Anastrozole Monotherapy

INDICATIONS FOR USE:

<table>
<thead>
<tr>
<th>INDICATION</th>
<th>ICD10</th>
<th>Regimen Code</th>
<th>*Reimbursement Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment of hormone receptor positive locally advanced or metastatic breast cancer in post-menopausal women.</td>
<td>C50</td>
<td>254a</td>
<td>CDS</td>
</tr>
<tr>
<td>Adjuvant treatment of postmenopausal women with hormone receptor positive invasive early breast cancer</td>
<td>C50</td>
<td>254b</td>
<td>CDS</td>
</tr>
<tr>
<td>Extended adjuvant treatment of hormone-dependent-invasive breast cancer in postmenopausal women who have received 2 to 3 years of adjuvant tamoxifen.</td>
<td>C50</td>
<td>254c</td>
<td>CDS</td>
</tr>
</tbody>
</table>

*If the reimbursement status is not defined*, 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 patient's 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.

<table>
<thead>
<tr>
<th>Day</th>
<th>Drug</th>
<th>Dose</th>
<th>Route</th>
<th>Diluent &amp; Rate</th>
<th>Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Anastrozole</td>
<td>1mg daily</td>
<td>PO</td>
<td>NA</td>
<td>Continuous daily as indicated until disease progression or unacceptable toxicity.</td>
</tr>
</tbody>
</table>

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.

ELIGIBILITY:

- 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 a written plan by a medical oncologist.
NCCP Chemotherapy Regimen

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:
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 should be encouraged.

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.
NCCP Chemotherapy Regimen

ATC CODE:
Anastrozole - L02BG03

REFERENCES:

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

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

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1 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/proinfo/medonc/cdmp/