6.13 ETONOGESTREL, Subcutaneous implant 68 mg, Implanon NXT®, Organon Pharma Pty Ltd

1 Purpose of submission

1.1 The Category 3 submission requested a price adjustment for the contraceptive implant Implanon-NXT (hereafter referred to as etonogestrel implant). Etonogestrel implant is currently listed on the Pharmaceutical Benefits Scheme (PBS) as a General Schedule unrestricted benefit.

1.2 The adjusted price was requested on the basis of a comparison with prices of recently listed contraceptives (drospirenone with ethinylestradiol tablets, drospirenone tablets and etonogestrel with ethinylestradiol vaginal ring), with the submission stating that the price for recently listed contraceptives is an approved ex-manufacturer price (AEMP) of $15.15 per month.

2 Background

Registration status

2.1 Implanon was first registered by the Therapeutic Goods Administration (TGA) in the late 1990s. The currently approved product is Implanon NXT, approved by the TGA in November 2010. This preparation differed from Implanon by the addition of barium to the implant to make it radio-opaque.

2.2 The submission stated that an application was submitted to the TGA in October 2025 to extend the use of etonogestrel implant as a contraceptive for 3 years to 5 years and expand its use to include immediate postpartum, immediate post-abortion, and women with higher BMI. No TGA documentation relating to this application was included in the submission.

Previous PBAC consideration

2.3 The PBAC has previously noted that cost comparisons for recently introduced contraceptives are complicated by the fact that most combined oral contraceptives were recommended for listing before cost-effectiveness analysis was required (Paragraph 12.6, drospirenone with ethinylestradiol Public Summary Document [PSD], July 2024 PBAC Meeting with November 2024 Addendum). Other PBAC considerations relevant to the submission pre-date the practice of providing detailed Public Summary Documents, so no details of the evidence considered or of the comparator used (if any) are available.

2.4 Etonogestrel 68 mg implant (as Implanon) was recommended for PBS listing at the December 1999 PBAC meeting as being "of similar safety and efficacy to medroxyprogesterone acetate".[1]

2.5 The brand Implanon NXT was listed on the PBS on 1 June 2011. In March 2012 the PBAC recommended that etonogestrel subcutaneous implant is suitable for inclusion in the list of PBS medicines for prescribing by authorised midwives.

2.6 Levonorgestrel 52 mg intra-uterine device (IUD) was recommended for listing at the September 2002 PBAC Meeting, as "providing contraception for five years compared with etonogestrel implant for three years while being at the same price. Other costs of insertion and removal do not increase the comparative costs.[2]

2.7 In July 2013 and March 2014, the PBAC considered levonorgestrel 13.5 mg IUD. The nominated comparators were levonorgestrel 52 mg IUD and etonogestrel 68 mg implant, but the PBAC considered that the 52 mg levonorgestrel IUD was the appropriate comparator because "populations using injection or sub-dermal implant are likely to differ, in terms of their preferences, from those using an intra-uterine contraceptive device" (Paragraph 6, levonorgestrel PSD, March 2014 PBAC Meeting). Levonorgestrel 13.5 mg was recommended for listing, but its TGA registration was cancelled at the sponsor's request in August 2021.[3]

2.8 In March 2019 PBAC considered levonorgestrel 19.5 mg IUD. The comparator was levonorgestrel 52 mg IUD (Paragraph 5.1, levonorgestrel PSD, March 2019 PBAC Meeting). The PBAC considered whether etonogestrel 68 mg implant should be a comparator but repeated its view that the population preferring injections and the population preferring IUD would be different (Paragraph 7.4, levonorgestrel PSD, March 2019 PBAC Meeting).

2.9 Recent considerations of combined oral contraceptives have consistently used other combined oral contraceptives (COC) as comparators (Paragraph 7.4, drospirenone with ethinylestradiol PSD, July 2024; Paragraph 5.1, estetrol with drospirenone PSD, March 2025), and in the consideration of drospirenone the comparator was other progesterone-only pills (Paragraph 5.1, Drospirenone PSD, November 2024).

2.10 In the May 2025 consideration of ethinylestradiol with etonogestrel as contraceptive vaginal ring (NuvaRing) the nominated primary comparator was depot medroxyprogesterone acetate (DMPA). However, PBAC considered that this was not appropriate, and recommended that Nuvaring should be listed on the basis of cost-minimisation against recently listed combined oral contraceptives (Paragraph 5.8, 7.2, etonogestrel with ethinylestradiol PSD, May 2025 PBAC Meeting).

