1.01.32	Tonic Motor Activation for Restless Legs Syndrome		
Original Policy Date:	March 1, 2026	**Effective Date:**	March 1, 2026
Section:	1.0 Durable Medical Equipment	**Page:**	Page 1 of 13

Policy Statement

I. Tonic motor activation as a treatment for restless legs syndrome refractory to medication is considered **investigational**.

NOTE: Refer to Appendix A to see the policy statement changes (if any) from the previous version.

Policy Guidelines

Coding

See the Codes table for details.

Description

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.

Summary of Evidence

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.

Additional Information

Not applicable.

Related Policies

- Implantable Peripheral Nerve Stimulation for Chronic Pain Conditions
- Percutaneous Electrical Nerve Stimulation, Percutaneous Neuromodulation Therapy, and Restorative Neurostimulation Therapy
- Transcutaneous Electrical Nerve Stimulation and Transcutaneous Afferent Patterned Stimulation

Benefit Application

Benefit determinations should be based in all cases on the applicable member health services contract language. To the extent there are conflicts between this Medical Policy and the member health services contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal law may prohibit health plans from denying FDA-approved Healthcare Services as investigational or experimental. In these instances, Blue Shield of California may be obligated to determine if these FDA-approved Healthcare Services are Medically Necessary.

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."[2,]

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. Randomized controlled trials are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Tonic Motor Activation in Individuals with Restless Legs Syndrome Refractory to Medication

Clinical Context and Therapy Purpose

The purpose of tonic motor activation (TOMAC) in individuals who have restless legs syndrome (RLS) is to provide a treatment option for those who are refractory to medication.

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest are individuals with RLS who are refractory to medication.

Interventions
The therapy being considered is TOMAC. 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.

Comparators
The following therapies are currently being used to treat RLS: iron supplementation, gabapentinoids, and lifestyle modifications (e.g., exercise, sleep hygiene, cognitive behavioral therapy, etc.).

Outcomes
The general outcomes of interest are symptom relief, functional outcomes, quality of life, and medication use. Relevant health outcome measures are summarized in Table 1.

Follow-up of at least 6 months is recommended to monitor outcomes.[3,]

Table 1. Health Outcome Measures Relevant to Restless Legs Syndrome

Outcome	Measure (Units)	Description and Administration	Thresholds for Improvement/Decline or Clinically Meaningful Difference (if known)
International Restless Legs Syndrome Score (IRLS)[4,5,]	10-item questionnaire, each scored 0 to 4; patient-reported	Measures the severity of RLS symptoms over the past week.	Scores: 1-10, mild 11-20, moderate 21-30, severe 31-40, very severe A ≥9-11-point reduction is often considered clinically meaningful.
Patient/Clinician Global Impression of Improvement (PGI-I/CGI-I)[5,]	Single-item, 7-point, likert scale; patient- or clinician-reported	Measures the patient's or clinician's perception of improvement or worsening.	Scores of 1 ("very much improved") and 2 ("much improved") indicate meaningful improvement.
Medical Outcomes Study (MOS) Sleep Scale[6,]	6- or 12-item patient-reported survey	Measures sleep quality, disturbances, and adequacy.	Higher scores indicate worse sleep.

CGI-I: Clinician Global Impression of Improvement; IRLS: International Restless Legs Syndrome Score; MOS: Medical Outcomes Study; PGI-I: Patient Global Impression of Improvement; RLS: restless legs syndrome.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.

