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Use of Optical Coherence Tomography (OCT) in the Diagnosis and Treatment of Auditory System Conditions

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Related Policies (if applicable)
None

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Coverage

This medical policy has become inactive as of the end date above. There is no current active version and this policy is not to be used for current claims adjudication or business purposes.

The use of optical coherence tomography (i.e., OtoSight™ Middle Ear Scope, formally known as PhotoniCare *TOMi* Scope device) in the diagnosis and treatment of auditory system conditions **is considered experimental, investigational and/or unproven.**

Policy Guidelines

None.

Description

Optical coherence tomography (OCT) is a noninvasive diagnostic imaging technique that is used in multiple clinical applications. Historically, OCT applications of the head and neck have primarily focused on characterizing cancer and diseases of the larynx. The expanded use of OCT is being evaluated in patients with otitis media (OM). (1)

Otitis media is a common, prevalent diagnosis in infants, especially those 6-18 months old. The main cause of OM is middle ear infections caused by bacteria and/or viruses and cannot be visualized with current technology. Typically, the otoscope is used to assess the condition of the tympanic membrane (TM) surface. This subjective observation can be challenging since no quantitative depth-resolved imaging technology exists for imaging the middle ear and assessing the characteristics of effusion that might be present. These limitations often result in an incorrect diagnosis, which may subsequently affect treatment and patient outcomes. To address these limitations of standard otoscopy, OCT for non-invasive assessment and quantification of the microstructure of the TM and middle ear was employed. (1)

OCT is a diagnostic imaging modality that combines low coherence light with interferometry to produce high-resolution cross-sectional images of living tissues. (2) OCT generates cross-sectional images by using the time delay and intensity of light reflected from the internal tissue structure. The image produced by the reflected light is analyzed and can be used to differentiate air from fluid as well as characterize fluid properties due to scattering of the imaging signal from particles in the fluid. (3) OCT has a higher resolution than ultrasound but more shallow penetration of tissue. Tissue resolution of 15-20 axial and 20-40 lateral has been achieved, which is significantly greater than ultrasound. However, the technique is limited by its inability to penetrate more than several millimeters (mm) in depth (1-2.5 mm OCT, 10 mm ultrasound). (4)

Regulatory Status

On December 5, 2019, the *TOMi* Scope (PhotoniCare, Champaign, IL) was granted 510(k) clearance by the United States (U.S.) Food and Drug Administration (FDA) for use in children and adults as an imaging tool for real-time visualization of the human tympanic membrane and fluid or air within the middle ear space. In the presence of middle ear fluid, the TOMi Scope is used to visualize the fluid density and provide surface images of the ear canal and tympanic membrane. The device is designed to look and handle like a standard otoscope while providing cross-sectional images of the middle ear in combination with high-resolution video of the surface of the eardrum. Additionally, the images can be saved for later analysis. (5)

In preparation for its commercial launch, PhotoniCare Inc. rebranded the *TOMi* Scope to the OtoSight™ Middle Ear Scope. Product code: QJG. (6, 7)

Rationale

In 2008, Djalilian et al. (2) used optical coherence tomography (OCT) to image the tympanic membrane (TM) microstructure in the office setting. In this prospective clinical trial, the normal

and diseased TM in 10 adult subjects were studied. Each subject underwent direct microscopic examination before OCT imaging to provide visual coregistration of associated subsites including the anulus fibrosus, pars tensa, pars flaccida, and umbo. The probe from the imaging system (1,310-nm central wavelength, 15-microm coherence length, Niris; Imalux, Cleveland, OH, USA) was introduced into the ear canal to obtain lateral cross-sectional images. Systematic imaging of the TM was performed with characterization of the epithelial and collagenous layers. The overall TM thickness was also demonstrated and quantified. The study concluded that the ability to noninvasively study middle ear microstructures in vivo is essential in the treatment of diseases of the ear. The authors indicated that OCT may provide the physician with the ability to image pathology such as cholesteatoma, dimeric TMs, and chronic otitis media (OM), gauge the response to pharmacological therapy, and monitor postsurgical changes after tympanoplasty and other procedures. Limitations to the use of this device include scattering of light which prevents collection of photons to generate images and optically dense structures such as bone or blood can reflect or absorb the surface light which limits signal penetration into the deeper structures of the ear.

