pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
June 7, 2017	June 6, 2017	*See Below

SUBJECT

Prior Authorization of Oncology Agents, Breast Cancer – Pharmacy Services

BY

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Office of Medical Assistance Programs

New IMPORTANT REMINDER: All providers must revalidate the Medical Assistance (MA) enrollment of each service location every 5 years. Providers should log into PROMISe to check the revalidation dates of each service location and submit revalidation applications at least 60 days prior to the revalidation dates. Enrollment (revalidation) applications may be found at: http://www.dhs.pa.gov/provider/promise/enrollmentinformation/S_001994.

PURPOSE:

The purpose of this bulletin is to:

1. Inform providers that the Department of Human Services (DHS) will require prior authorization of prescriptions for letrozole.

2. Issue handbook pages that include the requirements for prior authorization and the type of information needed to evaluate requests for prior authorization of prescriptions for letrozole 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 delivery system, including pharmacy services to residents of long term care facilities.

BACKGROUND:

*01-17-26	09-17-25	27-17-24	
02-17-24	11-17-24	30-17-25	
03-17-24	14-17-24	31-17-26	
08-17-27	24-17-24	32-17-24	33-17-25

COMMENTS AND QUESTIONS REGARDING THIS BULLETIN SHOULD BE DIRECTED TO:

The appropriate toll free number for your provider type

Visit the Office of Medical Assistance Programs Web site at
http://www.dhs.pa.gov/provider/healthcaremedicalassistance/index.htm

The Department's Drug Utilization Review (DUR) Board meets semi-annually to review provider prescribing and dispensing practices for efficacy, safety, and quality and to recommend interventions for prescribers and pharmacists through DHS' Prospective Drug Use Review and Retrospective Drug Use Review programs.

DISCUSSION:

During the March 22, 2017 DUR Board meeting, the DUR Board recommended that DHS require prior authorization of letrozole to ensure appropriate drug utilization for all medically accepted indications, except treatment to promote fertility. Letrozole is designated as a preferred agent in the Preferred Drug List class of Oncology Agents, Breast Cancer, but the scope of coverage in the MA Program does not include treatment for infertility. The provisions in 42 U.S. Code § 1396r-8(d)(2) give the State Medicaid program the option to exclude from coverage agents when used to promote fertility. In accordance with the Pennsylvania State Plan, as approved by the Centers for Medicare & Medicaid Services, the MA program does not provide coverage of agents when used to promote fertility. The DUR Board recommended guidelines to determine medical necessity of letrozole which were subject to public review and comment, and subsequently approved for implementation by DHS.

PROCEDURE:

The procedures for prescribers to request prior authorization of Oncology Agents, Breast Cancer are located in SECTION I of the Prior Authorization of Pharmaceutical Services Handbook. DHS 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 Oncology Agents, Breast Cancer) 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.

ATTACHMENTS:

Prior Authorization of Pharmaceutical Services Handbook - Updated pages

SECTION II
Oncology Agents, Breast Cancer

I. Requirements for Prior Authorization of Oncology Agents, Breast Cancer

A. Prescriptions That Require Prior Authorization

Prescriptions for Oncology Agents, Breast Cancer that meet any of the following conditions must be prior authorized:

1. A prescription for a non-preferred Oncology Agent, Breast Cancer, regardless of the quantity prescribed. See Preferred Drug List (PDL) for the list of preferred Oncology Agents, Breast Cancer at: https://papdl.com

2. A prescription for letrozole regardless of the quantity prescribed

3. A prescription for a preferred Oncology Agent, Breast Cancer with a prescribed quantity that exceeds the quantity limit. See Quantity Limits for the list of drugs with quantity limits at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm

GRANDFATHER PROVISION – The Department of Human Services will grandfather prescriptions for Fareston (toremifene) when the PROMISe Point-Of-Sale On-Line Claims Adjudication System verifies that the beneficiary has a record of a paid claim for Fareston within the past 90 days from the date of service of the new claim. If the beneficiary has a record of a paid claim for Fareston, a prescription or a refill for Fareston will be automatically approved.

B. Clinical Review Guidelines and Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Oncology Agent, Breast Cancer, the determination of whether the requested prescription is medically necessary will take into account the following: :

1. For a non-preferred agent, whether the beneficiary has a history of therapeutic failure, contraindication or intolerance to the preferred Oncology Agents, Breast Cancer

OR

2. For letrozole, whether the beneficiary is being treated for a condition in which use of letrozole is a Federal Food and Drug Administration (FDA) approved indication or other medically

accepted indication, excluding use to promote fertility. The requesting prescriber must provide documentation from the medical record of the diagnosis,

OR

3. Does not meet the clinical review guidelines listed above, but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

AND

4. In addition, if a prescription for either a preferred or non-preferred Oncology Agent, Breast Cancer is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

C. Automated Prior Authorization

Prior authorization of a prescription for letrozole at or below the quantity limit will be automatically approved when the PROMISe Point-of-Sale Online Claims Adjudication System verifies a record of paid claim(s) within 90 days prior to the date of service that documents the medical necessity of the drug.

D. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above, to assess the medical necessity of the request for a prescription for an Oncology Agent, Breast Cancer. If the guidelines in Section B are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

References:

1. Epidemiology and pathogenesis of the polycystic ovary syndrome in adults. Up To Date. Accessed February 3, 2017
2. Femara (letrozole) Package Insert, Novartis January 2014

3. Legro, R.S. et al. (2014) Letrozole versus Clomiphene for Infertility in the Polycystic Ovary Syndrome. New England Journal of Medicine **371**: 119-129
4. Ovulation induction with letrozole. Up To Date. Accessed January 13, 2017