Fulvestrant Therapy

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 postmenopausal women with oestrogen receptor positive, locally advanced or metastatic breast cancer for disease relapse on or after adjuvant anti-oestrogen therapy.</td>
<td>C50</td>
<td>00361a</td>
<td>CDS</td>
</tr>
<tr>
<td>Treatment of postmenopausal women with oestrogen receptor positive, locally advanced or metastatic breast cancer for disease progression on or after adjuvant anti-oestrogen therapy.</td>
<td>C50</td>
<td>00361b</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.

Fulvestrant is administered on day 1 and day 14 for cycle 1 and then on day 1 of a 28 day cycle for all subsequent cycles until disease progression or unacceptable toxicity occurs.

<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, 14</td>
<td>Fulvestrant</td>
<td>500 mg</td>
<td>IM</td>
<td>N/A</td>
<td>1</td>
</tr>
<tr>
<td>1</td>
<td>Fulvestrant</td>
<td>500 mg</td>
<td>IM</td>
<td>N/A</td>
<td>Continuous</td>
</tr>
</tbody>
</table>

Administered as two consecutive 5 ml injections by slow intramuscular injection (1-2 minutes/injection), one in each buttock.

ELIGIBILITY:
- Indications as above
- ECOG performance status 0-2

EXCLUSIONS:
- Hypersensitivity to fulvestrant or any of the excipients
- Severe hepatic impairment
- Pregnancy

PRESCRIPTIVE AUTHORITY:
The treatment plan must be initiated by a Consultant Medical Oncologist

TESTS:
Baseline tests:
- FBC, renal and liver profile

Regular tests:
- Liver profile as clinically indicated.
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:
- Any dose modification should be discussed with a Consultant.

Renal and Hepatic Impairment:

Table 1: Dose modification of fulvestrant in renal and hepatic impairment

<table>
<thead>
<tr>
<th>Renal Impairment</th>
<th>Hepatic Impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td>No dose adjustments are recommended for patients with mild to moderate renal impairment (creatinine clearance ≥30 ml/min). Safety and efficacy have not been evaluated in patients with severe renal impairment (creatinine clearance &lt;30 ml/min), and, therefore, caution is recommended in these patients.</td>
<td>No dose adjustments are recommended for patients with mild to moderate hepatic impairment. However, as fulvestrant exposure may be increased, fulvestrant should be used with caution in these patients. There are no data in patients with severe hepatic impairment.</td>
</tr>
</tbody>
</table>

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL: Minimal (Refer to local policy).

PREMEDICATIONS:
None required

OTHER SUPPORTIVE CARE:
No specific recommendations

ADVERSE EFFECTS / REGIMEN SPECIFIC COMPLICATIONS
The adverse effects listed are not exhaustive. Please refer to the relevant Summary of Product Characteristics for full details.
Due to the intramuscular route of administration, fulvestrant should be used with caution if treating patients with bleeding diatheses, thrombocytopenia or those taking anticoagulant treatment.

DRUG INTERACTIONS:
- Current drug interaction databases should be consulted for more information.

ATC CODE:
Fulvestrant - L02BA03
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></td>
<td></td>
<td>Prof Maccon Keane</td>
</tr>
<tr>
<td>2</td>
<td>26/11/2018</td>
<td>Updated to new NCCP format.</td>
<td>Prof Maccon Keane</td>
</tr>
</tbody>
</table>

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/profinfo/medonc/cdmp/