
Medical Policy



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***Current Policy Effective Date: 9/1/19**
(See policy history boxes for previous effective dates)

Title: Automated Audiometry

Description/Background

An audiometer or automated audiometer is an electroacoustic device that produces controlled levels of test tones and signals intended for use in conducting diagnostic hearing evaluations and assisting in the diagnosis of possible otologic disorders.

Hearing loss affects millions of people in the United States and is more common among older adults than children. It is estimated that by the age of 65, one out of three people has a hearing loss. Hearing loss may result from genetic factors, infection, head trauma, mechanical problems in the external or middle ear, damage to sensory structures of the inner ear, auditory nerve or auditory nerve pathways in the brain, or exposure to noise.

Hearing loss may be identified by a primary care physician or other trained health care professional during a physical examination. If potential hearing loss is identified, a referral is made for an audiologic evaluation, which is performed or supervised by a qualified audiologist. The purpose of the evaluation is to determine the degree, type, and configuration of the hearing loss. The audiologic evaluation includes a case history, physical examination of the ear structures, and pure-tone audiometry, which tests for responses to tones at varying frequencies and intensities. Speech audiometry, which includes speech reception threshold and word recognition, may also be performed. Additional testing may include auditory evoked potentials, otoacoustic emissions (OAE) and acoustic immittance measures, which include tympanometry, acoustic reflex and static acoustic impedance.

The standard method for determining hearing sensitivity is manual pure tone audiometry testing. Automated computer-based audiometry systems have been developed in an effort to provide greater diagnostic accuracies and increased efficiencies among various audiologic tests. Otogram™ Hearing Diagnostic System from Ototronix, LLC is an automated audiometry system which is commercially available. Since Otogram™ is a self-administered hearing test

device the patient receives brief instructions before beginning the testing process. The Otogram is purported to perform the following diagnostic hearing tests: pure-tone air and bone conduction, speech reception threshold, speech discrimination, tympanometry, acoustic reflex and OAE.

Regulatory Status

The FDA (2007) reviewed Section 510(k) premarket notification (K070118) and determined that the device does not require approval of a premarket approval application (PMA). The device may therefore be marketed subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act for the indications stated below:

Indications for use:

The Otogram is a computer-controlled, audiometric instrument combining the functions of an Audiometer, Distortion Product Otoacoustic Emissions Analyzer and Auditory Acoustic Impedance/Admittance Tester (i.e. Tympanometer) The Otogram is indicated for use by trained healthcare professionals on both adult and pediatric subjects for measurement of audiometric parameters to identify and supply data to help diagnose hearing loss and ear disorders.

The Otogram is an auditory diagnostic instrument intended to administer, under supervision by a trained healthcare professional, a battery of diagnostic and screening procedures that include the following:

- 1) Pure tone air and bone conduction audiometry with autofaded masking
 - 2) Speech recognition threshold with automated masking
 - 3) Speech discrimination with automated masking
 - 4) Tympanometry
 - 5) Acoustic reflex threshold, both ipsilateral and contralateral
 - 6) Distortion product otoacoustic emissions
 - 7) Pure tone Stenger
 - 8) Patient survey
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Medical Policy Statement

Automated audiometry is not equivalent to a manual, comprehensive evaluation performed by a qualified audiologist. The effectiveness and clinical utility of automated audiometry have not been established; therefore, it is considered experimental/investigational.

Inclusionary and Exclusionary Guidelines (Clinically based guidelines that may support individual consideration and pre-authorization decisions)

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

0208T

0209T

0210T

0211T

0212T

Rationale

To date, there are only a few published studies comparing automated audiometry to manual audiometry performed by an audiologist.

