Anthem

Clinical UM Guideline

Subject: Myringotomy and Tympanostomy Tube Insertion
Guideline #: CG-SURG-46
Status: Reviewed

Publish Date: 04/10/2024
Last Review Date: 02/15/2024

Description

This document addresses myringotomy and tympanostomy tube insertion, which are procedures used to decompress and ventilate the middle ear when fluid builds up due to infection, trauma, or other conditions. Tympanostomy tubes are also known by other terms, including grommet, T-tube, ear tube, pressure equalization (PE) tube, vent, or myringotomy tube.

Clinical Indications

Medically Necessary:

The use of combined myringotomy and tympanostomy tube insertion is considered **medically necessary** for individuals who meet any of the following criteria:

A. Children or adults with recurrent acute otitis media (AOM) (more than 3 episodes in 6 months or more than 4 episodes in 12 months) with or without otitis media with effusion (OME) who have middle ear effusion at the time of assessment for tube candidacy; **or**
B. Children with unilateral or bilateral OME for greater than or equal to 3 months with hearing loss greater than 20 dB in one or both ears; **or**
C. Children with recurrent AOM or OME of any duration when the child is at risk for speech, language, or learning delay or disorder from OM based on baseline sensory, physical, cognitive, or behavioral factors including, but not limited to, the following:
    1. Confirmed speech or language delay or disorder.
    2. Autism spectrum disorder or other pervasive developmental disorder.
    3. Syndromes (for instance, Down) or craniofacial disorders that include cognitive, speech, or language delays.
    4. Intellectual disability, learning disorder, or attention-deficit/hyperactivity disorder.
    5. Blindness or uncorrectable visual impairment.
    6. Cleft palate, with or without associated syndrome; **or**
D. Children or adults with structural damage to the tympanic membrane (TM) or middle ear, such as cholesteatoma, chronic retraction of tympanic membrane or pars flaccida; **or**
E. Children or adults with barotitis (barotrauma); **or**
F. Children or adults with autophony due to patulous eustachian tube; **or**
G. Children or adults with middle ear dysfunction due to head and neck radiation or skull base surgery; **or**
H. Children or adults with a severe complication of acute otitis media including, but not limited to: meningitis, intracranial abscess, mastoiditis, or facial nerve paralysis; **or**
I. Adults with OME greater than 3 months and continued symptoms of aural pressure or hearing loss; **or**
J. Children or adults with persistent AOM despite at least 2 different courses of recommended empiric antibiotic therapy.

The use of myringotomy as a stand-alone procedure is considered **medically necessary** for individuals who meet one or more of the following criteria:

A. Neonates with otitis media who are either:
    1. 16 or fewer weeks of age for full term infants; **or**
    2. Premature infant whose adjusted age (actual age – # weeks premature) is less than 16 weeks; **or**
B. Individual with acute otitis media and an immunocompromising condition such as cancer chemotherapy or use of anti-rejection medications following a transplant; **or**
C. Individual who meets criteria for tympanostomy and tube insertion but for whom tube insertion is not feasible due to the degree of ear inflammation.

Not Medically Necessary:

The use of myringotomy alone is considered **not medically necessary** when the criteria above have not been met and for all other indications.

The use of combined myringotomy and tympanostomy tube insertion is considered **not medically necessary** when the criteria above have not been met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this guideline are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

When services may be Medically Necessary when criteria are met:

CPT	
69420	Myringotomy including aspiration and/or eustachian tube inflation
69421	Myringotomy including aspiration and/or eustachian tube inflation requiring general anesthesia
69433	Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia
69436	Tympanostomy (requiring insertion of ventilating tube), general anesthesia
0583T	Tympanostomy (requiring insertion of ventilating tube), using an automated tube delivery system, iontophoresis local anesthesia

ICD-10 Procedure

099500Z	Drainage of right middle ear with drainage device, open approach
09950ZZ	Drainage of right middle ear, open approach
099600Z	Drainage of left middle ear with drainage device, open approach
09960ZZ	Drainage of left middle ear, open approach
099700Z	Drainage of right tympanic membrane with drainage device, open approach
09970ZZ	Drainage of right tympanic membrane, open approach
099800Z	Drainage of left tympanic membrane, with drainage device, open approach
09980ZZ	Drainage of left tympanic membrane, open approach

ICD-10 Diagnosis

All diagnoses

When services are Not Medically Necessary:
For the procedure codes listed above when criteria are not met or for situations designated in the Clinical Indications section as not medically necessary.

Discussion/General Information

According to the American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS), myringotomy is defined as a surgical procedure in which a small incision is made in the tympanic membrane (ear drum) for the purpose of draining fluid or providing short-term ventilation. The procedure is also used to relieve pressure caused by excessive buildup of fluid or to drain pus from the middle ear. It is most commonly done as a treatment for OME but may also be considered as a treatment for ear trauma (including pressure-related barotrauma) and eustachian tube dysfunction in adults.

