SUMMARY

somatropin

GENOTONORM 0.6 mg, 0.8 mg, 1.0 mg, 1.2 mg, 1.4 mg, 1.6 mg, 1.8 mg, 2.0 mg, 5.3 mg and 12 mg

solution for injection

Reassessment at the request of the CT

Original French opinion adopted by the Transparency Committee on 10 April 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for reimbursement only in "growth disturbance (current height SDS or <-3 and parental adjusted height SDS <-1) in short children born small for gestational age (SGA) with a birth weight and/or length below -2 SD, who failed to show catch-up growth (HV SDS <0 during the last year) by 4 years of age or later."

Transparency Committee's conclusions

Clinical Benefit

- Growth disturbance in children born small for gestational age (SGA), who failed to show catch-up growth by 4 years of age, is characterised by isolated short stature of unidentified origin.
- GENOTONORM (somatropin) proprietary medicinal products are symptomatic medicinal products.
- The efficacy/adverse effects ratio of GENOTONORM (somatropin) in this indication is moderate, given the results of the observational studies identified in the literature, the European SAGhE study, the methodological limitations of which make it impossible to demonstrate a causal link between the signal for an excess risk of mortality and treatment with GENOTONORM (somatropin), and the absence of any new safety signals.
- There are medicinal alternatives, all of which are somatropin-based.
- These proprietary medicinal products are first-line medicinal products.

➔ Public health benefit

Considering:

- the seriousness of the disease and its prevalence,
- the partially met medical need,
- the lack of evidence of an additional impact on morbidity and mortality or on quality of life based on the new data available,
- the lack of evidence of an additional impact on the organisation of care or on the care or life pathway in the absence of data supplied,

GENOTONORM (somatropin) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of GENOTONORM (somatropin) is moderate in the indication of growth disturbance (current height SDS <-3 and parental adjusted height SDS <-1) in short children born small for gestational age (SGA) with a birth weight and/or length below -2 SD, who failed to show catch-up growth (height velocity (HV) SDS <0 during the last year) by 4 years of age or later.

The Committee issues a favourable opinion for maintenance of inclusion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the abovementioned indication and at the MA dosages.

➔ Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 100%