MEDICAL POLICY

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<tr>
<th>POLICY TITLE</th>
<th>PHARYNGOMETRY AND RHINOMETRY</th>
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<tr>
<td>POLICY NUMBER</td>
<td>MP 2.088</td>
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| Original Issue Date (Created): | 3/1/2012 |
| Most Recent Review Date (Revised): | 11/29/2016 |
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I. POLICY

Pharyngometry and rhinometry are considered *investigational* as techniques for screening, diagnosis, or treatment planning in persons with known or suspected obstructive sleep apnea (OSA) and for all other indications. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with these procedures.

**Cross-references:**
- MP 2.045 Diagnosis and Medical Management of Obstructive Sleep Apnea
- MP 1.128 Surgical Treatment of Snoring and Obstructive Sleep Apnea

II. PRODUCT VARIATIONS

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

**FEP PPO***

* The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity.

III. DESCRIPTION/BACKGROUND

Rhinomanometry, acoustic rhinometry, and optical rhinometry are techniques to objectively measure nasal patency. Several clinical applications are proposed including allergy testing, evaluation of obstructive sleep apnea, and patient assessment prior to nasal surgery.
Nasal patency is a complex clinical issue that can involve mucosal, structural and psychological factors. The perception of nasal obstruction is subjective and does not always correlate with clinical examination of the nasal cavity, making it difficult to determine which therapy might be most likely to restore satisfactory nasal breathing. Therefore, procedures that objectively measure nasal patency have been sought. Discussion of 3 techniques that could potentially be useful in measuring nasal patency follows.

Rhinomanometry is a test of nasal function that measures air pressure and the rate of airflow in the nasal airway during respiration. These findings are used to calculate nasal airway resistance. Rhinomanometry is intended to be an objective quantification of nasal airway patency.

Acoustic rhinometry is a technique intended for assessment of the geometry of the nasal cavity and nasopharynx and for evaluating nasal obstruction. The technique is based on an analysis of sound waves reflected from the nasal cavities.

Optical rhinometry uses an emitter and a detector placed at opposite sides of the nose and can detect relative changes in nasal congestion by the change in transmitted light. This technique is based on the absorption of red/near-infrared light by hemoglobin and the endonasal swelling-associated increase in local blood volume.

Acoustic pharyngometry also uses acoustic reflection for volume analysis of oro-pharyngeal parameters to establish a correlation between morpho-volumetric variations of oro-pharyngolaryngeal spaces and the presence and severity of disease. Acoustic pharyngometry is a method of investigating obstruction in sleep disordered breathing together with other exams such as cephalometrics, computed tomography, magnetic resonance imaging and fibronasopharngolaryngoscopy etc. It is also used to monitor medical and surgical treatments for the management of obstructive sleep apnea.

**Acoustic Pharyngometer**
The Eccovision® Acoustic Pharyngometer (Sleep Group Solutions) is a device which uses acoustic reflection technology to measure the patient’s pharyngeal airway size and stability from the Oral Pharyngeal Junction to the Glottis. Sound waves are projected down the airway and reflected back in such a way that the Pharyngometer software can analyze and quantify changes in the airways cross-sectional area. The data is graphically displayed showing the relationship between the cross-sectional area of the airway and distance in centimeters. Studies suggest a relationship between the existence of obstructive sleep apnea and a narrow, collapsible, airway. The test is completed with the patient awake and seated during the exam which takes 2-5 minutes to complete.

**Acoustic Rhinometer**
The Eccovision® Acoustic Rhinometer (Sleep Group Solutions) also uses acoustic reflection technology and measures nasal patency and maps out the topography of the nasal airway.
identifying the location and severity of airway obstruction. The test is completed with the patient awake and seated during the exam which takes 30 seconds to complete.

