Clinical Policy Title: Ear tubes (tympanostomy)

Clinical Policy Number: 11.03.05

Effective Date: January 1, 2015
Initial Review Date: September 17, 2014
Most Recent Review Date: September 21, 2016
Next Review Date: September 2017

Related policies:

CP# 11.03.04  Tonsillectomy and/or adenoidectomy in children up to 12 years old

ABOUT THIS POLICY: AmeriHealth Caritas Northeast has developed clinical policies to assist with making coverage determinations. AmeriHealth Caritas Northeast’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by AmeriHealth Caritas Northeast when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. AmeriHealth Caritas Northeast’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. AmeriHealth Caritas Northeast’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, AmeriHealth Caritas Northeast will update its clinical policies as necessary. AmeriHealth Caritas Northeast’s clinical policies are not guarantees of payment.

Coverage policy

AmeriHealth Caritas Northeast considers the use of ear tubes to be clinically proven and, therefore, medically necessary when either of the following criteria is met:

- Uni- or bilateral chronic otitis media with effusion (OME), with symptoms of at least three months’ duration and with documentation of vestibular, behavioral or school performance problems; ear discomfort; or reduced quality of life (QoL).
- Chronic bilateral OME greater than three months with hearing difficulty, documented by a hearing test.

Adenoidectomy may or may not also be performed in addition to ear tube surgery, refer to policy #11.03.04 (Tonsillectomy and/or Adenoidectomy in children up to 12 years old).

Limitations:

Policy contains:
- Ventilation tubes.
- Myringotomy.
- Tympanostomy tubes.
- Grommets.
- Otitis media with effusion.
AmeriHealth Caritas Northeast considers the use of ear tubes to be investigational and, therefore, not medically necessary in the following circumstances:

- In children or adults with a single OME episode < three months’ duration (date of onset or diagnosis, whichever is known).
- In children or adults with recurrent acute otitis media (AOM) who do not have effusion in either ear at the time of assessment.
- In children 6 months old or less (Rosenfeld, 2013: table below).

**Background**

There are 2.2 million new cases of OME diagnosed in the U.S. annually, affecting 50 to 90 percent of children by age five (Rosenfeld, 2004). About four episodes of new-onset OME per child occur annually, with a mean duration of 17 days (Mandel, 2008). Although many cases resolve routinely, at least 25% of OME episodes persist for over three months (Rosenfeld, 2003). Chronic cases of OME, defined as those persisting for over three months are frequently associated with hearing loss, vestibular problems, poor school performance, behavioral problems, ear discomfort, recurrent otitis media, or reduced quality of life (Rosenfeld, 2013).

Surgery, including the insertion of ear tubes, is among the various options for treating children with OME. Children with chronic OME who do not receive tubes should be re-evaluated every six months until effusion is no longer present, significant hearing loss is detected or structural abnormalities (tympanic membrane or middle ear) are detected. Recurrent otitis media (OM) or OME of any duration may put children at risk for speech, language or hearing problems.

Ear tubes are tiny cylinders placed through the eardrum (tympanic membrane) to allow air into the middle ear. They also may be called tympanostomy tubes, myringotomy tubes, ventilation tubes, pressure-equalization (PE) tubes or grommets.

These tubes can be made out of various materials and may have a coating intended to reduce the possibility of infection. There are two basic types of ear tubes: short-term and long-term. Short-term tubes are smaller and typically stay in place for six months to a year before being extruded on their own. Long-term tubes are larger and have flanges that secure them in place for longer. Long-term tubes may fall out on their own but removal by an otolaryngologist may be necessary.

Ear tubes are often recommended when a person experiences repeated middle ear infection (acute otitis media) or has hearing loss caused by the persistent presence of middle ear fluid OME. These conditions occur commonly in children, but may also affect teenagers and adults; they can lead to speech and balance problems, hearing loss or changes in the structure of the eardrum. Less common conditions that may warrant the placement of ear tubes are malformation of the eardrum or Eustachian tube, Down syndrome, cleft palate and barotrauma (injury to the middle ear caused by a reduction of air pressure — usually seen with altitude changes in flying and scuba diving).
Each year, more than half a million ear tube surgeries are performed on children, making it the most common childhood surgery performed with anesthesia. The average age for ear tube insertion is 1 to 3 years old. Inserting ear tubes may:

- Reduce the risk of future ear infection.
- Restore hearing loss caused by middle ear fluid.
- Improve speech and balance problems.
- Improve behavior and sleep problems caused by chronic ear infections.

