6.01 TRIPTORELIN, Powder for I.M. injection (prolonged release) 3.75 mg (as embonate) with solvent, syringe and needles, Diphereline®, Ipsen Pty Ltd.

1 Purpose of submission

1.1 The Category 2 submission requested an unrestricted General Benefit listing for triptorelin 3.75 mg intramuscular (IM) injection.

1.2 Listing was requested on the basis of a cost-minimisation approach versus goserelin 3.6 mg subcutaneous implant (SCI).

Table 1: Key components of the clinical issue addressed by the submission

Component	Description
Population	All patients for whom GnRH agonist treatment is clinically appropriate. Current PBS listings for all GnRH agonists are for patients with prostate cancer, breast cancer, endometriosis, premature ovarian failure, central precocious puberty, and assisted reproductive technology.
Intervention	Triptorelin 3.75 mg intramuscular injection monthly
Comparator	Goserelin 3.6 mg subcutaneous implant monthly
Outcomes	Defined only for adjuvant treatment of pre-menopausal women with estrogen-receptor positive breast cancer: disease free survival, event free survival, overall survival.
Clinical claim	Triptorelin is no worse than goserelin in safety or efficacy.

Source: constructed from the submission text during the evaluation.

2 Background

Registration status

2.1 The registration status of triptorelin is complicated by differences in approved indications for the embonate salt and the acetate salt and for the various vial sizes intended for monthly, three monthly and six monthly administration.

2.2 Registered indications and PBS listings for the various doses and salts of gonadotrophin releasing hormone (GnRH) agonists currently available in Australia are shown in Table 2.Table 1

2.3 Goserelin 3.6 mg is registered for a wider variety of indications than other GnRH agonists. At the request of the sponsor, goserelin 3.6 mg will be de-listed from the PBS on 1 November 2026. Initially, the sponsor stated that it would also no longer supply goserelin 3.6 mg to patients with private prescriptions, but it has subsequently announced that "[f]or patients without suitable treatment pathways" it will provide goserelin 3.6 mg at no cost. Both continuing and new patients will be eligible, but what will count as a suitable treatment pathway has not been defined. The sponsor of goserelin has stated that it is preparing an application for TGA approval and PBS listing

of goserelin 10.8 mg implant for the indication of hormone-receptor positive breast cancer but not whether applications for approval and listing for the other indications, notably endometriosis, will also be made.[1,2]

2.4 Triptorelin is not TGA registered for treatment of breast cancer or endometriosis; triptorelin (as acetate) is registered for the treatment of breast cancer in Europe and the UK but not in the USA. It is also registered for endometriosis in the UK.

Table 2: TGA and PBS indications for GnRH agonists/antagonist

Indication	goserelin 3.6 mg -1 monthly		goserelin 10.8 mg 3-monthly		nafarelin		leuprorelin		triptorelin		relugolix [3]		degarelix	
	TGA	PBS	TGA	PBS	TGA	PBS	TGA	PBS	TGA	PBS	TGA	PBS	TGA	PBS
Metastatic and locally advanced prostate cancer	✓	✓	✓	✓	×	×	✓	✓	✓	✓	×	×	✓	✓
Breast cancer (HR+) [1]	✓	✓	×	×	×	×	×	×	×	×	×	×	×	×
Endometriosis	✓	✓	×	×	✓	✓	×	×	×	×	✓	✓	×	×
Uterine Fibroids[2]	✓	×	×	×	×	×	×	×	×	×	✓	×	×	×
Endometrial thinning[2]	✓	×	×	×	×	×	×	×	×	×	×	×	×	×
Assisted Reproductive Technology	✓	×	×	×	✓	✓	×	×	✓	✓	×	×	×	×
Anticipated premature ovarian failure (POF)[1]	×	✓	×	×	×	×	×	×	×	×	×	×	×	×

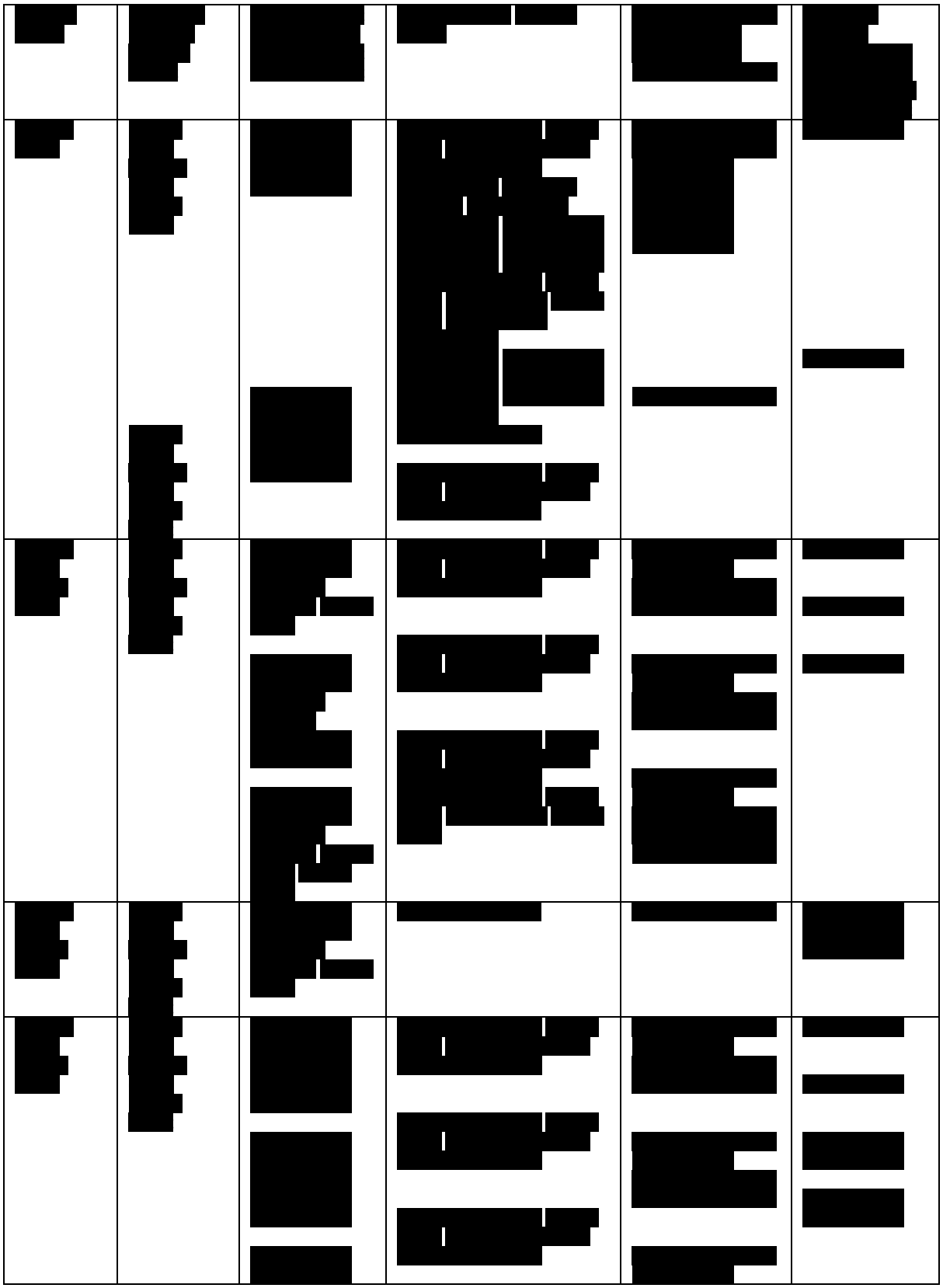
[1] No PBS alternative, [2] TGA only, no PBS listing. Goserelin (Zoladex) is an implant. [3] Relugolix is only listed as a triple fixed dose combination product with oestradiol and norethisterone.

