Service Specifications

Service Specification No.	
Service	Administration of Gonadorelins - LHRH Analogues (including any new licensed drugs).
Commissioner Lead	NHS Lincolnshire Integrated Care Board (ICB)
Period	1st April 2023 – 31st March 2024
Date of Review	March 2023

1. Population Needs

1.1 Local Context

Lincolnshire's Integrated Care System and Integrated Care Board

The NHS Lincolnshire Integrated Care System (ICS) was created on 1 July 2022 following an amendment of the Health and Social Care Act 2006.

The ICS is a partnership that brings together providers and commissioners of NHS services across Lincolnshire with local authorities and other local partners (such as the voluntary sector), to collectively plan health and care services to meet the needs of their population.

The 4 aims of the ICS are:

- improve outcomes in population health and healthcare
- tackle inequalities in outcomes, experience, and access
- enhance productivity and value for money
- help the NHS support broader social and economic development

NHS Lincolnshire Integrated Care Board (ICB) is the statutory body within Lincolnshire ICS responsible for the provision of health services, in accordance with the Health and Care Act 2022.

Lincolnshire ICB will use its resources and powers to collaboratively tackle complex challenges, including:

- improving the health of children and young people
- supporting people to stay well and independent
- acting sooner to help those with preventable conditions
- supporting those with long-term conditions or mental health issues
- caring for those with multiple needs as the population ages
- getting the best from collective resources so people get care as quickly as possible

Lincolnshire ICB statistics

- Lincolnshire ICB has 82 practices
- The total registered population is 813,240 (as of January 2023)
- The registered population live in 7 different lower tier Local Authorities
- As of 2021, the male average life expectancy in Lincolnshire (78.3 years) is slightly lower than the national average (78.7 years). The average Lincolnshire life expectancy for females is 82.8 years, which is the same as the national average
- The 2021 overall premature mortality rate in Lincolnshire (deaths <75 years per 100,000) is 366.3, which is slightly higher than the national figure of 363.4

- The average level of deprivation in England as of 2019 was 21.7. Lincolnshire ICB as a whole is slightly less deprived than this, at 20.2. However, there are pockets of deprivation across the county that are within the national 20% most deprived areas (mainly around coastal and inner urban areas)

2. Outcomes

2.1 NHS Outcomes Framework Domains & Indicators

Domain 1	Preventing people from dying prematurely	
Domain 2	Enhancing quality of life for people with long-term conditions	X
Domain 3	Helping people to recover from episodes of ill-health or following injury	X
Domain 4	Ensuring people have a positive experience of care	X
Domain 5	Treating and caring for people in a safe environment and protecting them from avoidable harm	X

2.2 Local defined outcomes

The Commissioner wishes to ensure that the administration of gonadorelins is readily available in Primary Care, where an appropriate shared care agreement is in place between secondary care and the practice provider. A Practice based service will provide more convenient and timely care to the patient.

It has been recognised that the administration of gonadorelins, previously a predominantly hospital based treatment, in primary care has significant benefits to patients which include:

- Greater patient convenience.
- Timely service – able to provide urgent same day sampling.
- Minimal travel.
- Available expertise is shared via a protocol between primary and secondary care, through improved integration
- Holistic approach to patient care.

The following principles underpin the service:

- The majority of care should take place as close to the patient's home as possible.
- Practices work in partnership with secondary care to provide a comprehensive local service.

Where GP practices do not wish to provide the service other providers will be available to provide in the locality.

3. Scope

3.1 Aims and objectives of service

Prostate Cancer - patients with an established diagnosis of carcinoma of prostate.

a. Gonadorelins – LHRH Analogues are synthetic lutenising hormone releasing hormone (LHRH) analogues administered by subcutaneous depot injection. LHRH is normally released by the hypothalamus in a pulsatile manner. Chronic administration of these synthetic hormones produces an initial rise (hormonal flare) then within a few weeks, a fall in pituitary derived Lutenising hormone.

