TREMOR ANALYSIS

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

The section identified as “Description” defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as “Criteria” defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

Description:

Analysis that uses devices attached to an individual's arm to measure tremor. Once the devices are attached the individual is asked to do several tasks such as resting with their hands in their lap, holding their arms straight out in front of them and extending their arm and touching their nose. Tremor analysis is used to diagnose and differentiate types of tremors and to assess tremor response or control of treatment interventions.
TREMOR ANALYSIS (cont.)

Criteria:

- Tremor analysis is considered **medically necessary** with documentation of **ANY** of the following:
  1. To diagnose and differentiate the type of tremor
  2. To assess tremor response or control of treatment interventions

- Tremor analysis for all other indications not previously listed is considered **experimental or investigational** based upon:
  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

Resources:


FDA 510K Summary for Kinesia™:

- FDA-approved indication: To monitor physical motions and muscle activity to quantify kinematics of movement disorder symptoms such as tremor and assess activity in any instance where quantifiable analysis of motion and muscle activity is desired.