Exemestane Monotherapy

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	Reimbursement Status
Adjuvant treatment of postmenopausal women with hormone receptor positive invasive early breast cancer.	C50	00376a	CDS
Extended adjuvant treatment of hormone-dependent invasive breast cancer in postmenopausal women who have received prior adjuvant endocrine therapy.	C50	00376b	CDS
Advanced breast cancer after relapse or disease progression, in women with natural or artificially induced postmenopausal endocrine status.	C50	00376c	CDS

TREATMENT:

The starting dose of the drugs detailed below may be adjusted downward by the prescribing clinician, using their independent medical judgement, to consider each patients individual clinical circumstances.

Exemestane is administered orally once daily continuously during treatment.

Duration of treatment will be determined by the prescribing Consultant and depends on disease progression or unacceptable toxicity.

Drug	Dose	Route	Diluent & Rate	Cycle
Exemestane	25mg	PO	NA	Continuous
Daily oral supplement of calcium and Vit D are recommended for duration of therapy.				
If a dose of exemestane is missed, the patient should not take an additional dose, but take the next prescribed dose as usual.				
The tablets should **not** be chewed or crushed				
Exemestane is available as 25mg tablets				

ELIGIBILITY:

- Indications as above

EXCLUSIONS:

- Hypersensitivity to exemestane or any of the excipients
- Pre-menopausal women
- Pregnancy
- Lactation

PRESCRIPTIVE AUTHORITY:

The treatment plan must be initiated by a Consultant Medical Oncologist or General Practitioner under direction of plan written by medical oncologist.

TESTS:

Baseline tests:

- FBC, renal and liver profile
- Check FSH, LH, oestradiol levels if less than 55 and prior hysterectomy or uncertain menopausal status due to young age or other factors.
- Consider baseline bone density assessment in appropriate patients

Disease monitoring:
Disease monitoring should be in line with the patient's treatment plan and any other test/s as directed by the supervising Consultant.

DOSE MODIFICATIONS:

- No recommended dose modifications
- Any dose modification should be discussed with a Consultant.

Renal Impairment	Hepatic Impairment
No dose adjustment required	**No dose adjustment required**

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL: Minimal (Refer to local policy).

PREMEDICATIONS: Not usually required

OTHER SUPPORTIVE CARE:

Daily oral supplements of calcium and vitamin D are recommended for the duration of the therapy.
Lifestyle modification including regular exercise, particularly weight bearing exercises

ADVERSE EFFECTS / REGIMEN SPECIFIC COMPLICATIONS

The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.

- Change in bone density: Exemestane is a potent oestrogen lowering agent, and a reduction in bone mineral density (BMD) and an increased fracture rate have been observed following administration.
- Hyperlipidemia: An increase in cholesterol or triglyceride levels may occur when an aromatase inhibitor is initiated. Consideration should be given to checking levels during the first few months of therapy, especially in those patients with prior significant lipid elevations

DRUG INTERACTIONS:

- Current drug interaction databases should be consulted for more information.
- Reduced efficacy of exemestane possible with CYP3A4 inducers due to increased clearance.
- Exemestane should not be coadministered with oestrogen-containing medicines as these would negate its pharmacological action.

ATC CODE:

Exemestane - L02BG06

REFERENCES:

1. van de Velde CJH, Rea D et al. Adjuvant tamoxifen and exemestane in early breast cancer (TEAM): a randomised phase 3 trial Lancet 2011; 377, p321–331
2. Coombes RC, Kilburn LS, Snowdon CF, et al. Survival and safety of exemestane versus tamoxifen after 23 years tamoxifen treatment (Intergroup Exemestane Study): a randomised controlled trial. Lancet 2007;369(9561):559-570.
3. Eisen A, Trudeau M, Shelley W, et al. Aromatase inhibitors in adjuvant therapy for hormone receptor positive breast cancer: a systematic review. Cancer Treat Rev 2008;34(2):157174.
4. Kaufmann M, Bajetta E, Dirix LY, et al. Exemestane is superior to megestrol acetate after tamoxifen failure in postmenopausal women with advanced breast cancer: results of a phase III randomized double-blind trial. The Exemestane Study Group. J Clin Oncol 2000;18(7):1399-1411.
5. Aromasin Summary of Product Characteristics. Accessed December 2020. Available at https://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA0822-111-001_25062018103042.pdf

Version	Date	Amendment	Approved By
1	11/11/2016		Prof Maccon Keane
2	26/11/2018	Updated to new NCCP template Clarification on duration of treatment	Prof Maccon Keane
3	6/01/2021	Reviewed	Prof Maccon Keane

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.