Clinical Policy: Toremifene (Fareston)

Reference Number: CP.PMN.126
Effective Date: 04.01.10
Last Review Date: 05.18
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 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 per day (1 tablet/day);
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

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 per day (1 tablet/day);
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   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, new dose does not exceed 60 mg per day (1 tablet/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.
   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 twice daily	40 mg per day
anastrozole (Arimidex®)	1 mg once daily	1 mg per day
exemestane (Aromasin®)	25 mg once daily	25 mg per day
letrozole (Femara®)	2.5 mg once daily	2.5 mg per day
sulindac (Clinoril®)	150 - 200 mg twice daily	400 mg per day
naproxen sodium (Anaprox®, Anaprox DS®)	275 - 550 mg orally twice daily	1650 mg/day
salsalate (Disalcid®)	500 - 750 mg orally three times daily, titrated up to 3000 mg/day	3000 mg/day
piroxicam (Feldene®)	10 - 20 mg orally daily	20 mg/day
indomethacin (Indocin®)	25 - 50 mg orally twice daily to three times daily	200 mg/day
indomethacin SR (Indocin® SR)	75 mg orally daily to orally twice daily	150 mg/day
meclofenamate (Meclomen®)	50 - 100 mg orally every 4-6hr	400 mg/day
meloxicam (Mobic®)	7.5 – 15 mg orally daily	15 mg/day
ibuprofen (Motrin®)	400 - 800 mg orally every 6-8hr	3200 mg/day
fenoprofen (Nalfon®)	200 mg orally every 4-6hr	3200 mg/day
naproxen (Naprosyn®)	250 – 500 mg orally twice daily	1500 mg/day
ketoprofen (Orudis®)	25 - 75 mg orally every 6-8hr	300 mg/day
nabumetone (Relafen®)	1000 mg orally daily or 500 mg orally twice daily	2000 mg/day
tolmetin (Tolmetin® DS)	400 mg orally three times daily, titrated up to 1800 mg/day	1800 mg/day
diclofenac sodium (Voltaren®)	50 mg orally three times daily	150 mg/day
oxaprozin (Daypro®)	600 - 1200 mg orally twice daily	1800 mg/day
etodolac (Lodine®)	400 - 500 mg orally twice daily	1200 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.

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.; May 2017. Available at: www.fareston.com. Accessed January 21, 2018.
2. Breast cancer (Version 3.2017). In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed January 21, 2018.
3. Soft tissue sarcoma (Version 1.2018): In: National Comprehensive Cancer Network Guidelines. Available at NCCN.org. Accessed January 22, 2018.

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

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.

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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.