Policy

*Please see amendment for Pennsylvania Medicaid at the end of this CPB.

Aetna considers myringotomy and tympanostomy tube (also known as ventilation tube and grommet) insertion medically necessary for any of the following indications:

1. Autophony due to patulous eustachian tube; or
2. Barotitis media control; or
3. Children with cleft palate and history of otitis media with effusion and persistent hearing loss; or
4. Cholesteatoma; or
5. Chronic retraction of tympanic membrane or pars flaccida; or
6. Complications of otitis media such as meningitis, facial nerve paralysis, coalescent mastoiditis, or brain abscess; or
7. Otitis media with effusion after 3 months or longer and bilateral hearing impairment (defined as 20 dB hearing threshold level or worse in both ears) (tympanostomy tube); or
8. Recurrent episodes of acute otitis media (more than 3 episodes in 6 months or more than 4 episodes in 12 months) (tympanostomy tube); or
9. Severe otalgia in acute otitis media (myringotomy); or

Policy History

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Review History

Definitions

Additional Information

Clinical Policy Bulletin Notes
10. To obtain a culture (diagnostic tympanocentesis/myringotomy) of the middle ear fluid prior to beginning or changing antimicrobial therapy (this may be necessary in situations such as otitis media that has failed to respond to appropriate antimicrobial therapy, or for otitis media in individuals or neonates who are immunocompromised).

Notes:

OtoScan laser-assisted myringotomy (also called tympano-laserostomy, laser-assisted tympanostomy [LAT] or OtoLAM) is considered to be as effective as traditional myringotomy and is safe. The same selection criteria apply to both laser myringotomy and the traditional myringotomy.

Tympanostomy tube insertion is considered not medically necessary for children with a single episode of otitis media with effusion (OME) of less than 3 months’ duration

Tympanostomy tube insertion is considered not medically necessary for children with recurrent acute otitis media (AOM) who do not have middle ear effusion in either ear at the time of assessment for tube candidacy.

Aetna considers myringotomy and tympanostomy tube insertion experimental and investigational for all other indications (e.g., the prevention of hearing impairment in children with Cornelia de Lange syndrome without above-listed indications for tube placement) because its effectiveness for indications other than the ones listed above has not been established.

Aetna considers the use of (i) phosphorylcholine-coated tympanostomy tube and (ii) vancomycin-coated tympanostomy tube experimental and investigational because their effectiveness has not been established.

Aetna considers the EarPopper device for the treatment of otitis media with effusion and all other conditions (e.g., eustachian tube dysfunction and negative pressure as a consequence of elevation changes from airline travel, diving, and sinusitis surgery, etc.) experimental and investigational because of insufficient
evidence of its effectiveness.

Aetna considers endoscopic balloon dilation of the Eustachian tube for the treatment of Eustachian tube dysfunction experimental and investigational because of insufficient evidence of its effectiveness.

**Background**

*Myringotomy and Tympanostomy Tube:*

A myringotomy is an incision of the tympanic membrane to allow ventilation of the middle ear, drainage of middle ear fluid, or to obtain cultures from an infected middle ear. In children with middle-ear effusions, initial treatment often consists of observation or antibiotic therapy even though recent evidence indicated that the benefit of antibiotics for otitis media with effusion (Lous et al, 2005) and acute otitis media (Schilder et al, 2004) is limited. Most cases of otitis media with effusion resolve spontaneously within 3 months of onset.

An alternative to myringotomy with tube placement is a new tympanostomy procedure by CO2 laser without ventilation tubes, (also called tympanolaserostomy or laser-assisted tympanostomy [LAT]). OtoLAM™ (ESC Medical Systems, Needham, MA) is performed with a computer-driven laser and a video monitor to pinpoint the exact location for the hole. It programs the precise size of the hole into the computer. The laser then takes just 1/10 of a second to create the opening, without damaging surrounding skin or structures in the ear. The hole stays open for several weeks and this provides ventilation of the middle ear without the need for tube placement. Studies showed that the CO2 laser was especially effective in vaporizing the tympanic membrane, especially when there was fluid behind the tympanic membrane to protect the promontory. Laser myringotomies maintain patency slightly longer than that produced by cold-knife myringotomy (3 to 6 weeks versus 48 to 72 hours) but have not been proven to be more efficacious in the management of effusion than simple myringotomy. A randomized controlled
study (n = 208) found that laser myringotomy is safe but less effective than ventilation tube in the treatment of chronic otitis media with effusion (Koopman et al, 2004).

In an update of the 1994 clinical practice guideline *Otitis Media With Effusion in Young Children*, developed by the AHCPR, the American Academy of Family Physicians, American Academy of Otolaryngology-Head and Neck Surgery, and the American Academy of Pediatrics Subcommittee on otitis media with effusion (2004) recommended that clinicians should manage children with otitis media with effusion (OME, aged 2 months through 12 years) who are not at risk with watchful waiting for 3 months from the date of effusion onset (if known), or from the date of diagnosis (if onset is unknown). Children with persistent OME who are not at risk should be re-examined at 3- to 6-month intervals until the effusion is no longer present, significant hearing loss is identified, or structural abnormalities of the eardrum or middle ear are suspected. When a child becomes a surgical candidate, tympanostomy tube insertion is the preferred initial procedure. Candidates for surgery include children with OME lasting 4 months or longer with persistent hearing loss or other signs and symptoms, recurrent or persistent OME in children at risk regardless of hearing status, and OME and structural damage to the tympanic membrane or middle ear. The tube usually remains in place for several months, although it may be rejected sooner or remain in place for years. Adenoidectomy should not be performed unless a distinct indication exists (nasal obstruction, chronic adenoiditis); repeat surgery should consist of adenoidectomy plus myringotomy, with or without tube insertion. Furthermore, tonsillectomy alone or myringotomy alone should not be used to treat OME (Rosenfeld et al, 2004).

