

Pediatric Otitis Media with Effusion Guideline

These clinical guidelines are designed to assist clinicians by providing an analytical framework for the evaluation and treatment of patients. They are not intended to replace a clinician's judgment or to establish a protocol for all patients with a particular condition. A guideline will rarely establish the only approach to a problem.

GUIDELINE HISTORY and APPROVAL

ACTION	SEED GUIDELINE and/or MAIN INFORMATION & GROUP SOURCE(S)	DATE	ORGANIZATION
guideline reviewed and approved	1. Institute for Clinical Systems Improvement (ICSI) Diagnosis and Treatment of Otitis Media in Children. (July 1998 Version) 2. Otitis Media with Effusion in Young Children Clinical Practice Guideline, AHCPR, PHS, U.S. HHS. 1994.	July 28, 1999	Geisinger Health Plan/Quality Improvement Committee
NCQA review deadline		July 28, 2001	Geisinger Health Plan/Quality Improvement Committee
guideline reviewed, revised and approved	1. Institute for Clinical Systems Improvement (ICSI) Diagnosis and Treatment of Otitis Media in Children. (July 1998 Version) 2. Otitis Media with Effusion in Young Children Clinical Practice Guideline, AHCPR, PHS, U.S. HHS. 1994.	January 04, 2001	Geisinger Health Plan/Clinical Guideline Committee
NCQA review deadline		January 24, 2003	Geisinger Health Plan/Quality Improvement Committee
guideline reviewed, revised and approved	1. Institute for Clinical Systems Improvement (ICSI) Diagnosis and Treatment of Otitis Media in Children (May 2001 Version) 2. <i>Pediatr. Infect. Dis. J.</i> , 1999;18: 1-9.	December 11, 2002	Geisinger Health Plan Guideline Review Conference
guideline reviewed and approved	Same as above.	January 2, 2003	Geisinger Health Plan/Clinical Guideline Committee
guideline reviewed and approved	Same as above.	January 22, 2003	Geisinger Health Plan/Quality Improvement Committee
guideline reviewed, revised, and approved	1. American Academy of Pediatrics (AAP) Practice Guidelines. Diagnosis and Management of Acute Otitis Media Clinical Practice Guideline. <i>Pediatrics</i> . Vol. 113 No. 5 May 2004, pp. 1451-1465. 2. Institute for Clinical Systems Improvement (ICSI) Diagnosis and Treatment of Otitis Media in Children (5/2004 version).	August 10 - September 20, 2004	Geisinger Health Plan Pediatric Otitis Guideline Team
guideline reviewed and approved	Same as above.	September 21 - September 24, 2004	Geisinger Health Plan Medical Directors
guideline reviewed and approved	Same as above.	September 24, 2004	Geisinger Health Plan Medical Management Administrative Committee (MMAC)

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guideline reviewed and approved	Same as above.	September 24 - September 27, 2004	Geisinger Health Plan Guideline Committee
guideline reviewed and approved	Same as above.	October 27, 2004	Geisinger Health Plan Quality Improvement Committee
guideline reviewed revised and approved	Same as above.	Feb. 23 – 24, 2006	Geisinger Health Plan Pharmacy Dept.
guideline reviewed and approved	Same as above	May 3-12, 2006	Geisinger Health Plan Medical Directors
guideline reviewed and approved	Same as above	June 5, 2006	Geisinger Health Plan Medical Management Committee (MMC)
guideline reviewed and approved	Same as above	July 26, 2006	Geisinger Health Plan Quality Improvement Committee
Guideline reviewed	1. American Academy of Pediatrics (AAP) Practice Guidelines. Diagnosis and Management of Acute Otitis Media Clinical Practice Guideline. Pediatrics. Vol. 113 No. 5 May 2004, pp. 1451-1465. 2. Institute for Clinical Systems Improvement (ICSI) Diagnosis and Treatment of Otitis Media in Children (1/05 version).	Nov.16, 2007	Geisinger Health Plan Guideline Committee
Guideline reviewed	Same as above	Feb 15 – Mar.14, 2008	Geisinger Health Plan Pharmacy Dept.
Guideline reviewed	Same as above	May 23 – June 9, 2008	Geisinger Health Plan Medical Directors
Guideline reviewed	Same as above	July 23, 2008	Geisinger Health Plan Quality Improvement Committee
Guideline reviewed	1. American Academy of Pediatrics (AAP) Practice Guidelines. Diagnosis and Management of Acute Otitis Media Clinical Practice Guideline. Pediatrics. Vol. 113 No. 5 May 2004, pp. 1451-1465. 2. Institute for Clinical Systems Improvement (ICSI) Diagnosis and Treatment of Otitis Media in Children Jan. 2008.	Dec. 21, 2009 - June 21, 2010	Geisinger Health Plan Guideline Committee
Guideline reviewed	Same as above	June 21, 2010	Geisinger Health Plan Pharmacy Dept
Guideline reviewed	Same as above	July 21, 2010	Geisinger Health Plan Medical Management Committee (MMC)
Guideline reviewed	Same as above	July 28, 2010	Geisinger Health Plan Quality Improvement Committee

