5.20 CETRORELIX, Solution for injection 250 micrograms (as acetate) in 1 mL single use pre-filled syringe, Femvi®, SUN PHARMA ANZ PTY LTD.

1 Purpose of Submission

1.1 The Category 4 submission requested listing of a new brand and form of cetrorelix (Femvi®) solution for injection 250 microgram/mL, prefilled syringe under the same circumstances as the currently listed cetrorelix (Cetrotide®) 250 microgram powder for reconstitution injection and inert substance diluent (1 mL syringe) for use in assisted reproductive technology. The submission stated that Femvi contains the same active ingredient as the originator brand and that, at the point of injection, both products are aqueous solutions at 250 microgram/mL.

1.2 The submission proposed no change to clinical criteria and sought a restriction that aligns with Section 100 – IVF Program (Authority Required – Streamlined), on the basis of a cost-minimisation to the currently listed Cetrotide.

2 Background

Registration status

2.1 Femvi (cetrorelix acetate 250 microgram/mL, prefilled syringe) was TGA-registered on 5 March 2025 (ARTG ID 444616; Sponsor: Sun Pharma ANZ Pty Ltd).

2.2 Approved indication (exact wording; formatting adjusted for readability):

- Prevention of premature luteinisation and ovulation in patients undergoing a controlled ovarian stimulation followed by oocyte pick up and assisted reproductive techniques.
- In clinical trials cetrorelix was used with human menopausal gonadotrophin (HMG), however limited experience with recombinant FSH suggested similar efficacy.

2.3 The TGA-approved indication for Femvi is the same as the indication for Cetrotide.

Previous PBAC consideration

2.4 Femvi has not been previously considered by the PBAC, it is proposed to be listed under the same circumstances as Cetrotide. While both deliver cetrorelix 250 microgram/mL subcutaneously at the time of injection, the presentations differ:

Cetrotide is supplied as a lyophilised powder with a diluent for reconstitution, whereas Femvi is supplied as a ready-to-use prefilled syringe.

2.5 Cetrorelix (Cetrotide) has been PBS-listed since 1 December 2010 for use in ART under Section 100 – IVF (Authority Required – Streamlined) for prevention of premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation.

3 Requested listing

3.1 The submission requested the following listing and proposed no changes to the existing listing

Add new medicinal product pack as follows:

MEDICINAL PRODUCT medicinal product pack	**PBS item code**	**Max. qty packs**	**Max. qty units**	**№.of Rpts**	**Available brands**
CETRORELIX					
cetrorelix 250 microgram/mL injection, 1 mL prefilled syringe	NEW	10	10	0	Femvi
Restriction Summary *5046* / Treatment of Concept: *5046*					
	Category / Program: ☒ Section 100 – IVF Program (Code IF)				
	Prescriber type: ☒Medical Practitioners				
	Restriction type: ☒Authority Required (Streamlined) 5046				
	Indication: Assisted Reproductive Technology				
	Clinical criteria:				
	The treatment must be for prevention of premature luteinisation and ovulation.				
	AND				
	Clinical criteria:				
	Patient must be undergoing controlled ovarian stimulation				
	AND				
	Clinical criteria:				
	Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule				
	Note: No increase in the maximum number of repeats may be authorised.				

3.2 The submission requested 'a'-flagging to enable pharmacist brand substitution between Femvi and Cetrotide. Given the drug is the same active ingredient, same strength and same clinical use, with aqueous solution at the point of injection for both, 'a'-flagging appears appropriate. The Secretariat proposes inclusion of a dispensing note as an administrative advice to assist quality use of medicines due to the different presentations of the medicines as follows:

Pharmaceutical benefits that have the brand Cetrotide and pharmaceutical benefits that have the brand Femvi are equivalent for the purposes of substitution. Device/presentation differs between brands (Femvi is supplied as a prefilled syringe,

whereas Cetrotide is supplied as a powder with separate diluent for reconstitution). Prescribers and pharmacists should ensure patients receive appropriate administration advice.

3.3 The PBAC advised that substitution ('a'-flagging) under s101(4AACD) of the *National Health Act 1953* is appropriate, and that Femvi and Cetrotide should be marked as equivalent for the purposes of substitution. The PBAC advised that the dispensing note as administrative advice was appropriate.

