HERPC
Hull & East Riding Prescribing Committee

Prescribing Framework for Fulvestrant

Patient's Name:……..… NHS Number: ……

Patient's Address:……...……(Use addressograph sticker)

GP's Name:……..

Communication

We agree to treat this patient within this Prescribing Framework

Specialist Prescriber's Name…… Prof Reg. No. ……

Specialist Prescriber's Signature…… Date:……

Where prescriber is <u>not</u> a consultant:
Consultant's Name: …… GMC No …….

Consultant's Signature ……... ……. Date:……

GP's Signature:…… Date:……

GP's Name (if different from listed above)……..

The front page of this form should be completed by the specialist and the form sent to the patient's general practitioner.
The patient's GP should sign and **send back to specialist**, to confirm agreement to enter into shared care arrangement. If the General Practitioner is **<u>unwilling</u>** to accept prescribing responsibility for the above patient the specialist should be informed within two weeks of receipt of this framework and specialist's letter.

Full copy of framework can also be found at :
https://www.hey.nhs.uk/herpc/amber/

1. Background

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) or progesterone receptor positive (PgR+ve) tumours should be given hormonal therapy.

This document should be read in conjunction with the guidance "Responsibility for prescribing between Primary & Secondary/Tertiary Care" https://www.england.nhs.uk/wp-content/uploads/2018/03/responsibility-prescribing-between-primary-secondary-care-v2.pdf

