

5.18 HUMAN MENOPAUSAL GONADOTROPHIN, Injection 600 I.U. in 0.96 mL pre-filled multi-dose pen, Injection 1200 I.U. in 1.92 mL pre-filled multi-dose pen, Menopur[®], Ferring Pharmaceuticals Pty Limited

1 Purpose of Submission

- 1.1 The Category 4 submission requested a Section 100 (IVF program) Authority Required (STREAMLINED) listing of 600 IU/0.96 mL (Menopur[®] 600 Pen) and 1200 IU/1.92 mL (Menopur[®] 1200 Pen) pre-filled multi-dose pen forms of human menopausal gonadotrophin (hereafter referred as HMG) under the same circumstances as the current powder for injection (PFI) 600 IU (Menopur[®] 600 PFI) and 1200 IU (Menopur[®] 1200 PFI) forms.

2 Background

- 2.1 The PFI forms of HMG (Menopur[®] 600 and Menopur[®] 1200) are currently listed on the PBS as Section 100 (IVF program) Authority Required (STREAMLINED) listings for assisted reproductive technology.

Registration status

- 2.2 Menopur[®] 600 Pen and Menopur[®] 1200 Pen were registered in the Australian Register of Therapeutic Goods (ARTG) by the Therapeutic Goods Administration (TGA) on 24 January 2022 for the treatment of infertility in the following clinical situations:
- Anovulatory infertility, including polycystic ovarian disease (PCOD), in women who have been unresponsive to treatment with clomiphene citrate.
 - Controlled ovarian hyperstimulation to induce the development of multiple follicles for assisted reproductive technologies (ART) (e.g., in vitro fertilisation/embryo transfer (IVF/ET), gamete intra-fallopian transfer (GIFT) and intracytoplasmic sperm injection (ICSI)).

3 Requested listing

- 3.1 The submission requested the following new listing. Suggested additions are in italics and deletions are in strikethrough.

Add new medicinal product pack as follows:

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
HUMAN MENOPAUSAL GONADOTROPHIN					
human menopausal gonadotrophin 600 units/0.96 mL injection, 0.96 mL pen device	NEW	3	3	0	Menopur
human menopausal gonadotrophin 600 units injection [1 vial] (&) inert substance diluent [1 mL syringe], 1 pack	2036E	3	3	0	Menopur 600
Category / Program: Section 100 – IVF Program					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [5027]					
Indication: Assisted Reproductive Technology					
Clinical criteria:					
Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule					

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	№.of Rpts	Available brands
HUMAN MENOPAUSAL GONADOTROPHIN					
human menopausal gonadotrophin 1200 units/1.92 mL injection, 1.92 mL pen device	NEW	4	4	0	Menopur
human menopausal gonadotrophin 1200 units injection [1 vial] (&) inert substance diluent [2 x 1 mL syringes], 1 pack	2038G	4	4	0	Menopur 1200
Category / Program: Section 100 – IVF Program					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [5027]					
Indication: Assisted Reproductive Technology					
Clinical criteria:					
Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule					

- 3.2 The sponsor requested amendment to the forms of the existing listings, as opposed to creating new listings. The sponsor stated that the pre-filled pen forms were intended to replace the existing PFI forms. The submission was evaluated as a request for the new forms to list alongside the current forms. A separate request to delist the current forms was considered at the July 2022 PBAC meeting.
- 3.3 The PBAC recommended that, under Section 101(4AACD) of the *National Health Act 1953*, HMG PFI and HMG Pen 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).

4 Comparator

- 4.1 The submission did not nominate a comparator but did perform a cost-minimisation analysis against the existing PFI forms.
- 4.2 The TGA considered the HMG PFI and HMG pre-filled pen forms to be bioequivalent. The PBAC considered that the existing PFI forms are appropriate comparators.

For more detail on PBAC’s view, see section 6 PBAC outcome.

5 Consideration of the evidence

Sponsor hearing

- 5.1 There was no hearing for this item.

Consumer comments

- 5.2 The PBAC noted that no consumer comments were received for this item.

Pricing consideration

- 5.3 The sponsor proposed the approved ex-manufacturer prices (AEMPs) for Menopur 600 Pen and Menopur 1200 Pen be consistent with the AEMPs for Menopur 600 PFI and Menopur 1200 PFI (\$252.31 and \$504.62 respectively at the time of submission).
- 5.4 The submission requested listing the pre-filled pen forms on a cost-minimisation basis to the PFI forms at a 1:1 unit equivalence. The PBAC advised this was appropriate.

