

6.01 SOMATROPIN,

Solution for injection 6 mg (18 i.u.) in 1.03 mL cartridge (with preservative),

Solution for injection 12 mg (36 i.u.) in 1.5 mL cartridge (with preservative),

Saizen[®],

Merck Healthcare Pty Ltd

1 Purpose of Submission

- 1.1 The Category 3 submission sought to extend the Pharmaceutical Benefits Scheme (PBS) listing of somatropin solution for injection 6 mg (18 i.u.) in 1.03 mL and 12 mg (36 i.u.) in 1.5 mL (Saizen[®]) to include the treatment of severe late onset growth hormone deficiency (GHD).

2 Background

- 2.1 Saizen 6 mg, 12 mg and 20 mg are currently listed on the PBS as Authority Required (in writing only via post/HPOS upload) listings under the Section 100 Growth Hormone Programme for the treatment of:
- short stature and slow growth
 - short stature associated with biochemical growth hormone deficiency
 - growth retardation secondary to an intracranial lesion, or cranial irradiation
 - risk of hypoglycaemia secondary to growth hormone deficiency in neonates/infants
 - biochemical growth hormone deficiency and precocious puberty
 - hypothalamic-pituitary disease secondary to a structural lesion, with hypothalamic obesity driven growth
 - short stature associated with Turner syndrome
 - short stature due to short stature homeobox (SHOX) gene disorders
 - short stature associated with chronic renal insufficiency.
- 2.2 The submission stated that the sponsor had been advised by the clinical community that there was a high and urgent clinical need for an additional somatropin product on the PBS. This is due to the fact that one brand of somatropin PBS-listed for severe late onset GHD, Norditropin FlexPro[®], is experiencing a worldwide supply shortage, and another PBS-listed brand, NutropinAq[®], will be discontinued in Australia next

year. The submission stated that the sponsor was uncertain whether the only remaining somatropin product currently PBS-listed for late onset GHD, Genotropin GoQuick®, would experience similar supply shortages in the near future due to the increased demand.


- 2.3 This submission sought to extend the PBS-listing of Saizen 6 mg and 12 mg to include this indication.
- 2.4 The submission noted that the sponsor has been advised by clinicians that somatropin solution for injection 20 mg (60 i.u.) in 2.5 mL cartridge (with preservative) (Saizen) will not be used in adult patients. The submission therefore did not seek to extend the PBS-listing of this strength of Saizen to include adult indications.

Registration status

- 2.5 Somatropin solution for injection 6 mg and 12 mg (Saizen) was Therapeutic Goods Administration (TGA) registered on 22 August 2011 for:
- treatment of growth failure in children due to human GHD
 - treatment of growth failure in girls with gonadal dysgenesis (Turner syndrome), confirmed by chromosomal analysis
 - replacement therapy in adults with pronounced GHD as diagnosed in two different dynamic tests for GHD and defined by peak GH concentrations of less than 2.5 nanogram/mL. Adults must also fulfil the following criteria:
 - Childhood onset: Patients who were diagnosed as growth hormone deficient during childhood, must be retested and their GHD confirmed before replacement therapy with Saizen is started
 - Adult onset: Patients must have GHD as a result of hypothalamic or pituitary disease and at least one other hormone deficiency diagnosed (except for prolactin) and adequate replacement therapy instituted, before replacement therapy using growth hormone may begin
 - treatment of growth disturbance (growth retardation) in pre-pubertal children due to chronic renal insufficiency.

Previous PBAC consideration

Committee-In-Confidence information

2.6 

End Committee-In-Confidence information

- 2.7 At its July 2011 meeting, the PBAC did not recommend the PBS-listing of Genotropin® (somatropin 5 mg and 12 mg, injection in 1 mL cartridge), Genotropin GoQuick (somatropin 5 mg and 12 mg, powder for injection with diluent in pre-filled pen) and

Genotropin MiniQuick® (somatropin 0.6 mg – 2 mg, injection with diluent in single use syringe) for the treatment of adults with severe GHD, on the basis of uncertain clinical benefit and highly uncertain cost-effectiveness.

