The Christie NHS
NHS Foundation Trust

SHARED CARE PROTOCOL for FULVESTRANT (FASLODEX®) INJECTION	**Unique Identifier**
Scope Fulvestrant may be considered for shared care arrangements for the treatment of metastatic breast cancer for disease relapse.	**Classification SHARED CARE PROTOCOL**

Issue date April 2010	**Replaces** SCP April 2008	
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To be read in conjunction with the following documents	The Summary of Product Characteristics (SPC)	
Authorised by	Medicines Management Group	**Date** April 2010
Review Date	April 2012	

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1.0 Introduction

Breast cancer is the commonest female malignancy with a 1:12 lifetime risk of developing the disease.

In early disease, following surgical removal of the tumour, adjuvant treatment is given to reduce the risk of recurrence. Radiotherapy, chemotherapy and hormone therapy, or a combination of these, are all options for adjuvant treatment. Patients with oestrogen receptor positive (ER+ve) tumours should be given hormonal therapy.

If advanced disease, or recurrence of previously controlled disease is identified or suspected, the patient should be referred immediately to hospital for further investigation. The treatment algorithm (next page) gives an overview of the options available for treatment of postmenopausal women with advanced breast cancer.

2.0 Purpose

These guidelines will now go on to look at the shared care management of patients with metastatic breast cancer treated with Fulvestrant.

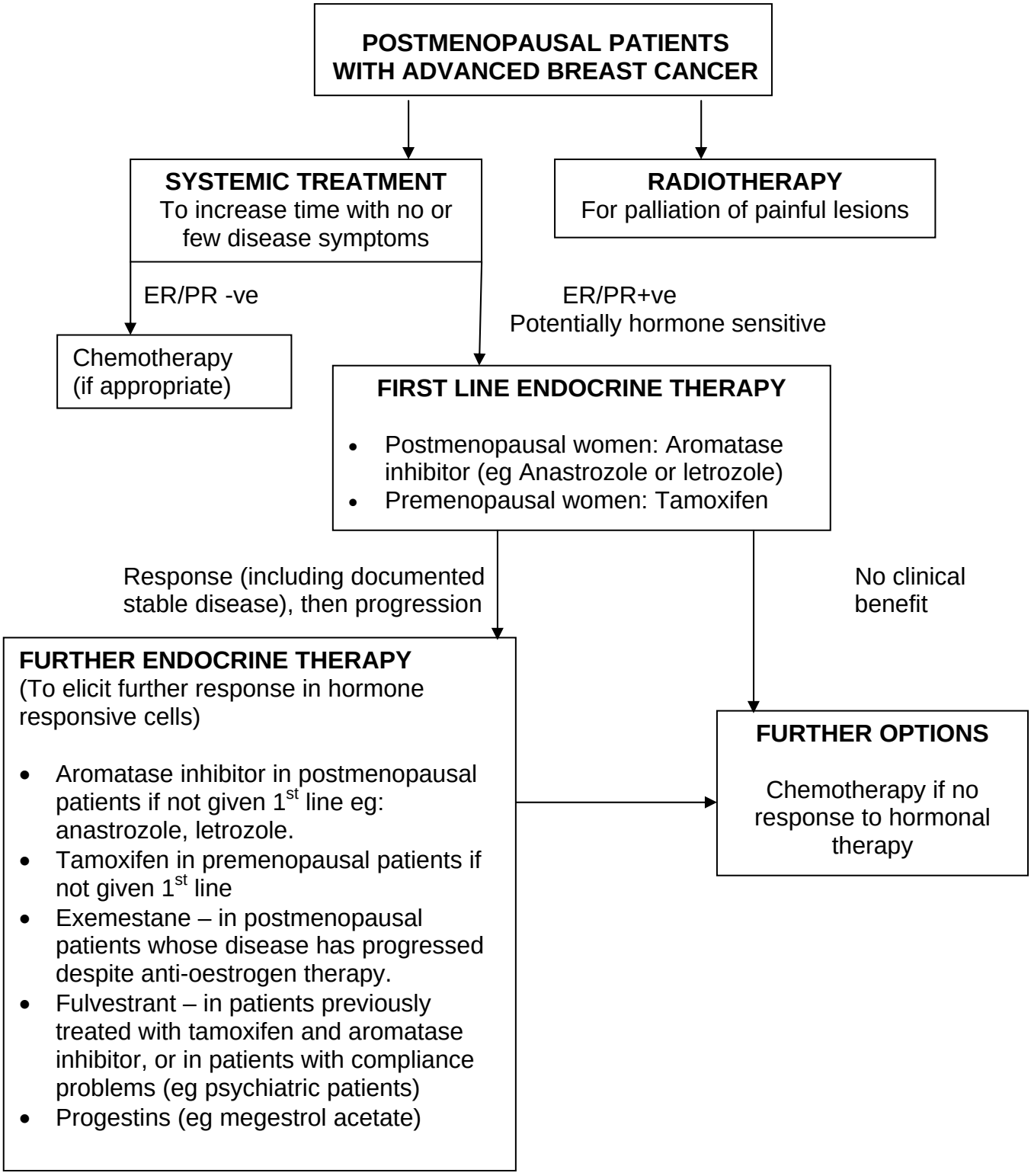
3.0 Scope

Fulvestrant may be considered for shared care arrangements for the treatment of postmenopausal women with metastatic breast cancer for disease relapse.