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1 https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/pdf/1999-dec-pbac-outcomes-positive-recommendations.pdf, accessed 29 May 2026.

2 https://www.pbs.gov.au/info/industry/listing/elements/pbac-meetings/pbac-outcomes/pbac-recommendations-sep-2002, accessed 29 May 2026.

3 https://www.tga.gov.au/resources/cancellations-by-sponsors/jaydess-levonorgestrel-135-mg-intrauterine-drug-delivery-system-sachet-cancelled-under-section-301c-act, accessed 4 April 2026.

3 Requested listing

MEDICINAL PRODUCT medicinal product pack	Max. qty packs	Max. qty units	№.of Rpts	Available brands
etonogestrel 68mg implant, 1	1	1	0	Implanon-NXT

Source: Constructed during the evaluation.

3.1 The current AEMP for etonogestrel implant is $144.67 (DPMQ, $172.12). The submission requested an AEMP of $[redacted] (DPMQ $[redacted]) which is an increase of [redacted]%. No other changes to the listing were proposed.

4 Population and disease

4.1 Sixty-five to seventy percent of Australian women of reproductive age currently use contraception (Contraception in Australia, 2005-2018, Family Planning NSW, 2020, referred to below as CiA).[4]

4.2 About 30% of women using contraception use oral contraceptives, about 5% use implants and 5% use IUD; the use of oral contraceptives is declining slightly and that of implants and IUD is rising (Figure 3.7, CiA).

4.3 DMPA is used less often than implant or IUD, its use is declining, and it is no more likely to be used by women in remote areas than by women in regional areas (Figure 3.6, Figure 3.16, CiA).

4.4 Women in remote areas who use contraception are much more likely to use IUD or implant than oral contraceptives (Table 3.8, CiA). The submission stated that LARC uptake, particularly for etonogestrel implant, is proportionally higher in regional and remote areas and among Aboriginal and Torres Strait Islander women, accounting for approximately 40% of prescribed volume (according to data held by the sponsor). The submission stated that evidence suggests that LARCs may be more acceptable and appropriate for some of these communities compared with short-acting methods, which may be associated with access barriers, stigma or discontinuation due to adverse effects.

4.5 Most Aboriginal and Torres Strait Islander people live in major cities (41.1%) or Inner Regional areas (25.1%); 5.4% live in Remote areas and 9.1% in Very Remote areas, where they account for 30% of the population.[5] Aboriginal and Torres Strait Islander women in major cities, regional areas and remote Australia have a pattern of contraceptive use similar to that of the overall population of women in the same regions (Figure 3.25, CiA).

4.6 The population of women using implants is most similar to the population of women using IUD.

[4] https://www.fpnsw.org.au/sites/default/files/assets/Contraception-in-Australia_2005-2018_v20200716.pdf

[5] https://www.abs.gov.au/statistics/people/aboriginal-and-torres-strait-islander-peoples/census-population-and-housing-counts-aboriginal-and-torres-strait-islander-australians/latest-release accessed 4 April 2026.

5 Comparator

5.1 The submission did not specifically nominate a comparator. The submission requested that the price of etonogestrel 68 mg implant should be calculated with reference to recently PBS-listed COCs.

5.2 The place in treatment proposed by the submission for etonogestrel 68 mg implant was as a long-acting reversible contraceptive (LARC). The other contraceptives classified as LARC on the PBS are hormonal IUD. LARCs such as copper or copper/silver IUD are classified by the TGA as devices and are not eligible for PBS.

5.3 The PBAC recalled its previous consideration that LARCs should be compared with LARCs, or with injectable contraception, but not with oral contraceptives.

5.4 The Pre-PBAC response stated that oral contraceptives were a suitable price comparator for etonogestrel. The Pre-PBAC response agreed with the evaluation that users of sub-dermal implants may differ in their preferences from those using intrauterine contraceptive devices (see paragraph 2.7). However, the Pre-PBAC response did not provide evidence that supported oral contraceptives as a relevant direct comparator for etonogestrel.