- 2.8 At its November 2016 meeting, the PBAC deferred making a decision on whether to list somatropin on the PBS for the treatment of adults with severe GHD and substantially impaired quality of life at baseline. The PBAC considered that although there was a place for this drug in the treatment of adults with severe GHD, the clinical benefit in terms of quality of life was uncertain and the magnitude was likely overestimated. The PBAC therefore considered that the cost-effectiveness of somatropin for this indication was uncertain.
- 2.9 At its July 2017 meeting, the PBAC again considered, and recommended, the PBS-listing of somatropin for the treatment of adults with severe GHD, and substantially impaired quality of life at baseline, on the basis that it should be available only under special arrangements under Section 100 (Growth Hormone Programme). The PBAC was satisfied that somatropin provides, for some patients, a significant improvement in efficacy over standard care (paragraph 7.1, somatropin Public Summary Document (PSD), July 2017 PBAC meeting). The submission was made by two professional organisations (Endocrine Society of Australia (ESA) and Australian Paediatric Endocrine Group (APEG)).
- 2.10 In making its recommendation, the PBAC recalled its view that a reduction in drug cost would likely improve the cost-effectiveness of somatropin in this setting, that the high uncertainty in quantifying the clinical benefit of somatropin treatment would be mitigated, and that the cost-effectiveness of somatropin in this setting would be acceptable at a lower incremental cost effectiveness ratio (paragraph 7.9, somatropin PSD, July 2017 PBAC meeting).
- 2.11 The PBAC noted there were five sponsors of forms of PBS-listed somatropin with TGA registration for the treatment of adults with severe GHD, and that the PBAC recommendation would only apply to these products (paragraph 7.5, somatropin PSD, July 2017 PBAC meeting).
- 2.12 Following this recommendation, Ipsen Pty Ltd listed Genotropin GoQuick for this indication on 1 December 2018, followed by Pfizer Australia listing NutropinAq (1 April 2019) and Novo Nordisk Pharmaceuticals Pty. Limited listing Norditropin FlexPro (1 February 2020).
- 2.13 In July 2019 the PBAC ratified changes to the PBS eligibility restrictions for adult use somatropin which will provide that childhood onset GHD patients with congenital, genetic or structural causes who have previously received PBS-subsidised therapy as children are no longer required to provide provocation tests to meet the eligibility criteria for adult use somatropin (paragraph 2.3, somatropin PSD, August 2019 PBAC meeting).

- 2.14 In July 2019 the PBAC also ratified that childhood onset GHD patients who have previously received non-PBS therapy as children will be required to demonstrate the same level of evidence as adult onset GHD patients (paragraph 2.4, somatropin PSD, August 2019 PBAC meeting).
- 2.15 At its March 2019 meeting the PBAC recommended that the Quality of Life Assessment of GHD in adults was to be removed due to accessibility issues. This change was implemented 1 September 2019 (paragraph 2.5, somatropin PSD, August 2019 PBAC meeting).
- 2.16 At its August 2019 meeting the PBAC ratified amendments to the adult-use somatropin restrictions for childhood onset GHD patients with a congenital, genetic or structural cause to commence from when this cohort reaches skeletal maturity rather than the chronological age of 18 years (paragraph 5.1, somatropin PSD, August 2019 PBAC meeting).
- 2.17 In line with processes for reviewing and remaking positive PBAC listing recommendations that have not been accepted by applicants, the PBAC rescinded its July 2017 recommendation at its July 2021 meeting, with support from the organisations who made the original submission. This recommendation was made publicly available on the PBS website (www.pbs.gov.au/industry/listing/elements/pbac-meetings/pbac-outcomes/2021-07/july-2021-pbac-web-outcomes-07-2021.pdf). The ESA and the APEG were advised of this consideration as they provided the original submission, however individual sponsors of the relevant products were not contacted directly. The sponsor of Saizen, Merck Healthcare Pty Ltd (Merck) stated they were unaware that this recommendation had been rescinded.

