

**Locally Enhanced Service for the Administration of  
Hormone Implants (e.g. ZOLADEX)**

Reference: LES35

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## 1. Financial Details

This agreement is for the financial year 2010/11.

For the administration of hormone implants (*Zoladex* for prostate cancer being the most widely-prescribed, though there may be a small number of oestrogen, testosterone or *Prostap* injections) will be made quarterly in arrears based on the number of patients receiving treatment per quarter £43.36.

## 2. Service Aims

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**

Gonadorelins are used primarily, though not exclusively, in the treatment of carcinoma of the prostate (it may form part of treatment for breast cancer). 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.

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. Others are given subcutaneously or intra-muscularly, depending upon the indications and the preparation.

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

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

## Aims

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Service	Specific Service Criteria
<p data-bbox="224 247 747 281"><b>Administration of Hormone Implants</b></p> <p data-bbox="224 281 483 315"><b>Read code 7G2A6</b></p> <p data-bbox="224 315 771 415">The administration of gonadorelins within primary care is designed to be an enhanced service in which:</p> <ul data-bbox="224 457 795 1171" style="list-style-type: none"><li data-bbox="224 457 795 625">• Patients with an established diagnosis and agreed treatment plan of Carcinoma of the Prostate can undergo part of their treatment safely, effectively and conveniently close to their home.</li><li data-bbox="224 667 795 898">• 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</li><li data-bbox="224 940 795 1171">• Where clinically indicated, the use of <i>Zoladex</i> in breast cancer treatment and the provision of other hormone implants may be counted against this specification. The numbers, however, are likely to be low in comparison to Prostate Cancer.</li></ul>	<p data-bbox="820 247 1096 281"><b>i. GP practices will:</b></p> <p data-bbox="820 281 1388 415"><b>Provide a register</b> - Practices will need to produce and maintain a valid up-to-date register of patients being treated as part of this enhanced service.</p> <p data-bbox="820 420 1372 625"><b>ii. Demonstrates a call and recall system</b> - 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.</p> <p data-bbox="820 630 1372 928"><b>iii. Agrees a joint clinical management programme</b> - 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.</p> <p data-bbox="820 932 1388 1243"><b>iv. Support the education of both newly diagnosed patients and those with established disease.</b> 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. ( see info Appendix B)</p> <p data-bbox="820 1247 1388 1478"><b>v. Record keeping</b> - 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.</p> <p data-bbox="820 1482 1388 1789"><b>vi. Provide safe and suitable facilities for undertaking invasive procedures</b> – The PCT should be satisfied that practices undertaking to provide the “Gonadorelin “Administration Enhanced Service” have adequate and appropriate facilities and equipment comparable to those required for the safe provision of any invasive procedure.</p>

## 4. Monitoring and Evaluation

Participating practices are expected to submit data on the number of patients under their care at regular quarterly intervals using the PCT activity monitoring system. Given that the introduction of the LES is based on incentivising a shift of workload from secondary to primary care, the costs and benefits of the LES will need to be evaluated in advance of 2011/2012

## 5. Accreditation

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 hormone implant enhanced service.

It is a condition of participation in this LES that practitioners will give notification, within 72 hours, of the information becoming known to him/her, to the PCT clinical governance lead, of all relevant significant adverse events, emergency admissions or deaths of any patient treated under this service. This is in addition to any statutory obligations.

- I. The collection of activity related to the provision of these services including type of activity, number of contacts and who provides the service.
- II. Maintenance of adequate records of the services provided, incorporating all known information relating to any significant events.
- III. Each practice must ensure that all staff involved in providing any aspect of care under the scheme has the necessary training and skills to do so. In particular the following criteria for standards for nurses in general practice should be applied:

### Training

- Receive annual mandatory training (e.g.) anaphylaxis, BLS, infection control)
- Receive appropriate, assessed education and training in the administration of Hormone Implants (e.g. ZOLADEX) and annual updates

### Professional development support

- Be supported to work within their scope of competence
- Belong to a local practice nurse forum/group
- Have a source of professional advice and support available through the PCT.

### Quality

- Have their competence in a new role assessed by a qualified assessor
- Regularly update protocols based on the latest national guidance
- Maintain a 'competence file' providing a safe record of what they can and cannot do.
- Carry out regular audits
- Evaluate patient satisfaction with nursing care

## 6. Coding

Recording of hormone implant administration should be under the following Read codes:

Item	Code
Insertion of Hormone Implant	7G2A600

Insertion of Testosterone Implant	7G2A5
Insertion of Oestrogen Implant	7G2A4
Insertion of Gonadorelin analogue Implant	7G2AC

## 7. Addendum – Web-Based Patient Information

### GOSERELIN (ZOLADEX)

Your doctor has recommended a medication called Zoladex as treatment for your illness. This page provides extra information about your medicine, summarises possible side effects and methods to alleviate them.