5.5 Etonogestrel 68 mg implant was originally recommended for PBS-listing on the basis that its effectiveness and cost were similar to DMPA. DMPA is not classified as LARC, but the PBAC has previously suggested that women preferring an injection or implant may be a different population to women preferring an IUD, so DMPA is also a potential comparator.

5.6 The Pre-PBAC response stated that DPMA was a less relevant comparator as the use of DPMA in Australia was low and declining in the Australian population.

6 Consideration of the evidence

Sponsor hearing

6.1 There was no hearing for this item.

Consumer inputs

6.2 The PBAC noted and welcomed the input from an individual (1) via the Consumer Comments facility on the PBS website. The input noted the comparative ease of insertion for Implanon compared to an intimate gynaecological procedure required for an intrauterine device such as Mirena. However, the comments also noted the shorter effective period of Implanon compared to Mirena (currently 3 versus 8 years), as well as potential side effects for some consumers.

Claims from the submission

6.3 The submission stated that etonogestrel implant has demonstrated effectiveness of 99.95% for a three-year period compared to 93% effectiveness for OCPs when considering real-world adherence and user error. No clinical data were presented to support this claim.

6.4 The Pre-PBAC response noted that LARCs are recommended as first-line contraception for many women of reproductive age[6]. It also stated the PBAC had previously recognised the higher reported effectiveness of Implanon-NXT (99.95%) compared to contemporary COCs (93%) and IUDs (99.75%) (Yaz/Yasmin July 2024 PSD, p. 6).

6.5 The submission referred to the key priority areas of the National Women's Health Strategy 2020-2030 and the Australian Government's commitment of $124.6 million over three years from 2025–26, with ongoing funding of $44.7 million per annum from 2028–29, to improve access to LARCs. The submission stated that ensuring the continued availability of etonogestrel implant on the PBS directly contributed to Priority area 1 of the National Women's Health Strategy - Increased access to sexual and reproductive health care information, diagnosis, treatment and services. The submission stated that etonogestrel implant contributes to this priority area through facilitating equitable access to highly effective contraception and maintaining contraceptive options to empower women's choices

6.6 The submission also referred to the oral contraceptive stakeholder meeting held in October 2024.[7] The submission noted that following this meeting the PBAC recommended the listing of drospirenone, drospirenone with ethinylestradiol, and etonogestrel with ethinylestradiol contraceptive vaginal ring at a price higher than would be justified on the basis of cost-minimisation against older combined oral contraceptives. The submission noted that, in making this decision, the PBAC considered the importance of ensuring availability of a range of subsidised hormonal contraceptive options so that cost does not constitute a barrier to accessing the most clinically appropriate option at different life stages and also that newer oral contraceptives may be more appropriate in specific clinical circumstances.

6.7 The submission argued that these considerations were relevant to PBAC's consideration of the requested increase in the AEMP of etonogestrel 68 mg implant. However, the PBAC noted these considerations related to defined benefits of newer oral contraceptives for some women , such as those raised by clinicians related to anti-androgenic effects of drospirenone. The stakeholder meeting also cited experience from clinicians' that not every individual responds the same way to OCPs, and that it is highly individualised as to which contraceptive medicines people may or may not tolerate. The submission did not suggest that etonogestrel 68 mg implant had newly identified benefits that had not been taken into consideration when it was first considered by the PBAC.

6.8 The stakeholder consultation also heard that "certain contraceptives have higher manufacturing costs due to their form or raw ingredients, and that manufacturing costs are higher than when oral contraceptives currently on the PBS were first listed", and PBAC noted that this was relevant to its consideration of drospirenone with ethinylestradiol (Paragraph 12.5, drospirenone with ethinylestradiol PSD, July 2024

[6] Mason and Black 2025; Temple-Smith 2017

[7] https://www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-stakeholder-meetings/Oral-Contraceptives-Stakeholder-Meeting-October-2024-Outcome-Statement.pdf accessed 29 May 2026.

PBAC Meeting with November 2024 Addendum). No suggestion was made in the submission that there has been any change to ingredient or manufacturing costs for etonogestrel 68 mg implant.

6.9 The submission stated that the AEMP for etonogestrel implant in Australia is the lowest among OECD countries, although the exact ranking would be sensitive to the currency exchange rate applied. The AEMP requested would be higher than that in any other OECD country presented in the submission.

