

GUIDELINES & PROTOCOLS

ADVISORY COMMITTEE

Otitis Media: Acute Otitis Media (AOM) & Otitis Media with Effusion (OME)

Effective Date: January 1, 2010

Scope

This guideline applies to otherwise healthy children over the age of six months presenting with AOM or OME. It does not include children with craniofacial abnormalities, immune deficiencies, complications of AOM (e.g. mastoiditis, facial paralysis, etc.) or serious underlying disease.

Definitions

Acute otitis media (AOM) is defined as the presence of inflammation in the middle ear accompanied by the rapid onset of signs and symptoms of an ear infection.¹ Otitis media with effusion (OME) is defined as the presence of fluid in the middle ear without signs and symptoms of an ear infection.

Diagnostic Codes: 381 (Nonsuppurative otitis media and Eustachian tube disorders)
382 (Suppurative and unspecified otitis media)

Prevention and Risk Factors

Hand washing prevents colds and flu - the major risk factor for otitis media.² Other risk factors for AOM include: environmental tobacco smoke, daycare attendance, pacifier use, and bottle feeding in a supine position.³⁻⁵ Breastfeeding^{5,6} or immunizations²⁴ may offer some protection against AOM.

Diagnosis and Investigation

Children with AOM present with combinations of ear pain (otalgia), loss of landmarks and an opaque, bulging, inflamed tympanic membrane on direct otoscopy. Additional non-specific symptoms include: irritability, fever, night waking, poor feeding, cold symptoms, conjunctivitis and occasional balance problems.⁷

Otitis media with effusion (OME) is defined as the presence of fluid in the middle ear without acute infection. The child may have ear discomfort but the ear is not acutely painful. The fluid may range from clear to opaque. Decreased mobility on pneumatic otoscopy supports the diagnosis of OME.¹

Although pneumatic otoscopy is helpful in the diagnosis of AOM, it is not routinely performed as it may elicit severe pain.

It is important to distinguish between AOM and OME. Ear discomfort, a red tympanic membrane, or fever alone are not specific diagnostic criteria for AOM.⁷ Pneumatic otoscopy is a useful tool in diagnosing OME.

If acute otitis media (AOM) is diagnosed or suspected, proceed to Part I

If otitis media with effusion (OME) is diagnosed or suspected, proceed to Part II

Part I: Acute Otitis Media

Management of AOM

For most children, antibiotics are not warranted. Spontaneous resolution of AOM is to be expected in approximately 80 per cent of children. ⁴⁻¹⁰

- AOM does not always require antibiotics, providing that good follow up is provided.¹¹
- Aggressively manage pain with adequate systemic analgesics (not ASA).^{1,12-16}
- If a child is significantly unwell after 48-72 hours of analgesics, treat with antibiotics regardless of age.
- Decongestants, antihistamines and steroids are not beneficial in the treatment of AOM.^{4,12,15}

