

5.14 CHORIONIC GONADOTROPHIN

Injection set containing 3 vials powder for injection 1,500 units and 3 vials diluent 1 mL,

Injection set containing 1 vial powder for injection 5,000 units and 1 vial diluent 1 mL,

Pregnyl[®], Merck Sharp & Dohme (Australia) Pty Ltd

1 Purpose of Application

- 1.1 The minor submission requested the listing of a new powder for injection vial form of chorionic gonadotrophin with the same restriction as the current PBS listed ampoule form of chorionic gonadotrophin.

2 Requested listing

- 2.1 The submission requested listings for the same indications as the existing listings for chorionic gonadotrophin (item codes 1581F, 6178E, 6181H):
- Restricted Benefit listing for the treatment of anovulatory infertility, infertility, combined deficiency of human growth hormone and gonadotrophins and hypogonadism or delayed puberty; and
 - Section 100 (In-Vitro Fertilisation) Authority Required (STREAMLINED) listing for Assisted Reproductive Technology.

For more detail on PBAC's view, see section 5 "PBAC outcome"

3 Background

- 3.1 Chorionic gonadotrophin is currently TGA registered for the following indications:

In the male:

- Hypogonadotrophic hypogonadism;
- Delayed puberty associated with insufficient gonadotrophic pituitary function;
- Cryptorchism, not due to an anatomic obstruction; and
- Sterility, in selected cases of deficient spermatogenesis.

In the female:

- Sterility due to the absence of follicle-ripening or ovulation.

- 3.2 Chorionic gonadotrophin is currently listed on the PBS as ampoules containing powder for injection corresponding to 1500 IU and 5000 IU. It is currently listed under the Section 100 (IVF) Program for assisted reproductive technology and as a restricted benefit for the treatment of anovulatory infertility, infertility, combined deficient of human growth hormone and gonadotrophins and hypogonadism or delayed puberty.

- 3.3 The minor submission stated that the currently listed ampoule form of chorionic gonadotrophin would be not be manufactured in the future and would then be delisted from the PBS. The sponsor anticipated that both the ampoule and vial forms of chorionic gonadotrophin would be available on the PBS for a period of time to manage the transition to the vial form. Although not a matter for the committee, the PBAC noted advice from the Department that the listing of another bioequivalent form of chorionic gonadotrophin would trigger a 16% statutory price reduction under section 99ACB of the *National Health Act 1953*.

For more detail on PBAC's view, see section 5 "PBAC outcome"

4 Consideration of the evidence

Sponsor hearing

- 4.1 There was no hearing for this item as it was a minor submission.

Consumer comments

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

Estimated PBS usage & financial implications

- 4.3 The minor submission stated that there would be no additional financial impact to the government as the proposed listing would directly substitute for the ampoule form of chorionic gonadotrophin currently listed on the PBS.

For more detail on PBAC's view, see section 5 "PBAC outcome"

5 PBAC Outcome

- 5.1 The PBAC recommended the listing of chorionic gonadotrophin vials containing powder for injection corresponding to 1500 IU and 5000 IU under the same conditions as the currently PBS-listed chorionic gonadotrophin ampoules.
- 5.2 The PBAC noted that there would be no financial impact to the PBS as a result of the listing as the new form would be listed at the same price as the currently listed form of chorionic gonadotrophin. The PBAC noted advice from the Department that listing of the new form would trigger a 16% statutory price reduction.
- 5.3 Consistent with the existing arrangements for the currently listed form of chorionic gonadotrophin, the PBAC advised that chorionic gonadotrophin was not suitable for prescribing by nurse practitioners.
- 5.4 The PBAC advised that the Early Supply Rule should not apply as it does not apply to the listings for the currently listed form of chorionic gonadotrophin.

- 5.5 The PBAC advised that the vial forms of chorionic gonadotrophin and ampoule forms of chorionic gonadotrophin should be considered equivalent for the purposes of substitution.
- 5.6 The PBAC noted that this submission is not eligible for Independent Review as it is for a new form of a currently listed drug.