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OVERVIEW

One of the more common problems in children is an ear infection. Otitis media, “inflammation of the middle ear”, is also the most common cause of hearing loss in children. Almost half of all children will have at least one middle-ear infection during their first year and by age three, two-thirds of all children will have had a middle-ear infection. This results in approximately 24.5 million visits per year for otitis media. The combination of direct and indirect costs for otitis media is \$3.5 billion per year and antibiotic costs alone are \$240 million. Despite this, the necessity of antibiotics and the issue of appropriate drug use remain an issue of contention. In addition, there has been a significant increase in the prevalence of recurrent otitis media among children in the United States.

This guideline is targeted at children at least 6 months old but less than 12 years of age

SEED GUIDELINE

The Institute for Clinical Systems Improvement (ICSI), a collaboration of health care organizations, is an objective voice dedicated to championing health care quality and to helping its member organizations identify and accelerate the implementation of best clinical practices for their patients.

An independent, non-profit organization, ICSI provides health care quality improvement services to 18 medical groups affiliated with HealthPartners, a Minnesota-based HMO serving more than 800,000 members. The medical groups range in size from 14 practitioners in Shoreview, Minnesota to more than 1,000 physicians and medical scientists at Mayo Clinic in Rochester. The combined medical groups represent nearly 2,500 physicians. More information can be obtained by accessing the ICSI website at: www.icsi.org.

American Academy of Pediatrics (AAP) Practice Guidelines. Diagnosis and Management of Acute Otitis Media Clinical Practice Guideline. Pediatrics. Vol. 113 No. 5 May 2004, pp. 1451-1465.

This can be found at: <http://aappolicy.aappublications.org/cgi/content/full/pediatrics;113/5/1451>

Institute for Clinical Systems Improvement (ICSI) Diagnosis and Treatment of Otitis Media in Children Jan. 2008

This can be found at:

http://www.icsi.org/otitis_media/diagnosis_and_treatment_of_otitis_media_in_children_2304.html

GOALS



1. Improve parent/caretaker knowledge of symptoms suggestive of otitis media and appropriate indicators for a provider visit, risk factors, and outcomes of otitis media by increasing parent (caretaker) education.
2. Increase provider understanding of diagnostic criteria of acute otitis media and otitis media with effusion by providing clear operational definitions of acute otitis media, and otitis media with effusion.
3. Increase provider understanding of appropriate antibiotic usage for middle ear infections by ensuring that first line medications are prescribed for patients when appropriate.
4. Decrease inappropriate emergency room visits for otitis media.
5. Increase provider understanding of ENT referral criteria.

FAST FACTS

- ◆ Pediatric otitis media is a common problem that may be distressing to many children and parents, but it is not a medical emergency.
- ◆ Appropriate initial treatment of acute otitis media is a 10-day course of amoxicillin.
- ◆ Acute otitis media (AOM) is characterized by middle ear effusion with signs of acute inflammation (redness, bulging). Tympanometry is usually not necessary to establish the diagnosis of AOM.
- ◆ Parents/caretakers need to be educated regarding the symptoms suggestive of otitis media, appropriate indicators for a provider visit, risk factors, and outcomes of otitis media.

