
North Dakota Medicaid Pharmacy Program Quarterly News

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Welcome to the “North Dakota Medicaid Pharmacy Program Quarterly News,” a pharmacy newsletter presented by the North Dakota Department of Human Services and published by Health Information Designs, LLC. This newsletter is published as part of a continuing effort to keep the Medicaid provider community informed of important changes in the North Dakota Medicaid Pharmacy Program.

The North Dakota Department of Human Services has contracted with Health Information Designs, LLC (HID) to review and process prior authorizations (PAs) for medications. For a current list of medications requiring a PA, as well as the necessary forms and criteria, visit www.hidndmedicaid.com, or call HID at (866) 773-0695 to have this information faxed. An important feature on this website is the NDC Drug Lookup. This allows you to determine if a specific NDC is covered (effective date), reimbursement amount, MAC pricing, copay information, and any limitations (prior authorization or quantity limits).

This newsletter provides a quick overview of acute otitis media and current treatment guidelines.

The North Dakota Medicaid Pharmacy Program team appreciates your comments and suggestions regarding this newsletter. To suggest topics for inclusion, or to make comments, please contact Health Information Designs, LLC at (334) 502-3262, call toll free at 1-800-225-6998, or e-mail us at info@hidinc.com.



Helpful Numbers

PA Help Desk	866-773-0695
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To report adverse reactions	800-FDA-1088

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A Quick Overview of Acute Otitis Media and the Current Treatment Guidelines

An inflammation of the middle ear space known as **Otitis media (OM)** is typically caused by an infection by bacteria (3 most common: *S. pneumonia*, *H. influenza*, *M. catarrhalis*) or viruses that travel from the nose, sinuses and throat area up the eustachian tube into the middle ear. Bacterial or viral infected OM is typically referred as Acute Otitis Media (AOM).

OM is the 15th most common reason for an office visit in the United States. It accounts for more than 15 million emergency room and clinic visits annually. It is common in infants and children, 75% of whom will have at least 1 episode in the first 12 months of life. More than 80% of patients seen for AOM receive a prescription, as it remains the most common condition for antibacterial agents for children in the United States. The direct and indirect costs associated with managing it add up to almost \$3 billion annually.

Previous guidelines by the American Academy of Pediatrics (AAP) in 2004 defined the diagnostic criteria for Uncomplicated AOM as meeting the 3 clinical signs:

- Acute onset
- Middle ear inflammation
- Middle ear effusion (MEE) (also known as bulging of the tympanic membrane)

The 2004 AAP guidelines and updates would state that if it did not meet all 3 criteria, then the diagnosis is classified as uncertain. The new 2013 guideline has more stringently addressed this issue by saying that the MEE is a requirement for the diagnosis of AOM, and without MEE, it cannot be diagnosed as AOM.

There is no gold standard for the diagnosis of AOM because it has a spectrum of signs as the disease develops. Diagnosis is essentially **based on signs, symptoms, history, and exam** including a pneumatic otoscope to look into the ear.

Risk Factors for developing AOM include modifiable and non modifiable traits as defined below:	
Non-Modifiable	Modifiable
<ul style="list-style-type: none"> ● Genetics, Family history ● Male ● Siblings ● Low economic status ● Native American 	<ul style="list-style-type: none"> ● Tobacco smoke ● Supine bottle feeding ● Not breastfeeding within the first 6 months of life ● Pacifier use in the second 6 months of life
Risk factors for Drug Resistant <i>S. pneumonia</i> Acute Otitis Media infection	
<ul style="list-style-type: none"> ● Attendance at child care centers ● Antibiotic treatment within the last 30 days ● Younger than 2 years old 	
Typical symptoms of AOM(unilaterally or bilaterally) can include:	
<ul style="list-style-type: none"> ● Ear pain (otalgia) ● Irritability or excessive crying ● Ear discharge (otorrhea), which can be a sign of draining ear tubes or a burst ear drum ● Rubbing or tugging at the ears 	<ul style="list-style-type: none"> ● Lethargy ● Decreased appetite ● Runny nose and cough ● Vomiting ● Fever

Treatment goals: include pain management, a decision to initiate antibiotics, and preventative care measures. The Pain management options as addressed in the guidelines are summarized below.

