*Health Policy & Clinical Effectiveness Program*
Evidence Based Clinical Practice Guideline

# Otitis Media
## In children 2 months to 6 years of age
## Publication Date: March, 1999

## These guidelines are intended for use in the following described patients

Children of age greater than 2 months and up to 6 years of age with otitis media and no comorbid conditions increasing the risk or severity of otitis media. These comorbid conditions include immunodeficiencies, craniofacial or neurologic abnormalities, or sensory deficits. Children with pressure equalizing tubes in place are also excluded.

**Abbreviations and Definitions as used in this Guideline** ***(Modified and Adapted from Rosenfeld 1996)***

| Otitis Type | Definition | Comment |
|---|---|---|
| **MEE (middle ear effusion)** | Any fluid in middle ear space regardless of cause | Assess function by pneumatic otoscopy or tympanometry |
| **Myringitis** | Erythema of tympanic membrane (TM) without MEE (May be mimicked by crying) | Most often viral. Does not respond to antibiotics. May, be seen in early AOM or during resolution. |
| **AOM (acute otitis media)** | MEE with rapid onset of one or more of otalgia, ear pulling, otorrhea, fever irritability, anorexia, vomiting, or diarrhea. | Most frequent diagnosis by pediatricians: 50% of children by 1 year, 65% by 2 years, and 70% by age 3 years. |
| **Sporadic AOM** | AOM occurring more than 3 months after a prior episode of AOM | Compare to Recurrent AOM |
| **Recurrent AOM (otitis-prone condition)** | At least 3 separate episodes of AOM within 6 mos or 4 episodes in 12 mos. | Affects about 15-30% of children. |
| **OME (otitis media with effusion)** | MEE without signs or symptoms of infection; | Childhood prevalence of about 15%. Often follows AOM. |
| **Chronic OME** | OME with duration 2 to 3 months | |

# Guideline Highlights

*References in parentheses ( ) Evidence strengths in brackets [ ]*
*(See last page for definitions)*

1. **Use pneumatic otoscopy and tympanonometry to enhance accuracy when diagnosing AOM.**

   - Because of the well known uncertainties of being correct in diagnosing AOM *(Froom 1990[C])*, It is recommended that practitioners use pneumatic otoscopy *(Pelton 1998[S])* or tympanometry as supportive tests *(Brookhauser 1998[S]*.

2. **For the first or sporadic episode of AOM use antibiotics sparingly.**

   - AOM is more likely associated with bacterial rather than viral etiologies. Antibiotics likely shorten the period of fever and discomfort. However, the incidence of complications following AOM episodes is very low today. Also, using antibiotics significantly increases the risk of producing bacterial resistant organisms that subsequently may be more invasive *(Klein 1976[C])*. In addition there is lack of evidence demonstrating the long term efficacy of antibiotics in reducing compromises in hearing and speech nor evidence that antibiotics reduce the need for surgical interventions later *(Klein 1998[S,E])*. It is estimated that 70-90% of AOM episodes resolve without therapy within 7-14 days *(Rosenfeld 1994[S,E])*.

3. **When a decision is made to trial antibiotics it is recommended that amoxicillin, in the dose range of 80-90 mg/kg/day, be selected as the first choice drug**

   - If for a first episode of AOM the practitioner elects to start antibiotics, it is recommended unless there are other contraindications such as known allergy or uncertainty about compliance *(Bauchner 1997[S])*, that oral amoxicillin (80-90mg/kg/day in twice a day dosing) be considered as the drugs of first choice. Amoxicillin given at recommended dose is estimated to be effective for 2/3 of intermediate resistant and 1/3 or resistant strains of pneumococcal organisms *(Seikel 1997[F], McCracken 1998[S,E])*.

   - For children under 2 years of age a 10 day course of antibiotics is recommended *(Hoberman 1997[A], Dowell 1998[S,E])*.

   - For children 2 years of age and older, a 5 day course of antibiotics is recommended *(Dowell 1998[S,E])*.

4. **For the first or a sporadic episode of AOM when the initial therapeutic approach fails reevaluate the antibiotic decision.**

   - If within 24-72 hours of initial presentation with AOM the child is not clearly improved, is febrile, or uncomfortable, and reexamination continues to suggest that AOM is appropriate diagnosis, then recommendation is to consider starting Amoxicillin if not already initiated or to review and, if appropriate, change to an alternative antibiotic if child already on first line drug.