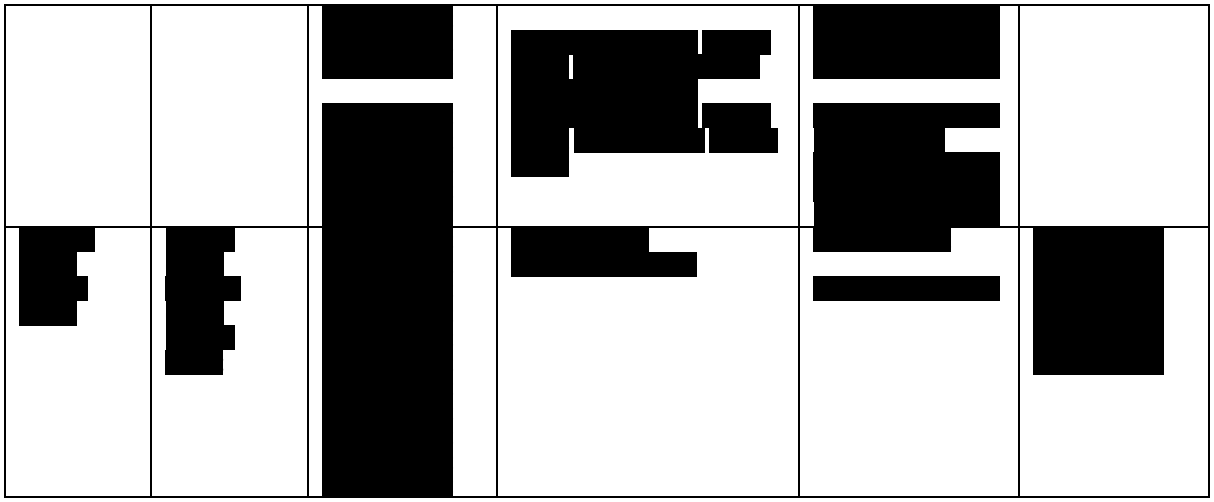
Diphereline - triptorelin 3.75 mg, triptorelin 11.25 mg and 22.5 mg forms are currently listed on the PBS for prostate cancer
Diphereline - triptorelin 22.5 mg form is also listed on the PBS for central precious puberty.
Decapetyl - triptorelin acetate 100 mg/ mL injection – is only listed on the PBS for assisted reproductive technology.

[1] https://www.pbs.gov.au/news/2026/05/delisting-of-goserelin-3-6-mg-implant-zoladex-implant-from-the-pharmaceutical-benefits-scheme accessed 18 July 2026.

[2] https://www.pbs.gov.au/news/2026/07/update-on-access-to-goserelin-3-6-mg-implant-zoladex-implant accessed 19 July 2026.

Committee-In-Confidence information





End Committee-In-Confidence information

Previous PBAC consideration

2.5 The PBAC has previously considered triptorelin (as embonate, 3.75 mg and 11.25 mg) in 2006 for treatment of locally advanced or metastatic carcinoma of the prostate; in 2016 (as acetate, 100 microgram/mL) for use in assisted reproductive technology programs; and in 2021 (as embonate, 22.5 mg) for the treatment of central precocious puberty. Triptorelin is currently PBS listed for these three indications.

2.6 Goserelin 3.6 mg implant is PBS-listed for the treatment of prostate cancer, endometriosis (6 months treatment only), breast cancer, and prevention of premature ovarian failure in women receiving alkylating agents. The listings for endometriosis and breast cancer predate the practice of reporting the comparator used for assessment of cost-effectiveness. Goserelin 10.8 mg implant is PBS-listed only for treatment of prostate cancer.

2.7 In 2017 the PBAC considered goserelin for the prevention of premature ovarian failure in patients undergoing treatment with alkylating agents although this was not (and is not) a TGA-approved indication. To deal with this, the sponsor had proposed the alternatives of an unrestricted listing (as in the present submission) or a restricted benefit listing for "cancer".

2.8 The PBAC considered that "an unrestricted listing would introduce a considerable risk of leakage, which could not be sufficiently managed by a risk share arrangement". *For contemporary consideration of this issue, see Paragraph 7.4.*

2.9 The PBAC also considered that because alkylating agents are used in conditions other than cancer "the potential benefit of goserelin in preventing [premature ovarian failure] was not restricted to women undergoing treatment for cancer, and therefore did not consider the restricted benefit proposed by the sponsor to be appropriate" (Paragraph 6.3, Goserelin Public Summary Document [PSD], July 2017 PBAC Meeting).

2.10 The PBAC determined that the best course was to have a specific restriction for prevention of premature ovarian failure, although this was not consistent with the

TGA-approved indications: "there was insufficient incentive for the sponsor to apply to the TGA to extend the TGA-approved indications for a long-established medicine for relatively small gain in any revenue, and therefore that a pragmatic approach to ensure equity of access for an area of clinical need, whilst also managing the risk of higher than expected utilisation, would be to enable PBS-subsidised treatment through a specific restriction" (Paragraph 6.3, Goserelin PSD, July 2017 PBAC Meeting).

3 Requested listing

MEDICINAL PRODUCT medicinal product pack	DPMQ	Max. qty packs	Max. qty units	№.of Rpts	Available brands
TRIPTORELIN					
Triptorelin (PI) 3.75mg injection [1 vial] (&) inert substance diluent [2 mL ampoule]	$213.50 published price	1	1	5	Diphereline
Category / Program: General Schedule					
Prescriber type: ☐Dental ☒Medical Practitioners ☒Nurse practitioners ☐Optometrists ☐					
Restriction type: ☒Unrestricted benefit					

3.1 Although the submission focussed on the use of triptorelin as an alternative to goserelin in the treatment of breast cancer, it is likely that in the event that triptorelin has an unrestricted listing it will replace goserelin not only in the treatment of the other conditions for which goserelin is listed but also in the treatment of conditions for which goserelin is used off-label and outside the current PBS restriction.

3.2 The size of the populations that may be treated off-label and outside current PBS restrictions is difficult to quantify, and the PBAC has never considered the cost-effectiveness of GnRH agonist treatment in these populations.

3.3 Proposed additional draft restrictions for triptorelin based on the existing restrictions for goserelin 3.6 mg are shown below

Category / Program: General Schedule
Prescriber type: ☐Dental ☒Medical Practitioners ☒Nurse practitioners ☐Optometrists ☐
Restriction type ☒Restricted benefit
Indication: endometriosis
Clinical criteria:
The condition must be visually proven
AND
Clinical criteria:
The treatment must be for the short-term (up to 6 months)

Treatment criteria:
Must be treated by a medical practitioner; **OR**
Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine.
Administrative Advice: Only 1 course of not more than 6 months' therapy will be authorised.

Category / Program: General Schedule
Prescriber type: ☐Dental ☒Medical Practitioners ☒Nurse practitioners ☐Optometrists ☐
Restriction type ☒Restricted benefit
Indication: breast cancer
Clinical criteria:
The condition must be hormone receptor positive
AND
Treatment criteria:
Must be treated by a medical practitioner, **OR**
Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine.

Category / Program: General Schedule
Prescriber type: ☐Dental ☒Medical Practitioners ☒Nurse practitioners ☐Optometrists ☐
Restriction type ☒Restricted benefit
Indication: anticipated premature ovarian failure
Clinical criteria:
Patient must be receiving treatment with an alkylating agent for a malignancy or an autoimmune disorder that has a high risk of causing premature ovarian failure,
AND
Clinical criteria:
Patient must not receive more than 6 months' of treatment for this condition in a lifetime.
Population criteria
Patient must be pre-menopausal.
Treatment criteria:
Must be treated by a medical practitioner, **OR**
Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine.