In 2014, Burkhardt and colleagues (8) believed high-speed doppler OCT had the potential to describe the oscillatory behavior of the TM surface in a phase-sensitive manner and the ability to acquire a three-dimensional (3D) image of the underlying structure. With repeated sound stimuli from 0.4 kHz to 6.4 kHz, the whole TM can be set in vibration and the spatially resolved frequency response functions (FRFs) of the TM can be recorded. Typical points, such as the umbo or the manubrium of malleus, can be studied separately as well as the TM surface with all stationery and wave-like vibrations. Thus, OCT can be a promising technique to distinguish between normal and pathological TMs and support the differentiation between ossicular and TM diseases.

In 2015, Guder et al. (9) conducted a small prospective study (n=11) in which a microscope-based OCT device was used to assess the microanatomy of TM patients with chronic myringitis. OCT measurements of the TM were performed on 11 patients with myringitis with a microscope-based spectral domain OCT system. The in vivo findings were compared with those findings of a control group consisting of 36 patients with retraction pockets or atrophic TMs (n=13), myringosclerosis (n=12) and perforations (n=11). In active chronic myringitis, the thickness of the TM is increased compared to healthy membranes and to other pathological conditions of the TM. Consistent changes of the microanatomy of the TM were found in chronic myringitis with OCT. Serial OCT measurements revealed no biofilm suspicious findings in all patients with active chronic myringitis. The authors concluded in this small study that intraoperative and in vivo OCT measurements may help to detect microanatomical changes of the TM in chronic myringitis and in other conditions of the TM.

In 2015, Hubler et al. (10) developed an OCT system for high-resolution, depth-resolved, cross-sectional imaging of the TM and middle ear and for the quantitative assessment of in vivo TM thickness including the presence or absence of a middle ear biofilm. A novel algorithm was developed and demonstrated for automatic, real-time, and accurate measurement of TM thickness to aid in the diagnosis and monitoring of OM as well as other middle ear conditions.

The segmentation algorithm applies a Hough transform to the OCT image data to determine the boundaries of the TM to calculate thickness. The use of OCT and this segmentation algorithm was demonstrated first on layered phantoms and then during real-time acquisition of in vivo OCT from humans. For the layered phantoms, measured thicknesses varied by approximately 5 µm over time in the presence of large axial and rotational motion. In vivo data also demonstrated differences in thicknesses both spatially on a single TM, and across normal, acute, and chronic OM cases. Real-time segmentation and thickness measurements of image data from both healthy subjects and those with acute and chronic OM demonstrate the use of OCT and this algorithm as a robust, quantitative, and accurate method for use during real-time in vivo human imaging.

In 2017, Park et al. (11) believed that conventional otoscopes and oto-endoscopes, which are used to examine the TM, do not provide tomographic information. OCT non-invasively reveals the depth-resolved internal microstructure of the TM with very high spatial resolution. We designed this study to examine the TMs with middle ear diseases using a handheld otoscope employing 860 nm spectral domain OCT, combined with video camera and to demonstrate the clinical applicability of this system. A total of 120 patients with otologic symptoms were enrolled. TM images were obtained using the handheld OCT-based otoscope (860 nm central wavelength, 15 µm axial resolution, 15 µm lateral resolution, and 7 mm scanning range using relay lens). Both OCT and oto-endoscope images were compared according to the clinical characteristics such as perforation, retraction, and postoperative healing process. The objective grade about the thickness of perforation margins and the accurate information about the extent of TM retraction that was not distinguishable by oto-endoscopic exam could be identified using this system. The postoperative healing process of TMs could also be followed using the OCT device. These analyses from the surgeon-oriented perspective suggest that the handheld OCT device would be another useful application.

In 2020, Preciado et al. (3) conducted a cross-sectional study to evaluate clinical usability and image readability by clinical personnel in the detection and differentiation of middle ear effusions using an OCT otoscope. Seventy pediatric patients 7 years of age and older undergoing tympanostomy tube placement were preoperatively imaged using an OCT otoscope. Readable images were collected in 65 ears from 45 participants. Bilateral imaging was attempted when possible. Images were sorted into 3 groups: no fluid, serous fluid, and non-serous fluid (purulent or mucoid). The groups assigned to read OCT images included otolaryngologists, pediatricians, physician extenders and non-medical professionals. Blinded reader analysis of OCT images for identifying presence and type of fluid was then compared with intraoperative findings to determine the sensitivity, specificity, accuracy, positive/negative predictive values, and inter/intrareader agreement of OCT otoscopy. The results showed reader detection of middle ear effusions had a 90.6% accuracy, 90.9% sensitivity, 90.2% specificity, 94.5% positive predictive value, 84.2% negative predictive value, and intra/interreader agreement of 92.9% and 87.1% respectively, with no statistically significant differences between those with and without OCT experience. The authors concluded that OCT has the potential to be a viable diagnostic tool in the hands of many users and is at least as accurate as other diagnostic tools in terms of accuracy and specificity, although this study is limited by the

small number of participants, lack of standardization and does not address the clinical utility of OCT.

