SUMMARY

somatropin

OMNITROPE 5 mg/1.5 ml, 10 mg/1.5 ml and 15 mg/1.5 ml,

solution for injection

Reassessment at the request of the CT

Original French opinion adopted by the Transparency Committee on 19 July 2023

The legally binding text is the original French opinion version

Transparency Committee's conclusions

Clinical Benefit

Growth disturbance in children born small for gestational age

- 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.
- OMNITROPE (somatropin) proprietary medicinal products are symptomatic medicinal products.
- The efficacy/adverse effects ratio of OMNITROPE (somatropin) in this indication is moderate, given the results of the PATRO Children post-registration observational study demonstrating a progressive increase in median height and the European SAGhE study whose methodological limitations make it impossible to demonstrate a causal link between the signal for an excess risk of mortality and treatment with OMNITROPE (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 condition and its prevalence, estimated to be 2,200 patients in France,
- the partially met medical need,
- the absence of new clinical data on morbidity and mortality or quality of life,
- the absence of any demonstrated additional impact on morbidity and mortality or on quality of life based on the new observational data available,
- the lack of any demonstrated additional impact on the organisation of care or on the care or life pathway in the absence of data supplied,

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

Considering all these elements, the Committee deems that the clinical benefit of OMNITROPE (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 hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the abovementioned indication and at the MA dosages.

Recommended reimbursement rate: 100%

Replacement therapy in adults with pronounced growth hormone deficiency

- Severe growth hormone (GH) deficiency in adults is a long-term condition, of variable origin, that can lead to a deterioration in quality of life and cardiovascular complications.
- OMNITROPE (somatropin) proprietary medicinal products are symptomatic medicinal products.
- The efficacy/adverse effects ratio in this indication remains moderate, given the results of the PATRO Adults post-registration observational study and the European SAGhE observational study whose methodological limitations make it impossible to demonstrate a causal link between the signal for an excess risk of mortality and treatment with OMNITROPE (somatropin).
- There are medicinal alternatives, all of which are somatropin-based.
- OMNITROPE (somatropin) proprietary medicinal products are first-line medicinal products.

Public health benefit:

Considering:

- the seriousness of the condition and its prevalence, estimated to be 3,000 patients in France,
- the partially met medical need,
- the absence of new clinical morbidity and mortality data,
- the absence of any demonstrated additional impact on morbidity and mortality or on quality of life based on the new observational data available,
- the lack of any demonstrated additional impact on the organisation of care or on the care or life pathway in the absence of data supplied,

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

Considering all these elements, the Committee deems that the clinical benefit of OMNITROPE (somatropin) remains moderate in the MA indication.

The Committee issues a favourable opinion for maintenance of inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the indication and at the MA dosages.

Recommended reimbursement rate: 100%

Clinical Added Value

Growth disturbance in children born small for gestational age

Considering:

- the results from the PATRO C post-registration observational study concerning a cohort of 880 SGA children treated with OMNITROPE (somatropin) demonstrating the achievement of a final height (target height or deemed satisfactory) for 29.6% of patients with a safety profile in line with the known profile of OMNITROPE (somatropin),
- safety data from the SAGhE European observational study concerning a large number of patients, with methodological limitations making it impossible to establish with certainty a causal link between treatment with somatropin and the signal for an excess risk of mortality observed in certain subgroups; this excess mortality signal having been identified by the Committee in its previous opinions,
- significant experience with the use of somatropin in its various indications, in a context of reinforced pharmacovigilance monitoring, considering the previously identified safety signals (excess mortality, tumour development), which have not been confirmed to date,

the Committee considers that the new data are unlikely to modify the previous conclusions relative to the clinical added value of OMNITROPE (somatropin) in the indication of growth disturbance in children born small for gestational age (CAV V compared to GENOTONORM (somatropin)).

Pronounced growth hormone deficiency in adults

Considering:

- the results of the PATRO A France post-registration observational study conducted in a cohort of 100 adults treated with OMNITROPE (somatropin), which responded to the Committee's request for efficacy and safety data in the treatment of pronounced growth hormone (GH) deficiency in adults,
- safety data from the SAGhE European observational study concerning a large number of patients, with methodological limitations making it impossible to establish with certainty a causal link between treatment with OMNITROPE (somatropin) and the signal for an excess risk of mortality observed in certain subgroups; this excess mortality signal having been identified by the Committee in its previous opinions,

- significant experience with the use of somatropin in its various indications, in a context of reinforced pharmacovigilance monitoring, considering the previously identified safety signals (excess mortality, tumour development), which have not been confirmed to date,

the Committee considers that the new data are unlikely to modify the previous conclusions relative to the clinical added value of OMNITROPE (somatropin) in the indication of pronounced growth hormone (GH) deficiency in adults (CAV V compared to GENOTONORM (somatropin)).