

Specification for a Local Enhanced Service for Administration of Gonadorelins and Degarelix

1. Introduction

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

This specification is based on a model agreed between the Welsh Assembly Government and the General Practitioners Committee (Wales) for the administration of gonadorelins for patients with Ca prostate. Hywel Dda University Health Board will also commission the administration of goserelin (Zoladex) for those other conditions for which it is licensed (at March 2017 these are: endometriosis, endometrial thinning, uterine fibroid and advanced breast cancer in pre-and postmenopausal women). Hywel Dda University Health Board will commission the administration of degarelix (a gonadotrophin-releasing hormone antagonist) for patients with Ca prostate. Hywel Dda UHB will commission the administration of gonadorelins for the treatment of gender dysphoria as outlined in WHC(2016)040 under the direction of a GIC or local endocrine Consultant.

2. Background

There are a number of treatment regimes, that vary in the detail of their programme of administration and main purpose. Broadly they can be divided on the basis of progress of the disease into advanced local disease and metastatic disease. The central usage, however, remains the treatment of metastatic cancer of the prostate and currently it is estimated that over 95% of the prescriptions for gonadorelin analogues are written for this purpose.

Degarelix (a gonadotrophin-releasing hormone antagonist) was recommended for use by AWMSG (Dec 2012) and is included in the HDUHB Formulary. The position in therapy is for: newly presenting patients with advanced prostate cancer and any of the following:

- at risk of impending spinal cord-compression
- at risk of impending ureteric obstruction and hydronephrosis
- high baseline PSA (> 20 nanograms/ml)
- increased LFTs.
- Severe pain from bone metastases'

Treatment should be initiated by Urology and first loading dose should be given in secondary care.

Virtually all prescriptions issued for injectable gonadorelins are written by GPs and most of these are administered by GPs or an appropriately trained practice nurse. The great majority of prescriptions are issued for Zoladex (generic name goserelin), that is administered subcutaneously into the anterior abdominal wall as a depot implant. Others are given subcutaneously or intramuscularly, depending upon the indications and the preparation.

Different treatments are in place for treatment of prostatic cancer that are either injectable or implants. Degarelix is given by deep subcutaneous injection.

The [Welsh Health Circular \(2016\) 040](#): Update on general practitioners' and other primary care professionals' roles and responsibilities for prescribing hormone therapy for trans*/transgender adults advises that the prescribing and monitoring of hormone therapy can be carried out safely in primary care without specialist input, although specialists are expected to provide support and advice to individual GPs when this is requested. This LES will cover the administration of gonadorelins under the direction of a GIC or local endocrine Consultant. The GIC or Specialist Consultant will provide the GP with a protocol to support the prescribing and administration of hormone therapy. It should be noted that gonadorelins are not currently licensed for the treatment of gender dysphoria, although clinical experience provides evidence of tolerability and safety. It is the responsibility of the specialist to assess the capacity of the patient to give meaningful informed consent to use such treatment, to explain its potential risks, benefits and limitations, to explain that the treatment is not approved for this indication and the implications thereof, and to obtain and document consent before making a recommendation to a GP to prescribe treatment for their patient. Inclusion of gender dysphoria in the gonadorelin LES will reduce some of the barriers that transgender patients meet in gaining treatment.

Goserelin (Zoladex 3.6mg monthly depot injection) is indicated for the treatment of oestrogen-receptor-positive breast cancer as an alternative to oophorectomy. The decision to treat and discussion & counselling of the patient will be taken by the Specialist MDT Oncology Team prior to a recommendation to the GP to prescribe and administer. The other indications that Zoladex may be administered for under this LES are endometriosis, endometrial thinning and uterine fibroids,

3. Service Aim

This Local Enhanced Service (LES) seeks to ensure a consistent approach in the administration of gonadorelins and degarelix in the primary care sector.

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

- Patients with an established diagnosis and agreed treatment plan, can undergo part of their treatment safely, effectively and conveniently close to their home.
- With greater integration of primary and secondary care services, this specification recognizes the increasing contribution that primary care can make in medical management and treatment of the hitherto predominantly hospital based approach.

Hywel Dda will commission the following under this LES:

- the administration of gonadorelins for patients with Ca prostate;
- the administration of goserelin (Zoladex), only for those other conditions for which it is licensed (as at March 2017 these are:
 - endometriosis;
 - endometrial thinning
 - uterine fibroid
 - advanced breast cancer in pre-and postmenopausal women);
- the administration of degarelix (a gonadotrophin-releasing hormone antagonist) for patients with Ca prostate
- the administration of gonadorelins for the treatment of gender dysphoria as outlined in WHC(2016)040.
- the administration of gonadorelins for the treatment of breast cancer.