6.10 The key information relied on by the submission was a price comparison versus other PBS-listed contraceptives (the submission), shown in Table 1. The submission did not include IUDs in the comparison, but these have been added during the evaluation.

Table 1: Price comparison of selected contraceptives in Australia

	Contraceptive duration per pack	AEMP	Price per month
Recent COC			
Drospirenone 3 mg with ethinylestradiol 20 mcg (Yaz)	3 months	$45.45	$15.15
Drospirenone 3 mg with ethinylestradiol 30 mcg (Yasmin)	3 months	$45.45	$15.15
Drospirenone 3 mg with estetrol 14.2 mg (Nextstellis)	3 months	$45.45	$15.15
POP			
Drospirenone 4 mg (Slinda)	4 months	$60.60	$15.15
Vaginal ring			
Etonogestrel 11.7 mg with ethinylestradiol 2.7 mg (Nuvaring)	3 months	$45.45	$15.15
Injection			
Depot medroxyprogesterone acetate 150 mg (Depot-Provera)	3 months	$14.13	$4.71
Implant			
Etonogestrel 68 mg implant (Implanon-NXT)	3 years	$144.67	$4.02
Etonogestrel 68 mg implant (Implanon-NXT)	Proposed 5 years	$144.67	$2.41
IUD			
Levonorgestrel 52 mg (Mirena)	*8 years*	*$162.33*	*$1.69*
Levonorgestrel 19.5 mg (Kyleena)	*5 years*	*$144.67*	*$2.41*

Source: Table 1.3, p11 of the submission; ex-manufacturer-prices-non-efc-2026-04-01 accessed 5 April 2026.
AEMP, agreed ex-manufacturer price; COC = combined oral contraceptive; IUD = intra-uterine device; POP = progesterone only pill.
Source: PBS 2026.

6.11 The submission noted that the AEMP for etonogestrel 68 mg implant has changed since its original listing in 2001 because of statutory price reductions, and provided the data shown in

6.12 Table 2. The price requested in the current submission exceeds the historical AEMP as at 1 October 2012, when AEMP was first implemented, replacing the previous 'approved price to pharmacists' (PTP).

Table 2: Change in AEMP of etonogestrel 68 mg implant since first listing (of Implanon NXT)

Date	Reason	AEMP
1 June 2011	-	*$191.50†*
1 October 2012	-	*$178.11*
1 January 2016	-	$178.11
1 April 2016	5% 5-year anniversary cut	$169.20
1 June 2018	14.5% 15-year anniversary cut	$144.67
1 July 2022	Current AEMP	$144.67
1 April 2023	Proposed 22.22% catch-up cut. Upon request by the Sponsor, Ministerial discretion was provided to not apply the catch-up reduction	$144.67

Source: Table 1.2, p10 of the submission. Text added during evaluation is in *italics*.
AEMP = approved ex-manufacturer price.
† Ex-manufacturer price is presented as Price to Pharmacy (PTP). Prior to 2012, PTP was used in pricing agreements.

6.13 Based on the submission's proposed metric of price per month and the current TGA approved duration of use of three years, the current cost per month for etonogestrel implant is higher than other LARCs and slightly lower than that of depot medroxyprogesterone acetate.

6.14 The evaluation noted that the higher price currently paid for levonorgestrel 52 mg IUD arises from weighting of the AEMP by its additional listing for treatment of menorrhagia (Levonorgestrel PSD, March 2007 PBAC Meeting, where the comparator was hysterectomy).

6.15 The submission claimed that value erosion at the current price is commercially unsustainable and may prohibit the Sponsor from proceeding with the five-year use and other additional benefits currently under development for the Australian market. The submission stated that the proposed price is critical to maintaining the commercial viability of etonogestrel implant in Australia. The Pre-PBAC response provided the current cost of goods for Implanon-NXT. It claimed there were additional costs in supplying Implanon-NXT as a procedure-dependent medicine, including investment in clinician training, insertion and removal support, and patient education.

6.16 The submission further claimed that in the absence of etonogestrel implant, utilisation would be expected to shift towards comparatively more costly and less clinically effective contraceptive alternatives, leading to higher overall expenditure to government driven by increased medicine acquisition costs, greater health service utilisation, and a rise in unintended pregnancy–related costs. The Pre-PBAC response reiterated this claim.

