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Clinical Practice Pathway: Antibiotic Treatment of Acute Otitis Media

Background/Rationale and Purpose

Studies of children with acute respiratory tract infections have shown that broad-spectrum antibiotics do not improve clinical or patient-centered outcomes compared to narrow-spectrum antibiotics. Moreover, broad-spectrum antibiotics are associated with a higher incidence of adverse events. This guideline provides best practice recommendations for the management of children with Acute Otitis Media (AOM). It emphasizes the use of narrow-spectrum antibiotics for most children with acute respiratory tract infections to minimize unnecessary risks while maintaining effective treatment.

Guideline Eligibility

Inclusion Criteria

- Children aged **6 months to 12 years** with AOM in the **ambulatory setting**.

Exclusion Criteria

- Children **without middle ear effusion**, as determined by pneumatic otoscopy and/or tympanometry.
 - Children with **tympanostomy tube otorrhea**.
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Recommendations (Appendix A)

Diagnosis

- **AOM Diagnosis:**
 - Moderate to severe **bulging of the tympanic membrane (TM)** or new onset of **otorrhea** not caused by acute otitis externa.
 - Mild bulging of the TM with **recent (less than 48 hours) onset of ear pain** (holding, tugging, or rubbing of the ear in a nonverbal child) or **intense erythema of the TM**.

Antibiotic Therapy Indications

- **Immediate antibiotic therapy** is recommended for:
 - Children aged **6 months or older** with **severe signs or symptoms**, including:
 - Moderate or severe **otalgia**.
 - Ootalgia lasting **48 hours or more**.
 - Temperature $\geq 39^{\circ}\text{C}$ (**102.2°F**).

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- **Bilateral AOM** in children aged **6–23 months** without severe signs or symptoms (e.g., mild otalgia for <48 hours, temperature <39°C [102.2°F]).
- **Either antibiotic therapy or observation with close follow-up** is appropriate for:
 - **Unilateral AOM** in children aged **6–23 months** without severe signs or symptoms.
 - Children aged **24 months or older** without severe signs or symptoms (e.g., mild otalgia for <48 hours, temperature <39°C [102.2°F]).

Antibiotic Choice

- **First-line therapy:**
 - **Amoxicillin** is the preferred choice if:
 - The child has not received amoxicillin in the past 30 days.
 - The child does not have concurrent **purulent conjunctivitis**.
- **Alternative therapy:**
 - Prescribe an antibiotic with additional **β-lactamase coverage** if:
 - The child has received **amoxicillin in the last 30 days**.
 - The child has concurrent **purulent conjunctivitis**.
 - The child has a history of **recurrent AOM unresponsive to amoxicillin**.
 - For children with non-severe (non-type I) hypersensitivity to penicillin, use a third-generation oral cephalosporin (cefpodoxime or cefdinir)
 - For children with a severe or type I hypersensitivity to penicillin, use azithromycin or clindamycin or a respiratory fluoroquinolone
 - Severe penicillin allergy includes anaphylaxis, angioedema, cardiac arrest, respiratory distress, severe cutaneous reaction (e.g., Stevens-Johnson syndrome, erythema multiforme, DRESS and TEN).

Goals and Metrics

- Rates of broad-spectrum antibiotics as a proportion of all antibiotics prescribed for Group A streptococcal pharyngitis ≤10%

	Narrow Spectrum	Broad Spectrum
Acute Otitis Media	Amoxicillin	Amoxicillin-Clavulanate, Azithromycin, Cefdinir, Cefprozil, Cefuroxime Axetil, Levofloxacin

Patient and family education:

- PCORI Choosing an Antibiotic for Your Child’s Ear, Nose, or Throat Infection: <https://www.pcori.org/sites/default/files/PCORI-Evidence-Update-for-Parents-Narrow-Broad-Antibiotics.pdf>
- EPIC patient education links:
 - Otitis media, child