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	
HUMAN CHORIONIC GONADOTROPHIN				
human chorionic gonadotrophin 1500 units injection [3 vials] (& inert substance diluent [3 x 1 mL vials], 1 pack	1	0	Pregnyl	Merck Sharpe & Dohme (Australia) Pty Ltd
human chorionic gonadotrophin 5000 units injection [1 vial] (& inert substance diluent [1 mL vial], 1 pack	2	0		

Category / Program	Section 100 – IVF
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Assisted Reproductive Technology
PBS Indication:	Assisted Reproductive Technology
Restriction Level / Method:	<input type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input checked="" type="checkbox"/> Streamlined
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 chorionic gonadotrophin ampoule and chorionic gonadotrophin vial are equivalent for the purposes of substitution.</i>

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Name, Restriction, Manner of administration and form	Max. Qty	No. of Rpts	Proprietary Name and Manufacturer	
HUMAN CHORIONIC GONADOTROPHIN				
human chorionic gonadotrophin 1500 units 1 injection [3 vials] (&) inert substance diluent [3 x 1 mL vials], 1 pack	1	5	Pregnyl	Merck Sharpe & Dohme (Australia) Pty Ltd

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Anovulatory infertility
PBS Indication:	Anovulatory infertility
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required - Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Administrative Advice	<p>Except in cases of hypopituitarism or primary amenorrhoea, the patient should have been adequately treated with clomifene citrate and/or gonadorelin and failed to have conceived.</p> <p>Women who have had apparent ovulation induced by other agents and have failed to conceive should have laparoscopic evidence that there is no other impediment to conception.</p> <p>Oligomenorrhoea should have been present for at least twelve months or amenorrhoea for at least six months prior to treatment.</p> <p>Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment.</p> <p><i>Pharmaceutical benefits that have the form chorionic gonadotrophin ampoule and chorionic gonadotrophin vial are equivalent for the purposes of substitution.</i></p>

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Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Infertility
PBS Indication:	Infertility
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Clinical criteria:	The condition must be due to hypogonadotrophic hypogonadism.
Population criteria:	Patient must be male.
Administrative Advice	Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment. <i>Pharmaceutical benefits that have the form chorionic gonadotrophin ampoule and chorionic gonadotrophin vial are equivalent for the purposes of substitution.</i>

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Infertility
PBS Indication:	Infertility
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Clinical criteria:	The condition must be associated with isolated luteinising hormone deficiency.
Population criteria:	Patient must be male.
Administrative Advice	Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment. <i>Pharmaceutical benefits that have the form chorionic gonadotrophin ampoule and chorionic gonadotrophin vial are equivalent for the purposes of substitution.</i>

Public Summary Document – March 2017 PBAC Meeting

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Combined deficiency of human growth hormone and gonadotrophins
PBS Indication:	Combined deficiency of human growth hormone and gonadotrophins
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Clinical criteria:	Patient must be one in whom the absence of secondary sexual characteristics indicates a lag in maturation.
Population criteria:	Patient must be male.
Administrative Advice	Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment. <i>Pharmaceutical benefits that have the form chorionic gonadotrophin ampoule and chorionic gonadotrophin vial are equivalent for the purposes of substitution.</i>

Category / Program	GENERAL – General Schedule (Code GE)
Prescriber type:	<input type="checkbox"/> Dental <input checked="" type="checkbox"/> Medical Practitioners <input type="checkbox"/> Nurse practitioners <input type="checkbox"/> Optometrists <input type="checkbox"/> Midwives
Condition:	Hypogonadism or delayed puberty
PBS Indication:	Hypogonadism or delayed puberty
Restriction Level / Method:	<input checked="" type="checkbox"/> Restricted benefit <input type="checkbox"/> Authority Required - In Writing <input type="checkbox"/> Authority Required - Telephone <input type="checkbox"/> Authority Required – Emergency <input type="checkbox"/> Authority Required - Electronic <input type="checkbox"/> Streamlined
Clinical criteria:	Patient must show clinical evidence of the condition, AND The treatment must not extend beyond 6 months.
Population criteria:	Patient must be male, AND Patient must be aged 16 years or older.
Administrative Advice	Patients with hyperprolactinaemia should have had appropriate surgical or medical treatment prior to treatment. <i>Pharmaceutical benefits that have the form chorionic gonadotrophin ampoule and chorionic gonadotrophin vial are equivalent for the purposes of substitution.</i>

- 6.2 Flow-on changes to the Administrative Advice of the current chorionic gonadotrophin Restricted Benefit listings for Infertility, Combined deficiency of human growth hormone and gonadotrophins, and Hypogonadism or delayed puberty will be required to ensure that only the relevant Administrative Advice appears for each of these restrictions. The content of wording and the restrictions are unchanged. Additionally, the Administrative Advice “Pharmaceutical benefits that have the form chorionic gonadotrophin ampoule and chorionic gonadotrophin vial are equivalent for the purposes of substitution” is required to be added to all existing restrictions for chorionic gonadotrophin.

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

The sponsor had no comment.