   In men this results in a reduction in testosterone production to levels equivalent to castrate levels for the duration of treatment.

b. As most tumours are testosterone dependent this can retard or halt tumour growth.

c. This treatment is supported by a strong evidence base see Guidelines on the Management of Prostatic Carcinoma from British association of Urological surgeons 2013 and NICE Guidance CG 131.

d. The entire course of treatment is usually given in primary care under the supervision of a consultant urologist or oncologist by informal shared care arrangements (i.e. a written protocol may not exist). However for the purpose of this service we will assume the following allocation of responsibilities which reflect common UK practice:

e. The consultant should:

   i. Assess the need for LHRH analogue treatment
   ii. Recommend treatment with an LHRH analogue
   iii Liaise with the GP/Provider to agree to share care
   iv Prescribe 3 weeks treatment of bicalutamide at commencement of treatment
   v Review the patient, 3-6 monthly (while still under secondary care)

f. The GP/Provider should:

   i. Prescribe the recommended LHRH analogue - with reference to PACE bulletin Vol 10 No 15 PACE_Bulletin_Vol_10_No_15_Dec16_Gonadorelin_Analogues.pdf (lincolnshire-pacef.nhs.uk)
   ii. Administer the recommended LHRH analogue (this may be delegated to suitably trained GP or practice nurse).
   iii. Liaise with the consultant regarding any complications
   iv. Record any side effects and/or complications
   v. Regulary review the patient to monitor PSA levels and refer back to consultant with concerns.

g. Recommended dosage & preparations & administration:

   i. During the first 1-2 weeks of treatment in non-castrated patients, there may be a progression of the prostate cancer. If present in the spine this can result in cord compression. Therefore anti-androgen therapy is required for 2 weeks prior to commencement and for the first week of therapy. Bicalutamide 50mg daily is recommended (total of 3 weeks). This should be prescribed by the consultant; GPs should ensure that treatment with an LHRH analogue does not commence unless this has been strictly adhered to.

ii. Treatment may continue for up to 3 years – and beyond if remaining responsive.
iii. - Leuprorelin (Prostap® SR/Prostap® 3) - By subcutaneous or intramuscular injection 3.75mg every 28 days. The 11.25mg preparation is subcutaneously every 12 weeks.
iv. Triptorelin Decapeptyl® SR/Gonapeptyl Depot®) - Decapeptyl® SR – by intramuscular injection 3mg every 4 weeks. The 11.25mg preparation is every 3 months or 22.5mg every 6 months. Gonapeptyl Depot® - by subcutaneous or intramuscular injection 3.75mg every 4 weeks.
v. Goserelin (Zoladex®/Zoladex LA®) - By subcutaneous injection into the anterior abdominal wall. Recommended dose is 3.6mg every 28 days or 10.8mg every 12 weeks.

Endometriosis - patients with an established diagnosis of endometriosis, or pelvic pathology under the recommendation of a consultant.

a. The aims of treatment of endometriosis are to relieve symptoms & improve fertility (if desired). Treatment can include surgery, division of adhesions, and ablation of endometriotic deposits or be medical, using drug therapy to inhibit growth of endometriotic tissue. Drug treatments include the oral contraceptive pill, danazol and use of LHRH analogues.

b. LHRH analogues induce a hypo-oestrogenic state by inhibiting FSH and LH release. They have been shown to alleviate symptoms & reduce the size and number of endometriotic deposits.

c. The use of LHRH analogues in the treatment of endometriosis is fully supported by the European Society of Human Reproduction and Embryology Management of Women with Endometriosis Sept 2013.

d. The entire course of treatment may be administered in General Practice under the supervision of a consultant gynaecologist. Treatment is usually for a maximum of 6 months, however in certain circumstances the duration of treatment may be extended by the addition of “add back” HRT on specialist advice. Treatment and repeat treatments should not be initiated by primary care.

e. The consultant is responsible for:
   i. Recommendation of treatment options after referral
   ii. Provision of prescribing advice to the GP
   iii. Reporting any adverse effects to the CSM
   iv. Reviewing the patient after 3-6 month intervals.

f. The GP will be responsible for:
   i. Prescribing & administration of LHRH analogue
   ii. Reporting of adverse effects to the consultant & CSM
   iii. Reporting to & seeking advice from the consultant on any aspects of patient care which may affect treatment.

g. Recommended dosage and administration:

   i. These agents should be used for a maximum of 6 months only.
   ii. Goserelin (Zoladex®) - By subcutaneous injection into the anterior abdominal wall. Recommended dose is 3.6mg every 28 days.

iii. Leuprorelin (Prostap® SR) - By subcutaneous or intramuscular injection 3.75mg in the first 5 days of menstrual cycle and then every 28 days, or 11.25mg by intramuscular injection in the first 5 days of menstrual cycle and every 3 months.
iv. Triptorelin (Decapeptyl®SR) - By intramuscular injection 3mg every 4 weeks or 11.25mg every 3 months.

