

6.12 FOLLITROPIN ALFA WITH LUTROPIN ALFA, Injection 900 I.U. - 450 I.U. in 1.44 mL multi-dose cartridge, Pergoveris[®], MERCK HEALTHCARE PTY LTD

1 Purpose of Submission

- 1.1 The Category 3 submission requested the following changes to the existing listing for follitropin alfa (r-hFSH) 900 IU with lutropin alfa (r-hLH) 450 IU in a 1.44 mL multi-dose cartridge (Pergoveris[®]) for the stimulation of follicular development:
- An increase in the maximum quantity from two to five per prescription.
 - Removal of the requirement for dose titration of individual follicle-stimulating hormone (FSH) and luteinising hormone (LH) therapies before using the fixed-dose combination medicine, Pergoveris, in the clinical criteria.

2 Background

- 2.1 Pergoveris 900 IU/450 IU solution for injection (equivalent to 65.52 microgram of r-hFSH and 18 microgram of r-hLH) is currently listed on the PBS as a Section 100 (IVF Program) Authority Required (STREAMLINED) listing for the stimulation of follicular development.
- 2.2 Pergoveris (150 IU/75 IU powder for injection) was first recommended by the PBAC at its March 2015 meeting for the same indication. The PBAC considered an additional clinical criterion, requiring patients to have been titrated to the FSH and LH doses in the combination product after at least one cycle of treatment, as the best way to ensure that the use of Pergoveris was restricted to patients for whom treatment with the combination product was considered appropriate (paragraphs 7.1 and 7.3, Pergoveris, Public Summary Document (PSD), March 2015 PBAC Meeting).
- 2.3 At its March 2016 meeting, the PBAC recommended amending the maximum quantity from seven to 14 vials to be consistent with the maximum quantities available for other medicines used for ovarian stimulation, which could provide for at least 11 to 15 days of treatment. (paragraphs 6.1 and 6.2, Pergoveris, PSD, March 2016 PBAC Meeting).
- 2.4 At its November 2018 meeting, the PBAC recommended a new form of Pergoveris (900 IU/450 IU solution for injection in a multi-dose pen device) with a maximum quantity of two, which would provide sufficient treatment for six daily doses over 12 days (paragraph 5.3, Pergoveris, PSD, November 2018 PBAC Meeting).

- 2.5 Under the current PBS listing, prescribers are able to request authority approval for an increased quantity to provide five or more units to patients by telephoning Services Australia or applying electronically through Online PBS Authorities (OPA) system.

3 Requested listing

- 3.1 The submission requested the following changes to the existing listing of Pergoveris (PBS item code: 11667C).

Amend existing listing as follows:

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
FOLLITROPIN ALFA + LUTROPIN ALFA					
follitropin alfa 900 units (65.52 microgram)/1.44 mL + lutropin alfa 450 units/1.44 mL injection, 1.44 mL pen device	11667C	≥ 5	≥ 5	0	Pergoveris
Restriction Summary / Treatment of Concept:					
	Category / Program: <input checked="" type="checkbox"/> Section 100 – IVF/GIFT Treatment				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required: Streamlined				
	Administrative Advice: No increase in the maximum number of repeats may be authorised.				
	Indication: Stimulation of follicular development				
	Clinical criteria:				
	Patient must have severe LH deficiency				
	AND				
	Clinical criteria:				
	Patient must be considered appropriate for treatment with the combination product after titration of FSH and LH after at least one cycle of treatment				
	AND				
	Clinical criteria:				
	Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule				

- 3.2 The submission requested no other changes to the existing listing for Pergoveris.
- 3.3 PBS 10% sample data (Table 4) showed that approximately 80% of treatment cycles required 1 or 2 scripts (2 to 4 pens) with the current maximum quantity to complete a treatment cycle and a small proportion of treatment cycles (less than 20%) needed more than 4 pens. Prescribers can request authority approval for an increased quantity for patients from Services Australia when necessary, and for patients requiring more than 4 pens of Pergoveris, prescribers could still request to increase the maximum quantity. The evaluation proposed an increase to the maximum

quantity from two pens to four, rather than the requested five, to minimise the potential for increased wastage with a higher maximum quantity.

- 3.4 The pre-PBAC response reiterated that increasing the maximum quantity to five pens would cover the dosage needs of most patients and align with the maximum quantity for follitropin alfa therapy (e.g., Gonal-f® Pen). The pre-PBAC response also argued that clinicians would prescribe only the necessary quantity, therefore, the requested increase to 5 pens is expected to reduce financial and administrative burdens for patients and clinicians without increasing wastage.