In 2009, Ho et al published a small prospective nonrandomized validation study comparing computer-assisted audiometry using the Otogram versus interrater and intrarater accuracy and reliability for audiologists. Forty-eight patients referred to an otology outpatient clinic had two pure tone audiograms. The level of agreement in air-conduction and bone-conduction thresholds between the audiologist and the Otogram on the same patient was equivalent to the inter-rater level of agreement between pairs of audiologists. Approximately 94 percent of air-conduction thresholds and 91 percent of bone-conduction thresholds measured by the Otogram fell within 10 dB of thresholds measured by an audiologist. Intrarater comparisons between audiologists were very good for air-conduction and bone-conduction. The intrarater level of agreement between repeated Otogram thresholds was just as good for air-conduction and bone-conduction thresholds. The researchers concluded that “the Otogram is just as reliable as audiologists at determining hearing thresholds. We recommend that the Otogram can be safely used in a controlled clinical setting supervised by audiologists.”

The researchers noted that further studies are required to determine the most appropriate patient population for computer-assisted audiometry.

Yu et al (2011) reported on a small study assessing the validity of the Otogram on patients with bilateral mixed, bilateral conductive and unilateral conductive hearing loss, which are deemed “difficult-to-test”. In this study, 28 difficult to test individuals were given three audiograms, two were performed by an audiologist and the third by the Otogram. The audiograms conducted by the audiologist were compared to establish test-retest reliability. The Otogram was then compared with the testing performed by the audiologists. The authors reported that the audiograms performed by the audiologists had high levels of agreement with over 90 percent of air and bone conduction thresholds within 10dB of each other. In the Otogram versus audiologist comparison, only air conduction conditions had high levels of agreement with the percentage of thresholds within 10 dB. Bone conduction conditions did not yield the same high levels of agreement as did the air conduction conditions. The authors concluded that additional research is needed to determine the reason for these differences and ways to control for them.

Mahomed et al (2013) performed a meta-analysis of studies reporting comparisons of manual and automated audiometry. The researchers found overall average differences between manual and automated air conduction audiometry to be comparable with test-retest differences for manual and automated audiometry. However, the researchers found limited data on automated audiometry in children and difficult-to-test populations, automated bone conduction audiometry, and data on the performance of automated audiometry in different types and degrees of hearing loss.

The American Speech-Language-Hearing Association position is that hearing screening should be performed by audiologists holding a Certificate of Clinical Competence (CCC-A) from the American Speech-Language-Hearing Association (ASHA) and state licensure where applicable, speech-language pathologists holding a Certificate of Clinical Competence (CCC-SLP) from the ASHA and state licensure where applicable and other personnel under the supervision of an ASHA-certified audiologist.

Brennan-Jones et al (2016) published a small study which compared intra- and inter- observer agreement between remote interpretations of manual and automated audiometry. Five audiologists were blinded to whether manual or automated audiometry was used with 42 patients. Audiograms were independently interpreted, together with the other available information (age, gender, and tympanometry; a full patient history was not available to participating audiologists). Audiologists were aware that some of the audiograms for interpretation were obtained by automated testing and would be compared to manual audiograms. However, they were not aware that they would be interpreting matched pairs of manual and automated audiograms. They were asked to provide a determination of: 1) the level and type of hearing loss; 2) a management plan for the patient given their audiometric results; and 3) their judgment of the reliability of the audiogram. There are no universally agreed standards for determining the type and level of hearing loss, management plan or reliability of the audiogram; these are normally the result of professional training and local clinic protocols. Inter-observer agreement varied from moderate to substantial in regards to the level of hearing loss, type of hearing loss and management for both automated and manual audiometry. There is a lack of agreement between audiologists when interpreting audiograms, whether recorded with automated or manual audiometry. The main variability in remote audiogram interpretation is likely to be individual clinician variation, rather than automation.

Pereira et al (2018) published a report regarding the clinical use of automated audiometry when used to screening pediatric hearing. Hearing thresholds for 0.5, 1, 2, 4, 6, and 8 kHz were collected in 32 children ages 6-12 years using standard audiometry and tablet-based automated audiometry in a soundproof booth. Test administration time, test preference, and medical history were also collected. Results exhibited that the majority (67%) of threshold differences between automated and standard were within the clinically acceptable range (10 dB). The threshold difference between the two tests showed that automated audiometry thresholds were higher by 12 dB in 6-year-olds, 7 dB in 7- to 9-year-olds, and 3 dB in 10- to 12-year-olds. In addition, test administration times were similar, such that standard audiometry took an average of 12.3 min and automated audiometry took 11.9 min. Results varied regarding the use of tablet-based audiometry, indicating that at least some types of tablet based automated audiometry may not be feasible for certain age groups.

