Clinical Policy: Toremifene (Fareston)

Reference Number: CP.PMN.126
Effective Date: 04.01.10
Last Review Date: 05.20
Line of Business: Medicaid

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(s)

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 (such as office chart notes, lab results or other clinical information) 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 recurrent or metastatic breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Failure of a 1-month trial of tamoxifen at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced;
5. Failure of a 1-month trial of an aromatase inhibitor (e.g., anastrozole, exemestane, letrozole) at up to maximally indicated doses, unless contraindicated or clinically significant adverse effects are experienced (*see Appendix B*);
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 60 mg (1 tablet) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Soft Tissue Sarcoma – Desmoid Tumors (off-label) (must meet all)**:**

1. Diagnosis of desmoid tumor or aggressive fibromatosis;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;

4. Failure of a non-steroidal anti-inflammatory drug at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced (*see Appendix B*);
5. Failure of tamoxifen at up to maximally indicated doses unless contraindicated or clinically significant adverse effects are experienced;
6. Request meets one of the following (a or b):*
   a. Dose does not exceed 60 mg (1 tablet) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

C. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Currently receiving medication via Centene benefit, or documentation supports that member is currently receiving Fareston for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 60 mg (1 tablet) per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

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.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.PMN.53 for Medicaid.

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 policies – CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
tamoxifen (Nolvadex®)	20-40 mg/day in divided doses PO BID	40 mg per day
anastrozole (Arimidex®)	1 mg PO QD	1 mg per day
exemestane (Aromasin®)	25 mg PO QD	25 mg per day
letrozole (Femara®)	2.5 mg PO QD	2.5 mg per day
sulindac (Clinoril®)	150 - 200 mg PO BID	400 mg per day
naproxen sodium (Anaprox®, Anaprox DS®)	275 - 550 mg PO BID	1,650 mg/day
salsalate (Disalcid®)	500 - 750 mg PO TID	3,000 mg/day
piroxicam (Feldene®)	10 - 20 mg PO QD	20 mg/day
indomethacin (Indocin®)	25 - 50 mg PO BID-TID	200 mg/day
indomethacin SR (Indocin® SR)	75 mg PO QD-BID	150 mg/day
meclofenamate (Meclomen®)	50 - 100 mg PO Q4-6H	400 mg/day
meloxicam (Mobic®)	7.5 – 15 mg PO QD	15 mg/day
ibuprofen (Motrin®)	400 - 800 mg PO Q6-8H	3,200 mg/day
fenoprofen (Nalfon®)	200 mg PO Q4-6H	3,200 mg/day
naproxen (Naprosyn®)	250 – 500 mg PO BID	1,500 mg/day
ketoprofen (Orudis®)	25 - 75 mg PO Q6-8H	300 mg/day
nabumetone (Relafen®)	1000 mg PO QD or 500 mg PO BID	2,000 mg/day
tolmetin (Tolmetin® DS)	400 mg PO TID	1,800 mg/day
diclofenac sodium (Voltaren®)	50 mg PO TID	150 mg/day
oxaprozin (Daypro®)	600 - 1200 mg PO BID	1,800 mg/day
etodolac (Lodine®)	400 - 500 mg PO BID	1,200 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
- Contraindication(s): hypersensitivity; QT prolongation; hypokalemia; hypomagnesemia
- Boxed warning(s): QT prolongation

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Breast cancer	60 mg PO QD	60 mg/day

VI. Product Availability
Tablet: 60 mg

VII. References

1. Fareston Prescribing Information. Bridgewater, NJ: ProStrakan Inc.; May 2017. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/020497s009lbl.pdf. Accessed February 17, 2020.
2. Breast cancer (Version 2.2020). In: National Comprehensive Cancer Network Guidelines. Available at www.NCCN.org. Accessed February 17, 2020.
3. Soft tissue sarcoma (Version 6.2019): In: National Comprehensive Cancer Network Guidelines. Available at www.NCCN.org. Accessed February 17, 2020.
4. Toremifene citrate. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed February 17, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
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
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	03.17	05.17
2Q 2018 annual review: removed strength of tamoxifen to be used; removed requirement that member is a postmenopausal female as NCCN allows use in men and premenopausal women; added soft tissue sarcoma criteria per NCCN; added Commercial line of business; references reviewed and updated.	02.06.18	05.18
Removed Commercial line of business as policy is only applicable to Medicaid	06.14.18	
2Q 2019 annual review: no significant changes; references reviewed and updated.	02.04.19	05.19
2Q 2020 annual review: no significant changes; references reviewed and updated.	02.18.20	05.20

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.