- Consistent with a 'best available evidence approach,' within each category of study design, studies with larger sample sizes and longer durations were sought.
- Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Randomized Controlled Trials

The pivotal trial, published by Bogan et al (2023), was a multicenter, randomized, double-blind, sham-controlled clinical trial (RESTFUL Study) evaluating the efficacy and safety of TOMAC for treating medication-refractory RLS (N=133).[7,] Adults with moderate-to-severe primary RLS unresponsive to standard medications were randomized 1:1 to receive either active TOMAC or sham treatment for 4 weeks (stage 1), followed by 4 weeks of open-label active TOMAC for all participants (stage 2). The primary endpoint, the Clinical Global Impression of Improvement (CGI-I) responder rate, was significantly higher in the TOMAC group compared to the sham group (45% vs. 16%; difference: 28%; 95% CI: 14% to 43%; p=.00011). Secondary endpoints 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; p=.00093). No serious device-related adverse events occurred. Mild discomfort and site irritation were the most common side effects, both resolving quickly and decreasing over time. Limitations included some loss of blinding due to perceived treatment, short study duration, and lack of medication washout.

Singh et al (2024) conducted a multicenter, randomized, participant-blinded, sham-controlled clinical trial evaluating the efficacy and safety of TOMAC for treating moderate-to-severe RLS in both medication-naïve and medication-refractory adults (N=45).[8,] Participants were randomized 1:1 to receive either TOMAC or sham treatment over two weeks, with self-administered 30-minute sessions during symptomatic periods. The primary outcome was the change in IRLS score, and secondary outcomes included the Patient Global Impression of Improvement (PGI-I) and sleep quality indices (MOS-I and MOS-II). TOMAC significantly reduced IRLS scores compared to sham (-6.59 vs. -2.17; p=.004) (mean difference = 4.42; 95% CI: 1.57 to 7.26; p=.0040), with similar effect sizes in both medication-naïve and refractory subgroups. PGI-I responder rates were notably higher in the TOMAC group (36% vs. 4%; p=.0073). The device was well tolerated, with no serious adverse events; mild discomfort and site irritation were the most common issues. Limitations included the short treatment duration and underpowered sample.

Buchfuhrer et al (2021) conducted a randomized, participant-blinded, crossover trial investigating the efficacy and safety of TOMAC as a treatment for moderate-to-severe RLS (N=43).[9,] Participants self-administered both TOMAC and sham treatments nightly for 14 days each, in randomized order. The TOMAC device delivered 30-minute electrical stimulation sessions to the common peroneal nerve via wearable units. The primary outcome was change in the IRLS, with secondary outcomes including the CGI-I scale and numerical rating scales (NRS) for symptom severity. TOMAC significantly reduced IRLS scores by 6.81 points versus 3.38 for sham (p<.01), and yielded a 66% CGI-I responder rate compared to 17% for sham (p<.01). No moderate or serious device-related adverse events were reported; mild events included transient discomfort and skin irritation. Limitations included potential unblinding due to paresthesia, short treatment duration, and underpowered sample.

A summary of study characteristics and key results are presented in Tables 2 and 3. Study relevance and design and conduct limitations are summarized in Table 4 and 5.

Table 2. Summary of Key Randomized Controlled Trials Characteristics

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
					TOMAC	Sham
Bogan (2023)[7,]; RESTFUL Study	US	7	2021-2022	Individuals with medication-refractory moderate-to-	N=68	N=65

Study; Trial	Countries	Sites	Dates	Participants	Interventions	
				severe primary RLS		
Singh (2024)[8],	US	3	2022-2023	Adults with primary moderate-to-severe RLS	N=22 (medication-refractory, n=12; medication-naive, n=10)	N=23 (medication-refractory, n=13; medication-naive, n=10)
Buchfuhrer (2021)[9],	US	3	NR	Adults with moderate-to-severe primary RLS (IRLS ≥ 15)	N=21	N=18

IRLS: International Restless Legs Syndrome Score; NR: not reported; RLS: restless legs syndrome; TOMAC: tonic motor activation.

Table 3. Summary of Key Randomized Controlled Trials Results

Study	IRLS Score Change	CGI-I/PGI-I, %
Bogan (2023)[7],; RESTFUL Study		
TOMAC (N=68)	-7.2	45
Sham (N=65)	-3.8	16
p-value	.00093	.00011
Singh (2024)[8],		
TOMAC (N=22)	-6.59	36
Sham (N=23)	-2.17	4
p-value	.004	.0073
Buchfuhrer (2021)[9],		
TOMAC (N=21)	-6.81	66
Sham (N=18)	-3.38	17
p-value	<.01	<.01

CGI-I: Clinician Global Impression of Improvement; IRLS: International Restless Legs Syndrome Score; PGI-I: Patient Global Impression of Improvement.

