Government of **Western Australia**
Department of **Health**

# Enhanced Access Community Pharmacy Pilot

## Acute otitis media

## Clinical practice guideline

**Service restricted to patients aged 2 years or over.**

Ineligibility for treatment as part of a prescribing service does not preclude a patient from accessing services provided as part of usual pharmacy care.

The information and content in this clinical practice guideline do not constitute medical advice, diagnosis, or treatment recommendations for individual patients. Pharmacists must exercise professional discretion and judgement consistent with their qualifications and legislative authority. This guideline does not override the responsibility of the pharmacist to undertake clinical assessments and to make decisions appropriate to the circumstances of the individual and the relevant standards of care, in consultation with the patient and/or their parent/caregiver. This clinical practice guideline may only be used by pharmacists who have been approved by the Department of Health to participate in the Enhanced Access Community Pharmacy Pilot (EACPP) and are authorised to prescribe under the *Medicines and Poisons Regulations 2016* (WA). This document alone does not provide an authorisation for a pharmacist to prescribe.

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- The patient is aged below 2 years (does not preclude a patient from accessing usual pharmacy care)
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- Severe symptoms or rapidly worsening symptoms
- Signs or symptoms of sepsis
- Tympanic membrane (TM) 'red flag' signs:
- crust/scab or granulation in attic region (discharge/odour may be present)
- severely retracted (sucked in) TM or retraction pocket in attic area of eardrum
- dull white mass behind TM or chalky patches
- perforation or retraction in attic region, near the edge of the TM, or medium to large in size (refer to Figure 1)
- Otoscopic examination is not possible or TM cannot be visualised (see Refer when section)
- TM perforation still evident after 6 weeks following initial consultation.

## Treat and concurrently refer

- Otic discharge/otorrhea present
- Children presenting with signs and symptoms of a complication or at a high risk of complications from acute otitis media (AOM) (refer to Table 1)
- Symptoms that do not improve or worsen after 48 hours of appropriate analgesia and supportive management
- Recurrent symptoms (≥ 3 episodes in 6 months or ≥ 4 episodes in 12 months)
- Persistent otitis media with effusion (glue ear).

## Key points

- Acute otitis media (AOM) is predominantly a childhood infection, however, it may also occur in adults[1]. The peak age prevalence is 6 to 18 months[2].
- AOM is commonly viral but may also be bacterial, or a combination of both[3].
- In the majority of paediatric cases, AOM is self-limiting and spontaneously resolves without the requirement for antibiotics[2,3].
- The mainstay of treatment for AOM is conservative management with regular and adequate analgesia. Antibiotics can be safely withheld in most cases and are often inappropriately prescribed[3].
- Pain alone is not sufficient to diagnose AOM. An otoscopy is required to diagnose and exclude other ear conditions with similar presentations[3].
- Ear conditions are often very painful, particularly for young children, and it is important to approach with care[4].
  If the patient will not allow for otoscopic examination due to pain, advice should be provided on appropriate analgesia and the patient referred to an appropriate healthcare provider.

## Refer when

Refer the patient to an appropriate healthcare provider (including emergency services, if required) in the following situations:

- the patient is aged below 2 years (does not preclude a patient from accessing usual pharmacy care)
- unclear diagnosis
- recent significant ear or head trauma (may be associated with hearing loss or balance issues)
- severe symptoms or rapidly worsening symptoms, including intense pain, headache, or facial paralysis/palsy, balance issues, confusion, focal neurological signs and red, swollen, and tender behind the ear
- signs or symptoms of sepsis (e.g. fever, hypothermia, respiratory distress, tachycardia, rash, hypotension, cold extremities), or other significant systemic symptoms including signs of dehydration, weakness, significant irritability, lethargy, paleness, loss of appetite
- tympanic membrane (TM) 'red flag' signs:
  - crust/scab or granulation in attic region (discharge/odour may be present)
  - severely retracted (sucked in) TM or retraction pocket in attic area of ear drum
  - dull white mass behind TM or chalky patches
  - perforation or retraction in attic region, near the edge of the TM, or medium to large in size (refer to Figure 1)
- otoscopic examination is not possible or TM cannot be visualised**
- TM perforation still evident after 6 weeks following initial consultation
- **If the TM cannot be visualised in a paediatric patient at first presentation and antibiotic therapy is not indicated, they can be advised on appropriate analgesia and asked to return within 48 to 72 hours for reassessment. They should be advised to seek care from an appropriate healthcare provider if their condition deteriorates.

