



# Augmentin® 875 mg Tablets

Amoxicillin as trihydrate 875 mg

Clavulanic Acid as potassium salt 125 mg



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References



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**Steve...**

48 years.  
Sales manager and a known  
case of Type II Diabetes Mellitus  
since past 7 years.



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Steve travelled extensively



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Since few days,  
he was febrile and had productive cough with sputum



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Steve took medications for symptomatic relief but did not have much relief.



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**Advised****Routine laboratory investigations****Chest X-ray**

- Blood pressure : 120/73
- Pulse: 102 and regular
- Respiratory rate : 25 / min.
- Temperature: 100.9°F / 38.27°C
- Lung examination revealed the presence of right lower lung crackles with decreased breath sounds in this area as well.



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## KEY RECOMMENDATIONS FOR PRACTICE<sup>1</sup>

Clinical recommendations	Evidence rating	References
In patients with clinically suspected CAP, chest radiography should be obtained to confirm the diagnosis.	C	12
Evaluation for specific pathogens that would alter standard empiric therapy should be performed when the presence of such pathogens is suspected on the basis of clinical and epidemiologic clues; this testing usually is not required in outpatients.	C	12
Mortality and severity prediction scores should be used to determine inpatient versus outpatient care for patients with CAP.	A	22-24
All patients with CAP who are admitted to the intensive care unit should be treated with dual therapy.	A	28
Prevention of CAP should focus on universal influenza vaccination and pneumococcal vaccination for patients at high risk of pneumococcal disease.	B	12, 35-37

CAP = community-acquired pneumonia.

A = consistent, good-quality patient-oriented evidence; B = inconsistent or limited-quality patient-oriented evidence; C = consensus, disease-oriented evidence, usual practice, expert opinion, or case series. For information about the SORT evidence rating system, go to <http://www.aafp.org/afpsort.xml>.

**In patients with clinically suspected CAP, chest radiography should be obtained to confirm the diagnosis.**

- Watkins R, Lemonovich T, et al. Diagnosis and Management of Community-Acquired Pneumonia in Adults. American Academy of Family Physicians 2011; 83 (11): 1299-1306.



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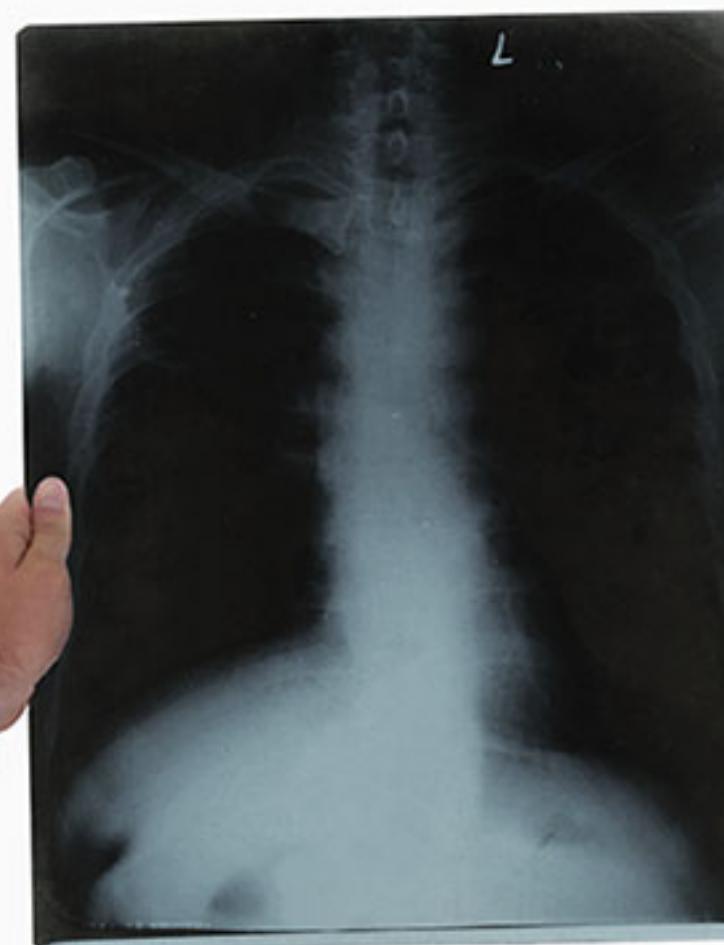
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## Results of investigation

Routine lab investigations were suggestive of infection

### Chest X-ray

- Right lower lobe infiltrate
- No evidence of pleural effusion or abscess



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## Diagnosis of Pneumonia



"In addition to a constellation of **suggestive clinical features**, a demonstrable **infiltrated by chest radiograph** or other imaging technique with or without supporting microbiological data, is required for the diagnosis of pneumonia."<sup>1</sup>

1. Mandell L, Richard G, Wunderink, et al. Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in adults, Clin Infect Dis. 2007; 44(2):S27-72.

Prognostic variables<sup>\*2</sup>

- ✗ Confusion**
- ✗ Blood urea nitrogen level > 20 mg per dL (7.14 mmol per L)**
- ✗ Respiratory rate ≥ 30 breaths per minute**
- ✗ Blood pressure (systolic < 90 mm Hg or diastolic ≤ 60 mm Hg)**
- ✗ Age ≥ 65 years**

Score	Inpatient vs. outpatient	30-day mortality (%)
0 or 1 point	Treat as outpatient	0.7 to 2.1
2 points	Treat as inpatient	9.2
≥3 points	Treat in intensive care unit	15 to 40

\*-Assign 1 point for each variable.

2. Watkins R, Lemonovich T, et al. Diagnosis and Management of Community-Acquired Pneumonia in Adults. American Academy of Family Physicians 2011; 83 (11): 1299-1306.



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## Recommendations on 'culture tests'

such as blood and sputum cultures. Currently, these cultures may have a major impact on the care of an individual patient and are important for epidemiologic research, including antibiotic susceptibility patterns used to develop treatment guidelines. A list of clinical indications for more extensive diagnostic testing (Table 1) was, therefore, developed, primarily on the basis of 3 criteria: (1) when the result is likely to change individual antibiotic management and (2) when the test is likely to have the highest yield.

(1) **Routine diagnostic tests to identify an etiologic diagnosis are optional for inpatients with CAP.** (Deutsche medizinische Gesellschaft für Pneumologie und Thoraxchirurgie recommendations, level II evidence.)