4. Requirements of Service Delivery

It is a requirement of this LES that the contractor:

- a) **Provides a register** – the practice will need to produce and maintain a valid up-to-date register of patients being treated as part of this enhanced service.
- b) **Demonstrates a call and recall system** – the practice 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.
- c) **Agrees a joint clinical management programme** – patients should be managed on the basis of individual treatment plans that will normally be drawn up by local consultants. The practice will be expected to follow these treatment plans unless there has been discussion and agreement with local consultants to modify them.
- d) **Supports 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.
- e) **Provides an outline individual management plan** – wherever possible the practice should ensure that the patient has an outline individual management plan consistent with any shared care protocols and giving:
 - a. The reason for treatment;
 - b. The agreed treatment programme;
 - c. The planned duration.
- f) **Maintains adequate records** – the practice should keep adequate records of the service provided incorporating all known information relating to any significant events eg adverse reactions, hospital admissions and relevant deaths of which the practice has been notified.
- g) **Ensures primary care staff training** – the practice should ensure that all staff involved in providing any aspect of care under this scheme have the necessary training and skills to do so. The practice should be able to demonstrate that they have in place a policy to cover staff training and maintenance of skills.
- h) **Provides safe and suitable facilities for undertaking invasive procedures** – the practice should be able to demonstrate that they not only have appropriate facilities but also the policies and procedures in place for their correct use.
- i) **Reports untoward events** – the practice must undertake to notify the Health Board clinical governance lead of untoward events within 72 hours of their occurrence. These are in addition to any statutory obligations and should include:
 - a. Significant adverse events;
 - b. Emergency admissions or deaths of any patient treated under this service.

5. Accreditation

A practice may be accepted for the provision of this enhanced service if it has a partner or partners, employee or sub-contractor, who has the necessary skills and experience to carry out the contracted procedures.

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

Clinicians taking part in this enhanced service should be competent in resuscitation and, as for other areas of clinical practice, have a responsibility for ensuring that their skills are regularly updated.

Doctors carrying out gonadorelin administration should demonstrate a continuing sustained level of activity, conduct regular audits, be appraised on what they do and take part in necessary supportive educational activities.

Those doctors who have previously provided services similar to this enhanced service and who satisfy at appraisal and revalidation that they have such continuing medical experience, training and competence as is necessary to enable them to contract for the enhanced service shall be deemed professionally qualified to do so.

Please register your Practice's intention to provide this LES via the Annual Return.

6. Pricing

Given the different modes of administering gonadorelins and degarelix, a fee per injection has been set in order to provide an individual treatment package for patients as set out in this specification.

The tariff is:

All patients entering the scheme will attract a fee of:

£8.84 per monthly injection

£26.56 per quarterly injection

Claims can be made on submission of the number of monthly and/or quarterly injections administered each month to Contractor Payments, NWSSP. See also [Appendix A](#). Every effort should be made by the contractor to submit regular claims, except at year end when the following will apply:

Claims for previous (financial) year's activity will only be accepted up to the first week of July following the year of provision. Claims made after this date will only be considered in extenuating circumstances and in these cases payment will be totally at the discretion of HDUHB.

Practices should ensure that claims are properly recorded and kept on file and that each such claim has a clear audit trail for Post Payment Verification (PPV) reasons.



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Bwrdd Iechyd Prifysgol
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University Health Board

Ein cyf/Our ref: JP/EL/jm/011216

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Dear Owen

At the Liaison Meeting on 17th November the issue of payment for Gonadorelin management and administration was discussed, with specific reference to whether this payment was appropriate if the administration was undertaken by Health Board employed staff.

The team has reviewed the specification and considered it in line with other enhanced service payment levels. Whilst the wording of the LES does clearly indicate that the specification includes the administration element it is not overly specific. We have had many discussions in the past about the detailed nature of such specifications and there needs to be a balance between specifying every detail and keeping the documentation concise yet encompassing of the key features. We would not want to add more detail to specifications and hope we can work in a trusting environment with our General Medical Services contractors.

We have considered payments for the Gonadorelin Enhanced Service in this context and also considered that administration by District Nurses is occasional and not the routine method. Therefore, if a patient is demonstrably housebound, the District Nurses could continue to deliver this with the Practice administering the process and prescribing. This is on the assumption that the practice continues to provide and administer the service for all patients physically capable of attending the practice.

We hope you will accept that this is a reasonable position to take which does not risk continued care delivery to patients.

Yours sincerely



Jill Paterson
Interim Executive Director of Commissioning/Primary Care/Therapies & Health Science

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