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Rhinomanometry, Acoustic Rhinometry, Optical Rhinometry and Acoustic Pharyngometry

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Related Policies (if applicable)
None

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Coverage

Rhinomanometry, acoustic rhinometry and optical rhinometry **are considered experimental, investigational, and/or unproven.**

Acoustic pharyngometry **is considered experimental, investigational and/or unproven** for all indications.

Policy Guidelines

None.

Description

Rhinomanometry, Acoustic Rhinometry and Optical Rhinometry

Rhinomanometry, acoustic rhinometry (AR), and optical rhinometry are techniques to objectively measure nasal patency. Several clinical applications are proposed including allergy testing, evaluation of obstructive sleep apnea (OSA) 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. (1) Therefore, procedures that objectively measure nasal patency have been sought. Three techniques that could potentially be useful in measuring nasal patency are as follows:

1. 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 and provides a functional measurement of the pressure/flow relationships during the respiratory cycle. Rhinomanometry is intended to be an objective quantification of nasal airway patency and may be used for the assessment of nasal decongestion, polyps, enlarged adenoids and for evaluating changes in the volume of the nasal passage due to allergies, surgical procedures or medications. (2)
2. AR is a technique intended for assessment of the geometry of the nasal cavity and nasopharynx and for evaluating nasal obstruction. A spark generator produces an acoustic click, which travels past a microphone and is directed through the nasal passages via a conduit; the click is reflected back from the various nasal contours and received by the microphone. A computer program analyzes the sounds, producing a graph of the cross-sectional area (CSA) of the nasal passage from the vestibule to the nasopharynx. AR gives an anatomic description of a nasal passage and is used to evaluate nasal patency and may be used for the assessment of fixed lesions (e.g., septal deviations, or alterations in CSA induced by allergens or drugs). (3, 4)
3. Optical rhinometry is a test that uses an emitter and a detector placed at opposite sides of the nose to provide continuous measurement of changes in blood flow (optical density) within the nasal vessels while simultaneously monitoring oxygen saturation by evaluating change(s) 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. Optical rhinometry may be used to provide real-time measurements in the case of polyps, perforation, and deviated septum. (5)

Acoustic Pharyngometry

An acoustic pharyngometry (Eccovision®) device uses acoustic reflection technology to map the size, structure and collapsibility of the oral airway. The device measures pharyngeal airway size and stability from the oral pharyngeal junction to the glottis. The pharyngometer graphically displays the relationship between the CSA of the airway and distance down the airway in centimeters. Sound waves are projected down the airway and reflected back so that the software can analyze and quantify changes in the airways. Acoustic pharyngometry is minimally invasive and takes 2-5 minutes to complete. (6) Several clinical applications have been

proposed including but not limited to the assessment of patients who may benefit from mandibular appliances and for the evaluation of the site and severity of airway obstruction. (7)

Regulatory Status
Several models of rhinomanometers or ARs have received marketing clearance by the United States (U.S.) Food and Drug Administration (FDA) through the 510(k)-clearance process. (2, 8). Refer to <https://www.accessdata.fda.gov> for a comprehensive list of FDA approved devices.

Optical rhinometry is a technique developed in Europe; to date, no devices have received clearance for marketing in the U.S.

In 2002, the acoustic pharyngometry (Eccovision®) device received marketing clearance by the U.S. FDA through the 510(k)-clearance process. (9)

FDA product code: BXQ

Rationale

This policy was originally created in 1990 and has been updated regularly with searches of the PubMed database. Most recently, the literature was searched through March 11, 2024. Following is a summary of the key literature to date.

Medical policies assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life (QOL), and ability to function-including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Rhinomanometry, Acoustic Rhinometry and Optical Rhinometry

In 2009, Andre and colleagues performed a systematic review of studies on nasal patency, rhinomanometry and acoustic rhinometry (AR). (10) 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 (MCA) if AR 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 RCTs. Sample sizes of individual studies ranged from 10-200. Due to 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 AR.

In 2009, a study conducted in Turkey by Canakcioglu et al. included 7283 individuals with the sensation of nasal obstruction and compared nasal airway resistance values assessed by rhinomanometry in several subgroups. (11) 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; therefore, it could not calculate correlations between patient self-assessment and rhinomanometry.