3 Requested listing

- 3.1 The Product Information for Saizen recommends the following dose for the treatment of GHD in adults:
- ‘At the start of Saizen therapy, low doses of 0.15 – 0.3 mg are recommended, given as a daily subcutaneous injection. The dose should be titrated carefully guided by IGF-1 age-adjusted normal values and on the basis of clinical effect and adverse events. The recommended final Saizen dose seldom exceeds 1.0 mg/day. In general, the lowest efficacious dose should be administered. With women showing an increasing IGF-1 sensitivity over time, dose adjustment may be required for women, especially for those on oral estrogen replacement. In older or overweight patients, lower doses may be necessary.’
- 3.2 The submission requested Saizen 6 mg and 12 mg be listed under the same circumstances as the somatropin products currently PBS-listed for severe late onset GHD (somatropin powder for injection 5 mg (15 i.u.) with diluent and 12 mg (36 i.u.) with diluent (Genotropin GoQuick), somatropin solution for injection 5 mg (15 i.u.) in

1.5 mL (Norditropin FlexPro) and somatropin solution for injection 10 mg (30 i.u.) in 2 mL (NutropinAq)).

4 Comparator

- 4.1 The somatropin submission considered by the PBAC in July 2017 nominated standard care as the main comparator. Now that alternative somatropin products are currently PBS-listed for the treatment of severe late onset GHD, somatropin powder for injection 5 mg (15 i.u.) with diluent and 12 mg (36 i.u.) with diluent (Genotropin GoQuick), somatropin solution for injection 5 mg (15 i.u.) in 1.5 mL (Norditropin FlexPro), and somatropin solution for injection 10 mg (30 i.u.) in 2 mL (NutropinAq) would be appropriate comparators.
- 4.2 The PBAC considered that the claim of non-inferior comparative effectiveness and safety with other somatropin products PBS-listed for the treatment of severe late onset GHD was reasonable.

5 Consideration of the evidence

- 5.1 The submission stated that despite the July 2017 recommendation being rescinded, it considered that the clinical basis for PBS listing somatropin for the treatment of adults with severe GHD remained relevant, particularly when uncertainty in clinical benefit could partly be addressed with a reduced price for this indication (paragraph 7.2, somatropin PSD, July 2017 PBAC meeting). The submission stated that the evidence that was presented and considered in July 2017 remained relevant and applicable to this consideration.

Sponsor hearing

- 5.2 There was no hearing for this item.

Consumer comments

- 5.3 The PBAC recalled that no consumer comments were received for this item at its July 2017 meeting and that at its November 2016 consideration of somatropin for adults with GHD it received substantial input from individuals (68), health care professionals (2) and organisations (2) via the Consumer Comments facility on the PBS website. Due to the nature of the clinical need for this product given the shortage, no consumer comments were sought to expedite consideration.

Economic analysis

- 5.4 The submission noted that, since the July 2017 recommendation and listing of somatropin products for adult patients with severe GHD, the approved ex-manufacturer price (AEMP) of somatropin products has decreased by 24.79% due to a catch-up statutory price reduction on 1 April 2023.

- 5.5 The submission proposed an AEMP for Saizen 6 mg and 12 mg to match those of Norditropin FlexPro, NutropinAq and Genotropin GoQuick on a per milligram basis, that would apply to both paediatric and adult indications. The submission stated this was a 3.1% reduction in the current AEMP of Saizen 6 mg and 12 mg (see Table 1).

Table 1: Proposed Saizen (somatropin) prices if PBS-listed for adult patients with severe GHD

Saizen product	Currently		Proposed		Price change
	AEMP	Price per mg	AEMP	Price per mg	
Solution for injection 6 mg (18 i.u.) in 1.03 mL cartridge (with preservative)	\$187.63 ^a	\$31.27	\$181.81	\$30.30	-3.10%
Solution for injection 12 mg (36 i.u.) in 1.5 mL cartridge (with preservative)	\$375.27	\$31.27	\$363.62	\$30.30	-3.10%

Source: Table 2 of the submission, p.3.

AEMP: approved ex-manufacturer price; GHD: growth hormone deficiency; i.u.: international units; PBS: Pharmaceutical Benefits Scheme

^aThe submission stated the current AEMP for Saizen 6 mg was \$167.83, however as at August 2023 the AEMP for Saizen 6 mg is \$187.63.

- 5.6 As a Category 3 submission, the economic analysis has not been independently evaluated.

