WHEEZE RATE AND COUGH MONITORING DEVICES

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.

This Medical Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

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.

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Description:

Acoustic markers such as wheezes, rhonchi and cough are recorded using proprietary lung-sound sensors. The data is analyzed by patented algorithms and signal-processing techniques.
WHEEZE RATE AND COUGH MONITORING DEVICES (cont.)

Criteria:

➢ Use of intermittent or continuous computerized or electronic wheeze and/or cough detectors for all indications are 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, and
4. Insufficient evidence to support improvement outside the investigational setting.

Resources:


WHEEZE RATE AND COUGH MONITORING DEVICES (cont.)

Resources: (cont.)


FDA 510 (k) Approval Database for Personal Wheezometer®:

- FDA-approved indication: Intended for quantifying the presence of wheezing. This device should be used under the direction of a physician or licensed healthcare professional for monitoring acoustic pulmonary functions.

FDA 510 (k) Approval Database for PulmoTrack 5050 Wholter®, Model 505:

- FDA-approved indication: Intended to acquire record and store ambulatory respiratory activity from patients for up to 24 hours. It works in concert with the PulmoTrack® Series for playback, review, analysis, editing and printing of respiratory data. It is indicated for but not limited to recording of signals that reflect symptoms such as wheeze and cough.

FDA 510K Approval Database for SonoSentry™ WheezeRate™ Detector:

- FDA-approved indication: Intended to detect and record abnormal breath sounds (continuous adventitious breathe sounds/CABS) at the windpipe (trachea). Reported as WheezeRate in adults and children 2 years and older, it represents the percentage of abnormal breath sound detected during the measurement time.