OTITIS MEDIA

CHI Formulary Indication Review

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Council of Health Insurance

INDICATION UPDATE

ADDENDUM- December 2023

To the CHI Original Otitis Media Clinical Guidance- Issued February 2020

Contents

Related Documents

Related SOPs

- IDF-FR-P-02-01-IndicationsReview&IDFUpdates
- IDF-FR-P-05-01-UpdatedIndicationReview&IDFUpdates

Related WI:

- IDF-FR-WI-01-01SearchMethodologyGuideForNewIndications

List of Tables

List of Figures

Abbreviations

AAFP	American Academy of Family Physician
AAP	American Academy of Pediatrics
AOM	Acute Otitis Media
CADTH	Canadian Agency for Drugs and Technologies in Health
CHI	Council of Health Insurance
CPG	Clinical Practice Guideline
CPS	Canadian Pediatric Society
CQ	Clinical Question
CSF	Cerebrospinal Fluid
CSOM	Chronic Suppurative Otitis Media
DS	Down Syndrome
EAC	External Auditory Canal
ENT	Ear Nose Throat
HAS	Haute Autorite de Sante
HTA	Health Technology Assessment
IAP	Indian Academy of Pediatrics
IDF	Insurance Drug Formulary
ME	Middle Ear
MEE	Middle Ear Effusion
NICE	National Institute for Health and Care Excellence
NSAID	Non-Steroidal Anti-Inflammatory Drug
NTHi	Non-Typeable *Haemophilus influenzae*
OM	Otitis Media
OME	Otitis Media with Effusion
PMDA	Pharmaceuticals and Medical Devices Agency
QOL	Quality of Life
rAOM	Recurrent Acute Otitis Media
RSV	Respiratory Syncytial Virus
SFDA	Saudi Food and Drug Authority
TM	Tympanic Membrane
TS	Tympanostomy Tube Insertion
TT	Tympanostomy Tube
TTO	Tympanostomy Tube Otorrhoea

Executive Summary

Otitis media (OM) is defined as an infection of the middle ear space. It is a spectrum of diseases that includes acute otitis media (AOM), chronic suppurative otitis media (CSOM), otitis media with effusion (OME), and adhesive OM[1, 2]. AOM is the second most common pediatric diagnosis in the emergency department, following upper respiratory infections. Although OM can occur at any age, it is most seen between the ages of 6 to 24 months[1].

Infection of the middle ear can be viral, bacterial, or coinfection. The most common bacterial organisms causing OM are *Streptococcus pneumoniae*, followed by non-typeable *Haemophilus influenzae* (NTHi) and *Moraxella catarrhalis*. Following the introduction of the conjugate pneumococcal vaccines, the pneumococcal organisms have evolved to non-vaccine serotypes. The most common viral pathogens of otitis media include the respiratory syncytial virus (RSV), coronaviruses, influenza viruses, adenoviruses, human metapneumovirus, and picornaviruses[1].

The following are proven risk factors for OM: prematurity and low birth weight, young age, early onset, family history, race (Native American, Inuit, Australian aborigine), altered immunity, craniofacial abnormalities, neuromuscular disease, allergy, day care, crowded living conditions, low socioeconomic status, tobacco and pollutant exposure, use of pacifier, prone sleeping position, fall or winter season, absence of breastfeeding, and prolonged bottle use[2].

OM is diagnosed clinically via objective findings on physical exam (otoscopy) combined with the patient's history and presenting signs and symptoms. Several diagnostic tools are available such as a pneumatic otoscope, tympanometry, and acoustic reflectometry, to aid in the diagnosis of otitis media. Pneumatic otoscopy is the most reliable and has a higher sensitivity and specificity as compared to plain otoscopy, though tympanometry and other modalities can facilitate diagnosis if pneumatic otoscopy is unavailable[1].

Although one of the best indicators for OM is otalgia, many children can present with non-specific signs and symptoms, which can make the diagnosis challenging. These symptoms include pulling or tugging at the ears, irritability, headache, disturbed or restless sleep, poor feeding, anorexia, vomiting, or diarrhea. Approximately two-thirds of the patients present with fever, which is typically low-grade[1].

Headache and fever are the most frequently observed early manifestations of complications associated with OM. Other manifestations are as follows[2]:

- Severe otalgia
- Vertigo
- Lethargy

- Nausea and vomiting
- Mental status changes
- Fetid otorrhea

Spread of infection from the ear and temporal bone causes intracranial complications of otitis media. Spread of infection occurs through 3 routes, namely, direct extension, thrombophlebitis, and hematogenous dissemination. Extracranial complications are usually direct sequelae of localized acute or chronic inflammation. The complications of otitis media include chronic suppurative otitis media, postauricular abscess, facial nerve paresis, labyrinthitis, labyrinthine fistula, mastoiditis, temporal abscess, petrositis, intracranial abscess, meningitis, otitic hydrocephalus, sigmoid sinus thrombosis, encephalocele, and cerebrospinal fluid (CSF) leak[2].

Once the diagnosis of AOM is established, the goal of treatment is to control pain and treat the infectious process with antibiotics. Non-steroidal anti-inflammatory drugs (NSAIDs) or acetaminophen can be used to achieve pain control. There are controversies about prescribing antibiotics in early OM, and the guidelines may vary by country, as discussed above. Watchful waiting is practiced in European countries with no reported increased incidence of complications. However, watchful waiting has not gained wide acceptance in the United States. If there is clinical evidence of suppurative AOM, however, oral antibiotics are indicated to treat this bacterial infection, and high-dose amoxicillin or a second-generation cephalosporin are first-line agents. If there is a TM perforation, treatment should proceed with ototopical antibiotics safe for middle-ear use, such as ofloxacin, rather than systemic antibiotics, as this delivers much higher concentrations of antibiotics without any systemic side effects[1].

Treatment of OM with antibiotics is controversial and directly related to the subtype of otitis media in question. Without proper treatment, suppurative fluid from the middle ear can extend to the adjacent anatomical locations and result in complications such as tympanic membrane (TM) perforation, mastoiditis, labyrinthitis, petrositis, meningitis, brain abscess, hearing loss, lateral and cavernous sinus thrombosis, and others. This has led to the development of specific guidelines for the treatment of OM. In the United States, the mainstay of treatment for an established diagnosis of AOM is high-dose amoxicillin, and this has been found to be most effective in children under two years of age. Treatment in countries like the Netherlands is initially watchful waiting, and if unresolved, antibiotics are warranted. However, the concept of watchful waiting has not gained full acceptance in the United States and other countries due to the risk of prolonged middle ear fluid and its effect on hearing and speech, as well as the risks of complications discussed earlier. Analgesics such as non-steroidal anti-inflammatory medications such as

ibuprofen can be used alone or in combination to achieve effective pain control in patients with otitis media[1].

The incidence for OM is usually high: on an annual basis, approximately 10% of the world's population will develop AOM. CSOM has a smaller incidence and will affect approximately 0.45% of the world's population. Children under 5 years old are the primary demographic for otitis media: 51% of the global incidence of AOM and 22.6% of the global incidence of CSOM are under 5 years old. People of Caucasian, African, and Greenlandic descent are most prone to otitis media. For children under 20 months old, males are more likely to develop otitis media due to differing rates of respiratory maturity. OM is most prevalent in developing countries, specifically Sub-Saharan West Africa, Southeast Asia, and Oceania. Risk factors that heighten otitis media presence in developing countries include greater cases of malnutrition, more exposure to HIV, higher chance of water contamination, and larger proportion of the populations being children under 5 years old. Fatal cases of otitis media are very rare, with the case fatality rate being approximately .003% of all otitis media cases[3].

Prevalence of OM in Riyadh reaches 10% in school children. Age less than 10 years, family size more than 5 members in the household, mother education less than secondary school education, living in rural area and in this population of children, otoscopy should be used as screening tools for OM[4].

CHI issued Otitis Media guidelines in February 2020. Updating clinical practice guidelines (CPGs) is a crucial process for maintaining the validity of recommendations. Below is a description of sections that need updates.

This report functions as an addendum to the prior CHI Otitis Media clinical guidance and seeks to offer guidance for the effective management of Otitis Media. It provides an **update on the Otitis Media Guidelines** for CHI Formulary with the ultimate objective of updating the IDF (CHI Drug Formulary) while addressing **the most updated best available clinical and economic evidence related to drug therapies.**

Main triggers for the update are summarized, being the **updated guidelines** added to the report such as **NICE** guidelines for antimicrobial prescribing in acute otitis media [**2022**], and the **new guidelines** added to the report such as clinical practice guidelines for the diagnosis and management of otitis media with effusion (OME) in children in **Japan** [**2015** and **2022**], the **Indian Academy of Pediatrics** standard treatment guidelines on AOM [**2022**], the **Italian Society of Pediatrics** updated guidelines for the management of AOM: diagnosis, prevention, treatment (**2019**), and the **Spanish Association of Pediatrics** update of the consensus document on the etiology, diagnosis and treatment of AOM and sinusitis (**2023**).

After carefully examining clinical guidelines and reviewing the SFDA drug list, there are new SFDA registered drugs to include in the CHI formulary Phenazone with

Lidocaine Hydrochloride while removing: CLAVULANIC ACID 62.5 mg, Powder for oral suspension as it is no longer registered on the SFDA Drug List of November 2023. There have been no changes or updates made to any of the previously listed drugs in terms of drug information and prescribing edits since February 2020.

All recommendations are well supported by reference guidelines, Grade of Recommendation (GoR), Level of Evidence (LoE) and Strength of Agreement (SoA) in all tables reflecting specific drug classes' role in the Otitis Media therapeutic management.