4 Comparator

4.1 The submission nominated comparator: cetrorelix (Cetrotide), the currently PBS-listed brand for ART.

4.2 This is considered appropriate as the medicines have the same active ingredient, same strength (250 microgram/mL), subcutaneous administration, and aqueous solutions at injection (Femvi prefilled syringe vs Cetrotide powder + diluent). The submission seeks listing under the same circumstances with no change to clinical criteria.

4.3 The TGA was satisfied that Femvi "can be considered bioequivalent to CETROTIDE cetrorelix powder for injection."

4.4 Cetrotide is the only currently PBS listed brand of cetrorelix.

5 Consideration of the evidence

Sponsor hearing

5.1 There was no hearing for this item.

Consumer comments

5.2 The PBAC noted and welcomed the input from medical organisations (1) via the Consumer Comments facility on the PBS website. The PBAC noted the advice received from the Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG) providing support for increasing "availability, accessibility and affordability of medications for women and girls in Australia". RANZCOG did not provide a specific comment regarding Femvi.

Clinical claim

5.3 The submission claimed non-inferior comparative effectiveness and non-inferior comparative safety of Femvi compared with Cetrotide.

5.4 This claim was made on the basis of:

- Same active (cetrorelix), same strength (250 microgram/mL), same route (subcutaneous); both aqueous solutions at the point of injection (Femvi prefilled syringe; Cetrotide powder + diluent).

- Regulatory alignment: Femvi is TGA-registered (ARTG 444616) with the same indication wording as Cetrotide. The TGA was satisfied that Femvi "can be considered bioequivalent to CETROTIDE cetrorelix powder for injection."

5.5 The PBAC advised that the claim of non-inferior effectiveness and non-inferior safety is reasonable for the requested PBS circumstances.

Economic analysis

5.6 The submission presented a cost-minimisation analysis (CMA) vs Cetrotide, with equi-effective doses: Femvi 250 microgram SC = Cetrotide 250 microgram SC.

Pricing considerations

5.7 The submission proposed an AEMP of $29.55 which assumed application of the 25% First New Brand (FNB) statutory price reduction (SPR) to the current AEMP of Femvi.

5.8 Cetrorelix is subject to a 26.1% 15-year anniversary price reduction on 1 April 2026.

Drug cost/patient/course: $295.50

5.9 The estimated drug cost per patient per course is $295.50, based on a 10-dose course duration.

Estimated PBS usage and financial implications

5.10 The requested price was based on the AEMP of Cetrotide as currently listed in the PBS in September 2025, with an AEMP of $39.40. PBS/RPBS impact (less co-payments): With 1:1 substitution at the same price, incremental cost is nil in each year and over six years. Refer to Table 1.

5.11 The submission estimated that 500 to < 5,000scripts would be supplied for Femvi over the first six years of listing (< 500 in Year 1 to 561 in Year 6).

Table 1: Estimated use and financial implications

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed	[redacted][1]	[redacted][1]	[redacted][2]	[redacted][2]	[redacted][2]	[redacted][2]
Estimated financial implications of Femvi						
Cost to PBS/RPBS less co-payment	[redacted][3]	[redacted][3]	[redacted][3]	[redacted][3]	[redacted][3]	[redacted][3]
Estimated financial implications of Cetrotide						
Cost to PBS/RPBS less co-payment	[redacted][3]	[redacted][3]	[redacted][3]	[redacted][3]	[redacted][3]	[redacted][3]
Net financial implications						
Net cost to PBS/RPBS	[redacted][3]	[redacted][3]	[redacted][3]	[redacted][3]	[redacted][3]	[redacted][3]

Abbreviations: MBS = Medical Benefits Scheme; PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme.
Source: Table 7, p.7 and Table 8, p.8 of the submission.
The redacted values correspond to the following ranges:
[1] *< 500*
[2] *500 to < 5,000*
[3] *$0 to < $10 million*

Quality use of medicines

5.12 The two brands have different presentations but same dose via the same type of injection (subcutaneous). At administration both brands deliver cetrorelix 250 microgram/mL subcutaneously; Femvi is a ready-to-use prefilled syringe, Cetrotide is powder + diluent (reconstitution required). Fewer preparation steps are needed for Femvi.

5.13 Femvi prefilled syringe includes an automatic safety system; clinicians and pharmacists should counsel patients on correct activation and safe disposal. Pharmacists should also confirm differences in preparation technique when substituting brands.