Tympanostomy is a companion procedure to myringotomy and involves the insertion of a small tube into the eardrum through a myringotomy incision in order to keep the middle ear aerated for a prolonged period of time, and to prevent the accumulation of fluid in the middle ear. The procedure to place a tube involves myringotomy and is performed under local or general anesthesia. There are many different tube designs available on the market. The most commonly used type is shaped like a grommet. When it is necessary to keep the middle ear ventilated for a very long period, a "T"-shaped tube may be used, as these "T-tubes" can stay in place for 2-4 years.

The use of myringotomy and tympanostomy tube insertion has become a widely used and accepted method of treating various middle ear conditions in children and adults.

The American Academy of Otolaryngology-Head and Neck Surgery (AAO-HNS) published an updated clinical practice guideline addressing the use of tympanostomy tubes in children (Rosenfeld, 2022). The recommendations are substantially unchanged from the previous guideline with the following exceptions. Statement 8 concerning at-risk children has expanded criteria to include children with intellectual disability, learning disorder, or attention-deficit/hyperactivity disorder. Statement 10 recommends against a tympanostomy with “long-term tubes as initial surgery for children who meet criteria for tube insertion unless there is a specific reason based on an anticipated need for prolonged middle ear ventilation beyond that of a short-term tube.” Statement 13 recommends against routinely prescribing postoperative antibiotic ear drops after tympanostomy tube placement. In Statement 16, the guideline strongly recommends follow-up after tube placement and that the surgeon or designee should examine the ears of a child within 3 months of tympanostomy tube insertion. The guideline further offers a new option in Statement 11 that adenoidectomy may be performed “as an adjunct to tympanostomy tube insertion for children with symptoms directly related to the adenoids (adenoid infection or nasal obstruction) or in children aged 4 years or older to potentially reduce future incidence of recurrent otitis media or the need for repeat tube insertion.” The authors acknowledged a moderate to low level of evidence supporting this statement. This statement reflects that the expected benefit of adjunctive adenoidectomy is only a potential. Prospective randomized trials are needed in order to determine whether adjunctive adenoidectomy provides a net health benefit compared to tympanostomy tube insertion alone. This document provides the following recommendations related to criteria for tympanostomy tube placement:

- STATEMENT 1. OME OF SHORT DURATION: Clinicians should not perform tympanostomy tube insertion in children with a single episode of OME of less than 3 months’ duration, from the date of onset (if known) or from the date of diagnosis (if onset is unknown).
- STATEMENT 2. HEARING EVALUATION: Clinicians should obtain a hearing evaluation if OME persists for 3 months or longer OR prior to surgery when a child becomes a candidate for tympanostomy tube insertion.
- STATEMENT 3. Clinicians should offer bilateral tympanostomy tube insertion to children with bilateral OME for 3 months or longer AND documented hearing difficulties.
- STATEMENT 4. Clinicians may perform tympanostomy tube insertion in children with unilateral or bilateral OME for 3 months or longer (chronic OME) AND symptoms that are likely attributable, all or in part, to OME that include, but are not limited to, balance (vestibular) problems, poor school performance, behavioral problems, ear discomfort, or reduced quality of life.
- STATEMENT 6. Clinicians should not perform tympanostomy tube insertion in children with recurrent AOM who do not have MEE in either ear at the time of assessment for tube candidacy.
- STATEMENT 7. Clinicians should offer bilateral tympanostomy tube insertion in children with recurrent AOM who have unilateral or bilateral MEE at the time of assessment for tube candidacy.
- STATEMENT 8. Clinicians should determine if a child with recurrent AOM or with OME of any duration is at increased risk for speech, language, or learning problems from otitis media because of baseline sensory, physical, cognitive, or behavioral factors.
- STATEMENT 9. Clinicians may perform tympanostomy tube insertion in at-risk children with unilateral or bilateral OME that is likely to persist as reflected by a type B (flat) tympanogram or a documented effusion for 3 months or longer.
- STATEMENT 10. The clinician should not place long-term tubes as initial surgery for children who meet criteria for tube insertion unless there is a specific reason based on an anticipated need for prolonged middle ear ventilation beyond that of a short-term tube.

These recommendations are based on multiple studies addressing the use of tympanostomy, which demonstrate a “preponderance of benefit over harm” (Broen, 1996; Casselbrant, 1992; Gebhart, 1981; Gonzales, 1986; Hellstrom, 2011; Iino, 1999; Lous, 2012; Mandel, 1989, 1992; Paradise, 2001, 2005; Ponduri, 2009; Rosenfeld, 2011, 2016; Rovers, 2001a, 2001b, 2005; Sheahan, 2002).

