This policy statement is approved by Halton, Knowsley, Liverpool, Southport and Formby, South Sefton, St Helens, Warrington and West Lancashire CCGs

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PAN MERSEY APC

PAN MERSEY AREA PRESCRIBING COMMITTEE
PRESCRIBING POLICY STATEMENT
REF: PS46 FINAL
FIRST APC BOARD DATE: 12 MAR 2014
LAST APC BOARD DATE: 28 FEB 2018

NHS Pan Mersey Area Prescribing Committee

TRIPTORELIN (Decapeptyl® SR)

AMBER

The Pan Mersey Area Prescribing Committee recommends that TRIPTORELIN (Decapeptyl® SR 3mg, 11.25mg and 22.5mg) INTRAMUSCULAR INJECTION is first choice gonadorelin analogue for prostate cancer following specialist urologist / oncologist initiation under applicable local arrangement.

PATIENT RETAINED BY SPECIALIST

Triptorelin is a gonadorelin analogue (also known as a luteinising hormone releasing hormone (LHRH) analogue) available as a 4 weekly, 3 monthly and 6 monthly intramuscular (I/M) injection.

This recommendation applies ONLY to the treatment of prostate cancer <u>within the licensed indications</u> for the 4 weekly, 3 and 6 monthly injections of triptorelin.

Licensed indications[1,2] and cost[2]

	Triptorelin 3mg (I/M injection every 4 weeks) Decapeptyl® SR	Triptorelin 11.25mg (I/M injection every 3 months) Decapeptyl® SR	Triptorelin 22.5mg (I/M injection every 6 months) Decapeptyl® SR	Goserelin 10.8 mg (S/C injection every 12 weeks) Zoladex® LA	Leuprorelin 11.25mg (S/C injection every 3 months) Prostap® 3 DCS
Locally advanced, non-metastatic prostate cancer, as an alternative to surgical castration	✓	✓	✓	✓	✓
Metastatic prostate cancer	✓	✓	✓	✓	✓
Adjuvant treatment to radiotherapy in patients with high-risk localised or locally advanced prostate cancer	✓	✓	✓	✓	✓
Adjuvant treatment to radical prostatectomy in patients with locally advanced prostate cancer at high risk of disease progression	✓	✓	✓	✓	✓
Neo-adjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced prostate cancer	✓	✓	✓	✓	✓
Cost per patient per annum	**£897.00**	**£828.00**	**£828.00**	**£1018**	**£903**

Note: Patients who are not eligible for treatment under this statement may be considered on an individual basis where their GP or consultant believes exceptional circumstances exist that warrant deviation from the rule of this policy. In this situation, follow locally defined processes.

This recommendation has been designated suitable for inclusion on the Pan Mersey APC static list and so will only be reviewed if significant new evidence becomes available

TRIPTORELIN (Decapeptyl® SR)

EFFECTIVENESS	SAFETY
There is limited comparative data of the different gonadorelin analogues. There is evidence that gonadorelin analogues are similar in effectiveness to surgical castration in terms of survival, testosterone suppression, symptom control and prostate volume reduction.[3-5]	The side-effects associated with triptorelin reflect its efficacy in reducing testosterone and are similar to those seen with other gonadorelin analogues e.g. decreased libido, erectile dysfunction, asthenia, hyperhidrosis, hot flushes, paraesthesia in lower limbs or back pain, (very common adverse events, incidence ≥10%). See SPC[1] for detailed safety information.
COST In the period October 2016-September 2017, Pan Mersey locality spent £1,301,446 on Zoladex (goserelin) LA 10.8mg and Prostap 3 DCS (leuprorelin) 11.25mg injections. If triptorelin (Decapeptyl SR) 11.25mg or 22.5mg injections were prescribed instead of goserelin LA 10.8mg and leuprorelin 11.25mg for prostate cancer the cost savings to the Pan Mersey region would be estimated at £224,084. Source of prescribing data: ePACT.net[6]	**PATIENT FACTORS**[1] • gonadorelin analogues may cause a reduction in bone mineral density. Particular caution is necessary in patients with additional risk factors for osteoporosis e.g. long term therapy with anticonvulsant or corticosteroids, chronic alcohol abuse. • Patients with known depression should be monitored closely during therapy. • Patients at high risk of metabolic (e.g. glucose intolerance) or cardiovascular disease should be monitored at appropriate interval not exceeding 3 months. • Drugs which raise prolactin levels e.g. antipsychotics should not be prescribed concomitantly as they reduce LHRH receptors in the pituitary. • Concomitant use with drugs known to prolong the QT interval or able to induce Torsade de pointes should be carefully evaluated. • Subcutaneously administered drugs – goserelin or leuprorelin - may be preferable in anticoagulated patients, rather than triptorelin which is administered intramuscularly.

PRESCRIBING INFORMATION

- The recommended 3 or 6 monthly triptorelin injections enable treatment to be tailored to individual patient needs.
- Each formulation of triptorelin injection is packaged with a vial of powder, ampoule of solvent for reconstitution and 2 needles (one for reconstitution and one for administration).
- Once the injection has been appropriately prepared in accordance with the manufacturer's instructions the injection must be **immediately** administered to avoid precipitation.
- Triptorelin is administered via a much smaller sized needle (20 gauge) compared with goserelin LA 10.8mg (14 gauge) therefore minimising discomfort to patients. Triptorelin is given by intramuscular injection rather than a subcutaneous injection into the anterior abdominal wall and does not require use of a local anaesthetic.
- As with all gonadorelin analogues a transient increase in serum testosterone and potential transient worsening of disease symptoms (tumour flare or metastatic pain), during the first weeks of treatment can occur. During the initial phase of treatment, consideration should be given to the administration of a suitable anti-androgen to counteract the initial rise in serum testosterone and worsening of clinical symptoms.[1]

IMPLEMENTATION NOTES

- Training on correct administration is available from the manufacturers of triptorelin (Ipsen Ltd).
- All new patients should be considered for one of the triptorelin formulations if hormonal treatment with a gonadorelin analogue is the management choice recommended by the specialist.
- **Specialist may consider initiating treatment with 4 weekly formulation, with subsequent doses of 3 or 6 monthly formulation**.

References

1. Summary of Product Characteristics Decapeptyl® SR, Prostap® 3 DCS & Zoladex® LA www.emc.org.uk (27/11/2017)
2. BNF www.bnf.org/bnf/index.htm (Accessed 27/11/2017)
3. National Institute for Health and Care Excellence. Clinical Guideline 175. Prostate cancer: diagnosis and treatment. January 2014 http://www.nice.org.uk/guidance/CG175
4. Heidenreich A, Bastian PJ, Bellmunt J, Bolla M, Joniau S, Mason MD, et al. Guidelines on prostate cancer. European Association of Urology, 2012. A http://www.uroweb.org/gls/pdf/08 Prostate Cancer_LR March 13th 2012.pdf
5. London New Drugs Group APC/DTC Briefing document 2007 http://www.medicinesresources.nhs.uk/upload/documents/News/2008%20-%20March/17/Triptorelin1107.pdf
6. NHSBSA. ePACT.net accessed 01/12/2017