4 Consideration of the evidence

- 4.1 The submission stated that the proposed amendments were based on clinical evidence and feedback from clinicians, including advice from nine fertility clinicians in Australia. These amendments aim to allow the supply of more than two Pergoveris pens per prescription and remove the titration requirement with r-hFSH and r-hLH therapies prior to the use of Pergoveris. The submission claimed that these changes would simplify treatment, reduce patient burden, improve adherence, and potentially enhance treatment outcomes.

Sponsor hearing

- 4.2 There was no hearing for this item.

Consumer comments

- 4.3 The PBAC noted and welcomed the input from health care professionals (3) via the Consumer Comments facility on the PBS website. The comments described the benefits of a combination treatment with follitropin alfa and lutropin alfa (Pergoveris) for patients who had a poor response to follitropin alfa therapy alone, including reduced injections and simplified treatment. The comments also highlighted that the increased maximum quantity for Pergoveris, to align with other r-hFSH medicines would reduce financial and treatment burdens, allowing most patients to complete treatment with a single script.

Increase in maximum quantity

- 4.4 The submission stated that the maximum quantity of two provides a 12-day treatment at the recommended starting dose of 150 IU r-hFSH/75 IU r-hLH once daily, but most patients with severe LH deficiency would require a higher daily dose than 150 IU r-hFSH/75 IU r-hLH to achieve optimal results due to increased ovarian resistance and the need for more potent follicular stimulation.
- 4.5 The submission presented an analysis of the PBS 10% sample data for Pergoveris from 2018 to 2023 in Table 1. The results showed that, during this period, 36.1% of treatment cycles used one Pergoveris script to complete a treatment cycle, 45.3% used two scripts (3-4 pens), 14.8% used three scripts (5-6 pens), and 3.7% used four

or more scripts. Approximately 60% to 68% of cycles required more than one script to complete a treatment cycle.

- 4.6 The submission stated that this analysis supported the requested increase in the maximum quantity from two to five, which aligns with the advice provided by clinicians and the current listings of other r-hFSH 900 IU medicines (e.g., Gonal-f Pen and Ovaleap®) with a maximum quantity of five for Assisted Reproductive Technology treatment cycles.

Table 1: Distribution of ovarian stimulation cycles across different numbers of Pergoveris prescriptions required

Year	1 script	2 scripts	3 scripts	4+ scripts ^a	Total
Number of treatment cycles by number of Pergoveris scripts utilised per cycle					
2018	450	670	20	10	1,150
2019	940	1,550	380	90	2,960
2020	1,660	1,780	540	150	4,130
2021	1,850	2,460	590	180	5,080
2022	1,860	2,500	910	230	5,500
2023	2,580	2,760	1,400	300	7,040
2018 to 2023	9,340	11,720	3,840	960	25,860
Proportion of treatment cycles by number of Pergoveris scripts utilised per cycle					
2018	39.1%	58.3%	1.7%	0.9%	100.0%
2019	31.8%	52.4%	12.8%	3.0%	100.0%
2020	40.2%	43.1%	13.1%	3.6%	100.0%
2021	36.4%	48.4%	11.6%	3.5%	100.0%
2022	33.8%	45.5%	16.5%	4.2%	100.0%
2023	36.6%	39.2%	19.9%	4.3%	100.0%
2018 to 2023	36.1%	45.3%	14.8%	3.7%	100.0%

^a Treatment cycles requiring 4 or more scripts

Source: Tables 2-1 and 2-2 of the main submission, based on the PBS 10% sample data for Pergoveris from 2018 to 2023.

Note: Pergoveris scripts dispensed within a four-week period were considered as a single treatment cycle.

Removal of the titration requirement

- 4.7 The March 2014 and March 2015 submissions for Pergoveris provided clinical studies (Burgués, 2001¹ and Bühler and Naether, 2011²) and a survey of fertility clinicians in Australia as clinical evidence to support that the 2:1 dose ratio of r-hFSH to r-hLH contained in Pergoveris is clinically appropriate for most women with LH deficiency. When recommending Pergoveris in March 2015, the PBAC considered that the

¹ S Burgués; Spanish Collaborative Group on Female Hypogonadotrophic Hypogonadism. The effectiveness and safety of recombinant human LH to support follicular development induced by recombinant human FSH in WHO group I anovulation: evidence from a multicentre study in Spain, *Hum Reprod* 2001; 16(12):2525-32.