6.17 The submission's reference to "other additional benefits currently under development for the Australian market" was not explained in the submission body. The Pre-PBAC

response clarified that the "additional benefits" related to the proposed extended duration of use, and a label expansion to include additional populations (immediate postpartum, immediate post-abortion and women with higher body mass index (BMI)). The Pre-PBAC response further stated that reduced removal and reinsertion procedures due to the extended duration of use would result in cost savings and reduce out-of-pocket expense. These benefits were pending TGA registration of these indications.

Clinical claim

6.18 No formal clinical claim was made.

Economic analysis

6.19 The submission did not present an economic analysis. As noted in Table 1 above, the submission calculated a proposed price based on the cost per month of newly PBS listed COC of AEMP $15.15 per month, multiplied by the currently recommended duration of use of 36 months.

Drug cost/patient/year

6.20 The current cost per patient per year of Implanon-NXT, based on 3 years duration is (DPMQ) $172.12/3 = $57.37/year. At the proposed DPMQ of $[redacted], the cost per patient per year would be $[redacted]. Other price comparisons are shown in **Error! Reference source not found.**.

Estimated PBS usage & financial implications

6.21 The submission presented a market share approach to estimate the financial impact of the proposed price adjustment. The submission presented three scenarios: (1) the financial impact of the proposed price increase assuming 3 years duration of use; (2) the financial impact assuming that the 5 year duration of use is approved by the TGA and; (3) a scenario where etonogestrel 68 mg implant is not available. The base case presented used the current price of etonogestrel implant. The key inputs used in the analyses are shown in Table 3. The direct and indirect cost offsets (see Table 4) were presented in the submission but were not used in the estimates.

Table 3: Key inputs for financial estimates

Parameter	Value	Source	Comment
Market:			
Existing Market	91349 Scripts in 2025	PBS Item 8487Q Medicare Statistics;	*Appropriate*
Existing market adjusted for possible 5 year approval	Year 1 (2027): [redacted][1] Year 2 (2028): [redacted][2] Year 3 (2029): [redacted][2] Year 4 (2030): [redacted][1] Year 5 (2031): [redacted][1] Year 6 (2032): [redacted][3]	Based on 10% sample of PBS claims. Extrapolated from 2025 market based on the assumption that 1/3 of scripts in 2025 that would be renewed in 2028 will be delayed.	*Assumes static distribution of market for implant. Highly uncertain and may be an underestimate.*
% Growth Rate	Yr 1 (2027): 1.60% Yr 2 (2028): 1.60% Yr 3 (2029): 1.60% Yr 4 (2030): 1.60% Yr 5 (2031): 1.60% Yr 6 (2032): 1.60%	ABS statistics for population growth. Extrapolation from 2025/2026 actual and projected data	*Includes assumptions about anticipated growth trend taking account of increased public funding to support use of LARCS.*
Script Equivalence	Uses 1:1		*Appropriate*
MBS Impacts	Item 14206 $100.40 (100%) Item 30062 $105.15 (100%)	MBS Item number 14206, hormone implantation by cannula, 1 Service/Script MBS Item 30062 Removal of implant 0.89 services/script	*Appropriate; used 80% fee in analysis*
Alternative contraception (oral contraception)	Item 14791L $78.96 Item 14875X $78.96 Annual cost per patient less copayments assuming 3 packs per year	Based on new COCs, using Slinda as example	*Assumes all patients using Implanon would switch to COC rather than another LARC, and that they would continue indefinitely. May therefore be an overestimate.*

Source: Tables 3.1, 3.4, 3.8, pp18, 21 and 24 of the submission. ABS=Australian Bureau of Statistics; COC=combined oral contraceptives; LARC= long-acting reversible contraceptive

The redacted values correspond to the following ranges:

[1] *90,000 to < 1,00,000*

[2] *60,000 to < 70,000*

[3] *100,000 to < 200,000*

Table 4: Direct and indirect cost offsets.