Below is a table summarizing the major changes based on the different Otitis Media guidelines used to issue this report:

Table 1. General Recommendations for the Management of Otitis Media

Management of Otitis Media		
General Recommendations	**Level of Evidence/Grade of Recommendation**	**Reference**
Recommend eardrops containing an anesthetic and an analgesic. Phenazone 40 mg/g with lidocaine 10 mg/g: Apply 4 drops two or three times a day for up to 7 days Use only if an immediate oral antibiotic prescription is not given, and there is no eardrum perforation or otorrhea.	Not graded	NICE Guidelines for acute Otitis Media (Antimicrobial prescribing) [2022]
Carbocysteine is recommended as a treatment option for OME	Grade of Recommendation: A	Clinical practice guidelines for the diagnosis and management of otitis media with effusion (OME) in children in Japan [2022]
Oral corticosteroids have short- but not long-term efficacy for the treatment of OME in children but are not recommended because the risks outweigh the benefits.	Recommendation Strength: Strong negative recommendation, Evidence quality: A	Clinical practice guidelines for the diagnosis and management of otitis media with effusion

		(OME) in children in Japan [2022]
On the other hand, inhaled nasal corticosteroids for the treatment of OME in children are associated with a low risk of adverse events and have recently been shown to be effective.	Recommendation Strength: Recommendation, Evidence quality: B	Clinical practice guidelines for the diagnosis and management of otitis media with effusion (OME) in children in Japan [2022]
Second-generation antihistamines for treating OME in children should be considered a treatment option in patients with allergic rhinitis. The efficacy of first-generation antihistamines for the treatment of OME in children has not been demonstrated, and they are thus not recommended because the risks outweigh the benefits.	Recommendation Strength: Recommendation, Evidence quality: B	Clinical practice guidelines for the diagnosis and management of otitis media with effusion (OME) in children in Japan [2022]
Adenoidectomy: If adenoid hyperplasia is present, adenoidectomy is effective in the treatment of OME. However, it is a more invasive procedure and should be performed with the following considerations in mind: In the absence of a clear indication for adenoidectomy in upper airway disease, it is not recommended as the initial surgery for OME in patients under 4 years of age.	Recommendation Strength: No recommendation), Evidence Quality: A	Clinical practice guidelines for the diagnosis and management of otitis media with effusion (OME) in children in Japan [2022]
Adenoidectomy combined with TS tube insertion is expected to reduce the recurrence rate of OME in patients above 4 years of age. The	Recommendation Strength: Strong recommendation, Evidence Quality: A	Clinical practice guidelines for the diagnosis and management of otitis media with effusion

combination of adenoidectomy and TS tube insertion may be considered.		(OME) in children in Japan [2022]
Tonsillectomy should not be performed for the treatment of OME in children.	Recommendation Strength: There is sufficient evidence of no benefit), Evidence Quality: A	Clinical practice guidelines for the diagnosis and management of otitis media with effusion (OME) in children in Japan [2022]
<u>Management of OME in patients with Down Syndrome (DS) or cleft palate:</u> TS tube insertion is one of the treatment options. TS tube insertion is recommended as early as possible to help with speech development. However, if the TS tube remains in place for a long period, ME pathologies can develop as sequelae, such as persistent TM perforation and adhesive otitis media after extubation.	Not graded	Clinical practice guidelines for the diagnosis and management of otitis media with effusion (OME) in children in Japan [2022]
The decision of starting with an antibiotic depends on the laterality, presence of risk factors, age of the child, and severity of illness.: → For children <6 months, antibiotic should be started immediately (even with presumed episode of AOM). → For children 6 months to 2 years, with confirmed unilateral or bilateral AOM of any severity should be started on antibiotics. → For children > 2 years, with confirmed AOM, severe disease (i.e.,	Not graded	Indian Academy of Pediatrics (IAP), STANDARD TREATMENT GUIDELINES [2022]

temperature > 39°C (102.2°F) in the past 48 hours, significant otalgia, or toxic appearance) should be immediately started with an antibiotic. → Consider deferring antibiotic therapy or "watchful waiting" for 2–3 days with close follow-up in children >2 years with non-severe otitis media (OM) or questionable diagnosis and in children 6 months to 2 years with questionable diagnosis and non-severe disease.		
The therapeutic management of AOM should prioritize the assessment and treatment of otalgia	(Strong positive recommendation)	Italian Society of Pediatrics guidelines for management of acute otitis media-Treatment [2022]
The mainstay treatment of otalgia should be the administration of adequate doses of ibuprofen or paracetamol.	(Strong positive recommendation)	Italian Society of Pediatrics guidelines for management of acute otitis media-Treatment [2022]
Watchful waiting should be assessed on a case-by-case basis and discussed with the parents; it should only be applied where follow-up is possible within 48–72 hours.	(Strong positive recommendation)	Italian Society of Pediatrics guidelines for management of acute otitis media-Treatment [2022]
A watchful-waiting approach can be applied to children >2 years old with mild or severe unilateral AOM or mild bilateral AOM.	(Not graded)	Italian Society of Pediatrics guidelines for management of acute otitis media-Treatment [2022]
For uncomplicated AOM with mild signs and symptoms in children without risk factors for bacterial resistance and with no history of	(Strong positive recommendation)	Italian Society of Pediatrics guidelines for management of

recurrence, amoxicillin at a dose of 80–90mg/kg/day is recommended (strong positive recommendation)		acute otitis media-Treatment [2022]
For AOM in children who have taken antibiotics in the last 30 days, who have severe symptoms and/or purulent conjunctivitis, who have a history of recurrent AOM not responsive to amoxicillin, who have otorrhea from a spontaneous perforation or who present a high risk of bacterial resistance (day care attendance, not vaccinated against pneumococcus, living in area with a high prevalence of resistant isolates), *amoxicillin-clavulanic acid* 80–90mg /kg/day (dose of amoxicillin) is recommended	(Strong positive recommendation)	Italian Society of Pediatrics guidelines for management of acute otitis media-Treatment [2022]
Macrolides (clarithromycin 15mg/kg/day) should only be used in children with a documented history of recent and/or severe allergy to penicillin. Class II or III cephalosporins are recommended in children with mild/moderate allergy to penicillin, since cross reaction between these molecules is rare	(Strong positive recommendation)	Italian Society of Pediatrics guidelines for management of acute otitis media-Treatment [2022]
PAIN RELIEF TO BE USED: Analgesia with paracetamol or ibuprofen at appropriate doses is the cornerstone of treatment of AOM.	Quality of evidence: I Strength of recommendation: A	Update of the consensus document on the etiology, diagnosis and treatment of acute otitis media and sinusitis [2023]

At the end of the report, a **key recommendation synthesis section** is added highlighting the latest updates in **Otitis Media clinical and therapeutic management.**

Section 1.0 Summary of Reviewed Clinical Guidelines & Evidence

This section is divided into two parts: the first includes recommendations from **updated versions of guidelines** mentioned in the previous CHI Otitis Media report, and the second includes **newly added guidelines** that have helped generate this report.

1.1 Revised Guidelines

This section contains the **updated versions** of the guidelines mentioned in the February 2020 CHI Otitis Media Report and the corresponding recommendations:

Table 2. Guidelines Requiring Revision

Guidelines Requiring Revision	
Old Versions	**Updated versions**
1.1 **NICE** Guidelines for Acute Otitis Media (Antimicrobial Prescribing) [**2019**]	1.1.1 **NICE** guidelines for Otitis media (acute): antimicrobial prescribing [**2022**][5]
1.2 American Academy of Pediatrics (**AAP**) and American Academy of Family Physicians (**AAFP**) Clinical Practice Guideline for The Diagnosis and Management of Acute Otitis Media [**2013**]	N/A*
1.3 **American Academy of Otolaryngology –** Head and Neck Surgery Foundation, the American Academy of Pediatrics (**AAP**), and the American Academy of Family Physicians (**AAFP**) Clinical Practice Guideline: Otitis Media with Effusion (Update) [**2016**]	N/A*
1.4 Canadian Paediatric Society (**CPS**) Infectious Diseases and Immunization Committee Position Statement on the	N/A*

Management of Acute Otitis Media in Children Six Months of Age and Older [**2016**]	

*****: *No updated versions available*

1.1.1 National Institute of Health and Care Excellence (NICE) Guideline for Otitis Media (Acute): Antimicrobial Prescribing (Published 2018, Updated 2022)

*Please refer to **Section 1.1** of CHI Otitis Media original clinical guidance.*

The 2022 revised edition of the NICE guidelines on antimicrobial prescribing in AOM sets out an antimicrobial prescribing strategy with the aim to limit antibiotic use and reduce antimicrobial resistance[5]. Recommendations were published ungraded.

For all children and young people with acute otitis media, consider eardrops containing an anesthetic and an analgesic for pain:

The following table should be followed when prescribing treatment for children and young people with acute otitis media.

Table 2. Treatment for Children and Young People Under 18 Years. Adapted from the NICE 2022 Guideline.

Treatment	Choice, dosage, and course length
Eardrops containing an anesthetic and an analgesic	Phenazone 40 mg/g with lidocaine 10 mg/g: Apply 4 drops two or three times a day for up to 7 days Use only if an immediate oral antibiotic prescription is not given, and there is no eardrum perforation or otorrhea
First-choice oral antibiotic	Amoxicillin: 1 month to 11 months, 125 mg three times a day for 5 to 7 days 1 year to 4 years, 250 mg three times a day for 5 to 7 days 5 years to 17 years, 500 mg three times a day for 5 to 7 days
Alternative first choice for penicillin allergy or intolerance (for people who are not pregnant)	Clarithromycin: 1 month to 11 years: under 8 kg, 7.5 mg/kg twice a day for 5 to 7 days 8 kg to 11 kg, 62.5 mg twice a day for 5 to 7 days 12 kg to 19 kg, 125 mg twice a day for 5 to 7 days 20 kg to 29 kg, 187.5 mg twice a day for 5 to 7 days 30 kg to 40 kg, 250 mg twice a day for 5 to 7 days

	12 years to 17 years, 250 mg to 500 mg twice a day for 5 to 7 days
Alternative first choice for penicillin allergy in pregnancy	Erythromycin: 8 years 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 Erythromycin is preferred if a macrolide is needed in pregnancy, for example, if there is true penicillin allergy and the benefits of antibiotic treatment outweigh the harms.
Second-choice oral antibiotic (worsening symptoms on first choice taken for at least 2 to 3 days)	Co-amoxiclav: 1 month to 11 months, 0.25 ml/kg of 125/31 suspension three times a day for 5 to 7 days 1 year 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 6 years 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 12 years to 17 years, 250/125 mg, or 500/125 mg three times a day for 5 to 7 days
Alternative second choice for penicillin allergy or intolerance	Consult local microbiologist

Children and young people who may be less likely to benefit from antibiotics, consider no antibiotic prescription, considering:

- Evidence that antibiotics make little difference to symptoms (no improvement in pain at 24 hours, and after that the number of children improving is like 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 diarrhea and nausea.