² K Bühler, O Naether A 2:1 formulation of follitropin alfa and lutropin alfa in routine clinical practice: a large, multicentre, observational study, *Gynecol Endocrinol* 2011; 27(9):650-4.

requirement for prior titration of individual r-hFSH and r-hLH doses in the clinical criteria would ensure that the use of Pergoveris was restricted to patients for whom treatment with the combination medicine was considered appropriate.

4.8 The submission requested the removal of the titration requirement for Pergoveris based on the following reasons:

- The currently listed Pergoveris multi-dose (900 IU/450 IU) pen device allows dose adjustment, delivering 12.5 IU and 6.25 IU increments of r-hFSH and r-hLH, respectively, based on patient response. This reduces the need for prior titration with individual r-hFSH and r-hLH therapies, which was necessary for the form (150 IU/75 IU powder for injection in a vial) recommended at the March 2015 PBAC meeting.
- In clinical practice, the 2:1 dose ratio of r-hFSH to r-hLH provided by Pergoveris is considered appropriate and prescribed by clinicians for most patients with severe LH deficiency.
- The titration requirement in the restriction for Pergoveris increases the complexity of patients' treatment regimens and may present a higher risk of medication errors and adverse events during the dose adjustment period. Additionally, it doubles the number of prescriptions, patient co-payments, and injections for patients.
- Clinicians are familiar with Pergoveris and can identify the need for titration based on their clinical experience with patients in their second or subsequent treatment cycles. Further, clinicians would avoid prescribing Pergoveris in patients for whom the 2:1 dose ratio is inappropriate.

Economic analysis

4.9 The submission requested no change to the approved ex-manufacturer price (AEMP) of \$887.56 for Pergoveris (900 IU/450 IU).

Estimated PBS usage and financial implications

4.10 The submission adopted a market share approach to estimate the financial implications of increasing the maximum quantity and removing the clinical criterion to allow patients to be prescribed Pergoveris without prior use of separate r-hFSH and r-hLH therapies.

4.11 The submission used PBS prescription service data for Pergoveris and Luveris (see Table 2 and Table 3) and the PBS 10% sample data for the distribution of ovarian stimulation cycles across different numbers of Pergoveris scripts dispensed from 2018 to 2023 (Table 4). The submission assumed that scripts for Pergoveris dispensed within a four-week period were considered a single treatment cycle. That is, any additional scripts for Pergoveris required by patients within four-weeks of the initial script were accounted for in the same cycle.

Table 2: Prescriptions for Pergoveris processed by patient category

Actual usage (except 2024)	PBS				RPBS	Total
	General - Ordinary	General - Safety Net	Concessional - Ordinary	Concessional - Safety Net	RPBS - Ordinary	
2019	4,920	7	240	3	0	5,170
2020	7,583	4	359	5	0	7,951
2021	9,519	36	425	4	2	9,986
2022	12,030	55	472	13	3	12,573
2023	16,636	8	442	19	7	17,112
2024 estimated	17,091	8	454	20	7	17,580

Source: Utilisation and Cost Model workbook; 'Template'

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme

Table 3: Prescriptions for Lutropin alfa (Luveris) processed by patient category

Actual usage (except 2024)	PBS				RPBS	Total
	General - Ordinary	General - Safety Net	Concessional - Ordinary	Concessional - Safety Net	RPBS - Ordinary	
2019	6,746	3	244	0	2	6,995
2020	6,138	6	293	5	0	6,442
2021	7,104	9	316	16	0	7,445
2022	7,581	16	258	8	3	7,866
2023	8,178	7	237	29	7	8,458
2024 estimated	8,457	7	245	30	7	8,746

Source: Utilisation and Cost Model workbook; 'Template'

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme

Table 4: PBS 10% sample data for the distribution of Pergoveris prescriptions from 2018 to 2023

Distribution	1 script	2 scripts	3 scripts	4+ scripts	Total
Treatment cycle ^a	36.1%	45.3%	14.8%	3.7%	100.0%
Prescriptions ^b	19.4%	48.7%	23.9%	8.0%	100.0%

Source: Utilisation and Cost Model workbook; 'Template'

^a Proportion of treatment cycles by number of prescriptions utilised per cycle

^b Proportion of prescriptions utilised by patients requiring each number of prescriptions per cycle

