Clinical Policy Title: Ear tubes (tympanostomy)

Clinical Policy Number: 1135

Effective Date: January 1, 2015
Initial Review Date: September 17, 2014
Most Recent Review Date: August 1, 2018
Next Review Date: August 2019

Related policies:

CCP# 1102 Tonsillectomy and/or adenoidectomy in children up to 12 years old

ABOUT THIS POLICY: Prestige Health Choice has developed clinical policies to assist with making coverage determinations. Prestige Health Choice’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 Prestige Health Choice 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. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Prestige Health Choice’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Prestige Health Choice will update its clinical policies as necessary. Prestige Health Choice’s clinical policies are not guarantees of payment.

Coverage policy

Prestige Health Choice 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, 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.
- Chronic bilateral otitis media with effusion greater than three months duration with hearing difficulty, documented by a hearing test.

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

Limitations:
Coverage determinations are subject to benefit limitations and exclusions as delineated by the state Medicaid authority. The Florida Medicaid website may be accessed at http://ahca.myflorida.com/Medicaid/.

All other uses of ear tubes are not medically necessary, including the following circumstances:

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

**Alternative covered services:**

- Pharmacotherapy (e.g., antimicrobial agents, steroids, antihistamines and decongestants, and mucolytics).
- Myringotomy.
- Adenoidectomy.
- Tonsillectomy.
- Otolaryngologist consultation.

**Background**

Otitis media with effusion is the presence of fluid in the middle ear without signs or symptoms of acute ear infection (Rosenfeld, 2016). There are approximately 2.2 million new cases of otitis media with effusion diagnosed in the United States annually, mainly affecting children by age five years (Shekelle, 2003). Approximately four episodes of new-onset otitis media with effusion per child occur annually, with a mean duration of 17 days (Mandel, 2008).

Although many cases resolve routinely, at least 25 percent of otitis media with effusion episodes become chronic (Rosenfeld, 2003). Chronic cases of otitis media with effusion, defined as those persisting for more than three months, are frequently associated with hearing loss, vestibular problems, poor school performance, behavioral problems, ear discomfort, recurrent otitis media, and reduced quality of life (Rosenfeld, 2013).

Medical treatment for otitis media with effusion includes antimicrobial agents, steroids, antihistamines and decongestants, and mucolytics. Surgery, including the insertion of ear tubes, may be indicated for more persistent or recurrent cases. Children with chronic otitis media with effusion who do not receive tubes require periodic surveillance until effusion is no longer present, significant hearing loss is detected, or structural abnormalities (tympanic membrane or middle ear) are detected (Rosenfeld, 2013).
**Ear tubes (tympanostomy):**

Ear tubes are tiny cylinders placed through the eardrum (tympanic membrane) to allow air into the middle ear. They are called tympanostomy tubes, myringotomy tubes, ventilation tubes, pressure-equalization tubes, or grommets. These tubes are made out of various materials, may have a coating intended to reduce the possibility of infection, and are designed for either short-term or long-term use.

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 otitis media with effusion (Rosenfeld, 2013). These conditions occur commonly in young children, but may also affect teenagers and adults; left untreated, 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).

Risks associated with ear tube insertion include (Rosenfeld, 2013):

- 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**

Prestige Health Choice 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.

Searches were conducted on June 7, 2018. Search terms were: "ear tubes," “ear infections (MeSH),” “Middle ear ventilation (MeSH),” and “Otitis media with effusion (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**

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), Wallace (2014) conducted a systematic review of 41 studies to compare outcomes of various types of surgery for otitis media with effusion. Major findings, which found that ear tubes reduced otitis media with effusion and improved hearing (but also had some associated harms), included:

- Ear tubes decreased time with otitis media with effusion and improved hearing, compared to watchful waiting or myringotomy (or both).
- Adenoidectomy alone, as adjunct to myringotomy or combined with ear tube insertion, reduced otitis media with effusion 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 (71,353 total participants) assessed outcomes of primary tympanostomy tube placement and adenoidectomy in children with recurrent otitis media, otitis media with effusion, or otorrhea (Mikals, 2014). Repeated tympanostomy tube placement for children undergoing primary adenoidectomy (17.2 percent) was significantly lower than those undergoing primary tympanostomy tube placement (31.8 percent); no difference existed for a subset of children under age four. Tympanostomy tube insertion for those infants within 9 months of evaluation showed no difference in 48 developmental measures at ages 9 to 11 months compared with those infants who had delayed insertion.