Drug cost/patient/year: \$5,513.87 for females and \$3,798.45 for males

- 5.7 The July 2017 submission used a mean dose per day of 0.45 mg for females, and 0.31 mg for males to estimate the annual treatment cost (paragraph 6.20, somatropin PSD, July 2017 PBAC meeting). Using the same mean doses, and a mean DPMQ of \$33.57 per milligram of somatropin, the estimated drug cost/patient per year/course would be \$5,513.87 for females and \$3,798.45 for males, based on an ongoing treatment duration. It was noted that the mean DPMQ of \$33.57 assumed a 50:50 split between the two strengths whereas the financial workbook provided by the submission assumed a 55:45 split of 6 mg : 12 mg in year 1 and 57:43 split in year 6.

Estimated PBS usage and financial implications

- 5.8 The requested price was based on the AEMP of somatropin products listed on the PBS in August 2023 for severe late onset GHD (Genotropin GoQuick 5 mg and 12 mg, NutropinAq 10 mg and Norditropin FlexPro 5 mg), equivalent to \$30.30 per milligram of somatropin.
- 5.9 Table 2 which presents the estimated extent of use, cost of Saizen 6 mg and 12 mg to the PBS/RPBS, 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.
- 5.10 The submission stated that the estimated net financial impact to the PBS/RPBS for the listing of Saizen 6 mg and 12 mg is a net cost saving over six years (Year 1 and year 6 respectively: \$0 to < \$10 million and \$0 to < \$10 million).
- 5.11 The submission stated that as Saizen is expected to only replace the use of somatropin products currently PBS-listed for this indication, it is not expected to result in any incremental costs to the PBS/RPBS. The submission estimated a slight cost-saving to the PBS/RPBS due to the 6 mg and 12 mg strengths of Saizen requiring slightly less

frequent dispensing, therefore incurring less mark-up and fees compared to the 5 mg and 10 mg strengths currently PBS-listed. In addition, the submission claimed a slight cost-saving for the PBS/RPBS due to the proposed price reduction for Saizen 6 mg and 12 mg that are currently PBS-listed for paediatric indications. The PBAC noted the proposed price for Saizen reflects a weighted price across the current and proposed indications rather than a price reduction, therefore a cost-saving is unlikely.

Table 2: Financial estimates of PBS listing Saizen for adult patients with severe GHD

PBS	2023	2024	2025	2026	2027	2028
New listing	1	1	1	1	1	1
Changed listing	2	2	2	2	2	2
Net cost to PBS	2	2	2	2	2	2
RPBS	2023	2024	2025	2026	2027	2028
New listing	1	1	1	1	1	1
Changed listing	2	2	2	2	2	2
Net cost to RPBS	2	2	2	2	2	2
Net cost PBS / RPBS	2	2	2	2	2	2

Source: Table 3 of the submission, p.4.

GHD: growth hormone deficiency; PBS: Pharmaceutical Benefits Scheme; RPBS: Repatriation Pharmaceutical Benefits Scheme

The redacted values correspond to the following ranges:

¹ \$0 to < \$10 million

² net cost saving

6 PBAC Outcome

- 6.1 The PBAC recommended the listing of somatropin solution for injection 6 mg (18 i.u.) in 1.03 mL and 12 mg (36 i.u.) in 1.5 mL (Saizen) for the treatment of severe late onset GHD, on the basis that it should be available only under special arrangements under Section 100 (Growth Hormone Program), and under the same circumstances as somatropin products currently PBS-listed for this indication.
- 6.2 In making its recommendation, the PBAC recalled its previous recommendation in July 2017 to list somatropin for the treatment of severe late onset GHD and noted that three brands of somatropin are currently PBS-listed as a result of this recommendation. The PBAC further noted that its July 2017 recommendation in relation to the forms of somatropin where a listing for severe late onset GHD had not been implemented has now been rescinded.
- 6.3 The PBAC acknowledged that there is a clinical need for additional somatropin products for the treatment of severe late onset GHD, given the worldwide supply shortage of Norditropin FlexPro and the planned discontinuation of NutropinAq next year.
- 6.4 The PBAC was satisfied that Saizen demonstrates non-inferior comparative effectiveness and safety compared to other somatropin products PBS-listed for severe late onset GHD and accepted the other somatropin products as appropriate

comparators.