Breast Cancer - patients with an established diagnosis of ER+ve Breast cancer in a pre or peri-menopausal woman, who have chosen not to have chemotherapy.

a. Goserelin is a synthetic luteinising hormone releasing hormone (LHRH) analogue administered by subcutaneous depot injection. LHRH 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 luteinising hormone.

   In women this produces ovarian suppression and a fall in serum oestrogen to post-menopausal levels.

b. Goserelin may be used in the management of hormone sensitive (ER+ve) pre-menopausal breast cancer in the following situations:
   i. Adjuvant therapy prior to or after potentially curable breast surgery
   ii. Therapy of slow growing locally advanced or metastatic disease
   iii. Neo-adjuvant therapy of large operable disease prior to breast surgery (rare).

c. The entire course of treatment may be administered in General Practice under the supervision of an Oncologist/Specialist breast surgeon.

d. This therapy is evidence based see NICE Guidance CG101 Early and locally advanced breast cancer 2018: https://www.nice.org.uk/guidance/ng101

e. The consultant will:
   i. Assess the need for LHRH analogue treatment
   ii. Recommend treatment with Goserelin
   iii. Liaise with the GP to agree to share care

f. The GP will:
   i. Prescribe Goserelin 3.6mg. NB the 10.8mg Goserelin is not licensed for this use.
   ii. Administer Goserelin (this may be delegated to suitably trained GP or practice nurse).
   iii. Liaise with the consultant regarding any complications

g. Recommended dosage and administration
   i. The only drug licensed for this use is Goserelin 3.6mg depot (Zoladex). Zoladex LA 10.8mg is not licensed for the treatment of breast cancer and should not be used. The manufacturer state that it does not give reliable ovarian suppression for 12 weeks.
   ii. By subcutaneous injection into the anterior abdominal wall. Recommended dose is 3.6mg every 28 days.
   iii. Treatment can be up to 2 years in the adjuvant setting. The duration for metastatic disease depends on the response.

3.2 Service description/care pathway

Providers of this service will ensure that a register is maintained with up to date lists of patients being treated with LHRH analogues.

The Provider will demonstrate a call and re-call service and have a mechanism in place to identify defaulters.

Agree joint management plans drawn up by consultants in conjunction with the Provider. Providers will be expected to adhere to these plans unless agreement has been reached to vary them.

Support the continued education of patients both newly diagnosed & established in all aspects of their disease.

Have arrangements in place for patients experiencing problems and these are to be made known to the patient.

Notify the Commissioner within 72 hours of any significant untoward event occurring as a result of administration under this service.

3.2.1 Data Collection and Record Keeping

Adequate recording should be made regarding the patient's clinical history, with reference to the Shared care arrangements with the patient's secondary care consultant.

The site of injection, batch number and expiry date of the LHRH must be recorded.

In each case the patient must have been fully informed of the proposed administration of drugs by the secondary care consultant. The shared care protocol must be detailed within the patient's record.

The Provider must ensure that details of the patients monitoring as part of this enhanced service is included in his or her lifelong record. If the patient is not registered for primary medical services with the Provider of this service, the Provider must send this information to the patients registered General Practitioner for inclusion in their clinical records.

Providers should record all the required information detailed on the Minimum Data Set (MDS) which will inform a quarterly report. The required reporting template can be found in Schedule 6A of the contract

It is recommended that the practice use the following codes when recording the delivery of this enhanced service.

Procedure	READ codes	SNOWMED codes
Insertion of gonadorelin implant	XaKdO	417369003
Subcutaneous injection of gonadorelin analogue	XaamT	892651000000109

Intramuscular injection of gonadorelin analogue	Xaa4d	865211000000104

3.2.2 Reporting and Audit

The Provider must conduct an annual review as a minimum and this should include an audit of:

- The register of patients receiving LHRH analogues
- Complications
- Complaints
- Serious untoward incidents or significant events

The Provider will agree to participate in any formally notified additional audit/information requirements which will be used to improve the quality of both the existing and future opportunities of this scheme.

3.3 Population covered

Patients must be temporarily or permanently registered with a General Practice within the geographical boundary of Lincolnshire ICB.

Patients must meet the acceptance criteria for the service.

3.4 Any acceptance and exclusion criteria and thresholds

Acceptance:
Patients must be temporarily or permanently registered with a General Practice within the geographical boundary of Lincolnshire ICB.