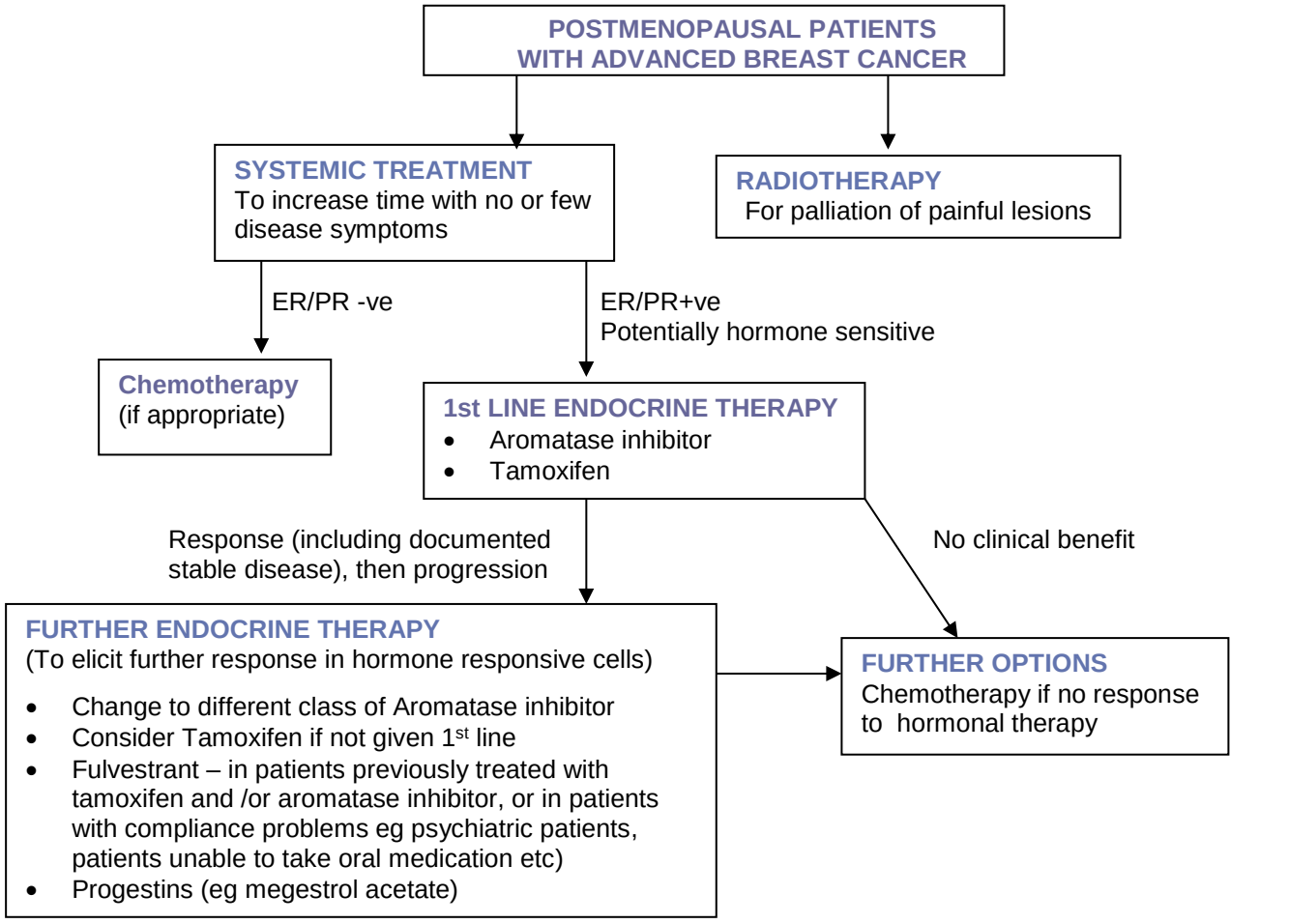
2. Indication

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.

Fulvestrant therapy should only be used as a fourth line endocrine therapy, where patients have progressed following treatment with tamoxifen, anastrozole/letrozole and exemestane (see algorithm below).

Criteria for use:

TREATMENT OPTIONS



Chemotherapy to be considered at any stage if clinically appropriate

3. Dose / administration

The recommended dose for fulvestrant is 500 mg once a month (every 4 weeks), with an additional 500 mg dose given two weeks after the initial dose.

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

4. Duration of treatment

For an average of 5 to 6 months.

5. Contraindications and cautions

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.

6. Adverse effects

The most commonly reported adverse reactions (>1in 100) are

- hot flushes
- nausea
- vomiting
- diarrhea
- anorexia
- rash
- urinary tract infections
- venous thromboembolism
- injection site reactions
- headache
- asthenia
- back pain
- hypersensitivity reactions
- increased hepatic enzymes
- elevated bilirubin.
- Joint and musculoskeletal pain

7. Interactions

Dosage adjustment is not necessary in patients who are co-prescribed fulvestrant and CYP 3A4 inhibitors or inducers.

8. Monitoring

Monitoring	GP
FBC, Biochemistry	Not required
Follow up	3 Monthly or as required

9. Information to patient

A patient information booklet will be provided to patient in hospital and contains the following:
Fulvestrant ingredients and manufacturer
What fulvestrant is and what it is used for
Before you use fulvestrant
How fulvestrant is given
Possible side effects
Storing fulvestrant
Further information

10. Responsibilities of clinicians involved

Stage of Treatment	Hospital Specialist	General Practitioner
Initiation	Assessing the patient and establishing a need for fulvestrant Providing information for the patient, including adverse effects, obtaining consent and initiating treatment. Contacting the GP to invite shared care for the patient.	
Maintenance	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.	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. 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.

Contact Details: The Queen's Centre for Oncology and Haematology
During Office hours: Tel: 01482 461098
Out of hours: Ward 32 Tel: 01482 461019

APPROVAL PROCESS

Written by:	**Marian Opoku-Fofie,** ***Updated By Marie Miller, Interface Pharmacist June 2012 and Jane Morgan, Interface Pharmacist May 17 Reviewed October 2021***
Consultation process:	**Breast Cancer Network Site Specific Group**
Approved by:	**MMIG**
Ratified by:	**HERPC May 2010 Updated June 2018, November 2021**
Review date:	**November 2024**