



# Otitis media (acute): antimicrobial prescribing

NICE guideline

Published: 28 March 2018

[nice.org.uk/guidance/ng91](https://www.nice.org.uk/guidance/ng91)

## Your responsibility

The recommendations in this guideline represent the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them and their families and carers or guardian.

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people using services wish to use it. They should do so in the context of local and national priorities for funding and developing services, and in light of their duties to have due regard to the need to eliminate unlawful discrimination, to advance equality of opportunity and to reduce health inequalities. Nothing in this guideline should be interpreted in a way that would be inconsistent with complying with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

## Contents

Overview .....	4
Who is it for? .....	4
Recommendations .....	5
1.1 Managing acute otitis media .....	5
1.2 Self-care.....	7
1.3 Choice of antibiotic.....	8
Summary of the evidence.....	10
Self-care.....	10
Oral corticosteroids.....	11
No antibiotic.....	12
Back-up antibiotics.....	14
Choice of antibiotic .....	16
Antibiotic course length.....	18
Antibiotic dose frequency .....	19
Other considerations.....	21
Medicines adherence .....	21
Resource implications .....	21

## Overview

This guideline sets out an antimicrobial prescribing strategy for acute otitis media (ear infection). It aims to limit antibiotic use and reduce antimicrobial resistance. Acute otitis media can be caused by viruses or bacteria. It lasts for about a week, and most children get better in 3 days without antibiotics. Serious complications are rare.

See a [2-page visual summary of the recommendations](#), including tables to support prescribing decisions.

NICE has also produced a guideline on [antimicrobial stewardship: systems and processes for effective antimicrobial medicine use](#).

### *Who is it for?*

- Health professionals
- Children and young people with acute otitis media and their families and carers

## Recommendations

### 1.1 *Managing acute otitis media*

#### All children and young people with acute otitis media

##### 1.1.1 Be aware that:

- acute otitis media is a self-limiting infection that mainly affects children
- acute otitis media can be caused by viruses and bacteria, and it is difficult to distinguish between these (both are often present at the same time)
- symptoms last for about 3 days, but can last for up to 1 week
- most children and young people get better within 3 days without antibiotics
- complications such as mastoiditis are rare.

##### 1.1.2 Assess and manage children under 5 who present with fever as outlined in the NICE guideline on [fever in under 5s](#).

##### 1.1.3 Give advice about:

- the usual course of acute otitis media (about 3 days, can be up to 1 week)
- managing symptoms, including pain, with self-care (see the recommendations on [self-care](#)).

##### 1.1.4 Reassess at any time if symptoms worsen rapidly or significantly, taking account of:

- alternative diagnoses, such as otitis media with effusion (glue ear)
- any symptoms or signs suggesting a more serious illness or condition
- previous antibiotic use, which may lead to resistant organisms.

#### **Children and young people who may be less likely to benefit from antibiotics (those not covered by recommendations 1.1.8 to 1.1.11)**

##### 1.1.5 Consider no antibiotic prescription or a [back-up antibiotic prescription](#) (see

recommendation 1.3.1 for [choice of antibiotic](#)), taking account of:

- evidence that antibiotics make little difference to symptoms (no improvement in pain at 24 hours, and after that the number of children improving is similar to the number with adverse effects)
- evidence that antibiotics make little difference to the development of common complications (such as short-term hearing loss [measured by tympanometry], perforated eardrum or recurrent infection)
- evidence that acute complications such as mastoiditis are rare with or without antibiotics
- possible adverse effects of antibiotics, particularly diarrhoea and nausea.

1.1.6 When no antibiotic prescription is given, as well as the general advice in recommendation 1.1.3, give advice about:

- an antibiotic not being needed
- seeking medical help if symptoms worsen rapidly or significantly, do not start to improve after 3 days, or the child or young person becomes systemically very unwell.

1.1.7 When a back-up antibiotic prescription is given, as well as the general advice in recommendation 1.1.3, give advice about:

- an antibiotic not being needed immediately
- using the back-up prescription if symptoms do not start to improve within 3 days or if they worsen rapidly or significantly at any time
- seeking medical help if symptoms worsen rapidly or significantly, or the child or young person becomes systemically very unwell.

See the evidence and committee discussion on [no antibiotic](#) and [back-up antibiotics](#).

