5.20 SOMATROPIN
0.4 mg (1.2 IU) with diluent in single use syringe, Genotropin® MiniQuick, Pfizer Australia Pty Ltd.

1 Purpose of Application

1.1 The minor submission requested the listing of lower strength of somatropin (Genotropin MiniQuick 0.4 mg (1.2 IU) injection) in the Section 100 (Growth Hormone Programme) on the PBS. The currently listed strengths are 1.8 IU (600 micrograms) and 2.4 IU (800 micrograms).

2 Requested listing

2.1 The submission requested the same listing conditions as the currently listed strengths of somatropin (Genotropin MiniQuick) 1.8 international units (600 microgram) injection (PBS item numbers - 9628R for Initial treatment, 10456H for continuing treatment and continuing treatment as reclassified patient, 10477K for recommencement and recommencement as reclassified patient).

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

3 Background

3.1 Genotropin MiniQuick was listed on the Australian register of Therapeutic Goods (ARTG) on 3 November 2000. This strength was registered on 15 October 2015.

3.2 Human growth hormone has, for many years, been available under various arrangements on the PBS under Section 100 of the *National Health Act*. In August 2002, the Genotropin MiniQuick 1.8 IU (600 micrograms) powder for injection was first listed on the PBS.

3.3 From 1 September 2015, the process by which prescribers receive approval to prescribe growth hormone was aligned with other authority-required PBS subsidised medicines.

3.4 Genotropin MiniQuick (all strengths) are TGA registered for:

- treatment of short stature due to decreased or failed secretion of pituitary growth hormone
- treatment of adults with severe growth hormone deficiency as diagnosed in the insulin tolerance test for growth hormone deficiency and defined by peak growth hormone concentrations of less than 2.5 nanogram/mL.
- growth disturbances associated with gonadal dysgenesis (Turner's syndrome).
- improvement of body composition and treatment of short stature associated with Prader-Willi syndrome (PWS) in paediatric patients.

- treatment of growth disturbance in children with chronic renal insufficiency whose height is on or less than twenty-fifth percentile and whose growth velocity is on or less than twenty-fifth percentile for bone age. Chronic renal insufficiency is defined as glomerular filtration rate of less than 50 mL/min/1.73m^2.

3.5 Genotropin MiniQuick 0.4 mg (1.2IU) has not been previously considered by the PBAC.

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.

Economic analysis

4.3 The requested ex-manufacturer price of $[redacted] for 0.4 mg (1.2 IU) is consistent with current strengths of somatropin, and results in a DPMQ of $[redacted].

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

Estimated PBS usage & financial implications

4.4 The submission states that the net PBS expenditure with listing of Genotropin MiniQuick 0.4 mg is expected to be less than $10 million per year for the next five years. Genotropin MiniQuick 0.4 mg utilisation is expected to be offset by a reduction in the use of Genotropin MiniQuick 0.6 mg by 30% (in smaller children).

4.5 Further information was provided in the pre-PBAC response.

Table 1: Net cost to the PBS of listing Genotropin MiniQuick 0.4 mg

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6
Forecasted PBS prescriptions						
Genotropin MiniQuick 0.4 mg	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Reduction in use of Genotropin MiniQuick 0.6 mg (30%)	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
Forecasted PBS cost of Genotropin MiniQuick 0.4 mg	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]
Less reduction in cost of Genotropin MiniQuick 0.6 mg	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]
Forecasted Net PBS cost	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]	$[redacted]

The redacted table shows the estimated number of patients was less than 10,000 per year, and the net cost to the PBS would be less than $10 million per year.

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

5 PBAC outcome

5.1 The PBAC recommended listing of the 0.4 mg strength of somatropin under the same circumstances to be consistent with the currently listed strengths of somatropin.

5.2 The PBAC noted that the submission claimed that Genotropin MiniQuick 0.4 mg would substitute for use of Genotropin MiniQuick 0.6 mg, but small increase in cost to Government was expected. The PBAC considered the justification of assumptions of prescription numbers and reasons for the increase cost to Government were not clear in the submission. The PBAC considered that the listing should only proceed if the cost to Government was neutral.

5.3 The PBAC noted that somatropin should be exempt from the Early Supply Rule as it currently does not apply to Section 100 (Growth Hormone Programme) listings.

5.4 The PBAC recommended that somatropin should not be treated as interchangeable on an individual patient basis with any other drug or medicinal formulation.

5.5 The PBAC advised that somatropin should not be available for prescribing by nurse practitioners, in line with current listings of somatropin.

Outcome:
Recommended

6 Recommended listing

6.1 Add new items as per current listings for PBS items: 9628R for Initial treatment, 10456H for continuing treatment and continuing treatment as reclassified patient, 10477K for recommencement and recommencement as reclassified patient.

Name, Restriction, Manner of administration and form	Max. Qty	№.of Rpts	Proprietary Name and Manufacturer	
GENOTROPIN MINIQUICK 1.2 IU (400 microgram) injection [7 x 400 microgram syringes] & inert substance diluent [7 x 0.25 mL syringes], 1 pack	1	7	Genotropin MiniQuick	Pfizer Australia

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

Pfizer welcomes PBAC's recommendation to list Genotropin® MiniQuick 0.4 mg (1.2 IU) which will make it easier to treat smaller children.

Listing will result in a cost-saving to the PBS due to decreased use of other more expensive somatropin products