- 6.5 The PBAC considered the equi-effective doses to be 1 mg of Saizen and 1 mg of other somatropin products PBS-listed for this indication and considered that all the different brands of somatropin are considered equivalent on a per mg basis.
- 6.6 The PBAC noted the submission proposed an AEMP for Saizen consistent with those somatropin products currently listed for this indication on a per mg basis and noted the proposal to apply this AEMP to currently listed and proposed expanded Saizen listings. The PBAC considered this approach appropriate.
- 6.7 The PBAC noted the sponsor had estimated a modest cost-saving to the PBS/RPBS. The PBAC considered listing at the proposed price would not result in an increased cost to Government.
- 6.8 The PBAC noted that its recommendation was on a cost-minimisation basis and advised that, because Saizen is not expected to provide a substantial and clinically relevant improvement in efficacy, or reduction of toxicity, over other somatropin products currently PBS-listed for severe late onset GHD, despite being expected to address a high and urgent unmet clinical need due to the shortage and discontinuation of alternative therapies for the treatment of severe late onset GHD, the criteria prescribed by the *National Health (Pharmaceuticals and Vaccines – Cost Recovery) Regulations 2022* for Pricing Pathway A were not met.
- 6.9 The PBAC noted that this submission is not eligible for an Independent Review because it received a positive recommendation.

Outcome:

Recommended

7 Recommended listing

7.1 Add new indication as follows:

Category / Program: Section 100 – Growth Hormone Programme								
MEDICINAL PRODUCT medicinal product pack				PBS item code	Max. qty packs	Max. qty units	No.of Rpts	Available brands
SOMATROPIN								
somatropin cartridge	6 mg/1.03 mL	injection,	1.03 mL	NEW MP	1	1	5	Saizen
somatropin cartridge	12 mg/1.5 mL	injection,	1.5 mL	NEW MP	1	1	5	Saizen
Authority Required								
Category / Program: Section 100 – Growth Hormone Programme								
Prescriber type: <input checked="" type="checkbox"/> Medical Practitioners								

<p>Administrative Advice (common to all restriction summaries attached): No increase in the maximum number of repeats may be authorised.</p>
<p>Indication: Severe growth hormone deficiency</p>
<p>Treatment Phase: Initial treatment of late onset growth hormone deficiency</p>
<p>Clinical criteria: Patient must have onset of growth hormone deficiency secondary to organic hypothalamic or pituitary disease diagnosed at chronological age of 18 years or older; or Patient must have onset of growth hormone deficiency diagnosed after skeletal maturity (bone age greater than or equal to 15.5 years in males or 13.5 years in females) and before chronological age of 18 years</p>
<p>AND</p>
<p>Clinical criteria: Patient must have a diagnostic insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre; or Patient must have a diagnostic arginine infusion test with maximum serum GH less than 0.4 micrograms per litre; or Patient must have a diagnostic glucagon provocation test with maximum serum GH less than 3 micrograms per litre</p>
<p>Treatment criteria: Must be treated by an endocrinologist</p>
<p>Prescribing Instructions: The authority application must be in writing and must include: <ol style="list-style-type: none"> 1. A completed authority prescription form; AND 2. A completed Severe Growth Hormone Deficiency supporting information form; AND 3. Results of the growth hormone stimulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender. </p>
<p>Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001</p>
<p>Authority Required</p>
<p>Indication: Severe growth hormone deficiency</p>
<p>Treatment Phase: Continuing treatment in a person with a mature skeleton or aged 18 years or older</p>
<p>Clinical criteria:</p>

Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause in a patient with a mature skeleton, or, in a patient with Prader-Willi syndrome and chronological age of 18 years or older; or
Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to late onset of growth hormone deficiency secondary to organic hypothalamic or pituitary disease in a patient with chronological age of 18 years or older; or
Patient must have previously received PBS-subsidised therapy with this drug for this condition under an initial treatment restriction applying to late onset of growth hormone deficiency diagnosed after skeletal maturity (bone age greater than or equal to 15.5 years in males or 13.5 years in females) and before chronological age of 18 years
Treatment criteria:
Must be treated by an endocrinologist
Administrative Advice: Applications for authorisation under this restriction may be made in real time using the Online PBS Authorities system (see www.servicesaustralia.gov.au/HPOS) or by telephone by contacting Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).
Authority Required
Indication: Severe growth hormone deficiency
Treatment Phase: Initial treatment of childhood onset growth hormone deficiency in a patient who has received PBS-subsidised treatment as a child
Clinical criteria:
Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause
AND
Clinical criteria:
Patient must have previously received PBS-subsidised treatment with this drug for this condition as a child
Treatment criteria:
Must be treated by an endocrinologist
Population criteria:
Patient must have a mature skeleton
Prescribing Instructions: Somatropin is not PBS-subsidised for patients with Prader-Willi syndrome aged 18 years or older without a documented childhood onset Growth Hormone Deficiency.
Prescribing Instructions: The authority application must be in writing and must include: <ol style="list-style-type: none"> 1. A completed authority prescription form; AND 2. A completed Severe Growth Hormone Deficiency supporting information form.