Estimated PBS utilisation and financial implications

- 5.5 The submission expected the new pre-filled pen forms to substitute directly with the existing PFI forms. As a result, the requested listing of the pre-filled pen forms would have negligible financial impact. The PBAC considered this was reasonable.

For more detail on PBAC’s view, see section 6 PBAC outcome.

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of 600 I.U and 1200 I.U pre-filled multi-dose pen forms of human menopausal gonadotrophin (HMG) on the basis that it should be available under the Section 100 (In Vitro Fertilisation (IVF) Program) as Authority Required (STREAMLINED) benefits for Assisted Reproductive Technology.
- 6.2 The PBAC’s recommendation for listing was based on, among other matters, its assessment that the cost-effectiveness for pen forms would be acceptable if it was cost-minimised against powder for injection (PFI) forms.
- 6.3 The PBAC advised that the equi-effective doses are 1.0 I.U. HMG pen forms to 1.0 I.U. HMG PFI forms.

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- 6.4 The PBAC advised, under Section 101 (4AACD) of the *National Health Act 1953*, that HMG Pen forms and HMG PFI forms of equivalent strength 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).
- 6.5 The PBAC noted that the new pen forms are expected to substitute directly with the existing PFI forms, and listing would therefore not result in any additional cost to Government.
- 6.6 The PBAC concurrently considered a delisting request for the HMG PFI forms at its July 2022 meeting and noted the delist would not result in an unmet clinical need.
- 6.7 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because HMG Pen forms are not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over HMG PFI forms, 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.
- 6.8 The PBAC noted that this submission is not eligible for an Independent Review as it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

- 7.1 Add new medicinal product packs (600 units and 1200 units pen devices) as follows (where the existing syringe packs and new pen devices are concurrently listed on the PBS):

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MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
HUMAN MENOPAUSAL GONADOTROPHIN					
human menopausal gonadotrophin 600 units/0.96 mL injection, 0.96 mL pen device	NEW	3	3	0	Menopur
human menopausal gonadotrophin 600 units injection [1 vial] (& inert substance diluent [1 mL syringe], 1 pack	2036E	3	3	0	Menopur 600
Restriction Summary 5027 / Treatment of Concept: 5027					
Category / Program: Section 100 – IVF Program					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [5027]					
Indication: Assisted Reproductive Technology					
Clinical criteria:					
Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule					
Administrative Advice: <i>Pharmaceutical benefits that have the form human menopausal gonadotrophin 600 units powder for injection and pharmaceutical benefits that have the form human menopausal gonadotrophin 600 units pre-filled multi-dose pen are equivalent for the purposes of substitution.</i>					

MEDICINAL PRODUCT medicinal product pack	PBS item code	Max. qty packs	Max. qty units	No. of Rpts	Available brands
HUMAN MENOPAUSAL GONADOTROPHIN					
human menopausal gonadotrophin 1200 units/1.92 mL injection, 1.92 mL pen device	NEW	4	4	0	Menopur
human menopausal gonadotrophin 1200 units injection [1 vial] (& inert substance diluent [2 x 1 mL syringes], 1 pack	2038G	4	4	0	Menopur 1200
Restriction Summary 5027 / Treatment of Concept: 5027					
Category / Program: Section 100 – IVF Program					
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners					
Restriction type: <input checked="" type="checkbox"/> Authority Required (Streamlined) [5027]					
Indication: Assisted Reproductive Technology					
Clinical criteria:					
Patient must be receiving medical services as described in items 13200, 13201, 13202 or 13203 of the Medicare Benefits Schedule					
Administrative Advice: <i>Pharmaceutical benefits that have the form human menopausal gonadotrophin 1200 units powder for injection and pharmaceutical benefits that have the form human menopausal gonadotrophin 1200 units pre-filled multi-dose pen are equivalent for the purposes of substitution.</i>					

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

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

Ferring welcomes the PBAC decision to recommend the PBS listing of MENOPUR (human menopausal gonadotrophin) Injection 600 I.U. in 0.96 mL pre-filled multi-dose pen and Injection 1200 I.U. in 1.92 mL pre-filled multi dose pen.