

**14.03 FOLLITROPIN ALFA WITH LUTROPIN ALFA  
Injection, 900 I.U., 450 I.U. in 1.44 mL multi-dose  
cartridge,  
Pergoveris<sup>®</sup>,  
Merck Serono Australia Pty Ltd**

**1 Purpose of Application**

- 1.1 The minor submission requested a Section 100 (IVF program) Authority Required (STREAMLINED) listing of a new form of follitropin alfa with lutropin alfa (Pergoveris<sup>®</sup>) for stimulation of follicular development, at the same per unit price as the currently listed formulation.

**2 Requested Listing:**

- 2.1 The minor submission sought the same listing as the currently listed follitropin alfa (*rch*) 150 units/lutropin alfa (*rch*) 75 units, powder for injection with diluent vial.
- 2.2 The new formulation is a multi-dose solution for injection cartridge in a pre-assembled pen. The requested listing is for the 900 IU/450 IU strength only.

Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Dispensed Price for Max. Qty	Proprietary Manufacturer	Name and Manufacturer
FOLLITROPIN ALFA + LUTROPIN ALFA follitropin alfa 900 units + lutropin alfa 450 units in 1.44 mL cartridge	2	0	\$1881.37	Pergoveris <sup>®</sup>	Merck Serono Australia Pty Ltd

<b>Category / Program</b>	Section 100 – IVF
<b>Prescriber type:</b>	<input checked="" type="checkbox"/> Medical Practitioners
<b>Condition:</b>	Stimulation of follicular development
<b>PBS Indication:</b>	Stimulation of follicular development
<b>Restriction Level / Method:</b>	<input checked="" type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	Patient must have severe LH deficiency, AND 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 Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

### **3 Background**

- 3.1 Follitropin alfa with lutropin alfa is TGA registered for the stimulation of follicular development in women with severe luteinising hormone (LH) and follicle-stimulating hormone (FSH) deficiency. The new liquid formulation was approved by the TGA in June 2018.
- 3.2 Pergoveris® has been listed on the PBS under the Section 100 IVF program for stimulation of follicular development since 1 September 2015 as a powder for injection that requires reconstitution.
- 3.3 A minor submission required an increase to the maximum quantities of follitropin alfa with lutropin alfa was submitted to the Committee for the March 2016 PBAC consideration from 7 to 14 vials.
- 3.4 At the March 2016 meeting, the PBAC noted that the maximum PBS quantity for other Section IVF drugs, including follitropin alfa, follitropin beta and human menopausal gonadotrophin, provide for at least 11 to 15 days of treatment. The PBAC considered increasing the maximum quantity to 14 vials would be clinically appropriate and would provide for a sufficient duration of treatment (Public Summary Document, March 2016 PBAC Meeting).

### **4 Pricing considerations**

#### ***Drug cost/patient/course: \$ 1881.37***

- 4.1 The proposed Approved Ex-Manufacturer Price (AEMP) is \$917.04, which is equivalent to 6 doses of the current follitropin alfa with lutropin alfa (powder for injection 150 I.U. – 75 I.U. with solvent). This results in a DPMQ of \$1881.37.

#### ***Estimated PBS usage & financial implications***

- 4.2 The minor submission proposed the new formulation will simplify the administration of follitropin alfa and may potentially decrease the wastage and the cost to the PBS. The PBAC noted the cost saving was not justified in the submission.

### **5 PBAC Outcome**

- 5.1 The PBAC recommended the Section 100 (IVF program) Authority Required (STREAMLINED) listing of a new form of follitropin alfa with lutropin alfa (Pergoveris®) for stimulation of follicular development, at the same cost per dose as the currently listed formulation.
- 5.2 The PBAC noted that the new form of follitropin alfa with lutropin alfa can be administered without the need for reconstitution at no additional cost to the PBS.

- 5.3 The PBAC noted that one cartridge is sufficient for six daily doses and proposed the maximum quantity of two would provide sufficient treatment for 12 days, which was clinically appropriate.
- 5.4 The PBAC noted the current listing provides a maximum quantity of 14, sufficient for 14 days of treatment.
- 5.5 The PBAC noted that this submission was not eligible for an Independent Review, as it received a positive recommendation.

**Outcome:**

Recommended

## 6 Recommended listing

### 6.1 Add new item

Name, Restriction, Manner of administration and form	Max. Qty	No.of Rpts	Proprietary Name and Manufacturer
FOLLITROPIN ALFA + LUTROPIN ALFA follitropin alfa 900 units + lutropin alfa 450 units in 1.44 mL cartridge	2	0	Pergoveris® Merck Serono Australia Pty Ltd

<b>Category / Program</b>	Section 100 – IVF
<b>Prescriber type:</b>	<input checked="" type="checkbox"/> Medical Practitioners
<b>Condition:</b>	Stimulation of follicular development
<b>PBS Indication:</b>	Stimulation of follicular development
<b>Restriction Level / Method:</b>	<input checked="" type="checkbox"/> Streamlined
<b>Clinical criteria:</b>	Patient must have severe LH deficiency, AND 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 Patient must be receiving medical treatment as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule.

## 7 Context for Decision

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

## **8 Sponsor's Comment**

Merck is pleased for patients that this new formulation of Pergoveris which simplifies administration will soon be available on the PBS.