<p>Administrative Advice: Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday). Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos Or mailed to: Services Australia Complex Drugs Reply Paid 9826 HOBART TAS 7001</p>
<p>Authority Required</p>
<p>Indication: Severe growth hormone deficiency</p>
<p>Treatment Phase: Initial treatment of childhood onset growth hormone deficiency in a patient who has received non-PBS subsidised treatment as a child</p>
<p>Clinical criteria: Patient must have a documented childhood onset growth hormone deficiency due to a congenital, genetic or structural cause</p>
<p>AND</p>
<p>Clinical criteria: Patient must have previously received non-PBS subsidised treatment with this drug for this condition as a child</p>
<p>AND</p>
<p>Clinical criteria: Patient must have current or historical evidence of an insulin tolerance test with maximum serum growth hormone (GH) less than 2.5 micrograms per litre; or Patient must have current or historical evidence of an arginine infusion test with maximum serum GH less than 0.4 micrograms per litre; or Patient must have current or historical evidence of a glucagon provocation test with maximum serum GH less than 3 micrograms per litre</p>
<p>Treatment criteria: Must be treated by an endocrinologist</p>
<p>Population criteria: Patient must have a mature skeleton</p>
<p>Prescribing Instructions: Somatropin is not PBS-subsidised for patients with Prader-Willi syndrome aged 18 years or older without a documented childhood onset Growth Hormone Deficiency.</p>
<p>Prescribing Instructions: The authority application must be in writing and must include:</p> <ol style="list-style-type: none"> 1. A completed authority prescription form; AND 2. A completed Severe Growth Hormone Deficiency supporting information form; AND 3. Results of the growth hormone stimulation testing, including the date of testing, the type of test performed, the peak growth hormone concentration, and laboratory reference range for age/gender.

Administrative Advice:

Any queries concerning the arrangements to prescribe may be directed to Services Australia on 1800 700 270 (hours of operation 8 a.m. to 5 p.m. Monday to Friday).

Prescribing information (including Authority Application forms and other relevant documentation as applicable) is available on the Services Australia website at www.servicesaustralia.gov.au

Applications for authority to prescribe should be submitted online using the form upload facility in Health Professional Online Services (HPOS) at www.servicesaustralia.gov.au/hpos

Or mailed to:

Services Australia

Complex Drugs

Reply Paid 9826

HOBART TAS 7001

Restriction summary numbers current as of 1 September 2023. Where restriction summary numbers are to update, the restriction summary numbers applying to Saizen at the time of listing are to be identical to those applying to the following PBS items for indication 19043 (Severe growth hormone deficiency):

MEDICINAL PRODUCT Form	PBS item code	Brand
somatropin 10 mg/2 mL injection, 2 mL cartridge	11650E	Nutropin Aq
somatropin 12 mg injection [1 chamber] (& inert substance diluent [1 mL chamber], 1 dual chamber pen device	11495B	Genotropin GoQuick
somatropin 5 mg injection [1 chamber] (& inert substance diluent [1 mL chamber], 1 dual chamber pen device	11493X	Genotropin GoQuick
somatropin 5 mg/1.5 mL injection, 1.5 mL cartridge	11895C	Norditropin FlexPro

- 7.2 At its July 2023 meeting, the PBAC recommended the removal of references to Prader-Willi Syndrome in the PBS restriction criteria for somatropin to align with the updated definitions of ‘adult’ and ‘child’ in the *National Health (Growth Hormone Program) Special Arrangement 2015*. These changes are yet to be implemented but will be included in the PBS-listings for Saizen 6 mg and 12 mg for severe late onset GHD.

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

The sponsor had no comment.