Pharmacy Policy Bulletin

Title: Tetracycline Policy
Policy #: Rx.01.144

Application of pharmacy policy is determined by benefits and contracts. Benefits may vary based on product line, group, or contract. Some medications may be subject to precertification, age, gender or quantity restrictions. Individual member benefits must be verified.

This pharmacy policy document describes the status of pharmaceutical information and/or technology at the time the document was developed. Since that time, new information relating to drug efficacy, interactions, contraindications, dosage, administration routes, safety, or FDA approval may have changed. This Pharmacy Policy will be regularly updated as scientific and medical literature becomes available. This information may include new FDA-approved indications, withdrawals, or other FDA alerts. This type of information is relevant not only when considering whether this policy should be updated, but also when applying it to current requests for coverage.

Members are advised to use participating pharmacies in order to receive the highest level of benefits.

**Intent:**

The following brand name medications Acticlate™, Adoxa®, Alodox®, Avidoxy®, Doryx® DR, Monodox®, Minocin®, and Vibramycin® are used for multiple indications (e.g. treatment of infections caused by gram-negative microorganisms)

Minocycline hydrochloride extended release (Solodyn®) is indicated for the treatment of any inflammatory lesions of nonnodular moderate to severe acne vulgaris in patients 12 years and older.

The use of brand tetracyclines requires prior authorization (i.e. clinical pharmacist and/or Medical Director review).

**Description:**

The tetracyclines are primarily bacteriostatic and are thought to exert their antimicrobial effect by the inhibition of protein synthesis. The tetracyclines, including doxycycline, have a similar antimicrobial spectrum of activity against a wide range of gram-positive and gram-negative organisms. Cross-resistance of these organisms to tetracyclines is common.

**Policy:**

The following brand name medications Acticlate™, Adoxa®, Alodox®, Avidoxy®, Doryx® DR, Monodox®, Minocin® and Vibramycin® are approved when there is documentation of an inadequate response or inability to tolerate a generic formulation of either doxycycline or minocycline.

Minocycline hydrochloride extended release (Solodyn®) is approved when all of the following inclusion criteria are met:

1. Member is 12 years of age or older
2. Diagnosis of moderate to severe acne vulgaris
3. Inability to tolerate or inadequate response to a generic formulation of minocycline

**Minocycline hydrochloride extended release (Solodyn®) Authorization Length:** Solodyn® will be authorized for a period of 12 weeks. Members are limited to one 12-week course of therapy every six months.

**Black Box Warning:**
None

**Guidelines:**
Refer to the specific manufacturer's prescribing information for administration and dosage details and any applicable Black Box warnings.

**BENEFIT APPLICATION**

Subject to the terms and conditions of the applicable benefit contract, the applicable drug(s) identified in this policy is (are) covered under the pharmacy benefits of the Company's products when the medical necessity criteria listed in this pharmacy policy are met. Any services that are experimental/investigational or cosmetic are benefit contract exclusions for all products of the Company.

**References:**


Applicable Drugs:

Inclusion of a drug in this table does not imply coverage. Eligibility, benefits, limitations, exclusions, precertification/referral requirements, provider contracts, and Company policies apply.

<table>
<thead>
<tr>
<th>Brand Name</th>
<th>Generic Name</th>
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<tbody>
<tr>
<td>Acticlate™</td>
<td>Doxycycline Hyclate</td>
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<tr>
<td>Adoxa®</td>
<td>Doxycycline Monohydrate</td>
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<tr>
<td>Alodox®</td>
<td>Doxycycline Hyclate</td>
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<tr>
<td>Avidoxy®</td>
<td>Doxycycline Monohydrate</td>
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<tr>
<td>Doryx DR®</td>
<td>Doxycycline Hyclate</td>
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<tr>
<td>Monodox®</td>
<td>Doxycycline Monohydrate</td>
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<tr>
<td>Minocin®</td>
<td>Minocycline HCL</td>
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<tr>
<td>Solodyn</td>
<td>Minocycline hydrochloride extended release</td>
</tr>
<tr>
<td>Vibramycin®</td>
<td>Doxycycline Hyclate</td>
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</tbody>
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Cross References:

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P&T Approval Date: July 10, 2014
Policy Effective Date: February 01, 2015
Next Required Review Date: July 10, 2015

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