**WHAT IS IN ZOLADEX** Goserelin contained within a slow release pellet given which is given as a subcutaneous (under the skin) injection around the area of the abdomen. The active chemical is released into the blood stream at a constant level over a one or three month period depending on the strength used (3.6mg for one month, 10.5 mg for three months). Zoladex belongs to group of medicines called "LHRH blockers" and have the effect of reducing the bodies hormones which are made in the testes in men and ovaries in women. They are used to treat female patients with Breast cancer and male patients with prostate cancer.

**HOW DO THEY WORK?** Some tumours such as breast & prostate cancer are stimulated by the bodies own hormones. For men this is testosterone from the testes and women oestrogen from the ovaries. Stopping the bodies hormones reaching the tumour can cause the cancer cells to stop growing and in some cases shrivel up and die completely (self destruct - apoptosis). One way of doing this is to surgically remove the ovaries or testis. Some drug therapies chemically do the same thing by blocking the signal from the brain to the ovaries or testis - these include goserelin (Zoladex), More specifically Zoladex blocks production of two hormones called Luteinising Hormone (LH) and Follicle Stimulating Hormone (FSH). Zoladex blocks their production and hence is sometimes called a LHRH blocker

**HOW WILL I & THE DOCTOR KNOW THEY ARE WORKING?** In most cases there is something the doctor can measure. This may be how you feel, a symptom related to you cancer, something which can be felt on examination (e.g. your prostate) or something seen on a scan. After 2-3 months a formal assessment of response is usually performed before continuing the tablets indefinitely - This may well involve repeating the xrays. For prostate cancer there is a blood test called PSA, the level of which will get lower if you are responding.

**SIDE EFFECTS** All medications have side effects. These can effect some people more than others. It its hard to predict the level and type of side effect for each individual, you may experience none, all, or only a few of these. You may also have a rare side effect not listed here - If you have any other side effects, please report them to your clinic. If side effects are severe, you may have to stop taking the drug and a different hormonal drug may be prescribed.

- **Flushes and sweats.** Similar to menopausal flushes in women. Often they gradually lessen over the first few months but some people continue to have them for as long as they take ZOLADEX. There are a number of ways to help reduce or control hot flushes and sweats. Some people find it helpful to avoid or cut down on tea, coffee, nicotine and alcohol. Evening primrose oil has been reported to be helpful in reducing sweats but it does not work for all people and it is expensive. There are also a lot of calories in Evening Primrose Oil so it may be fattening. When ZOLADEX is stopped hot flushes can get worse before they

- get better.
- **Sex drive (libido).** Zoladex in men has a significant impact on sex drive. In most cases it impairs the ability to have erections
  - **Lethargy** - It is common to have mild lethargy with Zoladex - it is most severe at the beginning but can wear off over time. [See coping with lethargy](#)
  - **Nausea and indigestion** Feelings of mild sickness (nausea) and indigestion can occur rarely but usually wears off after a few weeks. [see diet and indigestion](#)
  - **Weight gain** This is sometimes due to water retention but at other times a consequence of eating more either due to an increased appetite or mild nausea - "to settle the stomach" . [See coping with weight gain.](#)
  - **Breast swelling** (gynaecomastia) - occasionally in men the breast can become tender and enlarge (this can be prevented by a low dose of radiotherapy to the nipples as soon as it starts).
    - **Less common side effects include:-**
    - Allergic reactions – this may include skin rashes
    - Temporary thinning of the hair
    - Headaches – some people affected by migraine have noticed a change in the pattern of their headaches

There is no interaction between Zoladex and moderate amounts of alcohol. Zoladex does not usually affect your ability to drive. Some people find that when they start Zoladex that with the first treatment they experience a temporary increase in bone pain. This is due to the Zoladex causing a surge in FSH and LH levels, which initially creates an increase in the production of testosterone or oestrogen. To prevent this, additional oral medication is normally given for the first two weeks (usually either [Tamoxifen](#) (women), [Casodex](#), [Flutamide](#) or [Cyproterone acetate](#) (men)). These drugs are not required to cover subsequent injections.

**WHO GIVES THE INJECTION** - It is now most convenient for the patient that the General Practitioner continue prescribing Zoladex in the long term. This is called **shared care**. The injection itself is usually given by the district, or practice, nurse. A full description of this type of management can be found in the NHS Management Executive Letter EL(91) 127(1/11/91). The consultant is responsible for the decision to start and stop zoladex and monitoring the patient regularly. The GP is responsible for ensuring the drug is given on time and reporting any adverse events to the consultant. If you have been told to arrange repeat prescription from the GP show this information page to the receptionist when making the appointment so she knows when to make the appointment and for what reason. The following table may be helpful to remind all parties how long the zoladex should be given and when:-

First cycle of zoladex given .....	Next cycle of zoladex due .....
Duration required (delete or complete)	Until start of radiotherapy (cytoreduction usually 3-6 months for localised disease).
	Until informed from the clinic (usually more advanced disease)

Reference: <http://www.cancernet.co.uk/zoladex.htm>