(2) **Potassium-based samples for culture and an improved sputum sample for stain and culture (in patients with a productive cough) should be obtained from hospitalized patients with the clinical indications listed in Table 1 but are optional for patients without these indications. (Deutsche medizinische Gesellschaft für Pneumologie und Thoraxchirurgie recommendations, level I evidence.)**

(3) **Potassium-based sputum and culture of respiratory system should be performed only if a good-quality sample can be obtained and quality performance measures for collection, transport, and processing of sample (e.g., for test). (Deutsche medizinische Gesellschaft für Pneumologie und Thoraxchirurgie recommendations, level II evidence.)**

(4) **Patients with severe CAP, as defined above, should at least have blood samples drawn for culture, urinary antigen tests for Legionella pneumophila and *Escherichia coli* pneumonia performed, and expectorated sputum samples collected for culture. In hospitalized patients, an undiluted sputum sample should be chosen. (Deutsche medizinische Gesellschaft für Pneumologie und Thoraxchirurgie recommendations, level II evidence.)**

The most clear-cut indication for extensive diagnostic testing is in the critically ill CAP patient. Such patients should at least have blood drawn for culture and an undiluted sputum collected if they are hospitalized; consideration should be given to more extensive testing, including urinary antigen tests for *L. pneumophila* and *E. coli* pneumonia and a sputum culture of expectorated sputum in nonhospitalized patients, but only once without the diagnosis established in either setting. Extensive testing is optional (the test need not be done) in the following situations:

### **Ambulatory settings**

**Empirical antimicrobial therapy.** Empirical antibiotic recommendations (Table 2) have not changed significantly from those in previous guidelines. Increasing evidence has strengthened the recommendation for combination empirical therapy for severe CAP. Only 1 recently released antibiotic has been added to the monotherapy/combination regimens, as an acceptable  $\beta$ -lactam alternative for hospitalized patients with risk factors for infection with gram-negative pathogens other than *Pseudomonas aeruginosa*. At present, the committee is awaiting further evaluation of the safety of aztreonam by the US Food

and Drug Administration before making its final recommendations regarding the drug. Recommendations are generally for a class of antibiotics rather than for a specific drug, unless outcome data clearly favor one drug, because overall efficacy remains good for many classes of agents, the more potent drugs are given preference because of their benefits in decreasing the risk of selection for antibiotic resistance.

**Routine diagnostic tests to identify an etiologic diagnosis are optional for outpatients with CAP.<sup>1</sup>**

**1. *Gram-negative* pneumonia.** *Escherichia coli* pneumonia (1 g 2 times daily) or amoxicillin-clavulane (2 g 2 times daily) is preferred; alternatives include ceftriaxone, ciprofloxacin, and ceftazidime (300 mg 2 times daily) or ciprofloxacin (600 mg 2 times daily) or ceftazidime (600 mg 2 times daily).

**2. *Fungal* pneumonia.** *Candida* pneumonia (1 mg/kg/day amphotericin B) or voriconazole (6 mg/kg/day) should be considered. Consider the use of alternative agents based on the clinical presentation. (Deutsche medizinische Gesellschaft für Pneumologie und Thoraxchirurgie recommendations, level II evidence.)

**3. *Atypical* pneumonia.** *Legionella pneumophila* (testing recommendations, level I evidence).

**4. *Streptococcal* pneumonia.** *Streptococcal* pneumonia (ceftriaxone, amoxicillin-clavulane, or ampicillin-sulphacilline) or  $\beta$ -lactamase inhibitor +  $\beta$ -lactam (cefuroxime, cefixime, or cefotaxime) should be used for penicillin-allergic patients.

Increasing resistance rates have suggested that empirical therapy with a macrolide alone can be used only for the treat-

**American Thoracic Society Guidelines**

**Table 2. Patients with Acute Respiratory Illness Who Benefit from Chest Radiography**

**Chest radiography should be performed in any patient with at least one of the following clinical signs:**

- Temperature  $\geq 38^{\circ}\text{C}$  ( $100.4^{\circ}\text{F}$ )
- Heart rate  $> 100$  beats per minute
- Respiratory rate  $> 20$  breaths per minute
- Any patient with at least two of the following clinical findings:

  - Decreased breath sounds
  - Coughing
  - Abuse of alcohol
  - Reported risk factors for pneumonia (smoking, recent hospitalization, recent travel, immunosuppression, etc.)

**LABORATORY TESTING**

**Routine Laboratory testing to establish an etiology in outpatients with CAP is usually unnecessary.<sup>2</sup>**

**1. *Urinalysis.***

**2. *Indirect antigens.***

**3. *Direct antigens.***

**4. *Microbiology.***

**5. *Immunological assays.***

**6. *Genetic testing.***

**7. *Other.***

### **Community-Acquired Pneumonia**

**Radiographs.<sup>1,2</sup>** The routine use of chest radiographs may help identify the source of fever and assist with initial points of care, such as determining the cause of ventilation, and may also aid in the diagnosis of complications. (Deutsche medizinische Gesellschaft für Pneumologie und Thoraxchirurgie recommendations, level II evidence.)

**Antibiotic therapy.**

**Routine laboratory testing to establish an etiology in patients with CAP is usually unnecessary.<sup>2</sup>**

**1. *Microbiology.*** (Deutsche medizinische Gesellschaft für Pneumologie und Thoraxchirurgie recommendations, level II evidence.)

**2. *Other.*** (Deutsche medizinische Gesellschaft für Pneumologie und Thoraxchirurgie recommendations, level II evidence.)

**3. *Immunological assays.***

**4. *Genetic testing.***

**5. *Other.***

Adapted with permission from Mandell L, Wunderink R, eds. Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in adults. Clin Infect Dis. 2007; 44(2):S27-72.

June 1, 2011 • Volume 83, Number 11

www.ajcp.org

American Family Physician 1301

1. Mandell L, Richard G, Wunderink, et al. Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in adults, Clin Infect Dis. 2007; 44(2):S27-72.

2. Watkins R, Lemonovich T, et al. Diagnosis and Management of Community-Acquired Pneumonia in Adults. American Academy of Family Physicians 2011; 83 (11): 1299-1306.



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References



## CAP : Decision for Admission

Prognostic variables\*<sup>1</sup>

- ✗ Confusion
- ✗ Blood urea nitrogen level > 20 mg per dL (7.14 mmol per L)
- ✗ Respiratory rate ≥ 30 breaths per minute
- ✗ Blood pressure (systolic < 90 mm Hg or diastolic ≤ 60 mm Hg)
- ✗ Age ≥ 65 years

Score	Inpatient vs. outpatient	30-day mortality (%)
0 or 1 point	Treat as outpatient	0.7 to 2.1
2 points	Treat as inpatient	9.2
≥ 3 points	Treat in intensive care unit	15 to 40

\*—Assign 1 point for each variable.

- Watkins R, Lemonovich T, et al. Diagnosis and Management of Community-Acquired Pneumonia in Adults. American Academy of Family Physicians 2011; 83 (11): 1299-1306.



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## Guidelines for selection of antibiotics

such as blood and sputum cultures. Conversely, these cultures may have a major impact on the care of an individual patient and are important for epidemiologic issues, including the antibiotic susceptibility patterns used to develop treatment guidelines. A list of clinical indications for more extensive diagnostic testing (Table 3) was, therefore, developed, primarily on the basis of (1) criteria (1) when the result is likely to change individual antibiotic management and (2) when the cost is likely to have the highest yield.