Pharmacological Management* ^{1,4,6,7,11,12,17-20}

Table 1: Initial Treatment of AOM for Children Over 6 Months of Age			
Patient Type	Therapy	Dose	Comments
Otherwise healthy with mild symptoms <i>(see comments)</i>	Acetaminophen	10-15mg/kg/dose PO Q4H prn (max 75mg/kg/day)	For ages 6-24 months, observation with the use of systemic analgesics <u>without</u> the use of antibacterial agents is an option for selected children with uncomplicated AOM, based on diagnostic certainty, age, illness severity and assurance of follow-up. ^{7,8,14,16,21-23}
	Ibuprofen	5-10mg/kg/dose PO Q6-8H prn (max 40mg/kg/day)	If older than 24 months, most cases of AOM resolve and <u>do not</u> require antibiotics, as long as symptoms are manageable with systemic analgesics, the child has access to re-evaluation at 48 hours and symptoms do not persist. ^{1,13,14,16,24} If signs and symptoms of AOM persist in spite of using systemic analgesics for 48 to 72 hours, reassess and consider treatment with antibiotics. ^{6,7}
No daycare attendance and no antibiotics within 90 days	Amoxicillin	Standard Dose: 40-45 mg/kg/day PO div tid ≥2 years: treat for 5 days <2 years: treat for 10 days	High risk factors increase the risk of resistant Streptococcus pneumoniae (<i>S. pneumoniae</i>)
Daycare attendance and antibiotics within 90 days	Amoxicillin	High Dose: 80-90 mg/kg/day PO div tid ≥2 years: treat for 5 days <2 years: treat for 10 days	Amoxicillin retains the best activity of all oral B-lactam agents against <i>S. pneumoniae</i> , including penicillin intermediate resistant strains
β-lactam allergy**	The incidence of cephalosporin cross-reactivity with penicillin allergy is less than 2%. Consider allergy testing when infection resolves to confirm penicillin allergy.		
Penicillin allergy - Non anaphylactic	Cefuroxime axetil	30mg/kg /day PO div bid ≥2 years: treat for 5 days <2 years: treat for 10 days	Due to poor taste of cefuroxime suspension, recommend tablets if possible, can be crushed and put in to a palatable fluid
	or Cefprozil	30mg/kg/day PO div bid ≥2 years: treat for 5 days <2 years: treat for 10 days	Compared to cefuroxime, liquid cefprozil has a better taste but inferior coverage of <i>Haemophilus</i> and Penicillin Intermediate resistance - <i>S. pneumoniae</i>

Penicillin allergy - Anaphylactic or - Cephalosporin allergy	Clarithromycin	15 mg/kg/day/ div bid for 10 days***	TMP/SMX and macrolides are inferior options due to high resistance rates and clinical failure rates Consider referral to otolaryngologist for tympanocentesis
	or TMP/SMX	6-12 mg TMP/kg/day PO div bid ≥2 years: treat for 5 days <2 years: treat for 10 days	
	or Azithromycin	10mg/kg/day PO on the first day and 5mg/kg/day PO for 4 days	

* Abbreviations: div = divided; TMP/SMX = trimethoprim/sulfamethoxazole

** β-lactam = Any of a class of broad-spectrum antibiotics that are structurally and pharmacologically related to the penicillins and cephalosporins.

*** 10 days of therapy with macrolides is preferred because of lower activity in this class of medication compared to the beta lactams

Duration of Therapy for AOM

Five days of therapy has equal efficacy to the standard ten day regimen in children with uncomplicated AOM and is recommended in children two years of age and over.²⁵ For children less than two years of age or those who present with perforation of the tympanic membrane, ten days of antibiotic therapy are still recommended.²⁶ Failure of initial treatment of AOM with antibiotics is defined as the persistence or worsening of moderately severe symptoms (**pain and fever**) after three to five days of antibiotic therapy with findings of continued pressure and inflammation (bulging) behind the tympanic membrane.^{12,13}

Table 2: Failure of Initial Treatment of AOM

Patient Type	Therapy	Dose	Comments
Failure of standard dose amoxicillin	Amoxicillin	40-45 mg/kg/day PO div tid for 10 days	The combination is recommended to provide a high dose of amoxicillin (for penicillin intermediate resistance <i>S. pneumoniae</i>) and regular dose of amoxicillin-clavulanate (for coverage of β-lactamase producing <i>H. influenzae</i> and <i>M. catarrhalis</i>) without excessive clavulanate (>10mg/kg/day) – which may lead to increased incidence of diarrhea
	PLUS Amoxicillin – clavulanate (use 7:1 formulation)* (2 separate prescriptions should be given)	45 mg/kg/day PO div tid for 10 days (based on amoxicillin component)	
Failure of high dose amoxicillin	Amoxicillin – clavulanate (use 4:1 formulation)*	40 mg/kg/day PO div tid for 10 days (based on amoxicillin component)	Due to poor taste of cefuroxime axetil suspension, recommend tablets if possible, can be crushed and put in to a palatable fluid
	or Cefuroxime axetil	30mg/kg/day PO div bid for 10 days	
	or Cefprozil	30mg/kg/day po div bid for 10 days	
β-lactam (penicillin) allergy	Clarithromycin	15mg/kg/day PO div bid for 10 days	Therapeutic options for these patients are very limited. Consider referral to otolaryngologist for tympanocentesis. Macrolides and TMP/SMX are less efficacious than amoxicillin-clavulanate. There is significant macrolide resistance in <i>S. pneumoniae</i>
	or TMP/SMX	6-12 mg TMP/kg/day PO div bid for 10 days	
	or Azithromycin	10mg/kg PO first day then 5 mg/ kg/ day x 4 days	