Note: the same proportion of prescriptions was applied to Luveris

Abbreviations: PBS = Pharmaceutical Benefits Scheme

4.12 A change in the number of Pergoveris scripts resulting from the increased maximum quantity of five was estimated using the following methodology:

- Estimated the total number of Pergoveris scripts dispensed over the six-year period, assuming the current maximum quantity of two remains unchanged.
- Divided the estimated overall usage of Pergoveris into categories based on the number of prescriptions required per cycle: 1, 2, 3, or 4+, using the PBS 10% sample data between 2018 and 2023. For simplicity, cycles in the 4+ category were assumed to use 4 scripts.
- Converted the number of scripts with the current maximum quantity (2 pens) to the number of scripts that would be dispensed with the revised maximum quantity (5 pens) for 2, 3 and 4+ script cycles, assuming no change in the number of scripts for 1 script cycle. It was assumed that treatment cycles requiring 3 and

4 scripts with the maximum quantity of two would instead need 2 scripts with the maximum quantity of five.

4.13 The estimated number of scripts for Pergoveris with each maximum quantity is outlined in Table 5 and Table 6.

Table 5: Estimated utilisation of Pergoveris with the maximum quantity of two

	1 script ^a	2 scripts ^b	3 scripts ^c	4+ scripts ^d	Total ^e
Year 1	1	2	1	1	3
Year 2	1	3	2	1	4
Year 3	1	3	2	1	4
Year 4	1	3	2	1	4
Year 5	2	3	2	1	4
Year 6	2	3	2	1	4

Source: compiled by the Secretariat using Utilisation and Cost Model workbook; 'Template', 'Summary tables'

a, b, c, and d: Each estimated script, based on the number of scripts required to complete a treatment cycle, was calculated by multiplying the total estimated Pergoveris scripts^e by the proportion of prescriptions utilised by patients requiring each number of prescriptions per cycle in Table 4. For example, in 2026, the estimated scripts of 10,000 to < 20,000 requiring 2 scripts to complete a one cycle were calculated as 20,000 to < 30,000 x 48.7%.

The redacted values correspond to the following ranges:

1 500 to < 5,000

2 5,000 to < 10,000

3 10,000 to < 20,000

4 20,000 to < 30,000

Table 6: Estimated utilisation of Pergoveris with the maximum quantity of five

	1 script ^a	2 scripts ^b	3 scripts ^c	4+ scripts ^d	Total
Year 1	1	1	1	1	2
Year 2	1	3	1	1	2
Year 3	1	3	1	1	2
Year 4	1	3	1	1	2
Year 5	3	3	1	1	2
Year 6	3	3	1	1	2

Source: compiled by the Secretariat using Utilisation and Cost Model workbook; 'Template', Table 5, 'Summary tables'

The redacted values correspond to the following ranges:

1 500 to < 5,000

2 10,000 to < 20,000

3 5,000 to < 10,000

4.14 The financial model incorporated the increased number of Pergoveris scripts resulting from substituting each prescription for r-hFSH and r-hLH in patients who do not need dose titration, as the 2:1 dose ratio of r-hFSH to r-hLH is adequate after the deletion of the titration requirement.

- Estimated the utilisation of Luveteris over the same period (see Table 7), which was the basis for estimating the conversion to Pergoveris. This approach was adopted as the concomitant use of r-hLH with r-hFSH is required, but r-hFSH can be used alone otherwise.
- Divided the estimated overall usage of Luveteris into categories based on the number of Luveteris scripts required per cycle: 1, 2, 3, or 4+, using the distribution

of Pergoveris scripts per treatment cycle from the PBS 10% sample data. For simplicity, the submission assumed that cycles in the 4+ category used 4 scripts.

- Converted Luveris scripts to Pergoveris scripts for each category, assuming 12 vials of Luveris dispensed equal to 2 pens of Pergoveris. Based on clinical advice, the submission estimated 50% of Luveris scripts would be substituted by Pergoveris in Year 1, increasing to 75% from Year 2 onward (see Table 8).