11. Routine diagnostic tests to identify an etiologic agent are optional for complications with low-risk clinical recommendations; level II evidence.
12. Pneumonia: Microbiology and culture and isolated species identification and resistance testing should be performed with a pneumonia sample obtained from a patient with suspected pneumonia. Diagnostic tests based in Table 5 first and then in patients without these conditions. (Moderate recommendation; level I evidence.)
13. Pneumonia: Gram stain and culture of expectorated sputum should be performed only if a good-quality specimen can be obtained and quality performance measures for collection, transport, and processing of samples can be met. (Moderate recommendation; level II evidence.)

**Presence of comorbidities, such as chronic heart, lung, liver, or renal disease; diabetes mellitus; alcoholism; malignancies; aplasia; immunosuppressing conditions or use of immunosuppressing drugs; use of antimicrobials within the previous 8 months or other risks for DRSP infection: A  $\beta$ -lactam plus a macrolide (strong recommendation; level I evidence)**

(High-dose amoxicillin [e.g., 1g 3 times daily] or amoxicillin-clavulanate [2 g 2 times daily] is preferred).<sup>1</sup>

**American Thoracic Society Guidelines**

Table 7. Empiric therapy for Community-Acquired Pneumonia

Patient group	Initial therapy
Previously healthy outpatients, no antibiotics use in past three months	A macrolide or doxycycline
Outpatients with comorbidity* or antibiotics use in past three months	A respiratory fluoroquinolone (fluorouracil [floxacin], or moxifloxacin [moxa]), or a beta-lactam (high-dose amoxicillin, amoxicillin/clavulanate [Augmentin], or cefuroxime [Zinacef]) plus a macrolide
Inpatients, non-ICU	A respiratory fluoroquinolone (fluorouracil [floxacin], or moxifloxacin [moxa]), or a beta-lactam (high-dose amoxicillin, amoxicillin/clavulanate [Augmentin], or cefuroxime [Zinacef]) plus a macrolide or a respiratory fluoroquinolone
Inpatients, ICU	A beta-lactam (high-dose amoxicillin/clavulanate [Augmentin], ceftriaxone, imipenem/cilastatin [Primaxin], or doripenem [Dorbeno]), plus either ciprofloxacin (Cipro) or levofloxacin (Leva)
Special considerations Risk factors for Pseudomonas spp†	The above beta-lactam antibiotic or the above beta-lactam and respiratory fluoroquinolone (ciprofloxacin or levofloxacin)
Risk factors for methicillin-resistant Staphylococcus aureus (MRSA) infection	Cefazolin (Kefzol) or clindamycin (Cleocin) (handful or as directed)
Influenza virus	Oseltamivir (Tamiflu) or zanamivir (Relenza)

ICU = Intensive-care unit.

\*—Chronic heart, lung, liver, or renal disease; diabetes mellitus; alcoholism; malignancies; aplasia; immunosuppressing conditions or use of immunosuppressing drugs; use of antimicrobials within the previous 8 months (in which case an alternative from a different class should be selected); or other risk for DRSP infection.

†—Antibiotic from a different class should be used.

‡—Also recommended in regions with a rate of high-level amoxicillin resistance  $\geq 5\%$ .

§—For patients allergic to penicillin, a respiratory fluoroquinolone (e.g., ciprofloxacin).

Adapted with permission from Mandell LA, Wunderink GL, Anzueto A, et al: *Silverman's Manual of Community-Acquired Pneumonia*, 2nd edn, published on the management of community-acquired pneumonia.

**Drug-resistant *S. pneumoniae* is a concern in patients with comorbid illness or recent antibiotic therapy (within previous three months) and should be treated with an oral beta-lactam antibiotic (e.g., high-dose amoxicillin, amoxicillin/clavulanate [Augmentin], cefpodoxime) combined with a macrolide.<sup>2</sup>**

in the u...  
monobactam only for outpatients.<sup>3</sup>

All patients with CAP who are admitted to the ICU should be treated with dual therapy, which is associated with lower mortality from bacteremic pneumococcal pneumonia and improved survival in patients with CAP and shock.<sup>2</sup> Some patients with severe CAP, especially after an episode of influenza or viral illness, who are admitted to the ICU need added coverage for *S. aureus*, including MRSA. MRSA-associated CAP is characterized by a severe, bilateral, necrotizing pneumonia induced by *Panton-Valentine leukocidin* and other toxins.

1. Mandell L, Richard G, Wunderink, et al. Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in adults, Clin Infect Dis. 2007; 44(2):S27-72.

2. Watkins R, Lemonovich T, et al. Diagnosis and Management of Community-Acquired Pneumonia in Adults. American Academy of Family Physicians 2011; 83 (11): 1299-1306.



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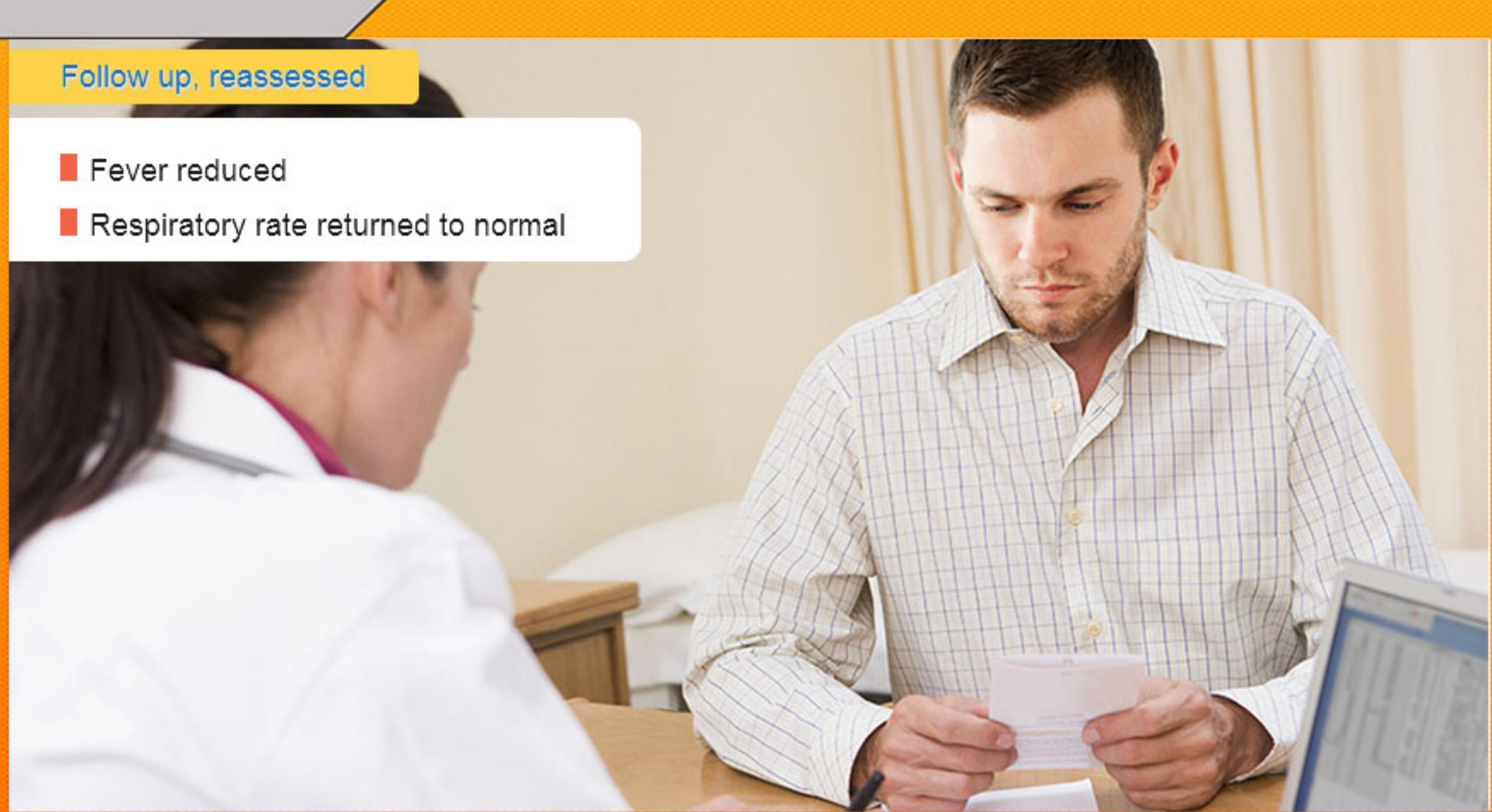
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## Follow up, reassessed

