

## HEALTH EVIDENCE REVIEW COMMISSION (HERC)

### **DRAFT COVERAGE GUIDANCE: MANAGEMENT OF RECURRENT ACUTE OTITIS MEDIA IN CHILDREN**

DATE: XX/XX/XXXX

#### HERC COVERAGE GUIDANCE

Prophylactic antibiotics should be covered for recurrent otitis media.\*

Tympanostomy tubes may be covered for acute otitis media only for recurrent acute otitis media.

Adenoidectomy or adenotonsillectomy should not be covered for the treatment of recurrent acute otitis media.

\*Recurrent otitis media is defined here as three or more episodes in six months or four or more episodes in one year.

Note: Coverage guidance for chronic otitis media with effusion is addressed in a separate document.

#### RATIONALE FOR GUIDANCE DEVELOPMENT

The HERC selects topics for guideline development or technology assessment based on the following principles:

- Represents a significant burden of disease
- Represents important uncertainty with regard to efficacy or harms
- Represents important variation or controversy in clinical care
- Represents high costs, significant economic impact
- Topic is of high public interest

Coverage guidance development follows to translate the evidence review to a policy decision. Coverage guidance may be based on an evidence-based guideline developed by the Evidence-based Guideline Subcommittee or a health technology assessment developed by the Health Technology Assessment Subcommittee. In addition, coverage guidance may utilize an existing evidence report produced by one of HERC's trusted sources, generally within the last three years.

## EVIDENCE SOURCES

Leach, A.J., & Morris, P.S. (2006). Antibiotics for the prevention of acute and chronic suppurative otitis media in children. *Cochrane Database of Systematic Reviews*, 4(CD004401), 1-70. [Assessed as up-to-date: 5 AUG 2010]. Retrieved September 27, 2012, from <http://summaries.cochrane.org/CD004401/antibiotics-to-prevent-acute-ear-infections-in-children>

McDonald, S., Langton Hewer, C.D., & Nunez, D.A. (2008). Grommets (ventilation tubes) for recurrent acute otitis media in children. *Cochrane Database of Systematic Reviews*, 4(CD 004741), 1-14. [Assessed as up-to-date: 10 JAN 2011]. Retrieved September 27, 2012, from <http://summaries.cochrane.org/CD004741/grommets-ventilation-tubes-for-recurrent-acute-otitis-media-in-children>

Shekelle PG, Takata G, Newberry SJ, Coker T, Limbos M, Chan LS, et al. (2010). *Management of Acute Otitis Media: Update*. Evidence Report/Technology Assessment No. 198. (Prepared by the RAND Evidence-Based Practice Center under Contract No. 290 2007 10056 I). Rockville, MD: Agency for Healthcare Research and Quality. Retrieved September 26, 2012, from <http://www.ncbi.nlm.nih.gov/books/NBK56132/>

The summary of evidence in this document is derived directly from these evidence sources, and portions are extracted verbatim.

## SUMMARY OF EVIDENCE

### **Clinical Background**

Acute Otitis Media (AOM) is a viral and/or bacterial infection of the middle ear and represents the most common childhood infection for which antibiotics are prescribed in the United States. A diagnosis of AOM requires 1) a history of acute onset of signs and symptoms, 2) the presence of middle ear effusion, and 3) signs and symptoms of middle-ear inflammation. There is a high rate of spontaneous resolution for AOM, but if left untreated it can occasionally lead to complications such as acute mastoiditis. The optimal duration of antibiotic therapy is not known and varies worldwide from none to 10 days. One recent strategy is to delay antibiotic treatment until symptoms persist or worsen after several days. Recurrent AOM is generally defined as three episodes in the previous six months or four episodes in the prior year, and has been treated with prophylactic antibiotics or pressure equalization tubes (PE tubes).

## Evidence Review

### Prevention of AOM in patients with recurrent OM – Medical therapy

The AHRQ review was unable to reach definitive conclusions regarding the comparative effectiveness of different antibiotics for AOM in children with recurrent otitis media. For recurrent otitis media, authors relied on an earlier version of the Leach systematic review to conclude that long-term antibiotic administration was found to decrease AOM episodes from 3 to 1.5 for every 12 months of treatment per otitis prone child during active treatment. The authors caution that the potential consequences of long-term treatment need to be considered.

A Cochrane review (Leach 2011) included 17 studies of children at increased risk of AOM. In seven of these, increased risk was defined as three episodes of AOM in the previous six months or four episodes in the previous year. The other studies defined high risk in a variety of ways, but most included prior episodes of AOM. All excluded children with immunodeficiency or craniofacial abnormalities. In this meta-analysis, long-term antibiotics reduced any episode of AOM and the number of episodes of AOM, with approximately five children needing to be treated long-term to prevent one child experiencing AOM. Antibiotics prevented 1.5 episodes of AOM for every 12 months of treatment per child. Long-term antibiotics were not associated with a significant increase in adverse events.