If an immediate oral antibiotic prescription is not given and there is no eardrum perforation or otorrhea, review treatment if symptoms do not improve within 7 days or worsen at any time.

1.2 Additional Guidelines

This part includes the added guidelines to the previous CHI Otitis Media report, along with their recommendations.

Table 3. List of Additional Guidelines

Additional Guidelines
Section 1.2.1 Clinical Practice Guidelines for the Diagnosis and Management of Otitis Media with Effusion (OME) in Children in **Japan** (**2022**)
Section 1.2.2 **Indian Academy of Pediatrics** (IAP) Standard Treatment Guidelines on Acute Otitis Media (**2022**)
Section 1.2.3 **Italian Society of Pediatrics** Updated Guidelines for the Management of Acute Otitis Media: Diagnosis, Prevention, Treatment (**2019**)
Section 1.2.4 **Spanish Association of Pediatrics** Update of the Consensus Document on the Etiology, Diagnosis and Treatment of Acute Otitis Media and Sinusitis (**2023**)

1.2.1 Clinical Practice Guidelines for the Diagnosis and Management of Otitis Media with Effusion (OME) in Children in Japan (2022)

This is an update of the 2015 Guidelines developed by the Japan Otological Society and Oto-Rhino-Laryngeal Society of Japan defining otitis media with effusion (OME) in children (younger than 12 years old) and describing the disease rate, diagnosis, and method of examination. Recommended therapies that received consensus from the guideline committee were updated in consideration of current therapies used in Japan and based on available evidence. Certain recommendations are unchanged from the 2015 guidelines[6], while others have been updated in the 2022 edition[7].

Table 4. Quality of Evidence and Strength of Recommendations (Japan 2015 Guidelines)

Level of Evidence	
Ia	Meta-analysis (with homogeneity) or randomized controlled trials
Ib	At least one randomized controlled trial.
IIa	At least one well-designed, controlled study but without randomization
IIb	At least one well-designed, non-experimental descriptive study
IV	Expert committee reports, opinions, and/or experience of respected authorities.

Strength of Recommendation	
A	Strongly recommended: strong evidence is available, benefits substantially outweigh harms
B	Recommended: sufficient evidence is available, benefits outweigh harms
C	No recommendation made: fair evidence is available, but the balance of benefits and harms is close
D	Recommended against: harms outweigh benefits
I	Insufficient evidence to determine the balance of benefits and harms

Table 5. Quality of Evidence and Strength of Recommendations (Japan 2022 Guidelines)

Evidence Quality	
A	Well-designed RCTs or diagnostic studies on relevant populations
B	RCTs or diagnostic studies with minor limitations; overwhelmingly consistent evidence from observational studies.)
C	Observational studies (case-control and cohort design
D	Expert opinions, case reports, reasoning from first principles
X	Exceptional situations in which validating studies cannot be performed and there is a clear preponderance of benefit over harm
Strength of recommendations	
Strong recommendation	A strong recommendation means the benefits of the recommended approach clearly exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation), and that the quality of the supporting evidence is excellent (grade A or B). In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to obtain (X) and the anticipated benefits strongly outweigh the harms.
Recommendation	A recommendation means the benefits exceed the harms (or that the harms clearly exceed the benefits in the case of a strong negative recommendation), but the quality of evidence is not as strong (grade B or C). In some clearly identified circumstances, strong recommendations may be made when high-quality evidence is impossible to

	obtain (X) and the anticipated benefits strongly outweigh the harms.
Option	An option means that either the quality of evidence that exists is suspect (grade D) or that well-done studies (A, B, or C) show little clear advantage to one approach over another
No recommendation	No recommendation means there is both a lack of pertinent evidence (grade D) and unclear balance between benefits and harms.

Monitoring of OME

- Watchful waiting for 3 months from the date of effusion onset or from the date of diagnosis is recommended for managing the child with OME who is not at risk, including pathological changes in the eardrum [Grade of Recommendation: A].
- The clinician has an option to continue close monitoring of OME patients beyond 3 months, specifically in cases without any pathological change (i.e., adhesion or retraction) in the eardrum [Grade of Recommendation: B].

Antibacterial agents for the treatment of OME

- In cases without bacterial infection of the surrounding organs, administration of antibacterial agents for OME in children is not recommended because the risks outweigh the benefits [Grade of Recommendation: D].
- Macrolide treatment (low-dose clarithromycin) is a therapeutic option in children with OME associated with rhinosinusitis [Grade of Recommendation: B].

Drug therapies other than antibacterial agents

- Carbocysteine is recommended as a treatment option [Grade of Recommendation: A].
- The efficacy of second-generation antihistamines and inhaled nasal steroids for the treatment of OME in children has not been proved, but these treatments should be considered as an option for patients with allergic rhinitis [Grade of Recommendation: I].
- Corticosteroids have short-term but not long-term efficacy for the treatment of OME in children and are not recommended because the risks outweigh the benefits. The efficacy of first-generation antihistamines for the treatment of

OME in children has not been demonstrated, and they are not recommended because the risks outweigh the benefits [Grade of Recommendation: D].

Corticosteroids

- Oral corticosteroids have short- but not long-term efficacy for the treatment of OME in children but are not recommended because the risks outweigh the benefits. [Recommendation Strength: Strong negative recommendation, Evidence quality: A]
- On the other hand, inhaled nasal corticosteroids are associated with a low risk of adverse events and have recently been shown to be effective. [Recommendation Strength: Recommendation, Evidence quality: B]

Antihistamines

- Second-generation antihistamines for treating OME in children should be considered a treatment option in patients with allergic rhinitis. The efficacy of first-generation antihistamines for the treatment of OME in children has not been demonstrated, and they are thus not recommended because the risks outweigh the benefits. [Recommendation Strength: Recommendation, Evidence quality: B]

Local treatment

- Although there is insufficient evidence as to whether local treatment of the paranasal sinus or ME inflation procedure on an outpatient basis at an ENT department is effective for treatment of OME in children, these treatments may be performed during the monitoring period prior to surgical treatment. [Recommendation Strength: Option, Evidence quality: C]

Autoinflation

- Autoinflation using a balloon more than 3 times a day is recommended as a treatment option. [Recommendation Strength: Recommendation, Evidence quality: B]

Myringotomy

- Myringotomy is recommended for the diagnosis and determination of treatment protocol for OME in children. It is effective for short-term prognosis, but it is not recommended for the purpose of long-term treatment. [Recommendation Strength: Option, Evidence quality: D]

Surgical indications for TS tube insertion

Clinicians should offer TS tube insertion for children with bilateral OME that has persisted for 3 months or more AND as follows:

- When pathological changes of the TM such as atelectasis and TM adhesion are observed. [Recommendation Strength: Strong Recommendation, Evidence Quality: B]
- When hearing difficulties with hearing loss (≥30 dB) of the ear on better-hearing side are documented. [Recommendation Strength: Recommendation, Evidence Quality: B]
- When clinical findings that may be caused by OME are revealed, such as impaired academic performance, problems in behavior, vestibular symptoms, hypoactivity, ear discomfort, and decrease in QOL. However, symptoms due to developmental disorders are excluded. [Recommendation Strength: Recommendation, Evidence Quality: B]

Management of tympanostomy tubes after surgery

- Early postoperative and routine follow-up (up to once every 4-6 months) is recommended to observe the postoperative condition of tympanostomy tubes and to evaluate hearing. Follow-up and evaluation of recurrence of OME and the necessity for additional treatment (including re-insertion) is required after a tympanostomy tube is extubated. [Recommendation Strength: Strong Recommendation, Evidence Quality: A]

Duration of tympanostomy tube insertion

- In cases of OME in children not at risk of becoming refractory, the standard duration of TS tube insertion should be about 2 years. Tube removal should also be considered in patients with otorrhea resistant to conservative treatment or with severe inflammatory changes (granulation) at the tube insertion site. [Recommendation Strength: Recommendation, Evidence Quality: C]

Effectiveness of adenoidectomy and tonsillectomy for OME

- If adenoid hyperplasia is present, adenoidectomy is effective in the treatment of OME. However, it is a more invasive procedure and should be performed with the following considerations in mind: In the absence of a clear indication for adenoidectomy in upper airway disease, it is not recommended as the initial surgery for OME in patients under 4 years of age. [Recommendation Strength: No recommendation), Evidence Quality: A]

- Adenoidectomy combined with TS tube insertion is expected to reduce the recurrence rate of OME in patients above 4 years of age. The combination of adenoidectomy and TS tube insertion may be considered. [Recommendation Strength: Strong recommendation, Evidence Quality: A]
- At the time of reoperation for recurrent cases of ventilation tube dislodgement after the initial surgery, adenoidectomy should be performed if the absence of cleft palate has been confirmed. [Recommendation Strength: Recommendation, Evidence Quality: B]
- Tonsillectomy should not be performed for the treatment of OME in children. [Recommendation Strength: There is sufficient evidence of no benefit), Evidence Quality: A]

Effectiveness of tympanostomy tube for unilateral OME

- Similar to the case of bilateral OME (3.CQ6), clinicians may consider TS tube insertion for children with unilateral OME complicated with pathological changes of the TM. Conversely, watchful waiting with monitoring of the bilateral hearing level is recommended in cases without such pathological changes. [Recommendation strength: Recommendation, Evidence Quality: C]
- Exceptions include children who are more susceptible to developing sequelae involving speech and language (at-risk children), and clinicians should offer more proactive management than for otherwise healthy children. Children suffering from unilateral OME should receive personalized medical care with monitoring of hearing on the contralateral side. [Recommendation strength: Recommendation, Evidence Quality: C]

Clinically assessment and management of children with OME complicated with adhesive otitis media

- Tympanoplasty can be recommended as an option for patients whose TM exhibits atrophy and adhesions, complicated with otorrhea and/or hearing loss, and cases progressing to cholesteatoma. [Recommendation strength: Recommendation, Evidence Quality: X]

Management of OME in patients with Down syndrome (DS)

- Babies with DS are strongly recommended to have a newborn hearing screening test to diagnose hearing impairment as early as possible.
- Early diagnosis and intervention are necessary. The main goal of the management of OME is to improve hearing acuity and associated language and speech development.