- Fever reduced
- Respiratory rate returned to normal

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## Criteria to judge patient's positive response



### CAP Guidelines 2010 Update

- For patients requiring hospitalization, empiric therapy should be initiated as soon as possible after diagnosis of CAP is made (Grade B).
- For low-risk CAP, treatment may be delayed (Grade C).

### 13. What initial antibiotics are recommended for the treatment of CAP?

- For low-risk CAP without comorbidities, aztreonam is the standard drug of choice (Grade A). Extended macrolides are recommended when atypical pathogens are suspected (Grade A).
- For low-risk CAP with stable comorbidities (diabetes,  $\beta$ -lactamase inhibitor combinations (BLIC) (Grade A) or second-generation cephalosporins (Grade A) with or without extended macrolides are considered first-line treatment (A) with no response, by the factors for failure of an *Gram* stain and culture, aztreonam, ceftazidime (i.e., with or without extended spectrum cephalosporins (BLIC, second-generation  $\beta$ -lactam, extended macrolide or IV ceftazidime) is recommended as initial treatment.

Temperature, respiratory rate, heart rate, blood pressure, sensorium, oxygen saturation and inspired oxygen concentration should be monitored to assess response to therapy.<sup>1</sup>

<sup>1</sup> Note, a combination of an IV antipseudomonal, non-pseudomonal  $\beta$ -lactam (BLIC, cephalosporin) with an extended macrolide and aztreonam (Grade A) or a combination of an IV antipseudomonal, non-pseudomonal  $\beta$ -lactam (BLIC, cephalosporin or carbapenem) and IV ciprofloxacin or high dose IV levofloxacin (Grade B).

### 14. How can response to initial therapy be assessed?

- Temperature, respiratory rate, heart rate, blood pressure, sensorium, oxygen saturation, and inspired oxygen concentration should be measured to assess response to therapy.

### CAP Guidelines

Doripenem is the newest of the carbapenems to be approved for the management of infections in the United States. In phase III trials, doripenem is noninferior to imipenem (clinical cure rate of 68.3% for doripenem vs. 64.8% for imipenem) and piperacillin-tazobactam (clinical cure rate of 61.2% for doripenem vs. 58.8% for piperacillin-tazobactam).

A patient is considered to have responded to treatment if...

- fever decreases within 72 hours
- temperature normalizes within 5 days
- respiratory signs, particularly tachypnea, return to normal

### 14. How can response to initial therapy be assessed?

- Temperature, respiratory rate, heart rate, blood pressure, sensorium, oxygen saturation and inspired oxygen concentration should be measured to assess response to therapy.
- Response to therapy. Failure indicates to repeat.
- Follow-up cultures of blood and sputum who are responding to treatment (OPTIONAL)

Most patients with uncomplicated bacterial pneumonia will respond to treatment within 24 to 72 hours; re-evaluation of patient, therefore, should be done after 72 hours of initiating therapy. A patient is considered to have responded to treatment if fever decreases within 72 hours, temperature normalizes within 5 days and respiratory signs, particularly tachypnea, return to normal. In patients with low-risk CAP showing good therapeutic response, a follow-up chest X-ray is not necessary. Follow-up cultures of blood and sputum are also not indicated for patients who respond to therapy.

### 15. When should de-escalation of empiric antibiotic therapy be done?

- De-escalation of initial empiric broad-spectrum antibiotic or combination parenteral therapy to a single narrow spectrum parenteral or oral agent based on available laboratory data is recommended once the patient is clinically improving, is hemodynamically stable and has a functioning gastrointestinal tract (Grade B).

1. Chua M, Villa. Ma, Alejandria M, et al. Philippine Clinical Practice Guidelines on the Diagnosis, Empiric Management, and Prevention of Community-acquired Pneumonia (CAP) in Immunocompetent Adults, available on [www.psmid.org.ph/clinical/cap\\_guidelines\\_2010.pdf](http://www.psmid.org.ph/clinical/cap_guidelines_2010.pdf) accessed on 5th Jan 2013.



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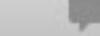
Steve was back to his normal life



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# Augmentin® 875 mg Tablets

**Amoxicillin as trihydrate 875 mg  
Clavulanic Acid as potassium salt 125 mg**

✓ 30 years of clinical experience



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# Augmentin® 875 mg Tablets

**Amoxicillin as trihydrate 875 mg**

**Clavulanic Acid as potassium salt 125 mg**

CAP treatment guidelines recommend Amoxicillin-Clavulanic acid

- Recommended empirical antimicrobial therapy for community acquired pneumonia in adults<sup>1</sup>
- Preferred oral therapy against beta-lactamase producing *Haemophilus influenzae* infection<sup>1</sup>
- Preferred initial empirical parenteral treatment regimen for high severity community acquired pneumonia in adults<sup>2</sup>

1. Lionel A. Mandell et al., Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults, Clinical Infectious Diseases 2007; 44(2):S27–72.
2. Lim WS, Baudouin SV, George RC, et al. BTS guidelines for the management of community acquired pneumonia in adults Update 2009, Thorax 2009;64(3):1-55.

\* A b-lactam plus a macrolide in Presence of comorbidities, such as chronic heart, lung,liver, or renal disease; diabetes mellitus; alcoholism; malignancies;asplenia; immunosuppressing conditions or use of immunosuppressing drugs; use of antimicrobials within the previous 3 months (in which case an alternative from a different class should be selected); or other risks for DRSP infection.



Dosage

Comparative studies

Azithromycin

Clarithromycin



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References





### IDSA Adults CAP guidelines, 2007

Recommend a **β-lactam plus a macrolide** (high-dose amoxicillin [e.g., 1 g 3 times daily] or **amoxicillin-clavulanate** [2 g, 2 times daily] is preferred) as empirical antimicrobial therapy in certain conditions\*<sup>1</sup>

1. Lionel A. Mandell et al., Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults, Clinical Infectious Diseases 2007; 44(2):S27–72.