Direct costs, average per unintended pregnancy	Miscarriage (public sector)	$767	Organon and HTANALYSTS, 2022. Estimates are costs to government, not only health sector	*Data in report insufficiently detailed to allow validation of methods and assumption. Highly uncertain.*
	Miscarriage (private sector)	$172		
	Still birth	$9594		
	Abortion (public sector)	$1883		
	Abortion (private sector)	$438		
	Live birth	$30961		
Indirect costs, average per unintended pregnancy	Still birth	$4447	Organon and HTANALYSTS, 2022. Estimates quoted are cost to government and cost to employer, not health sector.	*Data in report insufficiently detailed to allow validation of methods and assumption. Highly uncertain.*
	Parenting	$5776		
	Out of home care	$1736		

Source: Table 3.10, p26 of the submission

6.22 The Pre-PBAC response stated that the assumption for the 'Existing market adjusted for possible 5 year approval' was based on sponsor analysis of PBS 10% utilisation data from 2010-2025. The Pre-PBAC response stated this data showed that [redacted]% of patients initiating Implanon-NXT received a subsequent implant.

6.23 The Pre-PBAC Response reiterated that the growth rate was based on Australian Bureau of Statistic population projection data, and did not account for increased uptake from public funding the support use of LARCs.

6.24 The results for the different scenarios are shown in Table 5.

Table 5: Estimated use and financial implications

	Year 1 (2027)	Year 2(2028)	Year 3 (2029)	Year 4 (2030)	Year 5 (2031)	Year 6 (2032)
Estimated extent of use – current 3 year duration						
Number of scripts dispensed	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][2]	[redacted][2]
Estimated financial implications – current DPMQ						
Cost to PBS/RPBS less copayments	$[redacted][3]	$[redacted][3]	$[redacted][3]	$[redacted][3]	$[redacted][3]	$[redacted][3]
Cost to MBS - insertion	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]
Cost to MBS – removal	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]
Total cost to PBS/RPBS/MBS	$[redacted][5]	$[redacted][5]	$[redacted][5]	$[redacted][6]	$[redacted][6]	$[redacted][6]
Estimated Financial implications – proposed DPMQ, 3 year use						
Cost to PBS/RPBS less copayments	$[redacted][7]	$[redacted][7]	$[redacted][7]	$[redacted][7]	$[redacted][8]	$[redacted][8]
Cost to MBS – insertion	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]
Cost to MBS – removal	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]	$[redacted][4]
Total cost to PBS/RPBS/MBS	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]	$[redacted][9]
Net financial implications – change in DPMQ only						
Net additional cost to PBS/RPBS	$[redacted][10]	$[redacted][10]	$[redacted][10]	$[redacted][10]	$[redacted][10]	$[redacted][10]
Net additional cost to MBS	0	0	0	0	0	0
Scenario - 5 year duration of use, proposed DPMQ						
Number of scripts dispensed	[redacted][1]	[redacted][11]	[redacted][11]	[redacted][1]	[redacted][1]	[redacted][2]
Cost to PBS/RPBS less copayments	$[redacted][7]	$[redacted][6]	$[redacted][10]	$[redacted][7]	$[redacted][7]	$[redacted][8]
MBS impact						
Number of insertions avoided	[redacted][12]	-[redacted][13]	-[redacted][13]	-[redacted][14]	-[redacted][14]	-[redacted][14]
Cost	$[redacted][4]	-$[redacted][15]	-$[redacted][15]	-$[redacted]	-$[redacted][15]	-$[redacted][15]
Number of removals avoided	[redacted][12]	-[redacted][13]	-[redacted][13]	-[redacted][14]	-[redacted][14]	-1[redacted][14]
Cost	$[redacted][4]	-$[redacted][15]	-$[redacted][15]	-$[redacted][15]	-$[redacted][15]	-$[redacted][15]
Net cost to MBS	$[redacted][4]	-$[redacted][15]	-$[redacted][15]	-$[redacted][15]	-$[redacted][15]	-$[redacted][15]
Net cost to PBS/RPBS/MBS	$[redacted][7]	$[redacted][6]	$[redacted][6]	$[redacted][7]	$[redacted][7]	$[redacted][8]
Scenario –IMPLANON-NXT is not available						
Number of new patients needing alternative contraception/yr	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][1]	[redacted][2]	[redacted][2]
Total patients per year	[redacted][1]	[redacted][2]	[redacted][16]	[redacted][16]	[redacted][16]	[redacted][17]
Number of packs per patient per year	[redacted][12]	[redacted][12]	[redacted][12]	[redacted][12]	[redacted][12]	[redacted][12]
Cost to PBS/RPBS less copayments	$[redacted][3]	$[redacted][6]	$[redacted][10]	$[redacted][10]	$[redacted][10]	$[redacted][10]

Source: Attachment 3 of the submission plus Tables 3.4, 3.8, pp21, 24 of the submission.