5. **For the first episode of AOM establish expectations for residual OME with family.**

   - It is recommended that families be informed that persistent (OME) is expected to be present for a period of time following any episode of AOM. This can last for a long time, and can be difficult, on physical exam to distinguish from a continuing or recurrent episode of AOM.

6. **After each episode of AOM inform family of ways to limit potential for recurrences.**

   - It is strongly recommended that families be counseled on the increased risk of recurrence if the child is exposed to tobacco smoke and other children in a day care setting. It also is encouraged infant feeding practices be reviewed to assure that infants are offered bottle feedings while sitting in upright positions *(Rosenfeld 1996[S,E], Tully 1995[C])*.

7. **If AOM recurs and more than 3 months has lapsed since recovery from a prior episode of AOM it is recommended that the practitioner consider managing these sporadic episodes similarly to the first. If, however, the child has**

**recurrences within a shorter time period or has recently been on antibiotics for other reasons, it is suggested that advancing to an antibiotic other than amoxicillin is worth considering.**

- It is here noted that neither prolonged nor prophylactic antibiotic therapies are recommended as routine because they have not been documented to be efficacious in preventing hearing compromise or subsequent need for insertion of tympanostomy tubes except in a minority of patients with chronic OME and recurrent AOM *(Dowell 1998[S,E])*. Moreover the potential of acquiring a resistant organism is enhanced by use of prolonged therapies. If, however a practitioner does elect to trial prophylaxis, it is recommended to consider using only amoxicillin 20 mg/kg or sulfisoxazole 50 mg/kg in one dose at bedtime throughout the respiratory season and to only children who have three or more very well documented episodes of AOM in 6 months or four in 12 months. *(Klein 1998[SE], Dowell 1998[S,E])*.

8. **It is recommended that referral for hearing evaluation by a specialist in the testing of pediatric patients be considered if AOM recurs more than 3 times in 6 months, more than 4-6 times within 12 months, or OME persists for more than 3-4 months** *(Teele 1990[D,E], Mandel 1991[A], Bachman 1998[S,E], Hsu 1998[D])*.
9. 

- If chronic OME is present the subsequent decisions depend heavily on hearing compromise. And techniques are available for testing hearing in most children of any age.

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- Delaying evaluation pending repeat or prolonged trials of antibiotics are probably not warranted because antibiotics, while having some possible short term effects (1-2 weeks) in ameliorating OME, are not different than placebo when measuring long term outcomes *(Mandel 1991[A], Rosenfeld 1996[S,E])*.

10. **ENT referral for evaluation might occur for any indication, but is recommended especially for any child with a hearing deficiency and especially when the loss is bilateral (defined as a 20 decibel hearing threshold level or worse in the better-hearing ear).**

- The strength of this recommendation increases with the duration of the OME.

11. **Referral for speech and language evaluation is recommended for children with hearing deficits or evidencing signs of speech delay.**

- Because children with OME in the first 3 years of life have poorer school performances at 7 years of age *(Teele 1990[D])*, and the first 36 months of life are the most important period for language learning *(Bachman 1998[S,E])*, it is recommended that children with hearing deficits also be considered candidates for evaluation of speech development *(Hsu 1998[D])*.

12. **Steroids, antihistamines, and decongestants, have not been documented to be efficacious and are not recommended for routine therapies for AOM or OME** *(Otitis Media Guideline Panel 1994[S,E], Rosenfeld 1996[S,E])*.

