

Administration of Gonadorelins Local Enhanced Service Specification

Version Control		
Version	Date Amended	Summary of amendments
Gonadorelin LES specification Final 2013-14	July 2022	Fees amended. Document justified Claims, Monitoring & audit, termination, GMPI added
Gonadorelin LES specification Final 2013-14	May 2023	Fees amended.

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. Gonadorelins are used primarily, though not exclusively; in the treatment of carcinoma of the prostate, other indications may include breast Cancer, endometriosis, precocious puberty, infertility, anaemia due to fibroids (together with iron supplementation) and breast cancer. There are a number of treatment regimes, which vary in the detail of their programme of administration and main purpose.
3. 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 administer gonadorelins.
4. There are varying treatment models for administering gonadorelins to patients dependent on the clinical management programme agreed for that patient.

Aims

5. 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 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.
 - Where clinically indicated, the uses of either gonadorelin injectable or implant are eligible for inclusion in this specification.

Service Outline

6. 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. **supports the education of both newly diagnosed patients and those with established disease.** Secondary care 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. **ensures 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. **provides safe and suitable facilities for undertaking invasive procedures** - UHBs should be satisfied that practices undertaking to provide the "Gonadorelin Administration Local Enhanced Service" have adequate and appropriate facilities and equipment comparable to those required for the safe provision of any invasive procedure.

Untoward Events

- 7. It is a condition of participation in this LES that practitioner will give notification, within 72 hours, of the information becoming known to him/her, to the UHB 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.

Accreditation

- 8. UHBs are responsible for ensuring that enhanced services are delivered by professionals who are properly qualified to do the job and accreditation of the service should be based upon consideration of the enhanced service specification. This Local Enhanced Service has been classified as requiring **General Accreditation**.

An Enhanced Service that requires General Accreditation is defined as a named GP who has the necessary skills and experience to carry out a contracted specific service or procedure. It provides a means whereby **accredited persons will be responsible and accountable** for the delivery of the enhanced service on behalf of the practice. This enhanced service does not have to be delivered by the accredited GP however where components of the service are delivered by somebody other than the accredited GP, the accredited GP is responsible for ensuring that the appropriate skills are available to deliver the service safely.

Pricing

9. Given the different modes of administering gonadorelins, an annual fee has been set for providing an individual treatment package for patients as set out in the Service Outline of this specification.
10. The annual fees applicable are: £107.84 (*per patient per annum*)

Claims

11. Practices are required to make claims by following NWSSP claiming cycle guidelines. Claims must be submitted within 6 months from the end of the quarter in which the drug was delivered, to ensure payment.

End of Financial Year

Practices should endeavour to submit claims for the January – March quarter at the earliest convenience and in line with the claiming cycle provided by NWSSP. Any claims for this quarter submitted after the 15th of June will require approval from the Primary Care Team to be released and could cause a delay in payment. These claims are again subject to the six-month deadline for submission, after which they will not be paid.

Monitoring & Audit

12. The practice will be required to undertake an annual audit as agreed in advance with the UHB and provide the monitoring data to the UHB Primary Care team for annual review of the LES to inform service planning and to identify and share areas of good practice and/or areas for improvement where the service outline has not been met.

Termination Period

13. Should the practice wish to cease providing the Enhanced Service, it will be required to provide 3 months' notice in writing to the Health Board. Should the practice wish to suspend providing the Enhanced Service it should contact the Health Board for guidance prior to any action being taken.
14. If, for any reason, a practice terminates/suspends the Enhanced Service and, if claims have been made during the current financial year, any reporting/auditing requirements outlined in the specification must be submitted upon request.

General Medical Practice Indemnity

15. This Enhanced Service is covered by the scheme for General Medical Practice Indemnity (GMPI) which falls under the GMS Contract Wales.

This scheme relates to potential or actual clinical negligence claims arising from incidents on or after 1 April 2019, and captures all General Medical Practice (GP practice) staff undertaking NHS 'primary medical services' as defined in The National Health Service (Clinical Negligence Scheme) (Wales) Regulations 2019

The National Health Service (Clinical Negligence Scheme) (Wales) Regulations 2019, sets out the scope of the scheme, namely "primary medical services" which are defined as health services provided under a contract, arrangement or agreement made under or by virtue of the following sections of the National Health Service Wales Act 2006:

- (a) section 41(2) (primary medical services);
- (b) section 42(1) (general medical services contracts);
- (c) section 50 (arrangements by Local Health Boards for the provision of primary medical services).

The GMPI will include clinical negligence liabilities for NHS work arising from the activities of all GP practice staff, including: GP partners; salaried GPs; locum GPs, if on the All Wales Locum Register; Practice Pharmacists; Practice Nurses; Practice Healthcare assistants; and any other member of staff providing clinical services. GP trainees and trainee nursing students delivering general medical services will also be covered. The GMPI will also cover any healthcare professionals providing the delivery of NHS Primary Care through Primary Care cluster arrangements and any vicarious liability to practices where a cluster-based health professional is providing direct care to the practice's registered patients.

16. GP Locums who are registered with and working to the terms of the All Wales Locum Register (AWLT) for Wales have access to the scheme for GMPI.