- TS tube insertion is one of the treatment options. TS tube insertion is recommended as early as possible to help with speech development. However, if the TS tube remains in place for a long period, ME pathologies can develop as sequelae, such as persistent TM perforation and adhesive otitis media after extubation.
- Regular follow-up is mandatory. The assessment of otoscopic findings, hearing acuity, and speech development should be done once every 3 or 4 months, with removal of earwax.

Guidelines for the management of OME in cleft palate

- Early diagnosis of hearing loss using newborn hearing screening tests.
- If the result of a newborn hearing screening test is 'refer', a detailed hearing test should be performed as soon as possible.
- Prior to palatoplasty at around 1 year of age, observation of the TM and auditory evaluation should be performed to determine the indication for TS tube insertion.
- Cleft palate may require long-term or multiple TS tube insertions. The risks of infection and permanent perforation of the TM are therefore increased. The use of hearing aids should also be considered in future studies.
- If the TM findings are abnormal, imaging studies should be performed, but attempts should be made to minimize radiation exposure.
- Long-term follow-up is necessary.

1.2.2 Indian Academy of Pediatrics (IAP) Standard Treatment Guidelines on Acute Otitis Media (2022)

Recommendations (ungraded) from the 2022 edition of the Indian Academy of Pediatrics (IAP) standard treatment guidelines on the management of AOM are summarized below[8].

Diagnosis

- Acute otitis media is diagnosed in symptomatic children who present with:
    - Moderate-to-severe bulging of the tympanic membrane or new-onset otorrhea not caused by acute otitis externa.
    - Mild bulging and either recent-onset ear pain (<48 hours) or intense erythema of the tympanic membrane.

- Diagnosis should not be made in children without middle ear effusion (MEE). Otoscopy should be used for the assessment of the tympanic membrane. Pneumatic otoscopy is up to 94% sensitive and 90% specific for identifying MEE.

Symptomatic therapy

- Symptomatic therapy with oral ibuprofen or paracetamol is used for ear pain.
- Decongestants and antihistamines have an unproven role in symptom relief.
- Topical anesthetic eardrops and naturopathic eardrops have been found to decrease pain in some small studies, but overall evidence is insufficient to recommend routine use. They should be avoided if there is any concern for perforated tympanic membrane.

Indications for antibiotics

- The decision of starting with an antibiotic depends on the laterality, presence of risk factors, age of the child, and severity of illness.:
    - For children < 6 months, antibiotic should be started immediately (even with presumed episode of AOM).
    - For children 6 months to 2 years, with confirmed unilateral or bilateral AOM of any severity should be started on antibiotics.
    - For children > 2 years, with confirmed AOM, severe disease (i.e., temperature >39°C (102.2°F) in the past 48 hours, significant otalgia, or toxic appearance) should be immediately started with an antibiotic.
- Consider deferring antibiotic therapy or "watchful waiting" for 2–3 days with close follow-up in children > 2 years with non-severe otitis media (OM) or questionable diagnosis and in children 6 months to 2 years with questionable diagnosis and non-severe disease.

The choice of initial antimicrobial therapy depends on its clinical and microbiological efficacy, acceptability of oral preparation, side effects, convenience of dosing schedule, and cost as shown in the figure below:

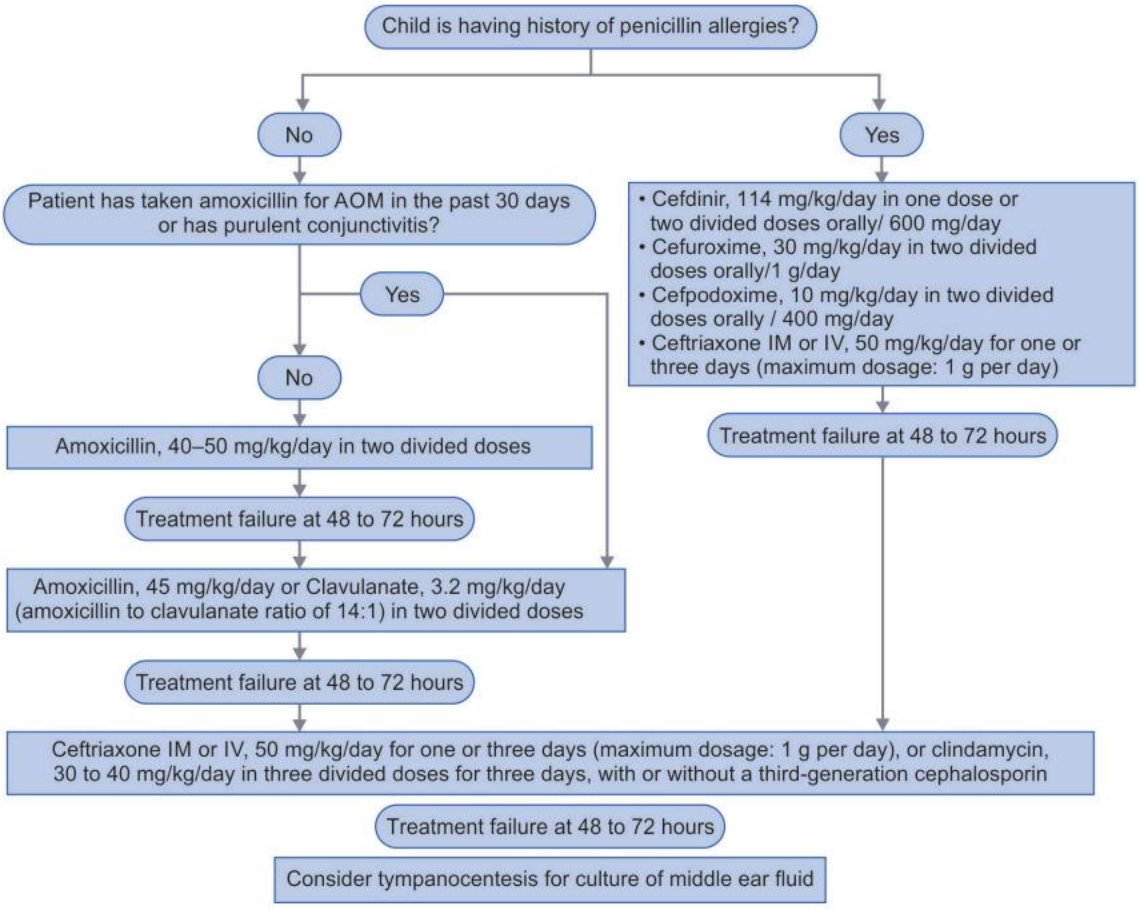

Figure 1. *Treatment algorithm for acute otitis media (AOM) management requiring antibiotics. Retrieved from the IAP 2022 guideline.*

Table 6 details drug regimens in case of severe reaction to beta-lactams including cephalosporins.

Table 6. Alternatives for Cases of Severe Reaction to Beta-Lactams Including Cephalosporins (Adapted from the IAP 2022 Guideline)

Drug	Dose	Max dose
Azithromycin	10 mg/kg once on day 1, then 5 mg/kg once a day from day 2 to 5, orally	500 mg on day 1, 250 mg on days 2–5
Clarithromycin	15 mg/kg/day in two doses	1 g/day
Clindamycin	20–30 mg/kg/day in three doses	1.8 g/day

For cases of persistent treatment failure, a referral to pediatric otolaryngologist and/or pediatric infectious disease expert is recommended.

Duration of treatment

- For amoxicillin, amoxicillin-clavulanate, oral cephalosporins, clarithromycin, and clindamycin:
    - Children < 2 years: 10 days
    - Children > 2 years: 5–7 days
- For ceftriaxone: one to three doses, depending on persistence of symptoms.
- For azithromycin: 5 days

Recurrent OM

Defined by development of signs and symptoms of AOM within 30 days of completion of successful treatment.

➔ **Approach:** Clinical evaluation, ENT referral, Investigation, Follow-up

Indications of tympanostomy tube insertion

For children with more than three episodes of AOM within 6 months or more than four episodes within 12 months with one episode in preceding 6 months.

1.2.3 Italian Society of Pediatrics Updated Guidelines for the Management of Acute Otitis Media: Diagnosis, Prevention, Treatment (2019)

In 2019, the Italian Society of Pediatrics issued three updated guidelines on the management of AOM, covering diagnosis[9], prevention[10], and treatment[11].

Table 7. Italian Society of Pediatrics' Grades of Recommendations

For the formulation of the recommendations, in agreement with the GRADE methodology, the following standard expressions were used as follows:	
Must be used	"Strong positive" recommendation
Could be used	"Weak positive" recommendation
Should not be used	"Weak positive" recommendation
Must not to be used	"Strong negative" recommendation

I. Diagnosis

Implementation of Medical Training on the Diagnosis of AOM by Means of Specific Programs?

