



EMBARGOED 1 October 2022

Government funds first long-acting growth hormone treatment for Aussie kids¹

Medical experts have joined the parents of children with a profound growth disorder in welcoming Federal Government funding for a new treatment that requires just one injection each week to stimulate childhood growth.^{1,2}

From 1 October 2022 Ngenla[®] (somatrogon), the first once-weekly growth hormone therapy for childhood growth hormone deficiency (GHD) in Australia, will be made available through the Pharmaceutical Benefits Scheme (PBS) for around 2,000 children living with this condition.¹

The families of eligible children will pay just \$6.90 (concession) or \$42.50 (general) each month for Ngenla. Without a PBS listing, the medicine would cost up to \$27,000 per year based on a child's weight.

Growth hormone deficiency is a condition that occurs when the pituitary gland, located at the base of the brain, does not produce or release a sufficient level of growth hormone.^{3,4}

Without treatment, children with growth hormone deficiency experience significant slowing in bone and muscle growth, leading to impaired development and significantly shortened height.^{3,4} When severe growth hormone deficiency is present from birth and never treated, as an adult their height can be as short as 122 to 165 cm.⁵

Ngenla is the first once weekly synthetic growth hormone for Australian children with growth hormone deficiency aged from three years.^{1,2} The therapy works to supplement the body's natural growth hormone production, encouraging the liver to produce insulin-like growth factor-1 (IGF-1), which acts to thicken and elongate bones, thereby improving height and helping grow muscles, reduce fat storage and improve wellbeing.^{2,3,6}

Until now, the treatment for growth hormone deficiency in children necessitated a daily injection of a synthetic growth hormone, given each evening to mimic the body's natural day-night hormone cycle.^{4,7}

Professor Maria Craig, Sydney paediatric endocrinologist, welcomed Government funding for Ngenla and the impact this will have on the families of children with growth hormone deficiency.

"Childhood growth is critical to long-term health and development," Professor Craig said.

"Unfortunately, some children lack the hormone required to grow to their full predicted height. In these cases, treatment is initiated to optimise the child's growth potential and prevent a range of physical and possible psychological issues.

"It's not always easy for families when a child has a long-term medical condition, especially when every missed dose of growth hormone therapy is a missed opportunity for better growth. Affordable access to a treatment given once weekly will be a major boost for many families.

"It is important to recognise that this is not only about helping kids become taller. We also aim to prevent potential social and mental health issues associated with the condition and its management," she said.

Families living with a child affected by growth hormone deficiency say they are "delighted" that Ngenla is being publicly funded for their children.

“As the parent of a child with growth hormone deficiency, the PBS listing of Ngenla is fantastic, we are over the moon,” said Marla Cawthorne, the mother of three-year-old Ruby.

“Like any parent, the growth and development of Ruby is our absolute priority and we’re grateful to have affordable treatment options available in Australia.”

Mrs Cawthorne is also the General Manager of the [Australian Pituitary Foundation](#) and says the PBS listing of Ngenla is an important milestone in the treatment of growth hormone deficiency among Australian children.

“The treatment burden associated with growth hormone deficiency is significant. Anything we can do to help children and families impacted by growth hormone deficiency is a major win,” she said.

“We would like to thank the Australian Government and those who advocated for the inclusion of Ngenla on the PBS. This is a very big day for our community.”

Ngenla is given through a pre-filled pen in a schedule that allows for once weekly injections at any time of the day under the skin of the stomach, thighs, buttocks or upper arms.²

All medicines have side-effects. The most common side-effects reported with Ngenla include pain, redness and itching at the place on the body the injection is given.²

About Growth Hormone Deficiency (GHD)

GHD occurs when the pituitary gland does not produce enough growth hormone. It can occur in children due to genetic abnormalities resulting in insufficient production and/or response to growth hormone, abnormal development of the pituitary gland, or structural defects of the brain that are present at birth.⁸

GHD can also occur at any stage after birth due to brain injury, infection, medical treatment or for no known reason.^{7,8}

In addition to children with GHD being shorter than their peers, they can also experience a range of other health and developmental issues, including:

- Appearing young-looking, with a rounder face and higher-pitched voice than other children.⁵
- Low levels of muscle and bone, leading to high levels of ‘baby fat’ around the abdomen.⁵
- Delayed developmental milestones, including appearance of adult teeth and puberty.^{5,7}
- Psychological issues including low self-esteem and anxiety.⁶

GHD can also impact adults. Symptoms of adult GHD include increased abdominal fat; lower muscle mass and strength; mild bone loss that increases the risk of osteoporosis; sleep disturbance; decreased energy levels and exercise performance; mild depression or moodiness; and a decrease in overall wellbeing.⁹ Adults with GHD are also at increased risk of high LDL cholesterol, which increases risk of heart disease.⁹

Ngenla Consumer Medicine Information is available at

<https://secure.guildlink.com.au/gc/ws/pf/cmi.cfm?product=pfcngeni>

This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. You can report side effects to your doctor, or directly at www.tga.gov.au/reportingproblems.

PBS Information: Authority Required.
Please refer to PBS Schedule for full authority information.

Issued on behalf of Pfizer Australia Pty Ltd.

Media contact:

For further information, please contact Candice Hitchcock (0466 586 758) or John Morton (0416 184 044) at Ethical Strategies.

No compensation was provided to Professor Craig or Mrs Cawthorne for their involvement in this media activity, and the opinions expressed are their own.

About Pfizer: Breakthroughs That Change Patients' Lives™

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us.

For more information, please visit: www.pfizer.com.au

References:

1. PBS Schedule of Pharmaceutical Benefits. Available at www.pbs.gov.au/pbs/home.
2. NGENLA Product Information. Available at <https://secure.guildlink.com.au/gc/ws/pf/pi.cfm?product=pfpngeni>
3. Hormones Australia. Endocrine Society of Australia. Growth Hormone Deficiency. Available at <https://www.hormones-australia.org.au/endocrine-diseases/growth-hormone-deficiency>
4. John Hopkins Medicine. Growth Hormone Deficiency. Available at <https://www.hopkinsmedicine.org/health/conditions-and-diseases/growth-hormone-deficiency>
5. Paediatric Endocrine Associates. Growth Hormone Deficiency. Available at <https://pediatricendocrinologynj.com/growth-hormone-deficiency/>
6. Akaltul I, et al. Growth Horm IGF Res 2018; 41:23-27.
7. MSD Manual. Growth Hormone Deficiency in Children. Available at [Growth Hormone Deficiency in Children - Pediatrics - MSD Manual Professional Edition \(msdmanuals.com\)](https://www.msdmanuals.com/pt/children/pediatrics/growth-hormone-deficiency-in-children)
8. Hormones Australia. Endocrine Society of Australia. GH Deficiency Fact Sheet. Available at <https://www.hormones-australia.org.au/wp-content/uploads/2019/10/Fact-Sheet-GH-Deficiency-20191031.pdf>
9. Merriam GR, et al. The Journal of Clinical Endocrinology & Metabolism 2011;96 (6): 33A–34A.

Pfizer Australia Pty Ltd. Sydney, Australia. PP-NGE-AUS-0083 August 2022