

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Tetracyclines PDL Edit
<b>First Implementation Date:</b>	June 21, 2012
<b>Proposed Date:</b>	June 18, 2020
<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:		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>• <b>Amzeeq™</b></li> <li>• Avidoxy™</li> <li>• Avidoxy™ DK</li> <li>• Doryx®</li> <li>• Doryx® MPC</li> <li>• <b>Doxycycline Hyclate Tabs (gen Acticlate®)</b></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>• Mondoxyne™ NL</li> <li>• Morgidox®</li> <li>• Nuzyra™</li> <li>• Seysara™</li> <li>• Solodyn®</li> <li>• Tetracycline</li> <li>• Vibramycin®</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: 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 no approval criteria are 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. 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: "Tetracyclines – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; April 2020.
5. Evidence-Based Medicine Analysis: "Tetracyclines", UMKC-DIC; April 2020.
6. Doryx [package insert]. Greenville, NC: Mayne Pharma; 2020.
7. Doryx MPC [package insert]. Greenville, NC: Mayne Pharma USA; 2020.
8. Vibramycin [package insert]. New York, NY: Pfizer Labs; 2018.
9. Morgidox [package insert]. Fairfield, NJ: Medimetriks Pharmaceuticals, Inc; 2018.
10. Minocin [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; 2019.
11. Oracea [package insert]. Fort Worth, Texas: Galderma Laboratories, L.P.; 2017.
12. Minolira Extended Release [package insert]. Charleston, SC: EPI Health, LLC; 2018.
13. Solodyn [package insert]. Bridgewater, NJ: Valeant Pharmaceuticals North America LLC; 2017.
14. Ximino [package insert]. Cranbury, NJ: Sun Pharmaceuticals Industries, Inc; 2017.
15. Nuzyra [package insert]. Boston, MA: Paratek Pharmaceuticals, Inc; 2020.

### SmartPA PDL Proposal Form

© 2020 Conduent Business Services, LLC. All rights reserved. Conduent™ and Conduent Design™ are trademarks of Conduent Business Services, LLC in the United States and/or other countries.

Other company trademarks are also acknowledged.