

Pursuant to **PhotoniCare's OtoSight Middle Ear Scope**, FDA (K191804) Indications for Use (IFU) statement cleared on December 5, 2019:

*"The **OtoSight Middle Ear Scope** is intended for use 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 **OtoSight Middle Ear Scope** is used to visualize the fluid density. The **OtoSight Middle Ear Scope** is also used to provide surface images of the ear canal and tympanic membrane. It is indicated for children and adults."*

The OtoSight Middle Ear Scope uses an advanced light-based technology to see through the eardrum. For the first time, healthcare providers can view a high-resolution depth image on-screen to learn what's going on in the middle ear.

The OtoSight Middle Ear Scope allows for real-time determination of middle ear fluid plus high-resolution video images of the eardrum surface. Cross-sectional images of the middle ear are shown on the system's screen. The healthcare provider can now simultaneously evaluate the revealing optical coherence tomography (OCT) visual images of the middle ear while viewing the otoscopic view of the eardrum surface. Both the OCT and otoscopic images can be saved for later analysis with the click of a button.

A select group of published, peer-reviewed articles relating to **PhotoniCare's OtoSight Middle Ear Scope** can be found on the company's website, under "Our Innovation". Alternatively, a full bibliography can be requested via the toll-free support line:

(866) 411-EARS (3277) Option #2.

SECTION 1: AMA CPT® Reporting

The American Medical Association created new Current Procedural Terminology (CPT) codes for provider use when working with the OtoSight Middle Ear Scope. The new Category III CPT codes went live on January 1, 2018. Services are reported as either unilateral (CPT 0485T) or bilateral (CPT 0486T).

CPT Code	Descriptor	Fee Schedule
0485T	Optical coherence tomography (OCT) of middle ear, with interpretation and report; unilateral	APC 5732 \$33.84
0486T	Optical coherence tomography (OCT) of middle ear, with interpretation and report; bilateral	

According to Medicare and URAC guidelines, all healthcare services provided should be reported on a claim form (UB-04 or CMS-1500) to the plan regardless of expectations of reimbursement. For physicians reporting services during an EVALUATION period whereby fair compensation has not been made for the provision of equipment or supply items, TRG recommends the use of modifiers

to provide specific information to the plans. **Modifier -26** should be considered for providers who wish to be compensated for the PROFESSIONAL COMPONENT only. Alternatively, if the provider is not requesting reimbursement, TRG suggests **Modifier -GY**.

It is the responsibility of the provider to ensure all services provided are reported – regardless of expectation of payment. Category III codes have not been formally surveyed by the Relative Value Update Committee; therefore, these codes may not have a formal fee schedule associated with the services. Instead, most payors will issue reimbursement as a percent of billed charges OR according to a percentile of historic billed charges across all service providers. To assist payors in the prompt processing of these services, we recommend populating the LOCAL USE field (Box 19 or electronic equivalent) on the claim form.

For OtoSight imaging services, please consider:

"PhotoniCare OtoSight Middle Ear Scope; FDA K191804 dated 12/5/2019"

SECTION 2: Supporting Medical Necessity

It is the obligation of the treating clinician to obtain and retain information relative to patient care and subsequent treatment decision-making. However, the strict definition of "medical necessity" varies by perspective (patient, plan, and provider) and valuation of evidence (quality and quantity of the evidence). Virtually all government and non-government plans provide written guidance on their requirements for documentation of medical necessity by indication.

The initial check for medical necessity is the listed primary and secondary ICD-10 diagnoses, as listed on the submitted claim. Beyond this check edit, plans generally defer to independent agencies in the development of indication-specific Care Guidelines. The two most notable agencies are MCG and InterQual.

Guidelines for the provision of **diagnostic imaging** are designed to guide both providers and reviewers to the most appropriate **diagnostic** tests based on a patient's unique circumstances.

Please note:

- Avoid terms such as "Rule out", "Possible", "Probable", and "Suspected".
- Report the precise signs or symptoms that led to the use of the OtoSight Middle Ear Scope. Charting of the patient's condition may be documented with specific primary and secondary diagnosis codes. A general statement supporting use may also be included in the chart:

"Patient presents as a higher complexity / higher diagnostic risk due to limited age, communication hindrances, or previous clinical history"

PhotoniCare has engaged TRG to assist their clients in coverage, coding, and reimbursement efforts.

Physician, facility, and patient customers may contact TRG Monday - Friday, from 8 am to 8 pm Eastern.

866-411-EARS (3277), Option #2

ICD-10-CM HCPCS TABLE:

ICD-10-CM	DESCRIPTOR
H65.01	Acute serous otitis media, right ear
H65.02	Acute serous otitis media, left ear
H65.03	Acute serous otitis media, bilateral
H65.04	Acute serous otitis media, recurrent, right ear
H65.05	Acute serous otitis media, recurrent, left ear
H65.06	Acute serous otitis media, recurrent, bilateral
H65.111	Acute and subacute allergic otitis media (mucoid) (sanguinous) (serous), right ear
H65.112	Acute and subacute allergic otitis media (mucoid) (sanguinous) (serous), left ear
H65.113	Acute and subacute allergic otitis media (mucoid) (sanguinous) (serous), bilateral
H65.114	Acute and subacute allergic otitis media (mucoid) (sanguinous) (serous), recurrent, right ear
H65.115	Acute and subacute allergic otitis media (mucoid) (sanguinous) (serous), recurrent, left ear
H65.116	Acute and subacute allergic otitis media (mucoid) (sanguinous) (serous), recurrent, bilateral
H65.191	Other acute nonsuppurative otitis media, right ear
H65.192	Other acute nonsuppurative otitis media, left ear
H65.193	Other acute nonsuppurative otitis media, bilateral
H65.194	Other acute nonsuppurative otitis media, recurrent, right ear
H65.195	Other acute nonsuppurative otitis media, recurrent, left ear
H65.196	Other acute nonsuppurative otitis media, recurrent, bilateral
H65.21	Chronic serous otitis media, right ear
H65.22	Chronic serous otitis media, left ear
H65.23	Chronic serous otitis media, bilateral
H65.31	Chronic mucoid otitis media, right ear
H65.32	Chronic mucoid otitis media, left ear
H65.33	Chronic mucoid otitis media, bilateral
H65.411	Chronic allergic otitis media, right ear
H65.412	Chronic allergic otitis media, left ear
H65.413	Chronic allergic otitis media, bilateral
H65.491	Other chronic nonsuppurative otitis media, right ear
H65.492	Other chronic nonsuppurative otitis media, left ear
H65.493	Other chronic nonsuppurative otitis media, bilateral
H66.001	Acute suppurative otitis media without spontaneous rupture of ear drum, right ear
H66.002	Acute suppurative otitis media without spontaneous rupture of ear drum, left ear
H66.003	Acute suppurative otitis media without spontaneous rupture of ear drum, bilateral
H66.004	Acute suppurative otitis media without spontaneous rupture of ear drum, recurrent, right ear
H66.005	Acute suppurative otitis media without spontaneous rupture of ear drum, recurrent, left ear
H66.006	Acute suppurative otitis media without spontaneous rupture of ear drum, recurrent, bilateral
H66.11	Chronic tubotympanic suppurative otitis media, right ear
H66.12	Chronic tubotympanic suppurative otitis media, left ear

ICD-10-CM	DESCRIPTOR
H66.13	Chronic tubotympanic suppurative otitis media, bilateral
H66.21	Chronic atticoantral suppurative otitis media, right ear
H66.22	Chronic atticoantral suppurative otitis media, left ear
H66.23	Chronic atticoantral suppurative otitis media, bilateral
H66.3X1	Other chronic suppurative otitis media, right ear
H66.3X2	Other chronic suppurative otitis media, left ear
H66.3X3	Other chronic suppurative otitis media, bilateral
H74.01	Tympanosclerosis, right ear
H74.02	Tympanosclerosis, left ear
H74.03	Tympanosclerosis, bilateral
H74.11	Adhesive right middle ear disease
H74.12	Adhesive left middle ear disease
H74.13	Adhesive middle ear disease, bilateral
H90.3	Sensorineural hearing loss, bilateral
H90.41	Sensorineural hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side
H90.42	Sensorineural hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side
H90.6	Mixed conductive and sensorineural hearing loss, bilateral
H90.71	Mixed conductive and sensorineural hearing loss, unilateral, right ear, with unrestricted hearing on the contralateral side
H90.72	Mixed conductive and sensorineural hearing loss, unilateral, left ear, with unrestricted hearing on the contralateral side
H90.A11	Conductive hearing loss, unilateral, right ear with restricted hearing on the contralateral side
H90.A12	Conductive hearing loss, unilateral, left ear with restricted hearing on the contralateral side
H90.A21	Sensorineural hearing loss, unilateral, right ear, with restricted hearing on the contralateral side
H90.A22	Sensorineural hearing loss, unilateral, left ear, with restricted hearing on the contralateral side
H90.A31	Mixed conductive and sensorineural hearing loss, unilateral, right ear with restricted hearing on the contralateral side
H90.A32	Mixed conductive and sensorineural hearing loss, unilateral, left ear with restricted hearing on the contralateral side
H92.01	Otalgia, right ear
H92.02	Otalgia, left ear
H92.03	Otalgia, bilateral
H92.11	Otorrhea, right ear
H92.12	Otorrhea, left ear
H92.13	Otorrhea, bilateral
H92.21	Otorrhagia, right ear
H92.22	Otorrhagia, left ear
H92.23	Otorrhagia, bilateral
H93.8X1	Other specified disorders of right ear
H93.8X2	Other specified disorders of left ear
H93.8X3	Other specified disorders of ear, bilateral

NOTE: The information detailed above, ICD-10-CM Diagnostic Table, is not an all-inclusive list. Providers are encouraged to be as specific as possible according to the patients' identified condition or disease state.



It is the responsibility of the provider to determine and report appropriate codes, modifiers, and charges for healthcare services rendered to patients in their care. This document is made available to U.S. customers and prospective customers of PhotonCare for notification of resources relevant to its products and services related to its products. The information contained in this document is provided for informational purposes only and represents no statement, promise or guarantee by PhotonCare concerning reimbursement, payment, or charges. Similarly, all ICD-10-CM, CPT-4, and HCPCS codes are referenced herein for informational purposes only and represent no statement, promise, or guarantee by The Reimbursement Group (a.k.a. TRG) or PhotonCare that these code selections are appropriate for any given prospective service/assessment, or that reimbursement will be made to the provider reporting these services. This document is not intended to increase or maximize reimbursement from any Payer. PhotonCare strongly recommends consulting your respective contracted Payer organization regarding to its coding and coverage medical policies. Language and coding provided in this document are derived from the American Medical Association's Current Procedural Terminology (CPT) as well as the Center for Medicare and Medicaid Services (CMS).