4 Population and disease

4.1 Triptorelin is an agonist of pituitary receptors for gonadotrophin releasing hormone (GnRH), which promotes the secretion by the pituitary of luteinising hormone (LH) and follicular stimulating hormone (FSH). Triptorelin causes an initial surge in serum testosterone and estrogen, but sustained use leads to de-sensitisation of the pituitary receptors, reduced FSH and LH secretion, and near-complete suppression of production of estrogen in women and testosterone in men.

4.2 It is not believed that GnRH agonists have therapeutic effects other than suppression of estrogen or testosterone. No differences among GnRH agonists in their ability to achieve suppression of estrogen or testosterone have been identified, except possibly in relation to some preparations with lower doses (Paragraphs 4.4, 7.1, Leuprorelin PSD, July 2019 PBAC Meeting).

4.3 The submission noted that PBS-subsidised use of goserelin 3.6 mg is predominantly in women, roughly evenly divided between breast cancer (44%) and endometriosis or impending ovarian failure (52%). Male patients, assumed to be treated for prostate cancer (i.e., male breast cancer was not considered) account for the remaining 4%.

4.4 Most women receiving goserelin for breast cancer are treated for longer than one year (DUSC Figure 9),[3] and because the aim is complete ovarian suppression dose adjustment is not required. The widespread use of goserelin 3.6 mg for this indication may reflect a preference for the dosing regimen used in the relevant trials,[4] and there is evidence that in pre-menopausal women with breast cancer one monthly and three monthly administration are similarly effective.[5]

4.5 On the other hand, treatment of endometriosis with goserelin is relatively brief in most women, with about half being treated for less than three months and only 15-20% reaching six months, the maximum duration of treatment allowed in the PBS listing (DUSC Figure 11). For this reason, goserelin 10.8 mg, or as an alternative triptorelin 11.5 mg, would be less suitable than goserelin 3.6 mg or triptorelin 3.75 mg for most women with endometriosis.

4.6 There is also some evidence that in women who do require long-term GnRH agonist treatment for endometriosis a reduced dose can achieve amenorrhoea and effective control of pain but allow sufficient estrogen production to limit vasomotor symptoms and bone loss. This can be achieved with nafarelin or with one monthly preparations of goserelin or triptorelin with the interval between doses extended from four to six weeks.[6]

4.7 GnRH agonists are used to suppress production of estrogen or testosterone in a wide variety of conditions. As well as the indications for which some or all are approved (breast cancer, prostate cancer, endometriosis, uterine fibroids, ART, precocious puberty) GnRH agonists are used:

- to suppress ovulation

[3] GnRH Agonists: Utilisation analysis prepared for the Drug utilisation sub-committee (DUSC), Public Release Document, June 2019 DUSC Meeting.

[4] Isaacs C. Adjuvant endocrine therapy for premenopausal females with hormone receptor-positive breast cancer. In: Connor RF, ed, UpToDate, Wolters Kluwer, accessed 3 July 2026.

[5] Lin J, Ouyang Y, Li Y, et al. Different dosage forms of gonadotropin-releasing hormone agonist with endocrine therapy in premenopausal hormone receptor-positive breast cancer. *J Natl Cancer Inst* 2024; 116:1587-1597.

[6] Hornstein MD. Endometriosis: Long-term treatment with gonadotropin-releasing hormone agonists and antagonists. In: Connor RF, ed, UpToDate, Wolters Kluwer, accessed 3 July 2026.

  - to protect ovarian function in patients treated with alkylating agents (this is not a TGA-approved indication for any GnRH agonist, but is a PBS-listed indication for goserelin 3.6 mg);
  - to treat dysmenorrhoea in patients without proven endometriosis;
  - to treat menstrual dysphoric disorder;
  - to reduce episodes of migraine, epilepsy or porphyria where these are precipitated by menstruation;
- to treat hyperandrogenism in post-menopausal women;
- to reduce sexual drive in men with paraphilias;
- to delay puberty in trans-gender adolescents.

5 Comparator

5.1 The submission appropriately nominated goserelin 3.6 mg as the comparator for triptorelin 3.75 mg.

5.2 As well as goserelin and triptorelin, leuprorelin and nafarelin are registered in Australia and PBS-listed for at least one indication.

5.3 Nafarelin requires twice daily administration and patients with imperfect adherence may not achieve long-term suppression of estrogen or testosterone production, but it may be preferred by patients who wish to avoid repeated injections and is used for conditions for which goserelin is sometimes used, such as endometriosis. For this reason, it may be an appropriate comparator for triptorelin 3.75 mg in the treatment of endometriosis or if an unrestricted listing for triptorelin is considered appropriate.

5.4 The higher dose formulations for three monthly use (goserelin 10.8 mg, triptorelin 11.25 mg and leuprorelin 22.5 mg) may also be appropriate comparators for the indication of breast cancer.

5.5 When PBAC considered triptorelin 3.75 mg and 11.25 mg for the treatment of metastatic or locally advanced prostate cancer in November 2006, the comparators were goserelin and leuprorelin (Paragraph 6, Triptorelin embonate PSD, November 2006 PBAC Meeting).

5.6 When PBAC considered leuprorelin for prostate cancer in 2019 it considered that leuprorelin might displace "any of the GnRH analogues listed on the PBS for prostate cancer (i.e. goserelin, triptorelin and degarelix), particularly the corresponding one- and three-month formulations" (Paragraph 5.2, Leuprorelin PSD, July 2019 PBAC Meeting).[7]

[7] Degarelix is an **antagonist** of GnRH at its pituitary receptors. It avoids the early surge in FSH and LH associated with GnRH agonists and is preferred in patients in whom early tumour enlargement may be dangerous - e.g., those with impending spinal cord compression. It causes a high rate of injection site reactions, and for this reason is used for ongoing treatment less often than GnRH agonists.

5.7 Goserelin 3.6 mg implant is the only GnRH agonist PBS-listed for breast cancer, and its listing pre-dates the practice of reporting the comparator used for assessing cost-effectiveness.

5.8 If an unrestricted listing for triptorelin was considered appropriate it may be used in the conditions listed in paragraph 4.3, for which goserelin is not currently available as a PBS benefit. In several of the conditions for which a GnRH agonist is used to suppress ovulation, including endometriosis, it is commonly second-line treatment after a combined oral contraceptive, although the current PBS-listing for use of goserelin in endometriosis does not require failed treatment with a combined oral contraceptive.

5.9 In the context of the cost-minimisation approach taken by the submission, a further consideration for PBAC is that, under Section 101(3B) of the *National Health Act 1953,* when the proposed medicine is substantially more costly than an alternative therapy, the committee cannot make a positive recommendation unless it is satisfied that, for some patients, the proposed medicine provides a significant improvement in efficacy and/or reduction of toxicity over the alternative therapy.

5.10 For the requested population of patients with endometriosis, other PBS-listed medicines may be considered alternative therapies because they could be replaced in practice. However, given goserelin is already listed for this indication, it may be reasonable to expect that there would be no further replacement or impact on the utilisation of these medicines if the listing of triptorelin is not expected to materially change the market share of GnRH agonists in this indication.

6 Consideration of the evidence

6.1 The submission claimed that triptorelin is non-inferior to goserelin for ovarian suppression in pre-menopausal women with hormone-sensitive early breast cancer, based on an indirect treatment comparison (ITC) with tamoxifen as the common comparator.

6.2 No data in relation to the other conditions for which goserelin 3.6 mg is PBS-listed was provided. The submission stated that "the broader body of evidence, clinical practice guidelines and clinical impression that triptorelin and goserelin are considered therapeutically equivalent, enables generalisability of the data presented to support a General Benefit listing for triptorelin 3.75 mg" .

6.3 The submission did not conduct a literature search to support the ITC. The SOFT trial was selected as the source of data for triptorelin and the ZIPP and Uslu (2014) trials were used as sources of data for goserelin. This was not appropriate, since no reason was given for this choice of comparator trials, and substantially more evidence is readily available.

