**Names:**
generic (trade)

**What are they?**
Non steroidal anti oestrogen (tamoxifen) and selective oestrogen receptor modulator (raloxifene)

**Indication (off label use)**
Prevention of breast cancer in women with a moderate to high risk family history

**Date decision last revised**
September 2013

**Decision status**
Final

**NICE Guidance**
NICE CG164 - recommended

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**HMMC Recommendation**
**RECOMMENDED FOR RESTRICTED USE, FOR INITIATION IN SECONDARY/TERTIARY CARE, AND CONTINUATION IN PRIMARY CARE, FOR A MAXIMUM DURATION OF 5 YEARS.**

- The use of raloxifene or tamoxifen in women without a personal history of breast cancer in this way is outside of the UK licensed indications for the products.
- NICE do consider however that there is good evidence to support use in this way (“off-label” use).
- Specialist services should obtain informed consent from the patient and initiate treatment before transferring prescribing responsibility to primary care.
- A template letter is attached to outline the expected communication between the Provider organisation and primary care.

**NICE RECOMMENDATION:**

**Tamoxifen – recommended groups for treatment:**
- Pre menopausal women at high risk of breast cancer
- Post menopausal women without a uterus and at high risk of breast cancer
- Post menopausal women with a uterus and at high risk of breast cancer

**Tamoxifen – groups recommended for consideration of treatment:**
- Pre menopausal women at moderate risk of breast cancer
- Post menopausal women without a uterus and at moderate risk of breast cancer
- Post menopausal women with a uterus and at moderate risk of breast cancer

**Raloxifene – recommended groups for treatment:**
- Post menopausal women with a uterus and at high risk of breast cancer

**Raloxifene – groups recommended for consideration of treatment:**
- Post menopausal women with a uterus and at moderate risk of breast cancer

**Exclusions to recommended groups:**
- Exclude patients with an increased risk of thromboembolic disease or endometrial cancer
- Do not offer tamoxifen or raloxifene to women who were at high risk of breast cancer but have had a bilateral mastectomy
- Do not continue treatment with raloxifene or tamoxifen beyond 5 years
- Tamoxifen treatment should be stopped at least 2 months before trying to conceive and 6 weeks before elective surgery
- Raloxifene treatment should be stopped for 3 days before elective surgery

DEAR COLLEAGUE.

RE YOUR PATIENT:

This lady with no personal history of breast cancer is at high/ moderate risk of developing breast cancer, due to her family history. She is not at increased risk of thromboembolic disease or of endometrial cancer, and I have therefore advised that she takes medication for 5 years to reduce her risk of developing breast cancer.

The medication I have prescribed is:

- Tamoxifen 20mg od (suitable for pre and postmenopausal women)
- Raloxifene 60mg od (suitable for post menopausal women only)

The use of these medications to reduce the chance of developing breast cancer is not covered in the product licenses, but is supported by strong evidence of a level of risk reduction of developing breast cancer in women at high or moderate risk due to their family history. The benefits outweigh the risks associated with treatment, which include an increased chance of developing thromboembolic disease such as deep vein thrombosis and pulmonary embolism and cancer of the lining of the womb (endometrial cancer).

I have discussed this with your patient and they have consented to the use of the medication outside the product license ("off-label use").

☐ I have advised that patients taking tamoxifen should stop the medication at least 2 months before trying to conceive and at least 6 weeks before planned surgery.
☐ I have advised that patients taking raloxifene should stop the medication 3 days before planned surgery.

The treatment should be stopped after 5 years, unless future guidance extends the period of treatment.

If you have any concerns about taking on the prescribing of this medication, please contact me to discuss this.

Yours sincerely