STEP THERAPY GUIDELINE

DEPARTMENT: Pharmacy	**DOCUMENT NAME:** Exemestane Step Therapy
PAGE: 1 of 5	**REFERENCE NUMBER:** NH.PST.05
EFFECTIVE DATE: 10/10	**REPLACES DOCUMENT:**
RETIRED:	**REVIEWED:** 11/11,11/12, 11/13, 07/16, 07/17
PRODUCT TYPE: All	**REVISED:** 12/14, 07/15

IMPORTANT REMINDER

This Clinical Policy has been developed by appropriately experienced and licensed health care professionals based on a thorough review and consideration of generally accepted standards of medical practice, peer-reviewed medical literature, government agency/program approval status, and other indicia of medical necessity.

The purpose of this Clinical Policy is to provide a guide to medical necessity. Benefit determinations should be based in all cases on the applicable contract provisions governing plan benefits ("Benefit Plan Contract") and applicable state and federal requirements, as well as applicable plan-level administrative policies and procedures. To the extent there are any conflicts between this Clinical Policy and the Benefit Plan Contract provisions, the Benefit Plan Contract provisions will control.

Clinical policies are intended to be reflective of current scientific research and clinical thinking. This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding results. 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.

Description: Aromatase Inhibitors (AI's) function by inhibiting aromatase, the enzyme (found in body fat, adrenal glands, and breast tissue as well as tumor cells) responsible for converting other steroid hormones into estrogen. Aromatase is the sole source of estrogen in postmenopausal women and likely the underlying reason that obesity (larger volume of body fat produces more estrogen) has been associated with a higher risk of breast cancer in postmenopausal patients. As the AIs have no effect on ovarian estrogen production, they are only effective in postmenopausal women.

Medications: exemestane (Aromasin): 25mg tablet

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FDA Labeled Indications:

1. For adjuvant treatment of postmenopausal women with hormone receptor positive early breast cancer.
2. For estrogen receptor positive early breast cancer in postmenopausal women who have already received 2 to 3 years of tamoxifen therapy.
3. For advanced breast cancer in postmenopausal women whose disease has progressed following tamoxifen therapy.
4. For the first-line treatment of locally advanced or metastatic, hormone-receptor positive or hormone-receptor unknown breast cancer in postmenopausal women.

Criteria for Approval:

Authorization of non-preferred medication will be carried out through electronic step-therapy edit.

1. Use of exemestane (Aromasin) will be allowed for patients with prior prescription claims for exemestane in prior 90 days. Claims history can be satisfied through claims look back or upon attestation by a health care provider during the authorization review.
2. Exemestane can be approved upon recognition of 60 days of claims history of a preferred aromatase inhibitor in the previous 180 days.
3. Aromatase inhibitor naïve patients must use a preferred agent unless rationale is provided by the physician regarding contraindications to one of the preferred options.
4. Aromatase Inhibitors are NOT approvable for the treatment of breast cancer in premenopausal women, estrogen receptor negative breast cancer, for the treatment of infertility or for any other non-FDA

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approved indication. Noted that generic anastrozole is not subject to review.

5. Coverage for other cancer diagnoses may be authorized provided effective treatment with such drug is recognized for treatment of such indication in one of the standard reference compendia **OR**
6. Clinically unacceptable risk with a change in therapy to a preferred drug

NOTE: The American Society of Clinical Oncology recommends that all postmenopausal women with estrogen receptor-positive early breast cancer receive adjuvant aromatase inhibitor therapy. Options include 5 years of an aromatase inhibitor or sequential therapy with 2 to 3 years or 5 years of tamoxifen followed by 2 to 3 years or 5 years of an aromatase inhibitor. The optimal duration of therapy and regimen is not known.

Approval:

Initial Approval: 12 months.
Continued Approval: Approval at 12 month intervals for a maximum of five years of therapy.
Quantity Limit: 30 tablets per 30 days.

Special Instructions
➢ NOTE: Patients with estrogen receptor-negative disease and patients who did not respond to previous tamoxifen therapy rarely respond to anastrozole. ➢ As the AIs have no effect on ovarian estrogen production, they are only effective in postmenopausal women. ➢ Common side effects of Ais include hot flashes (12-36%), arthralgia/arthritis (17%), headache (9-13%), vaginal dryness (2%), and mood changes (19%).

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- Adjunctive bisphosphonate therapy in metastatic breast cancer should be considered unless contraindicated.

References:

1. eMedicine® monograph on Breast Cancer, Updated: October 2014. Accessed October 2014. http://emedicine.medscape.com/article/283561-overview
2. Treatment approach to metastatic hormone receptor positive breast cancer: Endocrine Therapy. Matthew Ellis, MD et al. August 2014. Uptodate.com
3. Adjuvant Therapy for Breast Cancer. Rachel Swat, MD et al. http://emedicine.medscape.com/article/1946040-overview#aw2aab6b7. Updated October 2012. Accessed October 2014.
4. Clinical Pharmacology® Exemestane monograph. Accessed October 2014
5. Clinical Pharmacology® Letrozole monograph. Accessed October 2014
6. Clinical Pharmacology® Anastrozole monograph. Accessed October 2014
7. Winer EP, Hudis C, Burnstein HJ, et al. American Society of Clinical Oncology technology assessment on the use of aromatase inhibitors as adjuvant therapy for postmenopausal women with hormone receptor-positive breast cancer: status report 2004. J Clin Oncol 2005; 23:619-29.

Revision Log	
Revision	**Date**
Reviewed and determined that no changes are necessary.	11/11

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Reviewed and updated references.	11/12
References updated and new references added.	11/13
Updated wording throughout guideline, except FDA labeled indication information, from 'hormone receptor positive' to estrogen receptor positive'.	11/13
Updated references. Removed step from letrazole. Provided automation language to edit.	11/14
Renamed Aromatase Inhibitor as Exemestane Step Therapy	12/14
Added Coverage for other cancer diagnoses may be authorized provided effective treatment with such drug is recognized for treatment of such indication in one of the standard reference compendia	07/15
Added Clinically unacceptable risk with a change in therapy to a preferred drug	07/15
Annual Review, No Changes Made	07/16
Annual Review, No Changes	07/17

POLICY AND PROCEDURE APPROVAL

Pharmacy & Therapeutics Committee: Approval on file

V.P., Pharmacy Operations: Approval on file

Sr. V.P., Chief Medical Officer: Approval on file

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