\* in presence of comorbidities, such as chronic heart, lung, liver, or renal disease; diabetes mellitus; alcoholism; malignancies; asplenia; immunosuppressing conditions or use of immunosuppressing drugs; use of antimicrobials within the previous 3 months (in which case an alternative from a different class should be selected); or other risks for DRSP infection



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References





### IDSA Adults CAP guidelines, 2007

Recommend High-dose amoxicillin [e.g., 1 g 3 times daily] or **amoxicillin-clavulanate [2 g 2 times daily]** as preferred treatment of CAP in presence of comorbidities, such as chronic heart, lung, liver, or renal disease; diabetes mellitus; alcoholism; malignancies; asplenia; immunosuppressing conditions or use of immunosuppressing drugs<sup>1</sup>

1. Lionel A. Mandell et al., Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults, Clinical Infectious Diseases 2007; 44(2):S27–72.



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## BTS guidelines 2009

Recommend parenteral amoxicillin-clavulanate as the **preferred initial empirical treatment regimen** for high severity community acquired pneumonia in adults<sup>1</sup>

1. Lim WS, Baudouin SV, George RC, et al. BTS guidelines for the management of community -acquired pneumonia in adults update 2009, Thorax 2009, Thorax 2009;64(3):1-55



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## Augmentin 875 mg Tablets Indication:

Augmentin is indicated for the treatment of the following infections in adults and children:

- Acute bacterial sinusitis (adequately diagnosed)
- Acute otitis media
- Acute exacerbations of chronic bronchitis (adequately diagnosed)
- Community acquired pneumonia
- Cystitis
- Pyelonephritis
- Skin and soft tissue infections in particular cellulitis, animal bites, severe dental abscess with spreading cellulitis.
- Bone and joint infections, in particular osteomyelitis.

Consideration should be given to official guidance on the appropriate use of antibacterial agents.

### Dosage in adults<sup>1</sup>

Mild to moderate infections

875/125 mg given twice daily

Severe infections  
(including chronic and recurrent  
lower respiratory tract)

875/125 mg given 2 or 3 times daily

1. Augmentin PI MOH approved



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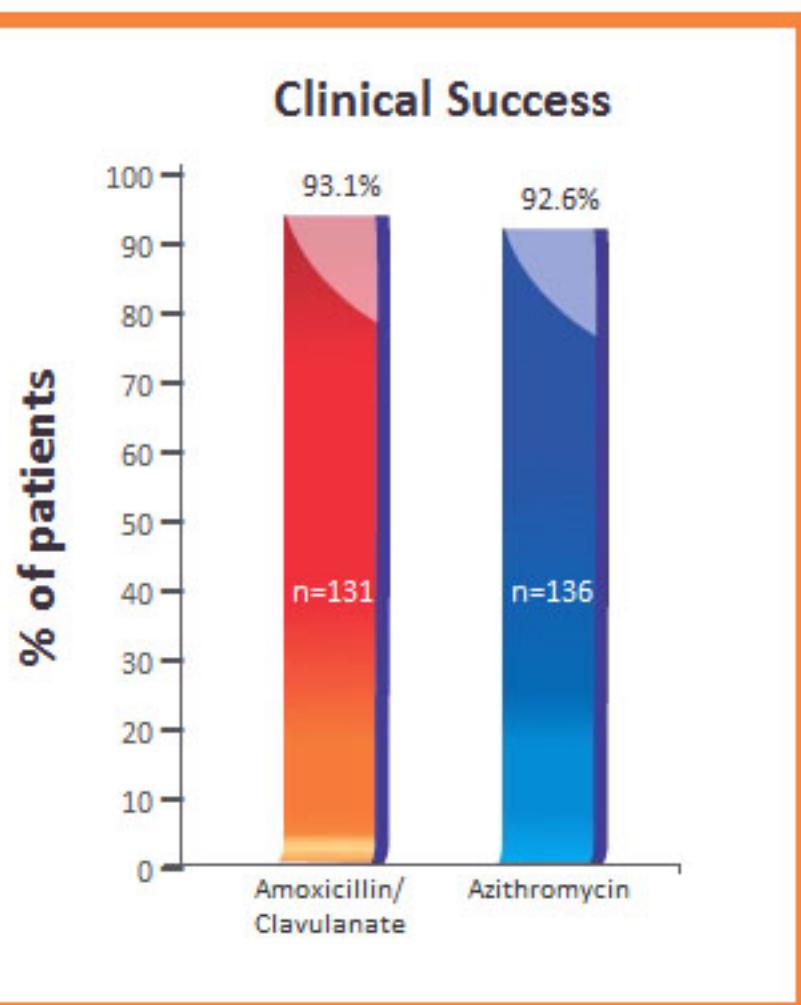
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## Comparable clinical efficacy vs. azithromycin in adult CAP patients<sup>1</sup>



### Abstract

An open-label randomised comparison of efficacy and safety of amoxicillin-clavulanate 875/125 mg twice daily for 7 days with azithromycin 1 g once daily for 3 days in the treatment of adult patients with community-acquired pneumonia showed the clinical success rate of azithromycin to be 92.6% whereas that of amoxicillin-clavulanate to be 93.1%.

- Clinical success rates were 92.6% for azithromycin and 93.1% for amoxicillin-clavulanate

1. Paris R, Confalonieri M, Mos L, et al. Efficacy and safety of azithromycin 1g once daily for 3 days in the treatment of community -acquired pneumonia:an open-label randomised comparison with amoxicillin-clavulanate 875/125 mg twice daily for 7 days. J Chemother. 2008 Feb; 20(1):77-86.



