



CLINICAL MEDICAL POLICY	
Policy Name:	Optical Coherence Tomography (OCT) of the Ear
Policy Number:	MP-160-MD-PA
Responsible Department(s):	Medical Management
Provider Notice/Issue Date:	09/28/2026
Effective Date:	12/01/2026
Next Annual Review:	12/2027
Revision Date:	05/20/2026
Products:	Highmark Wholecare SM Medicaid
Application:	All participating hospitals and providers
Page Number(s):	1 of 5

Policy History

Date	Action
12/01/2026	Provider effective date
08/27/2026	PARP Approval
06/17/2026	QI/UM Committee
06/17/2026	Policy initially developed based on DHS Memo MCOPS Memo # 03/2026-006

Disclaimer

Highmark WholecareSM medical policy is intended to serve only as a general reference resource regarding coverage for the services described. This policy does not constitute medical advice and is not intended to govern or otherwise influence medical decisions.

Policy Statement

Highmark WholecareSM may provide coverage under the medical-surgical benefits of the Company's Medicaid products for medically necessary optical coherence tomography (OCT).

This policy is designed to address medical necessity guidelines that are appropriate for the majority of individuals with a particular disease, illness, or condition. Each person's unique clinical circumstances warrant individual consideration, based upon review of applicable medical records.

(Current applicable Pennsylvania HealthChoices Agreement Section V. Program Requirements, B. Prior Authorization of Services, 1. General Prior Authorization Requirements.)

Definitions

Optical coherence tomography (OCT) - a noninvasive imaging method that ear care specialists use to produce cross-sectional images of an individual's ear. It works by measuring wavelengths of infrared light that reflect off the back of the middle and inner ear. OCT allows ear specialists to examine the ear in layers and to measure the depth of important structures, especially the inner and middle ear. This helps them diagnose and treat ear conditions.

Prior Authorization Review Panel (PARP) – A panel of representatives from within the PA Department of Human Services who have been assigned organizational responsibility for the review, approval and denial of all PH-MCO Prior Authorization policies and procedures.

Procedures

1. Optical coherence tomography (OCT) of the ear is generally considered to not be an established procedure, and the scientific effectiveness has not been determined. OCT of the ear may be considered medically effective under specific but very narrow clinical circumstances for a small number of individuals. Medical evidence is limited and not available in large clinical trials. Approvals will require the submission of a Program Exception request.
2. Post-payment Audit Statement
The medical record must include documentation that reflects the medical necessity criteria and is subject to audit by Highmark WholecareSM at any time pursuant to the terms of your provider agreement.
3. Place of Service
The proper place of service for OCT of the ear is outpatient.

Governing Bodies Approval

FDA

On December 5, 2019, the TOMi Scope (PhotoniCare, Champaign, IL.) was granted 510(k) clearance by the U.S. Food and Drug Administration (FDA) for noninvasive imaging of the middle ear. This device is designed to look 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.

CMS

The Centers for Medicare and Medicaid Services has no published guidance on this specific topic.

The Pennsylvania Department of Human Services Technology Assessment Group (TAG) workgroup meets quarterly to discuss issues revolving around new technologies and technologies or services that were previously considered to be a program exception. During this meeting, decisions are made as to whether or not certain technologies will be covered and how they will be covered. TAG's decisions are as follow:

- Option #1: Approved - Will be added to the Fee Schedule
- Option #2: Approved as Medically Effective - Will require Program Exception
- Option #3: Approved with (or denied due to) Limited/Minimal Evidence of Effectiveness - Will require Program Exception
- Option #4: Denied - Experimental/Investigational

As of March 2026, the TAG workgroup assigned OCT of the ear an Option # 3, specifically for procedure codes 0485T and 0486T.

Program Exception

OCT of the ear requires a Program Exception. The ordering physician must provide a supporting statement indicating why the requested therapy or device is medically necessary, and the alternative options have been or are likely to be ineffective, adversely affect patient compliance, or cause an adverse reaction.

Summary of Literature

Otitis media is a frequently occurring disease of the middle ear with a growing prevalence. By the age of one, at least 60% of infants have already suffered from acute otitis media. The origin is in the eustachian tube, resulting in accumulation of fluid in the tympanic cavity. The progression of the disease leads to a mucous and purulent liquid filling of the tympanic cavity, requiring antibiotics for preventing severe complications and residual hearing loss. The composition of the fluid in the tympanic cavity is difficult to determine non-invasively using the available diagnostics otoscopy and tympanometry. Thus, the selection of the appropriate therapy depends on the expertise of the physician, especially in case of inflammatory alterations (Kirsten et al, 2016).