*There are two formulations of amoxicillin:clavulanate, 4:1 and 7:1 ratios. Higher doses of clavulanate increase the likelihood of GI side effects. If a patient has **failed standard dose amoxicillin**, these patients should receive 2 prescriptions: one for amoxicillin and one for the **7:1 ratio** of amoxicillin:clavulanate. This combination gives a high dose of amoxicillin plus a therapeutic dose of beta lactamase inhibitor (clavulanate) which is low enough to reduce the risk of diarrhea. If a patient has **failed high dose amoxicillin**, they are more likely to have an illness caused by a beta lactamase producing bacteria, hence the **4:1 ratio** of amoxicillin:clavulanate **maximizes** the amount of beta lactamase inhibitor (clavulanate) but using this product increases the risk of diarrhea.

Table 3: Agents NOT Recommended for AOM ¹¹	
Cephalexin	No activity against Penicillin intermediate resistant <i>S. pneumoniae</i> No activity against <i>Haemophilus influenzae/ Moraxella catarrhalis</i>
Cefaclor	No activity against Penicillin intermediate resistant <i>S. pneumoniae</i> Marginal activity against <i>Haemophilus influenzae/ Moraxella catarrhalis</i>
Cefixime	No activity against Penicillin intermediate resistant <i>S. pneumoniae</i> Excellent activity against <i>Haemophilus influenzae</i>
Ceftriaxone	Routine use of this agent is not recommended due to potential for increased resistance to 3 rd generation cephalosporins. May be an option in severe cases who have failed therapy, in immunosuppressed patients or neonates. NB: 3 days of IM/IV therapy recommended. (single dose not as effective in eradicating penicillin resistant <i>S. pneumoniae</i>)
Clindamycin	No activity against <i>Haemophilus/ Moraxella spp.</i> (Clindamycin may be an option for <i>S. pneumoniae</i> in severe penicillin allergic patients)
Erythromycin	Poor activity against <i>Haemophilus influenzae</i> Significant macrolide resistance in <i>S. pneumoniae</i>

On Going Care

- Re-examine child if he/she is not improving within 48 to 72 hours.
- **If perforation occurs, this is not a serious complication as this generally heals without intervention.** Water and objects such as cotton tip swabs should be kept out of the ear canal. There is no need to refer to an otolaryngologist for a simple rupture of the tympanic membrane. Manage as for AOM. Refer to an otolaryngologist if the perforation does not heal in six weeks.
- Routine follow-up examination is not required until three to six months post-infection to evaluate OME.
- Refer to an otolaryngologist urgently if complications occur such as: facial paralysis or mastoiditis (symptoms include fever and persistent, throbbing otalgia; signs include purulent otorrhea, redness, swelling, tenderness, and fluctuation over the mastoid process; the pinna is typically displaced laterally and inferiorly).
- Refer to an otolaryngologist electively if three or more episodes of AOM occur in six months or four episodes of AOM occur in 12 months.

Rationale for AOM Recommendations

Studies have demonstrated that the number needed to treat during initial treatment may be as high as 20 to effect one cure and a greater percentage of children who receive antibiotics experience side effects such as vomiting, diarrhea and rash than those who receive placebo.^{5,7,9,27-30}

Twenty to 30 per cent of episodes of AOM are caused by viruses.^{1,4,13,15,28} Determining which cases of AOM are caused by bacteria is often challenging. Bacterial pathogens include *S. pneumoniae*, non-typable *Haemophilus influenzae*, *Moraxella catarrhalis*, Group A streptococcus, and *S. aureus*.¹ *S. pneumoniae* has the lowest spontaneous resolution rate and carries the highest morbidity.

