Exemestane (Aromasin)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Exemestane (Brand Name: Aromasin) is an aromatase inhibitor medication typically used in the treatment of certain types of breast cancer in postmenopausal women. By reducing the production of estrogen, a hormone which some breast cancers rely on for growth, exemestane can help inhibit disease progression. Similar agents used for hormone receptor-positive breast cancers include anastrozole, letrozole, and tamoxifen.

In addition to its primary use in treating breast cancer, exemestane can also be prescribed for other cancer types, such as endometrial carcinoma, fallopian tube cancer, persistent or recurrent epithelial ovarian cancer, primary peritoneal cancer, and various forms of uterine sarcoma. This medicine may also be used in combination with other treatments or interventions, such as ovarian suppression in premenopausal women or a gonadotropin-releasing hormone analogue in men with hormone receptor-positive breast cancer.

Definitions

"Adjuvant hormonal therapy" is therapy where medications are used alongside other anticancer therapies to suppress hormones that contribute to the growth of breast tissue.

"Menopause" is clinically defined by the National Comprehensive Cancer Network (NCCN) as the absence of a menstrual period for 12 months without another medical cause. It is when a woman stops having monthly periods, the ovaries stop releasing eggs and making the hormones estrogen and progesterone. NCCN states natural menopause usually occurs between the ages of 42-58 years.

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Breast cancer:

The Plan considers exemestane (Aromasin) medically necessary when ALL the following criteria are met for the applicable indication listed below:

1. The requested medication is being prescribed for ONE (1) of the following:
    a. A postmenopausal woman for ONE (1) of the following:
        i. Advanced breast cancer whose disease has progressed following tamoxifen therapy*; or*
        ii. Estrogen receptor–positive early breast cancer*; or*
        iii. Reducing the risk of invasive breast cancers (at increased risk of developing breast cancer)*; or*
        iv. Risk-reduction endocrine therapy for ipsilateral breast with estrogen receptor-positive ductal carcinoma in situ (DCIS) following surgery; *or*
        v. Invasive breast cancer as adjuvant endocrine therapy with hormone receptor positive tumors disease as first line therapy; *or*
    b. A premenopausal woman and BOTH of the following:
        i. For use in combination with ovarian ablation/suppression (e.g., triptorelin injection, bilateral oophorectomy, or bilateral ovarian irradiation)*; and*
        ii. The member has ONE (1) of the following:

1. Early-stage hormone receptor-positive breast cancer at higher risk of disease recurrence (i.e., younger age, larger or high-grade tumor, increased risk of lymph node involvement)*; or*
2. Received prior adjuvant chemotherapy (e.g., trastuzumab with or without pertuzumab)*; or*
3. Invasive breast cancer as adjuvant endocrine therapy with hormone receptor-positive disease; *or*

c. A male with hormone receptor-positive breast cancer in combination with a gonadotropin-releasing hormone analogue*; AND*

2. Chart documentation and supporting laboratory test results are provided for review to substantiate the above listed requirements.

Other Cancers:

The Plan considers exemestane (Aromasin) medically necessary when ALL the following criteria are met for the applicable indication listed below:

1. The requested medication is prescribed by or in consultation with an oncologist*; AND*
2. The member is 18 years of age or older*; AND*
3. The member has a diagnosis of ONE (1) of the following:
   a. Endometrial carcinoma*; or*
   b. Endometrial adenocarcinoma; *or*
   c. Fallopian tube cancer*; or*
   d. Persistent or recurrent epithelial ovarian cancer*; or*
   e. Primary peritoneal cancer*; or*
   f. Uterine sarcoma, including:
      i. Adenosarcoma*; or*
      ii. Endometrial stromal sarcoma (ESS)*; or*
      iii. PEComa*; or*
      iv. Undifferentiated uterine sarcoma (UUS)*; or*
      v. Uterine leiomyosarcoma (uLMS)*; or*
   g. The use is supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a level of evidence category of 1, 2A, or 2B*; AND*
4. Chart documentation and supporting laboratory test results are provided for review to substantiate the above listed requirements.

If the above prior authorization criteria are met, exemestane (Aromasin) will be approved for up to 12 months.

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Medical Necessity Criteria

The Plan considers exemestane (Aromasin) medically necessary when ALL the following criteria are met for the applicable indication listed below:

1. The member still meets the applicable initial criteria*; AND*
2. Recent chart documentation (within the last 12 months) shows the member has experienced a clinical benefit (e.g., disease or recurrence free survival, time to tumor progression).

If the above reauthorization criteria are met, the requested product will be authorized for up to 12 months.

Experimental or Investigational / Not Medically Necessary

Exemestane for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

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Clinical Guideline Revision / History Information

Original Date: 11/05/2020

Reviewed/Revised: 03/11/2021, 10/14/2021, 12/01/2021, 9/15/2022, 9/21/2023, 12/19/2024, 02/02/2026