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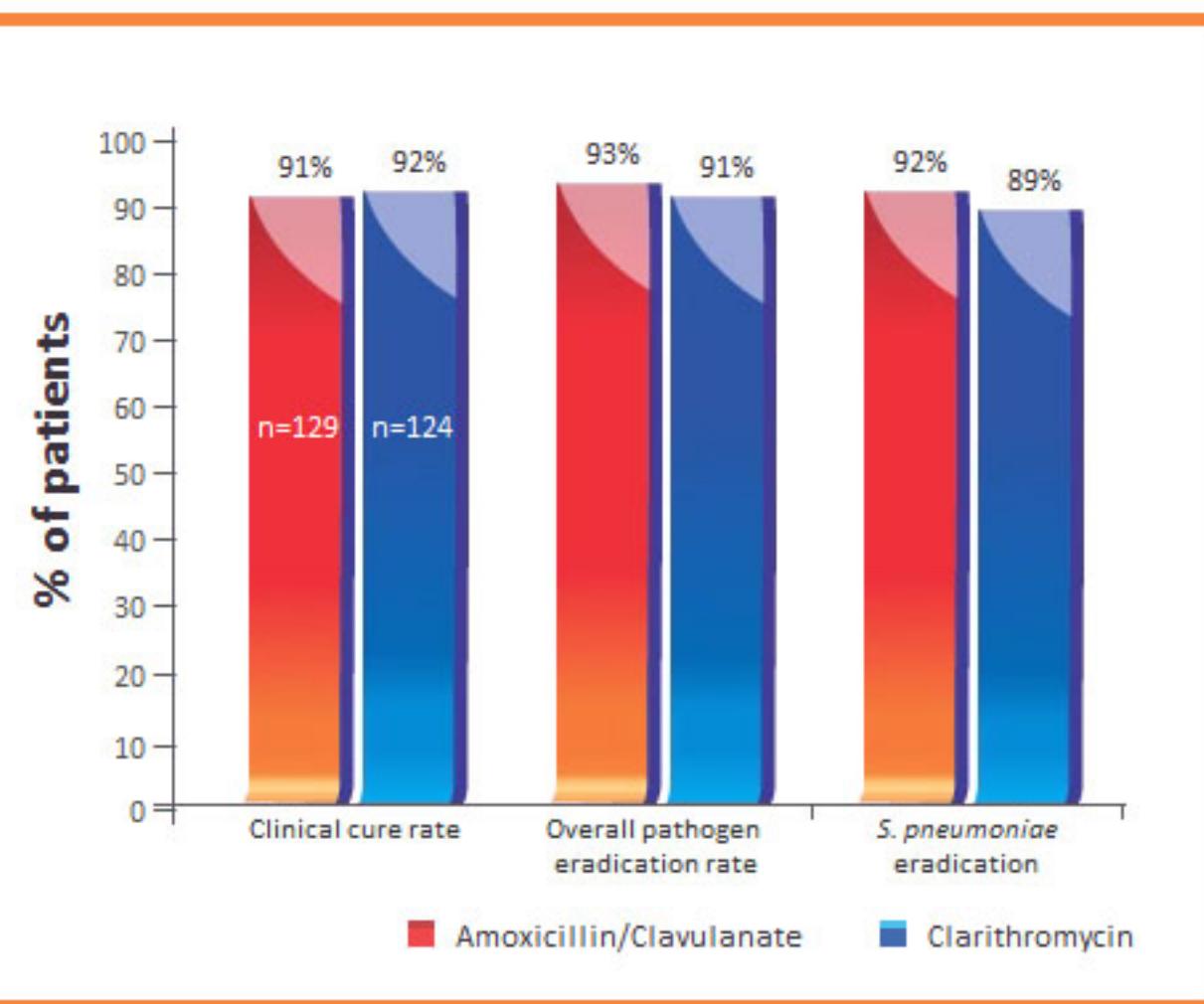
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## Comparable clinical efficacy vs. clarithromycin in CAP<sup>1</sup>



### Abstract

A comparative study of the safety and efficacy of clarithromycin and amoxicillin/clavulanic acid in patients with community-acquired pneumonia due to penicillin-resistant and/or macrolide-resistant *Streptococcus pneumoniae*, showed the overall eradication rate for pathogens to be 91% for clarithromycin and 93% for amoxicillin/clavulanic acid, and 89% and 92%, respectively, for *S.pneumoniae* strains.

1. Bonvehi P, Weber K, Busman T, et al. Comparison of Clarithromycin and Amoxicillin/Clavulanic acid for Community-Acquired Pneumonia in an Era of Drug-Resistant *Streptococcus pneumoniae*. Clin Drug Investig. 2003; 23(8): 491-501.



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# Augmentin® 875 mg Tablets

Amoxicillin as trihydrate 875 mg

Clavulanic Acid as potassium salt 125 mg

- Achieves adequate concentration in lungs<sup>1, 2</sup>
- Proven clinical and bacteriological efficacy in CAP<sup>3, 4</sup>
- Recommended by leading guidelines<sup>5, 6</sup>
- Available in > 100 countries<sup>7</sup>
- 3 decades of sustained clinical and bacteriological success rates<sup>8, 9, 10</sup>
- Enhanced formulation available<sup>11, 12, 13, 14</sup>



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5. Watkins R, Lemonovich T, et al. Diagnosis and Management of Community-Acquired Pneumonia in Adults. American Academy of Family Physicians 2011; 83 (11): 1299-1306.
6. Mandell LA, Wunderink RG, Anzueto A, et al. Infectious Diseases Society of America/American Thoracic Society consensus guidelines on the management of community-acquired pneumonia in adults. Clin Infect Dis. 2007 Mar 1;44 Suppl 2:S27-72.
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## Adequate concentration in lungs<sup>1</sup>

- Achieves concentrations well above the MIC<sub>50</sub> for the common bacterial respiratory pathogens including *H. influenzae*, *M. catarrhalis* and *S. pneumoniae*<sup>1</sup>
- Mean mucosal levels were 200% and 118% of the corresponding serum levels for amoxicillin and clavulanic acid respectively<sup>1</sup>

Dose of amoxicillin (co-amoxiclav) <sup>1</sup>	Serum levels (mg/l)	Bronchial mucosa levels (mg/l)
250 mg	2.6	4.1
500 mg	5.6	10.1
Dose of clavulanic acid (co-amoxiclav) <sup>1</sup>	Serum levels (mg/l)	Bronchial mucosa levels (mg/l)
125 mg	1.4	1.9
250 mg	2.3	2.4

1. Gould IM, et al. Penetration of amoxycillin/clavulanic acid into bronchial mucosa with different dosing regimens., Thorax, 1994 Oct;49(10):999-1001.



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## Proven clinical and bacteriological efficacy<sup>1,2</sup>



Year/Author	Augmentin dose	Comparator dose	Clinical efficacy	Bacteriological efficacy
Paris R, et al. 2008 (CAP)	7-day course of oral amoxicillin-clavulanate 875/125 mg twice daily	3-day course of oral azithromycin 1g once daily	Clinical success rates were 92.6% for azithromycin and 93.1% for amoxicillin clavulanate	Bacteriological efficacy
Bonvehi P, et al. 2003 (CAP)	875mg/125mg twice daily	Clarithromycin 500mg immediate-release	<ul style="list-style-type: none"> <li>● Clarithromycin=92%</li> <li>● Amoxicillin-clavulanic acid=91%</li> </ul>	<ul style="list-style-type: none"> <li>● Clarithromycin=91 %</li> <li>● Amoxicillin/clavulanic acid=93%</li> </ul>
Mouton Y, et al. 1991 (CAP)	Not specified	Ciprofloxacin (750mg b.i.d.)	Clinical recovery was achieved in of patients in; <ul style="list-style-type: none"> <li>● Clarithromycin=73.3%</li> <li>● Amoxicillin + clavulanic acid=81.8%</li> </ul>	