Another study examining the relationship between rhinomanometry and AR and patient satisfaction in patients prior to nasal surgery was examined. (12) This 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 AR at preoperatively and at 1-year follow-up. 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. 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 cm^2 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 AR 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.

In 2014, Lange et al. (13) evaluated AR in persons recruited from the general population and diagnosed with chronic rhinosinusitis (CRS) according to European Position Paper on Rhinosinusitis and Nasal Polyps (EPOS)**.** The criteria include subjective symptoms, such as nasal obstruction, and objective findings by endoscopy. AR is an objective method to determine nasal cavity geometry. AR measurements in persons with and without CRS based on the clinical EPOS criteria were investigated. As part of a trans-European study, 362 persons, comprising 91 persons with CRS and 271 persons without CRS were examined by an otolaryngologist including rhinoscopy. Minimum cross-sectional area, distance to minimum cross-sectional area, and volume in the nasal cavity were measured by AR and all participants underwent peak nasal inspiratory flow (PNIF) and allergy test. A difference in AR was found before and after decongestion, but no difference was seen between CRS patients and controls. Positive correlation between AR and PNIF was found, and AR was capable of identifying mucosal edema and septum deviation visualized by rhinoscopy. In conclusion, AR, as a single instrument, was not capable of discriminating persons with CRS from persons without CRS in the general population. However, AR correlates well with PNIF and was capable of identifying septum deviation and mucosal edema.

In 2014, Aziz et al. (14) performed a systematic review of the measurement tools utilized for the diagnosis of nasal septal deviation (NSD). Electronic database searches were performed and resulted in 23 abstracts. Fifteen abstracts were excluded due to lack of relevance. A total of 8 studies were systematically reviewed. The authors concluded that diagnostic modalities such as AR, rhinomanometry and nasal spectral sound analysis may be useful in identifying NSD in the

anterior region of the nasal cavity, but these tests in isolation are of limited utility. The authors concluded that compared to anterior rhinoscopy, nasal endoscopy, and imaging the above-mentioned tests lack sensitivity and specificity in identifying the presence, location, and severity of NSD.

There is no standardized method for the objective assessment of the pediatric nasal airway; therefore in 2015, Isaac et al. (15) studied the correlation between AR, subjective symptoms, and endoscopic findings in symptomatic children with nasal obstruction. A cross-sectional, exploratory, diagnostic study prospectively collected data from a multidisciplinary airway clinic pulmonology, orthodontics, and otolaryngology) database at a tertiary academic referral center. Data was collected over a 2-year period (2010-2012) from 65 non-syndromic children (38 boys) 7 years and older (range, 7-14 years), presenting with persistent nasal obstructive symptoms for at least 1 year, without signs and symptoms of sinus disease. We collected patient demographics and medical history information including allergy, asthma, and sleep-disordered breathing. Subjective nasal obstruction was scored using VAS. Sleep-disordered breathing was assessed using overnight pulse oximetry. The adenoid size, septal position, and visual severity of chronic rhinitis (endoscopic rhinitis score [ERS]) were rated on nasal endoscopy (NE) by 2 independent reviewers and validated by agreement. AR was undertaken before and after use of a decongestant. Outcomes included correlation and multiple regression analyses were performed to explore interrelationships between subjective nasal obstruction visual analog scale (VAS), AR, and nasal endoscopy. Among the 65 patients, 28 (43%) had symptoms of sleep-disordered breathing, 14 (22%) had allergic rhinitis, 10 (15%) had asthma, 27 (41%) had grade 3 or 4 adenoidal obstruction, 28 (43%) had an ERS of 2, 6 (9%) had an ERS of 3, and 19 (29%) had septal deviation. Significant correlations were found between subjective nasal obstruction VAS score and ERS ($r = -0.364$, $P = .003$), ERS and MCA before decongestion ($r = -0.278$, $P = .03$), and adenoid size and calculated nasal resistance after decongestion ($r = 0.430$, $P < .001$). Multiple regression analysis showed that the ERS was the only significant predictor of VAS score (β of -22.089; 95% CI, -35.56 to -8.61 [$P = .002$]). No predictors were identified for AR variables. Among the evaluated tools, endoscopy appears to be the most reliable tool to estimate the degree of subjective nasal symptoms. The authors noted that this study did not account for patient age and size in the assessment of the AR variables. Therefore, this study may have biased results because a “normal” MCA may be different for each patient in the study. Another limitation is that the study population had some inherent heterogeneity, with 22% of patients with allergic rhinitis and the small number of patients was unable to offer individual subgroup analysis. Furthermore, NE was only performed after nasal decongestion, which is a possible confounder because this would have altered the dimensions and observed degree of obstruction in the nasal cavity.