**Children and young people who may be more likely to benefit from antibiotics (those of any age with otorrhoea or those under 2 years with infection in both ears)**

1.1.8 Consider no antibiotic prescription with advice (see recommendation 1.1.6), a [back-up antibiotic prescription](#) with advice (see recommendation 1.1.7) or an

immediate antibiotic prescription (see recommendation 1.3.1 for [choice of antibiotic](#)), taking account of:

- evidence that acute complications such as mastoiditis are rare with or without antibiotics
- possible adverse effects of antibiotics, particularly diarrhoea and nausea.

1.1.9 When an immediate antibiotic prescription is given, as well as the general advice in recommendation 1.1.3, give advice about seeking medical help if symptoms worsen rapidly or significantly, or the child or young person becomes systemically very unwell.

See the evidence and committee discussion on [no antibiotic](#), [back-up antibiotics](#) and [choice of antibiotic](#).

### **Children and young people who are systemically very unwell, have symptoms and signs of a more serious illness or condition, or are at high-risk of complications**

1.1.10 Offer an immediate antibiotic prescription (see recommendation 1.3.1 for [choice of antibiotic](#)) with advice (see recommendation 1.1.9), or further appropriate investigation and management.

1.1.11 Refer children and young people to hospital if they have acute otitis media associated with:

- a severe systemic infection (see the NICE guideline on [sepsis](#))
- acute complications, including mastoiditis, meningitis, intracranial abscess, sinus thrombosis or facial nerve paralysis.

See the evidence and committee discussion on [choice of antibiotic](#).

## **1.2 Self-care**

### **All children and young people with acute otitis media**

1.2.1 Offer regular doses of paracetamol or ibuprofen for pain, using the right dose for the age or weight of the child at the right time, and maximum doses for severe pain.

- 1.2.2 Explain that evidence suggests decongestants or antihistamines do not help symptoms.

See the evidence and committee discussion on [self-care](#).

### 1.3 Choice of antibiotic

- 1.3.1 Follow table 1 when prescribing an antibiotic for children and young people with acute otitis media.

**Table 1 Antibiotics for children and young people under 18 years**

Antibiotic <sup>1</sup>	Dosage and course length <sup>2</sup>
<b>First choice</b>	
Amoxicillin	1 to 11 months, 125 mg three times a day for 5 to 7 days 1 to 4 years, 250 mg three times a day for 5 to 7 days 5 to 17 years, 500 mg three times a day for 5 to 7 days
<b>Alternative first choices for penicillin allergy or intolerance<sup>3</sup></b>	
Clarithromycin	1 month to 11 years: <ul style="list-style-type: none"> <li>• Under 8 kg, 7.5 mg/kg twice a day for 5 to 7 days</li> <li>• 8 to 11 kg, 62.5 mg twice a day for 5 to 7 days</li> <li>• 12 to 19 kg, 125 mg twice a day for 5 to 7 days</li> <li>• 20 to 29 kg, 187.5 mg twice a day for 5 to 7 days</li> <li>• 30 to 40 kg, 250 mg twice a day for 5 to 7 days</li> </ul> 12 to 17 years, 250 mg to 500 mg twice a day for 5 to 7 days
Erythromycin	1 month to 1 year, 125 mg four times a day or 250 mg twice a day for 5 to 7 days 2 to 7 years, 250 mg four times a day or 500 mg twice a day for 5 to 7 days 8 to 17 years, 250 mg to 500 mg four times a day or 500 mg to 1,000 mg twice a day for 5 to 7 days



Second choice (worsening symptoms on first choice taken for at least 2 to 3 days)	
Co-amoxiclav	<p>1 to 11 months, 0.25 ml/kg of 125/31 suspension three times a day for 5 to 7 days</p> <p>1 to 5 years, 5 ml of 125/31 suspension three times a day or 0.25 ml/kg of 125/31 suspension three times a day for 5 to 7 days</p> <p>6 to 11 years, 5 ml of 250/62 suspension three times a day or 0.15 ml/kg of 250/62 suspension three times a day for 5 to 7 days</p> <p>12 to 17 years, 250/125 mg or 500/125 mg three times a day for 5 to 7 days</p>
Alternative second choice for penicillin allergy or intolerance	
Consult local microbiologist	
<p><sup>1</sup> See <a href="#">BNF for children</a> for appropriate use and dosing in specific populations, for example, hepatic impairment and renal impairment.</p> <p><sup>2</sup> The age bands apply to children of average size and, in practice, the prescriber will use the age bands in conjunction with other factors such as the severity of the condition and the child's size in relation to the average size of children of the same age. Doses given are by mouth using immediate-release medicines, unless otherwise stated.</p> <p><sup>3</sup> Erythromycin is preferred in young women who are pregnant.</p>	

See the evidence and committee discussion on [choice of antibiotic](#) and [antibiotic course length](#).