The redacted values correspond to the following ranges:

[1] *90,000 to < 100,000*
[2] *100,000 to < 200,000*
[3] *$10 million to < $20 million*
[4] *$0 to < $10 million*
[5] *$20 million to < $30 million*
[6] *$30 million to < $40 million*
[7] *$50 million to < $60 million*
[8] *$60 million to < $70 million*
[9] *$70 million to < $80 million*
[10] *$40 million to < $50 million*
[11] *60,000 to < 70,000*
[12] *< 500*

[13] *30,000 to < 40,000*
[14] *500 to < 5,000*
[15] *net cost saving*
[16] *200,000 to < 300,000*
[17] *300,000 to < 400,000*

6.25 The total cost to the PBS/RPBS of etonogestrel implant at the proposed price and 3 year duration of use was estimated to be $60 million to < $70 million in Year 6, and a total of $300 million to < $400 million over the 6 years of listing. Based on the current price with an unchanged duration of use, the total cost over 6 years would be $80 million to < $90 million. Pending TGA approval, the total estimated cost of 5 year duration of use was $300 million to < $400 million over 6 years.

6.26 The evaluation considered that the key uncertainties in the estimates were:

- the assumption of a constant growth in the market supported by the investment in LARCs
- the assumption that the distribution of use within the etonogestrel 68 mg implant market will be consistently one third repeat users
- for the scenario where etonogestrel 68 mg implant is not available on the PBS, the assumption that all users would switch to newer COCs rather than other LARCs.

6.27 The scenario where etonogestrel implant is not available only considers an increase in prescriptions for drospirenone 4 mg. It does not account for the decrease in prescriptions of etonogestrel implant or any changes to the MBS.

6.28 The impact of these uncertainties is likely an underestimate of the financial cost (allowing for the increase in proposed price) for the 5 year approval scenario, and an overestimate of the proposed cost of the scenario where etonogestrel 68 mg implant was not available.

6.29 The submission did not provide additional sensitivity analyses.

Quality Use of Medicines

6.30 The submission presented information about the sponsor's approach to clinical training and public health education with respect to use of Implanon-NXT.

Financial Management – Risk Sharing Arrangements

6.31 The submission did not propose any risk sharing arrangements.

7 PBAC Outcome

7.1 The PBAC did not recommend a price increase for etonogestrel 68 mg subcutaneous implant. The PBAC noted the requested increase in the AEMP would result in a high cost to the PBS/RPBS. The PBAC advised that the requested increase to the AEMP was not justified, based on the data provided.

7.2 The PBAC noted the submission requested a price for etonogestrel implant that was consistent with the price per month of newer combined oral contraceptives.

7.3 The PBAC noted the submission referred to the October oral contraceptive stakeholder meeting outcomes, and it argued the PBAC's subsequent pricing recommendations for drospirenone, drospirenone with ethinylestradiol, and etonogestrel with ethinylestradiol contraceptive vaginal ring should also apply to etonogestrel implant.

7.4 The PBAC recalled its recommendations for an alternative pricing model for newer oral contraceptives was based on defined benefits for some women other than contraceptive efficacy. The PBAC advised that the submission did not provide evidence that etonogestrel implant had any newly identified benefits that the PBAC had not previously considered.

7.5 The PBAC noted that no clinical data was presented comparing etonogestrel to combined oral contraceptives or against other LARCs to support the proposed price increase for etonogestrel. The PBAC considered that the clinical claims in the submission were not adequately supported by the data provided, in the context of the price increase requested.

7.6 The PBAC noted that the estimated cost to the PBS/RPBS was high and considered that the utilisation estimates for the scenario for an extended duration of use (pending approval by the TGA) to be uncertain, and likely an underestimate of the financial cost.

7.7 The PBAC noted that this submission is not eligible for an Independent Review. Independent Review is only available to submissions seeking a change to the listing criteria (such as a request for a new indication, an objectively different subtype of disease or a new treatment population).

Outcome:

Not recommended

8 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.

9 Sponsor's Comment

The sponsor had no comment.