Several papers from Germany describe 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. (16) 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, AR and optical rhinometry were considered experimental, investigational, and/or unproven.

In 2016, Krzych-Fałta E. et al. (17) studied optical rhinometry since it is the only diagnostic tool for assessing real-time changes in nasal occlusion. The first attempts to standardize the method conducted by German researchers show the potential of optical rhinometry not only as regards to challenge tests, but also vice versa, in respect of the anemization of the mucosa it evaluates the extent of the edema which occurred in the pathomechanism of non-allergic rhinitis. The authors determined that there is a relatively a small number of publications on optical rhinometry and noted there is a need to conduct further research on the suitability of optical rhinometry for the evaluation of nasal patency.

In 2016, Umihanic et al. (18) evaluated the values of subjective parameters, and active anterior rhinomanometry parameters prior to and 3 months after septoplasty. The subjective parameters ("NOSE" scale), the active anterior rhinomanometry parameters according to International Committee on Standardization of Rhinomanometry, on 40 patients were assessed. Thirty healthy adult volunteers with no prior history of nasal surgery or active rhinological disease participated in the control group. The post-operative improvement in symptoms of nasal obstruction was obtained in 92.5% patients and the improvement parameters of the active anterior rhinomanometry was noted in 42.5% of the patients. The authors concluded that the correlation between the findings with rhinomanometry and subjective sensation of nasal patency remains uncertain. There still appeared to be only a limited argument for the use of rhinomanometry for quantifying surgical results although they stated that 3 months of post-operative findings were very early results to interpret permanent effects.

In 2016, Maalouf et al. (19) stated that nasal valve collapse is a dynamic abnormality that is currently diagnosed purely based on clinical features and thus subject to certain interpretation. In an observational, prospective study, these researchers developed a new and reliable functional test to objectively characterize nasal valve collapse. This trial included consecutive patients with chronic nasal congestion. Participants were classified into 2 groups according to their symptoms and clinical abnormalities: the nasal valve collapse (NV+) group when nasal valve collapse was clinically detected during moderate forced inspiration and/or when the feeling of nasal congestion improved during passive nasal lateral cartilage abduction (n = 32); and the no nasal valve collapse (NV−) group for the others (n = 23). All patients underwent posterior rhinomanometry and AR before and after topical nasal decongestion. The difference between the pressure flow of the inspiratory and expiratory phases during posterior rhinomanometry [flow rate inspiratory-expiratory difference (FRIED) test] was compared. The difference between the absolute value of inspiratory and expiratory flow was significantly higher in the NV+ group than in the NV− group both before and after topical decongestion. The cutoff value for the FRIED test was −0.008 l/s with a good sensitivity (82 %) and a specificity of 59 %. The authors suggested that the FRIED test constituted an objective and easy to apply technique to diagnose nasal valve collapse in daily practice. Moreover, these researchers noted

that measuring nasal compliance with AR is not a reliable way to characterize nasal valve collapse. Nevertheless, compliance measurements are of great interest when exploring nasal obstruction and could detect any potential dysfunction posterior to the valve. They stated that this study provided the 1st proof of principle of a useful, reliable, and easy to perform test to objectively and quantitatively characterize nasal valve collapse in patients complaining of nasal obstruction. In the future, the FRIED test could also be used to evaluate the efficacy of nasal valve treatments, both prosthetic and surgical.

