Fluoroquinolone Criteria for Use

VHA Pharmacy Benefits Management Strategic Healthcare Group and the Medical Advisory Panel

The following recommendations are dynamic and will be revised, as new clinical data become available. These criteria are not intended to interfere with clinical judgment. Rather, they are intended to assist practitioners in providing cost effective, consistent, high quality care.

Patient Selection: Please note that this document discusses the most common indications for fluoroquinolone use. It is not intended to be a comprehensive list of all appropriate uses of fluoroquinolones or to delineate all of the circumstances where one particular fluoroquinolone is the appropriate agent.[1-3]. It should be remembered that non-formulary requests for outpatient use of these agents should be reviewed in a timely manner, following the criteria.

Urinary tract infections:

Due to antimicrobial resistance fluoroquinolones may be the antimicrobial of choice for empiric treatment of urinary tract infections. For this indication, based on safety, efficacy and price ciprofloxacin is the fluoroquinolone of choice.

Community-acquired pneumonia:

Hospitalized patients**:** First line therapy is generally with the combined use of a macrolide and a beta-lactam agent active against penicillin-resistant *Streptococcus pneumoniae* (e.g., cefotaxime or ceftriaxone).

Outpatients: Use of fluoroquinolones requires radiological evidence of pneumonia and should be consistent with guidelines.[4] Oral moxifloxacin is an appropriate agent in these cases.

Other upper and lower respiratory tract infections:

Fluoroquinolones are generally second or third line agents based on the likely or proven susceptibility of known or probable infectious agents.[4-8]

Healthcare-associated pneumonia and hospital-acquired pneumonia:

Guidelines for the treatment of healthcare-associated pneumonia/hospital-acquired pneumonia need to be developed locally in recognition of local epidemiology of disease and patterns of antimicrobial resistance. Where fluoroquinolones are appropriate, the agents of choice are either levofloxacin (which has activity against *Streptococci* and *P. aeruginosa*) or ciprofloxacin (which has activity against *P. aeruginosa* but not against *S. pneumoniae*).

Safety concerns with fluoroquinolone therapy involve the use of these agents in specific populations.

Patients with a history of long QT syndrome, hypokalemia or who are receiving Class Ia or class III antiarrhythmic agents (quinidine, disopyramide, procainamide, sotalol, amiodarone, dofetilide, ibutilide) are predisposed to development of Torsades de Pointes or other cardiac arrhythmias. These arrhythmias have been reported with levofloxacin and moxifloxacin.

Disturbances of blood glucose, including symptomatic hypoglycemia and hyperglycemia, have been reported with all fluoroquinolones. The risk of dysglycemia is greatest in diabetic patients. However, hypoglycemia and particularly hyperglycemia have occurred in patients without a history of diabetes.

Criteria for use of Levofloxacin- both IV and oral

<table>
<tr><th>If the answer to either Indication for therapy or Identification of risk factors is "yes" the patient is eligible for levofloxacin therapy</th><th></th></tr>
<tr><td>Indication for therapy</td><td></td></tr>
<tr><td>Ventilator dependent pneumonia
Healthcare associated pneumonia</td><td>❑ yes
❑ no</td></tr>
<tr><td>Identification of risk factors</td><td></td></tr>
<tr><td>Patient at risk for P. aeruginosa; bronchectisis, cystic fibrosis, or previous antibiotic therapy within the past month?</td><td>❑ yes
❑ no</td></tr>
<tr><td>Patient shows no response to current antibiotic therapy</td><td>❑ yes
❑ no</td></tr>
<tr><td>Levofloxacin dosage</td><td></td></tr>
<tr><td>Healthcare associated/ventilator dependent pneumonia</td><td>Normal renal function 750 mg IV daily*
Impaired renal function
<table>
<tr><th></th><th>Initial</th><th>subsequent dosing</th></tr>
<tr><td>Ccr 20 to 49 mL/min</td><td>750 mg</td><td>750 mg every 48 h</td></tr>
<tr><td>Ccr 10 to 19 mL/min</td><td>750 mg</td><td>500 mg every 48 h</td></tr>
<tr><td>Hemodialysis</td><td>750 mg</td><td>500 mg every 48 h</td></tr>
<tr><td>CAPD</td><td>750 mg</td><td>500 mg every 48 h</td></tr>
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IV- intravenous, PO- orally

***- patients may be transitioned to oral levofloxacin therapy when appropriate, either after receiving IV levofloxacin or other appropriate IV therapy. Local consensus protocols should be consulted for specific antibiotic choice(s) and for relevant approval processes in these circumstances.**

References

1. Package insert Cipro® Bayer Corporation. West Haven, CT, 2004.
2. Package insert Levaquin®. Ortho Mc-Neil Pharmaceutical, Inc. Raritan NJ. 2004.
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4. Mandell LA, Bartlett JG, Dowell SF, File TM, Jr., Musher DM, Whitney C. Update of practice guidelines for the management of community-acquired pneumonia in immunocompetent adults. Clin Infect Dis. 2003; 37:1405-33.
5. Pauwels RA, Buist AS, Calverley PM, Jenkins CR, Hurd SS. Global strategy for the diagnosis, management, and prevention of chronic obstructive pulmonary disease. NHLBI/WHO Global Initiative for Chronic Obstructive Lung Disease (GOLD) Workshop summary. Am J Respir Crit Care Med. 2001; 163:1256-76.
6. Snow V, Mottur-Pilson C, Hickner JM. Principles of appropriate antibiotic use for acute sinusitis in adults. Ann Intern Med. 2001; 134:495-7.
7. Sinus and Allergy Health Partnership Antimicrobial treatment guidelines for acute bacterial rhinosinusitis Otolaryngology–Head and Neck Surgery. 2004; --130(suppl):1-45.
8. ---Guidelines for the Management of Adults with Hospital-acquired, Ventilator-associated, and Healthcare-associated Pneumonia. **Am J Respir Crit Care Med Vol 171. pp 388–416, 2005**
9. Mohr JF, McKinnon PS, Peymann PJ, Kenton I, Septimus E, Okhuysen PC. A retrospective, comparative evaluation of dysglycemias in hospitalized patients receiving gatifloxacin, levofloxacin, ciprofloxacin, or ceftriaxone. Pharmacotherapy. 2005 Oct;25(10):1303-9.
10. VHA National AUE Summary Report: Quinolones causing dysglycemia. PBM/MAP EZ minutes June 2004. http://vaww.pbm.va.gov/ezminutes/Ez-MinutesVol2Iss2Apr-June04.pdf