Priority Health

MEDICAL POLICY
No. 91648-R0

TONIC MOTOR ACTIVATION (ToMAc) PERONEAL NERVE STIMULATION FOR RESTLESS LEG SYNDROME (i.e., Nidra™) – MEDICARE ADVANTAGE

Effective Date: November 1, 2025	**Review Dates: 8/25**
Date Of Origin:	**Status: New**

I. SCOPE

- This medical policy is limited in scope to tonic motor activation (ToMAc) peroneal nerve stimulation for restless leg syndrome (i.e., Nidra™).
- This medical policy applies only to Medicare. For **commercial** and **Medicaid** lines of business, see *Priority Health Medical Policy No. 91634 – PERIPHERAL NERVE STIMULATION*.

II. POLICY/CRITERIA

A. **Tonic Motor Activation (ToMAc; Nidra™, Noctrix Health, Inc.)** for **restless leg syndrome (RLS)** may be considered medically necessary when ALL the following criteria are met:

a. Member is an adult age 22–79 years
b. Medication-refractory RLS (defined as having failed one or more medications commonly prescribed to treat RLS (ropinirole, pramipexole, gabapentin, pregabalin, gabapentin enacarbil, and/or rotigotine) for at least one of the following reasons: intolerable adverse effects, symptoms of augmentation, up-titration needed due to reduced efficacy, and insufficient response at maximum approved, recommended, or tolerated dosage)
c. Moderate-to-severe primary RLS (defined as an **International RLS Study Group Rating Scale (IRLS)** total score ≥ 15)
d. Symptoms ≥ 2 nights per week
e. Symptoms most significant in the lower legs and/or feet
f. Symptoms most significant at bedtime, after bedtime, and/or in the 2 hours before bedtime

III. GOVERNMENTAL REGULATIONS

Centers for Medicare & Medicaid Services (CMS)

National Coverage Determinations (NCDs)
None identified

Local Coverage Determinations (LCDs)	
CGS Administrators, LLC	None identified
First Coast Service Options, Inc.	None identified
National Government Services, Inc.	None identified
Noridian Healthcare Solutions, LLC	None identified
Novitas Solutions, Inc.	None identified
Palmetto GBA	None identified
WPS Insurance Corporation	None identified

IV. GUIDELINES

Winkelman JW, Berkowski JA, DelRosso LM, Koo BB, Scharf MT, Sharon D, Zak RS, Kazmi U, Falck-Ytter Y, Shelgikar AV, Trotti LM, Walters AS. Treatment of restless legs syndrome and periodic limb movement disorder: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2025 Jan 1;21(1):137-152. doi: 10.5664/jcsm.11390. PMID: 39324694; PMCID: PMC11701286.

V. FOOD & DRUG ADMINISTRATION

Nidra™ (Noctrix Health, Inc.), formerly known as the NTX100 Tonic Motor Activation (ToMAc) System, is a prescription-only, noninvasive, wearable electrical stimulator device designed to treat moderate to severe RLS and improve sleep quality in adults refractory to medication. The Nidra system works by electrically stimulating the peroneal nerves through bands worn on the lower legs, providing continuous tonic muscle activation designed to alleviate RLS symptoms, particularly during sleep.

Nidra™ (Noctrix Health, Inc.) was granted classification as a class II device (product code QWD, *stimulator, nerve, for restless legs syndrome*) by the U.S. Food and Drug Administration (FDA) under the de novo pathway on April 17, 2023 (DEN220059), defined as follows:

> *An external lower extremity nerve stimulator for Restless Legs Syndrome is a prescription device that uses external electrical stimulators and cutaneous electrodes to stimulate nerves in the lower extremity (e.g.,peroneal nerves) and evoke tonic, sustained muscle activation in the legs to reduce the symptoms of Restless Legs Syndrome.*

From the Classification Order:

Indications for use

The NTX100 Tonic Motor Activation (ToMAc) System® is intended to reduce symptoms of primary moderate-severe Restless Legs Syndrome (RLS) and to improve sleep quality in adults refractory to medications.

Device Description

The NTX100 Tonic Motor Activation (ToMAc) System® [Nidra™] is a non-surgical, non-implantable prescription device intended for the application of low-amplitude electrical stimulation to the common peroneal nerve at lateral side of the knees to reduce symptoms of moderate-severe Restless Legs Syndrome (RLS). Patients will be instructed to use the NTX100 ToMAc System® as needed for symptom relief for up to 120 minutes per 24-hour period.