The American Academy of Pediatrics (AAP) published their clinical practice guideline titled *The Diagnosis and Management of Acute Otitis Media* in 2013 (Lieberthal, 2013). This document includes the following Key Action Statement based on multiple studies (Casselbrant, 1992; Gebhart, 1981; Gonzales, 1986; Rosenfeld, 2000; Witsell, 2005):

- Clinicians may offer tympanostomy tubes for recurrent AOM (3 episodes in 6 months or 4 episodes in 1 year, with 1 episode in the preceding 6 months). (Evidence Quality: Grade B, Rec. Strength: Option).

The use of myringotomy and tympanostomy tube insertion has become accepted as a treatment method for individuals with severe complication of acute otitis media such as meningitis, intracranial abscess, mastoiditis, or facial nerve paralysis. While there is little evidence addressing such treatment, there is wide agreement in the otolaryngology community supporting it. In such cases it is deemed prudent to use myringotomy and tympanostomy to prevent further progression of complications.

In 2017, Steele and others published the results of a meta-analysis investigating the effectiveness of tympanostomy tubes in children with chronic otitis media with effusion and recurrent acute otitis media. The analysis involved 54 publications, with 29 studies describing the results of 16 RCTs and another 24 studies reporting the results of 24 non-randomized controlled trials. The authors reported that children with chronic otitis media with effusion who were treated with tympanostomy tubes had a net decrease in mean hearing threshold vs. watchful waiting of 9.1 dB at 1 to 3 months and 0.0 dB at 12 to 24 months. They noted that children with recurrent acute otitis media may have fewer episodes after placement of tympanostomy tubes. Finally, they found that adverse events are associated with tympanostomy tube placement are poorly defined and reported. They concluded,

> Tympanostomy tubes improve hearing at 1 to 3 months compared with watchful waiting, with no evidence of benefit by 12 to 24 months. Children with recurrent acute otitis media may have fewer episodes after tympanostomy tube placement, but the evidence base is severely limited. The benefits of tympanostomy tubes must be weighed against a variety of associated adverse events.

In 2021 Hoberman and colleagues reported the results of an RCT involving 250 children between 6 and 35 months of age with recurrent AOM assigned to treatment with either tympanostomy tubes (n=129) or medical management (n=121). At the end of the 2-year follow-up period, 208 participants had completed the trial, with 13 (10%) participants in the tube group not undergoing their procedure. In the medical group, 54 (45%) participants subsequently underwent tube placement procedures; 35 (29%) of whom received tube placement according to protocol due to recurrence of AOM and 19 (16%) at the request of the parent. The authors reported their results using a per protocol analysis that included in the tube group the 35 participants from the medical group who underwent tube placement. The primary outcome, rate of occurrence of AOM in during the study period, was found to not be significantly different between groups (p=0.66). Similarly, no significant differences between groups were found with regard to secondary outcomes, including percentage of episodes of AOM categorized as ‘probably severe’, the percentage of children who had protocol-defined diarrhea or medication-related diaper dermatitis, extent of antimicrobial resistance, quality of life, use of medical and nonmedical resources, or parental satisfaction with the treatment assignment. Some significant differences were reported in favor of the tube group for fewer days per year with otitis-related symptoms other than tube otorrhea and fewer days per year receiving systemic antimicrobial treatment (no p-values provided). In the medical group, 55 participants met treatment failure criteria. An analysis of this group found them to be younger at baseline than the 46 medical group participants who did not experience treatment failure nor underwent subsequent tube placement. The authors concluded, “Among children 6 to 35 months of age with recurrent acute otitis media, the rate of episodes of acute otitis media during a 2-year period was not significantly lower with tympanostomy-tube placement than with medical management.”

The procedure to place a tympanostomy tube is commonly performed in an operating room (OR) under general anesthesia. However, in 2019, a device intended to create a myringotomy and insert a tympanostomy tube under local anesthesia in a clinician’s office (Tula® Tympanostomy System) was approved by the FDA. The device was approved for use in adults and in pediatric individuals aged 6 months and older. Soon after, a similar device, the Hummingbird® Tympanostomy Tube System, was cleared for use in children 6-24 months old. Advantages of these devices include avoiding of the need for general anesthesia for tube placement. Risks may include inadequate local anesthesia, dizziness and other common tympanostomy procedure risks such as otorrhea and tympanosclerosis. Prospective, multicenter studies have demonstrated success rates of at least 90% for in-office tympanostomy tube procedures (Truitt, 2021; Zeiders, 2015). In selected individuals with AOM who have normal ear anatomy and can avoid excessive movement, the in-office procedure provides a reasonable alternative to inpatient tympanostomy tube insertion. The AAO-HNS concurs in their 2019 statement on in-office placement of tubes:

> The position of the AAO-HNS is that tympanostomy tubes are safe and effective for managing otitis media in children who meet current guidelines for tube insertion [Rosenfeld 2013]. Although insertion of tympanostomy tubes in children is generally accomplished in the operating room under general anesthesia, insertion in the clinic in appropriately selected patients using shared decision making between clinicians and families can be appropriate.