IV. RATIONALE

Literature published through 2006 suggested that that acoustic manometry and rhinomanometry are frequently used in research studies in which objective measurements of nasal obstruction may be important to determine treatment effects. However, no studies were found that investigated how use of these diagnostic procedures would improve outcomes compared to standard approaches, such as patient self-assessment. Moreover, no studies were identified that evaluated the reliability or accuracy of these diagnostic procedures compared to patient self-assessment. Thus, rhinomanometry and acoustic rhinometry were considered investigational.

A search of the MEDLINE database identified several papers from Germany that described the development of optical rhinometry; one compared optical rhinometry with rhinomanometry using histamine, allergens, solvent, and xylometazoline hydrochloride for nasal provocation in 70 normal subjects. There was a higher correlation between subject’s rating of nasal congestion and optical rhinometry ($r = 0.84$) than for rhinomanometry ($r = -0.69$). Although this early work suggested that optical rhinometry may provide a quantitative measurement that is more similar to patient’s assessment of nasal congestion than rhinomanometry, information on the clinical utility of these measurements was still lacking. Therefore, rhinomanometry, acoustic rhinometry, and optical rhinometry (an addition to the policy) were considered investigational; the policy statement was unchanged.

2010 Update

No recent studies were identified that evaluated clinical applications of optical rhinometry. A systematic review of studies on nasal patency and rhinomanometry and acoustic rhinometry was identified. To be included, studies needed to report correlations between subjective patient assessment and one of two objective outcomes, nasal airway resistance if rhinomanometry was used or minimal cross-sectional area if acoustic rhinometry was used. The review was not limited to studies of any particular application of the diagnostic tests and included presurgical use, allergy testing, and other uses. Sixteen studies were identified, none of which were randomized controlled trials. Sample sizes of individual studies ranged from 10-200. Because of differences in study design, findings were not pooled. The authors stated that they found “almost every possible combination of correlations or lack thereof in conjunction with the variables included.” They further stated that there was no clear relationship between study design and the likelihood of finding a correlation, and concluded that there was an uncertain association between patient self-assessment of patency and objective measurements with rhinomanometry and acoustic rhinometry.
A study conducted in Turkey included 7,283 individuals with the sensation of nasal obstruction and compared nasal airway resistance values assessed by rhinomanometry in several subgroups. Nasal airway resistance values were significantly higher in individuals with nasal septal deviation, both with and without allergic rhinitis, than in individuals with normal anatomy. Although this study had a large sample size, the sample was limited to individuals with a sensation of nasal obstruction so could not calculate correlations between patient self-assessment and rhinomanometry.

The 2010 search also identified one study examining the relationship between rhinomanometry/acoustic rhinometry and patient satisfaction in patients prior to nasal surgery. The study, conducted in Finland by Pirila and Tikanto, included 157 patients presenting for septal surgery due to a clinically obstructing nasal septal deviation. Patients were examined with anterior rhinoscopy, and with rhinomanometry and acoustic rhinometry at preoperative and 1-year follow-up visits. The procedures were performed both before and after decongestion. At the preoperative visit, the surgeon classified the degree of septum deviation as “very severe,” “severe,” “moderate,” or “mild.” The decision to operate was made entirely according to clinical judgment. At the 1-year follow-up visit, patients were asked by the operating surgeon to classify the benefit from their surgery on a subjective 4-point scale: “very high,” “high,” “moderate,” or “low.” No other clinical outcome measures were assessed. Follow-up data were potentially available for 117 of 157 (75%) patients; 5 did not return for follow-up, and 35 patients were excluded because it was found during surgery that they needed a turbinectomy. Septum classification data were reported for 110 patients (data on 7 patients were missing); 20 were classified as “very severe,” 45 as “severe,” and 45 as “moderate” or “mild.” Postoperative self-assessment data were reported for 114 patients (data on 3 patients were missing). The benefit of the surgery was classified as “very high” in 18 patients, “high” in 58 patients, “moderate” in 25 patients, and “low” in 13 patients. The responses were reclassified into 2 categories for the analysis; one category included the 76 patients who said they obtained “very high” or “high” benefit from the surgery, and the other included the 38 patients who said they had “moderate” or “low” benefit. The investigators examined various preoperative parameters to identify factors associated with the postoperative satisfaction ratings. Of the 26 parameters examined, the factor with the highest association was the preoperative post-decongestion overall minimum cross-section area on the deviation side from acoustic rhinometry. This association was statistically significant for all patients (p<0.01) and for the 85 patients classified preoperatively as having less than “very severe” deviations (p<0.01), but not for the 14 patients classified as having “very severe” deviations. The rhinomanometry parameter with the highest impact was the preoperative post-decongestion flow ratio; this also was significantly associated with patient satisfaction for all patients (p<0.011) and patients with deviations classified as “less severe” (p=0.026), but not for patients classified as having “very severe” deviations. Using receiver operating characteristic (ROC) curve analysis, the authors found that the optimum cut-off value for the overall close to 1:2. Using these cutoffs, the sensitivity of the tests for predicting patient satisfaction was around 65% and the specificity was around 60%. The authors concluded that anterior rhinoscopy was
sufficient for screening surgical candidates with severe deviation, but that rhinomanometry and acoustic rhinometry may be useful for screening patients with milder deviations. This study should be considered preliminary because the investigators examined multiple parameters to identify those that were significantly correlated with patient satisfaction. Additional prospective studies are needed to confirm these associations, as well as the cutoff values proposed in this study. Additional studies are also needed to demonstrate potential clinical utility.

