

NO. 91649

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

Effective: 09/01/2026
Committee Review: 08/2026
Last Updated: 08/2026

Instructions for use: This document is for informational purposes only. Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable. Eligibility and benefit coverage are determined in accordance with the terms of the member's plan in effect as of the date services are rendered. It is not an authorization, certification, explanation of benefits, or contract. Receipt of benefits is subject to satisfaction of all terms and conditions of coverage. 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policies are developed with the assistance of medical professionals and are based upon a review of published and unpublished information including, but not limited to, current medical literature, guidelines published by public health and health research agencies, and community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.

Policy 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

Related policies:

- 91634 – PERIPHERAL NERVE STIMULATION

I. MEDICAL NECESSITY 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:
1. Member is an adult age ≥18

2. 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)
3. Moderate-to-severe primary RLS (defined as an **International RLS Study Group Rating Scale (IRLS)** total score ≥ 15)
4. Symptoms ≥ 2 nights per week
5. Symptoms most significant in the lower legs and/or feet
6. Symptoms most significant at bedtime, after bedtime, and/or in the 2 hours before bedtime

II. CENTERS FOR MEDICARE & MEDICAID SERVICES (CMS) COVERAGE DETERMINATION

Any applicable federal or state mandates will take precedence over this medical coverage policy.

Medicare: Refer to the [CMS Online Manual System \(IOMs\)](#) and Transmittals.

For the most current applicable CMS National Coverage Determination (NCD)/Local Coverage Determination (LCD)/Local Coverage Article (LCA) refer to [CMS Medicare Coverage Database](#).

The information below is current as of the review date for this policy. However, the coverage issues and policies maintained by CMS are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. MAC jurisdiction for purposes of local coverage determinations is governed by the geographic service area where the Medicare Advantage plan is contracted to provide the service. Please refer to the Medicare [Coverage Database website](#) for the most current applicable NCD, LCD, LCA, and CMS Online Manual System/Transmittals.

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

III. BACKGROUND

IV. GUIDELINES / POSITION STATEMENTS

Medical/Professional Society	Guideline
American Academy of Sleep Medicine	Treatment of restless legs syndrome and periodic limb movement disorder: an American Academy of Sleep Medicine clinical practice guideline (2025)

V. REGULATORY (US FOOD AND DRUG ADMINISTRATION)

See [U.S. Food & Drug Administration \(FDA\) Medical Device Databases](#) for the most current information.

Device	Premarket Approval, 513(f)(2)(De Novo), or 510(k) Number	Decision date

VI. CODING

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

VII. 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, refer to the [Priority Health Provider Manual](#).

To access Evicore guidelines: Log into [Priority Health Prism](#) → Authorizations → Authorization Criteria Lookup.

To access InterQual guidelines: Log into [Priority Health Prism](#) → Authorizations → Authorization Criteria Lookup.

To access TurningPoint guidelines: Log into [Priority Health Prism](#) → Authorizations → Authorization Criteria Lookup.

To access EviCore, InterQual, or TurningPoint guidelines: Log into [Priority Health Prism](#) → Authorizations → Authorization Criteria Lookup.

Individual case review may allow coverage for care or treatment that is investigational yet promising for the conditions described. Requests for individual consideration require prior plan approval. All determinations of coverage for experimental, investigational, or unproven treatment will be made by a Priority Health medical director or clinical pharmacist. The exclusion of coverage for experimental, investigational, or unproven

treatment may be reviewed for exception if the condition is either a terminal illness, or a chronic, life threatening, severely disabling disease that is causing serious clinical deterioration.

VIII. APPLICATION TO PRODUCTS

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

- **HMO/EPO:** This policy applies to insured HMO/EPO plans.
- **POS:** This policy applies to insured POS plans.
- **PPO:** This policy applies 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. If there is a conflict between this policy and a self-funded plan document, the provisions of the plan document will govern.
- **INDIVIDUAL:** For individual policies, consult the individual insurance policy. If there is a conflict between this medical policy and the individual insurance policy document, the provisions of the individual insurance policy will govern.
- **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 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](#). If there is a discrepancy between this policy and the [Michigan Medicaid Provider Manual](#), 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.

IX. 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>

SUMMARY OF CHANGES

Changes:

- I.A.1. changed age range from 22-70 years to ≥ 18 to align with new AASM guideline recommendation

Past committee review dates: 8/25,8/26

AMA CPT Copyright Statement: All Current Procedure Terminology (CPT) codes, descriptions, and other data are copyrighted by the American Medical Association.

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.