Table 7: Estimated utilisation of Luveris with the dose titration required prior to the use of Pergoveris

	1 script	2 scripts	3 scripts	4+ scripts	Total
Year 1	1	1	1	1	2
Year 2	1	1	1	1	2
Year 3	1	1	1	1	3
Year 4	1	2	1	1	3
Year 5	1	2	1	1	3
Year 6	1	2	1	1	3

Source: compiled by the Secretariat using Utilisation and Cost Model workbook; 'Template' and Table 4

The redacted values correspond to the following ranges:

1 500 to < 5,000

2 5,000 to < 10,000

3 10,000 to < 20,000

Table 8: Increased prescriptions for Pergoveris due to the deletion of dose titration requirement

	1 script	2 scripts	3 scripts	4+ scripts	Total
Year 1	1	1	1	1	1
Year 2	1	1	1	1	1
Year 3	1	1	1	1	1
Year 4	1	1	1	1	1
Year 5	1	1	1	1	2
Year 6	1	1	1	1	2

Source: compiled by the Secretariat using Utilisation and Cost Model workbook; 'Template', Table 5, 'Summary tables'

The redacted values correspond to the following ranges:

1 500 to < 5,000

2 5,000 to < 10,000

4.15 The submission stated that the removal of the titration requirement allows suitable patients to use Pergoveris from the start, substituting for separate r-hFSH and r-hLH therapies. The financial model estimated the impact on the use of r-hFSH by calculating substituted scripts for follitropin alfa 900 IU (Gonal-f Pen), based on a 2:1 dose ratio with lutropin alfa (Luveris), considering that the current maximum quantity of follitropin alfa 900 IU per script is 5 pens. For instance, a 12-day follicular stimulation treatment using 300 IU of r-hFSH and 150 IU of r-hLH once daily would typically require 2 scripts of lutropin alfa (24 vials) and 1 script of follitropin alfa (4 pens). This would be replaced by 1 script of Pergoveris (4 pens), providing equivalent doses of both medications.

4.16 The submission did not account for the financial impact of increasing the maximum quantity from two to five in the 1 script cycle, assuming no change in the number of scripts for 1 script cycle, and that clinicians would only prescribe the quantity required

(i.e., 2 pens for 1 script cycle regardless of the maximum quantity allowed on the PBS). However, it is uncertain whether prescribers would prescribe the default maximum quantity or only the quantity required for their patients. Given that the total cost of 1 script cycle would differ significantly between dispensing 2 and 5 Pergoveris pens, and that 1 script cycle makes up about 19% of total Pergoveris scripts (see Table 4), the estimated financial impact presented in the submission would likely be inaccurate if prescribers default to the maximum quantity allowed.

- 4.17 Refer to Table 9, which presents the estimated extent of use and the net financial implications to the PBS/RPBS. The financial impact to Services Australia will be determined by that agency as part of the post PBAC process.
- 4.18 The submission estimated that the net financial implications of the requested changes to the existing listing for Pergoveris over six years would be a net cost saving to the PBS/RPBS. However, it is difficult to justify whether there would be cost savings to the PBS/RPBS or the extent of such savings due to uncertainties around the assumptions outlined in paragraph 4.16. If these assumptions are inappropriate, it could potentially result in higher costs and increased wastage.

Table 9: Utilisation and financial impact from the requested listing changes for Pergoveris

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Estimated extent of use						
Number of scripts dispensed for Pergoveris^a						
No. of scripts with the max qty of 2	-█ ¹	-█ ¹	-█ ¹	-█ ²	-█ ²	-█ ²
No. of scripts with the max qty of 5	█ ³	█ ³	█ ¹	█ ¹	█ ¹	█ ¹
Number of scripts impacted by the deletion of the titration requirement						
Increased scripts for Pergoveris	█ ⁴	█ ⁴	█ ⁴	█ ⁴	█ ³	█ ³
Substituted scripts for follitropin alfa 900 IU pen	-█ ⁴	-█ ⁴	-█ ⁴	-█ ³	-█ ³	-█ ³
Substituted scripts for lutropin alfa 75 IU vial	-█ ⁴	-█ ³	-█ ³	-█ ³	-█ ³	-█ ³
Estimated financial implications of Pergoveris						
Cost to PBS/RPBS less co-payment	█ ⁵	█ ⁶	█ ⁶	█ ⁶	█ ⁶	█ ⁶
Estimated financial implications of follitropin alfa 900 IU pen and lutropin alfa 75 IU vial						
Cost to PBS/RPBS less co-payment (follitropin alfa)	█ ⁷	█ ⁷	█ ⁷	█ ⁷	█ ⁷	█ ⁷
Cost to PBS/RPBS less co-payment (lutropin alfa)	█ ⁷	█ ⁷	█ ⁷	█ ⁷	█ ⁷	█ ⁷
Net cost to PBS/RPBS less co-payment	█ ⁷	█ ⁷	█ ⁷	█ ⁷	█ ⁷	█ ⁷
Net financial implications						
Net cost to PBS/RPBS	█ ⁷	█ ⁷	█ ⁷	█ ⁷	█ ⁷	█ ⁷

