Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 5/1/25**
(See policy history boxes for previous effective dates)

Title: Optical Coherence Tomography (OCT) of the Middle Ear (e.g., PhotoniCare ClearView® System)

Description/Background

Middle Ear Infection (Otitis Media)

Otitis media can be a bacterial or viral infection of the middle ear and is usually accompanied by upper respiratory infections. Although otitis media can occur at any age, it is most common between ages 3 months and 3 years. At this age, the Eustachian tube is structurally and functionally immature—the angle of the Eustachian tube is more horizontal, and the angle of the tensor veli palatine muscle and the cartilaginous Eustachian tube renders the opening mechanism less efficient. The main symptom of otitis media is ear pain and may include hearing loss. Systemic symptoms such as fever, nausea, vomiting and diarrhea can also occur in young children.[1]

Diagnosis

The diagnosis of otitis media is usually clinical, based on the presence of onset of pain, bulging of the tympanic membrane and, particularly in children, the presence of signs of middle ear effusion on pneumatic otoscopy.[1]

Treatment

Otitis media resolves spontaneously in 80% of cases. If the otitis media does not spontaneously resolve, treatment may include oral analgesics, antibiotics or myringotomy. Myringotomy may be done for a bulging tympanic membrane, particularly if severe or persistent pain, fever, vomiting or diarrhea is present.[1]

PhotoniCare ClearView® System
PhotoniCare is a medical device company that developed the ClearView® device.[2] Physicians generally use an otoscope to check for ear infections. With the otoscope, physicians cannot see beyond the eardrum into the middle ear. The ClearView® device is a hand held device that allows physicians to see into the middle ear using near-infrared light waves to provide 3D views inside living tissues. This technology is similar to ultrasound but uses light rather than sound waves. According to PhotoniCare, the ClearView® device may provide a more accurate diagnosis of ear infections leading to more careful prescribing of antibiotics.

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 noninvasive imaging of the middle ear.[3] This 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.[3, 4]

In preparation for its commercial launch, PhotoniCare Inc. rebranded the TOMi Scope to the OtoSight™ Middle Ear Scope. Product code: QJG. [4]

Medical Policy Statement

Optical Coherence Tomography (OCT) of the middle ear is not an established procedure. While this service may be safe, its effectiveness in this clinical indication has not been scientifically determined. Therefore, this service is experimental/investigational.

Inclusionary and Exclusionary Guidelines

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.):

0485T 0486T

Note: Code(s) may not be covered by all contracts or certificates. Please consult customer or provider inquiry resources at BCBSM or BCN to verify coverage.

Rationale

Imaging for the middle and inner ear may be challenging, as conventional computed tomography and magnetic resonance imaging show limited resolution in time and space. Although relatively few studies exist on optical coherence tomography in this field, in vitro and in vivo, it has been shown that morphological data concerning middle ear structures and pathology such as biofilm can be identified with resolution in the range of few µm. Image acquisition may now be fast enough to assess sound transmission of middle ear ossicles, as well as capillary blood flow within the cochlea in real time. Optical coherence tomography (OCT) could be a powerful new tool for the clinician as well as for the researcher in otology.[5]

Nguyen et al (2012) reported on the use of optical coherent ranging techniques to noninvasively assess the middle ear to detect and quantify biofilm microstructure.[6] This study involved adults with chronic OM, which is generally accepted as a biofilm-related disease. Based on more than 18,537 optical ranging scans and 742 images from 13 clinically infected patients and 7 normal controls using clinical findings as the gold standard, all middle ears with chronic OM showed evidence of biofilms, and all normal ears did not. Information on the presence of a biofilm, along with its structure and response to antibiotic treatment, may provide a better fundamental understanding of biofilm formation, growth, and eradication in the middle ear, but also may provide much-needed quantifiable data to enable early detection and quantitative longitudinal treatment monitoring of middle-ear biofilms responsible for chronic OM.

Nguyen et al (2013) investigated the acoustic effects of bacterial biofilms, confirmed using OCT, in adult ears.[7] Noninvasive OCT images were collected to visualize the cross-sectional structure of the middle ear, verifying the presence of a biofilm behind the tympanic membrane. Wideband measurements of acoustic reflectance and impedance (0.2 to 6 [kHz]) were used to study the acoustic properties of ears with confirmed bacterial biofilms. Compared to known acoustic properties of middle ears, each of the ears with a bacterial biofilm has an elevated power reflectance in the 1 to 3 [kHz] range, corresponding to an abnormally small resistance (real part of the impedance). These results provide assistance for the clinical diagnosis of a bacterial biofilm, which could lead to improved treatment of chronic middle ear infection and further understanding of the impact of chronic otitis media on conductive hearing loss.

Hubler et al (2014) developed an algorithm for automatic, real-time, and accurate measurement of tympanic membrane thickness to aid in the diagnosis and monitoring of otitis media and other middle ear conditions.[8] The segmentation algorithm applies a Hough transform to the OCT image data to determine the boundaries of the tympanic membrane 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 tympanic membrane and across normal, acute, and chronic otitis media cases. The authors concluded that real-time segmentation and thickness measurements of image data from both healthy patients and those with acute and chronic otitis media demonstrate the use of OCT and this algorithm as an accurate method for use during

In a case series, Monroy et al (2015) used OCT to noninvasively and quantitatively determine tympanic membrane thickness and the presence and thickness of any middle-ear biofilm located behind the tympanic membrane.[9] These new metrics may offer the potential to differentiate normal, acute, and chronic otitis media infections in pediatric patients. The tympanic membrane thickness of 34 pediatric patients was acquired using a custom-built, handheld OCT system following a traditional otoscopic ear exam.