In 2017, Bock and colleagues (20) evaluated the association between objective and subjective measurements of sinonasal involvement comparing nasal airflow obtained by active AR, nasal endoscopic findings, and symptoms assessed with the SinoNasal Outcome Test-20 (SNOT20) in patients with cystic fibrosis (CF). Nasal cavities were explored by active AR and findings were compared to inspiratory nasal airflow measured by active AR to quantify nasal patency and subjective health related QOL in sinonasal disease obtained with the SNOT-20 questionnaire. Relations to upper and lower airway colonization with Pseudomonas aeruginosa, medical treatment, and sinonasal surgery were analyzed. A total of 124 CF patients were enrolled (mean age of 19.9 ± 10.4 years, range of 4 to 65 years). A significant association of detection of nasal polyposis (NP) in rhinoscopy was found with increased primary nasal symptoms (PNS), which include "nasal obstruction", "sneezing", "runny nose", "thick nasal discharge", and "reduced sense of smell". In addition, patients with pathologically decreased airflow neither showed elevated SNOT-20 scores nor abnormal rhinoscopic findings. Altogether, rhinomanometric and rhinoscopic findings were not significantly related. The authors noted that among the SNOT-20 scores, the PNS subscore was related to rhinoscopically detected polyposis and sinonasal secretions. Therefore, the authors recommended including short questions regarding PNS into routine CF care. At the same time these findings showed that a high inspiratory airflow was not associated with a good sensation of nasal patency. They stated that rhinomanometry is not needed within routine CF care, but it can be interesting as an outcome parameter within clinical trials.

In 2018, Aksoy and colleagues (21) stated that seasonal allergic rhinitis (SAR) is common in children and hyposmia is a major symptom affecting QOL. The authors sought to assess olfactory dysfunction in pediatric patients with SAR and correlate the results with AR measurements. Forty children, diagnosed as moderate and severe SAR based on clinical findings, ARIA (Allergic rhinitis and its impact on asthma) classification and prick test results were enrolled in the study. Endoscopic nasal examination, acoustic rhinometry, total nasal symptom score (TNSS) and Connecticut Chemosensory Clinical Research Center (CCCRC) tests were performed 'in season' (May-August) and 'out of season' (November-February). Three patients did not appear in the 'out of season' examination therefore they were excluded from the study. The children ranged between 8 and 18 years with a hyposmia increased and odor identification decreased ($p < 0.005$, $p = 0.003$, respectively), whereas no differences were found between odor thresholds and the discrimination values ($p > 0.05$). Mean CCCRC value was obstruction score ($r = -0.340$, $p = 0.04$), subjective hyposmia ($r = -0.44$, $p = 0.007$) and TNSS ($r = -0.494$, $p = 0.02$). Although some of the AR parameters were lower during allergy season, there was no correlation between AR parameters and CCCRS values. The authors concluded that

nearly 50 % of the children with AR reported mild to moderate hyposmia during pollen season and there was a decrease in odor identification, which could be easily indicated by using a CCCRC test.

In 2018, Wartelle et al. (22) stated that the acoustic reflection method (ARM) is a noninvasive technique that utilizes the reflection of acoustic waves to measure the CSA of nasal cavities in adults and the patency of endotracheal tubes. Characteristics and volume of normal nasal cavities in preschool children has so far not been studied therefore, the goal of this study was to determine the optimal ARM recording and the MCA and nasal volume in healthy children. This prospective monocentric study using the ARM in 70 preschool children ages 2 to 5. Reliable measures were difficult to obtain in children younger than 2 years of age. The use of a standard nosepiece and a single-use surgical filter enabled reliable, serial recordings. Mean MCA values were 0.46, 0.53 and 0.58 cm^2 in the 24-35, 36-47 and 48-60 months-old age groups. Mean nasal volume were 2.14, 2.59, and 2.86 cm^3 in the same age groups. The MCA and nasal volume were significantly correlated with height, age and weight. The authors concluded that the ARM was feasible in children over the age of 2 and appeared to be a promising noninvasive tool to study the nasal cavity patency, anatomy, and volume.

In 2021 Ta and colleagues (23) noted that common sino-nasal disorders include CRS, AR, and a deviated nasal septum (DNS), which often co-exist with shared common symptoms including nasal obstruction, olfactory dysfunction, and rhinorrhea. Various objective outcome measures and patient-reported outcome measures (PROMs) are used to examine disease severity; however, there is limited evidence in the literature on the correlation between them. In a systematic review, these investigators examined the relationship between them and provided recommendations. They carried out a search of Medline and Embase; and identified studies quantifying correlations between objective outcome measures and PROMs for the sino-nasal conditions using a narrative synthesis. A total of 59 studies met inclusion criteria. For nasal obstruction, rhinomanometry showed a lack of correlation whereas PNIF showed the strongest correlation with PROMs ($r > 0.5$). The Sniffin' Stick test showed a stronger correlation with PROMs ($r > 0.5$) than the University of Pennsylvania Smell Identification Test (UPSIT) ($r < 0.5$); and CT sinus scores showed little evidence of correlation with PROMs and nasal endoscopic ratings (weak correlation, $r < 0.5$). The authors concluded that objective outcome measures and PROMs evaluating sino-nasal symptoms were poorly correlated, and they recommended that objective outcome measures be used with validated PROMs depending on the setting. PNIF should be used in routine clinical practice for nasal obstruction; rhinomanometry and AR may be useful in research. The Sniffin' Sticks test is recommended for olfactory dysfunction with UPSIT as an alternative. CT scores should be excluded as a routine CRS outcome measure, and endoscopic scores should be used in combination with PROMs until further research is carried out.