BIBLIOGRAPHY

American Academy of Pediatrics (AAP) Practice Guidelines. Diagnosis and Management of Acute Otitis Media Clinical Practice Guideline. *Pediatrics*. Vol. 113 No. 5 May 2004, pp. 1451-1465
This can be found at: <http://aappolicy.aappublications.org/cgi/content/full/pediatrics;113/5/1451>

Institute for Clinical Systems Improvement (ICSI) Diagnosis and Treatment of Otitis Media in Children
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This can be found at:
http://www.icsi.org/otitis_media/diagnosis_and_treatment_of_otitis_media_in_children_2304.html



**Pediatric Otitis Media Guideline
ALGORITHM**

2. Symptoms Suggestive Of Otitis Media Children < 2 Years

- 1 Irritability
- 2 Fever
- 3 Night waking
- 4 Poor feeding
- 5 URI not resolving
- 6 Conjunctivitis
- 7 Balance problems
- 8 Hearing loss
- 9 Ear pain

Children 2 years and older

- 1 Ear pain
- 2 Ear drainage
- 3 Hearing loss
- 4 Ear popping
- 5 Ear fullness

5. Diagnostic Criteria for Acute Otitis Media (AOM)

- Middle ear effusion (seen and exam and/or confirmed by pneumatic otoscopy) with either:
- Local signs for inflammation **and**
- Otalgia, otorrhea, irritability, restlessness, or poor feeding

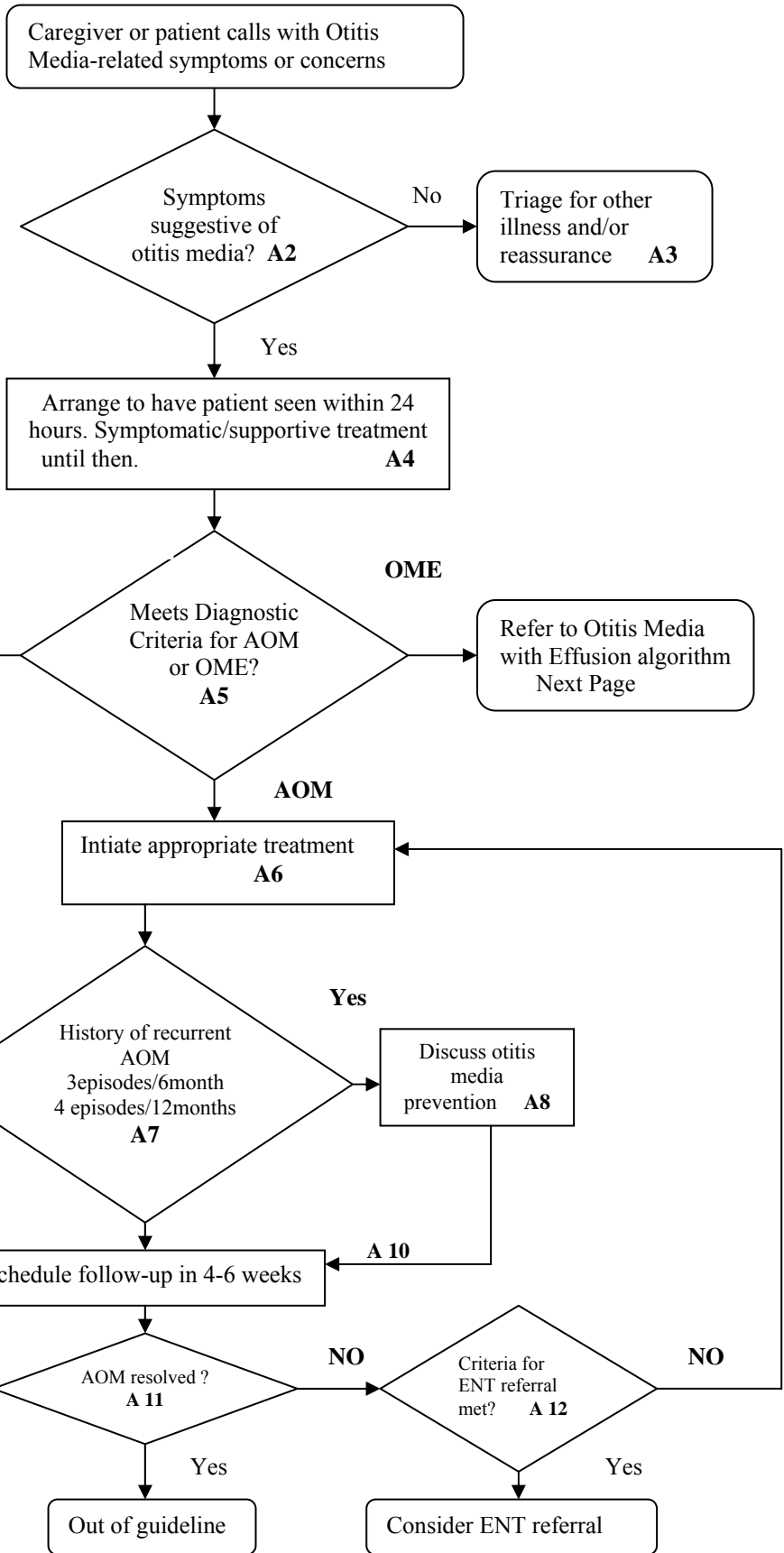
Diagnostic Criteria for Otitis Media with Effusion (OME)