- To improve and maintain adequate diagnostic skills, training programs are recommended; they should be conducted using appropriate tools, preferably otoscopy simulations and repeated at regular intervals—weak positive recommendation.

Criteria for a Correct Diagnosis of AOM

All the following elements must be present for a certain diagnosis:

- Acute (in the previous 48 hours) onset of symptoms associated with a middle ear inflammation (otalgia, touching of the ear, irritability, fever, disturbed sleep, and loss of appetite)
- Signs of inflammation, including intense hyperemia or yellow color of the tympanic membrane
- Presence of middle ear effusion, as indicated by bulging of the tympanic membrane or, in its absence, by greatly reduced/absence of mobility or by otorrhea, not secondary to external otitis, associated with a spontaneously perforated tympanic membrane must be considered in itself a certain objective sign of AOM.

AOM must only be diagnosed in the presence of a simultaneous finding of 1. acute onset of symptoms; 2. signs of inflammation of the tympanic membrane; and 3. presence of middle ear effusion. The sole presence of otorrhea, not secondary to external otitis, associated with a spontaneous perforation of the tympanic membrane should also be considered in itself a certain objective sign of AOM—strong positive recommendation.

Clinical Scoring System to Define the Severity of AOM

- The severity of the episode can be established on the basis of a clinical score. In any case, the presence and degree of signs and symptoms (such as fever, pain, irritability, TM hyperemia, bulging, mobility and otorrhea) should be assessed—weak positive recommendation.

Satisfactory Visibility of the Tympanic Membrane

- When performing diagnostic otoscopy, clear vision of the entire tympanic membrane is recommended, with the EAC free of cerumen and foreign bodies—strong positive recommendation.
- The removal of cerumen from the EAC can be performed by an appropriately trained pediatrician or by an ENT specialist with various operational and

organizational methods depending on the care setting, the level of the practitioner's expertise and the instruments available—weak positive recommendation.

Instruments that should Be Used to diagnose AOM

- To diagnose AOM, it is recommended to identify the presence of middle ear effusion. The recommended instrument is the pneumatic otoscope, fitted with an appropriate light source and a colorless speculum with a diameter suited to the anatomic characteristics of the child's EAC—strong positive recommendation.
- The description of the episode must include all the characteristics of the tympanic membrane (integrity, position, color, translucency, lighting and mobility) and indicate whether it is bilateral or unilateral—strong positive recommendation.
- In the absence of a pneumatic otoscope, pediatricians should make combined use of a static otoscope and a tympanometer, or, in the presence of diagnostic doubt, should reexamine the patient within 48 hours to define the diagnosis—weak positive recommendation.

II. Treatment

Pain Relief

- The therapeutic management of AOM should prioritize the assessment and treatment of otalgia (strong positive recommendation).
- The mainstay treatment of otalgia should be the administration of adequate doses of ibuprofen or paracetamol (strong positive recommendation).
- The topical administration of analgesic drops or the use of analgesic preparations based on natural extracts is not recommended, due to the lack of available high-quality evidence (weak negative recommendation).

Watchful-Waiting Strategy Be Used and Prompt Antibiotic Treatment to be Given

- Prompt antibiotic treatment is recommended for all children with otorrhea, intracranial complications and/or a history of recurrence and for children is recommended for all forms of unilateral and bilateral AOM, whether mild or severe. Prompt antibiotic treatment is also recommended for children > 2 years old with severe bilateral AOM.
- A watchful-waiting approach can be applied to children > 2 years old with mild or severe unilateral AOM or mild bilateral AOM.

- Watchful waiting should be assessed on a case-by-case basis and discussed with the parents; it should only be applied where follow-up is possible within 48–72 hours. (strong positive recommendation)

Drugs recommended for the Antibiotic Treatment of AOM?

- For uncomplicated AOM with mild signs and symptoms in children without risk factors for bacterial resistance and with no history of recurrence, amoxicillin at a dose of 80–90mg/kg/day is recommended (strong positive recommendation)
- For AOM in children who have taken antibiotics in the last 30 days, who have severe symptoms and/or purulent conjunctivitis, who have a history of recurrent AOM not responsive to amoxicillin, who have otorrhea from a spontaneous perforation or who present a high risk of bacterial resistance (day care attendance, not vaccinated against pneumococcus, living in area with a high prevalence of resistant isolates), *amoxicillin-clavulanic acid* 80–90mg /kg/day (dose of amoxicillin) is recommended (strong positive recommendation).
- *Macrolides* (clarithromycin 15mg/kg/day) should only be used in children with a documented history of recent and/or severe allergy to penicillin. Class II or III cephalosporins are recommended in children with mild/moderate allergy to penicillin, since cross reaction between these molecules is rare (strong positive recommendation)

Table 8. Recommended Antibiotic Treatment

Episode characteristics	Recommended treatment
Mild symptoms No otorrhea No recurrence No resistance factors*	Amoxicillin (80-90 mg/kg/day in 3 doses)
Severe symptoms of purulent conjunctivitis Otorrhea Recurrence	Amoxicillin/clavulanic acid (80-90 mg/kg/day in 3 doses) *Dose of amoxicillin*
*Risk factors for greater bacterial resistance: day care attendance, not vaccinated against pneumococcus, living in area with high prevalence of resistant isolates.	

Ideal Dose Fractioning for Treatment with Amoxicillin

- The division of amoxicillin or amoxicillin-clavulanic acid into 3 doses is recommended in all cases (weak positive recommendation)

The Optimal Duration of the Antibiotic Treatment

- The duration of treatment with amoxicillin or amoxicillin-clavulanic acid should be 10 days in children with risk factors for unfavorable evolution (<2 years old and/or with spontaneous otorrhea) (strong positive recommendation)
- The duration may be reduced to 5 days in children with no risk factors for unfavorable evolution (age >2 years, no otorrhea, unilateral disease and no severe signs or symptoms) (weak positive recommendation)

Treatment Failure definition and management

- The use of oral cephalosporins with a high activity against potentially resistant pathogens (cefpodoxime proxetil, cefuroxime axetil) or of intramuscular or intravenous ceftriaxone must be restricted to the management of treatment failure (weak positive recommendation).
- The use of quinolones following AOM treatment failure should be avoided (strong negative recommendation).

Treatments recommended in combination with antibiotic treatment

- The use of treatments other than pain relief in combination with antibiotic treatment is not recommended (strong negative recommendation)
- The use of systemic and topical decongestants and steroids should be avoided (strong negative recommendation).
- Removal of nasal secretions through nasal lavage is advisable as a complementary treatment (weak positive recommendation)

The role of Topical Antibiotic or Steroid Ear Treatments in AOM

- Ototopical antibiotic treatment, whether associated with steroid treatment, is not recommended except in subjects with tympanostomy tubes (strong negative recommendation)

III. Prevention

The role that Risk Factor Limitation Play in the Prevention of AOM

To reduce the risk of AOM, it is recommended:

1. to avoid exposure to passive smoking (strong positive recommendation)

2. to limit the use of pacifiers, especially after 6 months of age (weak positive recommendation)
3. to practice exclusive breastfeeding for at least 6 months (strong positive recommendation)
4. to restrict day-care attendance, especially in large groups and/or full-time attendance (weak positive recommendation)
5. to perform nasal irrigations and adopt suitable hygiene measures at home and in day-care centers (especially frequent hand washing) (weak positive recommendation)
6. to limit exposure to indoor and outdoor pollutants (weak positive recommendation)
7. to monitor BMI due to a possible association between obesity and risk of AOM (weak positive recommendation)

The Role of Influenza Vaccines the Prevention of AOM

- Influenza vaccination is recommended for the prevention of episodes of AOM (weak positive recommendation)

The Role of Antibacterial Vaccines Play in the Prevention of AOM

- It is recommended to perform pneumococcal vaccination to prevent the first episode of AOM (strong positive recommendation) and recurrences (weak positive recommendation)

The Role of Tympanostomy

- Grommets can be inserted in selected cases of recurrent AOM that did not respond to all other prevention strategies (weak positive recommendation).

The Role of Antibiotic Prophylaxis

- Antibiotic prophylaxis is not recommended for the prevention of recurrent AOM, except in certain carefully selected cases (weak negative recommendation)

The Role of Xylitol

- The use of xylitol, in any formulation, is not recommended for the prevention of AOM (weak negative recommendation)

The Role of Probiotic Administration

- The use of oral probiotics for the prevention of AOM is not recommended (weak negative recommendation). The use of topical probiotics for the prevention of AOM is not recommended on the basis of the limited evidence available (weak negative recommendation)

The Role of Vitamin D Supplementation

- The use of vitamin D for the prevention of AOM is not recommended on the basis of the limited evidence available (weak negative recommendation).

The Role of Other Complementary Therapies

- The use of complementary therapies for the prevention of AOM is not recommended on the basis of the limited evidence available (weak negative recommendation)

1.2.4 Spanish Association of Pediatrics Update of the Consensus Document on the Etiology, Diagnosis and Treatment of Acute Otitis Media and Sinusitis (2023)

The main recommendations published in 2023 by the Spanish Association of Pediatrics were published following the evidence grading detailed in table 9 and are summarized below[13].

Table 9. Evidence Grading Classification of the Infectious Disease Society of America and the US Public Health Service for Recommendations in Clinical Practice Guidelines

Strength of Recommendation	
A	Good evidence to support a recommendation for or against use
B	Moderate evidence to support a recommendation for or against use
C	Poor evidence to support a recommendation.
Quality of the Evidence	
I	Evidence from at least one properly randomized, controlled trial
II	Evidence from at least 1 well-designed clinical trial, without randomization; from cohort or case-controlled analytic studies (preferably from more than one centre); from multiple time-series; or from dramatic results from uncontrolled experiments
III	Evidence from opinions of respected authorities, based on clinical experience, descriptive studies, or reports of expert committees.