The results showed the overall thickness to be statistically different for normal, acute, and chronic infection groups (normal-acute and normal-chronic: p<.001); acute-chronic: p=.0016). Almost all observed scans from the chronic group had an accompanying biofilm structure. When the thickness of the tympanic membrane and biofilm were considered separately in chronic otitis media, the chronic tympanic membrane thickness correlated with the normal group (p=.68) yet was still distinct from the acute otitis media group (p<.001), indicating that the tympanic membrane in chronic otitis media returns to relatively normal thickness levels. The authors concluded that identifying these physical changes in vivo may provide new metrics for noninvasively and quantitatively differentiating normal, acute, and chronic otitis media.

MacDougall et al (2015) argues that while there is potential for OCT to play a role in clinical otology, there are some unique challenges for real-time, clinical use in humans.[10] These challenges include the need to work at a low numerical aperture, the deleterious effects of Transtympanic imaging on image quality at the ossicles, sensitivity requirements for clinical fidelity of images at real-time rates, and the high dynamic-range requirements of the ear.

Park et al (2017) believed that conventional otoscopes and oto-endoscopes, which are used to examine the tympanic membrane (TM), do not provide tomographic information. [11] OCT non-invasively reveals the depth-resolved internal microstructure of the TM with very high spatial resolution. This study was designed 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.

Preciado et al (2020) 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. [12] 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/inter reader 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.

SUMMARY OF EVIDENCE

Physicians generally use an otoscope to check for ear infections. PhotoniCare is a medical device company that developed the ClearView® device; a hand held device that allows physicians to see into the middle ear using near-infrared light waves to provide 3D views inside living tissues. Although the ClearView® device may be safe, noninvasive middle ear imaging using OCT presents some unique challenges for real-time, clinical use in humans. The evidence is insufficient to determine the effects of this technology on health outcomes.

SUPPLEMENTAL INFORMATION

PRACTICE GUIDELINES AND POSITION STATEMENTS

American Academy of Pediatrics (AAP)

The AAP guidelines on The Diagnosis and Management of Acute Otitis Media published in 2004 (last revised March 2013) does not include optical coherence tomography in the diagnosis or management of middle ear infections. [13]

American Academy of Otolaryngology (AAO)

The AAO updated clinical practice guideline: Otitis Media with Effusion published February 2016 (updated April 2021) does not include optical coherence tomography in the diagnosis or management of middle ear infections with effusion.[14]

Ongoing and Unpublished Clinical Trials

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

Table 1. Summary of Clinical 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 2027 (recruiting)

Government Regulations
National:
There is no national coverage determination (NCD) on optical coherence tomography of the middle ear.

The following codes 0485T and 0486T do not appear on the CMS 2023 physician fee schedule.

Local:
LCD: L35490, Category III Codes, effective on or after 11/17/2024.
Codes 0485T and 0486T do not appear in the covered service column.

(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

- Optical Coherence Tomography Imaging Anterior Eye
- Optical Coherence Tomography of the Breast and/or Axillary Lymph Nodes

References

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3. FDA – 510(k) Premarket Notification: TOMi Scope (K191804). (2019). U.S. Food and Drug Administration, Center for Devices and Radiologic Health. Available at https://www.fda.gov. Accessed December 2023.
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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. 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
13. Lieberthal AS, Carroll AE, Chonmaitree T, et al. The diagnosis and management of acute otitis media. Pediatrics. March 2013;131(3):e964-969.
14. Rosenfeld R. AAO-HNSF updated clinical practice guideline: otitis media with effusion. http://www.entnet.org/. Accessed January 2025.

The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through January 2, 2025, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
5/1/18	2/20/18	2/20/18	Joint policy established
5/1/19	2/19/19		Routine policy maintenance. No change in policy status.
5/1/20	2/18/20		Routine policy maintenance. No change in policy status.
5/1/21	2/16/21		Routine policy maintenance. No change in policy status.
5/1/22	2/15/22		Routine policy maintenance, no change in policy status.
5/1/23	2/21/23		Routine policy maintenance, no change in policy status. (ds)
5/1/24	2/20/24		Routine policy maintenance, no change in policy status. Vendor: N/A. (ky)
5/1/25	2/18/25		Routine policy maintenance, no change in policy status. Vendor: N/A. (ky)

Next Review Date: 1st Qtr. 2026

Pre-Consolidation Medical Policy History

Original Policy Date	Comments
BCN:	Revised:
BCBSM:	Revised:

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: OPTICAL COHERENCE TOMOGRAPHY (OCT) OF THE MIDDLE EAR (E.G., PHOTONICARE CLEARVIEW® SYSTEM)

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not Covered
BCNA (Medicare Advantage)	See government section
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.