Complications may include:

- Failure to resolve ear infections.
- Thickening of the eardrum over time, which affects hearing in a small percentage of patients.
- Persistent perforation after the tube falls out of the eardrum.
- Chronic ear drainage: the most common complication, occurring in 10 percent to 15 percent.
- Need for further and more aggressive surgery (such as tonsil, adenoid, sinus or ear surgery).
- Infection.
- Hearing loss.
- Scarring of the eardrum.
- Possible need to keep the ear dry and to use ear plugs.
- Foreign-body reaction to the tube itself — for example, an allergic reaction to the tube material (rare).

**Searches**

AmeriHealth Caritas Northeast searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality Guideline Clearinghouse and evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

Searches were conducted on August 10, 2016, using the terms "ear tubes" and “ear infections” [MeSH].

We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews**.
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

**Findings**

Despite the frequency of ear tube insertion, there was no clinical practice guideline on indications for surgery, with the exception of an expert panel representing 19 institutions (Rosenfeld, 2013).

Effectiveness of ear tubes in the treatment of OME has been addressed in numerous peer-reviewed articles. Following a review of 59 studies for the Agency for Healthcare Research and Quality (Berkman, 2013), researchers from Research Triangle Park NC conducted a systematic review of 41 studies to compare outcomes of various types of surgery for OME (Wallace, 2014). Major findings, which found that ear tubes reduced OME and improved hearing (but also had some associated harms), included:

- Ear tubes decreased time with OME and improved hearing, compared to watchful waiting or myringotomy (or both)
- Adenoidectomy alone, as adjunct to myringotomy or combined with ear tubes, reduced OME and improved hearing, compared to watchful waiting or myringotomy
- Ear tubes and watchful waiting did not differ in language, cognitive, or academic outcomes
- Otorrhea and tympanosclerosis were more common in ears with tubes
- Adenoidectomy increased risk of postsurgical hemorrhage

Another meta-analysis of 10 articles (n=71,353) assessed outcomes of primary tympanostomy tube placement (TT) and adenoidectomy (AD) in children with recurrent OM, OME, or otorrhea. Repeated TT for children undergoing primary AD (17.2%) was significantly lower than those undergoing primary TT (31.8%); no difference existed for when only children under age four were included. TT insertion for those infants within 9 months of evaluation showed no difference in 48 developmental measures at age 9-11, when compared with those infants who had delayed insertion (Mikals, 2014).

Other meta-analyses found mixed results. One documented that one in three children with tympanostomy tubes inserted would not have an acute otitis media episode for the following six months (Lous, 2011). Another, using the *Cochrane Database of Systematic Reviews*, found that tympanoplasty reduced hearing problems in the first six months post surgery, but that natural resolutions achieved the same gains thereafter (Browning, 2010) — which matched results of an earlier meta-analysis (Kay, 2001).

The extensive evidence on ear tube insertion continues to be used in professional guidelines. In 2013, the American Academy of Pediatrics and the American Academy of Family Physicians issued a guideline on uncomplicated acute OM in children age 6 months to 12 years (Lieberthal, 2013). Another recent guideline recommended no ear tube insertion for any child under six months (Rosenfeld, 2013).
Perhaps the most comprehensive guideline on the topic was created in 2004, and updated in 2016, by the American Academy of Otolaryngology-Head and Neck Surgery, American Academy of Pediatrics, and American Academy of Family Physicians. The more recent version included an additional four new clinical practice guidelines, 20 new systematic reviews, and 49 Randomized Controlled Trials (Rosenfeld, 2016), not included in the earlier version (Rosenfeld, 2004).

