Clinical Policy: Toremifene (Fareston)
Reference Number: CP.PPA.10
Effective Date: 04/10
Last Review Date: 05/17
Line of Business: Medicaid

Coding Implications
Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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 health plans affiliated with Centene Corporation® 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. ~~Documented one month minimum trial and f~~Failure of a 1 month trial of tamoxifen at 20-40 mg/day ~~at doses of 20-40 mg/day in two divided doses,~~ unless contraindicated or clinically significant adverse effects are experienced~~contraindicated or intolerant~~;
4. ~~Documented one month minimum trial and f~~Failure of a 1 month trial of a PDL aromatase inhibitor (~~the aromatase inhibitor,~~ anastrozole, exemestane, letrozole) ~~(Arimidex®)~~ at up to maximally indicated doses ~~,~~ unless contraindicated or clinically significant adverse effects are experienced~~unless contraindicated or intolerant~~;
5. ~~Request~~ Dose does not exceed 60 mg per day (1 tablet per day).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to 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 Centene benefit or member has previously met initial approval criteria;
~~1.~~2. Documentation of positive response to therapy;

~~2.~~3.If request is for a dose increase, new dose ~~Request~~ 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 Centene benefit and documentation supports positive response to therapy; or
2. Refer to 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 – 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. Workflow Document


CP.PPA.10
Toremifene (Faresto

~~VII.~~

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Field Code Changed

VIII. References

1. Fareston Prescribing Information. Bridgewater, NJ: ProStrakan Inc.; October 2012. Available at: www.fareston.com. Accessed January 11, 2017~~February 10, 2016~~.
~~2. Toremifene Drug Monograph. Clinical Pharmacology. Accessed February 10, 2016.~~
~~3. Tamoxifen Drug Monograph. Clinical Pharmacology. Accessed February 10, 2016.~~
~~4. Anastrozole Drug Monograph. Clinical Pharmacology. Accessed February 10, 2016.~~
~~5.~~2.Breast cancer (Version ~~2~~1.2016). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed January 11, 2017.~~February 10, 2016~~

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Criteria for Approval section updated to reflect preferred use of the aromatase inhibitor generic anastrozole. References updated to reflect current literature search.	05/11	05/11
References updated to reflect current literature search.	05/12	05/12
References updated to reflect current literature search.	05/13	05/13
References updated to reflect current literature search.	05/15	05/15
Criteria: Added diagnosis of metastatic breast cancer and postmenopausal requirement per PI indication; limited quantity to 1 tablet per day based on FDA approved dosing guidelines. Removed and inserted note defining failure (e.g., clinical contraindication, adverse effects) into the criteria; References updated to reflect current literature search.	02/16	05/16
~~No clinical changes to criteria~~ - Converted to new template - Modified trial/failure verbiage and added requirement for "documentation of positive response" for re-auth per updated template - Added other generic PDL aromatase inhibitors (exemestane, letrozole) as options for trial/failure - Updated references	03~~1~~/17	05/17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.