Novel service design – delivering prostate cancer medication implant administration via community pharmacy

Gursaran Singh Matharu (Raj)
CEO, Community Pharmacy South-East London

12th March 2025

This session is sponsored and funded by Aspire Pharma
Prescribing information can be found at the end of this presentation

10106062650 v1.0 February 2025

ASPIRE® PHARMA

Scope and intended outcomes

- This service is for the administration of a Gonadotropin releasing hormone analogue (GnRH-a) in a community pharmacy setting for the treatment of diagnosed prostate cancer
- It does not include other therapeutic indications, or the blood testing required as part of this treatment

---

- To develop a new service model to provide patients with options in line with the NHS Long Term Plan[1]
- To improve patient access and convenience[2]
- To improve adherence with timely treatment
- To better utilise the provision of clinical services from community pharmacies[3]
- To reduce workload in general practice[2]
- To improve the cost-effectiveness of treatment[4]

Background

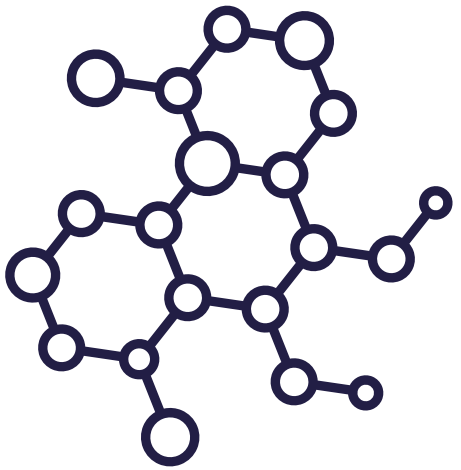
Gonadotropin Releasing Hormone Analogues (GnRH-a) are synthetic hormones used to reduce the levels of the hormone testosterone that is circulating in the body.

Different types of GnRH analogues are used to treat various conditions such as endometriosis, adenomyosis, uterine fibroids and prostate cancer.

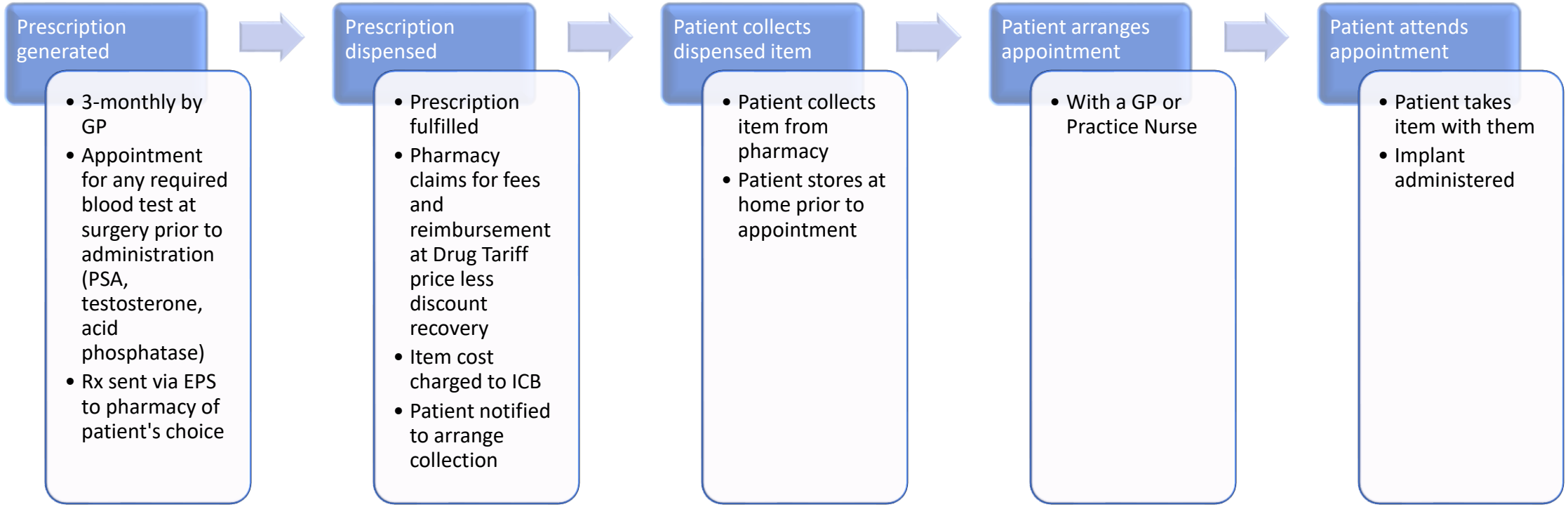
The following GnRH-a are some of the treatment options for prostate cancer:

- Leuprorelin Acetate 11.25mg
    - Staladex implant in a prefilled syringe
    - Prostap 3 DCS powder and solvent for injection
- Goserelin acetate 10.8mg
    - Zoladex LA implant in a prefilled syringe

Other treatment options are available



Patient journey - current



Patient journey - planned

Prescription generated

- Rx 3-monthly by GP
- Appointment for any required blood test at surgery prior to administration (PSA, testosterone, acid phosphatase)
- Prescription sent via EPS to pharmacy offering service of patient's choice

Prescription dispensed

- Prescription fulfilled
- Patient notified to arrange appointment for timely administration
- Item held in pharmacy under controlled conditions prior to appointment
- Appointment reconfirmed within 5 days of date

Patient attends appointment

- Informed consent taken
- Implant administered
- Patient health status checked post-administration

Data management

- Outcome data input completed and transferred to patient's GP
- Patient satisfaction questionnaire sent for completion

Logistics

- Pharmacist training – Clinically validated and provided by industry / accredited provider
- Stock outlay – extended credit provided by industry via defined wholesale provider
- Pharmacy Service and LCS paid for via PRESQIPP rebate
- Patient records handled via ECLIPSE, closing the loop with the prescribing GP practice

Barriers and lost opportunity

- Funding negotiation between ICB, LMC and LPC
- Speed to decision making
- Understanding by the LMC of the wider benefits to patients, ICB, GPs and pharmacy

---

- Across South London ICBs, potential savings equates to >£450K in 2024 alone*
- Missed opportunity to further protect the ongoing provision of community pharmacy across SE London

* Staladex cost savings calculator - GPPLPD Date Range: Sep-24 - Nov-24 10106062152 v2.0 February 2025

References

1. https://www.longtermplan.nhs.uk/ [accessed February 2025]
2. https://www.england.nhs.uk/publication/delivery-plan-for-recovering-access-to-primary-care/ [accessed February 2025]
3. https://www.england.nhs.uk/primary-care/pharmacy/independent-review-cpcs/ [accessed February 2025]
4. https://www.kingsfund.org.uk/insight-and-analysis/reports/better-value-nhs[accessed February 2025]

Staladex implant (leuprorelin acetate 11.25mg) prescribing information
(please refer to the full SmPC before prescribing)