4.0 Review

2 years

TREATMENT OPTIONS



5.0 Shared Care Protocol

5.1 Clinical Details

Fulvestrant is licensed for the treatment of postmenopausal women with oestrogen receptor positive, locally advanced or metastatic breast cancer for disease relapse on or after adjuvant anti-oestrogen therapy or disease progression on therapy with an anti-oestrogen.

It has been approved at the Christie Hospital NHS Trust for third line hormonal treatment, or use in patients with poor compliance with oral medication.

5.2 Product Information

The recommended dose is 500 mg at intervals of one month, with an additional 500 mg dose given two weeks after the initial dose. This should be administered as two consecutive 5 ml injections (250mg/5ml) by slow intramuscular injection (1-2 minutes/injection), one in each buttock.

In April 2010 the licensed dose of fulvestrant was been increased from 250mg to 500mg monthly. Any patient commencing fulvestrant will be initiated on the 500mg dosing schedule. Patients currently maintained on fulvestrant will continue on the 250mg dosing schedule.

Fulvestrant is an oestrogen receptor down regulator with no agonist effects. Time to progression was found to be 6.5 months with fulvestrant 500mg compared to 5.5 months for fulvestrant 250mg. Fulvestrant at the 250 mg monthly dose has been demonstrated to be at least as effective as anastrozole in terms of time to progression, objective response, and time to death.

Fulvestrant is contraindicated in patients with known hypersensitivity to the active substance or any of the excipients, pregnancy, in breast-feeding and in patients with severe hepatic impairment.

It should be used with caution in mild to moderate hepatic impairment and in severe renal impairment. As it is an intramuscular injection it should be used with caution in patients with clotting abnormalities.

5.3 Ancillary products/apparatus which may need to be prescribed by a GP

Two pre-filled syringes, each containing 5 ml (250mg) fulvestrant solution for injection. Safety needles (BD SafetyGlide™) for connection to each barrel are also provided. Appropriate sharps disposal is needed. The injection must be stored in a fridge. (2°C to 8°C). Keep in original packaging to protect from light.

5.4 Possible side effects of treatment

Fulvestrant is well tolerated with a side effect profile similar to anastrazole. It demonstrates a significantly reduced incidence of joint disorders (including arthralgia, arthrosis and arthritis) compared with anastrazole.

The most commonly reported adverse reactions are hot flushes, nausea, vomiting, diarrhoea, anorexia, rash, urinary tract infections, venous thromboembolism, injection site reactions, headache, asthenia and back pain.

5.5 Aspects of care for which the consultant is responsible

Assessing the patient and establishing a need for fulvestrant treatment.

Providing information for the patient, including adverse effects, obtaining consent and initiating treatment.
Ensuring that there are no contra-indications to therapy with fulvestrant.
The first two doses will be administered in the hospital setting at fortnightly intervals.
Contacting the GP to invite shared care for the patient.
Assessing the continued appropriateness for fulvestrant on a 3 monthly basis.
Reviewing any concerns regarding disease progression from the GP within 2 weeks.
Monitoring toxicity and reporting adverse events
Ensuring that all other medical professionals in the shared care team are kept informed of any changes in the patient's circumstances.

5.6 Conditions of assuming responsibility by the GP

	Consultant	**Usual GP**
FBC, Biochemistry	3 monthly	Not required
Follow up	3 monthly	Monthly

5.7 Aspects of care for which the GP is responsible

Initial referral to a consultant on suspicion of breast cancer.
Provision of general care and advice to the patient and her family/carers.
Assessment of continued well being of the patient.
Monitoring toxicity and reporting adverse events to the consultant.
Providing the patient with repeat prescriptions for Fulvestrant injection every 4 weeks, and arranging its administration
Referring for review if there are signs of disease progression.
Ensuring that all other medical professionals in the shared care team are kept informed of any changes in the patient's circumstances.

5.8 Product Patient Information Leaflet

See attached information

5.9 References

Baum M, Schipper H. Fast Fact Breast Cancer. 1st ed. Oxford (UK): Health Press Limited; 1998.
Howell A *et al.* Fulvestrant, formerly ICI 182,780, is as effective as anastrazole in postmenopausal women with advanced breast cancer progressing after prior endocrine treatment. *J Clin Oncol* 2002 Aug 15; 20 (16): 3396-3403
Faslodex Summary of Product Characteristics www.medicines.org.uk accessed 3.5.10

6.0 Back up details available from hospital to General Practitioner and patient e.g. contact name and number, especially for out of hours problems

7.0 Statement of Agreement.

Shared care is an agreement between the GP and the Consultant. This form is a request by the consultant to share the suggested care pathway of your patient. If you are unable to agree to the sharing of care and initiating the suggested medication, please make this known to the consultant within 14 days, ideally stating the nature of your concern