No additional randomized controlled trials for the use of OCT for auditory conditions were identified. Available literature consists mainly of review articles, case series and feasibility studies.

UpToDate

In 2024, UpToDate (12) evaluated all published literature related to acute otitis media in adults and noted that examination with a handheld otoscope is the standard method of diagnosis of acute OM. The addition of pneumatoscopy also allows evaluation of tympanic membrane (TM) motion and is recommended for diagnosis. Otomicroscopy, available in otorhinology specialty practices, allows even greater definition of the TM. Mastoid effusion is seen on all patients with AOM per computed tomography but in the vast majority of cases it is not clinically significant. If there is a concern for an intracranial complication (i.e., sigmoid sinus thrombosis, intracranial abscess), then a magnetic resonance imaging (MRI) scan should also be considered.

In 2024, UpToDate (13) accessed the published literature related to the diagnosis of acute otitis media (AOM) in children. UpToDate noted that the diagnosis of acute OM is facilitated by the systematic assessment of the TM using a pneumatic otoscope and diagnostic criteria to distinguish acute OM from OM with effusion. Otoscopy should be performed using appropriate tools and an adequate light source. Pneumatic otoscopy skills, including accurate interpretation of findings, can be improved through training. A pneumatic otoscope with a round head is preferred because it has the best seal.

Both UpToDate publications (noted above) do not mention the use of OCT for the diagnosis and treatment of auditory system conditions.

In 2025, UpToDate (14) evaluated published literature related to otitis media with effusion (OME) in children. The diagnosis of OME is usually made with otoscopy demonstrating middle ear effusion (e.g., impaired mobility of the TM). Noninvasive technologies that overcome some of the objective difficulties of standard otoscopy for the diagnosis of OME are under investigation. These include use of artificial intelligence algorithms, optical coherence tomography, transmastoid ultrasound, and quantitative tympanometry, among others.

Summary of Evidence

There is inadequate published literature to permit scientific conclusions regarding the use of optical coherence tomography (OCT) for the diagnosis and treatment of auditory system conditions. The goal of OCT is to improve early otitis media (OM) diagnosis and to reduce unnecessary treatment and procedures (e.g., antibiotics/myringotomy). Additional long term controlled studies that address OCT's clinical utility are warranted in order to determine the impact on health outcomes.

Professional Guidelines and Position Statements

American Academy of Pediatrics (AAP)

In 2013, the American Academy of Pediatrics (AAP) published guidelines on the diagnosis and management of acute OM (15) in children 6 months through 12 years of age. These guidelines affirm pneumatic otoscope as the standard tool used in diagnosing OM although, tympanometry should be obtained if the diagnosis is uncertain. The AAP guidelines does not specifically mention OCT in their guidelines.

Ongoing and Unpublished Clinical Trials

Some currently ongoing trials that might influence this policy are listed in Table 1.

Table 1. Summary of Key Trials

NCT Number	Title	Number of participants	Date of Completion
Ongoing			
NCT05353569	Otitis Media Diagnosis and Treatment: Coherent Optical Detection of Middle Ear Disease	235	Apr 2028

NCT: National Clinical Trial

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	0485T, 0486T
HCPCS Codes	None

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References

1. Cho N, Lee S, Jung W, et al. Optical coherence tomography for the diagnosis and evaluation of human otitis media. J Korean Med Sci. 2015 Mar; 30(3):328-335. PMID 4330490
2. Djalilian HR, Ridgway J, Tam M, et al. Imaging the human tympanic membrane using optical coherence tomography in vivo. Otol Neurotol. 2008 Dec; 29(8):1091-1094. PMID 18957904
3. Preciado D, Nolan RM, Joshi R, et al. Otitis media middle ear effusion identification and characterization using an optical coherence tomography otoscope. Otolaryngol Head Neck Surg. 2020 Mar; 162(3):367-374. PMID 31959053