VI. MEDICAL NECESSITY REVIEW

Prior authorization for certain drugs, devices, services, and procedures may or may not be required. In cases where prior authorization is required, providers will submit a request demonstrating that a drug, service, or procedure is medically necessary. For more information, please refer to the Priority Health Provider Manual.

VII. APPLICATION TO PRODUCTS

Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

- **HMO/EPO:** ***This policy does NOT apply to insured HMO/EPO plans.***
- **POS:** ***This policy does NOT apply to insured POS plans.***
- **PPO:** ***This policy does NOT apply to insured PPO plans. Consult individual plan documents as state mandated benefits may apply. If there is a conflict between this policy and a plan document, the provisions of the plan document will govern.***
- **ASO:** ***For self-funded plans, consult individual plan documents.***
- **INDIVIDUAL:** ***For individual policies, consult the individual insurance policy.***
- **MEDICARE:** ***Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS, this policy applies.***
- **MEDICAID/HEALTHY MICHIGAN PLAN:** ***For Medicaid/Healthy Michigan Plan members, this policy will NOT apply. Coverage is based on medical necessity criteria being met and the appropriate code(s) from the coding section of this policy being included on the Michigan Medicaid Fee Schedule located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_42542_42543_42546_42551-159815--,00.html. If there is a discrepancy between this policy and the Michigan Medicaid Provider Manual located at: http://www.michigan.gov/mdch/0,1607,7-132-2945_5100-87572--,00.html, the***

Michigan Medicaid Provider Manual will govern. If there is a discrepancy or lack of guidance in the Michigan Medicaid Provider Manual, the Priority Health contract with Michigan Medicaid will govern. For Medical Supplies/DME/Prosthetics and Orthotics, please refer to the Michigan Medicaid Fee Schedule to verify coverage.

VIII. BACKGROUND

Restless legs syndrome (RLS) is characterized by an uncomfortable urge to move the legs while at rest, relief upon movement or getting up to walk, and worsened symptom severity at night. RLS may be primary (idiopathic) or secondary to pregnancy or a variety of systemic disorders, especially iron deficiency, and chronic renal insufficiency. Genetic predisposition with a family history is common. The pathogenesis of RLS remains unclear but is likely to involve central nervous system dopaminergic dysfunction, as well as other, undefined contributing mechanisms. Some people with RLS have adequate symptom control with non-pharmacological measures such as massage or temperate baths. First-line management options include iron-replacement therapy in those with evidence for reduced body-iron stores or, alternatively, with prescribed gabapentin or pregabalin, and dopamine agonists such as pramipexole, ropinirole, and rotigotine. (Gossard et al., 2021) RLS significantly impacts patients' quality of life and remains a therapeutic area in need of innovation and a further pipeline of new, informed therapies.

The ToMAc system is a novel nonpharmacological, noninvasive treatment consisting of a pair of therapy units that are worn externally and bilaterally over the peroneal nerve at the head of the fibula bone in the lower leg. ToMAc stimulates afferent peroneal nerve fibers in a comfortable and nondistracting pattern that evokes sustained increases in tibialis anterior muscle tone. Through this established mechanism, ToMAc engages similar neuromuscular circuitry as voluntary leg movements such as walking or standing, which are known to suppress RLS symptoms, while remaining compatible with sleep. (Bogan et al., 2023)

A randomized controlled trial by Bogan and colleagues (the RESTFUL trial) was a multicenter, randomized, double-blind, sham-controlled trial in adults with medication-refractory moderate-to-severe primary RLS. Participants were randomized 1:1 to active or sham ToMAc for a double-blind, 4-week stage 1 and all received active ToMAc during open-label, 4-week stage 2. The primary endpoint was the **Clinical Global Impressions-Improvement (CGI-I)** responder rate at the end of stage 1. Key secondary endpoints included change to **International RLS Study Group (IRLS)** total score from study entry to the end of stage 1. A total of 133 participants were enrolled. CGI-I responder rate at the end of stage 1 was significantly greater for the active versus sham group (45% vs.