5.14 The PBAC advised that 'a'-flagging was appropriate and considered that the inclusion of the dispensing note as administrative advice in paragraph 3.2 was appropriate to support QUM.

6 PBAC Outcome

6.1 The PBAC recommended the listing of cetrorelix, solution for injection 250 micrograms (as acetate) in 1 mL single use pre-filled syringe, on the basis that it should be available only under the same special arrangements as the currently listed cetrorelix (Cetrotide®) 250 microgram powder for reconstitution injection and inert substance diluent (1 mL syringe) for use in assisted reproductive technology to prevent premature luteinisation and ovulation in patients undergoing controlled ovarian stimulation. The PBAC recommended the special arrangements of listing be under the Section 100 (IVF) schedule, Authority Required (Streamlined). This recommendation was on the basis of a cost-minimisation with the equi-effective dose of Femvi 250 microgram SC = Cetrotide 250 microgram SC. The PBAC also recommended that the two forms of cetrorelix be considered interchangeable ("a-flagged") with an administrative note added to the listing regarding the different presentation of the medicines (PFS compared to powder for reconstitution and inert substance diluent).

6.2 The PBAC advised that the restriction should be the same as that for the currently listed brand of cetrorelix. The PBAC advised that an administrative note on dispensing be added to the listings of both brands of cetrorelix regarding the different presentations of the SC injection, and that prescribers and dispensers should be aware of this if substituting one item for the other.

6.3 The PBAC advised the currently listed cetrorelix (Cetrotide) was an appropriate comparator for cetrorelix (Femvi).

6.4 The PBAC advised that the claim of non-inferior effectiveness and non-inferior safety is reasonable for the requested PBS listing.

6.5 The PBAC advised that the utilisation estimates of nil financial impact were reasonable, where Femvi would be listed under the same price and circumstances as Cetrotide.

6.6 The PBAC advised, under Section 101 (4AACD) of the *National Health Act*, that cetrorelix solution for injection 250 micrograms (as acetate) in 1 mL single use pre-filled syringe and cetrorelix 250 microgram powder for reconstitution injection and inert substance diluent (1 mL syringe) should be considered equivalent for the purposes of substitution (i.e., 'a' flagged in the Schedule with a NOTE stating PBS of one form and PBS of another form are equivalent for the purposes of substitution).

6.7 The PBAC noted the flow-on restriction changes to the currently listed cetrorelix (Cetrotide) to include the administrative advice for dispensing note regarding the different forms when substituting.

6.8 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because cetrorelix (Femvi) is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, compared to cetrorelix (Cetrotide), or not expected to address a high and urgent unmet clinical need given the presence of an alternative therapy, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.

6.9 The PBAC noted that as this submission was recommended, it is not eligible for an Independent Review.

Outcome:
Recommended

7 Recommended listing

7.1 Add new item and administrative advice (shown in *italics*) as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
CETRORELIX					
cetrorelix 250 microgram/mL injection, 1 mL prefilled syringe	*NEW*	*10*	*10*	*0*	*Femvi*
cetrorelix 250 microgram injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack	9599F	10	10	0	Cetrotide
Restriction Summary *5046* / Treatment of Concept: *5046*					
	Category / Program: ☒ Section 100 – IVF Program (Code IF)				
	Prescriber type: ☒Medical Practitioners				
	Restriction type: ☒Authority Required (Streamlined) [5046]				
	Indication: Assisted Reproductive Technology				
	Clinical criteria:				
	The treatment must be for prevention of premature luteinisation and ovulation.				
	AND				
	Clinical criteria:				
	Patient must be undergoing controlled ovarian stimulation				
	AND				
	Clinical criteria:				
	Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule				
	Administrative Advice: No increase in the maximum number of repeats may be authorised.				
	Administrative Advice: *Pharmaceutical benefits that have the brand Cetrotide and pharmaceutical benefits that have the brand Femvi are equivalent for the purposes of substitution. Device/presentation differs between brands (Femvi is supplied as a prefilled syringe, whereas Cetrotide is supplied as a powder with separate diluent for reconstitution). Prescribers and pharmacists should ensure patients receive appropriate administration advice.*				

These restrictions may be subject to further review. Should there be any changes made to the restriction the sponsor will be informed.

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

The sponsor had no comment.