### Prevention of AOM in patients with recurrent OM – Surgical therapy

The Cochrane systematic review addressed the effectiveness of tympanostomy tubes in children with recurrent acute otitis media (defined as three or more acute infections in six months, or four or more acute infections in a year). It included only two randomized controlled trials (RCTs) with a total of 176 children (McDonald 2008). Both trials included children under age three who had a history of at least three episodes of AOM in the six months prior to referral. In one trial, the control was no treatment and in the other, it was daily sulfamethoxazole/trimethoprim syrup at 12mg/kg/day. Both trials reported results categorically as “no episodes of AOM” or “one or more episodes of AOM”, and both found that PE tubes reduce the occurrence of AOM at a follow up of six months, with the larger trial that used a no-treatment control reaching statistical significance. There was no follow up in either trial longer than six months, nor were any harms reported.

The AHRQ report included five RCTs that addressed adenoidectomy, with or without tonsillectomy or tympanostomy. One trial compared adenoidectomy to sulfafurazole and found no significant difference, although the trend was toward favoring the drug. Two trials compared adenoidectomy to placebo, and while both favored the procedure,

neither reached statistical significance. The same was true for the trial that compared adenotonsillectomy to adenoidectomy alone; the trend favored adenotonsillectomy, but results did not reach statistical significance. When adenotonsillectomy was compared to placebo, there was 15% improvement in success rate (defined as no AOM episodes for one year), but given the wide confidence interval, this did not meet the required minimum clinically important difference of 5% adopted by the authors. Lastly, one trial compared adenoidectomy plus PE tubes to PE tubes alone, and found no difference between groups in number of episodes of AOM in the following year. Differences in harms, when reported, were either inconclusive or equivalent.

### Overall Summary

For recurrent AOM, prophylactic antibiotics modestly decrease the number of episodes of AOM, with a number needed to treat of five. Pressure equalization tubes may reduce the frequency of acute otitis media in the short-term. Adenoidectomy does not result in a clinically significant decrease in the frequency of AOM.

### PROCEDURE

Placement of pressure equalization tubes  
 Antibiotic Pharmacotherapy  
 Adenoidectomy  
 Adenotonsillectomy

### DIAGNOSES

Acute otitis media  
 Recurrent acute otitis media

### APPLICABLE CODES

<b>CODES</b>	<b>DESCRIPTION</b>
<b>ICD-9 Diagnosis Codes</b>	
381.0	Acute nonsuppurative otitis media
381.00	... unspecified
381.01	Acute serous otitis media
381.02	Acute mucoid otitis media
381.03	Acute sanguinous otitis media
381.04	Acute allergic serous otitis media
381.05	Acute allergic mucoid otitis media
381.06	Acute allergic sanguinous otitis media
381.4	Nonsuppurative otitis media, not specified as acute or chronic
382.0	Acute suppurative otitis media

<b>CODES</b>	<b>DESCRIPTION</b>
382.00	... without spontaneous rupture of eardrum
382.01	... with spontaneous rupture of eardrum
382.02	... in diseases classified elsewhere
382.4	Unspecified suppurative otitis media
382.9	Unspecified otitis media
315.34	Speech and language developmental delay due to hearing loss
389.00	Conductive hearing loss unspecified
389.03	Conductive hearing loss middle ear
389.05	Conductive hearing loss unilateral
389.06	Conductive hearing loss bilateral
389.08	Conductive hearing loss of combined types
389.2	Mixed conductive and sensorineural hearing loss
389.20	Mixed hearing loss, unspecified
389.21	Mixed hearing loss, unilateral
389.22	Mixed hearing loss, bilateral
389.9	Unspecified hearing loss
<b>ICD-9 Volume 3 (Procedure Codes)</b>	
None	
<b>CPT Codes</b>	
42820	Tonsillectomy and adenoidectomy; younger than age 12
42821	Tonsillectomy and adenoidectomy; age 12 and over
42830	Adenoidectomy, primary; younger than age 12
42831	Adenoidectomy, primary; age 12 and over
42835	Adenoidectomy, secondary; younger than age 12
42836	Adenoidectomy, secondary; age 12 and over
69433	Tympanostomy (requiring insertion of ventilating tube, local or topical anesthesia)
69436	Tympanostomy (requiring insertion of ventilating tube, general anesthesia)
69424	Ventilating tube removal requiring general anesthesia
<b>HCPCS Codes</b>	
None	

Note: Inclusion on this list does not guarantee coverage

Coverage guidance is prepared by the Health Evidence Review Commission (HERC), HERC staff, and subcommittee members. The evidence summary is prepared by the Center for Evidence-based Policy at Oregon Health & Science University (the Center). This document is intended to guide public and private purchasers in Oregon in making informed decisions about health care services.

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