

Local Enhanced Service Specification

Administration of Gonadorelins 2012-13

Introduction

1. All practices are expected to provide essential and additional services they are contracted to provide to all their patients. This specification outlines the more specialised services to be provided. The specification of this service is designed to cover enhanced aspects of clinical care of the patient, which go beyond the scope of essential services. No part of the specification by commission, omission or implication defines or redefines essential or additional services.

Background

2. A Local Enhanced Service Scheme exists for the administration of Gonadorelins for patients with Carcinoma (Ca) of the Prostate. The intention of this LES is to broaden the indications for inclusion in the LES to encompass Carcinoma of the Breast and preoperatively for women having hysterectomy, and Endometriosis.

3. Gonadorelins are used primarily, though not exclusively, in the treatment of carcinoma of the prostate. There are a number of treatment regimes, which vary in the detail of their programme of administration and main purpose. Broadly they can be divided on the basis of the progress of the disease into advanced local disease and metastatic disease. The central usage, however, remains the treatment of metastatic cancer of the prostate. Currently it is estimated that over 95% of the scripts for gonadorelin analogues are written for Ca prostate.

4. However, there is an increasing body of evidence for the use of gonadorelins in advanced breast cancer and in premenopausal women with oestrogen receptor positive tumours. Treatment is usually part of combination therapy, with the objective of improving outcomes.

5. Virtually all the prescriptions issued for injectable gonadorelins are written by GPs and most of these are also administered by GPs. In some practices an appropriately trained practice nurse will site the depot implants. The great majority of scripts are issued for Zoladex (generic name goserelin), which is administered subcutaneously into the anterior abdominal wall as a depot implant.

6. Different preparations are in place for treatment of Ca of prostate and breast, which are either injectable or implants. These are Buserelin, Goserelin, Leuprorelin Acetate or Triptorelin. The majority of preparations for treatment are either Goserelin implants or Leuprorelin injections.

7. There are varying treatment models for administering gonadorelins to patients with Ca prostate or breast dependent on the clinical management programme agreed for that patient.

Aims

8. The administration of gonadorelins within primary care is designed to be an enhanced service in which:

- Patients with an established diagnosis and agreed treatment plan for carcinoma of the prostate, Carcinoma of the Breast, preoperatively for women having hysterectomy, and Endometriosis can undergo part of their treatment safely, effectively and conveniently close to their home.
- There is much greater integration of primary and secondary care services and which recognises the increasing contribution that primary care can make in medical management and treatment of the hitherto predominantly hospital based approach.

Service Outline

9. It is a requirement of this Local Enhanced Service that the contractor;

i. provides a register - Practices will need to produce and maintain a valid up-to-date register of patients being treated as part of this enhanced service.

ii. demonstrates a call and recall system - Practices will need to ensure a systematic call and recall of patients on this register is taking place, and have in place the means to identify and follow up patients in default.

iii. agrees a joint clinical management programme - Patients should be managed on the basis of individual treatment plans which will normally be drawn up by local consultants. Practices will be expected to follow these treatment plans unless there has been discussion and agreement with local consultants to modify them.

iv. Support the education of both newly diagnosed patients and those with established disease. The secondary care oncology team will provide the main source of advice for both newly diagnosed patients and those with established disease. The practice will reinforce and supplement that advice where appropriate to do so.

v. Provides an outline individual management plan – Wherever possible to ensure that the patient has an outline individual management plan, which gives the reason for treatment, agreed treatment programme and the planned duration. This plan should be consistent with any agreed shared care protocols.

vi. Record keeping - To maintain adequate records of the service provided, incorporating all known information relating to any significant events e.g. adverse reactions, hospital admissions, and relevant deaths of which the practice has been notified.

vii. Ensure primary care staff training - Each practice must ensure that all staff involved in providing any aspect of care under this scheme have the necessary training and skills to do so. Practices should be able to

demonstrate that they have in place a policy to cover staff training and maintenance of skills.

viii. Provide safe and suitable facilities for undertaking invasive procedures - LHBs should be satisfied that practices undertaking to provide the "Administration of Gonadorelins Local Enhanced Service" have adequate and appropriate facilities and equipment comparable to those required for the safe provision of any invasive procedure.

Untoward events

10. It is a condition of participation in this LES that practices will give notification, in addition to their statutory obligations, within 72 hours of the information becoming known to him/her, to the Assistant Medical Director/ Local Clinical Director of all emergency admissions or death of any patient under this service. This is in addition to any statutory obligations.

Accreditation

11. Doctors will need to satisfy, at appraisal, that they have the necessary medical experience, training and competence necessary to enable them to provide for a safe and effective Administration of Gonadorelins enhanced service.

Pricing

12. Given the different modes of administering gonadorelins for Ca prostate, Ca and breast, preoperatively for women having hysterectomy, and Endometriosis an annual fee has been set for providing an individual treatment package for patients as set out in the Service Outline of this specification.

13. The annual fees applicable are:

All patients entering the scheme will attract an annual fee of £102.16 which will be payable quarterly in arrears, provided that at least one injection has been given in the relevant quarter. Existing patients, with an established diagnosis of Ca of Breast, who require continuation of their Gonadorelin treatment beyond May 1st 2007 will be regarded as new patients entering the scheme and will attract an annual retention fee of £100, which is payable quarterly in arrears, provided the patient has received at least one injection in the relevant quarter.

END

Application Form Service List
Claim Form

Annex 1

Current licensed indications for GnRH analogues are:

Dose frequency	Every month / 28 days / 4 weeks				Every 3 months / 12 weeks		
Drug & dose	Goserelin 3.6mg	Leuprorelin 3.75mg	Triptorelin 3mg	Triptorelin 3.75mg	Goserelin 10.8mg	Leuprorelin 11.25mg	Triptorelin 11.25mg
Brand name	Zoladex	Prostap SR	Decapeptyl SR	Gonapeptyl Depot	Zoladex LA	Prostap 3	Decapeptyl SR
Company	Astra Zeneca	Takeda	Ipsen	Ferring	Astra Zeneca	Takeda	Ipsen
Form	Implant in prefilled syringe	Powder to reconstitute	Powder to reconstitute	Microcapsules to reconstitute	Implant in prefilled syringe	Powder to reconstitute	Powder to reconstitute
Injection route	S/C	S/C or I/M	I/M	S/C or I/M	S/C	S/C	I/M
Licensed uses							
Prostate cancer	✓	✓ (advanced)	✓ (locally advanced & metastatic)	✓ (advanced)	✓	✓ (advanced)	✓ (locally advanced & metastatic)
Advanced breast cancer	✓						
Early breast cancer	✓						

Contractors are advised to consult the most recent British National Formulary for any alterations.