Diagnosis

- The diagnosis of AOM calls for more rigorous clinical criteria and should be based on the visualization of changes in the tympanic membrane. Quality of evidence: II. Strength of recommendation: A.
- The diagnostic criteria for confirmed AOM are as follows:
    - Otalgia with onset in the last 48 h. In preverbal children: rubbing or tugging ear, or less specific signs (Discomfort clearly attributable to the ear that interferes/precludes normal activity or sleep): irritability, difficulty sleeping, food refusal. With or without fever.
    - Signs of TM inflammation: intense erythema (Erythema of the TM is not considered diagnostic of AOM in isolation), yellow hue.
    - Signs of effusion in middle ear: TM bulging (The degree of bulging is not indicative of the severity of disease), otorrhea or absent/impaired mobility of TM.
- Avoid terms such as "uncertain" or "probable" diagnosis, and instead make a new assessment in 48 h whenever possible based on the characteristics of the patient. Quality of evidence: III. Strength of recommendation: C.
- Consider pneumatic otoscopy performed by an experienced examiner as a useful diagnostic test for assessment of exudate in the middle ear. Quality of evidence: II. Strength of recommendation: A.
- The routine diagnosis of sinusitis is clinical, and etiological diagnosis (performance of sinus puncture and aspiration) is only indicated in select cases. • Computed tomography is the imaging technique of choice for diagnosis of sinusitis complications, in addition to MRI in very select cases. Quality of evidence: II. Strength of recommendation: A.
- Ultrasound is promising in the case of maxillary sinusitis, although there is limited evidence of its use in paediatric patients. Quality of evidence: II. Strength of recommendation: C.

Treatment

- Analgesia with paracetamol or ibuprofen at appropriate doses is the cornerstone of treatment of AOM. Quality of evidence: I. Strength of recommendation: A.
- Myringotomy is not recommended for routine treatment of AOM. Quality of evidence: II. Strength of recommendation: B.
- Topical anesthetic drops should not be used routinely in the management of AOM. Quality of evidence: III. Strength of recommendation: C.

- Watchful waiting or delayed antibiotic prescribing, after educating caregivers appropriately, could be adequate strategies for the management of AOM in children aged more than 6 months if there are no risk factors. Quality of evidence: II. Strength of recommendation: A.
- The antibiotic agent of choice for AOM and sinusitis in children with moderate symptoms and no risk factors continues to be amoxicillin at 80–90 mg/kg/day given in 3 doses. Quality of evidence: II. Strength of recommendation: A.
- If there is evidence of severity, risk factors or suspicion of infection by H influenzae (age < 6 months, incomplete vaccination, association with purulent conjunctivitis, recurrence, antibiotherapy in the past 30 days): use amoxicillin-clavulanic acid at an 8:1 ratio (dosage: 80–90 mg amoxicillin/kg/day in 2 or 3 doses). Quality of evidence: II. Strength of recommendation: A.
- The duration of antibiotherapy should be individualized (especially in patients with an insidious course or at risk of complications), always considering the response to treatment. Quality of evidence: II. Strength of recommendation: A.
- The individualization of antibiotherapy is particularly important in patients allergic to amoxicillin and should be based in the results of culture whenever collection of a sample is indicated. Quality of evidence: II. Strength of recommendation: A.
- The presence or absence of IgE-mediated allergy to amoxicillin, the severity of the allergy and the clinical course should guide therapeutic decision-making. Quality of evidence: II. Strength of recommendation: A.
- The first step in the management of recurrent AOM should be the detection of predisposing factors, promoting protective factors, and avoiding risk behaviors. Quality of evidence: II. Strength of recommendation: A.
- The approach to the management of recurrent AOM should be individualized based on the characteristics of the patient: surgery in children aged less than 2 years in whom the disease is causing functional impairment in language or hearing and persistent OME (quality of evidence: I. Strength of recommendation: A) , antibiotic prophylaxis in children aged less than 2 years in whom the disease is causing functional impairment in language or hearing and with high surgical risk (Quality of evidence: I. Strength of recommendation: A) and watchful waiting in children aged more than 2 years. (Quality of evidence: II. Strength of recommendation: B).

Section 2.0 Drug Therapy in Otitis Media

This section comprises three subsections: the first contains the newly recommended drugs, the second covers drug modifications, and the third outlines the drugs that have been withdrawn from the market.

2.1 Additions

Since the publication of the previous CHI report in 2020, the drug combination of phenazone and lidocaine hydrochloride was registered by the SFDA for the management of OM.

2.1.1 Phenazone, Lidocaine Hydrochloride

This section includes pertinent information regarding the use of ***PHENAZONE, LIDOCAINE HYDROCHLORIDE*** in otitis media[14].

Table 10. Phenazone/Lidocaine Hydrochloride Drug Information

SCIENTIFIC NAME ***PHENAZONE, LIDOCAINE* HYDROCHLORIDE**	
SFDA Classification	Prescription
SFDA Approval	Yes
US FDA	Yes
EMA	Yes
MHRA	Yes
PMDA	No
Indication (ICD-10)	H65, H66
Drug Class	Otic Agent,
Drug Sub-class	Analgesic
ATC Code	S02DA30
Pharmacological Class (ASHP)	Analgesic
DRUG INFORMATION	
Dosage Form	Ear drops, solution
Route of Administration	Auricular use
Dose (Adult) [DDD]*	**Analgesia: Otic:** Instill 4 drops into affected ear 2 to 3 times daily for 7 to 10 days.
Maximum Daily Dose Adults*	4 drops two or three times daily

Dose (pediatrics)	**Analgesia:** Otic: Infants >6 months of age, Children, and Adolescents: Instill 4 drops into affected ear 2 to 3 times daily for 7 to 10 days.
Maximum Daily Dose Pediatrics*	4 drops two or three times daily
Adjustment	**Dosing: Altered Kidney Function: Adult** There are no dosage adjustments provided in the manufacturer's labeling. **Dosing: Hepatic Impairment: Adult** There are no dosage adjustments provided in the manufacturer's labeling.
Prescribing edits*	**ST**
AGE (Age Edit): N/A	
CU (Concurrent Use Edit): N/A	
G (Gender Edit): N/A	
MD (Physician Specialty Edit): N/A	
PA (Prior Authorization): N/A	
QL (Quantity Limit N/A	
ST (Step Therapy): Use only if an immediate oral antibiotic prescription is not given.	
EU (Emergency Use Only): N/A	
PE (Protocol Edit): N/A	
SAFETY	
Main Adverse Drug Reactions (Most common and most serious)	**Most common:** <1%: Local: Application-site reaction (auditory canal hyperemia), local hypersensitivity reaction, local irritation **Most serious:** *Methemoglobinemia:* Methemoglobinemia has been reported with local anesthetics; clinically significant methemoglobinemia requires immediate treatment along with discontinuation of the anesthetic and other oxidizing agents. Onset may be immediate or delayed (hours) after anesthetic exposure. Patients with

	glucose-6-phosphate dehydrogenase deficiency, congenital or idiopathic methemoglobinemia, cardiac or pulmonary compromise, exposure to oxidizing agents or their metabolites, or infants <6 months of age are more susceptible and should be closely monitored for signs and symptoms of methemoglobinemia (e.g., cyanosis, headache, rapid pulse, shortness of breath, lightheadedness, fatigue).
Drug Interactions	**Category C** • CAcetaminophen • CAminosalicylic Acid • CAmyl Nitrite • CBenzocaine • CCelecoxib • CChloroquine • CDapsone (Systemic) • CDapsone (Topical) • CFlutamide • CIsosorbide Dinitrate • CIsosorbide Mononitrate • CLidocaine (Systemic) • CLidocaine (Topical) • CMafenide • CMetoclopramide • CNicorandil • CNitric Oxide • CNitrofurantoin • CNitroglycerin • CNitroprusside • CPhenazopyridine • CPHENobarbital • CPhenytoin • CPrilocaine • CPrimaquine • CPropacetamol • CQuiNINE

	• CRasburicase • CSodium Nitrite • CSulfADIAZINE • CSulfamethoxazole • CSulfaSALAzine • CTetracaine (Topical) • CZopiclone
Special Population	N/A
Pregnancy	It is not known if antipyrine or lidocaine cross the placenta; however, when used in patients with an intact tympanic membrane at recommended doses, systemic absorption is unlikely.
Lactation	It is not known if antipyrine or lidocaine are present in breast milk; however, when used in patients with an intact tympanic membrane at recommended doses, systemic absorption is unlikely. Breastfeeding is not expected to result in significant exposure to a breastfed child.
Contraindications	Hypersensitivity to antipyrine, lidocaine, or any component of the formulation; infectious or traumatic perforation of the tympanic membrane (including presence of myringotomy).
Monitoring Requirements	N/A
Precautions	Appropriate use: Discontinue use and notify health care provider if ear pain worsens or persists for more than 10 days.
Black Box Warning	N/A
REMS	N/A

HEALTH TECHNOLOGY ASSESSMENT (HTA)

The table below lists the HTA reviews and recommendations of Otitis Media treatment options by the following agencies/institutes/authorities: National Institute for Health and Care Excellence (NICE), Canadian Agency for Drugs and Technologies in Health (CADTH), Haute Autorité de Santé (HAS), Institute for Quality and Efficiency

in Health Care (IQWIG), and Pharmaceutical Benefits Advisory Committee (PBAC) as applicable.

Table 11. Phenazone/Lidocaine Hydrochloride HTA Analysis

MEDICATION	AGENCY	DATE – HTA RECOMMENDATION
Phenazone: with Lidocaine Hydrochloride	NICE[15]	**March 11, 2022,** for all children and young people with acute otitis media: Consider eardrops containing an anesthetic and an analgesic for pain: *Phenazone:* 40 mg/g with lidocaine 10 mg/g: Apply 4 drops two or three times a day for up to 7 days Use only if an immediate oral antibiotic prescription is not given, and there is no eardrum perforation or otorrhea.
	CADTH	N/A
	HAS	N/A
	IQWIG	N/A
	PBS	N/A

Conclusion Statement – Phenazone with Lidocaine Hydrochloride

The use of phenazone + lidocaine hydrochloride is recommended by NICE for all children and young people less than 18 years of age with acute otitis media only if an immediate oral antibiotic prescription is not given, and there is no eardrum perforation or otorrhea[5].