The use of myringotomy alone is poorly studied in the medical literature. In most circumstances, there is no available evidence to demonstrate that the use of myringotomy without tube insertion has any incremental benefit over myringotomy with tube insertion for the treatment of OME or AOM; to the contrary, there is limited published literature indicating that it is inferior for these indications (Mandel, 1992). The use of tubes in conjunction with myringotomy in circumstances where myringotomy alone has been proposed adds longer-term benefits such as prolonged ventilation and drainage, and pressure release. Further, middle ear fluid cultures are generally considered unnecessary when planning or adjusting antibiotic choices, and could be accomplished via less invasive procedures, if required. However, there are some isolated circumstances where myringotomy alone may be warranted. Such circumstances may include when an individual’s tympanic membrane is inflamed to the point where tube placement is not possible or in neonates when tube placement presents too great a risk. Other instances for myringotomy alone may be presented in individuals who are immunocompromised and who may present with advanced OM requiring immediate treatment or to obtain cultures to identify the infectious agent.

Definitions

Acute otitis media (AOM): Middle ear infection characterized by a history of acute onset of signs and symptoms, the presence of middle-ear effusion, and signs and symptoms of middle-ear inflammation.

Autophony: A condition characterized by an unusually loud hearing of a person's own voice and/or breathing.

Barotitis (barotrauma): Damage to the middle ear caused by pressure changes.

Intra-cranial complication: In this instance, a problem such as an infection inside the skull, that is related to the otitis media.

Mastoiditis: An infection of the mastoid bone of the skull.

Myringotomy: A surgical procedure that creates a small hole in the eardrum.

Otitis media with effusion (OME): An ear condition characterized by the accumulation of fluid in the middle ear.

Pars flaccida: A part of the ear drum.

Patulous eustachian tube: A condition where the eustachian tube that runs from the middle ear to the nasopharynx, which is normally closed, stays intermittently open.

Retraction of tympanic membrane: A condition in which a part of the eardrum lies deeper within the ear than normal.

Tympanostomy tube: A small tube placed into a myringotomy incision to maintain the opening for prolong periods of time. Tympanostomy tubes are also known by other terms, including grommet, T-tube, ear tube, pressure equalization tube, vent, PE tube, or myringotomy tube.

Vestibular problems: Health conditions due to infection, inflammation, or damage to the vestibular system of the inner ear. This is usually characterized by balance problems.

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Government Agency, Medical Society, and Other Authoritative Publications:

1. American Academy of Family Physicians; American Academy of Otolaryngology-Head and Neck Surgery; American Academy of Pediatrics Subcommittee on Otitis Media With Effusion. Otitis media with effusion. Pediatrics. 2004; 113(5):1412-1429.
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Index

The use of specific product names is illustrative only. It is not intended to be a recommendation of one product over another, and is not intended to represent a complete listing of all products available.

History

Status	Date	Action
Reviewed	02/15/2024	Medical Policy & Technology Assessment Committee (MPTAC) review. Revised Discussion and References sections.
Reviewed	08/10/2023	MPTAC review. Added text to Discussion/General Information related to outpatient tympanostomy tube insertion. Updated References and Index sections. Updated Coding section; added 0583T; removed ICD-10-PCS codes 099780Z; 09978ZZ; 099880Z; 09988ZZ not applicable.
Revised	02/16/2023	MPTAC review. Revised MN criteria to add individuals with “Intellectual disability, learning disorder, or attention-deficit/hyperactivity disorder.” Updated Discussion/General Information and References sections.
Reviewed	02/17/2022	MPTAC review. Updated Rationale and References sections.
Reviewed	02/11/2021	MPTAC review. Reformatted Coding section.
Reviewed	02/20/2020	MPTAC review. Updated References section.
Reviewed	03/21/2019	MPTAC review. Updated References section.
Reviewed	05/03/2018	MPTAC review. The document header wording updated from “Current Effective Date” to “Publish Date.” Updated References section.
Reviewed	05/04/2017	MPTAC review. Updated formatting in Clinical Indications section. Updated References sections.
Reviewed	05/05/2016	MPTAC review. Updated Rationale and References sections.
Revised	11/05/2015	MPTAC review. Revised medically necessary statement criteria 1 to add “who have middle ear effusion at the time of assessment for tube candidacy”. Removed ICD-9 codes from Coding section.
Revised	08/06/2015	MPTAC review. Revised medically necessary indications to address additional indications for myringotomy and tympanostomy tube placement and myringotomy alone. Updated Discussion and References sections.
Reviewed	05/07/2015	MPTAC review. Updated Discussion and References sections.
New	02/05/2015	MPTAC review. Initial document development.