HERPC

Hull & East Riding Prescribing Committee

Prescribing Framework for Anastrazole for Chemoprevention of Familial Breast Cancer

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.
<u>The patient's GP should sign and send back to specialist</u>, 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 : http://www.hey.nhs.uk/amber.htm

1. Background

NICE CG164 provides recommendations for the care of people at risk of familial breast cancer including assessment of risk, surveillance and risk reduction strategies. Chemoprevention with anastrazole, tamoxifen or raloxifene is recommended for some women with moderate or high risk of developing breast cancer [unlicensed indication]. It is recommended that chemoprevention is initiated following recommendation from secondary or tertiary care and would continue for up to 5 years.

Pathways for assessment, referral and prescribing of chemoprevention can be found on **Yorkshire and the Humber Strategic Clinical Networks and Senate website** http://www.yhscn.nhs.uk/cancer/cancer-UsefulInformation/Breast.php

2. Indication

Women with moderate or high risk of developing familial breast cancer as per CG164

3. Dose

1mg once daily

4. Duration of treatment

5 years (beneficial effect is likely to last for an additional 10 years)

3. Contraindications and cautions

Contraindications

Pregnant or breastfeeding women. Patients with known hypersensitivity to anastrozole or to any of the excipients.

Anastrazole is not recommended for premenopausal women. As it lowers circulating estrogen levels it may cause a reduction in bone mineral density with a possible consequent increased risk of fracture. Offer Tamoxifen or Raloxifene instead of anastrazole to postmenopausal women with severe osteoporosis.

Avoid co-administration of tamoxifen or estrogen-containing therapies as this may diminish its pharmacological action.

Anastrazole is not recommended for use in children and adolescents. Anastrazole should not be used in boys or girls with growth hormone deficiency in addition to growth hormone treatment.

Use with caution

Treatment in patients with moderate and severe hepatic impairment should be based on a benefit-risk evaluation for the individual patient. Use with caution in patients with severe renal impairment.

4. Adverse effects

Common side effects

Headache, somnolence, carpal tunnel syndrome, sensory disturbances (including paraesthesia, taste loss and taste perversion), anorexia, hypercholesterolaemia, hot

flushes, nausea, diarrhoea, vomiting, increases in alkaline phosphatase, alanine aminotransferase and aspartate aminotransferase, rash, hair thinning (alopecia), allergic reactions, arthralgia/joint stiffness, arthritis, osteoporosis, bone pain, myalgia, vaginal dryness, vaginal bleeding, asthenia

Less common side effects

Hypercalcaemia (with or without an increase in parathyroid hormone), increases in gamma-GT and bilirubin, hepatitis, urticaria, erythema multiforme, anaphylactoid reaction, cutaneous vasculitis (including some reports of Henoch-Schönlein purpura), Stevens-Johnson syndrome angioedema, trigger finger

5. Interactions

There is no evidence of clinically significant interaction in patients treated with anastrazole and other commonly prescribed medicinal products. Avoid co-administration of tamoxifen or estrogen-containing therapies as this may diminish its pharmacological action.

Details of contraindications, cautions, drug interactions and adverse effects listed above are not exhaustive. For further information always check with BNF www.bnf.org.uk or SPC (www.medicines.org.uk).

6. Monitoring

Post-menopausal women started on Anastrazole should have a baseline bone density scan (DEXA). Bone density should be monitored every 2 years whilst on an Aromatase inhibitor. If the patient has been identified as having severe osteoporosis on the baseline DEXA scan, treatment options should be re-discussed and a change in treatment to Raloxifene considered.

7. Information to patient

Specialist team will discuss and give written information on the absolute risks and benefits of all options for chemoprevention to women at high risk or moderate risk of breast cancer. Discussion and information should include the side effects of drugs, the extent of risk reduction, and the risks and benefits of alternative approaches, such risk-reducing surgery and surveillance

8. Responsibilities of clinicians involved

Stage of Treatment	Specialist	General Practitioner
Initiation	Diagnosis of condition and ensuring other treatment options have been fully explored Discuss options with patient and provide information on risks and benefits of chemoprevention Checking for allergies, interactions and contra-indications Organize DEXA scan when indicated	Checking for allergies, interactions and contra-indications on initiation and when changing any other medication Prescribe on FP10
Maintenance	Provide adequate advice and support for the GP	Checking for interactions and contra-indications when changing any other medication Prescribe on FP10 Review patient for adverse drug effects as part of routine on-going care Refer patient for urgent investigation if post-menopausal bleeding Seek specialist advice where necessary

		DEXA scan every 2 years when indicated
Discontinuation	Provide advice to GP regarding discontinuation, if requested	Review patients after 5 years and stop treatment. Refer to specialist if required

Contact Details:

HUTH
Breast Family History Service, Breast Care Unit
Hull University Teaching Hospitals NHS Trust, Castle Hill Hospital
Castle Road, East Yorkshire, HU16 5JQ

Email Contacts:
Family history service: **e.khalifa@nhs.net**

Consultant Breast Surgeon-Family History lead: **kartikaegrover@nhs.net**

Secretary: Nicola Larard 01482 622654
Email;:Nicola.larard@nhs.net

Leeds Genetics Service
Yorkshire Regional Genetics Service
Chapel Allerton Hospital
Leeds
LS7 4SA

Consultant in Clinical Genetics, Dr Alison Kraus a.kraus@nhs.net
Contact number for secretary: 0113 392 4455
Dept email: **leedsth-tr.ClinicalGeneticsLeeds@nhs.net**
Website: https://www.leedsth.nhs.uk/a-z-of-services/pathology/clinical-genetics/
Decision Aids: NICE Decision aids together with any separate Service leaflet. NICE decision aids re Tamoxifen/ Anastrozole:
https://www.nice.org.uk/guidance/cg164/ifp/chapter/Information-about-treatments-to-reduce-risk

UK Cancer Genetics group chemoprevention leaflets Leaflets for premenopausal women at high and moderate risk and postmenopausal women at high and moderate risk.

https://www.ukcgg.org/information-education/documents-websites/

APPROVAL PROCESS

Written by:	***Kartikae Grover, Consultant Oncoplastic Breast Surgeon, updated March 2021 Jane Morgan, Interface Pharmacist***
Consultation process:	***Specialist team HEY and Yorkshire Regional Genetics Service Hull Prescribing Sub-committee***
Approved by:	***MMIG***
Ratified by:	***HERPC May 2021***
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