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AWMSG Secretariat Assessment Report – Limited submission

Triptorelin (Decapeptyl® SR) 3 mg and 11.25 mg powder for suspension for injection, 22.5 mg powder and solvent for suspension for injection

Company: Ipsen Ltd

Licensed indication under consideration:
Triptorelin (Decapeptyl® SR) for the adjuvant treatment to radiotherapy in patients with high-risk localised or locally advanced prostate cancer. As neoadjuvant treatment prior to radiotherapy in patients with high-risk localised or locally advanced prostate cancer.

Date of licence extensions: 24 November 2011 for adjuvant treatment to radiotherapy and 2 May 2013 for neoadjuvant treatment prior to radiotherapy.

Comparator(s)

- Goserelin (Zoladex® 3.6 mg implant, Zoladex® LA 10.8 mg)
- Leuprorelin (Prostap® 3 DCS, Prostap® SR DCS**)**

Limited submission details

The limited submission criteria were met based on:
- A minor licence extension.
- Anticipated usage in NHS Wales is considered to be of minimal budgetary impact.

Clinical effectiveness

- Triptorelin (Decapeptyl® SR) is a lutinising hormone releasing hormone agonist (LHRHa) that is an established treatment option in advanced prostate cancer. It was initially licensed as a monthly formulation (3 mg, 1994), followed by three-monthly (11.25 mg, 2002) and six-monthly (22.5 mg, 2010) formulations. The licence has since been extended to include indications for adjuvant and neoadjuvant treatment with radiotherapy. Similarly, goserelin and leuprorelin are also established LHRHa treatment options licensed for the same indications. The indications under consideration are included in the NICE clinical guideline on the diagnosis and management of prostate cancer.
- The Medicines and Healthcare Products Regulatory Agency (MHRA) state that current clinical guidelines/practices do not differentiate between LHRHas and were therefore satisfied that the goserelin trials provided evidence for the beneficial use of LHRHas as an adjuvant or neoadjuvant to radiotherapy. The MHRA concluded that the long-term adjuvant treatment with triptorelin is beneficial over short term treatment following radiotherapy, and that the results for triptorelin and other LHRHas (a large proportion of which was goserelin) were similar.
- The company submission included two post-hoc analyses of the pivotal EORTC 22916 trial to support the use of triptorelin as an adjuvant therapy in high-risk localised or locally advanced prostate cancer. The primary endpoint was overall survival (OS). Similar results were obtained for triptorelin and other LHRHas (HR 1.66, 95% CI 1.11–2.47). No difference in OS was observed following triptorelin long duration therapy versus goserelin long duration therapy (HR 1.10, 95% CI 0.68–1.77).
- The company submission also included a randomised, single-blind controlled trial

(EDVART) that compared neoadjuvant treatment with triptorelin and goserelin prior to radiotherapy in patients with localised prostate cancer. At 12 weeks triptorelin and goserelin showed a similar reduction in prostate volume (32.5% and 36.8%, respectively) supporting the efficacy of neoadjuvant triptorelin.
- An assessment of safety was included with the initial licensing of triptorelin 22.5 mg for 120 patients treated with triptorelin for 48 weeks. The most common adverse events that were considered treatment-related (occurring in ≥ 2% of patients) included hot flushes (71.7%), erectile dysfunction (10.0%), testicular atrophy (7.5%) and fatigue (4.2%). Serious adverse events were recorded in 17 patients (14.2%), but were not considered related to the study medicine. The MHRA deemed that there were no new safety concerns with the new licensed indications.

Budget impact

- The company estimated that 252 patients in Wales would be eligible for triptorelin. This estimation was calculated by applying data from the 2015 National Prostate Cancer Audit to the 2,583 new diagnoses of prostate cancer in Wales in 2014. The company estimated that 1,647 patients would have locally advanced or intermediate risk localised disease. Of these, 350 patients would be likely to undergo radiotherapy, of which 72% (252) would be expected to undergo adjuvant/neoadjuvant LHRHa treatment.
- The budget impact analysis is based on triptorelin being adopted by new patients rather than displacing ongoing comparator treatments: cost savings from using triptorelin was based on the current proportional prescribing of LHRHas in Wales (34.1% goserelin, 56.6% leuprorelin, and 9.3% triptorelin). Estimates have assumed that the incidence remains consistent at 252 new patients per year, and that each patient would receive three years ongoing adjuvant therapy. The company anticipate 50% uptake in years one and two, increasing to 75% in years three and four and finally 100% in year five. The company has estimated a cost saving of £6,791 in year one, rising to £67,905 in year five.
- There are limitations in the budget impact estimated by the company; however, the net impact will remain cost saving.

Additional information

- AWTTC is of the opinion that, if recommended, triptorelin (Decapeptyl® SR) for the indication under consideration may be appropriate for use within NHS Wales prescribed under specialist recommendation.

Evidence search

Date of evidence search: 3 October 2016
Date of range of evidence search: No date limits were applied to database searches.

Further information

This assessment report will be considered for review every three years.

References are available on request. Please email AWTTC at AWTTC@Wales.nhs.uk for further information.

This report should be cited as: All Wales Therapeutics and Toxicology Centre. AWMSG Secretariat Assessment Report. Triptorelin (Decapeptyl® SR) 3 mg and 11.25 mg powder for suspension for injection, 22.5 mg powder and solvent for suspension for injection. Reference number: 1658. October 2016.