A Cochrane review (Lous et al, 2005) stated that the most common medical treatment options for OME include the use of decongestants, mucolytics, steroids, anti-histamines and antibiotics. The effectiveness of these therapies, however, has not been established. Surgical treatment options include grommet (ventilation or tympanostomy tube) insertion, adenoidectomy or both. Moreover, the benefits of grommets in children appear small. The effect of grommets on hearing
diminished during the first year. Potentially adverse effects on the tympanic membrane are common after grommet insertion. Thus, an initial period of watchful waiting seems to be an appropriate management strategy for most children with OME. Randomised controlled studies are needed before more detailed conclusions about the effectiveness of grommets can be drawn.

In a multi-center, randomized controlled study (n = 395), Paradise et al (2005) concluded that in otherwise healthy children younger than 3 years of age who have persistent middle-ear effusion within the duration of effusion (9 months) that these patients were studied, prompt insertion of tympanostomy tubes does not improve developmental outcomes at 6 years of age.

In a "follow-up" study, Paradise et al (2007) examined tympanostomy tubes and developmental outcomes at 9 to 11 years of age. These researchers enrolled 6,350 infants soon after birth and evaluated them regularly for middle-ear effusion. Before 3 years of age, 429 children with persistent effusion were randomly assigned to undergo the insertion of tympanostomy tubes either promptly or up to 9 months later if effusion persisted. They assessed literacy, attention, social skills, and academic achievement in 391 of these children at 9 to 11 years of age. Mean (+/- SD) scores on 48 developmental measures in the group of children who were assigned to undergo early insertion of tympanostomy tubes did not differ significantly from the scores in the group that was assigned to undergo delayed insertion. These measures included the Passage Comprehension subtest of the Woodcock Reading Mastery Tests (mean score, 98 +/- 12 in the early-treatment group and 99 +/- 12 in the delayed-treatment group); the Spelling, Writing Samples, and Calculation subtests of the Woodcock-Johnson III Tests of Achievement (96 +/- 13 and 97 +/- 16; 104 +/- 14 and 105 +/- 15; and 99 +/- 13 and 99 +/- 13, respectively); and inattention ratings on visual and auditory continuous performance tests. The authors concluded that in otherwise healthy young children who have persistent middle-ear effusion, as defined in this study, prompt insertion of tympanostomy tubes does not improve developmental outcomes up to 9 to 11 years of age.
In an editorial that accompanied the study by Paradise and associates, Berman (2007) stated that the consistency of the findings of Paradise et al during prolonged follow-up periods provided convincing evidence that persistent middle-ear effusion in otherwise normal children does not cause developmental impairments.

Allen (2007) conducted a retrospective chart review to determine if intravenous access is necessary during the performance of myringotomy with tube insertion. The study included 50 pediatric patients divided equally into 2 groups: group 1, who did not have intravenous access established before the procedure, and group 2, who did have intravenous access established. To be enrolled, patients in both groups had to be less 12 years of age or younger, have an American Society of Anesthesiologists physical status classification of P1 or P2, and had to have undergone no adjunctive procedure with the myringotomy. Induction time was significantly shorter in group 1 (average: 6.96 +/- 2.72 mins) than in group 2 (average: 9.80 +/- 3.82 mins; p = 0.004). Operating time and total operating room time were not significantly different between the 2 groups. Additionally, 24 of 25 patients in group 1 had their pain managed with acetaminophen or no medication at all, while 9 of 25 group 2 patients received acetaminophen and 13 received intravenous pain medication. Interestingly, no patients in group 1 required anti-emetics, whereas 4 patients in group 2, who were given intravenous or intramuscular narcotics, received anti-emetic medications. These findings indicate that myringotomy with tube insertion can be safely accomplished without establishing intravenous access. Induction times and time under general anesthesia were significantly increased when intravenous access was obtained. The findings also suggest that acetaminophen provides adequate post-operative pain control in this patient population and that the use of intravenous or intramuscular narcotics increases the risk of post-operative nausea.

Spielmann et al (2008) stated that there is a paucity of evidence to guide the post-operative follow-up of patients undergoing middle-ear ventilation tube insertion for the first time. This study was undertaken to identify current practice at the authors'
institution and to inform subsequent change in their follow-up procedure. Two cycles of data collection and analysis were performed. All pediatric patients undergoing ventilation tube insertion for the first time were identified. Patients who had previously undergone ventilation tube insertion or additional procedures such as adenoidectomy or tonsillectomy were excluded. The first data collection period comprised all of the year 2000, and the second 18 months over 2003 to 2004. A minimum of 20 months' follow-up was allowed for. Data regarding clinical findings and audiometry were recorded at each follow-up appointment. A total of 50 patients meeting the criteria for inclusion in the first cohort were identified. There were a total of 156 appointments between surgery and data collection (a mean of 3.12 per child). A total of 113 (72 %) appointments lead to no medical intervention. The only statistically significant difference between patients requiring further ventilation tube insertion (n = 10) and those not requiring further treatment during the study period (n = 40) was the average hearing threshold (p < 0.01). These findings prompted a change in the post-operative regime; all patients undergoing ventilation tube insertion were subsequently seen at 3 months for a pure tone audiogram, and further review depended on clinical and audiometric findings. Records for 84 children were identified and collected for the second cohort, there were a total of 154 appointments (a mean of 1.83 per child). In only 18 appointments (12 %) were normal findings and hearing recorded and children given a further review appointment. Sixteen of 29 (55 %) children with abnormal clinical findings (otorrhea, tube blockage or extrusion) required some form of intervention (p < 0.05). Twenty-six had a mean hearing threshold worse than 20 dB at first review. Nineteen (73 %) required further intervention of some sort (p < 0.01). The authors concluded that these findings demonstrated that the vast majority of review appointments resulted in no clinical intervention. Thus, these investigators question the need for regular follow-up in this patient group. Twenty per cent (10 of 50 and 18 of 84) of the patients required further ventilation tube insertion within the study periods. This is consistent with rates reported in the literature. Children with abnormal clinical findings or a mean hearing threshold greater than 20 dB were significantly more
likely to require further intervention. The authors recommended one post-operative review with audiometry, 3 months after surgery. At this initial appointment, further review should be offered to those children with poor hearing, early extrusion, blockage or infection, as they are more likely to require further ventilation tube insertion.