Government Regulations

National/Local:

There is no national or local coverage determination specifically addressing automated audiometry.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Hearing Services

References

1. American Academy of Audiology, Public Policy Resolutions, “Automated Audiometry,” 2013; retrieved February 13, 2020 from: http://audiology-web.s3.amazonaws.com/migrated/Automated%20Audiometry.pdf_53a2a10fb49434.22250531.pdf.
2. American Medical Association, *CPT® Assistant*, “Manual and Automated Audiometry,” March 2011.
3. American Speech-Language-Hearing Association, “Hearing Screening and Testing,” retrieved February 13, 2020 from: <http://www.asha.org/public/hearing/Hearing-Testing/>.
4. Brennan-Jones, C., Eikelboom, R., Bennett, et al., “Asynchronous Interpretation of Manual and Automated Audiometry: Agreement and Reliability,” *Journal of Telemedicine and Telecare*, 2016 September.
5. Centers for Disease Control and Prevention (CDC), “Hearing Loss”; retrieved February, 2020 from: <http://www.cdc.gov/ncbddd/hearingloss/index.html>.
6. Centers for Medicare and Medicaid Services (CMS), *Medicare Benefit Policy Manual*, “Chapter 15 – Covered Medical and Other Health Services,” Section 80.3 Audiological Services, Rev. 132, Issued: 09-03-10, Effective: 09-30-10, Implementation: 09-30-10; retrieved February 13, 2020 from: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf>.
7. Ho, Allan Thiam Poh, Anthony J. Hildreth and Leon Lindsey, “Computer-Assisted Audiometry Versus Manual Audiometry,” *Otology & Neurotology*, Vol. 10, No.7, 2009, pp. 876-883.
8. Mahomed F et al, “Validity of automated threshold audiometry: A systematic review and meta-analysis.” *Ear Hear.* 2013 May 31.
9. Pereira, O et al., “Is There a Clinical Application for Tablet-Based Automated Audiometry in Children,” *Intern Journal of Pedia Otorhinolaryngology*, Vol. 110, pp. 87-92
10. United States Food and Drug Administration (FDA), 510(k) Summary, Otogram CA3350, March 2007; retrieved February 13, 2020 from: http://www.accessdata.fda.gov/cdrh_docs/pdf7/K070118.pdf.

11. Yu, J. et al., "Automated Hearing Tests: Applying the Otogram to Patients who are Difficult to Test," Journal of Otolaryngology-Head & Neck Surgery, Volume 40, issue 5, 2011, pp. 376-383.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through 2/13/20, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/10	3/16/10	2/16/10	Joint policy established
1/1/12	10/11/11	11/9/11	Routine maintenance
3/1/13	12/11/12	12/31/12	Routine maintenance; updated references and Medicare information. Title changed from "Computer Assisted Audiometry" to "Automated Audiometry".
7/1/14	4/10/14	4/15/14	Routine maintenance; removed "Otogram™" from title and MPS
7/1/15	4/24/15	5/8/15	Routine maintenance
7/1/16	4/19/16	4/19/16	Routine maintenance
7/1/17	4/18/17	4/18/17	Routine maintenance
7/1/18	4/17/18	4/17/18	Routine maintenance
7/1/19	4/16/19		Routine maintenance
9/1/19	4/14/20		Policy replaced: code incorporated into Hearing Services policy, EFD 9/1/19

Next Review Date: Policy Replaced; no longer subject to routine review.
Refer to JUMP policy, *Hearing Services*, EFD 9/1/19

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: AUTOMATED AUDIOMETRY

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered
BCNA (Medicare Advantage)	Refer to the Medicare information under the Government Regulations section of this policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.