Keystone First
Family of Health Plans

Optical coherence tomography imaging of the ear

Clinical Policy ID: CCP.1560

Recent review date: 6/2026

Next review date: 10/2027

Policy contains: optical coherence tomography, ear imaging, middle ear imaging, tympanic membrane imaging, otitis media, otitis media with effusion, middle ear effusion, OtoSight Middle Ear Scope, TOMi Scope, PhotoniCare.

Keystone First VIP Choice has developed clinical policies to assist with making coverage determinations. Keystone First VIP Choice's clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of "medically necessary," and the specific facts of the particular situation are considered by Keystone First VIP Choice, on a case by case basis, when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First VIP Choice's clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First VIP Choice's clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First VIP Choice will update its clinical policies as necessary. Keystone First VIP Choice's clinical policies are not guarantees of payment.

Coverage policy

Optical coherence tomography imaging of the ear, including unilateral and bilateral middle ear imaging is investigational/not clinically proven and, therefore, not medically necessary.

Limitations

No limitations were identified during the writing of this policy.

Alternative covered services

No alternative covered services were identified during the writing of this policy.

Background

Optical coherence tomography imaging of the ear is a noninvasive, noncontact optical imaging technique that uses low-coherence, near-infrared light to generate cross-sectional images of tissue microstructure. In otologic

use, handheld, otoscope-based, microscope-based, or endoscopic systems may image the tympanic membrane and adjacent middle ear space through the external auditory canal. The technology is intended to provide high-resolution structural information about the tympanic membrane, middle ear fluid or air, and other subsurface features that may not be visible with surface inspection alone (Matthews, 2020; Tan, 2018).

The proposed population includes individuals undergoing evaluation for middle ear effusion, acute otitis media, otitis media with effusion, recurrent acute otitis media, chronic otitis media with effusion, tympanic membrane abnormalities, and related otologic conditions. Conventional office evaluation generally includes visual inspection of the tympanic membrane with an otoscope, pneumatic otoscopy to assess tympanic membrane mobility, and tympanometry to assess middle ear function. These methods may be affected by examiner training, child cooperation, ear canal anatomy, cerumen, and the need for an adequate canal seal for pneumatic otoscopy or tympanometry (Neuberger, 2026; Preciado, 2020; Tan, 2018).

Optical coherence tomography imaging is proposed as an adjunctive or alternative diagnostic tool because it can image beneath the tympanic membrane without requiring a canal seal. Otoscope-based systems may combine video otoscopy with optical coherence tomography and may provide cross-sectional images, indicators of fluid presence, or turbidity information when middle ear fluid is present. These outputs are intended to assist clinical assessment in office or outpatient settings and to supplement interpretation of symptoms, otoscopic findings, and functional testing (Neuberger, 2026; Zambelli-Weiner, 2025).

The TOMi Scope (PhotoniCare Inc., Champaign, Illinois) received US Food and Drug Administration 510(k) clearance on December 5, 2019, for real-time visualization of the tympanic membrane and fluid or air within the middle ear space in children and adults (US Food and Drug Administration, 2019a, 2019b).

The OtoSight Middle Ear Scope (PhotoniCare Inc., Champaign, Illinois) received US Food and Drug Administration 510(k) clearance on September 26, 2022. The device is indicated for real-time visualization of the tympanic membrane and middle ear fluid or air, visualization of fluid density when middle ear fluid is present, and surface imaging of the ear canal and tympanic membrane in children and adults. The 510(k) summary states the device should not be used as a standalone diagnostic device and that images should be interpreted together with other clinical findings (US Food and Drug Administration, 2022a, 2022b).

Findings

Published evidence for optical coherence tomography imaging of the ear consists primarily of review articles, diagnostic accuracy and feasibility studies, one automated image-classification study, and one interim pragmatic randomized trial, with no identified guideline recommending the technology for diagnosis or management of middle ear effusion or otitis media. Standardized clinical criteria for image interpretation have not been established, and important evidence gaps remain, including limited prospective studies using independent reference standards, limited data in routine primary care and urgent care settings, incomplete standardization of image acquisition and interpretation, limited interobserver reliability data across typical clinical users, and limited evidence demonstrating improvement in treatment selection or clinical outcomes. Additional limitations include uncertainty regarding use in young children, cerumen obstruction, narrow ear canals, motion artifact, software-dependent turbidity scoring, automated interpretation methods, and generalizability outside specialized clinical settings.

Diagnostic accuracy

Neuberger et al. (2026), the largest identified diagnostic study, was a prospective single-visit clinic study of 164 pediatric participants and 328 ears that compared optical coherence tomography with otoscopy and tympanometry. Because tympanocentesis was not used, the investigators applied a latent class analysis informed by prior estimates of standard test performance. For all ears, optical coherence tomography demonstrated estimated sensitivity of 74% with 95% confidence interval 58% to 90% and specificity of 93% with 95% confidence interval 89% to 96%. Agreement was 77.7% between otoscopy and optical coherence tomography and 80.5% between tympanometry and optical coherence tomography. Agreement between clinical and nonclinical optical coherence tomography readers was moderate, with kappa 0.41 (Neuberger, 2026).

Preciado et al. (2020), a cross-sectional surgical-setting study, enrolled 70 pediatric participants undergoing tympanostomy tube placement and analyzed usable image data from 45 participants. Blinded reader interpretation for detection of middle ear effusion demonstrated 90.6% accuracy, 90.9% sensitivity, and 90.2% specificity, with intraobserver agreement of 92.9% and interobserver agreement of 87.1%. Differentiation of nonserous fluid was less consistent, with 70.8% accuracy, 53.6% sensitivity, 80.1% specificity, and interobserver agreement of 75.1%. These findings suggest greater reliability for identifying effusion presence than for characterizing fluid type (Preciado, 2020).

