Members

Oregon: Services requested for Oregon Health Plan (OHP) members follow the OHP Prioritized List and Oregon Administrative Rules (OARs) as the primary resource for coverage determinations. Medical policy criteria below may be applied when there are no criteria available in the OARs and the OHP Prioritized List.

POLICY CRITERIA

The Cefaly Supraorbital Transcutaneous Neurostimulator device is considered **investigational and not covered** as a treatment of any condition, including migraine headache.

Link to Policy Summary

BILLING GUIDELINES

Note: The following codes are not appropriate for the Cefaly device as they describe simulation using more than one lead:

- A4595
- E0720
- E0730

HCPCS CODES

All Lines of Business	
Unlisted Codes All unlisted codes will be reviewed for medical necessity, correct coding, and pricing at the claim level. If an unlisted code is billed related to services addressed in this policy then it will be **denied as not covered.**	
A9999	Miscellaneous dme supply or accessory, not otherwise specified

DESCRIPTION

Cefaly is a small, portable, battery-powered, supraorbital transcutaneous neurostimulator prescription device that resembles a plastic headband worn across the forehead and atop the ears. The device consists of an adhesive, gel-backed electrode that the patient places directly on the skin in the center of the forehead, connects the electrode to the generator, and then turns on a plastic-framed pulse generator. The pulse generator fits like a pair of glasses. A control button in the center of the device powers the unit and allows the patient to control the level of stimulation.

REVIEW OF EVIDENCE

A review of the ECRI, Hayes, Cochrane, and PubMed databases was conducted regarding the use of the Cefaly device as a treatment for migraine headaches. Below is a summary of the available evidence identified through June 2021.

Randomized Controlled Trials

Data from one, manufacturer-funded randomized controlled trial (RCT) indicated that between months 1 and 3 the number of headaches and use of acute migraine medication was reduced.[1] Authors concluded Cefaly was an effective and safe preventive therapy for migraine; however, the RCT did not demonstrate superiority over other preventive drug and non-drug antimigraine treatments. The trial also indicated that the device did not completely prevent migraines and the use of Cefaly did not reduce the severity of the headaches when they did occur.[1]

Non-Randomized Trials

In 2013, Magis et al., published a patient satisfaction survey which showed that approximately 53% of patients were satisfied with the Cefaly device and would be willing to buy the device for continued use.[2] However, over 46% of the patients were dissatisfied with treatment and returned the device. A compliance check indicated that those who returned the device had utilized it for less than 50% of the recommended time. Authors did not report on the percent of utilization by satisfied patients.

Recent studies (published between 2016-2018) regarding the use of the Cefaly device for treatment of migraine headache were identified; however, all were limited by small sample sizes (n=10-57), short

follow-up periods (two hours to four months), unblinded study design, surrogate endpoints, and a lack of control groups.[3-10] Two unblinded studies[9,10] that reported small but statically significant improvements in clinical endpoints among patients using Cefaly, also called for larger, randomized, sham-controlled studies to verify findings. In one manufacturer-sponsored survey of active Cefaly users in Europe, nearly half (48%) of respondents stated that "Cefaly doesn't provide sufficient relief" during a migraine attack.[4]

CLINICAL PRACTICE GUIDELINES

American Headache Society

In 2012, the American Headache Society did not address the use of Cefaly in their guidelines for the treatment of acute migraine headaches.[11]

National Institute for Health and Care Excellence

In 2016, NICE published guidelines on, "(t)ranscutaneous electrical stimulation of the supraorbital nerve for treating and preventing migraine." The guideline stated that while, "the evidence on efficacy is limited in quantity and quality," transcutaneous stimulation devices may be an option for patients in, "special arrangements for clinical governance, consent and audit or research." The guideline also recommended clinicians ensure that patients understand, "the uncertainty about the procedure's efficacy."[12]

American Academy of Neurology

In 2018, the American Academy of Neurology affirmed their 2010 guidelines in which migraines were not mentioned as an indication for transcutaneous electric nerve stimulation.[13]

CENTERS FOR MEDICARE & MEDICAID

As of 06/01/2021, two relevant Centers for Medicare & Medicaid guidance documents were identified (Local Coverage Article: Transcutaneous Electrical Nerve Stimulators (TENS) – Policy Article (A52520)[14] and Local Coverage Determination (LCD): Transcutaneous Electrical Nerve Stimulators (TENS) (L33802)).[15]

L33802 states that Transcutaneous Electrical Nerve Stimulators (TENS) therapy is approved only for acute post-operative pain, chronic low back pain and certain types of intractable pain. "Headache," however, is one of the "conditions for which TENS therapy is not considered to be reasonable and necessary."[15]

POLICY SUMMARY

There is not enough evidence to show that Cefaly improves overall health outcomes as a treatment for migraines. In addition, no clinical practice guidelines specifically recommend Cefaly as a treatment for

migraines. The Cefaly device is only FDA-approved for episodic migraine and acute migraine treatment and prevention. Therefore, the use of the Cefaly device is considered investigational and not covered for any indication, including but not limited to migraine headaches.

INSTRUCTIONS FOR USE

Company Medical Policies serve as guidance for the administration of plan benefits. Medical policies do not constitute medical advice nor a guarantee of coverage. Company Medical Policies are reviewed annually and are based upon published, peer-reviewed scientific evidence and evidence-based clinical practice guidelines that are available as of the last policy update. The Companies reserve the right to determine the application of Medical Policies and make revisions to Medical Policies at any time. Providers will be given at least 60-days notice of policy changes that are restrictive in nature.

The scope and availability of all plan benefits are determined in accordance with the applicable coverage agreement. Any conflict or variance between the terms of the coverage agreement and Company Medical Policy will be resolved in favor of the coverage agreement.

REGULATORY STATUS

Mental Health Parity Statement

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case. In cases where medical necessity is not established by policy for specific treatment modalities, evidence not previously considered regarding the efficacy of the modality that is presented shall be given consideration to determine if the policy represents current standards of care.

Food and Drug Administration

Cefaly Technology currently has four FDA 510(k) premarket review approvals for the Cefaly® supraorbital transcutaneous nerve stimulator device to be applied on the forehead (K160237, K171446, K173006, K201895).[16-19] The original Cefaly approval order (K160237, 2016) stated that the Cefaly device is indicated for prophylactic treatment of episodic migraine in patients 18 years of age or older. The Cefaly Dual (K173006, 2017 and K201895, 2020) is indicated for the acute treatment on migraine with or without aura in patients 18 years of age or older and the prophylactic treatment of episodic migraine in patients 18 years of age or older. The Cefaly Acute (K171446 2017) is indicated for the acute migraine with or without aura in patients 18 years of age or older.

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