Patients must meet the acceptance criteria for the service.

Any patient deemed appropriate, by the secondary care consultant, for the administration of the detailed drugs under a shared care protocol. If this applies to patients that are housebound then domiciliary care should be included.

Exclusions:
There are no exclusions as this is a secondary care led service any patient deemed inappropriate will not be referred to the practice for shared care.

3.5 Interdependence with other services/providers

The provider is expected to work within the Lincolnshire Health Economy. Partners within this pathway include (but not limited to):

- United Lincolnshire Hospitals NHS Trust
- Other Secondary Care providers i.e. NUH, PSHFT
- GPs

Providers are expected to cooperate and share information with others involved in a patients care, treatment and support while having regard to the patients' rights to confidentiality.

4. Applicable Service Standards

4.1 Applicable national standards (e.g. NICE)

This specification intends and expects compliance with the relevant standards of quality and safety across all provided regulated activities. This will be through registration with the Care Quality Commission. The new system is focused on outcomes and places the views and experience of people who use services at the centre. The new regulations are set out in the Health and Social Care Act 2008 (Regulated Activities) Regulations 2009 and the Care Quality Commission (Registration) Regulations 2009. These regulations replace 1) National Minimum Standards and 2) Standards for Better Health.

4.2 Applicable standards set out in Guidance and/or issued by a competent body (eg Royal Colleges)

4.3 Applicable local standards

4.3.1 Facilities

Practices must have policies in place that comply with current national guidelines. This should include:

- Infection control
- Disposal of clinical waste
- Provision of an appropriate room fitted with a couch and adequate space and equipment for resuscitation.
- Provision of sterile surgical equipment and other consumables

Provide safe & suitable facilities for the administration of LHRH analogues. This may include home administration.

4.3.2 Staffing

The Provider will identify a key co-ordinator to ensure that all aspects of this service are delivered as appropriate and through which the Commissioner can liaise with regards to the service.

The Provider will ensure that its employee and agents comply with all relevant legislation; codes of practice and regional and national guidance; and when required provide evidence of such compliance and the providers documentation.

The Provider will be responsible for employing adequate numbers of suitably trained and qualified staff to execute this contract and involve continuing professional development and registration.

4.3.3 Protocol

The Provider should have in place a protocol that outlines the actions and systems necessary to deliver the administration of LHRH analogues. This should define the roles and responsibilities of each individual involved in the programme and the timescales for delivery.

In order to minimise risk to both staff and patients and to deliver a safe service the following procedures should be in place:

- Incident reporting including serious untoward incidents
- Complaints reporting
- Safeguarding adults and children

4.3.4 Accreditation and Training

The Provider will ensure that all performers associated with administrating LHRH analogues are appropriately trained to undertake the service, in accordance with current guidance (in line with the most up-to-date Summary of Product Characteristics guidelines for LHRH analogues).

Clinicians who have previously provided similar services 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 this service shall be deemed professionally qualified to do so.

Clinicians not currently providing a similar service but who wish to do so must ensure that they familiarise themselves with the evidence outlined above & are specifically trained in the procedures for administering the drugs by the appropriate company representatives.

5. Applicable quality requirements and CQUIN goals

5.1 Practices which take part in the scheme must demonstrate that service provision is of high quality, evidence based, safe and effective, with robust governance systems and safeguards in place, staff have received appropriate training and equipment is maintained to the highest standard. Practices may be required to provide commissioners with assurance that services provided are within the criteria of the contract general conditions, service conditions and particulars.

The Service Provider will notify the ICB Quality Services Team, Cross O'Cliff Court, Bracebridge Heath, Lincoln, LN4 2HN directly or by email licb.clinicalriskincidents@nhs.net of all serious incidents. These must be reported by the service provider within one working day of the information becoming known to them.

The service provider will participate in a review of any serious incidents notified to the Head of Quality Services and demonstrate that any learning from the incident is acted upon to minimise future risk.

5.2 CQUIN goals will not be applied.

6. Location of Provider Premises

It is the obligation of the provider to secure premises for service delivery. The provider has the opportunity to use their own facilities within a practice or access current NHS accommodation in Lincolnshire; managed and accessed through NHS Property Services (to include premises owned by Lincolnshire Community Health Services, United Lincolnshire Hospital Trust and certain GP practices).

7. Individual Service User Placement

N/A