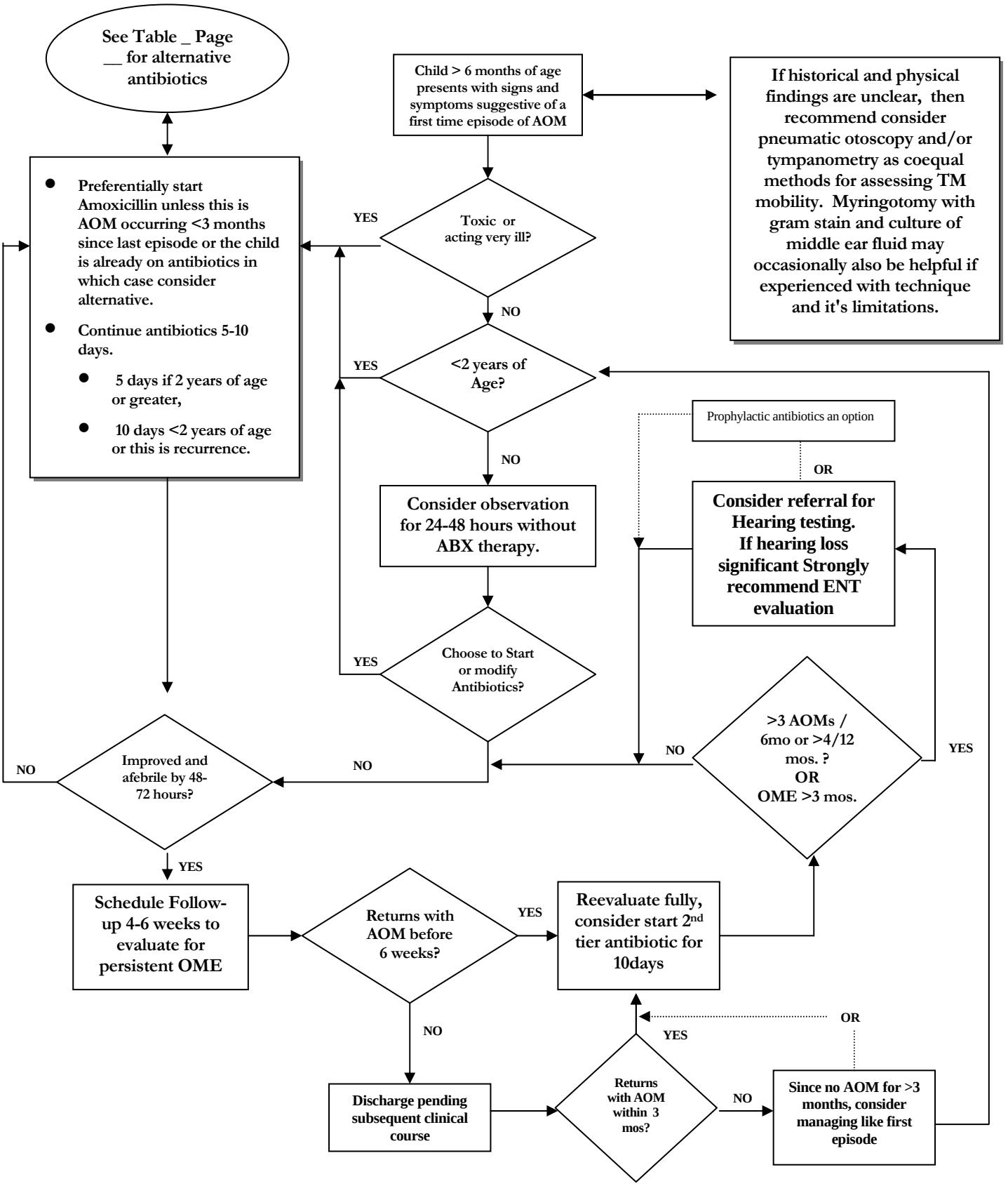
- **Steroid medications,** and especially in combination with antimicrobials have been trialed in selected patients with OME and found to be effective, but only for short periods of time and not to any statistically significant degree. These reports are therefore not currently of sufficient strength to recommended the use of steroids routinely to treat OME in a child of any age because the evidence of possible adverse effects outweighs the evidence for possible benefits. Before use of steroids, consultation with an otolaryngologist is recommended.

- **Antihistamine/decongestant therapy** is not recommended for treatment of otitis media with effusion in a child of any age.

- **Ear drops** for use in the external ear canal are not recommended for routine treatment of acute otitis media with or without perforation of the tympanic membrane.

- There are no randomized controlled studies or other evidences supporting the efficacies of chiropractic, holistic, naturopathic, traditional/ indigenous, or homeopathic, therapies for the treatment of otitis media with effusion. Therefore, no recommendations are made here regarding such other therapy.

