



<b>ISSUE DATE</b> July 22, 2013	<b>EFFECTIVE DATE</b> August 19, 2013	<b>NUMBER</b> *See below
<b>SUBJECT</b>  Prior Authorization of Acne Agents, Oral - Doxycycline - Pharmacy Services		<b>BY</b>    Vincent D. Gordon, Deputy Secretary Office of Medical Assistance Programs

**PURPOSE:**

The purpose of this bulletin is to inform providers that during the nationwide shortage of doxycycline, the Department of Public Welfare (Department) will:

1. Temporarily designate all forms of doxycycline in the Acne Agents, Oral class of drugs on the Preferred Drug list (PDL) as non-preferred; and
2. Temporarily apply the Centers for Disease Control and Prevention (CDC) recommendations for patient care, in addition to the guidelines to determine medical necessity listed in the Acne Agents, Oral handbook pages, when evaluating requests for medical necessity.

**SCOPE:**

This bulletin applies to all licensed pharmacies and prescribers enrolled in the Medical Assistance (MA) Program and providing services in the fee-for-service (FFS) delivery system, including pharmacy services to residents of long term care facilities.

**BACKGROUND:**

On June 12, 2013, the CDC published an official CDC Health Advisory announcing that the shortage of some forms of doxycycline caused by increased demand and manufacturing issues, as originally reported by the Food and Drug Administration (FDA), continues for some dosages and forms of doxycycline. The CDC provided advice on equally effective alternatives to doxycycline when available, and identified situations where there is no recommended alternative to doxycycline that have the same degree of efficacy or where alternatives have not been tested for efficacy.

*01-13-40	08-13-38	14-13-37	30-13-36	33-13-40
02-13-36	09-13-40	24-13-38	31-13-44	
03-13-36	11-13-36	27-13-38	32-13-36	

<p><b>COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:</b></p> <p>The appropriate toll free number for your provider type</p> <p>Visit the Office of Medical Assistance Programs Web site at <a href="http://www.dpw.state.pa.us/provider/healthcaremedicalassistance/index.htm">http://www.dpw.state.pa.us/provider/healthcaremedicalassistance/index.htm</a></p>
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**DISCUSSION:**

During the nationwide shortage of doxycycline, the Department is designating all forms of doxycycline as non-preferred. This temporary change in designation affects doxycycline hyclate and Vibramycin Suspension which are currently designated as preferred and will require prior authorization effective August 19, 2013. All other forms of doxycycline are already designated as non-preferred and require prior authorization.

The clinical review guidelines to determine medical necessity of all forms of doxycycline, located in the chapter related to Acne Agents, Oral ([http://www.dpw.state.pa.us/ucmprd/groups/webcontent/documents/bulletin\\_admin/d\\_005458.pdf](http://www.dpw.state.pa.us/ucmprd/groups/webcontent/documents/bulletin_admin/d_005458.pdf)), will continue to apply and will be temporarily expanded during the nationwide shortage to include the following CDC recommendations for patient care:

When evaluating a request for prior authorization of a prescription for doxycycline, the determination of whether the requested prescription is medically necessary will take into account whether the recipient:

1. Is being prescribed doxycycline for one of the following:
  - a. Treatment of a rickettsial infection
  - b. Prophylaxis of Lyme disease
  - c. Prophylaxis or treatment of malaria
  - d. Treatment of Lymphogranuloma venereum

**OR**

2. Has a diagnosis of Lyme disease **AND**
3. Has a documented history of therapeutic failure, contraindication or intolerance to amoxicillin and cefuroxime axetil

**OR**

4. Has a diagnosis of a sexually transmitted disease as addressed in the Detailed Disease Treatment Information section of the CDC Health Advisory **AND**
5. Has a documented history of therapeutic failure, contraindication or intolerance to the alternative recommended agents defined by the CDC Sexually Transmitted Diseases Treatment Guidelines

**PROCEDURE:**

The procedures for prescribers to request prior authorization of doxycycline are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. The Department will take into account the elements specified in the clinical review guidelines (which are included in the provider handbook pages in the SECTION II chapter related to Acne

Agents, Oral) and the temporary clinical review guidelines listed above when reviewing the prior authorization request to determine medical necessity.

As set forth in 55 Pa. Code § 1101.67(a), the procedures described in the handbook pages must be followed to ensure appropriate and timely processing of prior authorization requests for drugs that require prior authorization.