Treatment options	Comment
Acetaminophen, Ibuprofen	Mainstay of pain management for AOM and fever symptoms. Effective analgesia for mild to moderate pain.
Home remedies <ul style="list-style-type: none"> ● Distraction ● External application of heat or cold ● Oil drops in external auditory canal 	There are no controlled studies that directly address effectiveness of these treatments but they may provide limited benefit with minimal risks.
Narcotic analgesia with codeine or analogs.	Effective for moderate or severe pain, but these require a prescription and have a higher risk of Respiratory depression, Altered mental status, Gastrointestinal tract upset, and Constipation.
Tympanostomy	Requires skilled clinician and entails a potential risk

The following charts detail the current guideline recommendations in terms of antibiotic management. **Recommendations for Initial Management for Uncomplicated AOM (with certain diagnosis)**

Age	Otorrhea <u>with</u> AOM	Unilateral or Bilateral AOM <u>with</u> "Severe symptoms"	Bilateral AOM <u>without</u> Otorrhea	Unilateral AOM <u>without</u> Otorrhea
6 mo -2 yrs	Antibiotic therapy recommended	Antibiotic therapy recommended	Antibiotic therapy	Antibiotic therapy OR "additional observation"
2 yr and greater			Antibiotic therapy OR "additional observation"	
<p>"Severe symptoms": a toxic-appearing child, persistent otalgia more than 48 hr, temperature 39°C (102.2°F) in the past 48 h, or if there is uncertain access to follow up after the visit.</p> <p>"Additional Observation": a strategy in initial management that provides an opportunity for shared decision-making with the child's family for those categories appropriate for additional observation. If observation is offered, a mechanism must be in place to ensure follow up and begin antibiotics if the child worsens or fails to improve within 48 to 72 h of AOM onset. Many AOM infections may resolve on their own without antibiotics.</p>				

Recommendation for antibiotics for (initial or Delayed) treatment includes:

First-Line Treatment	Alternative Treatment (If Penicillin Allergy)
High dose Amoxicillin (80-90 mg/kg/ day in 2 divided doses)	Cefdinir (14mg/kg/day in 1 or 2 doses)
Or Amoxicillin-Clavulanate (90 mg/kg/day of amoxicillin, with 6.4 mg/kg/day (14:1 ratio) in 2 divided doses) if the patient had received amoxicillin within the previous 30 days or has otitis-conjunctivitis syndrome.	Cefuroxime (30mg/kg/day in 2 divided doses)
	Cefpodoxime (10mg/kg/day in 2 divided doses)
	Ceftriaxone (50mg IM or IV per day for 1-3 days) if unable to tolerate oral formulations

Treatment Failure is considered if symptoms worsen or treatment fails to show improvement after 48-72 hours of initiation of therapy. This situation warrants switching to an alternative therapy.

Recommendation for Change in therapy after 48-72 h of antibiotic treatment failure

First-Line Treatment	Alternative Treatment
Amoxicillin-Clavulanate (90 mg/kg/day of amoxicillin, with 6.4 mg/kg/day (14:1 ratio) in 2 divided doses) Or	Ceftriaxone 3 day course (50mg/kg/day IV o IM injection)
	Clindamycin (30-40mg/kg/day in 3 divided doses) with or without an antibiotic that covers <i>H. influenza</i> and <i>M. catarrhalis</i> , such as cefpodoxime or third generation cephalosporins: Cefdinir or Cefixime.
Ceftriaxone (50mg IM or IV per day for 1-3 days) if unable to tolerate oral formulations	Tympanocentesis Perform tympanocentesis/drainage if skilled in procedure or consult a specialist. If drainage reveals multidrug resistant bacteria, seek an infectious disease specialist.
Agents No longer recommended for AOM due to growing resistance: 2 nd Generation Cephalosporins, Bactrim, erythromycin-sulfisoxazole	

The Duration of therapy was defined by controlled trials that showed optimal efficacy based upon age and severity as summarized below.

Age group/severity	Duration
Children under 2 or has severe symptoms	10 days
Children age 2-5yr with mild or moderate symptoms	7 day
Children 6 and older with mild or moderate symptoms	5-7 day

The AAP guidelines also addressed certain preventative measures to reduce the AOM burden, including: **pneumococcal conjugate vaccination** to all children according to the ACIP guidelines, an **annual influenza vaccination** for ages 6 months and older, **avoidance of tobacco smoke** exposure, and the encouragement of **breast feeding** for at least the first 6 months of life.

The 2013 AAP Guidelines emphasize that a clinician **should not** prescribe prophylactic antibiotics (chemoprophylaxis) to reduce the frequency of episodes of AOM in children with recurrent AOM. This is based upon trial data showing no benefit with increased risks associated with chemoprophylaxis.

Sources:

American Academy of Pediatrics Subcommittee on Management of Acute Otitis Media. Diagnosis and management of acute otitis media. Pediatrics. March 2013;131(3):e964-e990.



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