

SmartPA Criteria Proposal

Drug/Drug Class:	Tetracyclines PDL Edit
First Implementation Date:	June 21, 2012
Proposed Date:	June 18, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<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"> • Doxycycline Hyclate Caps • Doxycycline Hyclate Tabs (gen Vibra-Tabs®, Periostat®) • Doxycycline Mono Susp • Minocycline Caps 	<ul style="list-style-type: none"> • Amzeeq™ • Avidoxy™ • Avidoxy™ DK • Benzodox™ • Demeclocycline • Doryx® • Doryx® MPC • Doxycycline Hyclate Tabs (gen Acticlate®) • Doxycycline Hyclate DR • Doxycycline Mono Caps/Tabs • Doxycycline Mono IR-DR • Minocin® • Minocycline ER • Minocycline Tabs • Minolira™ • Mondoxyne™ NL • Morgidox® • Nuzyra™ • Oracea® • Seysara™ • Solodyn® • Soloxide™ • Tetracycline • Vibramycin® • Xerava™ • Ximino™

- 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

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4. Evidence-Based Medicine and Fiscal Analysis: "Tetracyclines – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; April 2020.
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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

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