Fulvestrant Therapy

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	*Reimbursement Status
Treatment of postmenopausal women with oestrogen receptor positive, locally advanced or metastatic breast cancer for disease relapse on or after adjuvant anti-oestrogen therapy.	C50	00361a	CDS
Treatment of postmenopausal women with oestrogen receptor positive, locally advanced or metastatic breast cancer for disease progression on or after adjuvant anti-oestrogen therapy.	C50	00361b	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.

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.

Day	Drug	Dose	Route	Diluent & Rate	Cycle
1, 14	Fulvestrant	500 mg	IM	N/A	1
1	Fulvestrant	500 mg	IM	N/A	Continuous
Administered as two consecutive 5 ml injections by slow intramuscular injection (1-2 minutes/injection), one in each buttock					

ELIGIBILTY:

- 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

Renal Impairment	Hepatic Impairment
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 <30 ml/min), and, therefore, caution is recommended in these patients.	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

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:

1. Howell, A., J. Pippen, R. M. Elledge, et al. Fulvestrant versus anastrozole for the treatment of advanced breast carcinoma: a prospectively planned combined survival analysis of two multicenter trials. Cancer 2005;104(2):236-239.
2. Robertson JF, Llombart-Cussac A, et al. Activity of fulvestrant 500 mg versus anastrozole 1 mg as first-line treatment for advanced breast cancer: results from the FIRST study. J Clin Oncol. 2009;27(27):4530.
3. Di Leo A, Jerusalem G, et al. Final overall survival: fulvestrant 500 mg vs 250 mg in the randomized CONFIRM trial. J Natl Cancer Inst. 2014;106(1):djt337.
4. Robertson JF, Lindemann JP, Llombart- et al. Fulvestrant 500 mg versus anastrozole 1 mg for the first-line treatment of advanced breast cancer: follow-up analysis from the randomized 'FIRST' study. Breast Cancer Res Treat. 2012;136(2):503.
5. Ellis MJ, Llombart-Cussac A, et al. Fulvestrant 500 mg Versus Anastrozole 1 mg for the First-Line Treatment of Advanced Breast Cancer: Overall Survival Analysis From the Phase II FIRST Study J Clin Oncol. 2015 Nov;33(32):3781-7.
6. Falsodex Summary of Product Characteristics.Accessed Oct 2018. Available at http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-_Product_Information/human/000540/WC500021174.pdf

Version	Date	Amendment	Approved By
1			Prof Maccon Keane
2	26/11/2018	Updated to new NCCP format.	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/