In 2021 Hassegawa et al. (24) compared the nasal cavity geometry of children and teenagers with cleft lip and palate and maxillary atresia by 2 methods: cone-beam CT, considered the gold standard, and acoustic rhinometry. Data on cone-beam CT and AR examinations of 17 children and teenagers with cleft lip and palate and maxillary atresia, previously obtained for

orthodontic planning purposes, were evaluated prospectively. Using Dolphin Imaging 11.8 software, the nasal cavity was reconstructed by 2 evaluators, and the internal nasal volumes were obtained. Using rhinometry, the volumes of regions V1 and V2 were measured. The values of each examination were then compared at a significance level of 5%. Statistical analysis showed high intra- and inter-rater reproducibility in the cone-beam CT analysis. The mean internal nasal volumes (± standard deviation) obtained using AR and cone-beam CT corresponded to 6.6 ± 1.9 cm^3 and 8.1 ± 1.5 cm^3, respectively. The difference between the examinations was 17.7 %, which was considered statistically significant (p = 0.006). The authors concluded that nasal volumes measured by the 2 methods were different, presenting discrepancies in the measurements. The cone-beam CT (gold standard technique) identified larger volumes than AR in the nasal cavity. The researchers stated that determining which test reflects clinical reality is an essential future step.

In 2022, Gagnieur et al. (25) noted that internal valve collapse is a frequent cause of nasal obstruction but remains poorly understood therefore it sometimes treated inappropriately. No functional or imaging test for the condition has been validated and the reference diagnostic technique is physical examination. In a diagnostic accuracy case-control study, researchers examined the potential of 4-phase rhinomanometry as a diagnostic test for internal valve collapse. In this trial, the nostrils of adult patients consulting for chronic nasal obstruction were classified as "collapsed" or "non-collapsed" based on clinical findings; 4- phase rhinomanometry was performed in all patients. The area defined by the path of the flow/pressure curve in the 2 phases of inspiration (the "inspiratory loop area" or "hysteresis loop area") was calculated for bilateral nasal cavities and the threshold value with the highest Youden index was identified. A total of 66 patients (132 nostrils) were included with 72 nostrils classified as “collapsed” and 60 as “non-collapsed”. Prior to nasal decongestion, the inspiratory loop area with the highest Youden index was 17.3 Pa L s-1 and the corresponding sensitivity and specificity were 88.3 % (95 % CI: 80.0 % to 95.0 %) and 89.9 % (82.6 % to 95.7 %), respectively. The authors concluded that in these individuals, a cut-off inspiratory loop area in 4-phase rhinomanometry data reproduced clinical diagnoses of internal valve collapse with high sensitivity and specificity. Researchers stated that this method may offer a firmer basis for treatment indications than subjective physical examinations although larger studies with a pre-defined threshold loop area are warranted to confirm these results. The authors noted drawbacks of this study included its small size (n = 66 subjects) and the 4-phase rhinomanometry measurements were carried out on each nostril separately, even if the contralateral nostril was occluded with medical tape rather than a nasal plug to avoid altering the structure and biomechanical properties of the studied nostril.

UpToDate

In 2023, UpToDate (26) evaluated literature regarding the diagnosis and management of nasal obstruction which states:

- “Several other tests can be performed to help characterize nasal obstruction. The data supporting the use of these measurements are somewhat controversial and results can be less than definitive. Thus, these tests are usually ordered under select clinical situations

after specialist evaluation." Rhinomanometry and acoustic rhinometry are listed as examples of these controversial tests.