Sponsor hearing

6.4 There was no hearing for this item.

Consumer and Medical Professional Inputs

6.5 The Breast Cancer Network of Australia (BCNA) supported the listing of triptorelin 3.75 mg, on the grounds of preserving treatment choice, and weaknesses in the evidence base for use of goserelin 10.8 mg for some groups of women, "particularly in combination with aromatase inhibitors and in younger women undergoing fertility preservation".

6.6 Metastatic Breast Cancer Action Australia also supported the listing of triptorelin 3.75 mg.

6.7 Correspondence from Medical Oncology Group of Australia (MOGA) supported the listing of alternative GnRH agonists for monthly administration (whether triptorelin or leuprorelin), repeating the observation made by BCNA that goserelin 10.8 mg might be an inadequate substitute for goserelin 3.6 mg for women receiving aromatase inhibitors and that there is no randomised controlled trial evidence that goserelin 10.8 mg is effective in prevention of premature ovarian failure and preservation of fertility.

6.8 The MOGA correspondence referred to a review of the use of goserelin 10.8 mg for breast cancer which concluded that, compared to goserelin 3.6 mg, the longer-acting preparation was equally effective in suppressing ovarian function and may improve quality of life.[8] This study received financial support from TerSera Therapeutics, the Canadian licensee of goserelin 10.8 mg (but not of goserelin 3.6 mg).

6.9 An individual patient meta-analysis of trials of GnRH agonists for preservation of ovarian function and fertility in patients receiving chemotherapy for breast cancer was also referred to. This study reported an analysis of data from five trials, out of 13 identified as eligible. All trials randomised women receiving chemotherapy to GnRH agonist (goserelin 3.6 mg monthly in three trials and triptorelin 3.75 mg monthly in two). A total of 873 women were enrolled in the trials, with data for premature ovarian failure available for 722/873 (82.7%), and data for post-treatment pregnancies available for 726/873 (83.2%).[9]

6.10 Premature ovarian failure occurred in 14.1% of women receiving GnRH agonists and in 30.9% of those receiving placebo. At least one post-treatment pregnancy occurred in 10.3% of women receiving GnRH agonists and in 5.5% of those receiving placebo.[9]

[8] Le Vasseur N, Manna M, Jerzak KJ. An overview of long-acting GnRH agonists in premenopausal breast cancer patients: Survivorship challenges and management. *Curr Oncol* 2024; 31:4209-4224.

[9] Lambertini M, Moore HCF, Leonard RCF et al. Gonadotropin-releasing hormone agonists during chemotherapy for preservation of ovarian function and fertility in premenopausal patients with early breast cancer: A systematic review and meta-analysis of individual patient–level data. J Clin Oncol 2018; 36:1981-1990.

6.11 There was no effect of GnRH agonists on breast cancer survival outcomes: five-year disease-free survival (95% CI) was 79.5% (74.4, 83.5) in women receiving GnRH agonists and 80.0% (75.2, 83.9), and five-year overall survival (95% CI) was 90.2% (86.4, 92.9) in women receiving GnRH agonists and 86.3% (82.0, 89.7) in women receiving placebo.[9]

Clinical trials

6.12 The submission presented data from three trials, shown in Table 3.

Table 3: Trials and associated reports presented in the submission

Trial ID	Publication title	Publication citation
Triptorelin		
SOFT NCT00066690 ACTRN12605000416695	Francis PA, Regan MM, Fleming GF, et al. Adjuvant ovarian suppression in premenopausal breast cancer. Francis PA, Pagani O, Fleming GF, et al. Tailoring adjuvant endocrine therapy for premenopausal breast cancer.	*N Engl J Med* 2015; 372:436-446. *N Engl J Med* 2018. June 4, 2018. DOI: 10.1056/NEJMoa180316.
Goserelin		
ZIPP NCT00002460	Baum M, Hackshaw A, Houghton J, et al. Adjuvant goserelin in pre-menopausal patients with early breast cancer: Results from the ZIPP study Hackshaw A, Baum M, Fornander T, et al. Long-term effectiveness of adjuvant goserelin in premenopausal women with early breast cancer.	*Eur J Cancer* 2006; 42:895-904. *J Natl Cancer Inst* 2009; 101:341-349.
Uslu, 2014	Uslu A, Zengel B, Akpinar G, et al. The outcome effect of double-hormonal therapy in premenopausal breast cancer patients with high nodal-status: Result of a prospective randomized trial.	*Indian J Cancer* 2014; 51:582-586.

Source: Table 4, p14 of the submission.

6.13 The SOFT trial was discussed in the submission as a trial of triptorelin, but patients were randomised to ovarian function suppression (OFS) + tamoxifen or tamoxifen alone, then chose either triptorelin, oophorectomy, or ovarian irradiation as the method of OFS, so outcomes according to the method of OFS could not be reported. Patients who initially chose triptorelin could have oophorectomy or irradiation at any time during the trial and were counted as continuing protocol-assigned treatment.

6.14 It was stated by the submission that "943 (92.9%) patients [chose] GnRH analogue triptorelin 3.75 mg every 4 weeks for 5 years", but this is the number of women who initially chose triptorelin (943/1015 = 92.9%). Of the 943 women starting triptorelin, 110 (11.8%) had surgery or irradiation during the trial.[10] The rate of non-adherence with triptorelin in women who had not had surgery or irradiation at 0.5, 1, 2, 3, and 4 years after randomisation was 5.0%, 9.2%, 14.9%, 18.3%, and 21.9%, respectively (Francis, 2015, p7).

6.15 The key features of the included evidence are summarised in Table 4.

[10] This number was calculated during the evaluation; if 943/1015 initially chose triptorelin, 72 initially chose surgery or irradiation and never received triptorelin. The published study report stated that "18% of patients

Table 4: Key features of the included evidence.

Trial	N	Design/ duration	Risk of bias	Patient population	Primary Outcome(s)
SOFT	3066 but 2033 for included comparison	R, OL, 5 years; R 1:1:1 to tamoxifen, tamoxifen + OFS, exemestane + OFS.	Low	Premenopausal women with endocrine-responsive early breast cancer.	DFS
ZIPP	2710	Analysis of 4 related but not identical OL trials; multiple groups and primary analysis goserelin vs no goserelin; 2 years treatment with follow-up to 5 years.	Low	Premenopausal women with operable, stage I or II breast cancer, regardless of ER status.	EFS, OS
Uslu, 2014	101	OL, R to tamoxifen for 5 years or until menopause vs tamoxifen 5 years + goserelin for 2 years; terminated with only half of estimated sample size because of slow recruitment and investigators' impression of more treatment failure with tamoxifen alone.	High	Premenopausal women with endocrine-responsive Stage II (34%) or III (66%) breast cancer; all had received chemotherapy.	DFS

Source: Table 5, pp14-15 of the submission, and published trial reports.
DFS = disease-free survival; EFS = event-free survival; ER = estrogen receptor; OL = open label; OS = overall survival; R = randomised.

opted to undergo bilateral oophorectomy or bilateral ovarian irradiation at some point during adjuvant therapy" (Supplementary Appendix to Francis et al, 2015, p25), and 18% of 1015 = 182 and 182-72 = 110. This matched the submission's statement that 80.7% of women used only triptorelin (p17), since the number of women completing 5 years = 568 (Francis et al, 2015, Figure 3) and 80.7% of 568 = 458, implying that 110 had had surgery or irradiation.

