

6.12 LEUPRORELIN

22.5 mg injection: modified release [1 x 22.5 mg syringe] (& inert substance diluent [1 x 2 mL syringe], 1 pack

30 mg injection: modified release [1 x 30 mg syringe] (& inert substance diluent [1 x 2 mL syringe], 1 pack

7.5 mg injection: modified release [1 x 7.5 mg syringe] (& inert substance diluent [1 x 2 mL syringe], 1 pack

45 mg injection: modified release [1 syringe] (& inert substance diluent [1 syringe], 1 pack

Lucrin®, AbbVie Pty Ltd.

1 Purpose of Application

- 1.1 The minor submission requested amending the PBS listings of leuprorelin (Lucrin), in all current indications, from Authority Required to Restricted Benefit. The submission requested this change for consistency with another gonadotrophin releasing hormone agonist (GnRH), goserelin.

2 Background

- 2.1 Leuprorelin (Lucrin) intramuscular injection in 7.5 mg, 22.5 mg, 30 mg and 45 mg strengths is currently listed as an Authority Required (STREAMLINED) listing for 'Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate'.
- 2.2 Leuprorelin (Lucrin Depot Paediatric 30mg PDS) is also currently listed as Authority Required for initial (and grandfathering) treatment of central precocious puberty (CPP), and Authority Required (STREAMLINED) for the continuing treatment of this condition.
- 2.3 Goserelin 3.6 mg implant is currently listed for carcinoma of the prostate, endometriosis and breast cancer. Goserelin 10.8 mg implant is currently listed for carcinoma of the prostate. The restriction level of goserelin 3.6 mg was changed from Authority Required, and goserelin 10.8 mg was changed from Authority Required (STREAMLINED) to Restricted Benefit as part of the Post-market Review of Authority Required PBS Listings.

For more detail on PBAC's view, see section 5 "PBAC outcome"

3 Requested listing

- 3.1 The submission requested changing the restriction level to Restricted Benefit for the following listings:
- 8875D: Lucrin Depot 7.5 mg (prostate cancer)
 - 8876E: Lucrin Depot 22.5 mg (prostate cancer)
 - 8877F: Lucrin Depot 30 mg (prostate cancer)

- 10656W: Lucrin Depot 45 mg (prostate cancer)
- 10255R: Lucrin Depot Paediatric 30 mg PDS (continuing treatment for CPP)
- 10256T: Lucrin Depot Paediatric 30 mg PDS (initial/grandfather treatment for CPP)

For more detail on PBAC's view, see section 5 "PBAC outcome"

4 Consideration of the evidence

Sponsor hearing

4.1 There was no hearing for this item as it was a minor submission.

Consumer comments

4.2 The PBAC noted and welcomed the advice received from an organisation, the Australian Advanced Prostate Cancer Support Group, via the Consumer Comments facility on the PBS website. The correspondence advocated for a Restricted Benefit listing for leuprorelin to mirror that of goserelin, describing how the mechanism of action was the same for the two drugs, and outlining that they are both used to treat locally advanced and metastatic prostate cancer. The PBAC noted that this advice was supportive of the evidence provided in the submission.

Clinical trials

4.3 As a minor submission, no clinical trials were presented in the submission.

5 PBAC Outcome

5.1 The PBAC recommended amending the current PBS listings for intramuscular injection leuprorelin (Lucrin) for the treatment of locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate and central precocious puberty (CPP), from Authority Required and Authority Required (STREAMLINED) to Restricted Benefit, for consistency with goserelin.

5.2 The PBAC noted that the goserelin PBS listing was altered from Authority Required to Restricted Benefit on 1 May 2015 for the following indications: carcinoma of the prostate, endometriosis and breast cancer, as part of the Post Market Review of Authority Required PBS listings. The PBAC considered that as leuprorelin is in the same class as goserelin (GnRH agonist), a change from Authority Required (STREAMLINED) to Restricted Benefit, would ensure consistency between the two drugs.

5.3 The PBAC noted that leuprorelin is also currently listed on the PBS as a subcutaneous injection (Eligard) at four strengths: 7.5 mg, 22.5 mg, 30 mg and 45 mg. As a flow on from its recommendation, the PBAC considered that the subcutaneous leuprorelin listings should also be amended from Authority Required (STREAMLINED) to Restricted Benefit.

- 5.4 The PBAC also noted that triptorelin, another GnRH agonist, is currently PBS listed as Authority Required (STREAMLINED) at three strengths: 3.75 mg, 11.25 mg and 22.5 mg. The PBAC considered that these listings should also be amended to Restricted Benefit, to ensure consistency with leuprorelin and goserelin.
- 5.5 The PBAC further noted that nafarelin, also a GnRH agonist, is currently PBS listed as a 200 microgram actuation nasal spray for the treatment of endometriosis and Assisted Reproductive Technology (ART), and is Authority Required. The PBAC recommended that the nafarelin endometriosis listing should also be amended to restricted benefit, to ensure consistency with goserelin, however, the PBAC did not consider that the ART listing should be amended.

Outcome:

Recommended

6 Recommended listing

- 6.1 Amend the following PBS items for the treatment of locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate from Authority Required (STREAMLINED) to Restricted Benefit.

Leuprorelin:

- 8875D: Lucrin Depot 7.5 mg PDS
- 8876E: Lucrin Depot 3 month PDS 22.5 mg
- 8877F: Lucrin Depot 4 month PDS 30 mg
- 10656W: Lucrin Depot 6 month PDS 45 mg
- 8707G: Eligard 1 month 7.5 mg
- 8708H: Eligard 3 month 22.5 mg
- 8709J: Eligard 4 month 30 mg
- 8859G: Eligard 6 month 45 mg

Triptorelin:

- 9379P: Diphereline 11.25 mg
- 5297T: Diphereline 22.5 mg
- 9378N: Diphereline 3.75 mg

- 6.2 Amend the following PBS items for the treatment of Central Precocious puberty from Authority Required and Authority Required (STREAMLINED) to Restricted Benefit:

Leuprorelin:

- 10256T: Lucrin Depot Paediatric 30 mg PDS (initial/grandfather treatment)
- 10255R: Lucrin Depot Paediatric 30 mg PDS (continuing treatment)

- 6.3 Amend the following PBS item for the treatment of endometriosis from Authority Required to Restricted Benefit:

Nafarelin:

- 2962X: synarel 200 microgram/actuation nasal spray, 60 actuations

7 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised in Australia. It considers submissions in this context. A PBAC decision not to recommend listing or not to recommend changing a listing does not represent a final PBAC view about the merits of the medicine. A company can resubmit to the PBAC or seek independent review of the PBAC decision.

8 Sponsor's Comment

AbbVie welcomes the PBAC's decision to create consistency in the restrictions for these products, thereby creating less administrative burden on prescribers.