In a Cochrane review on grommets (ventilation tubes) for recurrent acute otitis media in children, McDonald et al (2008) concluded that ventilation tubes have a significant role in maintaining a "disease-free" state in the first 6 months after insertion. They stated that more research is needed to investigate the effect beyond 6 months. Furthermore, clinicians should consider the possible adverse effects of grommet insertion before surgery is undertaken.

Campbell and colleagues (2009) stated that primary ciliary dyskinesia is an autosomal recessively inherited group of disorders of ciliary ultra-structure. Otolaryngologists are frequently involved in the management of some of the most common symptoms of primary ciliary dyskinesia including chronic rhinitis, sinusitis, and OME. A dilemma for otorhinolaryngologists is whether ventilation tubes are of benefit in children with primary ciliary dyskinesia and OME and what effective alternatives exist. The authors addressed this issue via a literature review and case presentation. An extensive review of the literature was undertaken and a discussion of the advantages and disadvantages of ventilation tubes in the management of OME in these children was presented and compared with that of the general population. These investigators presented a case of a 9-month old boy with Kartagener's syndrome and chronic bilateral OME to illustrate their findings. A total of 8 papers were identified, all with small study numbers. The main outcome measures were hearing, otorrhea and tympanic membrane structural changes. The natural history of OME and hearing loss in primary ciliary dyskinesia appears to be fluctuant into adulthood. Thus, OME in primary ciliary dyskinesia does not resolve by the age of 9 years, regardless of treatment, as previously assumed. Ventilation tube insertion (VTI) improves hearing in primary ciliary dyskinesia, but may lead to a higher rate
of otorrhea when compared to the general population. Tympanic membrane changes were clinically insignificant. The patient eventually underwent successful insertion of bilateral ventilation tubes with a marked improvement in hearing and language with minimal otorrhea. The authors concluded that the highest level of evidence found for the management of OME in children with primary ciliary dyskinesia was level IV. Currently, the evidence is inconclusive and conflicting. While these findings are promising, clearly higher quality research on a larger number of patients is required to definitively evaluate the management options for OME in these children.

**Coated Tympanostomy Tubes:**

Methicillin-resistant staphylococcus aureus (MRSA) infections and colonization in children have increased in recent years. Moreover, bacterial biofilm formation has been implicated in the high incidence of persistent otorrhea following tympanostomy tube insertion. It has been suggested that the tube material may be an important factor in the persistence of such otorrhea. Development of MRSA otorrhea after tympanostomy tube placement is a growing concern. Jang and associates (2010) evaluated the effect of using vancomycin and chitosan coated tympanostomy tubes on the incidence of MRSA biofilm formation in-vitro. Three sets each of vancomycin-coated silicone tubes (n = 5), commercial silver oxide-coated silicone tubes (n = 5) and uncoated tympanostomy tubes (as controls; n = 5) were compared as regards resistance to MRSA biofilm formation after in vitro incubation. Scanning electron microscopy showed that the surfaces of the silver oxide-coated tubes supported the formation of thick biofilms with crusts, comparable to the appearance of the uncoated tubes. In contrast, the surface of the vancomycin-coated tympanostomy tubes was virtually devoid of MRSA biofilm. The authors concluded that vancomycin-coated tympanostomy tubes resist MRSA biofilm formation. They noted that pending further study, such tubes show promise in assisting the control of MRSA biofilm formation.

In a prospective, randomized, double-blind controlled trial, Hong et al (2011) compared the post-operative complication rates of
phosphorylcholine-coated fluoroplastic tympanostomy tubes versus uncoated fluoroplastic tympanostomy tubes. A total of 240 children with recurrent acute otitis media and chronic otitis media with effusion were randomized to receive a phosphorylcholine-coated tube in one ear and an uncoated tube in the other. Post-operatively, patients were assessed at 2 weeks and 4, 8, 12, 18, and 24 months to ascertain the incidence of otorrhea, tube lumen blockage, and early extrusion. Out of 240 children, 5 withdrew and 16 were lost to early follow-up. The mean age was 43.8 months. There were no statistically significant differences in the incidence of post-operative otorrhea, tube blockage, and extrusion. The authors concluded that phosphorylcholine-coated fluoroplastic ventilation tubes do not offer any advantages over uncoated standard fluoroplastic tympanostomy tubes.

The EarPopper Device:

The EarPopper is a non-invasive device for treating conditions such as otitis media with effusion, middle ear effusion, aerotitis/barotitis and eustachian tube dysfunction, without the need for surgery or antibiotics. It delivers a constant, regulated stream of air into the nasal cavity through the nostril with a 1-oz infant nasal syringe equipped with a plastic tip. During the moment of swallowing, the air is diverted up the eustachian tube clearing and ventilating the middle ear. The EarPopper relieves the negative ear pressure allowing any accumulated fluids to drain. The Australia and New Zealand Horizon Scanning Network's assessment on "EarPopper™ for the treatment of otitis media in children" (2007) deemed this technology as "yet to emerge"; and it does not receive approval from the Australian Therapeutic Goods Administration. The assessment noted that the evidence suggested that the EarPopper™ may provide a safe and effective treatment option in the short-term with minimal clinical impact on health practitioners as it can be used at home; and recommended that this technology be monitored.

