DRAFT Medical Coverage Policy | Tonic Motor Activation for Restless Legs Syndrome

EFFECTIVE DATE: 06|01|2026
POLICY LAST REVIEWED: 02|18|2026

OVERVIEW
Tonic motor activation (TOMAC) is a peroneal nerve stimulation device that uses electrodes worn on the lower legs to deliver bilateral high-frequency electrical stimulation to the common peroneal nerves located near the fibula in the lower legs. This stimulation is proposed to activate the tibialis anterior muscle, producing sustained, low-level muscle contractions that mimic the effects of voluntary leg movements like walking or stretching, which are activities known to relieve restless legs syndrome (RLS) symptoms.

MEDICAL CRITERIA
Not applicable

PRIOR AUTHORIZATION
Not applicable

POLICY STATEMENT
Medicare Advantage Plans
Tonic motor activation as a treatment for restless legs syndrome refractory to medication is not covered as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

Commercial Products
Tonic motor activation as a treatment for restless legs syndrome refractory to medication is not medically necessary as the evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

COVERAGE
Benefits may vary between groups/contracts. Please refer to the Evidence of Coverage or Subscriber Agreement for applicable not medically necessary benefits/coverage.

BACKGROUND
Restless Legs Syndrome
Restless legs syndrome (RLS) is a neurological condition characterized by an uncontrollable urge to move the legs, often accompanied by uncomfortable sensations. These symptoms typically worsen during periods of rest or inactivity, especially in the evening or at night, and are temporarily relieved by movement. RLS is frequently associated with sleep disturbances and periodic limb movements during sleep (PLMS), which can further impair rest and daytime functioning. When PLMS occurs without RLS or other related disorders, it is classified as periodic limb movement disorder (PLMD). Treatment for RLS generally involves pharmacologic therapy, with options including alpha-2-delta calcium channel ligands, dopaminergic agents, opioids, and benzodiazepines. Therapy is tailored based on symptom severity, patient age, comorbidities, and individual preferences, aiming to improve sleep quality and overall life functioning. Dopaminergic therapies have a known risk of augmentation.

For individuals with refractory RLS, where symptoms persist despite first-line treatments like gabapentinoids, alternative strategies are considered. These include combination pharmacotherapy using different drug

classes, low-dose opioids, and a thorough review of iron levels, potential exacerbating substances, behavioral interventions, and bilateral peroneal nerve stimulation.

Tonic Motor Activation
Tonic motor activation (TOMAC), also known as bilateral peroneal nerve stimulation, is proposed to work by delivering bilateral high-frequency electrical stimulation to the common peroneal nerves located near the fibula in the lower legs. This stimulation activates the tibialis anterior muscle, producing sustained, low-level muscle contractions that mimic the effects of voluntary leg movements like walking or stretching, which are activities known to relieve RLS symptoms.

The proposed biological mechanism involves afferent feedback. The stimulation sends signals back to the central nervous system, which may help suppress the abnormal sensory signals that drive the urge to move the legs. By activating the same circuits used during natural movement, TOMAC may modulate spinal and supraspinal pathways involved in RLS pathophysiology.

TOMAC differs from transcutaneous electrical nerve stimulation (TENS) devices. TOMAC targets the common peroneal nerve with a goal of tonic activation of motor pathways to mimic movement with high-frequency, sustained, bilateral stimulation. TENS targets superficial sensory nerves often with the goal of pain relief by administering pulsed, often intermittent, stimulation.

Clinical Pathway
TOMAC is not a first-line therapy for RLS. It is indicated for moderate-to-severe primary RLS that is refractory to pharmacologic treatment. First-line therapies include, iron supplementation, gabapentinoids, lifestyle modifications (eg, regular moderate exercise, sleep habits, etc.).

Regulatory Status
The NTX100 Tonic Motor Activation (TOMAC) System (Noctrix Health, Inc; Pleasanton, CA) received De Novo classification (DEN220059; Product Code: QWD) from the FDA for its intended use "to reduce symptoms of primary moderate-severe Restless Legs Syndrome (RLS) and to improve sleep quality in adults refractory to medication."

For individuals with restless legs syndrome (RLS) who are refractory to medication who receive tonic motor activation (TOMAC), the evidence includes randomized controlled trials (RCTs), nonrandomized studies, and a systematic review and meta-analysis. Relevant outcomes are changes in symptoms, functional outcomes, quality of life, and medication use. The pivotal RCT showed a higher Clinical Global Impression of Improvement (CGI-I) responder rate in the TOMAC group compared to the control group (45% vs. 16%; difference: 28%). They also showed greater reductions in International RLS Study Group Rating Scale (IRLS) scores in the TOMAC group compared to the sham group (-7.2 vs. -3.8). The meta-analysis, which includes the RCT results comparing TOMAC to sham controls, showed significantly reduced IRLS scores (mean difference: -3.66), improved Patient Global Impression of Improvement (PGI-I) response (risk ratio: 3.16), and enhanced sleep quality (MOS-I mean difference: -9.28; MOS-II mean difference: -10.06). Across studies, adverse events were mild with no serious device-related events reported. Limitations included underpowered sample sizes, short study durations, potential loss of blinding due to perceived treatment, a lack of long-term randomized data, and risk of bias from patient-reported outcomes. Sufficiently powered RCTs, with long-term follow-up to investigate safety and durability, are needed to further evaluate the net health outcomes. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

CODING

Medicare Advantage Plans and Commercial Products
The following CPT/HCPCS code(s) are not covered for Medicare Advantage Plans and not medically necessary for Commercial Products:

A4544 Electrode for external lower extremity nerve stimulator for restless legs syndrome
E0743 External lower extremity nerve stimulator for restless legs syndrome, each

RELATED POLICIES
Not applicable

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