6.16 Baseline characteristics of women in the three trials are shown in Table 5.

Table 5: Baseline characteristics of women in the trials used by the submission

	SOFT	ZIPP		Uslu, 2014	
	N = 2033	**Goserelin N = 1354**	**No goserelin N = 1356**	**Tamoxifen N = 51**	**Goserelin + tamoxifen N = 50**
Age, years, median (range) mean (SEM)	43 NR	44 (22-56) NR	44 (21-55) NR	NR 48.2 (0.8)	NR 46.6 (0.8)
Age < 40, n (%)	620 (30.5%)	280 (21%)	326 (24%)	NR	NR
Menopausal, n (%) Pre- Post- Unknown	 EC - -	 979 (72%) 78 (6%) 297 (22%)	 967 (71%) 72 (5%) 317 (24%)	 EC - -	
Estrogen receptor, n (%) Positive Negative Unknown	 EC - -	 672 (50%) 335 (25%) 347 (26%)	 713 (53%) 312 (23%) 331 (24%)	 19 (37.7%) 32 (62.7%) -	 27 (53.4%) 23 (46.4%) -
Positive nodes, n (%)	709 (34.9%)	558 (41%)	571 (42%)	EC	
Radiotherapy, n (%)	NR	817 (60%)	870 (64%)	NR	
Chemotherapy, n (%)	1084 (53.3%)	583 (43%)	590 (44%)	EC	

Source: Constructed during the evaluation from published reports.
EC = enrolment criterion and no protocol deviations reported; NR = not reported; SEM = standard error of the mean.

6.17 SOFT enrolled a higher proportion of young women, of premenopausal women, of estrogen-receptor positive women, and, except compared to Uslu, 2014, of women who had received chemotherapy.

6.18 Estrogen-receptor positivity is a requirement for PBS-subsidised use of goserelin 3.6 mg for breast cancer, so only about half of the patients in ZIPP and Uslu, 2014 would be eligible.

6.19 Most of the women in Uslu (2014) did not have early breast cancer (66% had Stage III disease) and all had received chemotherapy.

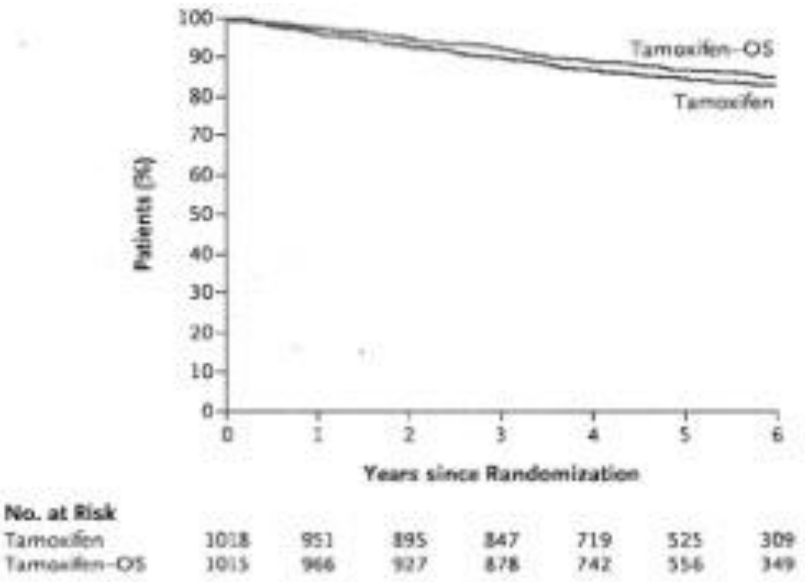
6.20 In Uslu, 2014, there was evidence of randomisation failure: women allocated to goserelin + tamoxifen were younger (P = 0.04) and more likely to be estrogen-receptor positive (P = 0.01).

Comparative Efficacy

Efficacy Outcomes in SOFT

6.21 Disease-free survival (DFS) was defined as freedom from recurrent breast cancer, a second invasive cancer, or death. DFS in SOFT is shown in Figure 1. After 5 years, recurrence, a second invasive cancer or death had occurred in 160/1018 women randomised to tamoxifen and in 139/1015 women randomised to tamoxifen + OFS, for 5-year disease free survival rates of 84.7% and 86.6% respectively, and a hazard ratio (95% CI) of 0.83 (0.66, 1.04).

Figure 1: Disease - free survival in SOFT



6.22 Previous chemotherapy was not associated with any difference in the effect of OFS on disease-free survival; the hazard ratio (95% CI) was 0.83 (0.52, 1.34) in woman who had not had previous chemotherapy and 0.82 (0.64, 1.07) in woman who had.

6.23 Death was recorded for 47/1015 (4.6%) women randomised to tamoxifen + OFS and 59/1018 (5.8%) women randomised to tamoxifen; the hazard ratio (95% CI) for overall survival (OS) was 0.74 (0.51, 1.09).

6.24 In women who had received chemotherapy, death was recorded for 39/542 (7.2%) randomised to tamoxifen + OFS and 57/542 (10.5%) randomised to tamoxifen; the hazard ratio (95% CI) for OS in this group was 0.64 (0.42, 0.96). The investigators suggested that the association of effect size with prior chemotherapy was due to women at higher risk of recurrence being given chemotherapy.

6.25 After 8 years of follow-up, recurrent breast cancer, a second invasive cancer, or death had occurred in 167/1015 (16.4%) women randomised to tamoxifen + OFS and in 208/1018 (20.4%) randomised to tamoxifen; the hazard ratio (95% CI) was 0.76 (0.63, 0.93). After 8 years, death had occurred in 61/1015 (6.0%) women randomised to tamoxifen + OFS and in 88/1018 (8.6%) randomised to tamoxifen; the hazard ratio (95% CI) for OS was 0.67 (0.48, 0.93).

6.26 Overall, SOFT showed that the addition to tamoxifen of OFS, predominantly achieved with triptorelin, improved outcomes of pre-menopausal women with early breast cancer.

ITC of triptorelin and goserelin

6.27 For the ITC, four pair-wise comparisons were made by the Bucher method: DFS at early follow-up, OS at early follow-up, DFS at late follow-up and OS at late follow-up. Because ZIPP only reported results for tamoxifen + goserelin versus tamoxifen at 12 years follow-up, the early follow-up comparisons were based on SOFT and Uslu, 2014, and because the investigators in Uslu, 2014 have not reported later results, the late follow-up comparisons were based on SOFT (8 years) and ZIPP (12 years).

6.28 The Cochrane review *(see below)* of adjuvant treatment of early breast cancer identified six trials as relevant to the comparison of OFS + tamoxifen versus tamoxifen, but these included neither ZIPP nor Uslu, 2014. ZIPP was excluded from this comparison because OFS + tamoxifen versus tamoxifen was not a pre-defined outcome and was not reported in the publication of five-year results. Because patients in Uslu, 2014 were required to have had chemotherapy it was included only for the comparison of OFS + chemotherapy + tamoxifen versus chemotherapy + tamoxifen.[11]

6.29 The results of the ITC are shown in Table 6.

[11] Bui KT, Wilson ML, Goel S, Beith J, Goodwin A. Ovarian suppression for adjuvant treatment of hormone receptor-positive early breast cancer. *Cochrane Database Syst Rev* 2020; 6;3(3):CD013538. doi: 10.1002/14651858.

Table 6: ITC results

	Disease-free survival, 5 year follow-up		Overall survival, 5 year follow-up	
	SOFT	**Uslu, 2014**	**SOFT**	**Uslu, 2014**
HR (95% CI), OFS or goserelin + tamoxifen vs tamoxifen	0.83 (0.66, 1.04)	0.55 (0.21, 1.46)	0.74 (0.51, 1.09)	0.93 (NR)
Pooled indirect HR (95% CI), goserelin vs triptorelin	1.51 (0.55, 4.11)		0.80 (0.53, 1.19)	
	Disease-free survival, 8-12 year follow-up		**Overall survival, 8-12 year follow-up**	
	SOFT	**ZIPP**	**SOFT**	**ZIPP**
HR (95% CI), OFS or goserelin + tamoxifen vs tamoxifen	**0.76 (0.62, 0.93)**	0.92 (0.80, 1.07)	**0.67 (0.48, 0.92)**	0.90 (0.75, 1.09)
Pooled indirect HR (95% CI), goserelin vs triptorelin	0.83 (0.64, 1.06)		0.74 (0.52, 1.06)	

Source: Tables 11 & 12, pp25-6 of the submission.