An Agency for Healthcare Research and Quality’s report on “Otitis media with effusion: Comparative effectiveness of treatments”
(AHRQ, 2012) stated that “Though not in widespread use, the technique of autoinflation [which is what EarPopper tries to accomplish] has been used as a treatment for OME. The goal of autoinflation is to use either a Valsalva maneuver or external device to equalize middle ear and oropharyngeal pressure, essentially transiently opening the Eustachian tube. A 2006 Cochrane Collaboration study included 6 RCTs examining the use of autoinflation versus no treatment for hearing loss associated with OME. Studies included children, adults, and special populations and concluded that the evidence for the use of autoinflation in the short-term was favorable; however, given the small number of studies and lack of long-term follow-up, the long-term effects could not be determined”.

In a randomized, single-blinded, controlled trial, Banigo et al (2016) provided an independent evaluation of the safety and effectiveness of the EarPopper in improving hearing outcomes in children with OME and reducing the ventilation tube insertion rate. A total of 29 children aged between 4 and 11 years diagnosed with persistent OME lasting at least 3 months with an average hearing of 25 decibels Hearing Level (dBHL) or worse in the better ear were randomized to a treatment or control group for 7 weeks using random computer-generated codes. Syndromic children, children with developmental delay, previous grommets and cleft palate were excluded. The audiologists were blinded at the final post-treatment audiogram. After the 7-week period, the mean improvement in air conduction across all frequencies was 10.9 dBHL in the treatment group (p < 0.001) and 3.6 dBHL in the control group (p = 0.201). At every frequency, the treatment group had larger improvements in air conduction, the largest being at 4 kHz where the mean air conduction in both ears improved by 14.8 dBHL. Compliance with the EarPopper was over 90%, the only side-effect reported being discomfort in the ears immediately after use, which resolved and did not affect compliance. The ventilation tube insertion rate was 53.3% in the treatment group and 78.6% in the control group. Median follow-up time for all patients is 47.7 months. The authors concluded that the findings of this study showed that the EarPopper is a safe and effective therapeutic option for children with hearing loss from persistent OME, and it reduces the rate of ventilation tube
insertion; they stated that more studies with larger sample sizes are needed to support their findings.

**Tympanostomy Tube Insertion in Children with Cleft Palate:**

Hornigold et al (2008) noted that between July 1984 and March 1987, all children that underwent repair for primary cleft palate at the Queen Victoria Hospital were enrolled in a clinical trial. Those found to have OME at time of surgery had a t-tube inserted into 1 randomized ear, while the other ear received no treatment. The object of the study was to re-assess patients from the original trial to discover the impact of the unilateral t-tube 20 years later. A total of 22 patients were identified as potential study participants. Of this group, 14 were contactable and 7 agreed to participate in the follow-up study. Main outcome measures were persistent symptomatology, otoscopy, pure tone audiometry and tympanometry. Follow-up results were compared within the original treatment groups from the primary study, on an intention-to-treat basis. Otoscopically the ears were normal in 2 of the 7 treated ears compared with 4 of the 7 non-treated ears. All the other ear ears had various types of chronic otitis media. Four of the 7 had hearing of greater than 10 dB in the treated ear compared with the non-treated ear. The authors concluded that these findings would indicate need for caution in the use of t-tubes in the cleft population and raises the question of long-term follow-up to assess for secondary cholesteatoma.

In a systematic review, Ponduri et al (2009) examined if early routine grommet insertion in children with cleft palate has a beneficial effect on hearing and speech and language development compared with conservative management. The main outcome measure was the effect of early routine grommet placement on the degree of conductive hearing loss. Secondary outcome measures included differences in hearing level, possible side effects, speech and language development, and quality of life. These researchers identified 368 citations for review. From a review of the titles, 34 potentially relevant papers were selected. Of these, 18 studies met the inclusion criteria, including 8 case series, 6 historical cohort studies, 3 prospective cohort studies, and 1 randomized trial. Most studies were either small or of poor
quality or both. The results of the studies were contradictory, with some studies suggesting early placement of grommets was beneficial and others reporting there was no benefit. The authors concluded that there is currently insufficient evidence on which to base the clinical practice of early routine grommet placement in children with cleft palate.

Boonacker et al (2014) stated that otitis media (OM) is a leading cause of medical consultations, antibiotic prescription and surgery in children. The surgical procedures offered to children with recurrent or persistent OM are insertion of grommets, adenoidectomy or a combination of the two. There is clear National Institute for Health and Care Excellence guidance for the use of grommets in subgroups of children with persistent OME, but similar guidance is not available for adenoidectomy, either in persistent OME or in recurrent AOM. These researchers (I) developed a model to predict the risk of children referred for adenoidectomy having a prolonged duration of their OM; (IIa) evaluated the overall effect of adenoidectomy, with or without grommets, on OM using individual patient data (IPD); and (IIb) identified those subgroups of children who are most likely to benefit from adenoidectomy with or without grommets. A number of electronic databases were searched from their inception including the Cochrane Ear, Nose and Throat Disorders Group Trials Register, the Cochrane Central Register of Controlled Trials (CENTRAL), PubMed, EMBASE, the Cumulative Index to Nursing and Allied Health Literature (CINAHL), metaRegister of Current Controlled Trials (mRCT), ClinicalTrials.gov, International Clinical Trials Registry Platform (ICTRP), ClinicalStudyResults.org and Google. Studies eligible for inclusion in this IPD meta-analysis were randomized controlled trials (RCTs) in children up to 12 years of age diagnosed with recurrent AOM and/or persistent OME in which adenoidectomy (with or without grommets) was compared with non-surgical treatment or grommets alone. The final selection of eligible studies and the quality assessment were carried out according to standard methods and disagreement was resolved by discussion. A total of 503 articles were identified of which 10 trials were included in the meta-analysis; 8 of these were at a low risk of bias and 2 were at moderate risk. The primary outcome was failure at 12 months, defined by a set of
persisting symptoms and signs. In the prognostic analysis 56% of those children referred for adenoidectomy (but randomized to the non-surgical group) failed to improve (38% of the children with recurrent AOM and 89% of the children with persistent OME). Children who had adenoidectomy had a greater chance of clinical improvement. The size of that effect is, in general, small but persists for at least 2 years. Two subgroups of children are most likely to benefit from adenoidectomy: (i) children aged less than 2 years with recurrent AOM -- 16% of those who had adenoidectomy failed at 12 months whereas 27% of those who did not have adenoidectomy failed (rate difference (RD) 12%, 95% CI: 6% to 18%; number needed to treat (NNT) = 9); (ii) children aged greater than or equal to 4 years with persistent OME -- 51% of those who had adenoidectomy failed at 12 months whereas 70% of those who did not have adenoidectomy failed (RD 19%, 95% CI: 12% to 26%; NNT = 6). No significant benefit of adenoidectomy was found in children aged greater than or equal to 2 years with recurrent AOM and children aged less than 4 years with persistent OME. The authors concluded that adenoidectomy is most beneficial in children with persistent OME aged greater than or equal to 4 years. A smaller beneficial effect was found in children with recurrent AOM aged less than 2 years.