## Summary of the evidence

The recommendations in this guideline are based on the evidence identified, which was for children and young people under 18 years.

### Self-care

#### Oral analgesia (paracetamol and ibuprofen)

- Paracetamol and ibuprofen were both more effective than placebo in reducing pain at 48 hours in children with acute otitis media (number needed to treat [NNT] 6 to 7 [range 4 to 27] for no pain at 48 hours; low to moderate quality evidence). This was based on a systematic review of randomised controlled trials (RCTs; [Sjoukes et al. 2016](#)). There were no significant differences in fever at 48 hours with paracetamol or ibuprofen compared with placebo (very low quality evidence).
- No significant differences were found between paracetamol and ibuprofen for pain or fever at various time points (very low to low quality evidence). Furthermore, using ibuprofen and paracetamol in combination was no more effective than paracetamol alone, although this was based on very small numbers of children (very low to low quality evidence; [Sjoukes et al. 2016](#)).
- Adverse events for paracetamol and ibuprofen were not significantly different from placebo (very low to low quality evidence). However, this should be interpreted cautiously because of the small number of children and the infrequent occurrence of adverse events ([Sjoukes et al. 2016](#)).

#### Topical analgesia (anaesthetic ear drops)

- Anaesthetic ear drops significantly increased the proportion of children with a 50% and a 25% reduction in pain compared with placebo (NNT 5 [range 3 to 16] for 50% pain reduction 10 minutes after receiving ear drops; low quality evidence). This was based on a systematic review and meta-analysis of RCTs ([Foxlee et al. 2011](#)). These children were aged 3 years and over without ear drum perforation and were also receiving oral analgesia, but no antibiotic.
- No adverse effects were observed with anaesthetic ear drops, but this was based on very small numbers of children (low quality evidence; [Foxlee et al. 2011](#)).

#### Decongestants and antihistamines

- Overall, decongestants and antihistamines, used alone or in combination, did not improve clinical outcomes in children with acute otitis media who were taking antibiotics (used in

- 14 out of 15 RCTs; very low to low quality evidence). This was based on a systematic review and meta-analysis of RCTs (Coleman et al. 2008). There was a reduction in the rate of persistent acute otitis media at 2 weeks with a combination of decongestant plus antihistamine compared with placebo (NNT 11 [range 6 to 104]; low quality evidence). However, a subgroup analysis of higher quality studies found no benefit with treatment.
- Adverse effects (excluding drowsiness and hyperactivity) were significantly increased with decongestants, but not with antihistamines or a combination of decongestant plus antihistamine, compared with placebo (very low quality evidence). However, there is considerable uncertainty about these results (Coleman et al. 2008).

#### Committee discussion on self-care

- The committee discussed the importance of managing a child's pain and felt that for parents this is the main priority. They agreed that paracetamol or ibuprofen needs to be taken at the right time and at the right dose, with maximum doses being used for severe pain.
- Based on evidence and their experience, the committee agreed that paracetamol or ibuprofen should be offered for pain associated with acute otitis media. Parents or carers could be advised to buy paracetamol or ibuprofen over the counter in line with local policies on the prescribing of such medicines.
- Based on evidence, the committee agreed that anaesthetic ear drops (in addition to oral analgesics) may relieve pain in children aged 3 years and over without eardrum perforation, but there is no product licensed for use in the UK.
- The committee agreed that evidence does not support using decongestants or antihistamines to help symptoms of acute otitis media.

### *Oral corticosteroids*

- Oral prednisolone taken for 5 days did not improve any clinical outcomes in children aged 3 months to 6 years with acute otitis media who were at risk of recurrence (at least 2 previous episodes of acute otitis media), compared with placebo (very low quality evidence). Outcomes included treatment failure during the first 2 weeks, duration of effusion and recurrence. This was based on a small RCT (Chonmaitree et al. 2003).
- Adverse effects or discontinuations because of adverse effects did not appear to be significantly different between prednisolone and placebo, although the study was very small and full data were not reported (low quality evidence; Chonmaitree et al. 2003).