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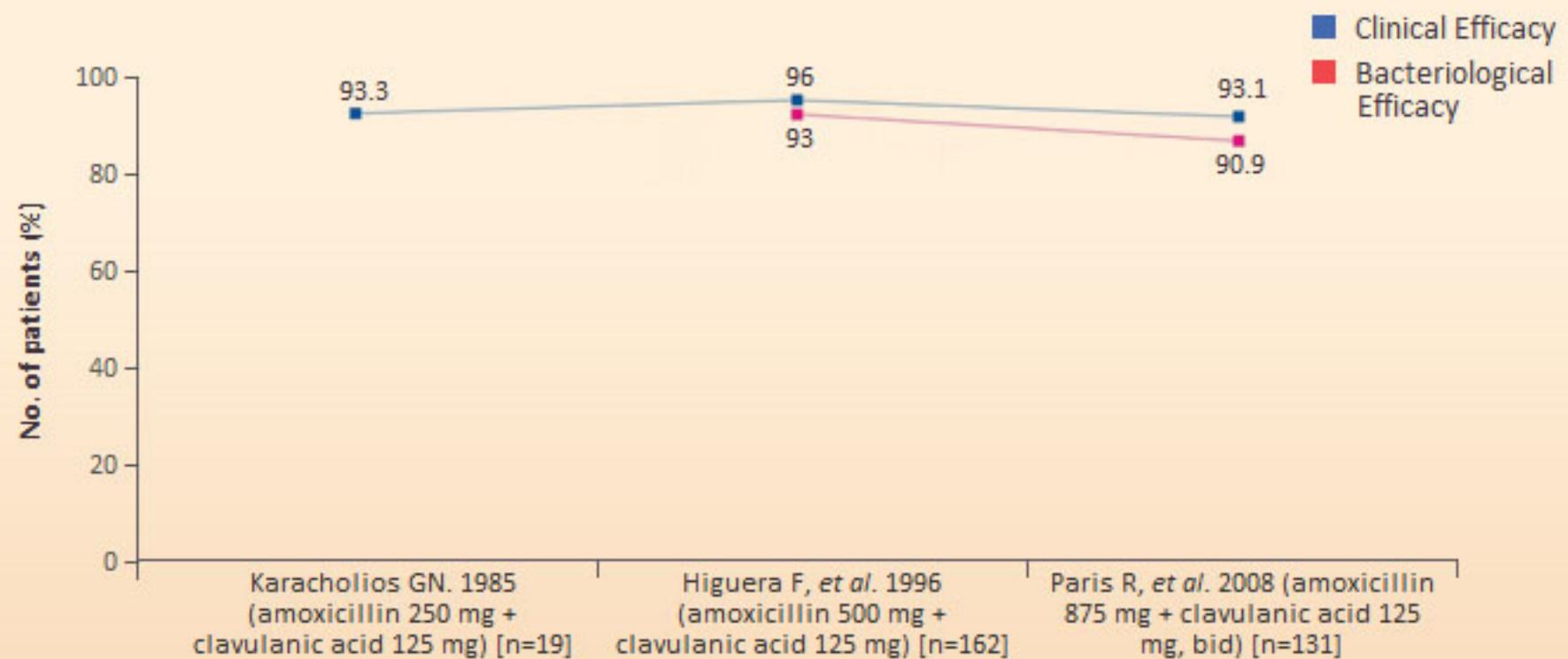


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Sustained clinical and bacteriological success rates<sup>1,2,3</sup>

Disclaimer: Data taken from separate studies with differing dosage forms

1. Karachalios GN. Treatment of respiratory tract infections with a combination of amoxycillin and clavulanic acid. *Int J Clin Pharmacol Ther Toxicol.* 1985 Dec;23(12):647-9.
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such as blood and sputum cultures. Conversely, these cultures may have a major impact on the care of an individual patient and are important for epidemiologic reasons, including the antibiotic susceptibility patterns used to develop treatment guidelines. A list of clinical indications for more extensive diagnostic testing (Table 5) was, therefore, developed, primarily on the basis of 2 criteria: (1) when the test is likely to change individual antibiotic management and (2) when the test is likely to have the highest yield.

11. Routine diagnostic tests to identify an etiologic diagnosis are optional for outpatients with CAP. (Moderate recommendation; level III evidence.)
12. Postmortem blood samples for culture and an expectorated sputum sample for stain and culture (in patients with a productive cough) should be obtained from hospitalized patients with the clinical indications listed in Table 5 but are optional for patients without these conditions. (Moderate recommendation; level I evidence.)
13. Postmortem Gram stain and culture of expectorated sputum should be performed only if a good-quality specimen can be obtained and quality performance measures for collection, transport, and processing of samples can be met. (Moderate recommendation; level II evidence.)
14. Patients with severe CAP, defined above, should have blood samples taken for culture, as well as antigen tests for *Legionella pneumophila*, *Campylobacter pneumoniae* (serology), and respiratory secretions samples collected for culture. For selected patients, non-diagnostic sputum samples should be obtained. (Moderate recommendation; level II evidence.)

The most clear-cut indication for extensive diagnostic testing is in the critically ill CAP patient. Such patients should at least have blood drawn for culture and an endotracheal aspirate obtained. If they are intubated, consideration should be given to more extensive testing, including urinary antigen tests for *E. pneumoniae* and *S. pneumoniae* and Gram stain and culture of expectorated sputum in nonintubated patients. For patients without the clinical indications listed in Table 5, diagnostic testing is optional (but should not be considered wrong).

#### **Antibiotic Treatment**

**Empirical antimicrobial therapy.** Empirical antibiotic recommendations (Table 7) have not changed significantly from those in previous guidelines. Increasing evidence has strengthened the recommendation for combination empirical therapy for severe CAP. Only 1 recently released antibiotic has been added to the recommended regimens, as an acceptable  $\beta$ -lactam alternative for hospitalized patients with risk factors for infection with gram-negative pathogens other than *Pseudomonas aeruginosa*. At present, the committee is awaiting further evaluation of the safety of telithromycin by the US Food

and Drug Administration before making its final recommendation regarding this drug. Recommendations are generally for a class of antibiotics rather than for a specific drug, unless outcome data clearly favor one drug. Because overall efficacy remains good for many classes of agents, the more potent drugs are given preference because of their benefit in decreasing the risk of selection for antibiotic resistance.

#### **Outpatient treatment**

15. Previously healthy and no risk factors for drug-resistant *S. pneumoniae* (DRSP) infection:
  - A. A macrolide (aztreonam, clarithromycin, or erythromycin) (strong recommendation; level I evidence)
  - B. Doxycycline (weak recommendation; level III evidence)
16. Presence of comorbidities, such as chronic heart, lung, liver, or renal disease; diabetes mellitus; alcoholism; malignancy; immunosuppressive conditions or use of immunosuppressive drugs; use of antimicrobials within the previous 3 months (in which case an alternative from a different class should be selected); or other risks for DRSP infection:
  - A. A respiratory fluoroquinolone (moxifloxacin, gatifloxacin, or levofloxacin [750 mg]) (strong recommendation; level I evidence)
  - B. A  $\beta$ -lactam plus a macrolide (using minimum doses; level I evidence) (High-dose amoxicillin [e.g., 8 times daily] or amoxicillin-clavulanate [2 g 2 times daily]). Preferred alternatives include ceftriaxone, cefdinir, and cefuroxime (500 mg 2 times daily); doxycycline (level II evidence) is an alternative to the macrolide.)
17. In regions with a high rate (>20%) of infection with high-level (MIC,  $\geq$ 16  $\mu$ g/ml) *S. pneumoniae*; consider the use of alternative agents listed above in recommendation 16 for all patients, including those without comorbidities. (Moderate recommendation; level III evidence.)

