HERPC

Hull & East Riding Prescribing Committee

Prescribing Framework for Raloxifene 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. This is an unlicensed use of a licensed medicine. 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

Post-menopausal women with moderate or high risk of developing familial breast cancer as per CG164

3. Dose

60mg once daily

4. Duration of treatment

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

3. Contraindications and cautions

Contraindications

- Previous allergic reaction
- Women with child bearing potential
- Breastfeeding women
- Personal history of endometrial carcinoma or unexplained uterine bleeding
- Active or past history of venous thromboembolic events (VTE), including deep vein thrombosis, pulmonary embolism and retinal vein thrombosis.
- Hepatic impairment including cholestasis.
- Severe renal impairment (eGFR < 30ml/minute/1.73m^2).

Use with caution

Risk factors for venous thromboembolism (discontinue if prolonged immobilisation) - GPs should ensure that surgical team are aware that patient is prescribed raloxifene as chemoprevention and surgical team will advise on whether raloxifene should be withheld.

- Risk factors for stroke
- History of oestrogen induced hypertriglyceridaemia – monitor triglycerides
- Mild to moderate renal impairment (eGFR < 90 ml/minute/1.73m^2)– monitor eGFR

4. Adverse effects

Common side-effects:

- Hot flushes
- Influenza-like symptoms
- Peripheral oedema

- Leg cramps: but advise if any symptoms suggestive of DVT then need to come for review.

If hot flushes are troublesome - treat with conservative measures: cooling measures, and reduction in tea / coffee / nicotine and alcohol. Consider clonidine. Other pharmacological measures not appropriate (e.g. anti-depressants / HRT). If symptoms are unmanageable with conservative or non-pharmaceutical measures, consider stopping raloxifene.

Less common side effects:

- Venous thromboembolic events, including deep vein thrombosis, pulmonary embolism, retinal vein thrombosis
- Superficial vein thrombophlebitis
- Rashes
- GI disturbances such as nausea, vomiting, abdominal pain, dyspepsia
- Arterial thromboembolism
- Headache (including migraine)
- Breast discomfort such as pain, enlargement and tenderness
- Thrombocytopenia

5. Interactions

- Coumarin anti-coagulants: May enhance anti-coagulant effect.
- Colestyramine – absorption of raloxifene reduced – avoid concomitant administration

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

There is NO routine monitoring necessary for patients on Raloxifene.

NB: ANY WOMAN WHO DEVELOPS POST-MENOPAUSAL BLEEDING SHOULD BE REFERRED VIA FAST-TRACK FOR URGENT INVESTIGATION, AND RALOXIFENE STOPPED.

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

In particular women should be advised to seek review if

- Post-menopausal bleeding
- Other symptoms suggestive of endometrial malignancy
- Symptoms suggestive of DVT / PE
- Visual disturbance

Women should be advised to stop raloxifene if prolonged period of immobilisation – discuss with GP and surgery team when surgery is planned.

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	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
Discontinuation	Provide advice to GP regarding discontinuation, if requested	Review patient 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:
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
e-mail: **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.

APPROVAL PROCESS

Written by:	***Marie Miller, Interface Pharmacist, updated by Jane Morgan, Interface Pharmacist Mar 2021***
Consultation process:	***Specialist team HEY and Yorkshire Regional Genetics Service Hull Prescribing Sub-committee***
Approved by:	***MMIG***
Ratified by:	***HERPC Nov 2014 Update May 2018, May 2021***
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