

## **Clinical Policy: Oncology Agents, Breast Cancer**

Reference Number: PHW.PDL.502

Effective Date: 01/01/2020

Last Review Date: 11/2024

### **Policy/Criteria**

*Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.*

It is the policy of PA Health & Wellness® that Breast Cancer Oncology Agents are **medically necessary** when the following criteria are met:

### **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.
2. A prescription for letrozole.
3. An Oncology Agent, Breast Cancer with a prescribed quantity that exceeds the quantity limit.

#### **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 member:

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 (FDA)-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 PA.CP.PMN.59 Quantity Limit Override.

NOTE: If the member 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 member, 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 member.

D. Automated Prior Authorization

Prior authorization of a prescription for letrozole with a prescribed quantity that does not exceed the quantity limit established by DHS 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. Approval Duration:

Arimedex (anastrozole)	12 months
Aromasin (exemestane)	12 months
Fareston (toremifene)	12 months
Femara (letrozole)	New Request: 6 months Renewal Request: 12 months
Soltamox (tamoxifen)	12 months

F. 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

Reviews, Revisions, and Approvals	Date
Policy created	01/01/2020
Q3 2020 annual review: no changes.	07/2020
Q1 2021 annual review: no changes.	01/2021
Q1 2022 annual review: no changes.	11/2021
Q1 2023 annual review: no changes.	11/2022
Q1 2024 annual review: no changes.	11/2023
Q1 2025 annual review: no changes.	11/2024