Table 4. Study Relevance Limitations

Study	Population[a]	Intervention[b]	Comparator[c]	Outcomes[d]	Duration of Follow-up[e]
Bogan (2023)[7],; RESTFUL Study				7. No medication washout	1. Not sufficient duration for benefit
Singh (2024)[8],	3. Medication-naive patients were included				1. Not sufficient duration for benefit
Buchfuhrer (2021)[9],	3. Medication-naive patients were included				1. Not sufficient duration for benefit

The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.

[a] Population key: 1. Intended use population unclear; 2. Study population is unclear; 3. Study population not representative of intended use; 4, Enrolled populations do not reflect relevant diversity; 5. Other.

[b] Intervention key: 1. Not clearly defined; 2. Version used unclear; 3. Delivery not similar intensity as comparator; 4. Not the intervention of interest (e.g., proposed as an adjunct but not tested as such); 5: Other.

[c] Comparator key: 1. Not clearly defined; 2. Not standard or optimal; 3. Delivery not similar intensity as intervention; 4. Not delivered effectively; 5. Other.

[d] Outcomes key: 1. Key health outcomes not addressed; 2. Physiologic measures, not validated surrogates; 3. Incomplete reporting of harms; 4. Not establish and validated measurements; 5. Clinically significant difference

not prespecified; 6. Clinically significant difference not supported; 7. Other.
[e] Follow-Up key: 1. Not sufficient duration for benefit; 2. Not sufficient duration for harms; 3. Other.

Table 5. Study Design and Conduct Limitations

Study	Allocation[a]	Blinding[b]	Selective Reporting[c]	Data Completeness[d]	Power[e]	Statistical[f]
Bogan (2023)[7]; RESTFUL Study		4. Some loss of blinding due to perceived treatment				3. Confidence intervals only reported for between group differences
Singh (2024)[8]					1. Power calculations not reported	3. Confidence intervals only reported for between group differences
Buchfuhrer (2021)[Buchfuhrer MJ, Baker FC, Singh H, et al. Noninvasi.... 7(8): 1685-1694. PMID 33949942]		4. Some loss of blinding due to perceived treatment		6. Modified ITT used	1. Power calculations not reported	3. Confidence intervals not reported

CGI-I: Clinician Global Impression of Improvement; ITT: intent to treat.
The study limitations stated in this table are those notable in the current review; this is not a comprehensive gaps assessment.
[a] Allocation key: 1. Participants not randomly allocated; 2. Allocation not concealed; 3. Allocation concealment unclear; 4. Inadequate control for selection bias; 5. Other.
[b] Blinding key: 1. Participants or study staff not blinded; 2. Outcome assessors not blinded; 3. Outcome assessed by treating physician; 4. Other.
[c] Selective Reporting key: 1. Not registered; 2. Evidence of selective reporting; 3. Evidence of selective publication; 4. Other.
[d] Data Completeness key: 1. High loss to follow-up or missing data; 2. Inadequate handling of missing data; 3. High number of crossovers; 4. Inadequate handling of crossovers; 5. Inappropriate exclusions; 6. Not intent to treat analysis (per protocol for noninferiority trials); 7. Other.
[e] Power key: 1. Power calculations not reported; 2. Power not calculated for primary outcome; 3. Power not based on clinically important difference; 4. Other.
[f] Statistical key: 1. Analysis is not appropriate for outcome type: (a) continuous; (b) binary; (c) time to event; 2. Analysis is not appropriate for multiple observations per patient; 3. Confidence intervals and/or p values not reported; 4. Comparative treatment effects not calculated; 5. Other.