2.2 Modifications

No modifications have been made since February 2020.

2.3 Delisting

The medications below are no longer SFDA registered[16], therefore, it is advisable to delist the following drugs from CHI formulary. *Please refer to* ***Drugs in the disease - section 2*** *of CHI Otitis Media original clinical guidance*

CLAVULANIC ACID 62.5 mg, Powder for oral suspension

Section 3.0 Key Recommendations Synthesis

Prevention

Vaccination

- Influenza vaccination is recommended for the prevention of episodes of AOM (weak positive recommendation)[17]
- It is recommended to perform pneumococcal vaccination to prevent the first episode of AOM (strong positive recommendation) and recurrences (weak positive recommendation)[17]

Hand washing and drying

- Children should wash and dry their hands after blowing their noses or coughing (into elbow). STRONG recommendation[17]
- Children's faces and hands should be kept clean for nasal discharge. STRONG recommendation[17]
- Discourage smoking: Strongly discourage people from smoking around children. STRONG recommendation[17]
- Zink Supplementation: Zinc supplementation does not prevent otitis media. Do not use. STRONG recommendation[17]

Treatment

- For all children and young people with acute otitis media, consider eardrops containing an anesthetic and an analgesic for pain Eardrops containing an anesthetic and analgesic (in addition to oral analgesics) may reduce antibiotic consumption and relieve pain in children who did not need immediate antibiotics[5].
- Eardrops containing anesthetic and analgesic should not be used in children with eardrum perforation or otorrhea. The rare adverse effect of methemoglobinemia (associated with topical anesthetics in very young children) was discussed and it was noted that the age of the children varied in the studies (from 1 year), but that there is no age-based restriction for using the licensed preparation (phenazone with lidocaine eardrops)[5].

Drug therapies other than antibacterial agents effective for the treatment of otitis media with effusion

- Carbocysteine is recommended as a treatment option [Grade of Recommendation: A].[7]

- Oral corticosteroids have short- but not long-term efficacy for the treatment of OME in children but are not recommended because the risks outweigh the benefits. [Recommendation Strength: Strong negative recommendation, Evidence quality: A][7]
- On the other hand, inhaled nasal corticosteroids are associated with a low risk of adverse events and have recently been shown to be effective. [Recommendation Strength: Recommendation, Evidence quality: B][7]
- Second-generation antihistamines for treating OME in children should be considered a treatment option in patients with allergic rhinitis. The efficacy of first-generation antihistamines for the treatment of OME in children has not been demonstrated, and they are thus not recommended because the risks outweigh the benefits. [Recommendation Strength: Recommendation, Evidence quality: B][7]

Watchful waiting strategy

- Watchful waiting should be assessed on a case-by-case basis and discussed with the parents; it should only be applied where follow-up is possible within 48–72 hours. (strong positive recommendation)[18]

Duration of Antibiotic Treatment

- Recommendation 11 The duration of treatment with amoxicillin or amoxicillin-clavulanic acid should be 10 days in children with risk factors for unfavorable evolution (<2 years old and/or with spontaneous otorrhea) (strong positive recommendation)[18].

Pain relief

- The therapeutic management of AOM should prioritize the assessment and treatment of otalgia (strong positive recommendation). [18]
- The mainstay treatment of otalgia should be the administration of adequate doses of ibuprofen or paracetamol (strong positive recommendation).[18]

Surgical Management

Myringotomy is recommended for the diagnosis and determination of treatment protocol for OME in children. It is effective for short-term prognosis, but it is not recommended for the purpose of long-term treatment. [Recommendation Strength: Option, Evidence quality: D][7]

Adenoidectomy combined with TS tube insertion is expected to reduce the recurrence rate of OME in patients above 4 years of age. The combination of adenoidectomy and TS tube insertion may be considered. [Recommendation Strength: Strong recommendation, Evidence Quality: A][7]

Tympanostomy tube effective for unilateral OME:

- Similar to the case of bilateral OME (3.CQ6), clinicians may consider TS tube insertion for children with unilateral OME complicated with pathological changes of the TM. Conversely, watchful waiting with monitoring of the bilateral hearing level is recommended in cases without such pathological changes. [Recommendation strength: Recommendation, Evidence Quality: C][7].

  Exceptions include children who are more susceptible to developing sequelae involving speech and language (at-risk children), and clinicians should offer more proactive management than for otherwise healthy children. Children suffering from unilateral OME should receive personalized medical care with monitoring of hearing on the contralateral side. [Recommendation strength: Recommendation, Evidence Quality: C][7].

- Tympanostomy tubes management after surgery: Early postoperative and routine follow-up (up to once every 4-6 months) is recommended to observe the postoperative condition of tympanostomy tubes and to evaluate hearing. Follow-up and evaluation of recurrence of OME and the necessity for additional treatment (including re-insertion) is required after a tympanostomy tube is extubated. [Recommendation Strength: Strong Recommendation, Evidence Quality: A][7].
- Tonsillectomy should not be performed for the treatment of OME in children. [Recommendation Strength: There is sufficient evidence of no benefit), Evidence Quality: A][7].

Section 4.0 Conclusion

This report serves as **an annex to the previous CHI Otitis Media report** and aims to provide recommendations to aid in the management of Otitis Media. It is important to note that these recommendations should be utilized to support clinical decision-making and not replace it in the management of individual patients with Otitis Media. Health professionals are expected to consider this guidance alongside the specific needs, preferences, and values of their patients when exercising their judgment.

Section 5.0 References

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Section 6.0 Appendices

Appendix A. Prescribing Edits Definition

I. Prescribing Edits (ensure consistent use of abbreviations, e.g., CU, ST)

Some covered drugs may have additional requirements, rules, or limits on coverage. These requirements and limits may include:

Prescribing edits Tools	Description
AGE (Age):	Coverage may depend on patient age
CU (Concurrent Use):	Coverage may depend upon concurrent use of another drug
G (Gender):	Coverage may depend on patient gender
MD (Physician Specialty):	Coverage may depend on prescribing physician's specialty or board certification
PA (Prior Authorization):	Requires specific physician request process
QL (Quantity Limits):	Coverage may be limited to specific quantities per prescription and/or time period
ST (Step Therapy):	Coverage may depend on previous use of another drug
EU (Emergency Use only):	This drug status on Formulary is only for emergency use
PE (Protocol Edit):	Use of drug is dependent on protocol combination, doses, and sequence of therapy

Appendix B. Otitis Media Scope

Section	Rationale/updates
Section 1.1 Nice guidelines for Otitis media (acute): antimicrobial prescribing **[2019]**	**Section 1.1.1** Nice guidelines for Otitis media (acute): antimicrobial prescribing **[2022]**[5] March 2022: - Added a new recommendation on eardrops containing an anesthetic and an analgesic (recommendation 1.1.5) because a licensed preparation is now available in the UK. - Moved recommendations on non-antimicrobial treatments earlier in the guideline. Recommendations are marked [2022]. - Made minor wording changes to reflect updated advice on the use of macrolides in pregnancy. *Minor changes since publication May 2021*: - Clarified that children and young people who are at high risk of serious illness should be offered an immediate antibiotic.
Section 1.2 American Academy of Pediatrics (AAP) and American Academy of Family Physicians CLINICAL PRACTICE GUIDELINE for The Diagnosis and Management of Acute Otitis Media **[2013]**	**N/A**
Section 1.3 Otolaryngology	**N/A**

Head and Neck Surgery Foundation, the American Academy of Pediatrics, and the American Academy of Family Physicians Clinical Practice Guideline: Otitis Media with Effusion (Update) **[2016]**	
Section 1.4 Canadian Paediatric Society, Infectious Diseases, and Immunization Committee Management of acute otitis media in children six months of age and older **[2016]**	**N/A**
N/A	**Section 1.2.1.** Clinical practice guidelines for the diagnosis and management of otitis media with effusion (OME) in children in Japan, ***2015***[6] Clinical practice guidelines for the diagnosis and management of otitis media with effusion (OME) in children in Japan – ***2022*** update[7] • Supplemental figures have been added to introductory remarks regarding the pathology, diagnosis, and medical treatment of otitis media with effusion (OME) in children. • In the Introduction (1.4.: representing Chapter 1- Section 4), international OME guidelines were

	reviewed in Section 1.5). • Terminology related to the topic has been added in the section defining OME in children (1.18). • Regarding the method for evaluating the quality of evidence and strength of recommendations, the committee referred to a proposal described in the Medical Information Network Distribution Service Japan (MINDS) Handbook for Clinical Practice Guideline Development 2014 and 2020 and the method recommended by the American Academy of Pediatrics (AAP). Again, the method recommended by the AAP was applied to evaluate recommendations, with reference to methods recommended in the MINDS Handbook and Guidelines of Recommendations Assessment, Development, and Evaluation (GRADE). • **In the 2015 JOS Guidelines, adenoidectomy was not recommended as an initial procedure for treating OME in children in the absence of clear indications regarding upper airway lesions. The committee revised recommendations on this issue according to recent meta-analyses and categorized the recommendations for patients under or above 4 years of age. In the latter group, adenoidectomy combined with tympanostomy (TS) tube insertion is expected to reduce the recurrence rate of OME. Therefore, the combination of adenoidectomy and TS tube insertion may be considered (3.CQ9).** • In the 2015 JOS OME Guidelines (Clinical Question [CQ]-9), myringotomy alone was not recommended for the treatment of OME in children. Based on recent evidence, however, the recommendation was revised as follows (3.CQ5): • **Myringotomy is recommended for the diagnosis and determination of treatment protocol for OME in children. It is effective for short-term prognosis, but it is not recommended for the purpose of long-term treatment.** • **In terms of indications for TS tube insertion attributed to hearing difficulties, children with moderate or severe hearing loss (≥40 dB) and those with hearing loss of 25-39 dB were graded with recommendations A and B, respectively. Conversely, the present guidelines have simplified and updated the recommendation for patients presenting with hearing difficulties, and hearing loss (≥30 dB) in the ear on the better-hearing side is documented (3.CQ6).** • **The committee added a new CQ focusing on unilateral OME, titled "Is the tympanostomy tube effective for unilateral OME?" (3.CQ10). Moreover, the Supplemental CQ titled "How do I take**