Consideration must be given to the balance between benefits and harms. Future research is required in a number of key areas, including defining the best methods of selecting, developing and administering patient-reported outcome measures to assess the value of treatments for children with persistent OME and recurrent AOM and upper respiratory infections; investigating the clinical effectiveness and cost-effectiveness of hearing aids (air or bone conduction) and the use of interventions to improve classroom acoustics for children with different degrees of persistence and severity of hearing loss associated with OME; and investigating why professionals' and parents'/carers' treatment preferences vary so much both nationally and internationally. The authors did not understand why adenoidectomy works in different subgroups at different ages, nor its effects in special populations, such as children with Down syndrome. They stated that there is also a need for further research on the impact and optimal management of otitis media in these special situations and others, such as in children with a cleft palate or
Kuo and colleagues (2014) stated that no consensus has yet been reached with regard to the link between OME, hearing loss, and language development in children with cleft palate. These researchers examined the effectiveness of VTI for OME in children with cleft palate. A dual review process was used to assess eligible studies drawn from PubMed, Medline via Ovid, Cumulative Index to Nursing and Allied Health Literature, Cochrane Library, and reference lists between 1948 and November 2013. Potentially relevant papers were selected according to the full text of the articles. Relevant data were extracted onto a data extraction sheet. A total of 9 high- or moderate-quality cohort studies were included in this study. Ventilation tube insertion was administered in 38% to 53% of the OME cases, and more severe cases appeared more likely to undergo VTI. Compared with conservative forms of management (e.g., watchful waiting), VTI has been shown to be beneficial to the recovery of hearing in children with cleft palate and OME. A growing body of evidence demonstrated the benefits of VTI in the development of speech and language in children with cleft palate and OME. These children face a higher risk of complications than those undergoing conservative treatments, the most common of which are eardrum retraction and tympano-sclerosis, with an incidence of approximately 11% to 37%. The authors concluded that this review provided evidence-based information related to the selection of treatment for OME in children with cleft palate. They stated that additional RCTs are needed to obtain bias-resistant evidence capable of reliably guiding treatment decisions.

Guidance from the National Institute for Health and Clinical Excellence (NICE, 2008) states that the care of children with cleft palate who are suspected of having OME should be undertaken by the local otological and audiological services with expertise in assessing and treating these children in liaison with the regional multidisciplinary cleft lip and palate team. Insertion of ventilation tubes at primary closure of the cleft palate should be performed only after careful otological and audiological assessment. Insertion of ventilation tubes should be offered as an alternative
to hearing aids in children with cleft palate who have OME and persistent hearing loss.

In a case-series with chart-review study, Kim and colleagues (2016) examined the effect of VTI on long-term hearing outcomes in children with cleft palate. Children with cleft palate diagnosis who underwent surgery at Rady Children's Hospital-San Diego between 1995 and 2002 were included in this analysis. The primary outcome studied was hearing acuity at 10 years of age. Independent variables studied included gender, age at palate repair and first VTI, total number of VTs, number of complications, and presence of tympanic membrane perforation.

An increased number of tubes was associated with a greater incidence of hearing loss at age 10, even after adjusting for total number of otologic complications. The timing of initial VTI did not have a significant effect on long-term hearing outcome in this study. The authors concluded that while children with worse middle ear disease were more likely to receive more tubes and have long-term conductive hearing loss as a result of ear disease, the results of this study suggested that multiple VTI may not contribute to improved long-term hearing outcomes. They stated that further research focusing on long-term outcomes is needed to establish patient-centered criteria guiding decision making for VTI in children with cleft palate.

Miscellaneous Information:

The American Academy of Otolaryngology-Head & Neck Surgery's clinical practice guideline on "Tympanostomy tubes in children" (Rosenfeld et al, 2013) provided the following recommendations:

- Clinicians should not perform tympanostomy tube insertion in children with a single episode of OME of less than 3 months’ duration
- Clinicians should obtain an age-appropriate hearing test if OME persists for 3 months or longer (chronic OME) or prior to surgery when a child becomes a candidate for tympanostomy tube insertion
- Clinicians should offer bilateral tympanostomy tube insertion to children with bilateral OME for 3 months or longer (chronic
OME) and documented hearing difficulties

- Clinicians should re-evaluate, at 3- to 6-month intervals, children with chronic OME who did not receive tympanostomy tubes until the effusion is no longer present, significant hearing loss is detected, or structural abnormalities of the tympanic membrane or middle ear are suspected.