Nonrandomized Studies

Roy et al (2023) reported results of the 24-week open-label extension of the RESTFUL study evaluating the long-term efficacy and safety of TOMAC in adults with medication-refractory moderate-to-severe primary RLS.[10] Among 44 participants receiving TOMAC, 72.7% were CGI-I responders and 75.0% were PGI-I responders at week 24, with a mean IRLS score reduction of -11.3 points (95% CI: -8.8 to -13.9; p<.0001) compared to baseline. Sleep quality improved significantly (MOS-II: -17.2; MOS-I: -15.8; both p<.0001), and symptom frequency decreased by 46%, from 5.9 to 3.2 days/week. Compared to 59 control participants receiving standard care, TOMAC produced significantly greater improvements across all endpoints (CGI-I: 72.7% vs. 13.6%, p<.0001; IRLS: -11.3 vs. -5.4, p=.0001). Benefits partially persisted after 8 weeks of treatment cessation without rebound above baseline. Safety showed no grade ≥2 device-related adverse events and only mild, transient discomfort in 6.8% of participants. Limitations included non-randomized control assignment, open-label design, and use of patient-reported outcomes.

Buchfuhrer et al (2023) conducted a prospective, open-label, single-arm clinical trial evaluating whether TOMAC could enable opioid dose reduction in patients with refractory RLS.[11] Twenty adults on ≤60 morphine milligram equivalents (MME)/day were enrolled, having failed an average of 3.2 prior RLS medications and maintained stable opioid therapy for an average of 5.3 years. Participants self-administered 30-minute TOMAC sessions bilaterally over the peroneal nerve during symptom onset. Opioid doses were tapered every 2–3 weeks until the CGI-I score exceeded 5. The primary endpoint, ≥20% opioid dose reduction with CGI-I ≤5, was achieved by 70% of participants (14/20), exceeding the prespecified 50% success criterion. The mean opioid dose reduction was 29.9% (SD 23.7%), from 39.0 to 26.8 MME/day. Of 15 participants who had any successful opioid dose reduction the average CGI-I score at the reduced dose was 4.0 (95% CI: 3.3 to 4.7) and the average change in IRLS score from baseline at the reduced dose was 3.4 (95% CI: 0.4 to 6.4). Adherence to TOMAC was 85%, and all adverse events were mild and non-serious. Limitations included the underpowered sample, lack of a control group, short study duration, and open-label design, which may introduce bias.

A summary of study characteristics and key results are presented in Tables 6 and 7.

Table 6. Summary of Key Nonrandomized Study Characteristics

Study	Study Type	Country	Dates	Participants	TOMAC	Follow-Up
Roy (2023)[10]	Prospective, open-label extension	US	2021-2022	Individuals with medication-refractory moderate-to-severe primary RLS	N=103 (n=44, TOMAC; n=59, Control)	24 weeks
Buchfuhrer (2023)[11]	Prospective, open-label, single-arm	US	2021-2023	Individuals with with medication-refractory primary RLS	N=20	2-3 weeks

RLS: restless legs syndrome; TOMAC: tonic motor activation.

Table 7. Summary of Key Nonrandomized Study Results

Study	IRLS, Change from Baseline (95% CI)	CGI-I Responder Rate, % (95% CI)
Roy (2023)[10]		
	24 Weeks	24 Weeks
TOMAC (n=44)	-11.3 (-8.8 to -13.9)	72.7 (58.2 to 83.7)
Control (n=59)	-5.4 (-3.7 to -7.2)	13.6 (7.0 to 24.5)
p-value	<.0001	<.0001
Buchfuhrer (2023)[11]		
	2 to 3 Weeks[a]	2 to 3 Weeks[a]
TOMAC (N=15)[b]	3.4 (0.4 to 6.4)	4.0 (3.3 to 4.7)
p-value	NR	NR

[a]Outomes reported at maximum reduced dose.
[b]Outcomes reported for participants with any successful opioid reduction.
CGI-I: Clinician Global Impression of Improvement; CI: confidence interval; IRLS: International Restless Legs Syndrome Score; NR: not reported.