Pneumatic otoscopy can detect the presence of fluid behind the tympanic membrane;¹ however, the pressure applied to an already infected ear may worsen the pain and should not be done. Perforation of the tympanic membrane allows the fluid to drain from the middle ear and often hastens the healing process. Rarely, meningitis, facial paralysis, and mastoiditis complicate an episode of AOM and require urgent medical or surgical referral.

Part II: Otitis Media with Effusion (OME)

OME is associated with ear discomfort and recurrences of acute otitis media (AOM) and often follows an episode of AOM. Transient hearing loss is frequently associated with OME. **Spontaneous resolution of OME occurs in 90 per cent of patients within three months of infection.**^{20,31}

On Going Care

When OME has been present for at least 12 weeks, observation is advised at 3 month intervals until the resolution of effusion. If there are concerns of 'significant' hearing loss or structural abnormalities of the tympanic membrane, a formal hearing evaluation and referral to an otolaryngologist is recommended.^{9,20,26,27,29,30}

Note: Decongestants, antihistamines, steroids, and antibiotics are NOT recommended in the treatment of OME.²⁰

Rationale for OME Recommendations

After an episode of AOM, fluid will be present in 50 per cent of patients after one month, in 25 per cent of patients after two months, and in 10 per cent of patients at three months.^{28,30,31} Pneumatic otoscopy can be a useful clinical skill to help detect the presence of fluid behind the tympanic membrane.¹ **OME does not require antibiotic treatment.**

While OME has been linked to hearing loss and impaired development in children, recent evidence indicates that persistent middle-ear effusion in otherwise normal children does not cause long term developmental impairments.^{8,10,30} Surgical treatment of chronic OME may prevent middle ear complications, including: atelectatic tympanic membrane, permanent conductive hearing loss, cholesteatoma, etc. If a child does become a candidate for surgery, tympanostomy tube insertion is the preferred initial procedure.⁷

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Resources:

For parents: <http://www.dobugsneeddrugs.org>

For physicians: <http://www.bugsanddrugs.ca>

Link to CPS for drug monographs: <http://www.e-therapeutics.ca>

Appendices

Appendix A- Prescription Medication Table for Acute Otitis Media

This guideline is based on scientific evidence current as of the Effective Date.

This guideline was developed by the Guidelines and Protocols Advisory Committee, approved by the British Columbia Medical Association and adopted by the Medical Services Commission.

A **PDA** version of this guideline is also available at www.Clinipearls.ca/BCGuidelines

The principles of the Guidelines and Protocols Advisory Committee are to:

- encourage appropriate responses to common medical situations
- recommend actions that are sufficient and efficient, neither excessive nor deficient
- permit exceptions when justified by clinical circumstances

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DISCLAIMER

The Clinical Practice Guidelines (the "Guidelines") have been developed by the Guidelines and Protocols Advisory Committee on behalf of the Medical Services Commission. The Guidelines are intended to give an understanding of a clinical problem, and outline one or more preferred approaches to the investigation and management of the problem. The Guidelines are not intended as a substitute for the advice or professional judgment of a health care professional, nor are they intended to be the only approach to the management of clinical problems.

Appendix A - Medication Table for Acute Otitis Media (AOM)