- Systemic effects (mineralocorticoid and glucocorticoid) may occur with oral corticosteroids, including a range of psychological or behavioural effects (particularly in children; [Drug Safety Update, September 2010](#)).

#### Committee discussion on oral corticosteroids

- The committee agreed, based on the evidence, not to make a recommendation on the use of oral corticosteroids to manage acute otitis media in children.

## No antibiotic

- Acute otitis media is a self-limiting infection of the middle ear. It can be caused by viruses or bacteria, and both are often present at the same time. In most children acute otitis media resolves without treatment.
- The most common bacterial causes of acute otitis media are *Streptococcus pneumoniae*, *Haemophilus influenzae*, *Moraxella catarrhalis* and *Streptococcus pyogenes* (Canadian Paediatric Society's [position statement](#), 2016).
- More common complications of acute otitis media are recurrence of infection, hearing loss (which is usually temporary) and perforated eardrum. However, antibiotics make little difference to the rates of these (see [efficacy of antibiotics](#)).
- Acute complications of acute otitis media (such as mastoiditis, meningitis, intracranial abscess, sinus thrombosis and facial nerve paralysis) are rare. The incidence of mastoiditis after otitis media is 1.8 per 10,000 episodes after antibiotics compared with 3.8 per 10,000 episodes without antibiotics. This gives a NNT of 4,831 to prevent 1 child from developing mastoiditis ([Thompson et al. 2009](#)).

## Efficacy of antibiotics

- Antibiotics did not significantly reduce pain at 24 hours compared with placebo in children with acute otitis media; around 60% of children in both groups had no pain (high quality evidence). Antibiotics did significantly reduce pain at 2 to 3 days, but the absolute difference was small; 88% of children had no pain in the antibiotic group compared with 84% in the placebo group (NNT 24 [range 15 to 70]; moderate quality evidence). This was based on a systematic review and meta-analysis of RCTs ([Venekamp et al. 2015](#)).
- Antibiotics significantly reduced the number of children with abnormal tympanometry findings (a surrogate measure for hearing loss) compared with placebo at 2 to 4 weeks, but not at

- 6 to 8 weeks or 3 months. However, the absolute difference was small; at 2 to 4 weeks, 39% of children had abnormal tympanometry findings with antibiotics compared with 48% with placebo (NNT 12 [range 18 to 21]; low quality evidence; Venekamp et al. 2015).
- Antibiotics significantly reduced the number of children with eardrum perforation. However, again the absolute benefits were small with 5% of children having a perforation in the placebo group compared with 2% in the antibiotic group (NNT 33 [range 20 to 100]; moderate quality evidence; Venekamp et al. 2015).
- Antibiotics did not reduce the number of children with late recurrence of acute otitis media (which was common in both groups: 18% of children taking antibiotics compared with 20% of children taking placebo, moderate quality evidence; Venekamp et al. 2015).
- Antibiotics seem to be more beneficial in 2 pre-defined groups of children, based on subgroup analyses of intervention studies comparing antibiotics with placebo. Firstly, children under 2 years with bilateral acute otitis media, where the NNT was 4 for symptom resolution (low quality evidence). Secondly, children with acute otitis media and otorrhoea (discharge following eardrum perforation), where the NNT was 3 for symptom resolution (moderate quality evidence). This was based on a meta-analysis of individual patient data from RCTs ([Rovers et al. 2006](#)). However, the literature search was not designed specifically to identify prognostic evidence.
- No systematic reviews or RCTs of topical antibiotics were identified.

## Safety of antibiotics

- Allergic reactions to penicillins occur in 1 to 10% of people and anaphylactic reactions occur in less than 0.05%. People with a history of atopic allergy (for example, asthma, eczema and hay fever) have a higher risk of anaphylactic reactions to penicillins. People with a history of immediate hypersensitivity to penicillins may also react to cephalosporins and other beta-lactam antibiotics ([BNE](#), December 2017). See the NICE guideline on [drug allergy](#) for more information.
- Antibiotic-associated diarrhoea occurs in 2 to 25% of people taking antibiotics, depending on the antibiotic used ([NICE Clinical Knowledge Summary on diarrhoea – antibiotic associated](#)).
- Adverse events (vomiting, diarrhoea or rash) were significantly increased in children with acute otitis media taking antibiotics compared with those taking placebo (moderate quality evidence). The number needed to harm (NNH) was 13 (range 9 to 25). This was based on a systematic review and meta-analysis of RCTs ([Venekamp et al. 2015](#)).

