Title: Rhinomanometry and Acoustic / Optical Rhinometry

**Professional**
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**Institutional**
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**DESCRIPTION**
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.

**Background**
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. Three techniques that could potentially be useful in measuring nasal patency are as 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.

The techniques are proposed for use in allergy testing, comparing decongestive action of antihistamines and corticosteroids, for evaluation of obstructive sleep apnea, and for assessment of the patient prior to nasal surgery.

**Regulatory Status**
Ten models of rhinomanometers or acoustic rhinometers received marketing clearance by the U.S. Food and Drug Administration (FDA) 510(k) mechanism between 1984 and 2002. Optical rhinometry is a technique developed in Europe; as of 2010, no devices had received clearance for marketing in the United States.

**POLICY**
Rhinomanometry and acoustic / optical rhinometry are considered **experimental / investigational**.

**RATIONALE**
The MEDLINE database was searched at the time of policy development and the policy was updated regularly with literature searches. 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. (1-11) 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 for the period of January 2007 through April 2008 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. (12) 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**

The MEDLINE database was searched for the period of May 2008 through January 2010. 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. (13) 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 state that they found “almost every possible combination of correlations or lack thereof in conjunction with the variables included.” They further state that there was no clear relationship between study design and the likelihood of finding a correlation, and conclude that there is an uncertain association between patient self-assessment of patency and objective measurements with rhinomanometry and acoustic rhinometry. A study conducted in Turkey included 7283 individuals with the sensation of nasal obstruction and compared nasal airway resistance values assessed by rhinomanometry in several subgroups. (14) 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. (15) 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 pre-operative 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 was 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 two 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 minimum cross-section area on the deviation side was approximately 0.40 cm² and for the flow ratio was 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 is 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.

Summary
Overall, the scientific evidence does not permit conclusions about the effect of rhinomanometry, acoustic rhinometry or optical rhinometry on net health outcome. To date, no studies have been published that evaluate the clinical utility of these tests. That is, none of the studies identified have prospectively compared patient outcomes with and without the use of one or more of these tests for any clinical condition. Therefore, the technologies are considered investigational.

Technology Assessments, Guidelines and Position Statements
None identified.
CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. 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.

CPT/HCPCS

92512 Nasal function studies (e.g., rhinomanometry)

Diagnoses

Experimental / investigational for all diagnoses related to this policy.

REVISIONS

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In Coding section:
- Removed diagnoses and added "Experimental / investigational for all diagnoses related to this policy."

REFERENCES


