pennsylvania
DEPARTMENT OF HUMAN SERVICES

MEDICAL ASSISTANCE BULLETIN

ISSUE DATE	EFFECTIVE DATE	NUMBER
September 5, 2019	January 1, 2020	*See below

SUBJECT

Prior Authorization of Oncology Agents, Breast Cancer – Pharmacy Services

BY

Sally A. Kozak, Deputy Secretary
Office of Medical Assistance Programs

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 issue updated handbook pages that include the requirements for prior authorization and the type of information needed to evaluate the medical necessity of prescriptions for Oncology Agents, Breast Cancer submitted for prior authorization.

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. Providers rendering services in the MA managed care delivery system should address any questions related to Oncology Agents, Breast Cancer to the appropriate managed care organization.

BACKGROUND:

The Department of Human Services' (Department) Pharmacy and Therapeutics (P&T)

*01-19-59	09-19-55	27-19-53	33-19-55
02-19-53	11-19-52	30-19-51	
03-19-52	14-19-51	31-19-58	
08-19-61	24-19-53	32-19-51	

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

Committee reviews published peer-reviewed clinical literature and makes recommendations relating to the following:

- Preferred or non-preferred status for new drugs in therapeutic classes already included in the Preferred Drug List (PDL);
- Changes in the status of drugs on the PDL from preferred to non-preferred and non-preferred to preferred;
- New quantity limits;
- Classes of drugs to be added to or deleted from the PDL; and
- New guidelines or revisions to existing guidelines to evaluate the medical necessity of prescriptions submitted for prior authorization.

DISCUSSION:

During the June 21, 2019, meeting, the P&T Committee recommended removing the grandfathering provision for Fareston (toremifene). The P&T Committee recommended that the determination of medical necessity of Fareston (toremifene) should be subject to and consistent with the same guidelines as other drugs within this class. The committee also recommended removing the automated prior authorization provision for agents in this class, with the exception of letrozole, to allow for medical necessity review by prior authorization personnel for all prior authorization requests.

The revisions to the guidelines to determine medical necessity of Oncology Agents, Breast Cancer, as recommended by the P&T Committee, were subject to public review and comment and subsequently approved for implementation by the Department.

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. 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 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

RESOURCES:

Prior Authorization of Pharmaceutical Services Handbook – SECTION I

Pharmacy Prior Authorization General Requirements
http://www.dhs.pa.gov/provider/pharmacyservices/pharmacypriorauthorizationgeneralrequirements/index.htm

Prior Authorization of Pharmaceutical Services Handbook – SECTION II
Pharmacy Prior Authorization Guidelines
http://www.dhs.pa.gov/provider/pharmacyservices/drugsrequiringclinicalpriorauthorization/index.htm

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 non-preferred Oncology Agent, Breast Cancer. See the Preferred Drug List (PDL) for the list of preferred Oncology Agents, Breast Cancer at: https://papdl.com/preferred-drug-list.

2. A prescription for letrozole.

3. An Oncology Agent, Breast Cancer with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

B. 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 whether the beneficiary:

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

2. For letrozole, is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration-approved package labeling OR a medically accepted indication, excluding use to promote fertility. The requesting prescriber must provide documentation from the medical record of the diagnosis; **AND**

3. If a prescription for an Oncology Agent, Breast Cancer is for 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.

   NOTE: If the beneficiary 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, the request for prior authorization will be approved.

C. 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 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.

D. Automated Prior Authorization

Prior authorization of a prescription for letrozole with a prescribed quantity that does not exceed the quantity limit established by the Department will be automatically approved when the Point-of-Sale On-Line Claims Adjudication System verifies a record of a paid claim(s) within 90 days prior to the date of service that documents that the guidelines to determine medical necessity listed in Section B. have been met.

E. 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.