Regimen Monograph

A - Regimen Name

ANAS Regimen

Anastrozole

Disease Site

Breast
Gynecologic
Endometrial

Intent

Palliative

Regimen Category

Evidence-Informed :

Regimen is considered appropriate as part of the standard care of patients; meaningfully improves outcomes (survival, quality of life), tolerability or costs compared to alternatives (recommended by the Disease Site Team and national consensus body e.g. pan-Canadian Oncology Drug Review, pCODR). Recommendation is based on an appropriately conducted phase III clinical trial relevant to the Canadian context OR (where phase III trials are not feasible) an appropriately sized phase II trial. Regimens where one or more drugs are not approved by Health Canada for any indication will be identified under Rationale and Use.

Rationale and Uses

- For the hormonal treatment of advanced breast cancer in postmenopausal women
- For the treatment of advanced endometrial cancer

Supplementary Public Funding

anastrozole
ODB - General Benefit (anastrozole) (ODB Formulary)

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B - Drug Regimen

anastrozole	1 mg	PO	Daily

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C - Cycle Frequency

CONTINUOUS TREATMENT

Until disease progression or unacceptable toxicity

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D - Premedication and Supportive Measures

Antiemetic Regimen: Not applicable

Other Supportive Care:

- Assess patient's risk factors for osteoporosis and consider calcium and vitamin D supplements and bisphosphonates where appropriate. Refer patients to the Bone Health During Cancer Treatment pamphlet for more information.

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E - Dose Modifications

Doses should be modified according to the protocol by which the patient is being treated.

Dosage with toxicity

Toxicity	Action
Myelosuppression	No adjustment required.
Severe hypercalcemia	Hold; discontinue if recurs.

Hepatic Impairment

Clearance is reduced by 30% in patients with cirrhosis, but plasma levels are within normal range.

Hepatic Impairment	Anastrozole Dose
Mild to Moderate	No adjustment is required.
Severe	Not studied; consider potential risk/benefit.

Renal Impairment

Clearance is reduced by 50% in severe renal impairment. However, renal excretion is a minor route of excretion and no adjustment is required.

Creatinine Clearance (mL/min)	Anastrozole Dose
≥ 30	No adjustment is required.
< 30	No adjustment is required. Consider potential risk/benefit.

Dosage in the Elderly

No dosage adjustment required.

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F - Adverse Effects

Refer to anastrozole drug monograph(s) for additional details of adverse effects.

Common (25-49%)	Less common (10-24%)	Uncommon (< 10%), but may be severe or life-threatening
• Estrogen deprivation symptoms • Musculoskeletal pain	• Fatigue • Mood changes (including depression) • Hypertension • Nausea, vomiting • Osteoporosis, fracture • Rash • Headache • Insomnia	• Arterial and venous thromboembolism • Ischemic cardiovascular events • Endometrial cancer • Hypercalcemia • Vasculitis • Hypersensitivity • Erythema multiforme • Stevens-Johnson syndrome • ↑ LFTs • Cataract

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G - Interactions

Refer to anastrozole drug monograph(s) for additional details.

- Do not co-administer with tamoxifen due to ↓ anastrozole concentration and no efficacy or safety benefit.
- Avoid estrogen-containing or estrogenic agents due to ↓ estrogen suppression.

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H - Drug Administration and Special Precautions

Refer to anastrozole drug monograph(s) for additional details.

Administration:

- Administer anastrozole with or without food.
- Tablets should be swallowed whole with a glass of water at the same time each day.
- Missed doses should be taken as soon as possible, but only if there are at least 12 hours before the next dose is due.
- Store at room temperature (15 to 30°C).

Contraindications:

- Patients with hypersensitivity to the drug or any of its components
- Pregnant or lactating women

Warnings/Precautions:

- Use is not recommended in premenopausal women*.
- Use with caution in patients with known osteoporosis or risk factors for osteoporosis, in patients with pre-existing cardiovascular disorders, severe liver or renal impairment.
- Anastrozole has not been studied in patients with brain, leptomeningeal or pulmonary lymphangitic disease.
- Use of formulations containing lactose should be carefully considered in patients with hereditary galactose intolerance, severe lactase deficiency or glucose-galactose malabsorption.