Drug	Pediatric Dose	Approx. Daily Dose (based on 10kg child~1yr)	Approx. cost (\$) per 10 day course* (based on 10kg child ~1yr) S = Suspension T= Tab	PharmaCare Coverage
Over-the-Counter Analgesics/Antipyretics				
<i>Acetaminophen (G)</i>	10-15mg/kg/dose PO Q4H prn (max 75mg/kg/day)	100-150mg PO Q4Hprn	Prices and formulations vary	No Coverage (over-the- counter)
<i>Ibuprofen(G)</i>	5-10mg/kg/dose PO Q6-8H prn (max 40mg/kg/day)	50-100mg PO Q6-8H prn	Prices and formulations vary	No Coverage (over-the- counter)
Opioid Analgesics				
<i>Codeine (G)</i> Δ Not approved for use in children ≤ 2yrs	0.5-1.5mg/kg/dose PO Q4-6H prn (max 90mg/dose)	<i>Not applicable</i>	Prices and formulations vary	Regular Benefit (F/P)
Antibiotics				
<i>Amoxicillin (G)</i>	40mg/kg/day div tid	135 mg tid	\$6 (S 125mg/5ml OR 250mg/5ml)	Regular Benefit (F/P), LCA
	90mg/kg/day div tid	300 mg tid	\$14 (S 125mg/5ml OR 250mg/5ml)	
<i>Amoxicillin/ Clavulanate (G)</i>	45mg**/ kg/day div tid	150 mg tid	\$14 (S 125mg/31.25mg/5ml) \$12 (S 250mg/62.5mg/5ml OR 400mg/57mg/5ml)	Regular Benefit (F/P), LCA
<i>Azithromycin (G)</i>	10mg/kg/day 1 then 5mg/kg/day on days 2-5	100 mg on day 1, then 50 mg on days 2-5	\$12 (S 100mg/5ml) \$9 (S 200mg/5ml)	Regular Benefit (F/P), LCA
<i>Cefprozil (G)</i>	30mg/kg/day div bid	150 mg bid	\$20 (S 125mg/5ml OR 250mg/5ml)	No Coverage
<i>Cefuroxime Axetil (G)</i>	30mg/kg/day div bid	150 mg bid	\$22 (S 125mg/5ml) \$13 (T 250mg)	Regular Benefit (F/P)†
<i>Clarithromycin (G)</i>	15mg/kg/day div bid	75 mg bid	\$18 (S 125mg/5ml OR 250mg/5ml)	Regular Benefit (F/P)†
Trimethoprim (TMP)/ Sufamethoxazole (G)	6-12mg TMP/kg/day div bid	30-60 mg bid	\$2 – \$3 (S 200mg/40mg/5ml)	Regular Benefit (F/P), LCA

* Pricing as of January 2009, **based on amoxicillin component, † not a benefit for all PharmaCare plans

Δ For **moderate to severe pain not relieved by over the counter analgesics**. Prescription required.

Nb: Please review product monographs and regularly review current listings of Health Canada advisories, warnings and recalls at:
http://www.hc-sc.gc.ca/ahc-asc/media/advisories-avis/index_e.html

G: Indicates that generics are available. See <http://www.health.gov.bc.ca/pharme/> for further information.

Regular benefit drugs: Do not require Special Authority. Patients may receive full (F) or partial coverage (P), since some of these drugs are included in the Low Cost Alternative (LCA) program or Reference Drug Program (RDP).

LCA: When multiple medications contain the same active ingredient (usually generic products), patients receive full coverage for the drug with the lowest average PharmaCare claimed price. The remaining products are partial benefits.

RDP: When a number of products contain different active ingredients but are in the same therapeutic class, patients receive full coverage for the drug that is medically effective and the most cost-effective. This drug is designated as the Reference Drug. The remaining products are partial benefits.

Limited coverage drugs: Require Special Authority. These drugs are not normally regarded as first-line therapies or there are drugs for which a more cost-effective alternative exists.

In all cases: Coverage is subject to drug price limits set by PharmaCare and to the patient's PharmaCare plan rules and deductibles.

Resource Documents

Canadian Pharmacists Association. Compendium of Pharmaceuticals and Specialties. Ottawa: Canadian Pharmacists Association; 2008 Canadian Pharmacists Association. Drug Prices: obtained from PharmaNet, for prescription medications, as of January 2009. Codeine dosing information from BC's Children's Hospital Paediatric Drug Dosage Guidelines 2002-2003.

Notes: A. If a medication has a generic equivalent; the drug cost is for the generic product.

B. For prescription medications, the price does not include professional fees.