- Middle ear effusion (seen on exam and/or confirmed by pneumatic otoscopy) or abnormal tympanometry without signs or symptoms of AOM.

6. Appropriate Treatment

- Antibiotic regimen using criteria for first vs. second line antibiotics **or**
- Observation for mildly symptomatic children

A= Annotation



Otitis media With Effusion Algorithm

5. Diagnostic Criteria for Acute Otitis Media

- Middle ear effusion (seen on exam and/or confirmed by pneumatic otoscopy) with either:
 - Local signs for inflammation
- And**
- Otalgia, otorrhea, irritability, restlessness, or poor feeding

Diagnostic Criteria for Otitis Media with effusion (OME)

- Middle ear effusion (seen on exam and/or confirmed by pneumatic otoscopy) **or**
- Abnormal tympanometry without signs or symptoms of AOM.

14. Treatment Options

1. Observe-recheck in 4-6 weeks
2. Course of Antibiotics prior to ENT referral

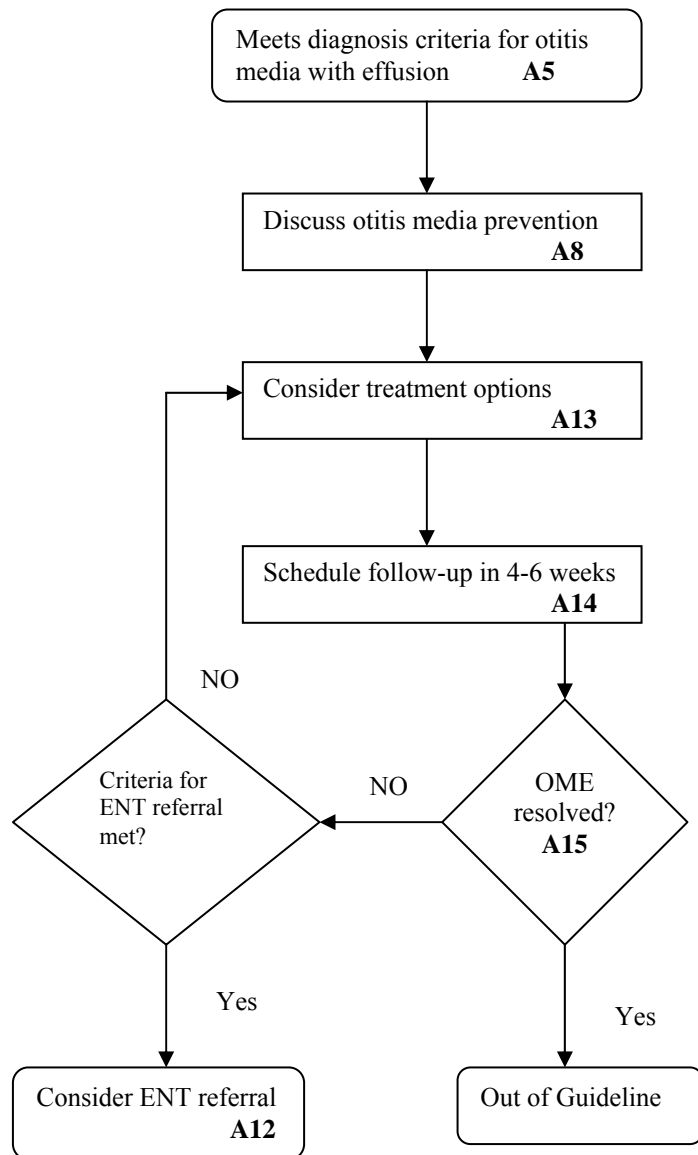
12. ENT Referral Criteria for OME

Bilateral or unilateral OME persisting for at least 3 months

Hearing loss with or without speech delay

See the Algorithm Annotations for a complete list of ENT referral criteria

A= Annotation



ANNOTATIONS

ANNOTATION 1

Caregiver or Patient Calls with Otitis-related Symptoms or Concerns or OM Found on Exam

Entrance into the guideline occurs when a caregiver calls regarding an ill child whose symptoms are suggestive of otitis media, or when a provider discovers finding of otitis media on exam.

