Anastrozole Monotherapy

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	*Reimbursement Status
Treatment of hormone receptor positive locally advanced or metastatic breast cancer in post-menopausal women.	C50	254a	CDS
Adjuvant treatment of postmenopausal women with hormone receptor positive invasive early breast cancer	C50	254b	CDS
Extended adjuvant treatment of hormone-dependent-invasive breast cancer in postmenopausal women whohave received 2 to 3 years of adjuvant tamoxifen.	C50	254c	CDS

**If the reimbursement status is not defined [1], the indication has yet to be assessed through the formal HSE reimbursement process.*

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.

Anastrozole 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.

Day	Drug	Dose	Route	Diluent & Rate	Cycle
1	**Anastrazole**	1mg daily	PO	NA	Continuous daily as indicated until disease progression or unacceptable toxicity.
Daily oral supplement of calcium and Vit D are recommended for duration of therapy.					
Tablet should be swallowed whole. Can be taken with food or on an empty stomach with a glass of water If nausea develops, anastrozole may be taken with or after food or at night. If patient vomits within a few hours of taking the drug, do not repeat the dose					
Missed doses should not be replaced, normal dosing should be resumed at the next scheduled daily dose					

ELIGIBILTY:

- Indications as above
- Contraindications to tamoxifen or intolerant of tamoxifen.

EXCLUSIONS:

- Hypersensitivity to anastrozole or any of the excipients.
- Hormone receptor-negative.
- Pre-menopausal women.

PRESCRIPTIVE AUTHORITY:

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

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TESTS:

Baseline tests: FBC, U&Es, LFTs.
Check FSH, LH, oestradiol levels if less than 55 and prior hysterectomy or uncertain menopausal status due to young age or other factors

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.

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL: Minimal Risk (**Refer to local policy).**

PREMEDICATIONS:
Not usually required

OTHER SUPPORTIVE CARE:
None usually required

ADVERSE EFFECTS / REGIMEN SPECIFIC COMPLICATIONS

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

- **Hepatic dysfunction**: Aromatase inhibitors are considered safe in mild-to- moderate hepatic dysfunction but have not been studied in severe hepatic dysfunction.
- **Bone density**: The long-term effects of aromatase inhibitors on bone density in adjuvant therapy patients are unknown. Supplementation with calcium and vitamin D and regular weight bearing exercise is recommended. A bisphosphonate should be considered if clinically indicated. Caution in patients with an already established diagnosis of clinically significant osteoporosis.
- **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:

- Co-administration of tamoxifen and aromatase inhibitors should be avoided.
- Oestrogen preparations (e.g. topical vaginal creams etc.) should be avoided as these may negate the effect of aromatase inhibitors.
- Current drug interaction databases should be consulted for more information.

ATC CODE:

Anastrozole - L02BG03

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REFERENCES:

1. Cuzick J, Sestak I et al. Effect of anastrozole and tamoxifen as adjuvant treatment for early-stage breast cancer: 10-year analysis of the ATAC trial. Lancet Oncol 2010; 11:1135-1141.
2. Eisen, A., M. Trudeau, W. Shelley, et al. Aromatase inhibitors in adjuvant therapy for hormone receptor positive breast cancer: a systematic review. Cancer Treat Rev 2008;34(2):157-174.
3. Jonat W, Gnant M, Boccardo F et al. Effectiveness of switching from adjuvant tamoxifen to anastrozole in postmenopausal women with hormone-sensitive early-stage breast cancer: a meta-analysis. Lancet Oncol. 2006;7:991-996.
4. Jakesz R, Jonat W. et al. Switching of postmenopausal women with endocrine-responsive early breast cancer to anastrozole after 2 years' adjuvant tamoxifen: combined results of ABCSG trial 8 and ARNO 95 trial. Lancet 2005; 366:455-462.
5. Howell A, Cuzick J et al. Results of the ATAC (Arimidex, Tamoxifen, alone or in combination) trial after completion of 5 years' adjuvant treatment for breast cancer. Lancet 2005;365(9453): 60-2
6. Bonneterre J, Buzdar A. et al. Anastrozole is superior to tamoxifen as first-line therapy in hormone receptor positive advanced breast carcinoma. Cancer 2001:92;2247-2258.
7. Amidex ® Summary of Product Characteristics Accessed Sept 2018 Available at http://www.hpra.ie/img/uploaded/swedocuments/LicenseSPC_PA0126-189-001_23062016120220.pdf

Version	Date	Amendment	Approved By
1	1/11/2014		Prof Maccon Keane
2	16/11/2016	Reviewed-clarified wording of indications	Prof Maccon Keane
3	26/11/2018	Updated with new NCCP regimen template. Clarified treatment duration	Prof Maccon Keane

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

[i] ODMS – Oncology Drug Management System
CDS – Community Drug Schemes (CDS) including the High Tech arrangements of the PCRS community drug schemes
Further details on the Cancer Drug Management Programme is available at;
http://www.hse.ie/eng/services/list/5/cancer/profinfo/medonc/cdmp/

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