Optical coherence tomography (OCT) is a relatively new medical diagnostic imaging modality. It is a cross-sectional imaging modality using non-ionizing light, typically, in the near-infrared region of 700-1800 nm. For imaging the middle and inner ear, OCT has several key properties that can be used on their own or as a complementary tool to existing technologies, such as ultrasound, MRI, CT, and light microscopy. OCT sensitivity is high to obtain cross-sectional images of the tympanic membrane and pathologies underneath it, middle ear structures in the cavity through intact eardrum, and some parts of the inner ear through the round window. The resolution of OCT is typically between 5 and 20 μm , which is sufficient to resolve

individual ossicles and the gross anatomy in the inner ear. The resolution can be improved to 1 μm to deliver images with near-cellular details. OCT can also measure mechanical vibrations using techniques known as phase-sensitive OCT, OCT vibrometry, or Doppler OCT. This functionality allows the measurements of acoustic transduction in the middle and inner ear and the assessment of conductive hearing function (Ramier et al, 2018).

OCT has a relatively shallow penetration depth in tissues compared to MRI and CT. The imaging depth of OCT is typically 1-3 mm in soft tissues and 0.5-1 mm in hard tissues. OCT imaging of the inner ear requires some surgical preparations to expose the region of interest. Intact cochlear walls are considered too thick to image through OCT (Ramier et al, 2018). Individuals have used OCT to look at the morphological information of the middle and inner ear, as well as the dynamic vibrations, and clinical applications of the OCT for diagnosis of middle ear diseases. Several studies have revealed OCT to show middle and inner ear structures, research about the anatomical accuracy of OCT is still lacking (Se-Joon et al, 2020).

A 2020 study investigated whether OCT provides useful information about the microstructures of the middle and inner ear via extratympanic approach and thereby could be utilized as an alternative diagnostic technology in ear imaging. Five rats and mice were included, and the OCT system was applied to confirm the extent of visibility of the middle and inner ear and measure the length or thickness of the microstructures in the ear. The cochlea was subsequently dissected following OCT and histologically evaluated to compare with the OCT images. The middle ear microstructures (ossicles, stapedial artery and oval window) could be confirmed in both rats and mice. It was also possible to obtain the inner ear images such as each compartment of the cochlea in the mice, but the bone covering bulla needed to be removed to visualize the inner ear structures in the rats which had thicker bulla. The bony thickness covering the cochlea could be measured, which showed no significant differences between OCT and histologic image at all turns of cochlea. OCT has been shown a promising technology to assess real-time middle and inner ear microstructures noninvasively with a high-resolution in the animal model. Therefore, OCT could be utilized to provide additional diagnostic information about the diseases of the middle and inner ear (Se-Joon et al, 2020)

in the human tympanic cavity. For this *ex vivo* study, a freshly excised human temporal bone was used. Pathologic alterations were excluded via otoscopic examination by an ENT physician. The external ear channel was removed to provide access to the entire tympanic membrane. The specimen was mounted using an articulated arm ensuring the orientation to be similar to a seating position of the patient. Otitis media with effusion was simulated by filling the tympanic membrane with different fluids through the Eustachian tube. A serous and transparent fluid filling was simulated using 0.9% saline solution. The highly scattering purulent liquid filling was simulated using SMOFlipid (Fresenius Kabi Deutschland GmbH). Structural OCT imaging allowed the three-dimensional visualization of the tympanic membrane, which had a thickness of about 140 μm in the pars tensa area. This study showed that structural OCT imaging alone is not suited for the detection of transparent fluid, where scattering particles are missing in the fluid. The study also showed that Doppler-OCT is suited for the indirect detection of scattering fluids and transparent fluids (Kirsten et al, 2016).

Coding Requirements

Procedure Codes

CPT Code	Description
0485T*	Optical coherence tomography (OCT) of middle ear, with interpretation and report; unilateral
0486T*	Optical coherence tomography (OCT) of middle ear, with interpretation and report; bilateral

*These procedure codes require a Program Exception will not be reimbursed without Medical Director approval.

Reimbursement

Participating facilities will be reimbursed per their Highmark WholecareSM contract.

Reference Sources

Pennsylvania Department of Human Services. Technology Assessment Group Coverage Managed Care Operations Memorandum MCOPS Memo# 03/2026-006. March 10, 2026. Accessed on April 20, 2026.

Cleveland Clinic. Optical Coherence Tomography (OCT). September 24, 2024. Accessed on April 20, 2026.

FDA – 510(k) Premarket Notification: TOMi Scope (K191804). U.S. Food and Drug Administration, Center for Devices and Radiologic Health. 2019. Accessed on April 21, 2026

Ramier A, Rosowski JJ, Seok-Hyun Y. Optical coherence tomography for imaging the middle and inner ears: A technical review. AIP Conference Proceedings 1965. May 31, 2018. Accessed on April 22, 2026.

Se-Joon O et al. Extratympanic Observation of Middle and Inner Ear Structures in Rodents Using Optical Coherence Tomography. Clin Exp Otorhinolaryngol. 2020. Accessed on April 22, 2026.

Kirsten L, Baumgärtner S, Erkkilä MT, et al. Doppler optical coherence tomography as a promising tool for detecting fluid in the human middle ear. Current Directions in Biomedical Engineering, vol. 2, no. 1. 2016. Accessed on April 22, 2026.