

**Nottinghamshire Area Prescribing Committee statement regarding prescribing of Gonadorelin analogues (GnRH) and degarelix in Primary Care for Prostate and Breast Cancer**

- Triptorelin (Decapeptyl SR<sup>®</sup>) is currently the most cost-effective gonadorelin analogue. If the gonadorelin analogue is being prescribed for a licensed indication, it is acceptable for the GP to prescribe the most cost-effective product, even if this is different from that originally recommended by secondary care. Therapy should be switched when the next dose of gonadorelin analogue is due.
- Goserelin (Zoladex<sup>®</sup> and Zoladex LA<sup>®</sup>) is currently the only product which is included on the formulary and licensed for breast cancer. As such, breast cancer patients should remain on goserelin (Zoladex<sup>®</sup>) unless directed otherwise by secondary care.
- Degarelix (Firmagon<sup>®</sup>) is a GnRH antagonist and is an option for treating advanced hormone-dependent prostate cancer in people with spinal metastases.

### Background

Triptorelin, leuprorelin and goserelin are gonadotrophin-releasing hormone (GnRH) analogues licensed for administration either monthly, 3-monthly or 6-monthly in the treatment of several indications. A summary of their licensed indications and administration schedules is given in Appendix 1. Triptorelin is classified as AMBER 2 (specialist initiation) for the indication of prostate cancer with the other GnRH analogues classified GREY for this indication.

Goserelin (Zoladex<sup>®</sup> and Zoladex LA<sup>®</sup>) is classified as AMBER 2 (consultant recommendation only) for breast cancer. The first dose of GnRH analogue will be given in Secondary Care. Other indications are classified as RED and prescribing should remain within Secondary Care.

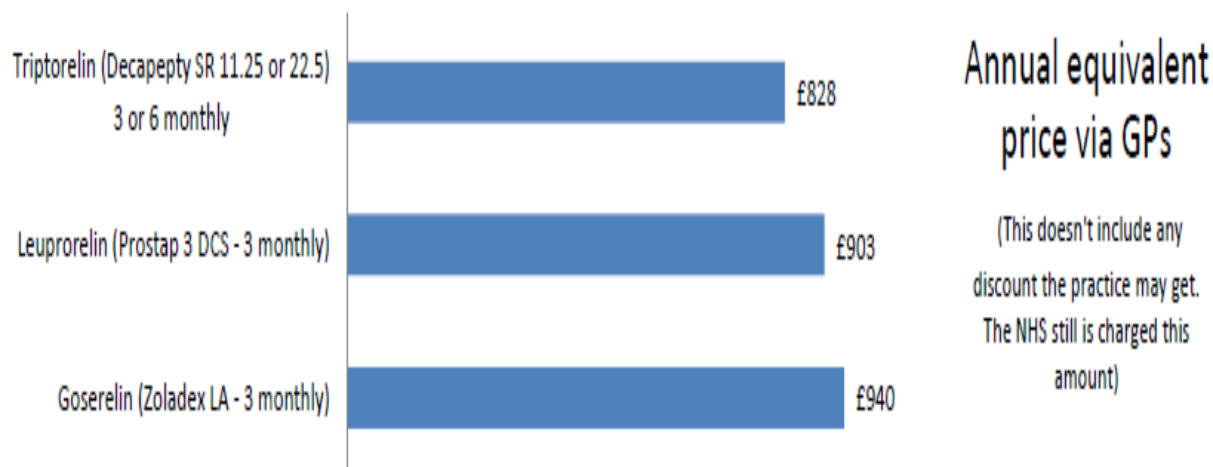
Degarelix (Firmagon<sup>®</sup>) is a GnRH antagonist and was approved for use in 2016 line with [NICE TA404](#) in 2016. It is recommended as an option for treating advanced hormone-dependent prostate cancer in people with spinal metastases and is classified as AMBER 2 (specialist initiation). A rebate scheme is in operation and NICE approval is dependent upon this being utilised.

### Prostate Cancer

NICE clinical guidance on Prostate cancer does not recommend which GnRH analogue should be prescribed. The selection of GnRH analogue should be driven by the licensed indications and evidence for use, the side-effect profile, the type of administration schedule desired and cost considerations. There is no conclusive evidence to suggest that one GnRH analogue is more effective or has fewer side effects than other analogues for the treatment of prostate cancer. Triptorelin (Decapeptyl SR<sup>®</sup>) is significantly less expensive to the NHS than other gonadorelin analogues and its preferential use could achieve significant cost savings across the health community. Triptorelin is administered via a smaller needle (20 gauge) compared with goserelin LA 10.8mg (14 gauge), minimising patient discomfort.