- See the [summaries of product characteristics](#) for information on contraindications, cautions and adverse effects of individual medicines.

#### Committee discussion on no antibiotics

- Acute otitis media can be caused by viral or bacterial infections, both of which are usually self-limiting and do not routinely need antibiotics.
- Based on evidence, the committee agreed that antibiotics make little difference to ear pain or to the rates of more common complications, such as recurrence of infection. The small increased risk of perforation was noted, but 33 children (range 20 to 100) would need to be treated with antibiotics to avoid 1 child experiencing perforation. Antibiotics also made little difference to short-term hearing loss as assessed by the surrogate marker of tympanometry.
- More serious complications of acute otitis media, such as mastoiditis, are rare and the number needed to treat with antibiotics to prevent 1 child from developing mastoiditis is approximately 5,000.
- The committee acknowledged the recommendation in the NICE guideline on [respiratory tract infections \(self-limiting\): prescribing antibiotics](#) for no antibiotic or a [back-up antibiotic prescription](#) for most children with acute otitis media.

### *Back-up antibiotics*

- A [back-up antibiotic prescription](#) or watchful waiting was as effective as immediate antibiotics in children with acute otitis media for reducing pain at 3 to 7 days (moderate quality evidence). There were also no significant differences between groups for abnormal tympanometry findings (a surrogate measure for hearing loss), eardrum perforation or recurrence of infection (very low to moderate quality evidence). This was based on a systematic review and meta-analysis of RCTs ([Venekamp et al. 2015](#)).
- A back-up antibiotic prescription was compared with no antibiotics and immediate antibiotics in a systematic review of RCTs ([Spurling et al. 2013](#)). In 1 RCT there was no significant difference between back-up antibiotics and no antibiotics for pain or fever on day 3 (very low to low quality evidence). In 1 RCT there was no significant difference between back-up antibiotics and immediate antibiotics for pain on day 3 (moderate quality evidence).
- Immediate antibiotics were associated with a significantly increased risk of adverse events (vomiting, diarrhoea or rash) compared with back-up antibiotics or watchful waiting (NNH 8

- [range 5 to 19]; moderate quality evidence; Venekamp et al. 2015).
- The incidence of vomiting or rash was not significantly different with back-up antibiotics compared with immediate antibiotics (very low quality evidence), but there was significantly less diarrhoea with back-up antibiotics (NNH 8 [range 5 to 15]; data pooled by NICE; high quality evidence; Spurling et al. 2013). No safety data were available on back-up antibiotics compared with no antibiotics.

#### Committee discussion on back-up antibiotics

- Based on evidence, the committee agreed that no antibiotic prescription or a back-up antibiotic prescription could be considered for most children with acute otitis media.
- The committee discussed that acute otitis media could have a viral or a bacterial cause, and distinguishing between these is difficult. However, both are usually self-limiting and do not routinely need antibiotics. The committee discussed that a back-up antibiotic prescription may be preferred over no antibiotic in some children, but that prescribers need to weigh up the small clinical benefits from antibiotics against their potential to cause adverse effects.
- The committee agreed that a back-up antibiotic prescription could be used if symptoms significantly worsen or do not improve within 3 days (by which time most self-limiting infections would be starting to resolve), or if they worsen rapidly or significantly at any time.
- The committee acknowledged the recommendations in the NICE guideline on [respiratory tract infections \(self-limiting\): prescribing antibiotics](#) that, for acute otitis media, a no antibiotic prescribing strategy or a back-up antibiotic prescribing strategy should be agreed, but that depending on clinical assessment of severity, immediate antibiotics can also be considered for children under 2 years with infection in both ears or children of any age with otorrhoea (discharge following perforation of the eardrum). For these subgroups the committee agreed that an immediate antibiotic prescription could also be considered as an option, because antibiotics may be more likely to be beneficial in these subgroups. The committee discussed that an immediate antibiotic may be preferred over no antibiotic or a back-up antibiotic prescription in some children based on clinical judgement.
- The committee agreed that immediate antibiotics are important for children who are systemically very unwell, have symptoms or signs of a more serious illness, or are at high risk of serious complications because of pre-existing comorbidity. This includes children with significant heart, lung, renal, liver or neuromuscular disease, immunosuppression, cystic fibrosis, and young children who were born prematurely.

