MEDICAL MUTUAL®

Drug Policy

Policy:	Tetracyclines (oral) Preferred Step Therapy Policy	Annual Review Date: 06/20/2024 Last Revised Date: 06/20/2024

OVERVIEW

Demeclocycline, doxycycline, minocycline, and tetracycline are broad-spectrum oral antibiotic agents. In general, these medications are Food and Drug Administration (FDA)-indicated to treat a wide variety of infections such as those caused by gram-negative and gram-positive microorganisms; in adjunct with other therapies for severe acne; and in situations where penicillin is contraindicated due to allergy.

POLICY STATEMENT

A step therapy program has been developed to encourage use of one Step 1 product prior to the use of a Step 2 product. If the step therapy rule is not met for a Step 2 agent at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 1 year in duration.

Automation: Patients with a history of one Step 1 drug within the 130-day look-back period are excluded from step therapy.

Step 1:

Product Name and Formulation	Strengths
Demeclocycline tablets	150 mg, 300 mg
Doxycycline hyclate tablets	20 mg, 100 mg
Doxycycline hyclate/ Morgidox capsules	50 mg, 100 mg
Doxycycline monohydrate capsules/tablets	50 mg, 75 mg, 100 mg, 150 mg (tablet only)
Doxycycline monohydrate/Avidoxy tablets	100 mg
Doxycycline monohydrate/Mondoxyne capsules	50 mg, 75 mg, 100 mg
Doxycycline monohydrate suspension	25 mg/ 5 ml
Minocycline hydrochloride IR capsules	50 mg, 75 mg, 100mg
Minocycline hydrochloride IR tablets	50 mg, 75 mg, 100mg
Tetracycline hydrochloride capsules	250 mg, 500 mg

IR – Immediate release.

Step 2:

Product Name and Formulation	Strengths
Acticlate tablets	75mg, 150 mg (brand and generic)
Avidoxy DK Kit	100 mg (brand)
Doryx DR tablets	50 mg, 80 mg, 200 mg (brand and generic)
Doryx MPC tablets	60 mg (brand), 120 mg (brand)
doxycycline hyclate DR tablets	75 mg, 100 mg (generic)
doxycycline hyclate DR tablets/Soloxide	150 mg (generic)

Doxycycline IR-DR capsules	40 mg (generic)
doxycycline monohydrate capsules	150 mg (generic)
Minolira ER tablet	105 mg, 135 mg (brand)
Monodox capsules	50 mg, 75 mg, 100 mg (brand)
Morgidox-Kit	50 mg, 100 mg (brand)
Oracea	40 mg (brand and authorized generic)
Seysara tablets	60 mg, 100 mg, 150 mg (brand)
Solodyn ER tablets	55 mg, 65 mg, 80 mg, 105 mg, 115 mg (brand and generic)
Targadox tablets	50 mg (brand and generic)
Tetracycline hydrochloride tablets	250 mg, 500 mg (generic)
Vibramycin cap, suspension, syrup	100 mg capsules, 50 mg/5 ml syrup (brand)
Ximino ER capsules	45 mg, 90 mg, 135 mg (brand and authorized generic)

IR – Immediate release DR – Delayed-release; ER – Extended-release.

CRITERIA

1. If the patient has tried a Step 1 agent, then authorization for a Step 2 agent may be given.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 365 days
B) *Extended Approval:* 365 days

Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent

available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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