Other meta-analyses found mixed results. One documented that one in three children with tympanostomy tubes inserted had no episodes of acute otitis media six months after surgery (Lous, 2011). A Cochrane review found that tympanoplasty reduced hearing problems in the first six months post surgery, but that natural resolutions achieved similar gains thereafter (Browning, 2010).
Despite the frequency of ear tube insertion, until recently, there had been no clinical practice guideline on indications for surgery, with the exception of an expert panel representing 19 institutions (Rosenfeld, 2013). For uncomplicated acute otitis media in children age 6 months to 12 years, the American Academy of Pediatrics and the American Academy of Family Physicians recommend tympanostomy tubes for recurrent acute otitis media (defined as three episodes in six months or four episodes in one year, with one episode in the preceding six months) (Lieberthal, 2013). The American Academy of Otolaryngology—Head and Neck Surgery 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 most recent version included 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:

In 2017, we found no new information to add. No policy changes are warranted at this time.

In 2018, we added two new peer-reviewed publications to the reference list. No policy changes are warranted at this time. Policy ID changed from 11.03.05 to CCP.1135.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mikals (2014)</td>
<td>Key points:</td>
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<tr>
<td>Comparison of outcomes of various types of surgery for otitis media</td>
<td>Rate of repeat tympanostomy tubes for children undergoing primary adenoidectomy was 17.2% vs. 31.8% for primary tympanostomy tubes (no difference for age &lt;4).</td>
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<td>391 infants &lt; age 3 evaluated for middle-ear effusion assigned to undergo insertion of tympanostomy tubes within 9 months versus delayed insertion.</td>
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<td>No difference in 48 developmental measures (reading, spelling, writing, calculation) between groups.</td>
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<td>Wallace (2014)</td>
<td>Key points:</td>
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<tr>
<td>Comparative effectiveness of surgical strategies to manage otitis media with effusion</td>
<td>Systematic review of 41 studies.</td>
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<td></td>
<td>Adenoidectomy alone or combined with tubes reduced otitis media with effusion and improved hearing.</td>
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<td>Tubes and watchful waiting not different in language, cognitive, academic outcomes.</td>
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<td></td>
<td>Adenoidectomy increased risk of postsurgical hemorrhage.</td>
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<tr>
<td>Rosenfeld (2013)</td>
<td>Key points:</td>
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<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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| **Typanostomy tubes in children** | • Guidelines and systematic reviews, 2005 – 2012, 113 studies.  
  • Tubes should not be inserted in children with a single otitis media with effusion episode < 3 months’ duration (date of onset or diagnosis, whichever is known).  
  • Tubes should be offered to: 1) chronic bilateral otitis media with effusion > 3 mos with hearing difficulty; or 2) uni- or bilateral chronic otitis media with effusion with symptoms > 3 mos. and documentation of vestibular, behavioral, or school problems, ear discomfort; or reduced quality of life.  
  • Surveillance of chronic otitis media with effusion: children who do not receive tubes should be reevaluated 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. |
| **Lous (2011)** | **Key points:**  
  • Five randomized controlled trials of children with insertion of tympanostomy tubes.  
  • One of three children had no acute otitis media episodes six months post-surgery. |
| **Browning (2010)** | **Key points:**  
  • Ten randomized controlled trials (grommets vs. no grommets), 1,728 total patients.  
  • Grommets beneficial in first six months (hearing differences), not at 12/18 months.  
  • No effects on language or speech development, behavior, or quality of life. |
| **McDonald (2008, updated 2011)** | **Key points:**  
  • Two randomized controlled trials, 1,480 total children < 16 mos. (tubes vs. antibiotics or other control),  
  • Grommets effective in maintaining a disease-free state for the first six months after insertion. Further research is needed for periods beyond six months.  
  • Possible adverse effects of surgical insertion should be weighed vs. benefits. |

**References**

**Professional society guidelines/other:**


**Peer-reviewed references:**


**CMS National Coverage Determinations:**

No National Coverage Determination was identified at the writing of this policy.

**Local Coverage Determinations:**

No Local Coverage Determination 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.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>69424</td>
<td>Ventilating tube removal requiring anesthesia</td>
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<tr>
<td>69433</td>
<td>Tympanostomy (requiring insertion of ventilation tube), local or topical anesthesia.</td>
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<tr>
<td>69436</td>
<td>Tympanostomy (requiring insertion of ventilation tube), general anesthesia.</td>
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<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tr>
<td>H65.20</td>
<td>Chronic serous otitis media, unspecified ear</td>
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<tr>
<td>H65.21</td>
<td>Chronic serous otitis media, right ear</td>
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<td>H65.22</td>
<td>Chronic serous otitis media, left ear</td>
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<td>H65.23</td>
<td>Chronic serous otitis media, bilateral</td>
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<td>H65.30</td>
<td>Chronic mucoid otitis media, unspecified ear</td>
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<tr>
<td>H65.413</td>
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<td>H65.499</td>
<td>Other chronic nonsuppurative otitis media, unspecified ear</td>
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