- Clinicians should not perform tympanostomy tube insertion in children with recurrent acute otitis media (AOM) who do not have middle ear effusion in either ear at the time of assessment for tube candidacy.

- Clinicians should offer bilateral tympanostomy tube insertion to children with recurrent AOM who have unilateral or bilateral middle ear effusion at the time of assessment for tube candidacy.

- 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. In the perioperative period, clinicians should educate caregivers of children with tympanostomy tubes regarding the expected duration of tube function, recommended follow-up schedule, and detection of complications.

- Clinicians should not encourage routine, prophylactic water precautions (use of earplugs, headbands; avoidance of swimming or water sports) for children with tympanostomy tubes.

Youssef and Ahmed (2013) compared long-term follow-up results of laser versus classical myringotomy with ventilation tube insertion over 5 years. A total of 86 patients with bilateral OME were divided into 2 groups: (i) laser myringotomy group and (ii) myringotomy with ventilation tube insertion group, with follow-up in hearing results and recurrence rates over 5 years. The mean patency time of myringotomy in laser group was 23 days, while the mean patency time of the ventilation tubes ears was 4.0 months in myringotomy group. Twelve patients in laser group (13.9 %) showed a recurrent OME compared to 9 patients in myringotomy group (10.4 %). The authors concluded that laser fenestration is a less effective alternative to myringotomy and tube placement. The recurrence rates after both procedures did
Follow-Up Care After Grommet Insertion:

Mughal and colleagues (2016) stated that grommet insertion is a common procedure in children. A lengthy otolaryngology follow-up can have an adverse impact on clinic waiting times, new patient appointment availability, and pecuniary disadvantage for the hospital. These investigators consolidated research and opinion concerning follow-up care following grommet insertion in a pediatric population. The literature between January 1990 and September 2015 was searched on Medline (Ovid), Google Scholar, PubMed and Web of Science databases. Guidelines and consensus of opinion from the United States advocate that an initial post-operative review should take place within 4 weeks, and subsequent appointments every 6 months until grommet extrusion. Recent audit reports from the United Kingdom have shown that some groups arrange their first post-operative review at 3 months, and subsequent appointments vary considerably from no further follow-up to up to 24 months. Up to 75 % of follow-up appointments were scheduled despite normal audiometry and clinical findings after grommet insertion, suggesting a large cohort of patients may undergo unnecessary specialist clinic reviews. General practitioners (GPs), audiologists or specialist nurses are potential alternative providers of regular reviews to ensure normal hearing thresholds and an adequate tympanic membrane healing course. The authors concluded that follow-up schedules are largely driven by consensus of opinion. They noted that a significant number of follow-up appointments in otolaryngology clinic appear to be redundant. Recently attention has been drawn to earlier discharge from otolaryngology clinic with subsequent follow-up in less resource- and cost-intensive clinics coordinated by GPs, audiologist or nurses, which may help alleviate some out-patient workload on acute hospital trusts.

Treatment of Hearing Impairment in Children with Cornelia de Lange Syndrome:
Jung and colleagues (2016) noted that Cornelia de Lange syndrome (CdLS) is a multiple developmental disorder including hearing loss. The hearing impairment in CdLS patients is not only sensori-neural hearing loss (SNHL), but also conductive hearing loss (CHL). The authors examined hearing loss causes in CdLS patients and evaluated the effect of VTI in the cases of CHL. A total of 32 patients clinically diagnosed with CdLS were included in this retrospective case review. Audiological evaluations and imaging studies such as a temporal bone computed tomogram or brain magnetic resonance imaging (MRI) were performed for all patients. Hearing rehabilitation (e.g., VTI, hearing aid fitting, or cochlear implantation) was chosen depending on the audiological condition. Among the 32 CdLS patients who underwent auditory brainstem response test, 81.2 % presented hearing loss. Imaging studies showed that only middle ear lesions without inner ear anomalies were identified in 56.3 %. Notably, the soft tissue lesion in middle ear was identified even in the neonatal MRI. When 7 patients were thought to have CHL due to OME, VTI was applied first. However, VTI rarely improved CHL post-operatively. Moreover, middle ear lesion was not fluid effusion but soft tissue lesion according to the intra-operative finding. These lesions were not eradicated even after revision surgery of VTI. The authors concluded that VTI was ineffective to improve hearing or eradicate OME in CdLS patients.

Janek and associates (2016) stated that patients with CdLS are reported to have CHL and SNHL, but there is little information pertaining to the progression of hearing loss over time. These investigators examined the prevalence of CHL and SNHL in adults and children with CdLS and looked for changes in SNHL over time. They carried out a retrospective chart review of patients with CdLS presenting to a CdLS clinic. Also, a written survey of clinical concerns was collected from additional patients/families seen in the clinic and through the Cornelia de Lange Foundation. A total of 78 patients (50 % female) were included in the chart-review. Mean age was 16.8 ± 11.4 years (range of 0.6 to 50 years) and mean age at diagnosis of hearing loss was 4.6 ± 10.6 years (n = 26); 5 patients (6.4 %) had severe to profound SNHL that improved with time, including 2 who had complete normalization of audiogram results; 35 families/patients completed the clinical
survey, and 45.5 % of the families reported a noticeable improvement of hearing over time. The authors concluded that CHL and SNHL are common in CdLS; and more than 50 % of the patients seen in an adult CdLS clinic reported improvement in hearing loss over time, and a subset of patients had an improvement in SNHL. In light of these findings, the authors recommended longitudinal evaluations of hearing loss in these patients with both auditory brainstem response and oto-acoustic emissions testing if SNHL is identified.

