Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 11/01/2018**
Policy Number: PA.CP.PPA.10	**Effective Date: 10/17/2018** **Revision Date: 10/17/2018**
Policy Name: Toremifene (Fareston)	**HC Approval Date:**

Type of Submission – Check all that apply:

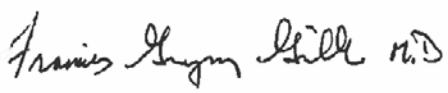
- ☐ **New Policy**
- ☐ **Revised Policy***
- ☐ **Annual Review – No Revisions**
- ☐ **Attestation of HC PARP Policy –** *This option should only be used during Readiness Review for Community HealthChoices. The policy must be identical to the PARP approved policy for the HealthChoices Program, with the exception of revisions/clarifications adding the term "Community HealthChoices" to the policy.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

This policy is being retired and replaced by the following policy:

PA.CP.PMN.126 Toremifene (Fareston)

Name of Authorized Individual (Please type or print): **Francis G. Grillo, MD**	**Signature of Authorized Individual:** 

Clinical Policy: Toremifene (Fareston)

Reference Number: PA.CP.PPA.10
Effective Date: 01/18
Last Review Date: 11/17

Coding Implications
Revision Log

Description
Toremifene (Fareston®) is an estrogen agonist/antagonist.

FDA approved indication
Fareston is indicated for the treatment of metastatic breast cancer in postmenopausal women with estrogen-receptor positive or unknown tumors.

Policy/Criteria
Provider must submit documentation (including office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of Pennsylvania Health and Wellness ® that Fareston is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Breast Cancer (must meet all)**:**

1. Diagnosis of metastatic breast cancer with estrogen-receptor positive or unknown tumors;
2. Member is postmenopausal female;
3. Failure of a 1 month trial of tamoxifen at 20-40 mg/day unless contraindicated or clinically significant adverse effects are experienced or patient new to the plan is currently established on medication;
4. Failure of a 1 month trial of a PDL aromatase inhibitor (anastrozole, exemestane, letrozole) at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced or patient new to the plan is currently established on medication;
5. Dose does not exceed 60 mg per day (1 tablet per day).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Breast Cancer (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met initial approval criteria or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies;
2. Documentation of positive response to therapy;
3. If request is for a dose increase, new dose does not exceed 60 mg per day (1 tablet per day).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care Policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

Approval duration: 12 months

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
PDL: preferred drug list

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Breast cancer	60 mg once daily	60 mg/day

VI. Product Availability

Tablet: 60 mg

VII. References

1. Fareston Prescribing Information. Bridgewater, NJ: ProStrakan Inc.; October 2012. Available at: www.fareston.com. Accessed January 11, 2017.
2. Breast cancer (Version 2.2016). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed January 11, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date