NCCP Chemotherapy Regimen

**Exemestane 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>Adjuvant treatment of postmenopausal women with hormone receptor positive invasive early breast cancer.</td>
<td>C50</td>
<td>00376a</td>
<td>CDS</td>
</tr>
<tr>
<td>Extended adjuvant treatment of hormone-dependent invasive breast cancer in postmenopausal women who have received prior adjuvant endocrine therapy.</td>
<td>C50</td>
<td>00376b</td>
<td>CDS</td>
</tr>
<tr>
<td>Advanced breast cancer after relapse or disease progression, in women with natural or artificially induced postmenopausal endocrine status.</td>
<td>C50</td>
<td>00376c</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.

Exemestane is administered orally once daily continuously during treatment.

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

<table>
<thead>
<tr>
<th>Drug</th>
<th>Dose</th>
<th>Route</th>
<th>Diluent &amp; Rate</th>
<th>Cycle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Exemestane</td>
<td>25mg</td>
<td>PO</td>
<td>NA</td>
<td>Continuous</td>
</tr>
</tbody>
</table>

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.

<table>
<thead>
<tr>
<th>Renal Impairment</th>
<th>Hepatic Impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td>No dose adjustment required</td>
<td>No dose adjustment required</td>
</tr>
</tbody>
</table>

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:

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

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.

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/