Presentation: Implant in a pre-filled syringe containing 10.72 mg leuprorelin (as leuprorelin acetate 11.25 mg). **Indications:** Treatment of metastatic prostate cancer. Locally advanced prostate cancer, as an alternative to surgical castration. As an adjuvant treatment to radiotherapy in patients with high-risk localised or locally advanced prostate cancer. As an adjuvant to radical prostatectomy in patients with locally advanced prostate cancer at high risk of disease progression. As neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced prostate cancer. **Dosage and method of administration:** Dose: One implant once every three months. Administration: Staladex should be administered only by healthcare professionals. Subcutaneous injection under the abdominal skin. Accidental intra-arterial injection must be avoided. Response to Leuprorelin therapy should be monitored by clinical parameters and by measuring prostate-specific antigen (PSA) serum levels. Serum concentrations of testosterone should be measured 28 days after each injection and before each re-administration of Staladex and additionally on the basis of other laboratory tests like acid phosphatase and PSA. Clinical studies have shown that testosterone levels increased during the first four days of treatment in the majority of non-orchidectomised patients, then decreased and reached castrate levels by 2-4 weeks. Once attained, castrate levels were maintained as long as drug therapy continued. If a patient's response appears to be sub-optimal, then confirm that serum testosterone levels have reached or are remaining at castrate levels. In patients treated with GnRH analogues for prostate cancer, treatment is usually continued upon development of castrate-resistant prostate cancer. Reference should be made to relevant guidelines. Treatment of advanced, hormone-dependent prostate cancer with Leuprorelin is usually a long-term treatment. Clinical data have shown that 3 years of androgen deprivation therapy used concomitantly with and after radiotherapy is preferable to a 6-month course of androgen deprivation therapy in locally advanced, hormone-dependent prostate cancer. Medical guidelines recommend a 2- to 3-year course of androgen deprivation therapy for patients (T3 - T4) receiving radiotherapy. See SmPC for further details. **Contraindications:** Hypersensitivity to leuprorelin or other GnRH analogues or to any of the implant excipients; patients who previously underwent orchiectomy; as the sole treatment in prostate cancer patients with spinal cord compression or evidence of spinal metastases; in women or paediatric patients. **Special warnings and precautions for use:** In the initial stages of therapy, a transient rise in levels of testosterone, dihydrotestosterone and acid phosphatase may occur. In some cases, this may be associated with a "flare" or exacerbation of the tumour growth resulting in temporary deterioration of the patient's condition. "Flare" may manifest itself as systemic or neurological symptoms. Patients may experience worsening of symptoms or onset of new symptoms, including bone pain, urinary obstruction, weakness of the lower extremities and paraesthesia. These symptoms usually subside on continuation of therapy. Additional administration of an appropriate anti-androgen may be administered beginning 3 days prior to leuprorelin therapy and continuing for the first two to three weeks of treatment, to prevent the sequelae of an initial rise in serum testosterone. Following surgical castration, leuprorelin does not lead to a further decrease in serum testosterone levels in male patients. Therapeutic success should be monitored regularly (particularly if there is evidence of progression despite appropriate treatment) by means of clinical examinations (digital rectal examination of the prostate, ultrasound, skeletal scintigraphy, computed tomography) and by checking phosphatases and/or PSA and serum testosterone. Cases of ureteral obstruction and spinal cord compression, which may contribute to paralysis with or without fatal complications, have been reported with GnRH agonists. If spinal cord compression or renal impairment develops, standard treatment of these complications should be instituted. Patients with vertebral and/or brain metastases as well as patients with urinary tract obstruction should be closely monitored during the first few weeks of therapy. Patients with hypertension should be carefully monitored. Long-term androgen deprivation either by bilateral orchiectomy or administration of GnRH analogues is associated with increased risk of bone loss which, in patients with additional risk factors, may lead to osteoporosis and increased risk of bone fracture. Apart from long lasting testosterone deficiency, increased age, smoking and consumption of alcoholic beverages, obesity and insufficient exercise may have an influence on the development of osteoporosis. During post-marketing surveillance, rare cases of pituitary apoplexy have been reported after the administration of GnRH-agonists, with a majority occurring within 2 weeks of the first dose, and some within the first hour. Pituitary apoplexy was presented as sudden headache, vomiting, visual changes, ophthalmoplegia, altered mental status, and sometimes cardiovascular collapse. Immediate medical attention is required. There is an increased risk of incident depression (which may be serious) in patients undergoing treatment with GnRH agonists such as leuprorelin. Patients should be informed of this risk and treated as appropriate if symptoms occur. Convulsions have been reported in both children and adults treated with leuprorelin acetate with or without a history of epilepsy, seizure disorders or risk factors for seizures. Leuprorelin use can produce positive results in doping tests. During androgen-deprivation therapy, changes in metabolism (reduction in glucose tolerance or aggravation of pre-existing diabetes mellitus) as well as an increased risk for cardiovascular diseases may occur. Patients with diabetes and those at increased risk of metabolic or cardiovascular diseases should be appropriately monitored during treatment. Androgen deprivation therapy may prolong the QT interval. In patients with a history of or risk factors for QT interval prolongation and in patients receiving concomitant medicinal products known to prolong the QT interval, physicians should carefully assess the benefit/ risk ratio including the potential for developing torsade de pointes prior to initiating therapy to Staladex. Hepatic dysfunction and jaundice with elevated liver enzyme levels have been reported with the use of leuprorelin acetate and close observation should be made, with appropriate measures taken. Abscesses at the injection site occur rarely; in one report, the absorption of leuprorelin from the depot appeared to be decreased. It is advised to determine testosterone levels in such cases. Idiopathic intracranial hypertension (pseudotumor cerebri) has been reported in patients receiving leuprorelin. Patients should be warned for signs and symptoms, including severe or recurrent headache, vision disturbances and tinnitus. If idiopathic intracranial hypertension occurs, discontinuation of leuprorelin should be considered. **Ability to drive/use machines:** May be impaired due to visual disturbances and dizziness. Fatigue is common, particularly during initiation of therapy, and may also be due to underlying malignancy. **Pregnancy and breastfeeding:** Staladex is not indicated for use in women and is generally contraindicated during pregnancy and lactation. **Side effects:** For full list of side effects consult SmPC. 'Very Common' (≥1/10) 'Common' (≥1/100 to <1/10) and 'Serious' side effects included in the prescribing information: Decreased appetite, insomnia, depression, mood changes (long term use), headache (occasionally severe), hot flushes, nausea, hyperhidrosis, muscle weakness, bone pain, athralgia, libido decreased, erectile dysfunction, testiculars atrophy, gynaecomastia, fatigue, injection site reactions (induration, erythema, pain, abscesses, swelling, nodules, ulcers and necrosis), peripheral oedema. **MA number:** PLGB 19255/0023 **Cost:** 1 pre-filled disposable injection: £206.00 **MAH:** Amdeepcha Limited, 85 Yarmouth Road, Blofield, Norwich, Norfolk, NR13 4LQ, United Kingdom **Legal Category:** POM **Date last reviewed:** January 2025 **Version number:** 10106062139 v 2.0 January 2025

ASPIRE® PHARMA

Thank you for listening

I welcome your thoughts on how this can be moved forward

For further information, contact myself or Aspire Pharma

Session sponsored by