Title SHARED CARE PROTOCOL for GOSERELIN in the treatment of breast cancer	**Unique Identifier**
Scope Goserelin may be considered for shared care arrangements for the treatment of breast cancer.	**Classification SHARED CARE PROTOCOL**

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To be read in conjunction with the following documents: The Summary of Product Characteristics		
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1.0 Introduction

There is evidence from a number of randomised clinical trials that ovarian ablation is as effective as cyclophosphamide, methotrexate, fluorouracil (CMF) chemotherapy in hormone receptor positive pre-menopausal women. However, there are no clinical trials comparing ovarian ablation to anthracycline containing regimens which are the current adjuvant treatment. Ovarian ablation can be considered as an alternative to chemotherapy in patients who have good-intermediate risk breast cancer.

Ovarian ablation can be achieved by surgery, radiotherapy or Lutenising Hormone Releasing Hormone (LHRH) analogues.

Goserelin is a synthetic gonadotrophin-releasing hormone (GnRH) analogue administered by subcutaneous depot injection. GnRH is normally released by the hypothalamus in a pulsatile manner. Chronic administration of goserelin produces an initial rise (hormonal flare) then, within a few weeks, a fall in pituitary derived lutenising hormone secretion. In women this produces ovarian suppression and a fall in serum oestrogen to post menopausal levels.

2.0 Purpose

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

3.0 Scope

Goserelin may be considered for shared care arrangements for the treatment of breast cancer as per SPC.

4.0 Review

2 years

5.0 Shared Care Protocol

5.1 Clinical Details

Goserelin is indicated for advanced breast cancer in pre and perimenopausal women suitable for hormonal manipulation.

Goserelin is indicated as an alternative to chemotherapy in the standard of care for pre/perimenopausal women with oestrogen receptor (ER) positive early breast cancer.

No dosage adjustment is required for hepatic or renal impairment, or in the elderly.

Goserelin is contraindicated in patients with a known hypersensitivity to the active substance, or to any of the excipients and in pregnancy and lactation.

The use of LHRH agonists in women may cause a reduction in bone mineral density. Following two years treatment for early breast cancer, the average loss of bone mineral density was 6.2% and 11.5% at the femoral neck and lumbar spine respectively. This loss has been shown to be partially reversible at the one year off treatment follow-up with recovery to 3.4% and 6.4% relative to baseline at the femoral neck and lumbar spine respectively, although this recovery is based on very limited data.

5.2 Product Information

The recommended dose is a 3.6mg depot injection every 28 days. It is given sub-cutaneously into the anterior abdominal wall.

Treatment is usually for 2 years in the adjuvant setting.

Caution in patients with known metabolic bone disease.
Ensure patient is not using hormonal methods of contraception.

There are no significant drug interactions.

NB: Zoladex LA® Safe System (a 10.8mg depot given every 12 weeks in the treatment of prostate cancer) is NOT licensed for the treatment of breast cancer and should not be used. Astra Zeneca state that their present LA form does not provide reliable ovarian suppression for 12 weeks.

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

Goserelin is available as a 3.6mg depot injection (Zoladex® Safe System, Astra Zeneca) in a single dose ready-to-use syringe, with a self activated needle guard to protect from needlestick injuries. Appropriate sharps disposal is needed.

Patients with hormone receptor positive breast cancer should not be prescribed Hormone Replacement Therapy (HRT). Menopausal symptoms eg: hot flushes may be treated with vitamin E (800 international units od), megrestrol acetate (20-40mg od) or venlafaxine (37.5mg od). Please note that venlafaxine should not be prescribed in patients with heart disease, electrolyte imbalance or hypertension. Also note that this is an off label use of the above products. This must be recorded in the patient's notes along with the consent obtained.

5.4 Possible side effects of treatment

The following have been reported:
Injection site hypersensitivity reaction
Menopausal symptoms (flushing, sweating, reduced libido, vaginal dryness, mood change, weight gain, change in breast size)
During early treatment some women may experience vaginal bleeding of variable duration and intensity. If vaginal bleeding occurs it is usually in the first month after starting treatment. Such bleeding probably represents oestrogen withdrawal bleeding and is expected to stop spontaneously.
Early hormonal flare worsening signs and symptoms of breast cancer including risk of hypercalcaemia and spinal cord compression if metastatic bone disease.
Arthralgia, paraesthesias
Hypotension, hypertension.
Headache, migraine, visual disturbance, dizziness
Hair loss
Peripheral oedema
Gastro-intestinal disorders
Sleep disturbance

5.5 Aspects of care for which the consultant is responsible

Assessing the patient and establishing a need for goserelin treatment.
Ensuring that there are no contra-indications to therapy with goserelin.
Providing information for the patient, including adverse effects, obtaining consent and initiating treatment.
Contacting the GP to invite shared care for the patient.
Assessing the continued appropriateness for goserelin on a 6 monthly basis.
Reviewing any concerns regarding disease progression from the GP within 2 weeks.
Monitoring toxicity, recording and reporting adverse events.
Monitoring bone mineral density.
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

No specific drug monitoring is required for goserelin treatment other than observation of any side effects as detailed above and disease response.

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 goserelin as appropriate, and arranging its administration according to specified time intervals.
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 leaflet

5.9 References

Summary of Product Characteristics for Zoladex®, Astra Zeneca., www.medicines.org.uk Accessed 8.4.08

Breast Cancer Management Guidelines, Breast Disease Orientated Group, Christie Hospital Foundation Trust, October 2009.

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