16%; Difference = 28%; 95% CI 14% to 43%; p = .00011). At the end of stage 2, CGI-I responder rate further increased to 61% for the active group. IRLS change at the end of stage 1 improved for the active versus sham group (−7.2 vs. −3.8; difference = −3.4; 95% CI −1.4 to −5.4; p = .00093). There were no severe or serious device-related adverse events (AEs). The most common AEs were mild discomfort and mild administration site irritation which resolved rapidly and reduced in prevalence over time. (Bogan et al., 2023)

A meta-analysis by Singh et al (2024) included the above-mentioned trial and a previous randomized clinical trial (Buchfuhrer et al., 2021) that enrolled medication-naïve RLS patients. The authors found that IRLS reduction was significantly greater for TOMAC than sham (TOMAC -6.59 vs. sham − 2.17; mean difference (MD) = − 4.42; 95 % confidence interval [CI] − 1.57 to − 7.26; p = 0.0040). Subgroup analysis showed similar IRLS mean difference for medication-refractory (MD = − 4.50; p = 0.02) and medication-naïve (MD = − 4.40; p = 0.08) cohorts, which was significantly different from sham only for the medication-refractory cohort. Meta-analysis of combined data from 33 medication-naïve RLS patients showed a significant reduction in mean IRLS score after two weeks for TOMAC compared to sham (MD = − 4.30; 95 % CI -1.36 to − 7.24; p = 0.004).

Guidelines/Position Statements

Treatment of Restless Legs Syndrome and Periodic Limb Movement Disorder: an American Academy of Sleep Medicine Clinical Practice Guideline (Winkelman et al., 2025)

> *"In adults with RLS, the AASM suggests the use of bilateral high-frequency peroneal nerve stimulation over no peroneal nerve stimulation (conditional recommendation, moderate certainty of evidence)."*

IX. CODING INFORMATION

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

X. REFERENCES

1. Bogan, R. K., Roy, A., Kram, J., Ojile, J., Rosenberg, R., Hudson, J. D., Scheuller, H. S., Winkelman, J. W., & Charlesworth, J. D. (2023). Efficacy and safety of tonic motor activation (TOMAC) for medication-refractory restless legs syndrome: a randomized clinical trial. Sleep, 46(10), zsad190. https://doi.org/10.1093/sleep/zsad190

2. Buchfuhrer, M. J., Baker, F. C., Singh, H., Kolotovska, V., Adlou, B., Anand, H., de Zambotti, M., Ismail, M., Raghunathan, S., & Charlesworth, J. D. (2021). Noninvasive neuromodulation reduces symptoms of restless legs syndrome. *Journal of clinical sleep medicine : JCSM : official publication of the American Academy of Sleep Medicine*, *17*(8), 1685–1694. https://doi.org/10.5664/jcsm.9404
3. Gossard TR, Trotti LM, Videnovic A, St Louis EK. Restless Legs Syndrome: Contemporary Diagnosis and Treatment. Neurotherapeutics. 2021 Jan;18(1):140-155. doi: 10.1007/s13311-021-01019-4. Epub 2021 Apr 20. PMID: 33880737; PMCID: PMC8116476.
4. Singh, H., Baker, F. C., Ojile, J., Adlou, B., Kolotovska, V., Rigot, S. K., & Charlesworth, J. D. (2024). Efficacy and safety of TOMAC for treatment of medication-naïve and medication-refractory restless legs syndrome: A randomized clinical trial and meta-analysis. *Sleep medicine*, *122*, 141–148. https://doi.org/10.1016/j.sleep.2024.08.017
5. Winkelman, J. W., Berkowski, J. A., DelRosso, L. M., Koo, B. B., Scharf, M. T., Sharon, D., Zak, R. S., Kazmi, U., Falck-Ytter, Y., Shelgikar, A. V., Trotti, L. M., & Walters, A. S. (2025). Treatment of restless legs syndrome and periodic limb movement disorder: an American Academy of Sleep Medicine clinical practice guideline. *Journal of clinical sleep medicine : JCSM : official publication of the American Academy of Sleep Medicine*, *21*(1), 137–152. https://doi.org/10.5664/jcsm.11390

as of the date services are rendered. Priority Health's medical policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community medical practices in the treatment and diagnosis of disease. Because medical practice, information, and technology are constantly changing, Priority Health reserves the right to review and update its medical policies at its discretion.

Priority Health's medical policies are intended to serve as a resource to the plan. They are not intended to limit the plan's ability to interpret plan language as deemed appropriate. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment they choose to provide.

The name "Priority Health" and the term "plan" mean Priority Health, Priority Health Managed Benefits, Inc., Priority Health Insurance Company and Priority Health Government Programs, Inc.