6.30 The ITC was uninformative because of the differences in trial design, in baseline characteristics of the trial populations, and methodological shortcomings in the case of Uslu (2014).

Systematic reviews and meta-analyses

6.31 Two systematic reviews and meta-analyses relevant to the clinical claims made in the submission and not included in the submission were identified during the evaluation, a Cochrane review and an individual patient (IP) meta-analysis of 23 trials. [11,12]

6.32 A Cochrane review of GnRH agonists for ovarian preservation in women undergoing chemotherapy for cancer was also identified.[13]

6.33 The pooled results of both meta-analyses reporting disease-free and overall survival for OFS + tamoxifen vs tamoxifen were similar to those of SOFT, but superior to those of ZIPP and inferior to those of Uslu, 2014.

6.34 In the Cochrane meta-analysis the pooled hazard ratio (95% CI) for disease-free survival for OFS + tamoxifen versus tamoxifen was 0.76 (0.63, 0.92) and for overall survival was 0.74 (0.59, 0.93). In the individual patient (IP) meta-analysis, the pooled number of events/woman.years of recurrent cancer was 434/20784 (2.1% per year) in women randomised to OFS + tamoxifen and 531/20577 (2.6% per year) in women randomised to tamoxifen, with a pooled rate ratio (95% CI) of 0.795 (0.695, 0.908).

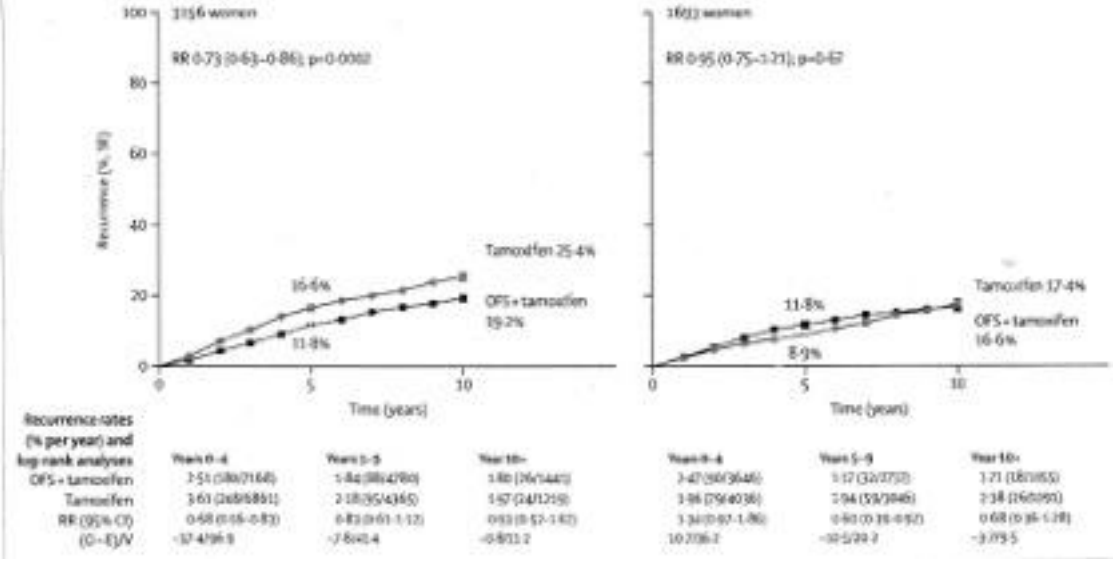
6.35 The Cochrane review found insufficient data to identify an effect of age on outcomes. The individual patient (IP) meta-analysis found that the reduction in the risk of

[12] Early Breast Cancer Trialists' Collaborative Group. Effects of ovarian ablation or suppression on breast cancer recurrence and survival: patient-level meta-analysis of 15 000 women in 23 randomised trials. *Lancet* 2026; 407:1699-1711.

[13] Weterings MAJ, Glanville E, van Eekelen R, Farquhar C. Interventions for fertility preservation in women with cancer undergoing chemotherapy. Cochrane Database of Systematic Reviews 2025, Issue 6. Art. No.: CD012891. DOI: 10.1002/14651858.CD012891.pub2 accessed 20 July 2026.

recurrence with OFS + tamoxifen versus tamoxifen alone was accounted for by pre-menopausal women younger than 45 years, with no benefit seen in women aged 45-54 years, although women aged 45-54 randomised to tamoxifen alone had a lower risk of recurrence than women aged less than 45 randomised to OFS + tamoxifen; the results are shown in Figure 2.

Figure 2: Cancer recurrence in pre-menopausal women treated with OFS + tamoxifen vs tamoxifen aged <45 years (left panel) and aged 45-54 years (right panel)



Source: EBCTCG, Lancet 2026; 407:1699-1711, Figure 4.

6.36 The Cochrane review of treatments for fertility preservation in women receiving cancer chemotherapy found low certainty evidence that GnRH agonists prevent premature ovarian failure, although the effect size was large (relative risk 0.43, 95% CI 0.30, 0.59). There was very uncertain evidence that GnRH agonists increased the frequency of post-treatment live births (relative risk 1.60, 95% CI 0.89, 2.87).

Comparative harms

Adverse events in SOFT

6.37 Adverse events were incompletely reported, and in particular there was no reporting of treatment discontinuation of withdrawal for adverse events. Reported adverse events are shown in Table 7.

Table 7: Adverse events in SOFT

	Tamoxifen N = 1006		**OFS + Tamoxifen N = 1005**	
	Any Event Patients with event, n (%)	Grade 3 or 4 Patients with event, n (%)	Any Event Patients with event, n (%)	Grade 3 or 4 Patients with event, n (%)
Hot flushes	803 (79.8%)	76 (7.6%)	939 (93.4%)	133 (13.2%)
Depression	469 (46.6%)	38 (3.8%)	522 (51.9%)	44 (4.4%)
Sweating	486 (48.3%)	0	621 (61.8%)	0
Insomnia	466 (46.3%)	29 (2.9%)	575 (57.2%)	46 (4.6%)
Urinary incontinence	162 (16.1%)	6 (0.6%)	185 (18.4%)	5 (0.5%)
Musculoskeletal symptoms	694 (69.0%)	63 (6.3%)	755 (75.1%)	55 (5.5%)
Decreased libido	427 (42.4%)	0	477 (47.5%)	0
Dyspareunia	238 (23.7%)	14 (1.4%)	262 (26.2%)	22 (2.2%)
Osteoporosis[1]	124 (12.3%)	1 (0.1%)	201 (20.0%)	3 (0.3%)
Fracture	49 (4.9%)	8 (0.8%)	54 (5.4%)	8 (0.8%)
Glucose intolerance	18 (1.8%)	3 (0.3%)	35 (3.5%)	14 (1.4%)
Hypertension	173 (17.2%)	54 (5.4%)	233 (23.2%)	75 (7.5%)
Myocardial ischaemia or infarction	5 (0.5%)	4 (0.4%)	3 (0.3%)	1 (0.1%)
Thrombosis or embolism	22 (2.2%)	17 (1.7%)	20 (2.0%)	17 (1.7%)
Cerebrovascular ischaemia or haemorrhage	20 (2.0%)	4 (0.4%)	12 (1.2%)	2 (0.2%)

Source: Francis, 2015, Table 2.

[1] Annual bone densitometry was recommended but not obligatory during the trial. Osteoporosis was defined as a T score less than -2.5.