Source: Table 4-1, 4-2 and 4-3 of the submission

Abbreviations: PBS = Pharmaceutical Benefits Scheme; RPBS = Repatriation Pharmaceutical Benefits Scheme; max qty = maximum quantity

^a The number of scripts for Pergoveris dispensed per year did not include the estimated number of scripts requiring 1 script to complete a treatment cycle.

The redacted values correspond to the following ranges:

1 10,000 to < 20,000

2 20,000 to < 30,000

3 5,000 to < 10,000

4 500 to < 5,000

5 \$0 to < \$10 million

6 \$10 million to < \$20 million

7 net cost saving

5 PBAC Outcome

5.1 The PBAC recommended the increase to the current maximum quantity for follitropin alfa (r-hFSH) 900 IU with lutropin alfa (r-hLH) 450 IU in a 1.44 mL multi-dose cartridge (Pergoveris) for the stimulation of follicular development from two to four per prescription. The PBAC also recommended the removal of the requirement for dose titration of individual follicle-stimulating hormone (FSH) and luteinising hormone (LH) prior to treatment with Pergoveris in the clinical criterion.

5.2 The PBAC noted that the current maximum quantity of two provides a 12-day treatment at the recommended starting dose of 150 IU r-hFSH/75 IU r-hLH once daily, while most patients with severe LH deficiency require a higher daily dose to achieve the desired therapeutic outcome. The PBAC considered an increase in the maximum quantity to 4 pens reasonable, based on PBS 10% sample data showing that

approximately 80% of treatment cycles required 1 or 2 scripts with the current maximum quantity of two to complete a treatment cycle. The PBAC did not agree to the proposed maximum quantity of 5 pens, noting a small proportion of treatment cycles (less than 20%) needed more than 4 pens, and prescribers can request authority approval for an increased quantity for patients from Services Australia when necessary. The recommended maximum quantity of 4 reduces administrative burden while minimising the potential for increased wastage.

- 5.3 The PBAC noted the change in the form of Pergoveris from a powder for injection (150 IU/75 IU) vial to a multi-dose (900 IU/450 IU) pen device, which allows dose adjustment since its recommendation for listing in March 2015, and considered it appropriate to remove the requirement for prior titration with individual r-hFSH and r-hLH therapies in the restriction for Pergoveris, as the 2:1 dose ratio of r-hFSH to r-hLH is commonly accepted in current practice.
- 5.4 The PBAC considered that the estimated financial implications from the proposed amendments to the Pergoveris restriction were reasonable.
- 5.5 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

6 Recommended listing

6.1 Amend existing listing as follows:

Additions are in *italics* and deletions are in ~~strikethrough~~

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
FOLLITROPIN ALFA + LUTROPIN ALFA					
follitropin alfa 900 units (65.52 microgram)/1.44 mL + lutropin alfa 450 units/1.44 mL injection, 1.44 mL pen device	11667C	2 4	2 4	0	Pergoveris
Amend Restriction Summary / Treatment of Concept:					
	Category / Program: <input checked="" type="checkbox"/> Section 100 – IVF/GIFT Treatment (Code IF)				
	Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners				
	Restriction type: <input checked="" type="checkbox"/> Authority Required: Streamlined				
	Administrative Advice: No increase in the maximum number of repeats may be authorised.				
	Indication: Stimulation of follicular development				
	Clinical criteria: Patient must have severe LH deficiency				

	AND
	Clinical criteria:
	Patient must be considered appropriate for treatment with the combination product after titration of FSH and LH after at least one cycle of treatment
	AND
	Clinical criteria:
	Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule

This restriction may be subject to further review. Should there be any changes made to the restriction the Sponsor will be informed.

7 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.

8 Sponsor’s Comment

Merck welcomes PBAC’s recommendation to increase the maximum quantity of PERGOVERIS® from two to four per prescription and remove the requirement for dose titration of individual FSH and LH prior to treatment with Pergoveris in the clinical criterion for the stimulation of follicular development. The recommended changes should help to reduce the treatment and cost burden for clinicians and patients and improve patient experience. We thank the many clinicians who advocated for better access for their patients.