	care of children with complicated adhesive otitis media?" was also added. • In Chapter 4, which focuses on the management of OME in children with Down syndrome (DS) or cleft palate, commentary was updated with reference to recent evidence, and the practical guidelines were clarified. • Supplemental notes referring to prospects for improving diagnostic techniques have been added in the final Chapter 5.
N/A	**Section 1.2.2**. Indian Academy of Pediatrics (IAP), STANDARD TREATMENT GUIDELINES ***2022***, Acute Otitis Media[20] Recommendations for: Diagnosis, Symptomatic therapy, Indications of Antibiotics, Initial Anti-microbial therapy, Duration of therapy, Recurrent Acute Otitis Media.
N/A	**Section 1.2.3.** Italian updated guidelines for the management of acute otitis media Diagnosis[21], Prevention[17], Treatment[18] **Implementation of Medical Training on the Diagnosis of AOM by Means of Specific Programs** • To improve and maintain adequate diagnostic skills, training programs are recommended; they should be conducted using appropriate tools, preferably otoscopy simulations and repeated at regular intervals—weak positive recommendation. **Instruments Used to Diagnose AOM?** • To diagnose AOM, it is recommended to identify the presence of middle ear effusion. The recommended instrument is the pneumatic otoscope, fitted with an appropriate light source and a colorless speculum with a diameter suited to the anatomic characteristics of the child's EAC—strong positive recommendation. **Pain Relief Used** • The therapeutic management of AOM should prioritize the assessment and treatment of otalgia (strong positive recommendation). • The mainstay treatment of otalgia should be the administration of adequate doses of ibuprofen or paracetamol (strong positive recommendation). • The topical administration of analgesic drops or the use of analgesic preparations based on natural extracts is not recommended, due to the lack of available high-quality evidence (weak negative

	recommendation). **Watchful-Waiting Strategy to be used. Prompt Antibiotic Treatment to be given.** • Prompt antibiotic treatment is recommended for all children with otorrhea, intracranial complications and/or a history of recurrence and for children is recommended for all forms of unilateral and bilateral AOM, whether mild or severe. Prompt antibiotic treatment is also recommended for children >2 years old with severe bilateral AOM. Recommendation 5 A watchful-waiting approach can be applied to children >2 years old with mild or severe unilateral AOM or mild bilateral AOM. **Drugs Recommended for the Antibiotic Treatment of AOM** • For uncomplicated AOM with mild signs and symptoms in children without risk factors for bacterial resistance and with no history of recurrence, amoxicillin at a dose of 80–90mg/kg/day is recommended (strong positive recommendation) • For AOM in children who have taken antibiotics in the last 30 days, who have severe symptoms and/or purulent conjunctivitis, who have a history of recurrent AOM not responsive to amoxicillin, who have otorrhea from a spontaneous perforation or who present a high risk of bacterial resistance (day care attendance, not vaccinated against pneumococcus, living in area with a high prevalence of resistant isolates), amoxicillin-clavulanic acid 80–90mg /kg/day (dose of amoxicillin) is recommended (strong positive recommendation). • Macrolides (clarithromycin 15mg/kg/day) should only be used in children with a documented history of recent and/or severe allergy to penicillin. Class II or III cephalosporins are recommended in children with mild/moderate allergy to penicillin, since cross reaction between these molecules is rare (strong positive recommendation) **Role of Influenza Vaccines played in the Prevention of AOM** • Influenza vaccination is recommended for the prevention of episodes of AOM (weak positive recommendation) **Role of Antibacterial Vaccines played in the Prevention of AOM?** • Perform pneumococcal vaccination to prevent the first episode of AOM (strong positive recommendation) and recurrences (weak positive recommendation)

	Role of Tympanostomy? • Grommets can be inserted in selected cases of recurrent AOM that did not respond to all other prevention strategies (weak positive recommendation).
N/A	**Section 1.2.4** Update of the consensus document on the etiology, diagnosis and treatment of acute otitis media and sinusitis ***2023***[13] • The diagnosis of AOM is still clinical, although more stringent criteria are proposed, which are based on the visualization of abnormalities in the tympanic membrane and the findings of pneumatic otoscopy performed by trained clinician. • Analgesia with acetaminophen or ibuprofen is the cornerstone of AOM management; watchful waiting or delayed antibiotic prescription may be suitable strategies in select patients. • The first-line antibiotic drug in children with AOM and sinusitis and moderate to severe disease is still high-dose amoxicillin, or amoxicillin-clavulanic acid in select cases. Short-course regimens lasting 5-7 days are recommended for patients with uncomplicated disease, no risk factors, and a mild presentation. • In allergic patients, the selection of the antibiotic agent must be individualized based on severity and whether the allergy is IgE-mediated. In recurrent AOM, the choice between watchful waiting, antibiotic prophylaxis or surgery must be individualized based on the clinical characteristics of the patient.

Appendix C. MeSH Terms PubMed

C.1 PubMed Search for Otitis Media:

Query	Filters	Search Details	Results
(((Otitis Media [MeSH Terms]) AND (Otitis Media [Title/Abstract])) OR (Middle Ear Inflammation [Title/Abstract])) OR (Middle Ear Inflammation [Title/Abstract])	Guideline, in the last 5 years	(("otitis media"[MeSH Terms] AND "otitis media"[Title/Abstract]) OR "middle ear inflammation"[Title/Abstract] OR "middle ear inflammation"[Title/Abstract]) AND ((y_5[Filter]) AND (guideline [Filter]))	7

Appendix D. Treatment Algorithm

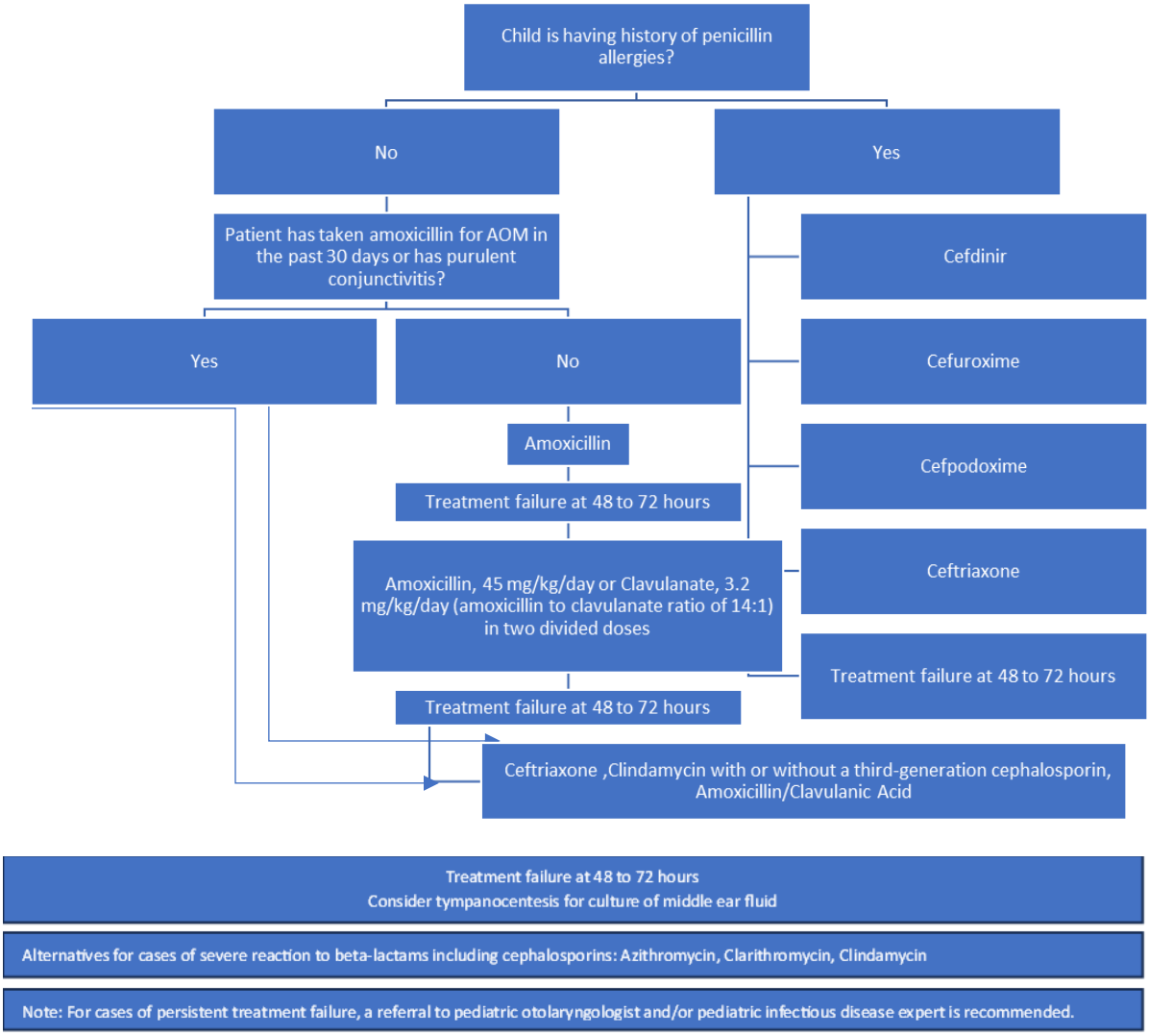

Figure 2. *Algorithm for acute otitis media (AOM) management requiring antibiotics.*