Policy updates:

This update produced four (4) new professional society guidelines and six (6) new peer-reviewed references, each of which has been included in this policy. The additional information from these sources has been incorporated into the Findings and Summary of Clinical Evidence sections.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
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<tbody>
<tr>
<td>Mikals (2014)</td>
<td>Key Points:</td>
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</table>
| Comparison of outcomes of various types of surgery for otitis media | • Repeat tympanostomy tubes (TT) for children undergoing primary adenoidectomy (Ad) was 17.2%, vs. 31.8% for primary TT (no difference for age <4)  
  • 391 infants < age 3 evaluated for middle-ear effusion assigned to undergo insertion of TT within 9 mos.  
  • No difference between the 391 infants at age 9-11 vs. group who had delayed insertion, for 48 developmental measures (reading, spelling, writing, calculation) |
| Wallace (2014)          | Key Points:                       |
| Comparing effectiveness of surgical strategies to manage OME | • Systematic review of 41 studies  
  • Ad alone or combined with tubes reduced OME and improved hearing  
  • Tubes and watchful waiting not different in language, cognitive, academic outcomes  
  • Adenoidectomy increased risk of postsurgical hemorrhage |
| Rosenfeld (2013)        | Key Points:                       |
| Tympanostomy tubes in children | • Guidelines and systematic reviews, 2005 – 2012., 113 studies  
  • Tubes should not be inserted in children with a single OME episode < 3 months’ duration (date of onset or diagnosis, whichever is known).  
  • Tubes should be offered to 1) chronic bilateral OME > 3 mos with hearing difficulty; 2) Uni- or bilateral chronic OME with symptoms > 3 mos. and documentation of vestibular, behavioral or school problems; ear discomfort; or reduced quality of life.  
  • Surveillance of chronic OME: children who do not receive tubes should be re-evaluated every six months until effusion is no longer present, significant hearing loss is detected, or middle ear abnormalities are detected.  
  • No tube insertion in children with recurrent AOM with no effusion in either ear |
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<tr>
<th>Lous (2011)</th>
<th><strong>Key Points:</strong></th>
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| Effect of tympanostomy tubes on children with recurrent otitis media | - RCTs (five total) children with insertion of tympanostomy tubes  
- One of three children have no acute otitis media episodes six months post-surgery. |

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<tr>
<th>Browning (2010)</th>
<th><strong>Key Points:</strong></th>
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| Grommets for hearing loss associated with otitis media with effusion in children | - 10 RCTs (grommets vs. no grommets), n=1728  
- Grommets beneficial in first 6 months (hearing differences), not at 12/18 months  
- No effects on language or speech development, behavior or quality of life |

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<tr>
<th>McDonald (2008/2011)</th>
<th><strong>Key Points:</strong></th>
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| Grommets for recurrent otitis media in children | - 2 RCTs, n=1480 (tubes vs. antibiotics or other control), children < 16  
- Grommets effective in maintaining a disease-free state for the first 6 months after insertion. Further research is needed for periods beyond 6 months.  
- Possible adverse effects of surgical insertion should be weighed vs. benefits. |

**Glossary**

**Ear tubes** — Also termed pressure equalization tubes (PE tubes), tympanostomy tubes, myringotomy tubes or ventilation tubes. These are synonyms for the colloquially used “ear tubes.”

**Middle ear** — The portion of the ear between the external ear and the oval window of the inner ear. It contains the three small bones (ossicles) that transmit vibrations of the eardrum to the fluids and membranes of the inner ear.

**Myringotomy** — Incision of tympanic membrane to allow ventilation of the middle ear, drainage of middle ear fluid, or obtain cultures from an infected middle ear.

**Otitis media with effusion** — Inflammation of the middle ear with accumulation of fluid, commonly known as “glue ear.”

**Otoscopy** — Examination of the ear with an instrument (otoscope) to ensure the passage to the eardrum is clear and the tympanic membrane free of perforations.

**Tinnitus** — Ringing in the ears.

**Tympanometry** — Examination of the inner ear/eardrum by creating vibrations of air in the ear canal.
**Tympanostomy** – Insertion of ear tubes.

**Otorrhea** — Postoperative ear discharge.

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**Clinical trials:**

Searched clinicaltrials.gov on June 10, 2016 using terms “ear tubes.” | Open Studies. 47 studies found, three (3) relevant.


**CMS National Coverage Determinations (NCDs):**

No NCD was identified at the writing of this policy.

**Local Coverage Determinations (LCDs):**

No LCD was identified at the writing of this policy.

**Commonly submitted codes**

Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

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