# SmartPA Criteria Proposal

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|---|---|
| **Drug/Drug Class:** | Fluoroquinolones, Oral PDL Edit |
| **First Implementation Date:** | June 1, 2005 |
| **Proposed Date:** | June 18, 2020 |
| **Prepared For:** | MO HealthNet |
| **Prepared By:** | MO HealthNet/Conduent |
| **Criteria Status:** | ☒Existing Criteria<br>☐Revision of Existing Criteria<br>☐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 |
|---|---|
| • Ciprofloxacin Tabs<br>• Levofloxacin Tabs | • Baxdela™<br>• Cipro®<br>• Ciprofloxacin ER<br>• Ciprofloxacin Susp<br>• Levaquin®<br>• Levofloxacin Soln<br>• Moxifloxacin<br>• Ofloxacin |

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| **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 no approval criteria are met

## Required Documentation

| | | | |
|---|---|---|---|
| Laboratory Results: | ☐ | Progress Notes: | ☐ |
| MedWatch Form: | ☐ | Other: | ☐ |

## Disposition of Edit

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

## Default Approval Period

1 year

## References


1. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
2. USPDI, Micromedex; 2020.
3. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.
4. Evidence-Based Medicine and Fiscal Analysis: “Fluoroquinolones – Therapeutic Class Review”, Conduent Business Services, L.L.C., Richmond, VA; April 2020.
5. Evidence-Based Medicine Analysis: “Fluoroquinolones (Oral)”, UMKC-DIC; April 2020.
6. Cipro [package insert]. Whippany, NJ: Bayer Healthcare Pharmaceuticals Inc; 2020.
7. Cipro XR [package insert]. Whippany, NJ: Bayer Healthcare Pharmaceuticals Inc; 2020.
8. Baxdela [package insert]. Lincolnshire, IL: Melinta Therapeutics, Inc.; 2019.
9. Levaquin [package insert]. Titusville, NJ: Jassen Pharmaceuticals Inc; 2020.
10. Ofloxacin [package insert]. Sacramento, CA: Nivagen Pharmaceuticals, Inc; 2018.