KAISER PERMANENTE® Mid-Atlantic States	**Nidra TOMAC Therapy** **Medical Coverage Policy**

UTILIZATION * ALERT*

- Prior to use of this MCP for evaluation of medical necessity, benefit coverage MUST be verified in the member's EOC or benefit document.
- For Medicare members, please consult the Medicare Coverage Database.

I. **Procedure: Nidra or NTX100 Tonic Motor Activation (NTX100 TOMAC) system**

II. Overview

The **NTX100 Tonic Motor Activation (NTX100 TOMAC) system** or **Nidra TOMAC Therapy (E0743)** is a non-invasive peripheral nerve stimulation device for Restless Legs Syndrome (RLS) relief of adults who are drug-refractory to RLS medication. It features a pair of wearable devices that are externally worn on each lower extremity to deliver bilateral electrical stimulation on the peroneal nerves.

III. **Clinical Indication**

Nidra, TOMAC therapy is medically necessary when **ALL** of the following are met.

A. Confirmed diagnosis of severe Restless Legs Syndrome (RLS) that is recalcitrant, medication refractory; **and**

B. Presence of documentation that RLS' exacerbating factors (such as alcohol, caffeine, antihistaminergic, serotonergic, antidopaminergic medications, untreated obstructive sleep apnea or other co-existing sleep disorders) have been addressed; **and**

C. Documentation that all other pharmacologic treatments or in combination with non-pharmacologic strategy for RLS were tried but ineffective, unable to be tolerated, contraindicated or failed

1. Primary RLS

a. Pharmacologic therapy

i. Gabapentin;
ii. Gabapentin enacarbil;
iii. Cabergoline;
iv. Pregabalin;
v. Intravenous ferric carboxymaltose in patients with appropriate iron status;

vi. Intravenous low molecular weight Iron dextran in patients with appropriate iron status;
vii. Ferrous sulfate in patients with appropriate iron status;
viii. Dipyridamole; or
ix. With caution, low dose opioids or extended-release oxycodone

2. **Secondary RLS**
There is documentation that treatment of the RLS' underlying cause was attempted but failed to reduce RLS symptoms.

IV. Exclusion

Except for severe recalcitrant, medication-refractory RLS, the use of Nidra neuromodulation device for any other condition is not medically necessary and considered to be experimental and investigational.

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Approval History

Effective June 01, 2016, state filing is no longer required per Maryland House Bill HB 798 – Health Insurance – Reporting

Date approved by RUMC	Date of Implementation
07/22/2025	07/22/2025

*The Regional Utilization Management Committee received delegated authority in 2011 to review and approve designated Utilization Management and Medical Coverage Policies by the Regional Quality Improvement Committee.

Note: Kaiser Permanente Mid-Atlantic States (KPMAS) include referral and authorization criteria to support primary care and specialty care practitioners, as appropriate, in caring for members with selected conditions. Medical Coverage Policies are not intended or designed as a substitute for the reasonable exercise of independent clinical judgment by a practitioner in any particular set of circumstances for an individual member.

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