- "The degree of nasal obstruction, as measured objectively by acoustic rhinometry, peak nasal airflow, or rhinomanometry, may not correlate with the patient's subjective degree of nasal obstruction. As an example, minimal changes in nasal patency may be experienced as substantially bothersome for an individual patient."
- "Posterior nasal structures are best visualized with nasal endoscopy."
- "Diagnostic imaging to assess both mucosal disorders and anatomical deformities is indicated when the diagnosis is not clear based upon the history and physical examination alone. Computed tomography (CT) scan of the nose and paranasal sinuses is the primary diagnostic imaging modality."
- "The evaluation of a patient with nasal symptoms involves a detailed history and physical examination. Some patients may require further evaluation involving nasal endoscopy or diagnostic imaging."
- "Most of the underlying causes of nasal obstruction can be identified with a thorough examination of the external nose, nasal cavity, and the nasopharynx. Anterior rhinoscopy and/or nasal endoscopy should be used for better visualization of internal nasal structures."
- "In cases where the diagnosis is not clear based upon the history and physical examination, computed tomography (CT) scan may be helpful in assessing for mucosal disorders and anatomic deformities. Plain film radiography lacks the sensitivity and specificity required in the diagnostic evaluation of nasal obstruction."

In 2023, UpToDate (27) published guidance for occupational rhinitis (OR) which is defined as "an inflammatory condition of the nose, which is characterized by intermittent or persistent symptoms (i.e., nasal congestion, sneezing, rhinorrhea, itching) and/or variable nasal airflow limitation and/or hypersecretion, due to causes and conditions attributable to a particular work environment and not to stimuli encountered outside of the workplace." Diagnosis is usually made clinically, although for research purposes, symptoms should be elicited and confirmed by direct nasal challenge. Direct nasal challenge, also known as nasal provocation test, is the gold standard for the diagnosis of OR. Responses may be quantified either by symptom score or by rhinomanometry, a technique that measures changes in nasal airway resistance although these techniques require special equipment and training and are not practical for most community clinicians or allergy specialists. The development of screening parameters to identify those individuals at highest risk for allergic OR is an area of active investigation, but validated methods for clinical application are still lacking.

In 2023, UpToDate (28) published guidance for upper airway imaging in adult patients with obstructive sleep apnea (OSA). This guidance offers the following recommendations: "Magnetic resonance imaging (MRI) and nasopharyngoscopy are the best choices among the available options for imaging the upper airway in patients with OSA. Other modalities include cephalometry, computed tomography, acoustic reflection, optical coherence tomography, and ultrasound. Acoustic reflection has been used primarily as a research tool and its clinical utility has not been carefully assessed."

Professional Guidelines and Position Statements

Academy of Allergy, Asthma and Immunology (AAAAI) and the American College of Allergy, Asthma and Immunology (ACAAI)

In 2020, the AAAAI and ACAAI updated their practice parameter for rhinitis. (29) This guideline discusses the diagnosis, assessment, and pharmacologic options for allergic rhinitis (AR) and nonallergic rhinitis (NAR). The workgroup does not specifically mention rhinomanometry, acoustic rhinometry and/or optical rhinometry within their recommendations although they offer the following guidance:

- "We recommend that the clinician complete a detailed history and a physical examination in an individual presenting with symptoms of rhinitis. (Strength of recommendation: Strong; Certainty of evidence: Low)".
- "We recommend that for individuals presenting with rhinitis symptoms, a review of all current medications should be completed to assess whether drug-induced rhinitis may be present. (Strength of recommendation: Strong; Certainty of evidence: Ungraded due to lack of studies addressing this specific issue although this was a unanimous vote in favor by the work group and the Joint Task Force on Practice Parameters)."

Acoustic Pharyngometry

In 2007, Gelardi et al. (30) evaluated variations of pharyngometry in patients with sleep disorders to establish a correlation between morpho-volumetric variations of oro-pharyngo-laryngeal spaces and the presence and severity of disease. One hundred ten patients, of which 70 with sleep disorders and 40 healthy patients as a control group were analyzed for 1 year (June 2004 through June 2005). All patients underwent acoustic pharyngometry to evaluate the mouth and hypopharynx based on an explanatory chart. A significant difference in parameters was observed between sleep disorder patients and the control group, especially in the amplitude of the I wave (significantly lower in patients with macroglossia), the extension of the O-F segment, and the amplitude of the O-F segment and hypopharyngeal area. Although not a standardized test, acoustic pharyngometry was proved to be a useful method both in the diagnosis and severity of OSA, and in post-operative monitoring of upper airway surgery in patients with sleep disorders. The findings of this study need to be validated by additional well-designed studies.