## Treat (if clinically appropriate) and concurrently refer

Provide initial treatment and concurrently refer to an appropriate healthcare provider (including emergency services, if required) in the following situations:

- otic discharge/otorrhea present
- children presenting with signs and symptoms of a complication or at high risk of complications from AOM (refer to Table 1)
- symptoms that do not improve or worsen after 48 hours of appropriate analgesia and supportive management
- recurrent symptoms (≥ 3 episodes in 6 months or ≥ 4 episodes in 12 months)
- persistent otitis media with effusion (glue ear).

## Patient history and assessment

In both children and adults, diagnosis of AOM is based on clinical history and ear examination using an otoscope[1,3,4,5].

Children with AOM may present with ear pain and signs of systemic illness including fever, vomiting, diarrhoea, irritability, poor feeding, and ear discharge. Tugging, holding, or rubbing the ear may indicate ear pain in younger children[3].

In children, a diagnosis of AOM requires the rapid onset (within 48 hours) of[6]:

- pain
- signs of acute inflammation of the TM:
  - TM is bulging and opaque
  - TM may be red from inflammation or white from pus in the middle ear
- signs of middle ear effusion:
  - otorrhoea can be indicative of TM

perforation and middle ear effusion if acute otitis externa (AOE) has been excluded[2,3,4,6]

- otitis media with effusion is characterised by middle ear effusion without other signs and symptoms of AOM. When present for longer than 3 months, this is suggestive of persistent otitis media with effusion (glue ear)[3]
- otorrhea that has been present for ≥ 2 weeks and a perforation is suggestive of chronic suppurative otitis media (CSOM)[4].

- A red TM or pain alone is not diagnostic of AOM[3].
- In adults, unilateral symptoms are most common and include mild to severe ear pain and decreased hearing:
  - an upper respiratory tract infection (URTI) or allergic rhinitis will often precede the onset of AOM[1]
  - other symptoms in adults include dizziness/vertigo (infrequent), systemic symptoms (particularly fever), partial or complete opacification of the TM, or erythema[1]
  - in adults, the key signs of AOM are bulging and reduced mobility of the TM[1].

## Patient history

Obtain sufficient information from the patient to assess the safety and appropriateness of any recommendations and medicines.

The patient history should consider:

- age
- weight
- pregnancy and lactation status (if applicable)
- whether the patient identifies as Aboriginal and Torres Strait Islander
- nature, severity and frequency of symptoms including pain, itch, discharge, hearing loss, a feeling of fullness, and dizziness/vertigo
- onset and duration of symptoms including preceding illnesses
- history of head or ear trauma
- recent history of URTI
- other presenting symptoms including temperature ≥ 38 °C or ≤ 35.5 °C, rash, increased respiratory rate/distress, dehydration and/or reduced urine output, runny nose, sore throat, or cough
- precipitating and relieving factors
- delayed speech or language development
- frequency and method of ear cleaning
- family history of ear conditions and hearing loss
- previous history of AOM, AOE, or other ear conditions:
  - hearing loss and recent hearing tests
  - patient age at first episode of ear conditions
  - under the care of an ENT specialist or audiologist
  - ear surgery, current or previous tympanostomy tubes (grommets)
  - prior treatment for AOM, otitis externa, or other ear conditions – when and what treatment[4]
- underlying medical conditions, e.g. immunocompromised (including diabetes), cochlear implant, craniofacial abnormalities, persistent hearing loss that mean the patient is at high risk of experiencing AOM complications (refer to Table 1)
- social history including arrangements to support management at home, ability to access further care and to undertake appropriate self-care
- current and recently ceased treatments (including prescribed medicines, vitamins, herbs, other supplements, and over-the-counter medicines)
- medication and other strategies tried to treat current symptoms
- drug allergies/adverse drug reactions
- immunisation status as per the *Australian Immunisation Handbook*.