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- Fever, pediatric
- Earache, pediatric
- Upper Respiratory Infection, Infant
- Upper Respiratory Infection, Pediatric

Abbreviations

AOM, Acute Otitis Media

mos, months

TM, tympanic membrane

Related resources

- URI PEDS SMARTSET
- ICD-10 diagnoses codes: H66.001-H66.019, H66.40- H66.43, H66.90-H66.93

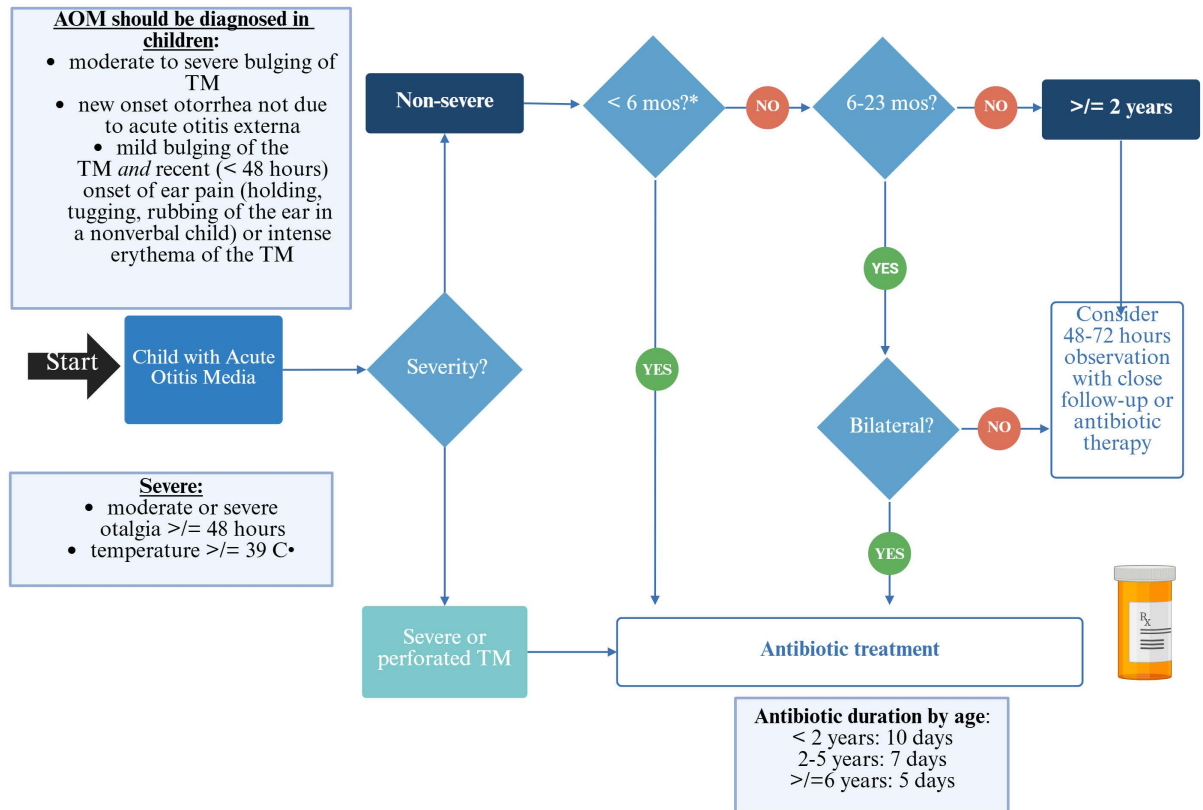
Basis for Recommendations

1. Allan S. Lieberthal, Aaron E. Carroll, Tasnee Chonmaitree, Theodore G. Ganiats, Alejandro Hoberman, Mary Anne Jackson, Mark D. Joffe, Donald T. Miller, Richard M. Rosenfeld, Xavier D. Sevilla, Richard H. Schwartz, Pauline A. Thomas, David E. Tunkel; The Diagnosis and Management of Acute Otitis Media. *Pediatrics* March 2013; 131 (3): e964–e999. 10.1542/peds.2012-3488
2. Gerber JS, Ross RK, Bryan M, Localio AR, Szymczak JE, Wasserman R, Barkman D, Odeniyi F, Conaboy K, Bell L, Zaoutis TE, Fiks AG. Association of Broad- vs Narrow-Spectrum Antibiotics With Treatment Failure, Adverse Events, and Quality of Life in Children With Acute Respiratory Tract Infections. *JAMA*. 2017 Dec 19;318(23):2325-2336. doi: 10.1001/jama.2017.18715. PMID: 29260224; PMCID: PMC5820700
3. Red Book: 2024–2027 Report of the Committee on Infectious Diseases By: Committee on Infectious Diseases, American Academy of Pediatrics. Edited by: David W. Kimberlin, MD, FAAP, Ritu Banerjee, MD, PhD, FAAP, Elizabeth D. Barnett, MD, FAAP, Ruth Lynfield, MD, FAAP, Mark H. Sawyer, MD, FAAP, <https://doi.org/10.1542/9781610027373>
4. CDC Antibiotic Prescribing and Use for Pediatric Outpatients: <https://www.cdc.gov/antibiotic-use/hcp/clinical-care/pediatric-outpatient.html>

Version	Date	Author(s)	Reviewer(s)	Revisions
1.0		Debbie-Ann Shirley, MD	Maria Kelly, MD Rachel Reise, pharmD Matthew Garber, MD Kalen Manasco, pharmD	-