Endoscopic Balloon Dilation of the Eustachian Tube:

Catalano and colleagues (2012) stated that Eustachian tube dysfunction is a common problem and trans-nasal endoscopic balloon dilation of the Eustachian tube (ET) is a new surgical technique. These researchers reviewed the evolution of this novel technique and studied the preliminary outcomes. Balloon catheter dilation of the 100 Eustachian tubes in 70 adults was performed at a tertiary medical center from January 2009 to January 2011. A 5-mm sinus balloon catheter was endoscopically placed trans-nasally into the proximal ET to dilate the cartilaginous ET. Cases were reviewed with respect to indications, outcomes, and complications. Of the 100 ETs, ear fullness and pressure were improved in 71 % of patients studied for 26.3 weeks (± 3.6). Of 8 patients followed for a minimum of 34 months, 87 % reported persistent improvement; 1 complication was reported. The authors concluded that endoscopic trans-nasal ET balloon dilation is a novel approach to treating ET dysfunction. Benefits can be durable up to 3 years. Moreover, they stated that this technique holds much promise and merits further investigation.

Jurkiewicz et al (2013) noted that the development of minimally invasive procedures such as the balloon dilation Eustachian tuboplasty (BET) is an alternative to the grommet tympanum membrane. BET is applied in the cases where, after elimination of all factors influencing the ET and middle ear functioning, no sufficient improvement is observed. These investigators presented the therapeutic benefits of the BET method in the treatment of ETD caused by disorders in the middle ear.
ventilation. The BET procedure was offered to 4 patients (3 men and 1 woman) after subjective, physical, otorhino-laryngological and audiometric examinations including pure tone audiometry, tympanometry and pressure-swallow test. As the method was novel, pre-interventional CT angiography of the carotid arteries was performed in all patients. Any complications were noticed during and after the procedure (bleeding or damage of regional mucosa) in any patients. These clinical studies assessed the feasibility and safety of the BET during a short-term period -- only a 6-week observation. The authors concluded that although patients revealed a significant improvement of ET score, longer long-term studies are needed to determine whether this method will demonstrate lasting benefits and safety in the treatment of chronic Eustachian tube dysfunction.

Moller et al (2014) stated that balloon dilation of Eustachian tube is a novel method for managing chronic ventilatory dysfunction in patients with chronic otitis media, as an alternative to classic grommet insertion. Although few retrospective studies have been conducted the method seems to be rapid, simple and safe with promising short-term results. These researchers presented the method and summarized the results of available studies. Optimization of patient selection is needed and the authors discussed the development of better objective measurement methods as well as the need for randomized prospective studies, which are currently being conducted.

In a retrospective, cohort study, Gurtler et al (2015) assessed Eustachian tube balloon dilation in the treatment of Eustachian tube dysfunction by objective analysis, especially tubomanometry. Patients undergoing Eustachian tube balloon dilation for treatment of Eustachian tube dysfunction were enrolled in this study. Main outcome measures included subjective improvement, otomicroscopic findings, tympanogram, air-bone gap in pure-tone audiogram, R-value in tubomanometry at 3 pressure measurements (30, 40, and 50 mbar) and the Eustachian Tube Score (ETS). Eustachian tube balloon dilation was performed in 21 patients. The ETS including the R-values, tympanogram, and air-bone gap all showed a statistically positive outcome (p < 0.005) after Eustachian tube balloon dilation.
Subjective improvement was seen in 76%. Normal R-values were achieved in 57%. Retraction processes of the tympanic membrane improved in 18% of patients. Only 1 minor bleeding complication occurred. The authors concluded that Eustachian tube balloon dilation constitutes a safe and very promising treatment option for patients with Eustachian tube dysfunction based on early-outcome analysis; ETS and specifically tubomanometry appeared promising as assessment tools but await validation for use in the diagnostic workup and outcome analysis after ETBD. The pathophysiologic mechanism of Eustachian tube balloon dilation remains unclear. They stated that long-term analysis and stratification of patients are needed to better evaluate the definite value of Eustachian tube balloon dilation.

In a retrospective analysis, Maier et al (2015) evaluated the role of balloon dilation of the Eustachian tube in a large cohort of children with Eustachian tube dysfunction who did not respond to other treatments and in whom a tumor could be ruled out as the cause. These researchers retrospectively analyzed the medical records of 66 children (mean age of 8.12 years, range of 4 to 14 years) who underwent balloon dilation of the Eustachian tube using the Bielefeld balloon catheter. There were no complications during surgery. Clinical symptoms improved in more than 80% of the patients. No patient reported a deterioration of symptoms. Of the participating parents, over 80% were very satisfied or satisfied with the treatment outcome. The authors concluded that balloon dilation is a rapid, simple, and safe method for treatment of both adults and children with Eustachian tube dysfunction who did not respond to other treatments. Moreover, they stated that further studies, ideally multi-center studies, are needed to optimize the definition of existing and potential new indications for this treatment approach, as well as to establish this treatment in the management of children with refractory chronic Eustachian tube dysfunction.

Randrup and Ovesen (2015) performed a systematic review and meta-analysis of the evidence on balloon Eustachian tuboplasty (BET) as a treatment modality for Eustachian tube dysfunction (ETD). These investigators followed the PRISMA guideline and
registered with PROSPERO No. CRD42014009461. They searched 12 databases including PubMed and Embase from January 1, 2010 to April 7, 2014 for studies of BET. Main outcome measures included change in symptoms, middle ear pathology, eardrum status, Eustachian tube function tests, hearing, adverse events, complications, and health-related quality of life. Study quality was assessed using the modified Delphi technique quality appraisal tool for case series studies. Risk of bias was assessed using the Cochrane Collaboration’s tool for assessing risk of bias. A total of 9 case-series studies with 443 patients (642 tubes) were included; population size ranged from n = 4 (7 tubes) to n = 210 (320 tubes). All studies were of poor quality and featured a high risk of bias. These researchers found reduction of patient symptoms in ETD questionnaire (p < 0.001), post-operative normalization of the tympanic membrane, conversion of type B or type C into type A tympanograms, reduced mucosal inflammation, increased number of positive Valsalva test and Swallowing tests, improvement in Eustachian tube score, reduction in Sino-Nasal Outcome Test (SNOT)-22 score (p = 0.001), and increased quality of life (p = 0.001). No serious adverse events were found. The authors concluded that the evidence of BET is poor and biased. No firm conclusions can be made to identify patients who will benefit from the procedure or to accurately predict surgical results. They stated that randomized controlled trials or case-control trials are needed.