ANNOTATION 2

Symptoms Suggestive of OM?

Children from 6 months old to 2 years old more often present with non-specific symptoms (irritability, fever, night waking, poor feeding, coryza, conjunctivitis, and occasionally balance problems.)

Approximately 90% of infants and toddlers with otitis media have associated rhinitis symptoms.

Ear pulling without associated symptoms may not be a symptom of otitis media.

ANNOTATION 3

Triage for Illness and/or Reassurance

For symptoms not suggestive of otitis media, reassurance and anticipatory education of the symptoms of otitis should be provided. Instructions should be given to call back if symptoms worsen, the child becomes more ill, or if the child becomes inconsolable. If symptoms suggestive of another illness are described, refer to the appropriate guideline.

ANNOTATION 4

Schedule Appointment Within 24 Hours

While symptoms of acute otitis media are often dramatic, the illness is rarely an emergency. Most children can be treated symptomatically through the night unless symptoms of a more serious illness are present. Comfort measures can be discussed with parent / caretaker. These measures may include:

- Application of warm compresses
- Gently wiping drainage as it appears
- Holding or rocking the child
- Over the counter (OTC) pain reliever as appropriate for the age and weight of the child
- Analgesic ear drops

Diagnosis of otitis media is made by exam. Diagnosis by phone should be avoided except in special circumstances (children with history of multiple sets of ventilating tubes or children in high risk categories, such as cleft palate or Down's syndrome, who present with bloody or purulent drainage and who are well known to the provider, and in whom follow-up is assured.)



ANNOTATION 5

Meets Diagnostic Criteria for AOM or OME?

Diagnostic criteria for AOM

1. Middle ear effusion (seen on examination and / or confirmed by pneumatic otoscopy) with either (a) or (b):
 - a) Local signs of inflammation (redness, bulging of the tympanic membrane)
 - b) Symptoms associated with AOM
 - > Otolgia
 - > Otorrhea
 - > Irritability
 - > Restlessness
 - > Poor feeding
 - > Fever
2. AOM is characterized by middle ear effusion with acute inflammation. (The tympanic membrane is usually full or bulging (decreased mobility by pneumatic otoscopy). Color is usually red, yellow or cloudy.) Symptoms may include otalgia, otorrhea, irritability, restlessness, poor feeding, or fever. Tympanometry is usually not necessary to establish the diagnosis of AOM. Pneumatic otoscopy is highly recommended and should be used routinely.

Diagnostic criteria for OME

1. Middle ear effusion (seen on examination and/or confirmed by pneumatic otoscopy) or abnormal tympanometry or acoustic reflectometry without signs or symptoms of AOM.
2. The diagnosis of OME is distinguished from AOM by the presence of an effusion with a lack of signs or symptoms of inflammation or pressure behind the eardrum. Tympanic membrane findings: opaque or yellow, position neutral or retracted, decreased mobility or air fluid level. Tympanometry may be helpful when diagnosis is equivocal.

ANNOTATION 6

Initiate Appropriate Treatment

Note: Pharmaceutical coverage is dependent upon individual pharmacy benefit design and certain drugs may require prior authorization. Providers are encouraged to review the GHP formulary at <http://www.thehealthplan.com>, or contact the GHP Pharmacy Department at 1-800-988-4861.

