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Medical policies in conjunction with other nationally recognized standards of care are used to make medical coverage decisions.

External Trigeminal Nerve Stimulation for ADHD Disorder Policy

Indication/Usage:

External or transcutaneous trigeminal nerve stimulation (TNS) is a non-invasive therapy that delivers signals to the brain via the trigeminal nerve. TNS is commonly delivered by applying stimulating electrodes on the skin of the forehead. The Monarch external Trigeminal Nerve Stimulation (eTNS) System is being developed to treat several conditions including attention deficit hyperactivity disorder (ADHD), epilepsy, and depression. In 2019 the FDA announced that they are permitting marketing of the 1st medical device to treat ADHD for NeuroSigma's Monarch external Trigeminal Nerve Stimulation (eTNS) System. This eTNS system is indicated for patients aged 7 to 12 years old who are not currently taking prescription ADHD medication and is the 1st non-drug treatment for ADHD granted marketing authorization by the FDA.

Medical Indications for Authorization Commercial and Medicare Members

SummaCare considers external trigeminal nerve stimulation for the treatment of ADHD disorder experimental and investigational due to insufficient evidence of efficacy.

There is currently no NCD or LCD per CMS

HCPCS Code

K1016 - Transcutaneous electrical nerve stimulator for electrical stimulation of the trigeminal nerve

Limitations

There is currently insufficient evidence to support the use of external trigeminal nerve stimulation for the treatment of ADHD. The long-term effects of the device are unknown and that the device is contraindicated in patients with an implanted cardiac, neurostimulation system or implanted metallic or electronic device in their head.

Coverage Decisions

Coverage decisions made per CMS, Hayes and industry standards research

Plans Covered By This Policy

Commercial and Medicare

Considered experimental and investigational for all lines of business

Sources Reviewed

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