Hwang et al (2016) stated that Eustachian tube dysfunction is a disorder for which there are limited medical and surgical treatments. Recently, Eustachian tube balloon dilation has been proposed as a potential solution. These investigators performed a systematic literature review. Abstracts were selected for relevance, and pooled data analysis and qualitative analysis was conducted. A total of 9 prospective studies, describing 713 Eustachian tube balloon dilations in 474 patients (aged 18 to 86 years), were identified. Follow-up duration ranged from 1.5 to 18 months. Ability to perform a Valsalva maneuver improved from 20 to 177 out of 245 ears following Eustachian tube balloon dilation and, where data were reported in terms of patient numbers, from 15 to 189 out of 210 patients. Tympanograms were classified as type A in 7 out of 141 ears pre-operatively and
in 86 out of 141 ears post-operatively. The authors concluded that prospective case series can confirm the safety of Eustachian tube balloon dilation. As a potential solution for chronic Eustachian tube dysfunction, further investigations are needed to establish a higher level of evidence of efficacy.

Williams et al (2016) measured the success of Eustachian tube balloon dilation by comparing pre- and post-operative middle ear pressures using tympanometric testing. A retrospective chart review was performed on all patients who underwent balloon dilation of the Eustachian tube by authors from 2010 to 2014. Pre and post-operative tympanograms were analyzed and categorized based on type (Type A, Type B, Type C). Success was defined by an improvement in tympanogram type: Type B or C to Type A, or Type B to type C. Pre- and post-operative tympanograms were further analyzed using middle ear pressure values. Follow-up ranged from 3 to 15 months. A total of 25 ears (18 patients) were included in the study. Overall 36 % of ears had improvement in tympanogram type, and 32 % had normalization of tympanogram post-operatively. The Jerger tympanogram type improved significantly following the procedure (p = 0.04). Patients also had statistically significant improvement in measured middle ear pressure post-operatively (p = 0.003). The authors concluded that the natural history of Eustachian tube dysfunction is poorly understood, and evidence for current treatments are limited. Eustachian tube balloon dilation is a safe procedure, and produces significant improvement in tympanogram values up to 15 months post-operatively. They stated that further refinement of patient selection and standardization of technique is needed to optimize the effect of this therapy; long-term follow-up data will clarify the persistence of the effect.

Furthermore, an UpToDate review on “Eustachian tube dysfunction” (Poe and Hanna, 2017) states that “The choice of management strategies for isolated Eustachian tube dysfunction remains controversial as randomized trial data are limited, study outcomes vary widely between studies, and much of what is known about the treatment of Eustachian tube dysfunction comes from animal rather than human studies ... Balloon dilation
is a novel tuboplasty method to increase the patency of the cartilaginous Eustachian tube. Similar to the concept of balloon sinuplasty for the treatment of chronic sinusitis, a balloon catheter is used to dilate the cartilaginous portion through a minimally invasive transnasal endoscopic approach. Initial cadaveric studies and clinical trials are promising. A 2015 systematic review including 9 case series (443 patients) concluded that balloon tuboplasty is a safe procedure but is still lacking good evidence of benefit.

CPT Codes / HCPCS Codes / ICD-10 Codes

*Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by "+":*

*ICD-10 codes will become effective as of October 1, 2015:*

CPT codes covered if selection criteria are met:

- 69420: Myringotomy including aspiration and/or eustachian tube inflation
- 69421: Myringotomy including aspiration and/or eustachian tube inflation requiring general anesthesia
- 69424: Ventilating tube removal requiring general anesthesia
- 69433: Tympanostomy (requiring insertion of ventilating tube), local or topical anesthesia
- 69436: Tympanostomy (requiring insertion of ventilating tube), general anesthesia

CPT codes not covered for indications listed in the CPB:

*EarPopper:*

No specific code

Other CPT codes related to the CPB:

- 31000 - 31230: Incision and excision of accessory sinuses
- 31231 - 31297: Sinus endoscopy
- 42820 - 42821: Tonsillectomy and adenoidectomy
ICD-10 codes covered if selection criteria are met:

- **H65.00** - Nonsuppurative otitis media
- **H65.93** - Suppurative otitis media
- **H66.001** - and unspecified otitis media
- **H66.93** - Patulous Eustachian tube
- **H69.00** - Nonsuppurative otitis media Suppurative and unspecified otitis media
- **H69.03** - Patulous Eustachian tube
- **H71.20** - Cholesteatoma of mastoid and unspecified part
- **H71.23** - [middle ear]
- **H71.90** - Cholesteatoma of mastoid and unspecified part
- **H71.93** - [middle ear]
- **H72.10** - Attic perforation of tympanic membrane [Pars flaccida]
- **H72.13** - Hearing loss
- **H90.0** - Hearing loss
- **H91.93** - Hearing loss
- **Q35.1** - Cleft lip and cleft palate
- **Q37.9** - Cleft lip and cleft palate
- **T70.0xx+** - Otitic barotrauma

The above policy is based on the following references:


30.


40.


41.


42.


43.


44.


45.


46.


47.


48.


49.


70. Mughal Z, Thirunavukarasu V, Darr A, Jindal M. Follow-up


82. Williams B, Taylor BA, Clifton N, Bance M. Balloon dilation

Amendment to
Aetna Clinical Policy Bulletin Number: 0418 Myringotomy and Tympanostomy Tube

There are no amendments for Medicaid.