**not receiving ovarian suppression*

Pregnancy/Lactation:

- This regimen is **contraindicated** for use in pregnancy. Adequate contraception should be used by patients and their partners while on treatment and after the last treatment dose. Recommended methods and duration of contraception may differ depending on the treatment. Refer to the drug monograph(s) for more information.
- Breastfeeding is **contraindicated** during this treatment and after the last treatment dose. Refer to the drug monograph(s) for recommendations after the last treatment dose (if available).
- Fertility effects: Probable

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I - Recommended Clinical Monitoring

Treating physicians may decide to monitor more or less frequently for individual patients but should always consider recommendations from the product monograph.

Recommended Clinical Monitoring

- Bone mineral density for patients at risk; Baseline and as clinically indicated
- Clinical toxicity assessment for fatigue, musculoskeletal, estrogen deprivation symptoms, mood changes (including depression), rash, edema, thromboembolism, cardiovascular, GI and GU effects; At each visit
- Grade toxicity using the current NCI-CTCAE (Common Terminology Criteria for Adverse Events) version

Suggested Clinical Monitoring

- Liver function tests; Baseline and as clinically indicated
- Electrolytes, including calcium; Baseline and as clinically indicated
- Cholesterol and lipid evaluation; Baseline and as clinically indicated

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J - Administrative Information

Outpatient prescription for home administration.

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K - References

Anastazole drug monograph. Ontario Health (Cancer Care Ontario).

Breast:

Bonneterre J, Buzdar A, Nabholtz JM et al. Anastrozole is Superior to Tamoxifen as First-Line Therapy in Hormone Receptor Positive Advanced Breast Carcinoma. Cancer 2001; 92(9):2247-58.

Bonneterre J, Thürlimann BJK, Robertson JFR et al. Anastrozole Versus Tamoxifen as First-Line Therapy for Advanced Breast Cancer in 668 Postmenopausal Women: Results of the Tamoxifen or Arimidex Randomized Group Efficacy and Tolerability Study. Journal of Clin Oncology 2000; 18(22):3748-57.

Buzdar A, Jonat W, Howell A, et al. Anastrozole, a potent and selective aromatase inhibitor, versus megestrol acetate in postmenopausal women with advanced breast cancer: results of overview analysis of two phase III trials. J Clin Oncol, 1996 July;14(7):2000-11.

Buzdar A, Jonat W, Howell A, Jones SE, et al. Anastrozole versus megestrol acetate in the treatment of postmenopausal women with advanced breast carcinoma: results of a survival update based on a combined analysis of data from two mature phase III trials. Cancer 1998;83(8):1142-52.

Nabholtz JM, Buzdar A, Pollak M, et al. Anastrozole is superior to Tamoxifen as first-line therapy for advanced breast cancer in postmenopausal women: results of a North American multicenter randomized trial. J Clin Oncol, 2000;18(22):3758-67.

Endometrial:

Ethier JL, Desautels DN, Amir E, MacKay H. Is hormonal therapy effective in advanced endometrial cancer? A systematic review and meta-analysis. Gynecologic Oncology 2017;147:158-166.

April 2024 Updated Pregnancy and Lactation section

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M - Disclaimer

Regimen Abstracts

A Regimen Abstract is an abbreviated version of a Regimen Monograph and contains only top level information on usage, dosing, schedule, cycle length and special notes (if available). It is intended for healthcare providers and is to be used for informational purposes only. It is not intended to constitute or be a substitute for medical advice, and all uses of the Regimen Abstract are subject to clinical judgment. Such information is provided on an "as-is" basis,

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Information in regimen abstracts is accurate to the extent of the ST-QBP regimen master listings, and has not undergone the full review process of a regimen monograph. Full regimen monographs will be published for each ST-QBP regimen as they are developed.

Regimen Monographs

Refer to the New Drug Funding Program or Ontario Public Drug Programs websites for the most up-to-date public funding information.

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