6.38 Adverse events related to estrogen deprivation were more common and more often severe in patients allocated to OFS + tamoxifen. Adverse effects on sexual function were more common with OFS + tamoxifen than with tamoxifen, although the difference was relatively small.

6.39 Reduced bone density was more common with OFS + tamoxifen than with tamoxifen, but the risk of fracture was similar in both groups.

6.40 GnRH agonists have been reported to increase the risk of diabetes, stroke, heart attack and sudden death in men receiving treatment for prostate cancer.[14] Hypertension and glucose intolerance were relatively uncommon in SOFT, consistent with the age of the population, but were probably increased in the OFS + tamoxifen group.

[14] Smith MR. Side effects of androgen deprivation therapy. In: Connor RF, ed, UpToDate, Wolters Kluwer, accessed 27 June 2026.

6.41 The ZIPP trial did not report adverse events for the pooled data. Limited adverse event data for patients receiving goserelin + tamoxifen and tamoxifen alone were reported for the largest of the trials used in ZIPP, the CRUK trial. These are shown in Table 8. Adverse events were not reported in Uslu (2014).

Table 8: Adverse events in the CRUK component of ZIPP

	Tamoxifen N = 463	**Goserelin + tamoxifen N = 457**
Hot flushes, n (%)	78 (17%)	200 (44%)
Sweating, n (%)	5 (1%)	23 (5%)
Anxiety/depression/irritability, n (%)	10 (2%)	26 (6%)
Musculoskeletal symptoms, n (%)	4 (1%)	11 (2%)

Source: Baum, 2006, Table 7.

6.42 The overall frequency of adverse events was lower in the CRUK trial than in SOFT. The pattern of more frequent adverse events with OFS + tamoxifen versus tamoxifen alone was also seen in the CRUK trial.

6.43 The Cochrane meta-analysis found a risk ratio (95% CI) for the adverse event of hot flushes with OFS + tamoxifen versus tamoxifen of 1.99 (1.56, 2.55) but this result was dominated by SOFT. Analysis of adverse effects on mood and sexual function were hampered by inconsistent reporting. Only 2/15 studies analysed reported data on cardiovascular risks and only SOFT reported data for osteoporosis.

6.44 No ITC of safety was carried out by the submission.

Benefits/harms

6.45 A benefits and harms table is not presented as the submission made a claim of non-inferiority.

Clinical claim

6.46 The submission described triptorelin 3.75 mg as non-inferior in terms of effectiveness compared to goserelin 3.6 mg in the treatment of pre-menopausal women with early breast cancer. This claim was not adequately supported by the data presented, but considering the totality of the available evidence and the extensive clinical experience with both treatments may be considered reasonable.

6.47 The submission suggested that the results of treatment in pre-menopausal women with early breast cancer can be extrapolated to all other conditions for which goserelin 3.6 mg is registered or in which it is used off-label. No evidence of efficacy in these conditions was presented. Considering the totality of the available evidence, it may be considered reasonable to conclude that triptorelin is non-inferior to goserelin in the treatment of endometriosis and other conditions in which suppression of ovulation is the effect sought.

6.48 The submission described triptorelin 3.75 mg as non-inferior in terms of safety compared to goserelin 3.6 mg. This claim was not adequately supported by the data presented, but considering the totality of the available evidence and the extensive clinical experience with both treatments it may be considered reasonable.

6.49 The PBAC considered that the claim of non-inferior comparative effectiveness of triptorelin 3.75 mg compared to goserelin 3.6 mg was reasonably supported by the extensive clinical experience and use with both treatments.

6.50 The PBAC considered that the claim of non-inferior safety was reasonable.

Economic analysis

6.51 The submission presented a cost minimisation approach comparing triptorelin 3.75 mg with goserelin 3.6 mg. The key components in the approach are shown in Table 9.

Table 9: Key components and assumptions of the cost-minimisation approach

Component	Claim or assumption
Therapeutic claim: effectiveness	Based on evidence presented in Section 2, effectiveness of triptorelin 3.75 mg is assumed to be non-inferior to goserelin 3.6 mg.
Therapeutic claim: safety	Based on evidence presented in Section 2, triptorelin 3.75 mg and goserelin 3.6 mg formulations have a similar safety profile.
Evidence base	Indirect comparison of triptorelin and goserelin based on randomised controlled trials.
Equi-effective doses	Triptorelin 3.75 mg is equi-effective to goserelin 3.6 mg, each medicine taken every 4 weeks.
Direct medicine costs	Equalising drug costs per 4 weeks (single administration) based on goserelin 3.6 mg DPMQ $213.50*
Other costs or cost offsets	Not included.

Source: Table 13, pp29-30 of the submission.* As of 26 July 2026, the DPMQ is $207.94.

6.52 The equi-effective doses were estimated as triptorelin 3.75 mg given as a monthly injection and goserelin 3.6 mg given as a monthly injection. Based on a review by DUSC of the GnRH analogues in 2019, the median duration of therapy with goserelin for breast cancer was 290 days, not accounting for breaks. The median duration of therapy accounting for breaks was 226 days.

6.53 No other costs were included in the analysis. The submission noted that although triptorelin is given intramuscularly and goserelin is a subcutaneous implant, both would be administered by a health practitioner and therefore the costs of administration were assumed to be the same.

6.54 Cost minimisation approaches for the PBS are normally done based on AEMP. For goserelin 3.6 mg, the AEMP as of 1 June 2026 was $181.32. The DPMQ used in the analysis changed slightly as of 1 July 2026, with a change in dispensing fee.

Table 10: Results of the cost-minimisation approach, AEMP

Component	Triptorelin 3.75 mg	Goserelin 3.6 mg
Cost per dose	$181.32	$181.32
Dose duration	Median 290 days	Median 290 days
Administrations per month	1	1
Total medicine cost per month	$181.32	$181.32
Difference in cost per month	$0	$0

Source: Calculated during the evaluation based on data in DUSC review 2019.

Drug cost/patient/course

6.55 The drug cost per patient assuming both products are the same DPMQ from 1 July 2026, based on the DUSC analysis of duration of treatment, is shown in Table 11.

Table 11: Drug cost per patient for proposed and comparator drugs

	Triptorelin 3.75 mg	Goserelin 3.6 mg
Mean dose (PI)	1 injection every 28 days	1 injection every 28 days
Mean duration (DUSC)	290 days	290 days
Cost/patient/month (DPMQ, 1 July 2026)	$206.98	$206.98
Cost/patient//course	$2143.72	$2143.72

Source: Calculated during the evaluation from sources as shown.

Estimated PBS usage & financial implications

6.56 This submission was not considered jointly by DUSC and ESC.

6.57 The submission used a market share approach to estimate the PBS usage and financial impact of General Benefit listing of triptorelin 3.75 mg. The key sources used in the approach were the PBS Services data for goserelin 3.6 mg. Triptorelin may also substitute for leuprorelin 7.5 mg, currently listed with a DPMQ of $271.33.