Treatment options for AOM

- Antibiotic regimen using criteria (Check Health Plan formulary listing for currently available medications)
- Observation for mildly symptomatic children

1. Therapeutic (10 day) course of antibiotic

- > Amoxicillin 40 mg/kg/day if low risk (>2yrs, no antibiotics in the previous 3 months)
- ≧ Amoxicillin 80-90 mg/kg/day if greater than low risk or if OM is resistant to lower dose
- ≧ Augmentin (amoxicillin/clavulanate potassium) 90 mg/kg/day amoxicillin component



- > Biaxin♦ (clarithromycin) 15 mg/kg/day
- > Ceftin (cefuroxime axetil) 30 mg/kg/day
- > Cefzil (cefprozil) 30 mg/kg/day
- > Cleocin (clindamycin) 30-40 mg/kg/day **
- > Omnicef (cefdinir) 14 mg/kg/day (as an alternative to amoxicillin if not type I hypersensitivity reaction)
- > Pediazole♦ (erythromycin/sulfa) 50 mg/kg/day of erythromycin
- > Rocephin (ceftriaxone) parenterally 50 mg/kg/day (1 dose for new onset, 3 doses in those who fail initial management)
- > Vantin (cefepodoxime proxetil) 10 mg/kg/day
- > Zithromax (azithromycin) 30 mg/kg given as a single dose or 10 mg/kg once daily for 3 days or 10 mg/kg as a single dose on the first day followed by 5 mg/kg/day on days 2 through 5.
- > Septra, Bactrim (trimethoprim-sulfamethoxazole) 40 mg/kg sulfamethoxazole and 8 mg/kg trimethoprim per 24 hours, given in two divided doses every 12 hours for 10 days
- > Ofloxacin otic ◇

♦ Not recommended when the patient has failed a course of amoxicillin

◇ With tympanostomy tubes

*Despite increasing importance of *H. influenzae*, including beta-lactamase-producing strains, high dose amoxicillin remains the preferred choice for initial therapy.

Amoxicillin should not be used as a first-line therapy in children who are at high risk for AOM caused by an amoxicillin-resistant otopathogen, such as:

- Children who were treated with antibiotics in the previous 30 days, particularly beta-lactam antibiotics;
- Children with concurrent purulent conjunctivitis; and
- Children receiving amoxicillin for chemoprophylaxis of recurrent AOM

* High dose amoxicillin may be used if patients considered at high risk for resistant organisms, e.g. *Streptococcus pneumoniae*. High risk features include age less than 2 yrs., day care exposure, and antibiotics in previous 30 days.

* **Does not cover *H. influenzae* or *M. cat.*

2. Observation with or without provisional prescription if symptoms of AOM should worsen. This option is not recommended in the acutely ill child but may be considered in an asymptomatic or only mildly symptomatic child with mild findings on exam. Parents should be instructed to call back if symptoms persist, if the child is inconsolable, or if the child is becoming more ill.

For a child with a draining ear due to a perforation or who has ventilating tubes, antibiotic ear drops (suspension) should be added to the treatment regimen. Topical quinolone drops may be more effective than aminoglycosides. Ophthalmic antibiotic solutions can also be used.

The use of nasal decongestants, antihistamines, and corticosteroids is not supported in the literature for the treatment of AOM.

3. Treatment of resistant AOM.

Resistant AOM is defined as persistence of moderately severe symptoms (pain and fever) after 3 to 5 days of antibiotic therapy with findings of continued pressure and inflammation (bulging) behind the tympanic membrane. A second antibiotic should be chosen; the alternative first line medication may be an appropriate choice. (Referral to ENT specialist may be indicated if significant pain and fever continue for 4-5 days on the second medication or if complications of otitis media occur.)

4. Treatment of persistent AOM

Persistent AOM is defined as continued findings of AOM present within 3 to 6 days of finishing a course of antibiotics. A second course of therapy with a different antibiotic is indicated for persistent AOM.

ANNOTATION 7

History of Recurrent AOM

- ◆ Immunization status (pneumococcus/Hib) should be reviewed and considered.

Diagnostic criteria for recurrent AOM

- ◆ Three or more episodes of AOM in a 6 month period or during a respiratory season or 4 or more in a year.
- ◆ Children at increased risk or recurrent AOM:
 - Cleft palate, craniofacial abnormalities & Down’s syndrome (very high risk category)
 - First episode early (under 6 months)
 - Family history of recurrent AOM in sibling or parent
 - Day care attendance
 - Exposure to tobacco smoke
 - Not breast-fed
 - Ethnic origin: Native American or Inuit (Eskimo)

ANNOTATION 8

Discuss Otitis Media Prevention

- ◆ Parents/caretakers should be counseled periodically about otitis media prevention. Elimination of controllable risk factors should be encouraged whenever possible.
- ◆ Otitis media prevention measures to discuss include:
 - encouraging breast feeding.
 - Feeding child upright if bottle fed
 - avoiding exposure to passive smoke.
 - limiting exposure to numbers of children to the extent possible.
 - teaching adults and children careful hand washing technique.
 - limiting exposure to viral upper respiratory infections.



