

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Fluoroquinolone Agents, Oral PDL Edit
<b>First Implementation Date:</b>	June 1, 2005
<b>Proposed Date:</b>	June 17, 2021
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input checked="" type="checkbox"/> Existing Criteria <input type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

**Why Issue Selected:** The fluoroquinolones are synthetic, broad-spectrum antibacterial agents that inhibit bacterial DNA synthesis by binding to DNA gyrase and DNA topoisomerase IV which causes DNA cleavage. DNA gyrase is an essential enzyme involved in the replication, transcription, and repair of bacterial DNA; inhibiting this enzyme will ultimately cause bacterial cell death. Each of the fluoroquinolones are effective in treating both gram-positive and gram-negative infections, and in treating urinary tract infections caused by susceptible organisms. Clinical evidence suggests that all the products within this therapeutic class are equally efficacious for the vast majority of respiratory tract infections. Each fluoroquinolone is absorbed from the upper gastrointestinal tract and most come in both oral and intravenous formulations. Dairy, antacids, multivitamins containing zinc, and other medications with cations can decrease the absorption of fluoroquinolones. Therefore, taking any of those products with a fluoroquinolone should be avoided or at least taken separately by at least 2 hours. In addition, most fluoroquinolones prolong the QT interval, so using these medications with other medications that prolong the QT interval should be avoided.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> <li>• Ciprofloxacin Tabs</li> <li>• Levofloxacin Tabs</li> </ul>	<ul style="list-style-type: none"> <li>• Baxdela®</li> <li>• Cipro®</li> <li>• Cipro XR®</li> <li>• Ciprofloxacin Susp</li> <li>• Ciprofloxacin ER</li> <li>• Levofloxacin Soln</li> <li>• Moxifloxacin Tabs</li> <li>• Ofloxacin Tabs</li> </ul>

**Type of Criteria:**  Increased risk of ADE  Preferred Drug List  
 Appropriate Indications  Clinical Edit

**Data Sources:**  Only Administrative Databases  Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Fluoroquinolones, Oral
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 1 or more preferred agents
  - Documented trial period of preferred agents **OR**
  - Documented ADE/ADR to preferred agents

## Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if all approval criteria are not met

## Required Documentation

Laboratory Results:  
MedWatch Form:

  

Progress Notes:  
Other:

  

## Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)  
Rule Type: PDL

## Default Approval Period

1 year

## References

1. USPDI, Micromedex; 2021.
2. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.
3. Evidence-Based Medicine and Fiscal Analysis: "Fluoroquinolones – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; June 2021.
4. Evidence-Based Medicine Analysis: "Fluoroquinolones (Oral)", UMKC-DIC; April 2021.
5. Cipro [package insert]. Whippany, NJ: Bayer Healthcare Pharmaceuticals Inc; March 2021.
6. Baxdela [package insert]. Lincolnshire, IL: Melinta Therapeutics, Inc.; February 2021.
7. Ofloxacin [package insert]. Sacramento, CA: Nivagen Pharmaceuticals, Inc; May 2020.