## *Choice of antibiotic*

- There were no major differences in treatment success between classes of antibiotics, including penicillins, cephalosporins and macrolides for treating uncomplicated acute otitis media in children. There was no difference in treatment success between ampicillin or amoxicillin compared with ceftriaxone; co-amoxiclav compared with ceftriaxone; co-amoxiclav compared with azithromycin; or cefaclor compared with azithromycin (low to moderate quality evidence). This was based on a systematic review and meta-analysis of RCTs ([Shekelle et al. 2010](#)).
- Co-amoxiclav was associated with significantly more adverse events than a cephalosporin (very low to moderate quality evidence) or azithromycin (moderate quality evidence; [Shekelle et al. 2010](#)).
- [Shekelle et al. \(2010\)](#) also considered evidence for treating recurrent or persistent acute otitis media in children. None of the studies found a significant benefit in treatment success for any particular antibiotic (moderate quality evidence). There were 5 individual RCTs that compared different antibiotic treatments: co-amoxiclav compared with gatifloxacin (2 RCTs), co-amoxiclav compared with levofloxacin (1 RCT), co-amoxiclav compared with azithromycin (1 RCT), and cefaclor compared with cefuroxime (1 RCT).



### Committee discussion on choice of antibiotic

- Based on evidence of no major differences in clinical effectiveness between classes of antibiotics, the committee agreed that the choice of antibiotic should largely be driven by minimising the risk of resistance.
- The committee discussed that, if an antibiotic is needed to treat an infection that is not life-threatening, a narrow-spectrum antibiotic should generally be first choice. Indiscriminate use of broad-spectrum antibiotics creates a selective advantage for bacteria resistant even to these 'last-line' broad-spectrum agents, and also kills normal commensal flora leaving people susceptible to antibiotic-resistant harmful bacteria such as *Clostridium difficile*. For infections that are not life-threatening, broad-spectrum antibiotics need to be reserved for second-choice treatment when narrow-spectrum antibiotics are ineffective.
- Based on evidence, their experience and resistance data, the committee agreed to recommend amoxicillin as the first choice because this is current practice for antibiotic treatment in children with acute otitis media, and the risk of resistance is acceptable. The dosage of 125 mg to 500 mg three times a day (based on age) is the usual dose, and was similar to that used in studies in the evidence review. The committee discussed that phenoxymethylpenicillin has a lower risk of resistance than amoxicillin, and microbiologically would be expected to be equivalent. However, medicines adherence is particularly important for children, and acute otitis media most commonly presents in young children. Amoxicillin has a three times a day dosage rather than four times a day for phenoxymethylpenicillin, and the liquid formulation is more palatable.
- Based on evidence, their experience and resistance data, the committee agreed to recommend clarithromycin or erythromycin as alternative first-choice antibiotics for use in penicillin allergy or amoxicillin intolerance. The doses recommended (based on weight and age) are the usual doses for children, and were similar to those used in studies in the evidence review. The committee discussed that there was evidence for another macrolide, azithromycin. However, they agreed not to recommend this because clarithromycin or erythromycin are current practice for antibiotic treatment for children with acute otitis media who have penicillin allergy or are intolerant to amoxicillin, and azithromycin should be reserved for more serious infections.
- Based on evidence, their experience and resistance data, the committee agreed to recommend co-amoxiclav as the second-choice antibiotic for use if symptoms worsen on a first-choice antibiotic taken for at least 2 to 3 days. This broad-spectrum treatment combines a penicillin (amoxicillin) with a beta-lactamase inhibitor, making it active against

- beta-lactamase-producing bacteria that are resistant to amoxicillin alone. People who do not respond to amoxicillin may be more likely to have an infection that is resistant to it. The dosage of 0.25 ml/kg of 125/31 suspension to 250/125 mg or 500/125 mg three times a day (based on weight and age) is the usual dose for children, and was similar to that used in studies in the evidence review.