One automated classification study evaluated 58 previously imaged participant datasets from an internal repository. Optical coherence tomography metrics alone demonstrated high classification performance in internal testing, and a leave-one-image-out analysis estimated 91.50% performance when physician otoscopic impression was used as the reference and 99.16% performance when expert optical coherence tomography reader labels were used as the reference. Interpretation is limited by the small sample size, internal validation methods, and lack of independent clinical outcome assessment (Monroy, 2019).

Clinical utility

One interim pragmatic cluster randomized study evaluated prescribing and treatment decisions in 248 pediatric participants across four sites and 16 providers. In the fully adjusted model, use of the optical coherence tomography otoscope was associated with lower odds of antibiotic prescribing compared with standard care, odds ratio 0.50, 95% confidence interval 0.45 to 0.56, P value < 0.001. Providers using optical coherence tomography were more likely to select a single therapeutic modality than providers using standard care, 91.6% versus 73.8%, P value < 0.001. Standard care providers were also more likely to prescribe antibiotics plus another treatment, relative risk ratio 4.73, 95% confidence interval 1.37 to 16.29, P value = 0.014 (Zambelli-Weiner, 2025).

The interim analysis did not evaluate long-term outcomes such as symptom resolution, hearing outcomes, recurrence rates, complication rates, antimicrobial resistance outcomes, or sustained reduction in antibiotic exposure. Follow-up analyses of referrals, adherence, and economic impact were underpowered at the interim database lock (Zambelli-Weiner, 2025).

A separate small NIH-funded clinical trial enrolled 75 children age 1 to under 7 years presenting to primary care clinics associated with an academic children's hospital. Following history, physical examination, and pneumatic otoscopy, each child received an initial diagnosis and treatment plan; optical coherence tomography was then performed and the plan was reassessed. The diagnosis and/or treatment plan changed for 15.3% of patients after optical coherence tomography, with the greatest influence observed in the subgroup with middle ear effusion without acute otitis media, in which 36% (5 of 14) had diagnosis and/or treatment plan changes. These

results are relevant to clinical decision-making but are limited by the small sample size, single-trial design, and before-after reassessment by the same providers, and do not establish long-term clinical outcomes (Kerschner, 2026; ClinicalTrials.gov NCT05353569).

Comparison with standard evaluation methods

Published studies primarily compared optical coherence tomography with otoscopy, pneumatic otoscopy, tympanometry, clinician impression, surgical visualization, or expert image-reader interpretation. Current evidence does not establish superiority over standard evaluation methods in routine primary care or urgent care settings. The surgical-setting study (Preciado, 2020) provided a stronger reference standard for effusion presence but included selected participants already scheduled for tympanostomy tube placement. The larger office-based study (Neuberger, 2026) reflected awake clinic use but did not include tympanocentesis as an independent reference standard.

Optical coherence tomography has been described as a high-resolution method capable of assessing tympanic membrane thickness, middle ear effusion, biofilm, cholesteatoma, and ossicular or tympanic membrane motion in selected research and clinical settings. Broader clinical adoption may depend on cost, ease of use, imaging speed, field of view, and demonstration of improved clinical outcomes relative to established diagnostic pathways (Matthews, 2020; Tan, 2018).

Feasibility and workflow considerations

Image acquisition was feasible but variable. In the surgical-setting study, readable images were obtained from 45 of 70 participants, or 64%. Image quality was higher in older children, and image capture improved over the study period from 50.0% to 69.8%, suggesting effects related to age, cooperation, training, or operator familiarity. Sequential ear examinations in young children may reduce cooperation and image quality (Preciado, 2020).

In the awake clinic study, optical coherence tomography generally provided tympanic membrane visualization, and nonphysician personnel obtained scans after basic training. Good visualization was reported in 50% of medical assistant scans and 65% of surgeon scans. Interpretation remained dependent on image quality, software workflow, placement of the analysis window, and subjective interpretation of turbidity categories (Neuberger, 2026).

The office-based study noted that handheld optical coherence tomography equipment may cost approximately three to five times more than an industry-standard tympanometer. Current Procedural Terminology category three codes 0485T and 0486T may support claims tracking and reimbursement, although category three coding does not establish comparative effectiveness or clinical utility (Neuberger, 2026).

Safety

Safety reporting was limited. The surgical-setting study reported no harms or adverse events over 16 months of enrollment. The automated classification study described optical output of 2.5 milliwatts onto tissue, below American National Standards Institute exposure limits for the system used. Review articles described optical coherence tomography as noninvasive and nonionizing. However, the available studies were not designed or powered to detect uncommon harms, and follow-up duration was generally limited (Matthews, 2020; Monroy, 2019; Preciado, 2020; Tan, 2018).

References

On 5/2026, we searched PubMed and the databases of the Cochrane Library, the U.K. National Health Services Centre for Reviews and Dissemination, the Agency for Healthcare Research and Quality, and the Centers for Medicare & Medicaid Services. Search terms were: optical coherence tomography" ". We included the best available evidence according to established evidence hierarchies (typically systematic reviews, meta-analyses, and full economic analyses, where available) and professional guidelines based on such evidence and clinical expertise. No systematic reviews, meta-analyses, formal economic evaluations, or evidence-based clinical guidelines specific to optical coherence tomography imaging of the ear were identified at the time of this search.

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Policy updates

Initial review date: 5/2026 and clinical policy effective date: 7/2026

6/2026: Policy created.

Related codes

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy CCP.1560. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

Code	Code description
0485T	Optical coherence tomography of middle ear, with interpretation and report; unilateral
0486T	Optical coherence tomography of middle ear, with interpretation and report; bilateral