Another limitation of the Pirila and Tikanto study was that the patient satisfaction measure was not validated and could be interpreted differently by different patients, and that patients were queried by the operating surgeon rather than an objective assessor.

2015 Update

No studies were found to support a change in policy statements. There is inadequate evidence of the clinical utility. These tests have not been demonstrated to be superior to physical examination, nasal endoscopy or CT imaging in selecting patients who would benefit from medical and/or surgical management of their nasal obstruction. Clinical studies published in the peer-reviewed medical literature are necessary to determine the value of rhinomanometry and acoustic rhinometry in the diagnosis and clinical management of patients with nasal obstruction.

2016 Update

Review of the literature revealed no new information that would alter the conclusions reached above. Therefore, the policy statement is unchanged.

Technology Assessments, Guidelines and Position Statements

None identified

Medicare National Coverage

No national coverage determination.

V. DEFINITIONS

510(K) is a premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

ACOUSTIC REFLECTION technology is based on the analysis of sound waves that are launched from a loudspeaker and travel along a wave tube into the subject’s airways where they are
reflected. Measurement of differences in the reflected wave signals enables a graphic representation of the variations in pharyngeal cross-sectional area at several anatomic levels.

ACOUSTIC PHARYNGOMETRY is a non-invasive technique using acoustic reflection that quantifies geometrically complex pharyngeal dimensions in order to assess the upper airway for possible site(s) of obstruction.

ACOUSTIC RHINOMETRY is a non-invasive technique using acoustic reflection to study nasal physiology. It may be used to evaluate the nasal cavity to aid in the identification of fixed lesions such as septal deviations or alterations in cross-sectional area induced by allergens or drugs.

VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

VII. DISCLAIMER

Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.
IX. REFERENCES


Other:


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**Sleep Group Solutions, Eccovision [Website]: http://sleepgroupsolutions.com/. Accessed September 13, 2016.**


### X. POLICY HISTORY

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<tr>
<th>MP- 2.088</th>
<th>CAC 10/25/2011 - New policy</th>
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<tr>
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<td>CAC 10/30/12 – Consensus review. No change to policy statements. References updated. Codes reviewed 10/31/12</td>
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<td>01/14/2013- Codes updated</td>
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<td>CAC 11/24/15 Consensus review. No change to policy statements. Reference and rationale update. Coding reviewed.</td>
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<td>CACA 11/29/16 Consensus review. No change to policy statements. Background, rationale and references updated. Variation reformating. Coding Reviewed.</td>
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