**Management of a child >6mos and up to 6 yoa with signs and symptoms of a first episode of AOM**
**(See Page 1 for definitions and additional information)**



# Some considerations when choosing antibiotics for therapy of Otitis Media

| Antibiotic | Dose (per Dose) | Frequency | Oral Dosage Forms | Taste *(Steele 1997)* | Relative Cost | Middle Ear Penetration | Comments |
|---|---|---|---|---|---|---|---|
| **Amoxicillin** | 40-45 mg/Kg | BID | Suspension (per 5mL): 125 or 250mg | OK | Low | Excellent; Can exceed MICs of intermediate and resistant s.pneumococci with higher doses *(Canafax 1998, Seikel 1997, Lister 1997)* | Recommended as first line therapy |
| | 20 - 30 mg/Kg | TID | | | | | |
| **Trimethoprim (TMP)-Sulfamethoxazole (SMX)** | 0.5ml (4mg/Kg TMP) | BID | Suspension (per 5 mL): 40mg (TMP)/200mg (SMX) | OK | Low | TMP-excellent SMX- good *(Craig, 1996)* | For trial in patient with persistent or recurrent disease or known beta-lactamase producing organisms. |
| **Amoxicillin-clavulanate (Augmentin)** | 20 - 22 mg/Kg | BID | Suspension(per 5mL, amoxicillin component) 125, 200, 250, 400mg<br>Chewable tablet: 125, 200, 250, 400mg | OK | High | Excellent *(Seikel, 1997)* | |
| **Azithromycin (Zithromax)** | (day 1)= 10 mg/Kg<br>(day 2-5)= 5 mg/Kg<br>Max dose: 250mg/day | QD | Suspension (per 5 mL): 100 or 200mg | OK | High | Unknown | |
| **Clarithromycin (Biaxin)** | 7.5 mg/Kg<br>Max dose: 1gm/day | BID | Suspension (per 5 mL): 125 or 250mg | OK | High | Good | MEF penetration is excellent after multiple doses *(Guay 1993)* |
| **Cefprozil (Cefzil)** | 15 mg/Kg<br>Max dose: 1 gm/day | BID | Suspension (per 5mL): 125 or 250mg | Unpleasant | High | Good *(Shyu 1994)* | Similar efficacy to amoxicillin-clavulanate with less GI side effects shown in one study *(Arguedas 1991)* |
| **Cefixime (Suprax)** | 8 mg/Kg<br>Max dose: 400 mg/day | QD | Suspension (per 5mL): 100mg | Very good | High | Good *(Craig 1996)* | |
| **Ceftriaxone (Rocephin)** | 50 mg /Kg<br>Max dose: 1 gm | one dose IM | | N/A | | Good *(Gudnason 1998)* | Reserve for those non-complian with oral therapy. Has been shown to be efficacious *(Barnett 1997, Green 1993, Chamberlain 1998).* |

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(**Note:** Some references included in this listing are not cited in the guidelines and are included for those interested in pursuing a further in-depth review of these subjects.)


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### Important Information

The recommendations contained in this document were formulated by a working group including community and hospital based physicians, nurses, speech and hearing specialist, and pharmacists, who examined current local clinical practices and performed extensive and critical literature reviews using the grading scale that follows.

| Evidence Based Grading Scale | | | |
|---|---|---|---|
| **A** | **Randomized controlled trial: large sample** | **S** | **Review article** |
| **B** | **Randomized controlled trial: small sample** | **M** | **Meta-analysis** |
| **C** | **Prospective trial or large case series** | **Q** | **Decision analysis** |
| **D** | **Retrospective analysis** | **L** | **Legal requirement** |
| **E** | **Expert opinion or consensus** | **O** | **Other evidence** |
| **F** | **Basic laboratory research** | **X** | **No evidence** |

During formulation of these guidelines, the committee members have remained cognizant of controversies and disagreements over the management of these patients. They have tried to resolve controversial issues where possible and, when not possible, to offer optional approaches to care in the form of information that includes best supporting evidence of efficacy for alternative choices.

The guidelines have been reviewed and approved by senior management, Legal Services, the Institutional Review Board, the hospital's Pharmacy and Therapeutics, Clinical Practices, Executive, and other committees and other individuals as appropriate to their intended purposes.

**NOTE: These recommendations result from review of literature and practices current at the time of their formulations. This protocol does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the guidelines to meet the specific and unique requirements of individual patients. Adherence to this pathway is voluntary. The physician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.**

*For more information about these guidelines, their supporting evidences and the guideline development process, contact the Health Policy & Clinical Effectiveness office at 513-636—2501 or HPCEInfo@cchmc.org.*