

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Tetracyclines PDL Edit
<b>First Implementation Date:</b>	June 21, 2012
<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 type="checkbox"/> Existing Criteria <input checked="" 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:** Tetracyclines are broad spectrum antibiotics used to treat bacterial infections, including respiratory tract infections (i.e. pneumonia), acne, infections of the skin, genital and urinary systems, and H. pylori. These products are also routinely used as alternatives to other medications for the treatment of Lyme disease and for the treatment of anthrax after inhalational exposure. Tetracyclines bind to the 30S subunit of microbial ribosomes and inhibit protein synthesis by blocking the attachment of the amino acid, aminoacyl-tRNA. Due to risk of bone growth inhibition and tooth discoloration, these agents are generally not recommended for use in pregnant women or children under eight years of age.

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>• Doxycycline Hyclate Caps</li> <li>• Doxycycline Hyclate Tabs (gen Vibra-Tabs®, Periostat®)</li> <li>• Doxycycline Mono Susp</li> <li>• Minocycline Caps</li> </ul>	<ul style="list-style-type: none"> <li>• Amzeeq®</li> <li>• Demeclocycline</li> <li>• Doryx®</li> <li>• Doryx® MPC</li> <li>• Doxycycline Hyclate Tabs (gen Acticlate®)</li> <li>• Doxycycline Hyclate DR</li> <li>• Doxycycline Mono Caps/Tabs</li> <li>• Doxycycline Mono IR-DR</li> <li>• Minocin®</li> <li>• Minocycline ER</li> <li>• Minocycline Tabs</li> <li>• Minolira™</li> <li>• Mondoxyne™ NL</li> <li>• Morgidox®</li> <li>• Nuzyra®</li> <li>• Oracea®</li> <li>• Solodyn®</li> <li>• Tetracycline</li> </ul>

	<ul style="list-style-type: none"> <li>• Vibramycin®</li> <li>• Xerava™</li> <li>• Ximino®</li> <li>• Zilxi™</li> </ul>
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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: Tetracyclines
- Age range: All appropriate MO HealthNet participants

## Approval Criteria

- For demeclocycline: approvable as first-line therapy with a documented diagnosis of chronic syndrome of inappropriate secretion of antidiuretic hormone in the past 2 years **OR**
- Failure to achieve desired therapeutic outcomes with trial on 2 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: "Tetracyclines – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; June 2021.
4. Evidence-Based Medicine Analysis: "Tetracyclines", UMKC-DIC; March 2021.

*SmartPA PDL Proposal Form*  
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6. Doryx MPC [package insert]. Greenville, NC: Mayne Pharma USA; February 2020.
7. Vibramycin [package insert]. New York, NY: Pfizer Labs; April 2021.
8. Morgidox [package insert]. Fairfield, NJ: Medimetriks Pharmaceuticals, Inc; December 2020.
9. Minocin [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; 2019.
10. Oracea [package insert]. Fort Worth, Texas: Galderma Laboratories, L.P.; August 2017.
11. Minolira Extended Release [package insert]. Charleston, SC: EPI Health, LLC; June 2018.
12. Solodyn [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; September 2017.
13. Ximino [package insert]. Scottsdale, AZ: Journey Medical Corp.; January 2021.
14. Nuzyra [package insert]. Boston, MA: Paratek Pharmaceuticals, Inc; October 2020.

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