Systematic Reviews and Meta-Analyses

Two systematic reviews and meta-analyses have been published evaluating the efficacy and safety of TOMAC for RLS.[12,13] Winkleman et al (2025) only included 2 of the available RCTs and will not be further discussed in this review.

Mohamed et al (2025) conducted a systematic review and meta-analysis evaluating the efficacy and safety of TOMAC for moderate-to-severe RLS.[12] Three RCTs and an open-label extension study (N=320) were included, with primary outcomes being changes in International IRLS scores, PGI-I responder rates, and sleep quality indices (MOS-I, MOS-II). TOMAC significantly reduced IRLS scores compared to sham (mean difference [MD]: -3.66; 95% CI: -5.07 to -2.25; p<.00001), improved PGI-I

response (risk ratio [RR]: 3.16; 95% CI: 1.35 to 7.37; p=.008), and enhanced sleep quality (MOS-I MD: -9.28; p <.00001; MOS-II MD: -10.06; p <.00001). Adverse events were more frequent with TOMAC (RR: 1.68; p=.004) but were mild and self-limiting, with no severe or device-related discontinuations. Limitations include the small number of RCTs with underpowered samples sizes, inclusion of medication-naive individuals in the overall analysis, short follow-up durations, and limited data on long-term safety.

An overview of included trials and characteristics of the systematic review and meta-analysis are summarized in Tables 8 and 9. Results of the systematic review and meta-analysis are summarized in Table 10.

Table 8. Comparison of Trials Included in Systematic Reviews and Meta-Analyses

Study	Mohamed (2025)[12]
Singh (2024)[8]	●
Bogan (2023)[7]	●
Roy (2023)[10]	●
Buchfuhrer (2021)[9]	●

Table 9. Systematic Reviews and Meta-Analyses Characteristics

Study	Dates	Trials	Participants	N (Range)	Design	Duration
Mohamed (2025)[12]	2021-2024	4	Adult with moderate-to-severe RLS	320 (39-133)	RCTs and open-label extension	2 to 24 weeks

RCT: randomized controlled trial; RLS: restless legs syndrome.

Table 10. Systematic Reviews and Meta-Analyses Results

Study	IRLS Mean Difference (Change from Baseline)	CGI-I/PGI-I Risk Ratio	MOS-I Mean Difference (Change from Baseline)	MOS-II Mean Difference (Change from Baseline)	Any AE Risk Ratio	Device-Related AE Risk Ratio	Grade 1 AE Risk Ratio
Mohamed (2025)[12]							
Overall	N=250	N=178	N=178	N=178	N=250	N=250	N=250
Pooled effect (95% CI)	-3.66 (-5.07 to -2.25)	3.16 (1.35 to 7.37)	-9.28 (-13.43 to -5.13)	-10.06 (-14.17 to -5.94)	1.68 (1.18 to 2.40)	1.90 (1.22 to 2.94)	1.7 (1.17 to 2.46)
p-value	<.00001	.004	<.00001	<.00001	.004	.004	.005
I^2 (P)	0% (.83)	20% (.26)	0% (.85)	0% (.81)	0% (.96)	0% (.66)	0% (.51)
Medication Refractory	N=198	N=158					
Pooled effect (95% CI)	-4.50 (-7.57 to -1.46)	2.72 (1.58 to 4.70)					
p-value	.008	.0003					
I^2 (P)	0% (.95)	0% (.64)					

AE: adverse event; CGI-I: Clinician Global Impression of Improvement; IRLS: International Restless Legs Syndrome Score; MOS: Medical Outcomes Study; PGI-I: Patient Global Impression of Improvement; RLS: restless legs syndrome.

Section Summary: Tonic Motor Activation in Individuals with Restless Legs Syndrome Refractory to Medication

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.

Summary of Evidence

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.

Supplemental Information

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the evidence review conclusions.

