Clinical Policy: Exemestane (Aromasin)

Reference Number: CP.PST.05
Effective Date: 10.01.10
Last Review Date: 11.17
Line of Business: Medicaid

Revision Log

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

Description
Exemestane (Aromasin®) is an aromatase inhibitor.

FDA Approved Indication(s)
Aromasin is indicated:

- For the adjuvant treatment of postmenopausal women with estrogen receptor positive early breast cancer who have received two to three years of tamoxifen and are switched to exemestane for completion of a total of five consecutive years of adjuvant hormonal therapy
- For the treatment of advanced breast cancer in postmenopausal women whose disease has progressed following tamoxifen therapy

Policy/Criteria
Provider must submit documentation (which may include 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 Aromasin is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Electronic Step Therapy for Exemestane (must meet all)**:**

1. Age ≥ 18 years;
2. Previous use of ≥ 60 days of a PDL aromatase inhibitor (e.g., anastrozole) in the previous 180 days, unless all are contraindicated or clinically significant adverse effects are experienced;
3. Dose does not exceed 25 mg/day (1 tablet/day).

Approval duration: 12 months

II. Continued Therapy

A. Electronic Step Therapy for Exemestane (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Documentation supports that member is currently receiving Aromasin for breast cancer, has received this medication for at least 90 days, and is responding positively to therapy;
2. If request is for a dose increase, new dose does not exceed 25 mg/day (1 tablet/day).

Approval duration: 12 months

III. Appendices/General Information

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

IV. Dosage and Administration

Drug	Dosing Regimen	Maximum Dose
Aromasin	1 tablet (25 mg) by mouth once per day after a meal	25 mg/day

V. Product Availability

Tablet: 25 mg

VI. Workflow Document

N/A

VII. References

1. Aromasin Prescribing Information. New York, NY: Pharmacia and Upjohn Company, LLC; October 2016. Available at: www.aromasin.com. Accessed August 7, 2017.
2. Breast Cancer (Version 2.2017). In National Comprehensive Cancer Network Guidelines. Available at www.NCCN.org. Accessed August 7, 2017.
3. Exemestane. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.NCCN.org. Accessed August 7, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Renamed Aromatase Inhibitor as Exemestane Step Therapy	12.14	12.14
Updated FDA labeled indications; All aromatase inhibitor are on the PDL list, therefore removed all references to non-PDL agent; Since step therapy criteria may be authorized electronically, limitation based on diagnosis will only apply for manual review, therefore this limitation was removed to allow same criteria to be applied on electronic and manual review; Remove the 5 year limitation on approval AI may be indicated for longer time duration per NCCN. Reviewed and updated references.	11.15	11.15
Converted to integrated template; updated references.	09.16	11.16
Converted to new template. Added age limit as safety and efficacy have not been established in pediatric populations. Added anastrazole as an example of a core PDL aromatase	08.07.17	11.17

Reviews, Revisions, and Approvals	Date	P&T Approval Date
inhibitor (does not require ST).		

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.

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.