In 2013, DeYoung et al. (31) stated the gold-standard method of diagnosing OSA is polysomnography, which can be inefficient. The authors sought to determine a method to triage these patients at risk of OSA, without using subjective data, which are prone to misreporting. They hypothesized that acoustic pharyngometry in combination with age, gender, and neck circumference would predict the presence of moderate to-severe OSA. Untreated subjects with suspected OSA were recruited from a local sleep clinic and underwent polysomnography. They also included a control group to verify differences. While seated in an upright position and breathing through the mouth, an acoustic pharyngometer was used to measure the MCA of the upper airway at end-exhalation. Sixty subjects were recruited (35 males, mean age 42 years, range 21-81 years; apnea-hypopnea index (AHI) 33 ± 30 events/h (mean ± standard deviation), Epworth Sleepiness Scale score 11 ± 6, body mass index 34 ± 8

kg/m^2). In univariate logistic regression, MCA was a significant predictor of mild-no OSA (AHI < 15). A multivariate logistic regression model including MCA, age, gender, and neck circumference significantly predicted AHI < 15, explaining approximately one-third of the total variance (χ^2 (4) = 37, p < 0.01), with only MCA being a significant independent predictor (adjusted odds ratio 54, standard error 130; p < 0.01). Data suggest that independent of age, gender, and neck size, objective anatomical assessment can significantly differentiate those with mild versus moderate to-severe OSA in a clinical setting and may have utility as a component in stratifying risk of OSA. The DeYoung study offers several study limitations to include a small sample size, the pharyngometry does not provide insight to the mechanism of the underlying airway obstruction, and the data does not address the mechanism of decreased MCA. Further studies are warranted to validate these findings in an occupational setting.

In 2014, Friedman and colleagues (32) examined the role of regional upper airway obstruction measured with acoustic pharyngometry as a determinant of oral appliances. This retrospective case-series included patients with OSA-hypopnea syndrome. Patients were fitted with a custom oral appliance. Regions of maximal upper airway collapse were determined on acoustic pharyngometry: retropalatal, retroglossal, or retroepiglottic. AHI improvement at polysomnography titration was assessed against regional collapse. Seventy-five patients (56 [75%] men; mean [SD] age, 49.0 [13.6] years; mean body mass index [calculated as weight in kilograms divided by height in meters squared], 29.4 [5.2]; and mean AHI, 30.6 [20.0]) were assessed, and data was grouped based on region of maximal collapse at pharyngometry (retropalatal in 29 patients, retroglossal in 28, and retroepiglottic in 18). The overall reduction in AHI at obstructive apnea titration showed no significant difference between groups. There was no significant difference in the response rate to treatment, defined as more than 50% AHI reduction plus an AHI of less than 20 (response rate, 69% for retropalatal, 75% for retroglossal, and 83% for retroepiglottic collapse; P = .55) or the cure rate, defined as an AHI of less than 5 (cure rate, 52% for retropalatal, 43% for retroglossal, and 72% for retroepiglottic collapse; P = .15). The correlation between MCA and response trended toward significance (r = 0.20; range -0.03 to 0.41; P < .10). Oral appliance therapy achieves reasonable response and cure rates in patients with primary retropalatal, retroglossal, or retroepiglottic obstruction at the time of initial polysomnography titration. However, success is not predicted by identification of the region of maximal upper airway collapse measured with acoustic pharyngometry.

UpToDate

In 2023, UpToDate (33) evaluated literature regarding upper airway imaging techniques in adult patients with OSA. The summary concluded:

- "Upper airway imaging is not yet part of the routine diagnostic evaluation for OSA because it can neither confirm nor exclude the disorder. However, the authors found imaging to be clinically useful in the planning of upper airway surgery, although validation of this approach has not been addressed with well-performed clinical trials.
- MRI and nasopharyngoscopy (including drug-induced sleep endoscopy) are the best choices among the available options for imaging the upper airway in patients with OSA.