Please note this information reflects the best information as of the revised date above and is provided as a general guide for our patient care. Clinical judgment and critical thinking regarding a particular patient remains with the patient’s provider.

APPENDIX A: TREATMENT OF ACUTE OTITIS MEDIA (AOM) IN CHILDREN



AOM	First-line treatment of AOM	Alternative therapy for Beta-lactam allergy
Initial therapy if no amoxicillin in the prior 30 days	Amoxicillin, PO \leq 3 months*: 30 mg/kg/day in 2 divided doses \geq 3 months*: 90 mg/kg/day in 2 divided doses (max 2,000 mg/dose)	NON-SEVERE PCN ALLERGY: Cefdinir, PO \geq 6 months: 14 mg/kg/ day divided twice daily for 5-10 day duration or 14 mg/kg/dose daily for 10 day durations (max 600 mg/day) Cefpodoxime, PO \geq 2 months: 10 mg/kg/day in 2 divided doses (max 200 mg/dose)
Initial therapy if Amoxicillin received in the preceding 30 days or has concurrent conjunctivitis (suggests beta-lactamase producer)	Amoxicillin-Clavulanate, PO \leq 3 months*: 30 mg/kg/day of amoxicillin component in 2 divided doses \geq 3 months*: 90 mg/kg/day of amoxicillin component in 2 divided doses Max: 2,000 mg/dose For oral of Amoxicillin-Clavulanate suspension, use ES formulation and for tablet, use ER formulation	SEVERE PCN ALLERGY: Clindamycin, PO 30 mg/kg/day divided 3 times a day (max 600 mg/dose) Azithromycin, PO 10 mg/kg once on day 1 (max 500 mg/dose), then 5 mg/kg once per day on days 2 through 5 (max 250 mg/dose)
Amoxicillin failure	As above for Amoxicillin-Clavulanate	N/A
Amoxicillin-clavulanate or oral cephalosporin failure	Ceftriaxone, IV or IM: 50 mg/kg daily for 3 days (max 1,000 mg/dose)	Levofloxacin, PO: \geq 6 months and < 5 years: 20 mg/kg/day divided twice daily (max 375 mg/dose) \geq 5 years: 10 mg/kg/dose daily (max 750 mg/dose)

*Infants < 6 months are excluded from pathway, but dosing guidance is provided for young infants, as clinically indicated