Table 12: Key inputs for financial estimates

Parameter	Value	Source	Comment
Market:			
Existing Market	94019 Scripts in 2025 408 Scripts in 2025	1454M – goserelin 9378N – triptorelin	Goserelin is listed for multiple indications including breast cancer. Based on DUSC analysis provided in covering letter, breast cancer may be approximately 40% of the use.
% Growth Rate	Yr 1 (2026): -5% Yr 2 (2027): 1.2% Yr 3 (2028): 2.4% Yr 4 (2029): 2.1% Yr 5 (2030): 1.9% Yr 6 (2031): 1.7%	Extrapolation of data from January 2019- April 2026, data for 2026 pro-rated using Jan-April data. Logarithmic extrapolation was line of best fit.	Reasonable. However, extrapolated from baseline year 2026 for 6 years - may need to be extended.
% Treatment Uptake Rate	Yr 1: [redacted]% Yr 2: [redacted]% Yr 3: [redacted]% Yr 4: [redacted]% Yr 5: [redacted]% Yr 6: [redacted]%	Sponsor Assumption, based on withdrawal of goserelin	[redacted]% switch is reasonable but there are also alternative products available that have not been included in analysis.
Script Equivalence	1:1	Product information; trial data	Appropriate
MBS Impacts	None	-	Appropriate

6.58 In its covering letter, the submission included data from an analysis by the DUSC Secretariat of PBS use of goserelin 3.6 mg for the current indications. As indications are not recorded in the existing PBS indications, they were inferred using proxy methods based on patient sex and co-prescribing patterns. Female patients who had received an antineoplastic medicine (ATC L01) at any time during the observation period were classified as breast cancer, while other female use was grouped as endometriosis or ovarian failure. All male patients were classified as prostate cancer. These patient estimates must therefore be interpreted with these assumptions in mind. The estimates are shown in Table 13.

Table 13: Patients using goserelin 3.6 mg 2022-2025, according to inferred indication.

Year	Endometriosis or ovarian failure	Breast cancer	Carcinoma of the prostate	Total
2022	18028	6210	1782	26020
2023	18346	8603	1547	28496
2024	19015	10890	1453	31358
2025	18850	13313	1426	33589

Source: Covering letter, the submission.

6.59 The estimated use and financial implications of listing triptorelin as presented in the submission are shown in Table 14.

Table 14: Estimated use and financial implications

	Year 1 2026	Year 2 2027	Year 3 2028	Year 4 2029	Year 5 2030	Year 6 2031
Estimated extent of use						
Number of scripts dispensed	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]
Estimated financial implications of triptorelin						
Cost to PBS/RPBS less copayments	$[redacted][2]	$[redacted][3]	$[redacted][3]	$[redacted][2]	$[redacted][2]	$[redacted][2]
Estimated financial implications for goserelin						
Cost to PBS/RPBS less copayments	-$[redacted][2]	-$[redacted][3]	-$[redacted][3]	-$[redacted][3]	-$[redacted][2]	-$[redacted][2]
Net financial implications						
Net cost to PBS/RPBS	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]	-$[redacted][4]
Net cost to MBS	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]	[redacted][4]

Source: Sheet 4b, UCM attachment and Table 14, p 31 of the submission.

The redacted values correspond to the following ranges:

[1] *100,000 to < 200,000*

[2] *$20 million to < $30 million*

[3] *$10 million to < $20 million*

[4] *$0 to < $10 million*

6.60 The estimates included a full year for 2026, based on an extrapolation of data from up to April 2026. The total cost to the PBS/RPBS of listing triptorelin was estimated to be $20 million to < $30 million in Year 6, and a total of $100 million to < $200 million in the first 6 years of listing. The net cost to the PBS, given the de-listing of goserelin and price reduction of triptorelin, was estimated to be a saving of approximately $0 to < $10 million over the forward estimates.

6.61 The submission did not present any sensitivity analyses. Given the potential for use outside the currently PBS listed indications, a sensitivity analyses estimating this use and cost would be relevant but was not possible based on the data the provided in the submission.

Quality Use of Medicines

6.62 The submission did not provide information about quality use of medicines for triptorelin other than to note that promotional activities would be limited to the TGA approved indications for triptorelin.

Financial Management – Risk Sharing Arrangements

6.63 The submission did not propose a risk sharing arrangement.

7 PBAC Outcome

7.1 The PBAC recommended that the restrictions for triptorelin 3.75 mg intramuscular (IM) injection be removed from the General Benefit listing. The PBAC's recommendation for removing the restrictions was based on, among other matters, its assessment that the cost effectiveness of triptorelin 3.75 mg for a broader population would be acceptable if it were cost minimised against goserelin 3.6 mg subcutaneous implant (SCI).

7.2 The PBAC acknowledged and thanked the sponsor for their cooperation throughout the evaluation process and in bringing forward the submission for consideration.

7.3 The PBAC noted that the submission nominated goserelin 3.6 mg implant as the comparator. The PBAC noted that goserelin 3.6 mg was the only gonadotrophin releasing hormone (GnRH) agonist injection available listed on the PBS for the treatment of breast cancer, endometriosis and premature ovarian failure. The PBAC considered that it was an appropriate comparator. The PBAC considered the equi-effective doses were triptorelin 3.75 mg monthly by intramuscular injection and goserelin 3.6 mg monthly by subcutaneous injection. The PBAC noted that the most robust comparative data was that in breast cancer and considered that it was reasonable that this is likely to be similar across other uses.

7.4 The PBAC considered that the place of GnRH agonists in clinical practice was established. The PBAC acknowledged that an unrestricted listing for triptorelin 3.75 mg may increase the utilisation beyond existing PBS use however use of triptorelin would likely be used for indications that were supported by evidence-based guidelines and aligned with current contemporary clinical practice. On this basis the PBAC considered the financial risks associated with removing the current PBS restrictions were not expected to exceed current expenditure.

7.5 The PBAC acknowledged and welcomed input from consumer groups and medical professionals supporting the listing of triptorelin 3.75 mg injection in response to the delisting of goserelin 3.6 mg implant. The PBAC noted the input from Breast Cancer Network of Australia (BCNA) which claimed there are 'weaknesses in the evidence base for use of goserelin 10.8 mg for some groups of women' and triptorelin 3.75 mg should be listed to preserve treatment choice.

7.6 The PBAC noted the submission presented a market share model to estimate the PBS usage and financial impact of an unrestricted listing for triptorelin 3.75 mg. The PBAC noted the underlying assumptions presented in the model, including an uptake rate of [redacted]% for triptorelin based on the anticipated withdrawal of goserelin 3.6 mg implant from the PBS. The PBAC noted that overall, the submission estimated a small net saving to the PBS over the 6 year forward estimates, primarily driven by a price reduction from the current listing price of triptorelin 3.75 mg for existing listed indications. The PBAC noted that the market for triptorelin is likely to remain stable and aligned with contemporary and evidence based clinical practice. Subsequent to the PBAC meeting the Department estimated that the volume of scripts dispensed on the private market, was, on average, <1% of the total script volume.

7.7 The PBAC advised that a review of triptorelin 3.75 mg utilisation should be completed 2 years after the amendment to the PBS listing to determine whether there are any changes to the utilisation compared to what is expected.

7.8 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

8 Recommended listing

8.1 *Amend existing listing as follows:*

MEDICINAL PRODUCT medicinal product pack	**PBS Item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
TRIPTORELIN					
Triptorelin 3.75 mg injection [1 vial] (&) inert substance diluent [2 mL ampoule]	9378N	1	1	5	Diphereline
Category / Program: General Schedule					
Prescriber type: ☐Dental ☒Medical Practitioners ☒Nurse practitioners ☐Optometrists ☐					
Restriction type: ☐~~Restricted benefit~~ ☒*Unrestricted*					
~~**Indication**: Locally advanced (stage C) or metastatic (stage D) carcinoma of the prostate~~					
~~**Treatment criteria:**~~					
~~Must be treated by a medical practitioner~~					
~~OR~~					
~~Must be treated by a nurse practitioner where both of the following are occurring: (i) patient care is being shared with a medical practitioner, (ii) the prescription continues existing therapy with this medicine.~~					

9 Context for Decision

The PBAC helps decide whether and, if so, how medicines should be subsidised through the Pharmaceutical Benefits Scheme (PBS) in Australia. It considers applications regarding the listing of medicines on the PBS and provides advice about other matters relating to the operation of the PBS in this context. A PBAC decision in relation to PBS listings does not necessarily represent a final PBAC view about the merits of the medicine or the circumstances in which it should be made available through the PBS. The PBAC welcomes applications containing new information at any time.

10 Sponsor's Comment

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