- MRI is one of the preferred imaging modalities because upper airway soft tissue resolution is excellent and there is no radiation exposure. In addition, it is widely available, and both the cross-sectional area and volume of the upper airway can be accurately quantified.
- Nasopharyngoscopy is a widely available and easy way to evaluate the lumen of the nasal passages, oropharynx, and vocal cords. It can be performed during wakefulness, spontaneous sleep, or sedative-induced sleep, with the patient in either the sitting or supine position. Nasopharyngoscopy does not involve radiation exposure, but it is invasive and requires nasal anesthesia. Drug-induced sleep endoscopy should be considered in patients undergoing upper airway surgery in which the site of airway obstruction needs to be determined."

Professional Guidelines and Position Statements

American Academy of Sleep Medicine Clinical Practice Guideline

The 2018 American Academy of Sleep Medicine Clinical Practice Guideline (34) states polysomnography is the only diagnostic test which can diagnose OSA. There is no mention of acoustic pharyngometry as a diagnostic tool within the context of the guideline.

Summary of Evidence

Current literature suggests that rhinomanometry, acoustic rhinometry (AR) or optical rhinometry is 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 the use of these diagnostic procedures would improve health outcomes compared to standard approaches, such as patient self-assessment, physical exam and nasal endoscopy. Additional long term clinical studies with larger sample sizes are necessary to determine the value of these procedures in the diagnosis and clinical management of patients with nasal obstruction therefore, rhinomanometry, acoustic rhinometry (AR) and optical rhinometry are considered experimental, investigational and/or unproven.

Acoustic pharyngometry is a technique utilized to map the size, structure and collapsibility of the oral airway. Much of the published literature utilizes this technology to evaluate obstructive sleep apnea (OSA). Additional long-term studies are needed to determine the value of acoustic pharyngometry in the diagnosis of OSA especially compared to the use of standard approaches, including polysomnography therefore, acoustic pharyngometry is considered experimental, investigational and/or unproven.

Coding

Procedure codes on Medical Policy documents are included **only** as a general reference tool for each policy. **They may not be all-inclusive.**

The presence or absence of procedure, service, supply, or device codes in a Medical Policy document has no relevance for determination of benefit coverage for members or reimbursement for providers. **Only the written coverage position in a Medical Policy should be used for such determinations.**

Benefit coverage determinations based on written Medical Policy coverage positions must include review of the member's benefit contract or Summary Plan Description (SPD) for defined coverage vs. non-coverage, benefit exclusions, and benefit limitations such as dollar or duration caps.

CPT Codes	92512, 92520
HCPCS Codes	None

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Centers for Medicare and Medicaid Services (CMS)

The information contained in this section is for informational purposes only. HCSC makes no representation as to the accuracy of this information. It is not to be used for claims adjudication for HCSC Plans.

The Centers for Medicare and Medicaid Services (CMS) does not have a national Medicare coverage position. Coverage may be subject to local carrier discretion.

A national coverage position for Medicare may have been developed since this medical policy document was written. See Medicare's National Coverage at <http://www.cms.hhs.gov>.

Policy History/Revision

Date	Description of Change
05/15/2024	Document updated with literature review. Coverage unchanged. Added reference 25; others updated.
03/15/2023	Reviewed. No changes.
05/15/2022	Document updated with literature review. Coverage unchanged. Added references 23, 24, 33; others updated and/or removed.
02/15/2021	Reviewed. No changes.
05/01/2020	Document updated with literature review. Coverage unchanged. Added references 6, 7, 18-22, 24-25.
10/01/2018	Reviewed. No changes.
11/01/2017	Document updated with literature review. Added to Coverage "Acoustic pharyngometry is considered experimental, investigational and/or unproven for all indications." Title changed from Rhinomanometry, Acoustic Rhinometry, Optical Rhinometry.
07/01/2016	Reviewed. No changes.
10/15/2015	Document updated with literature review. Coverage unchanged.
09/01/2014	Reviewed. No changes.
10/15/2013	Document updated with literature review. The following change(s) were made: Optical rhinometry was added to the Coverage statement as another type of rhinometry.
10/01/2007	Revised/Updated Entire document

08/15/2003	Revised/Updated Entire document
07/01/1994	Revised/Updated Entire document
04/01/1994	Revised/Updated Entire document
05/01/1990	New Medical Policy