### Reminder

Pharmacists can access a range of clinical information in a patient's My Health Record, including details about current and past medication history, allergies, and current medical conditions.

## Examination

- Conduct assessment of vital signs.
- Examine for tender or enlarged cervical lymph nodes.
- Conduct visual examination and palpation of mastoid area.

## Ear examination using otoscopy

Physical examination including otoscopy of both ears is required to differentiate between AOE, AOM, and other ear conditions[1,3,5].

Ear examination should be conducted in accordance with the Queensland Health and Royal Flying Doctors Primary Clinical Care Manual[4]. An ear differential diagnosis flowchart is also included[4].

Before performing the ear examination, the ear canal must be gently cleaned to remove any discharge with a tissue rolled up to a point (dry mopping) to visualise the ear drum[4,7]. The Kimberley Clinical Guideline - Ear Problems in Children contain a guide for dry mopping[8].

The TM must be visualised to confirm a diagnosis of AOM, although this can be difficult in the presence of extensive otorrhoea[3]. TM presentations that suggest a serious complication require immediate referral to an appropriate healthcare provider, see Refer when.

- If the TM cannot be visualised in paediatric patients when they first present and antibiotics are not indicated, they should be advised on appropriate analgesia and asked to return within 48 to 72 hours for reassessment. They should seek care from an appropriate healthcare provider if their condition deteriorates[3]
- If the TM cannot be visualised in adult patients, they should be referred to an appropriate healthcare provider
- Perforation of the TM in children is common and may result in ear discharge and relief of pain[4]
- In AOM with perforation, the pharmacist should document the size and position of the perforation to allow ongoing assessment of progression of the condition and to guide use of therapies[9].

If pain levels allow, consider looking for movement of intact ear drum(s) by pneumatic otoscopy, tympanometry (if no discharge, Type A is normal), or gentle Valsalva (hold nose and blow):

- if the TM moves freely back and forward, perforation and fluid in the middle ear (AOM) can generally be excluded[4]
- reduced mobility of an intact TM is a good indication of the presence of middle ear fluid[9].

Check for other symptoms if required (nose, throat, cough)[4].

Figure 1. Guide for size of perforation of tympanic membrane[8]


NB: Further images can be found here: Hole in the Ear Drum Images | McGovern Medical School[10]

## Complications of AOM

Aboriginal and Torres Strait Islander children are generally at higher risk of complications from AOM. Complications in adults and non-Aboriginal and Torres Strait Islander children are less common[4,6].

Children at high risk of complications are outlined in Table 1.

**Table 1: Children at high risk of complications from AOM[4]**

- Aboriginal and Torres Strait Islander children
- Immunocompromised
- Cochlear implant
- Craniofacial abnormalities including cleft palate
- Developmental delay, Down syndrome
- Severe visual impairment
- Current hearing loss.

All children presenting with signs or symptoms of a complication, or at high risk of complications, must be referred (concurrent to commencement of antibiotic therapy where appropriate) to an appropriate healthcare provider for management.

In rare cases, AOM infection may spread from the middle ear (intracranial spread) causing mastoiditis, petrositis, or labyrinthitis[6]. Intracranial spread can cause meningitis or other intracranial complications that are slow to resolve, particularly in immunocompromised patients.

Signs of intracranial complications include severe headache, confusion, focal neurologic signs, facial paralysis/palsy, and dizziness/vertigo[6]. Patients with these signs or symptoms of a complication must be referred for immediate assessment, see Refer when.