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Academy of Sleep Medicine

In 2025, the American Academy of Sleep Medicine (AASM) published clinical practice guidelines on the treatment of RLS and periodic limb movement disorder.[14,] The AASM gave a conditional recommendation with moderate certainty of evidence for the use of bilateral high-frequency peroneal nerve stimulation over no peroneal nerve stimulation in adults with RLS.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials

Some trials that might influence this review are listed in Table 11.

Table 11. Summary of Key Trials

NCT No.	Trial Name	Planned Enrollment	Completion Date
Ongoing			
NCT06076499[a]	A Post-Market Observational Clinical Study to Determine the Long-Term Effectiveness and Safety of the Noctrix NTX100 TOMAC (Tonic Motor Activation) System for the Treatment of Restless Legs Syndrome - The THRIVE Study	325 (estimated)	Dec 2026
NCT07144631	PENS-P: Peroneal Electrical Nerve Stimulation in Pregnancy for Restless Legs Syndrome (RLS)	15 (estimated)	Oct 2026
Completed			
NCT04698343[a]	Exploratory Study Assessing the Response of Restless Legs Syndrome (RLS) Patients to Non-invasive Peripheral Nerve Stimulation (NPNS) During Opioid Medication Reduction	21 (actual)	Mar 2023
NCT05196828[a]	Open-label Extension Study to Evaluate Longer-Duration Response to the NTX100 Neuromodulation System for Patients With Medication-Refractory Primary Restless Legs Syndrome (RLS)	103 (actual)	Nov 2022
NCT04874155[a]	A Multi-Center, Randomized, Double-Blind, Sham-Controlled Study to Evaluate the NTX100 Neuromodulation System for Patients With Medication-Refractory Primary Restless Legs Syndrome (RLS) - The RESTFUL Study	133 (actual)	Apr 2022
NCT04700683[a]	Chronic Efficacy and Usability of Transcutaneous Electrical Nerve Stimulation in Subjects With Restless Leg Syndrome (RLS)	43 (actual)	Mar 2020
Unpublished			
NCT05214963[a]	Exploratory Clinical Study to Assess Tolerability, Safety, and Response to Non-invasive Peripheral Nerve Stimulation (NPNS) in Medication-naïve and Medication-refractory Restless Legs Syndrome (RLS) Patients	58 (actual)	Oct 2023

NCT: national clinical trial.

[a] Denotes industry-sponsored or cosponsored trial.

References

1. Charlesworth JD, Adlou B, Singh H, et al. Bilateral high-frequency noninvasive peroneal nerve stimulation evokes tonic leg muscle activation for sleep-compatible reduction of restless legs syndrome symptoms. J Clin Sleep Med. Jul 01 2023; 19(7): 1199-1209. PMID 36856064
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Documentation for Clinical Review

- No records required

Coding

The list of codes in this Medical Policy is intended as a general reference and may not cover all codes. Inclusion or exclusion of a code(s) does not constitute or imply member coverage or provider reimbursement policy.

Type	Code	Description
CPT®	None	
HCPCS	A4544	Electrode for external lower extremity nerve stimulator for restless legs syndrome
	E0743	External lower extremity nerve stimulator for restless legs syndrome, each

Policy History

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

Effective Date	Action
03/01/2026	New policy.

Feedback

Blue Shield of California is interested in receiving feedback relative to developing, adopting, and reviewing criteria for medical policy. Any licensed practitioner who is contracted with Blue Shield of California or Blue Shield of California Promise Health Plan is welcome to provide comments, suggestions, or concerns. Our internal policy committees will receive and take your comments into consideration. Our medical policies are available to view or download at www.blueshieldca.com/provider.

For medical policy feedback, please send comments to: MedPolicy@blueshieldca.com

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as member health services contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member health services contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.

Appendix A

POLICY STATEMENT	
BEFORE	AFTER Blue font: Verbiage Changes/Additions
New Policy Policy Statement N/A	Tonic Motor Activation for Restless Legs Syndrome 1.01.32 Policy Statement: I. Tonic motor activation as a treatment for restless legs syndrome refractory to medication is considered **investigational**.