- Avoid or reduce pacifier use, especially when sleeping.
- Ensure immunizations are up to date, including influenza and PCV7

ANNOTATION 10

Schedule Follow-up in 6 Weeks

- ◆ The appropriate timing of follow-up for middle ear effusion after AOM is considered to be 6 weeks. We recommend:
 - Recheck all children
- ◆ Timing of Rechecks
 - Recheck in 6 weeks
 - Reassess for symptoms of unresponsive otitis: pain, fever or irritability continuing after 3-5 days of treatment. (Refer to Annotation #6, Resistant AOM.)

ANNOTATION 11

AOM Resolved?

- ◆ Resolution is defined as a return to normal on examination with no evidence of effusion or inflammation and/or normal mobility. Tympanometry is not routinely needed to document resolution.

ANNOTATION 12

Consider ENT Referral

- ◆ Criteria for ENT referral for consideration of ventilating tubes:
 1. Recurrent AOM which fails medical management (3 episodes in 6 months or 4 episodes in one year); or
High risk category:
 - craniofacial anomalies
 - cleft palate
 - ethnic origin: Native American or Inuit (Eskimo)
 - speech and language delay
 - pre-existing hearing loss
 - day care
 2. Refractory acute otitis media with moderate to severe symptoms unresponsive to at least 2 antibiotics. (Refer to Annotation #6, Resistant AOM).
 3. Bilateral or unilateral OME persisting for at least 3 months and who has a bilateral hearing deficiency (20 decibel or greater).
 4. OME persisting for at least 3 months.
 5. Development of advanced middle ear disease involving tympanic membrane atrophy, retraction pockets, ossicular erosion or cholesteatoma.
 6. Medical treatment failure secondary to multiple drug allergy or intolerance.
 7. At least 2 recurrences of otitis media within 2-3 months following ventilating tube extrusion with failed medical management.
 8. Impending or actual complication of otitis media including:
 - a. Mastoiditis
 - b. Facial nerve paralysis
 - c. Lateral sinus thrombosis



- d. Meningitis
- e. Brain abscess
- f. Labyrinthitis

◆ **Counseling Messages**

When counseling parents/caregivers about otitis media prevention, encourage measures to diminish risk factors when possible. (Refer to Annotation #8). Discussion with parents/caregivers should take place regarding medical versus surgical treatment.

ANNOTATION 13

Consider Treatment Options

- ◆ Treatment options to be considered include:
 - a. Observe-rechecking in 4-6 weeks. Most cases of OME resolve spontaneously.
 - b. One 10-day course of antibiotics using first and second line criteria, prior to ENT referral. (Refer to Annotation #6, Appropriate Treatment). Tympanometry may be performed to confirm suspected OME.

ANNOTATION 14

Schedule Follow-up in 4-6 Weeks

- ◆ More frequent rechecking than every 4-6 weeks of OME is unnecessary and inappropriate. 90 to 95% of OME will resolve in 3-4 months. Continued observation to assure complete resolution is appropriate since hearing loss accompanies OME.

A child who has had fluid in both middle ears for a total of 3 months should undergo hearing evaluations

ANNOTATION 15

OME Resolved?

- ◆ Mobility of the eardrum should be normal or results of tympanogram or pneumatic otoscopy should confirm resolution.

MEASURES

Source of Data: GHP members initially identified by claims data, then chart abstraction of measures.

- ◆ Denominator-members at least 6 months old, but less than 12 years of age with pediatric otitis media.
 - > Use Primary ICD-9CM principal diagnosis codes to identify an uncomplicated episode of acute otitis media: 382.0, 382.00, 382.01, 382.1, 382.2, 382.4, OR 382.9.
 - > Use initial visit for otitis media in the timeframe.
 - > No episode of otitis media in the preceding 3 months (to be determined at time of chart abstraction).



- ◆ Numerator
 - > Percent of patients receiving first line antibiotic agent (amoxicillin).
 - > Percent of patients who return within one month for re-evaluation/re-treatment.
 - > Percent of patients referred to ENT within one month of initial visit.

