www.scottishmedicines.org.uk

Advice document
SMC2629

somapacitan solution for injection in pre-filled pen (Sogroya®)

Novo Nordisk

04 October2024

The Scottish Medicines Consortium (SMC) has completed its assessment of the above product and, following review by the SMC executive, advises NHS Boards and Area Drug and Therapeutics Committees (ADTCs) on its use in NHSScotland. The advice is summarised as follows:

ADVICE: following an abbreviated submission

somapacitan (Sogroya®) is accepted for restricted use within NHSScotland.

Indication under review: for the replacement of endogenous growth hormone (GH) in children aged 3 years and above, and adolescents with growth failure due to growth hormone deficiency (paediatric GHD), and in adults with growth hormone deficiency (adult GHD).

SMC restriction: for children aged 3 years and above and adolescents with growth failure due to growth hormone deficiency (paediatric GHD).

Somapacitan offers an additional treatment choice in the therapeutic class of recombinant human growth hormones for this indication.

Chair
Scottish Medicines Consortium

Published 11 November 2024

1. Clinical Context

1.1. Medicine background

Somapacitan is a long-acting recombinant human growth hormone (GH) derivative. It is licensed for the replacement of endogenous GH in children aged 3 years and above, and adolescents with growth failure due to growth hormone deficiency (paediatric GHD), and in adults with growth hormone deficiency (adult GHD). The submitting company has requested that somapacitan is restricted for use in paediatric and adolescent patients. Somapacitan is administered once weekly by subcutaneous injection. The initial dose in paediatric patients is 0.16 mg/kg/week. The dose may be individualised and adjusted based on growth velocity, adverse reactions, body weight and serum insulin-like growth factor I (IGF-I) concentrations. Further details are included in the Summary of product characteristics (SPC).[1, 2]

1.2. Relevant comparator(s)

Somapacitan is in the same therapeutic class as somatropin and somatrogon. Somatropin is a daily GH therapy available for the treatment of growth failure due to paediatric GHD. Seven somatropin preparations are available in NHSScotland: Genotropin®, Humatrope®, Norditropin® (including NordiFlex® and FlexPro® devices), NutropinAq®, Omnitrope®, Saizen® and Zomacton®. Previous appraisals have concluded that there is likely no difference in the clinical effectiveness of the various preparations. Somatrogon (Ngenla®) is a long-acting GH therapy administered once weekly, which is accepted for use by SMC for the treatment of children and adolescents from 3 years of age with growth disturbance due to insufficient secretion of growth hormone (SMC2493).

2. Summary of Clinical Evidence

2.1. Evidence to support comparable efficacy with relevant comparators

Evidence from a randomised, multicentre, open-label, phase III study (REAL 4) showed that somapacitan was non-inferior in increasing annualised height velocity at week 52 in GH treatment-naive prepubertal children with GHD, compared with somatropin (Norditropin®; 0.034 mg/kg/day), with an estimated treatment difference of -0.5 cm/year (95% confidence interval: -1.1 to 0.2).[1, 2]

No direct evidence was presented in the company submission against somatrogon. The company presented pairwise comparisons from a Bayesian network meta-analysis (NMA), using data from four studies. The results suggest that somapacitan is likely to have similar efficacy to somatrogon in treating paediatric GHD.

3. Company Estimate of Eligible Population, Uptake and Budget Impact

3.1. Company's number of patients assumed to be eligible for treatment*

The company estimated that there would be 258 patients eligible for treatment with somapacitan in year 1, increasing to 306 patients in year 5.

3.2. Budget Impact assumption

Medicines reviewed under the abbreviated submissions process are estimated to have a limited net budget impact and resource allocation across NHS Scotland.

References

1. Novo Nordisk Limited. Somapacitan solution for injection in pre-filled pen (Sogroya®) Summary of product characteristics. Electronic Medicines Compendium. www.medicines.org.uk Last updated 06 October 2023.

2. Miller BS, Blair JC, Rasmussen MH, Maniatis A, Kildemoes RJ, Mori J*, et al.* Weekly Somapacitan is Effective and Well Tolerated in Children with GH Deficiency: The Randomized Phase 3 REAL4 Trial. J Clin Endocrinol Metab. 2022. Epub 20220905. 10.1210/clinem/dgac513

This assessment is based on data submitted by the applicant company up to and including **10 September 2024.**

Medicine prices are those available at the time the papers were issued to SMC for consideration. SMC is aware that for some hospital-only products national or local contracts may be in place for comparator products that can significantly reduce the acquisition cost to Health Boards. These contract prices are commercial in confidence and cannot be put in the public domain, including via the SMC Detailed Advice Document. Area Drug and Therapeutics Committees and NHS Boards are therefore asked to consider contract pricing when reviewing advice on medicines accepted by SMC.

Advice context:

No part of this advice may be used without the whole of the advice being quoted in full.

This advice is based on the estimation of at least similar comparative efficacy and limited net budget impact compared with other medicinal products, within the same therapeutic class, that are in routine use within NHSScotland.

This advice represents the view of the Scottish Medicines Consortium and was arrived at after evaluation of the evidence submitted by the company. It is provided to inform the considerations of Area Drug & Therapeutics Committees and NHS Boards in Scotland in determining medicines for local use or local formulary inclusion. This advice does not override the individual responsibility of health professionals to make decisions in the exercise of their clinical judgement in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.