### *Antibiotic course length*

- A short course of antibiotics (more than 48 hours but less than 7 days) was associated with significantly higher treatment failure at 8 to 19 days, or 1 month or less, compared with a long course (7 days or longer). Treatment failure (defined as a lack of clinical resolution, relapse or recurrence of acute otitis media within 1 month of starting treatment) occurred in 18.0% of the short-course group compared with 14.4% of the long-course group at 8 to 19 days (NNT 28 [range 17 to 77]; very low quality evidence), and in 20.5% of the short-course group compared with 17.5% of the long-course group at 1 month or less (NNT 34 [range 20 to 124]; low quality evidence). However, there was no difference in treatment failure between short and long courses at other time points. This was based on a systematic review and meta-analysis of RCTs (Kozyrskyj et al. 2010).
- There were significantly fewer gastrointestinal adverse events with a short course of antibiotics (more than 48 hours but less than 7 days) compared with a long course (7 days or longer; very low quality evidence). However, this result was based on the reported odds ratio and was not statistically significant when the relative risk was calculated (Kozyrskyj et al. 2010).

### Committee discussions on antibiotic course length

- The committee agreed that, when an antibiotic is appropriate, the shortest course that is likely to be effective should be prescribed to minimise the risk of antimicrobial resistance.
- Based on evidence, their experience and resistance data, the committee agreed that a 5- to 7-day course of all the recommended antibiotics was sufficient to treat acute otitis media in children. This takes into account both the evidence for clinical effectiveness and the evidence for safety and tolerability of antibiotics, and minimises the risk of resistance. Studies on the use of specific antibiotics to treat acute otitis media sometimes had longer course lengths than 7 days.
- The committee noted that no studies were identified that directly compared a 5-day course of antibiotics with a 7-day course.
- Based on evidence, the committee recognised that more children may have treatment failure with an antibiotic course of less than 7 days compared with a course of 7 days or more. However, the absolute difference is small. At 8 to 19 days, 82% of children taking antibiotics for less than 7 days were better, compared with 86% of those taking antibiotics for 7 days or more. They agreed that, if a decision to prescribe an antibiotic is made, a 5-day course may be sufficient for many children, reserving 7-day courses for those with a clinical assessment of more severe or recurrent infection.

### *Antibiotic dose frequency*

- Once or twice daily dosing of amoxicillin or co-amoxiclav was as effective as three times a day dosing for clinical cure rates at the end of antibiotic treatment (high quality evidence). The duration of treatment was 10 days in most studies, and the dose of amoxicillin or co-amoxiclav varied. There were no significant differences in the rates of recurrence (very low to low quality evidence), adverse effects (very low to low quality evidence) and adherence (high quality evidence). This was based on a systematic review and meta-analysis of RCTs ([Thanaviratananich et al. 2013](#)).

#### Committee discussions on antibiotic dose frequency

- The committee discussed the evidence for once or twice daily dosing of amoxicillin and co-amoxiclav, but it is unknown if this would have a detrimental effect on the risk of resistance to these antibiotics. The evidence supporting once or twice daily dosing is for different doses and longer treatment durations. This goes against the general principle of antimicrobial stewardship to prescribe the shortest course that is effective.
- The committee agreed that, when prescribing amoxicillin or co-amoxiclav, a dosing frequency of three times a day should be prescribed, as is current practice.

See the [full evidence review](#) for more information.

## Other considerations

### *Medicines adherence*

- Medicines adherence may be a problem for some people with medicines that require frequent dosing (for example, some antibiotics) or longer treatment duration (see the NICE guideline on [medicines adherence](#)).

### *Resource implications*

- Respiratory tract infections, including acute otitis media, are a common reason for consultations in primary care, and therefore are a common reason for potential antibiotic prescribing.
- There is potential for resource savings if no antibiotic or a [back-up antibiotic prescription](#) is used. There was significantly lower antibiotic use with back-up antibiotics compared with immediate antibiotics, both when the back-up antibiotic prescription was given at the time of consultation (38% compared with 87%; moderate quality evidence) and when the prescription had to be collected on a separate visit (24% compared with 87%; high quality evidence). There was no significant difference between groups in re-consultation rates (low quality evidence). This was based on a systematic review of RCTs ([Spurling et al. 2013](#)).
- Recommended antibiotics are all available as generic formulations, see the [Drug Tariff](#) for costs.

ISBN: 978-1-4731-2901-6

## *Accreditation*

