CarePartners of Connecticut MEDICARE ADVANTAGE

Medical Necessity Guidelines: **Tonic Motor Activation for the Treatment of Restless Leg Syndrome**

Effective: August 1, 2025

Prior Authorization Required If REQUIRED, submit supporting clinical documentation pertinent to service request to the FAX numbers blow.	Yes ☒ No ☐
Notification Required IF REQUIRED, concurrent review may apply	Yes ☐ No ☒

Applies to:

☒ CarePartners of Connecticut Medicare Advantage HMO plans, Fax 857-304-6463
☒ CarePartners of Connecticut Medicare Advantage PPO plans, Fax 857-304-6463

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Restless Leg Syndrome (RLS) is a neurological condition that causes an overwhelming urge to move the legs, often described as an uncomfortable sensation like tingling, burning, itching, or aching. RLS symptoms are often worse in the evening and night, causing difficulty to fall asleep and remain asleep leading to disrupted sleep that interferes with daily activities. RLS is often treated with medication and/or lifestyle changes. A polysomnography is not required for the diagnosis of restless leg syndrome

Tonic Motor Activation – TOMAC, is a treatment for RLS that involves a noninvasive wearable device which delivers electrical stimulation to the peroneal nerves in the lower extremity. Use of the device is limited to the lower extremity only. The stimulation causes the muscles in the lower leg to contract and relax in a specific pattern which can help relieve RLS symptoms in people who have tried and failed with medication or lifestyle changes. The Nidra Tonic Motor Activation device (NTX150) (Noctrix Health ®) is the first FDA approved TOMAC therapy for RLS. It was granted a “Breakthrough Device Designation” in May 2020 and subsequent market authorization in April 2023.

The NTX150 system delivers treatment in 30-minute sessions and relief can typically start immediately after tuning on the device, lasting for 2 hours after the end of the treatment session. Treatment is recommended for just before or at the time in which someone is going to sleep. The device is worn around the legs directly under the knees and can be used frequently. Trial studies indicate that long term use of the NTX150 at proper times of the day may result in fewer days per week with RLS symptoms.

For the service of Tonic Motor Activation for the treatment of Restless Leg Syndrome evidence is sufficient for coverage. The Nidra TOMAC device, which received FDA approval in April 2023, is the first treatment for medication refractory moderate to severe RLS. Nidra is a treatment option for members whose RLS do not respond well to pharmacologic treatments, lifestyle changes, and non-pharmacologic treatment. This FDA approval is based on the results from the clinical trials showing a reduction in intensity and frequency of RLS symptoms after consistent use of the device.

The use of this criteria in the utilization management process will ensure access to evidence based clinically appropriate care. See the References section below for all evidence assessed in the development of these criteria.

Clinical Guideline Coverage Criteria

The Plan considers a 6-month trial FDA approved tonic motor activation device for the treatment of restless leg syndrome as reasonable and medically necessary when documentation confirms **ALL** of the following:

1. Age 18 years of age or older; **and**

2. Diagnosed by a sleep specialist certified by an approved specialty board of the American Board of Medical Specialties (e.g., ABIM) with moderate to severe primary restless leg syndrome based on an International Restless Leg Syndrome Study Group[1] score ≥ 15; **and**
3. Iron deficiency has been excluded as a contributing factor for RLS symptoms as confirmed by blood test
    a. If iron deficiency is identified, treatment with iron supplements has been initiated and serum ferritin level is ≥75 ng/dl
4. Failure one or more pharmacologic therapies such as gabapentinoids, dopamine agonists, and/or opioids to-treat RLS symptoms or member has a contraindication and/or intolerance to medical therapy; **and**
5. RLS symptoms occur two or more nights per week; **and**
6. RLS symptoms are most significant in the lower legs and/or feet

The Plan considers coverage for continuation of an FDA approved TOMAC device for the treatment of primary restless leg syndrome as reasonable and medically necessary when documentation confirms **ALL** of the following:

1. RLS symptoms have decreased with consistent use of the device
2. Attestation from provider that device is being used appropriately and consistently

[1]International Restless Leg Syndrome Study Group Diagnostic Criteria:

1. Urge to move and uncomfortable sensation
2. Onset or worsening during rest
3. Relief with movement
4. Evening/nighttime worsening
5. Exclusion of other conditions

[1]International Restless Leg Syndrome Study Group Diagnostic Score:

1. Very Severe = 31-40 points
2. Severe = 21-30 points
3. Moderate = 11-20 points
4. Mild = 1-10 points
5. None = 1-10 points

Limitations

TOMAC for RLS is considered experimental/investigational when any of the following are present:

1. Presence of another inadequately treated primary sleep disorder other than Restless Leg Syndrome (e.g., Obstructive Sleep Apnea, Periodic Limb Movement Disorder)
2. In situations where medications (e.g., antidepressants) may be contributing to or exacerbating RLS Symptoms
3. Peripheral neuropathy involving lower extremities
4. Member is pregnant – safe use of TOMAC has not been established for this condition

Codes

The following codes require prior authorization:

Table 1:

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

References:

1. Bogan RK, Roy A, Kram J, et al. Efficacy and safety of tonic motor activation (TOMAC) for medication-refractory restless legs syndrome: a randomized clinical trial. Sleep. 2023;46(10):zsad190. doi:10.1093/sleep/zsad190
2. Buchfuhrer, M.J., Roy, A., Rodriguez, S. *et al.* Adjunctive tonic motor activation enables opioid reduction for refractory restless legs syndrome: a prospective, open-label, single-arm clinical trial. *BMC Neurol* **23**, 415 (2023). https://doi.org/10.1186/s12883-023-03462-6

3. Food and Drug Administration. De Novo Classification Request for NTX100 Tonic Motor Activation (NTX100 ToMAC) System. https://www.accessdata.fda.gov/cdrh_docs/reviews/DEN220059.pdf
4. Roy A, Ojile J, Kram J, et al. Long-term efficacy and safety of tonic motor activation for treatment of medication-refractory restless legs syndrome: A 24-Week Open-Label Extension Study. *Sleep*. 2023;46(10):zsad188. doi:10.1093/sleep/zsad188
5. Ryschon, A. M., Roy, A., & Pietzsch, J. B. (2024). Cost-effectiveness of TOMAC therapy for medication-refractory restless legs syndrome: an updated analysis based on Extension study data. *Journal of Medical Economics*, *27*(1), 1320–1327. https://doi.org/10.1080/13696998.2024.2410595
6. Walters AS, LeBrocq C, Dhar A, et al. Validation of the International Restless Legs Syndrome Study Group rating scale for restless legs syndrome. *Sleep Med*. 2003;4(2):121-132. doi:10.1016/s1389-9457(02)00258-7
7. Winkelman JW, Berkowski JA, DelRosso LM, et al. Treatment of restless legs syndrome and periodic limb movement disorder: an American Academy of Sleep Medicine clinical practice guideline. *J Clin Sleep Med*. 2025;21(1):137-152. doi:10.5664/jcsm.11390

Approval And Revision History

June 18, 2025: Reviewed by the Medical Policy Approval Committee (MPAC) as a new Medical Necessity Guideline requiring prior authorization effective August 1, 2025

Subsequent endorsement date(s) and changes made:

- June 11, 2025: Reviewed by Utilization Management Committee as a new Medical Necessity Guideline requiring Prior Authorization, effective August 1, 2025

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.