

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Macrolides PDL Edit
<b>First Implementation Date:</b>	May 25, 2005
<b>Proposed Date:</b>	September 15, 2022
<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:** Macrolide antibiotics reversibly bind to the P-site of the 50S ribosomal subunit of susceptible organisms and may inhibit RNA-dependent protein synthesis. They may be bacteriostatic or bacteriocidal, depending on such factors as drug concentration. There are currently four macrolides available in the U.S. They are all equally efficacious for the treatment of most community-acquired infections, but some have better tolerability and allow for once to twice daily dosing. The most common adverse effects are gastrointestinal in nature (i.e., abdominal discomfort, vomiting, diarrhea), are often dose dependent, and occur more often in children. Macrolides, particularly erythromycin and clarithromycin, pose a risk of QT prolongation and should be used cautiously in patients at risk of developing arrhythmias or when used concomitantly with other medications that may alter cardiac function.

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>• Azithromycin Pwd Packet/Susp/Tabs</li> <li>• Clarithromycin Susp/Tabs</li> <li>• E.E.S. 200<sup>®</sup> Susp</li> <li>• EryPed<sup>®</sup> Susp</li> <li>• Erythromycin Base DR Caps</li> <li>• Erythromycin Ethylsuccinate Tabs</li> </ul>	<ul style="list-style-type: none"> <li>• Clarithromycin ER</li> <li>• E.E.S. 400<sup>®</sup></li> <li>• Ery-Tab<sup>®</sup></li> <li>• Erythromycin Base Tabs</li> <li>• Erythromycin Base DR Tabs</li> <li>• Erythromycin Ethylsuccinate Susp</li> <li>• Zithromax<sup>®</sup></li> </ul>

**Type of Criteria:**  Increased risk of ADE  
 Appropriate Indications

Preferred Drug List  
 Clinical Edit

**Data Sources:**  Only Administrative Databases

Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Macrolide Agents

### SmartPA PDL Proposal Form

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- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- Failure to achieve desired therapeutic outcomes with trial on 2 or more preferred agents
  - Documented trial period for 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

- Evidence-Based Medicine Analysis: "Macrolides", UMKC-DIC; February 2022.
- Evidence-Based Medicine and Fiscal Analysis: "Macrolides - Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; June 2021.
- USPDI, Micromedex; 2022.
- Facts and Comparisons eAnswers (online); 2022 Clinical Drug Information, LLC.