4. Prati F, Regar E, Mintz GS, et al. Expert review document on methodology, terminology, and clinical applications of optical coherence tomography: physical principles, methodology of image acquisition, and clinical application for assessment of coronary arteries and atherosclerosis. Eur Heart J. 2010; 31(4):401-415. PMID 19892716
5. FDA – 510(k) Premarket Notification: TOMi Scope (K191804). U.S. Food and Drug Administration, Center for Devices and Radiologic Health. (2019). Available at <https://www.accessdata.fda.gov> (accessed May 20, 2025).
6. PhotoniCare – In the news: Photonicare announces rebranding of first-in-class technology for imaging the middle ear, now called OtoSight Middle Ear Scope. Available at <https://photoni.care.com> (accessed May 20, 2025).
7. FDA – 510(k) Premarket Notification: OtoSight Middle Ear Scope (K222655). U.S. Food and Drug Administration, Center for Devices and Radiologic Health. (2019) Available at <https://www.accessdata.fda.gov> (accessed May 20, 2025).
8. Burkhardt A, Kirsten L, Bornitz M, et al. Investigation of the human tympanic membrane oscillation ex vivo by Doppler optical coherence tomography. J Biophotonics. 2014 Jun; 7(6):434-441. PMID 23225692
9. Guder E, Lankenau E, Fleischhauer F, et al. Microanatomy of the tympanic membrane in chronic myringitis obtained with optical coherence tomography. Eur Arch Otorhinolaryngol. 2015 Nov; 272(11):3217-3223. PMID 25384576
10. Hubler Z, Shemonski ND, Shelton RL, et al. Real-time automated thickness measurement of the in vivo human tympanic membrane using optical coherence tomography. Quant Imaging Med Surg. 2015 Feb; 5(1):69-77. PMID 25694956
11. Park K, Cho NH, Jeon M, et al. Optical assessment of the in vivo tympanic membrane status using a handheld optical coherence tomography-based otoscope. Acta Otolaryngol. 2017 Nov; 10:1-8. PMID 29125012
12. Limb C, Lustig L, Durand M. Acute otitis media in adults. 2024. In: UpToDate, Deschler D. (Ed), UpToDate, Waltham, MA. Available at <https://www.uptodate.com> (accessed May 20, 2025).
13. Wald E. Acute otitis media in children: Clinical manifestations and diagnosis. 2024. In: UpToDate, Edwards M, Isaacsom G (Ed), UpToDate, Waltham, MA. Available at <https://www.uptodate.com> (accessed May 20, 2025).
14. Marom T, Morris P. Otitis media with effusion (serous otitis media) in children: Clinical features and diagnosis. 2025. In: UpToDate, Isaacson G. Palazzi D (Ed), UpToDate, Waltham, MA. Available at <https://www.uptodate.com> (accessed May 20, 2025).
15. Lieberthal A, Carroll A, Chonmaitree T, et al. American Academy of Pediatrics. Clinical practice guideline: The Diagnosis and Management of Acute Otitis Media. Pediatrics. 2013 Mar; 131(3):e964-999. PMID 23439909

Centers for Medicare and Medicaid Services (CMS)

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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 <https://www.cms.hhs.gov>.

Policy History/Revision	
Date	**Description of Change**
12/31/2025	Document became inactive.
07/15/2025	Document updated with literature review. No change in Coverage. Added reference 14; others updated.
03/15/2024	Document updated with literature review. No change in Coverage. Added references 3, 7; others updated.
03/15/2023	Reviewed. No changes.
04/15/2022	Document updated with literature review. The following editorial change was made in Coverage: Updated device name to state "(i.e., OtoSight™ Middle Ear Scope, formally known as PhotoniCare TOMi Scope device)". Added reference 5; others updated.
02/15/2021	Reviewed. No changes.
04/15/2020	Document updated with literature review. The following change was made in Coverage: Changed device name to state (i.e., PhotoniCare *TOMi* Scope device). Added references 4, 5. Some references removed.
11/01/2018	Reviewed. No changes.
01/01/2018	New medical document. The use of optical coherence tomography (i.e., PhotoniCare ClearView imaging device) in the diagnosis and treatment of auditory system conditions is considered experimental, investigational and/or unproven.