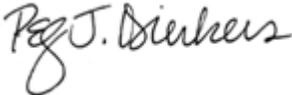


	<b>MEDICAL ASSISTANCE BULLETIN</b> COMMONWEALTH OF PENNSYLVANIA * DEPARTMENT OF PUBLIC WELFARE	
	<b>SUBJECT</b>  Prior Authorization of Viagra and Other Drugs for Erectile Dysfunction Treatment Criteria, Limits and Procedures	<b>BY</b>    <b>Peg J. Dierkers, Ph.D.</b> Deputy Secretary for Medical Assistance Programs
<b>NUMBER:</b>	99-99-08	
<b>ISSUE DATE:</b>	November 22, 1999	
<b>EFFECTIVE DATE:</b>	December 1, 1999	

**PURPOSE:**

The purpose of this bulletin is:

1. to inform providers that the Department will require prior authorization on all prescriptions for sildenafil citrate (Viagra) and other drugs indicated for the treatment of Erectile Dysfunction.
2. to advise all providers of the criteria, the limits and the procedures needed to approve prescriptions for Viagra in the Medical Assistance (M A) Program fee-for-service delivery system.

**SCOPE:**

This bulletin applies to all providers enrolled in the M A Program, including providers enrolled in a managed care organization (MCO) under contract with the Department.

**BACKGROUND:**

Section 443.6(b)(7) of the Public Welfare Code (62 P.S. section 443.6(b)(7)) authorizes the Department to add other items and services to its list of services requiring prior authorization by publication of notice in the *Pennsylvania Bulletin*. On November 20, 1999, the Department published a notice in the *Pennsylvania Bulletin* that all drugs indicated for the treatment of Erectile Dysfunction will require prior authorization effective December 1, 1999.

When Viagra, a drug indicated for the treatment of Erectile Dysfunction in men, became available on the marketplace, the Health Care Financing Administration (HCFA) strongly urged state Medicaid agencies to take any necessary measures to prevent abuse and misuse of Viagra and to ensure appropriate use and cost effectiveness. HCFA recommended for states to establish prior authorization programs to assure that health professionals meet their responsibilities when prescribing Viagra. HCFA also recommended placing limits on the number of refills or the quantity per prescription to discourage waste, fraud, and abuse. Prior to December 1, 1999, the Department and the MCOs have been meeting the HCFA requirement for coverage by having these drugs available through the program exception process. The Department is now moving the coverage of these products to the prior authorization process through the fee-for-service delivery system.

**DISCUSSION:**

As a result of HCFA's recommendations, the Department will begin to require prior authorization on all prescriptions for Viagra and other drugs for the treatment of Erectile Dysfunction in the fee-for-service delivery system effective December 1, 1999. The Department has established criteria to approve prescriptions for Viagra and similar products and has placed limits on all prescriptions for Viagra. In order to receive approval for Viagra and similar drugs under the Fee-For-Service Program, the prescriber must certify to all of the following:

1. The patient must be a male 19 years old or over.
2. The patient must have a stated diagnosis of Erectile Dysfunction.
3. Any patient being prescribed Viagra must not be concurrently or intermittently using organic nitrates in any form.

4. The patient must have had a medical evaluation (physical and history) within one year of the request.

The Department will issue prior authorization if the prescriber can document all of the criteria listed above and will require the prescriber to maintain this documentation in the individual's patient medical file. The prescriber must be able to provide this documentation to the Department in writing upon request.

Viagra will be subject to the following limitations:

1. There will be no refills authorized on any prescription for Viagra or other drugs indicated for the treatment of Erectile Dysfunction. Subsequent prescriptions will require a new prescription and a new prior authorization request and approval.
2. Quantities of Viagra are limited to 4 total tablets per month (30 days), regardless of the strength.
3. Since there is no instance for the immediate need of Viagra or any other drug used in the treatment of Erectile Dysfunction, there will be NO emergency supplies authorized. "Immediate need" has been defined by HCFA as a situation where the lack of a certain drug would involve immediate and severe consequences, continuation of immediate and severe consequences, or pose an immediate threat to the patient's life.
4. All prescriptions for Viagra and other similar drugs will be subject to copayment unless exempted by Federal or State Law.

#### **PROCEDURES:**

- A. To request approval for Viagra and other similar drugs indicated for the treatment of Erectile Dysfunction under the Fee-For-Service Program, the prescriber must follow this procedure:
  1. Call the M A Program Prior Authorization Unit at 1-888-379-3668 between the hours of 9:00 A.M. and 4:00 P.M., Monday through Friday, beginning December 1, 1999.
  2. Be prepared to give the name and ACCESS Card number of the recipient, your prescriber license number, the strength and quantity of the prescription. (Remember that quantities for Viagra are limited to 4 total tablets per 30 days and no refills).
  3. Be prepared to attest to the established criteria. If the criteria are met, the Department will immediately issue a 10-digit prior authorization number applicable to that prescription only. Subsequent prescriptions require a new prescription and prior authorization number.
  4. Write the 10-digit prior authorization number on the front of the prescription.
  5. Maintain the prior authorization number for that prescription in the patient's medical file.
- B. To request approval for Viagra or other similar drugs under managed care, follow the procedures defined by the MCO.
- C. To submit a claim for Viagra and other similar drugs in the Fee-For-Service Program, the pharmacy must follow this procedure:
  1. Be certain the prescriber included the prior authorization number on the front of the prescription. These drugs will not be covered unless the Department has issued a prior authorization for that prescription only. DO NOT CALL THE PRIOR AUTHORIZATION UNIT FOR APPROVAL TO FILL THE PRESCRIPTION. THIS TELEPHONE NUMBER IS RESERVED FOR PRESCRIBERS ONLY.
  2. Prepare the claim using the Electronic Claims Management (ECM) point-of-sale, on-line claims adjudication system by entering the prior authorization number in the prior authorization field (NCPDP PA/MC field 416).
  3. Transmit the claim to the Department through ECM.
  4. Remember that the Department will NOT cover emergency supplies of Viagra or any other drug product indicated for Erectile Dysfunction. If you dispense any interim quantities of these drugs without prior authorization, you do so at your own risk.

5. For patient prescribed Viagra, if you detect a drug-drug interaction for organic nitrates in any form or if you know the recipient is on nitrates, call the prescriber immediately to determine what subsequent steps you should take.

D. To submit a claim for Viagra and other similar drugs in managed care, follow the procedures defined by the MCO.

**COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:**

The appropriate toll-free inquiry line for your provider type.

Visit the Office of Medical Assistance Programs website at [www.dpw.state.pa.us/omap](http://www.dpw.state.pa.us/omap).