# Develop management plan

**Pharmacists must ensure that they are prescribing medicines according to the specified sections of the current online version of the Therapeutic Guidelines.**

Pharmacist management of patients with AOM involves[NB1]:

- **non-pharmacological measures:**
  - care at home in accordance with The Royal Children's Hospital Melbourne Fact sheet: Ear infections and glue ear[11] and the Australian Medicines Handbook: Drugs for ear infections[12]
  - if discharge is present, advice and education regarding keeping ears dry and the use of dry mopping with tissue spears. Kimberley Clinical Guideline - Ear Problems in Children contains a guide for dry mopping[8]
- **pharmacotherapy:**
  - oral analgesia in accordance with the Therapeutic Guidelines: Pain and Analgesia (Pharmacological management of acute pain - Mild, acute nociceptive pain)[13]
  - oral antibiotic therapy[NB2-3] in accordance with the Therapeutic Guidelines: Antibiotic (Ear, nose and throat infections - Otitis media)[3]
  - consider immunisation where the patient has not received all routine vaccines in accordance with the Australian Immunisation Handbook[14].

**NB1:** There is limited evidence to guide the management of AOM in adult patients. The Therapeutic Guidelines states that management of AOM in adults is similar to management in children. Adequate and regular analgesia is the primary treatment[3]. As with paediatric patients, a shared decision-making approach is required to manage patient expectations of antibiotic treatment[3].

**NB2:** Antibiotic therapy in paediatric patients should only be commenced in accordance with the Therapeutic Guidelines and the Otitis Media Guidelines for Aboriginal and Torres Strait Islander Children for children:[3,4,9]

- with discharge/otorrhoea (from a small perforation which is not in the attic region or near the edge of the TM)
- presenting with signs and symptoms of a complication or at high risk of complications from AOM (see Table 1)
- with symptoms that have not improved or have worsened after 48 hours of appropriate analgesia and supportive management
- with recurrent symptoms (≥ 3 episodes in 6 months or ≥ 4 episodes in 12 months)
- with persistent otitis media with effusion (glue ear).

**NB3:** Antibiotic therapy may be commenced if there is uncertainty with access to follow-up[4].

# Confirm management is appropriate

Consult the *Therapeutic Guidelines, Australian Medicines Handbook* and other relevant resources to confirm that management is appropriate, including for:

- contraindications and precautions
- drug interactions
- pregnancy and lactation.

## Reminder

The prescribing and use of antibiotics should be consistent with the principles described in the Therapeutic Guidelines: Antibiotic. Pharmacists should carefully assess whether antibiotic therapy is clinically indicated, and if so, consider local antimicrobial resistance patterns and relevant clinical factors when selecting therapy.[NB1]

# Communicate agreed management plan

Comprehensive advice and counselling (including supporting written information when required) should be provided to the patient regarding:

- individual product and medicine use
- non-pharmacological measures
- how to manage adverse effects
- when to seek further care and/or treatment (including recognising patient deterioration)
- when to return for follow-up.

It is the pharmacist's responsibility to ensure the suitability and accuracy of any resources and information provided to patients (and/or parents/caregivers), and to ensure compliance with all copyright conditions.

The agreed management plan should be shared with members of the patient's multidisciplinary healthcare team, with the patient's consent.

## Patient resources

- The Royal Children's Hospital Melbourne Fact sheet: Ear infections and glue ear [11].
- Middle ear infection: should my child take antibiotics? | Australian Commission on Safety and Quality in Health Care

## General advice

AOM symptoms should start to improve within 48 to 72 hours after onset, regardless of whether antibiotic treatment is required. However, full resolution of symptoms may take up to 7 days (or longer for effusion)[3]:

- middle ear effusion that persists for several weeks after AOM is common and is not a sign of treatment failure[12]
- an acute perforation and discharge should resolve within 14 days[4].

Decongestants, antihistamines, or corticosteroids are not effective for AOM and should not be recommended[2,12].

