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SUBJECT Preferred Drug List (PDL) New Drugs to Market Handbook Pages Pharmacy Services		BY  Michael Nardone, Deputy Secretary Office of Medical Assistance Programs

PURPOSE:

The purpose of this bulletin is to issue Prior Authorization of Pharmaceutical Services Handbook pages for new drugs introduced to the marketplace that are included in therapeutic classes of drugs subject to the Preferred Drug List (PDL). The handbook pages include instructions on how to request prior authorization of prescriptions for new drugs to market that require prior authorization, including the type of medical information needed to evaluate 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 September 19, 2005, the Department of Public Welfare (Department) issued MA Bulletin Number 99-05-18, SUBJECT: Preferred Drug List, announcing that the Department was establishing a PDL, phasing in implementation, and would designate each drug within a therapeutic class of drugs subject to the PDL as preferred or non-preferred with non-preferred drugs requiring prior authorization. The MA Bulletin also stated that as new drugs in a therapeutic class already included on the PDL become available in the marketplace, they will be designated as non-preferred and will require prior authorization.

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02-09-51	11-09-51	30-09-51
03-09-51	14-09-51	31-09-62
08-09-60	24-09-57	32-09-51

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DISCUSSION:

The MA Program is required to provide coverage of outpatient drugs of a manufacturer that participates in the Federal Drug Rebate Program. When a new drug becomes available in the marketplace, and the manufacturer has in effect a rebate agreement with the Centers for Medicare and Medicaid Programs (CMS), the Department automatically adds the new drug to the Department's Drug Reference File in order to ensure compliance with Federal requirements for coverage of outpatient drugs. If the new drug is in a therapeutic class already included on the PDL, the drug is designated as non-preferred pending a review by the Department's Pharmacy & Therapeutics (P&T) Committee.

The Department's P&T Committee meets semi-annually to review published peer-reviewed clinical literature and make recommendations relating to the PDL, including a recommended designation of preferred or non-preferred for new drugs in therapeutic classes already included in the PDL. All classes of drugs subject to the PDL are reviewed by the P&T Committee annually.

In summary, new drugs to market that are in a therapeutic class already included on the PDL are covered under the MA Program, are designated as non-preferred, require prior authorization, and will remain non-preferred pending the annual review of the therapeutic class of drugs by the P&T Committee.

The only exception to the automatic designation of non-preferred is when the new drug to market is a generic version of a brand name drug that has been designated as a preferred drug, and the therapeutically equivalent generic is determined to be more cost effective than the brand name drug. In that situation, the Department will designate the generic drug as preferred and the brand name drug as non-preferred, pending the annual review of the therapeutic class of drugs by the P&T Committee.

PROCEDURE:

The procedures for prescribers to request prior authorization of non-preferred drugs and for pharmacies to dispense an emergency supply of medication when necessary and without prior authorization 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 chapters related to specific therapeutic classes of drugs) in reviewing the prior authorization request to determine medical necessity.

The requirements for prior authorization and clinical review guidelines to determine medical necessity of New Drugs to Market and handbook chapter are included in the attached updated provider handbook pages.

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.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

SECTION II

New Drugs to Market