**The use of triptorelin 6-monthly (Decapeptyl SR<sup>®</sup> 22.5mg) reduces the number of appointments needed for administration. Patients with a stable PSA currently prescribed a 3-monthly dosing schedule can be switched to a 6-monthly schedule within the Primary Care setting.**

## Annual cost of Prostate cancer treatments in primary care



Taking this into account, and in liaison with Secondary Care clinicians, triptorelin (Decapeptyl SR<sup>®</sup>) products are recommended in Nottinghamshire as the preferred GnRH analogues for prostate cancer. Patients may be prescribed triptorelin, even if this is different from the GnRH analogue originally recommended by Secondary Care. Please note that if a patient is at risk of adverse events from IM injection eg due to anticoagulation, a licensed product that can be administered via the subcutaneous route is recommended. Therapy should be switched when the next dose of gonadorelin analogue is due.

### Breast Cancer

The Zoladex<sup>®</sup> and Zoladex LA<sup>®</sup> brands of goserelin are currently the only gonadorelin analogues on the formulary licensed for breast cancer. Prostap SR DCS<sup>®</sup> and Prostap 3 DCS<sup>®</sup> (Leuprorelin) are also licensed for breast cancer but are less cost-effective than the Zoladex<sup>®</sup> and Zoladex LA<sup>®</sup> brands (goserelin). Off-label gonadorelin analogues for this indication should only be prescribed by GPs on the recommendation of a specialist.

### GnRH Analogues for Transgender Adults

Most transgender female patients will start treatment with oestrogens which also have the effect of suppressing testosterone. For most patients, testosterone suppression will not be enough to put the testosterone level into the female range. GnRH analogues are usually required to achieve maximum suppression of the secondary male sexual characteristics. All the GnRH analogues available are classified as AMBER 2 and used off-label for this indication. The clinicians at the Nottingham Centre for Transgender Health recommend triptorelin preparations for reasons of cost-effectiveness and convenience reasons.

### References:

- NICE CG175: Prostate cancer: diagnosis and management (2014). [online]. Available at: <https://www.nice.org.uk/guidance/cg175> [accessed 22.06.23]
- Individual Summary of Product Characteristics (2023). [online]. Available at: [www.medicines.org.uk/emc/](http://www.medicines.org.uk/emc/) [accessed 22.06.23]
- Luteinising hormone-releasing hormone (LHRH) agonists in prostate cancer (2020). [online]. Available at: <https://www.prescqipp.info/umbraco/surface/authorisedmediasurface/index?url=%2fmedia%2f4931%2f257-lhrh-agonists-20.pdf> [accessed 22.06.23]

Version	Date	Changes
1.1	Update approved by Nottinghamshire APC: Dec 21	Noted those with stable 3-monthly administration can be offered a switch to 6 monthly triptorelin. Price graph updated.
2	August 2023	Document reviewed; hyperlinks to SPC updated, indications for Zoladex LA updated as per SPC, statement included for transgender adults.

**Appendix 1: Summary of gonadorelin analogues and their licensed indications** (prices correct as of June 2023)

Frequency	Every month/4 weeks				Every 3 months/12 weeks				Every 6 months
Drug & Dose	<a href="#">Goserelin acetate 3.6mg</a>	<a href="#">Leuprorelin acetate 3.75mg</a>	<a href="#">Triptorelin acetate 3mg</a>	<a href="#">Triptorelin acetate 3.75mg</a>	<a href="#">Goserelin acetate 10.8mg</a>	<a href="#">Leuprorelin acetate 11.25mg</a>	<a href="#">Triptorelin pamoate 11.25mg</a>	<a href="#">Triptorelin embonate 11.25mg</a>	<a href="#">Triptorelin pamoate 22.5mg</a>
Brand Name	Zoladex	Prostap SR DCS	Decapeptyl SR	Gonapeptyl Depot	Zoladex LA	Prostap 3 DCS	Decapeptyl SR	Salvacyl	Decapeptyl SR
Form	Implant in prefilled syringe	Powder to reconstitute	Powder to reconstitute	Powder to reconstitute	Implant in prefilled syringe	Powder to reconstitute	Powder to reconstitute	Powder to reconstitute	Powder to reconstitute
Injection Route	S/C	S/C or I/M	I/M	S/C or I/M	S/C	S/C (prostate cancer), I/M (endometriosis)	I/M	I/M	I/M
NHS list price	£70.00	£75.24	£69.00	£81.69	£235.00	£225.72	£207.00	£248.00	£414.00
Cost/month	£70.00	£75.24	£69.00	£81.69	£78.33	£75.24	£69	£82.67	£69
Licensed indications (Refer to the Summary of Product Characteristics for more detailed information in licensed indications)									
Prostate Cancer	•	•	•	•	•	•	•		•
Endometriosis	•	•	•	•		•	•		
Endometrial thinning	•	•							
Uterine fibroids	•	•	•	•					
Advanced Breast Cancer	•	•			•	•			
Early Breast Cancer	•	•	•		•	•			
Precocious puberty		•		•		•	•		•
Assisted reproduction	•								
Severe sexual deviation								•	