Antibiotics have limited benefit in AOM and are not required for most patients[3]:

- the use of antibiotics can cause harm, including adverse effects, serious hypersensitivity reactions, and can contribute to bacterial resistance[3]
- pharmacists should address misconceptions regarding antibiotic effectiveness and discuss the relative harms and benefits of treatment[2].

Patients commenced on antibiotics who have been concurrently referred to an appropriate healthcare provider should be advised (and/or parents/caregivers) to seek further urgent care where:

- the response has been inadequate after 48 to 72 hours of antibiotic treatment
- signs or symptoms worsen or their condition deteriorates
- new signs or symptoms develop, including systemic symptoms
- otorrhea continues for ≥ 2 weeks[3,4].

Patients who have not been prescribed antibiotic therapy at the initial consultation should be advised (and/or parents/caregivers) to see an appropriate healthcare provider if:

- they develop otic discharge/otorrhoea
- their symptoms do not improve after 48 hours of appropriate analgesia and supportive management
- their signs or symptoms worsen, new signs or symptoms develop, or symptoms are recurrent, see Refer when[3].

For all patients, it is important to avoid local trauma to the ear canal, including not using cotton ear buds and dry mopping with a tissue spear instead[4].

Pharmacists should provide advice on the importance of preventing ear infections in children to avoid associated hearing loss, and poor language and social skills[9]. Preventative advice that can be provided includes:

- ensuring vaccinations against *S. pneumoniae, H. influenzae* type B, and influenza are up to date
- minimising exposure to smoke e.g. cigarettes and woodfires
- encouraging personal hygiene e.g. frequent hand and face washing and drying, nose blowing techniques[3,9,12,15].

Advise parents/caregivers of children under the age of 5 years to seek review by an appropriate healthcare provider if there is any concern regarding the child's speech, language, behaviour, or school progress[4,16]. Clinician Assist WA provides a list of services for Audiology requests[17].

## Clinical review

Clinical review with the pharmacist (or the patient's chosen healthcare provider) should occur in line with recommendations in the Therapeutic Guidelines.

- Patients with an intact TM should return for a follow up consultation at 3 months to check for persistent fluid behind the TM. If fluid is still present or the patient experiences a recurrence of AOM during this time, refer the patient to an appropriate healthcare provider[4].
- Patients with small acute perforations should return for a follow up consultation in 6 weeks to assess healing. If the perforation is still evident, refer the patient to an appropriate healthcare provider[4].

Decisions regarding the timing and necessity of clinical review should be individualised to the patient's clinical presentation and response to treatment.

Pharmacists should prescribe a quantity of medicine that aligns with the expected duration of therapy. Advise patients (and/or parents/caregivers) to see an appropriate healthcare provider if the condition does not improve or resolve (see Refer when and General advice).

## Pharmacist resources

- Western Australia:
  - Clinician Assist WA: Acute otitis media
- Therapeutic Guidelines:
  - Otitis media
  - Pharmacological management of acute pain
  - Mild, acute nociceptive pain
- Australian Medicines Handbook:
  - Otitis Media
  - Drug for ear infections
  - NSAIDs
  - Drugs for pain relief
- Australian Immunisation Handbook:
  - Pneumococcal disease
  - Influenza (flu)
  - Haemophilus influenzae type b (Hib)
- MSD Manual (Professional version): Otitis media (Acute)
- Remote Primary Health Care Manuals:
  - Clinical Procedures Manual
  - CARPA Standard Treatment Manual
- Queensland Health and Royal Flying Doctors Service (Queensland branch): Primary Clinical Care Manual 12th edition 2025
- The Royal Children's Hospital: Clinical Practice Guidelines – Acute otitis media
- 2020 Otitis Media Guidelines for Aboriginal and Torres Strait Islander Children
- McGovern Medical School: Ear disease photo book

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Produced by Clinical Excellence Division


CED-015081 AUG'26