#### **Inpatient, non-ICU treatment**

18. A respiratory fluoroquinolone (strong recommendation; level I evidence)
19. A  $\beta$ -lactam plus a macrolide (strong recommendation; level I evidence) (Preferred  $\beta$ -lactam agents include aztreonam, ceftriaxone, and ampicillin; ciprofloxacin for selected patients, with doxycycline (level III evidence) as an alternative to the macrolide. A respiratory fluoroquinolone should be used for penicillin-allergic patients.)

Increasing resistance rates have suggested that empirical therapy with a macrolide alone can be used only for the treat-

**A  $\beta$ -lactam plus a macrolide (strong recommendation; level I evidence) (High-dose amoxicillin [e.g., 1 g 3 times daily] or amoxicillin-clavulanate [2 g 2 times daily] is preferred<sup>1</sup>**

**IDSA Guidelines 2007**

ISPA 071-Guideline for CAP in Adults + CDP 2007 (Suppl 2) + 12W

1. Lionel A. Mandell *et al.*, Infectious Diseases Society of America/American Thoracic Society Consensus Guidelines on the Management of Community-Acquired Pneumonia in Adults, *Clinical Infectious Diseases* 2007; 44(2):S27–72.



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## Community-Acquired Pneumonia

**Table 7. Empiric Therapy for Community-Acquired Pneumonia**

Patient group	Initial therapy
Previously healthy outpatients; no antibiotic use in past three months	A macrolide or doxycycline
Outpatients with comorbidities* or antibiotic use in past three months	A respiratory fluoroquinolone (levofloxacin [Levaquin], moxifloxacin [Avelox]), or mifleroxacin [Aztreonam], or a beta-lactam antibiotic (aztreonam amoxicillin, amoxicillin-clavulanate [Augmentin]), or cefpodoxime plus a macrolide
Inpatients, non-ICU	A respiratory fluoroquinolone, or a beta-lactam antibiotic plus a macrolide
Inpatients, ICU	A beta-lactam antibiotic (aztreonam, ceftazidime [Ceftazidime], ceftriaxone [Rocephin], cefotaxime [Ceftazidime] or ceftazidime [Ceftazidime] plus aztreonam [Zefazin]), plus aztreonam (Zefazin) or a respiratory fluoroquinolone
Special considerations:	
Risk factors for <i>Pseudomonas</i> species	A beta-lactam antibiotic (imipenem/cilastatin [Primaxin], meropenem [Merrem]), or carbapenem either (iprifloxacine [Ciprofloxacin] or levofloxacin)
Risk factors for methicillin-resistant <i>Staphylococcus aureus</i>	The above beta-lactam antibiotic plus an aminoglycoside and aztreonam
Influenza virus	The above beta-lactam antibiotic plus an aminoglycoside and an antipseudomonal respiratory fluoroquinolone (aztreonam or imipenem/cilastatin)
ICU = intensive care unit.	
*—Chronic heart, lung, liver, or renal disease; diabetes mellitus; alcoholism; malignancy; asthma.	
—Antibiotic from a different class should be used.	
—Adults recommended in regions where a rate of high-level macrolide-resistant <i>Streptococcal pneumoniae</i> of greater than 20 percent.	
—For patients allergic to penicillin, a respiratory fluoroquinolone plus aztreonam (Zefazin) are recommended.	
Adapted with permission from Marsteller LA, Bhandarkar AG, Anzueto A, et al. Infectious Diseases Society of America/American Thoracic Society joint clinical guidelines on the management of community-acquired pneumonia in adults. Clin Infect Dis. 2007;44(Suppl 3):S1-S22.	

are listed in Table 7.<sup>21</sup> One of the major differences between U.S. and European guidelines for treatment of CAP is that all patients in the United States receive treatment for *S. pneumoniae* and atypical organisms because CAP is more often caused by these pathogens in North America.<sup>22</sup> Macrolides (e.g., aztreonam [Zefazin], clarithromycin [Bacitracin]) can be used for outpatients with no cardiopulmonary disease or recent antibiotic use.

Drug-resistant *S. pneumoniae* is a concern in patients with comorbid illness or recent antibiotic therapy (within previous three months) and should be treated with an oral beta-lactam antibiotic (e.g., high-dose amoxicillin, amoxicillin/clavulanate [Augmentin], cefpodoxime combined with a macrolide). A respiratory fluoroquinolone is another choice. If a patient has used an antibiotic in the previous three months, a drug from a different class should be prescribed to decrease the risk of pseudomonal resistance. For hospitalized patients not admitted to the ICU, an intravenous respiratory fluoroquinolone

alone or an intravenous beta-lactam antibiotic combined with a macrolide or doxycycline should be given. A study showed doxycycline to be comparable to levofloxacin (Levaquin) in effectiveness, length of hospital stay, and failure rate for empiric treatment of CAP; doxycycline is also a less-expensive option for hospitalized patients who are not admitted to the ICU.<sup>23</sup> However, the sample size in the study was small and IDSA/ATS guidelines recommend doxycycline only for outpatients.<sup>21</sup>

All patients with CAP who are admitted to the ICU should be treated with dual therapy, which is associated with lower mortality from bacteremic pneumococcal pneumonia and improves survival in patients with CAP and shock.<sup>24</sup> Some patients with severe CAP, especially after an episode of influenza or viral illness, who are admitted to the ICU need added coverage for *S. aureus*, including MRSA. MRSA-associated CAP is characterized by a severe, bilateral, necrotizing pneumonia induced by Panton-Valentine leukocidin and other toxins.

1304 American Family Physician

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Volume 83, Number 11 • June 1, 2011

AAFP Guidelines 2011

Drug-resistant *S. pneumoniae* is a concern in patients with comorbid illness or recent antibiotic therapy (within previous three months) and should be treated with an oral beta-lactam antibiotic (e.g., high-dose amoxicillin, amoxicillin/clavulanate [Augmentin], cefpodoxime) combined with a macrolide<sup>21</sup>

with a macrolide<sup>21</sup>

- Watkins R, Lemonovich T, et al. Diagnosis and Management of Community-Acquired Pneumonia in Adults. American Academy of Family Physicians 2011; 83 (11): 1299-1306.



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### MAIN SAFETY DATA<sup>1</sup>

- ▶ The most common adverse effects are diarrhoea, nausea, vomiting and mucocutaneous candidiasis<sup>1</sup>
- ▶ Nausea is more often associated with higher oral dosages. If gastrointestinal reactions are evident, they may be reduced by taking Augmentin at the start of a meal<sup>1</sup>
- ▶ Careful inquiry should be made concerning previous hypersensitivity reactions to penicillins, cephalosporins or other allergens, before initiating therapy with Augmentin<sup>1</sup>
- ▶ Should be used with caution in patients with evidence of hepatic dysfunction<sup>1</sup>

Reference 1: Augmentin 875 PI MOH approved



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