SUMMARY

glycopyrronium (bromide)

SIALANAR 320 µg/mL

oral solution

Modification of the listing conditions

Original French opinion adopted by the Transparency Committee on 28 February 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for reimbursement in the “symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders”.

Transparency Committee’s conclusions

Clinical Benefit

- Although sialorrhoea is considered to be physiological during the very first years of life, it is considered to be pathological beyond 3 to 6 years of age. Pathological drooling may cause significant social embarrassment and problems with hygiene and skin irritation that can impact quality of life.
- This is a symptomatic medicinal product.
- The efficacy/adverse effects ratio is high.
- It is a second-line treatment after failure of a sufficiently long period of appropriate rehabilitation in the treatment of severe sialorrhoea in children and adolescents aged 3 years and older in view of the therapies available.

Public health benefit

Considering:

- the seriousness of the disease (risk of choking and severe consequences for oral and dental health) and its prevalence;
- the insufficiently covered medical need,
- the partial additional response to the identified need, due to:
  - evidence of an additional impact on morbidity, on the responder rate and on drooling; but without evidence of an impact on respiratory morbidity and quality of life in the absence of robust data,
  - the lack of evidence of an impact on the care and/or life pathway,

SIALANAR (glycopyrronium bromide) 320 µg/mL oral solution is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of SIALANAR (glycopyrronium bromide) 320 µg/mL oral solution is substantial in the MA indication.

The Committee issues a favourable opinion for maintenance of inclusion of SIALANAR (glycopyrronium bromide) 320 µg/mL oral solution in both the list of covered drugs for inpatients and the list of covered drugs for outpatients approved for use in the MA indication and at the MA dosages.

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%**

Clinical Added Value

Considering:

- demonstration of the superiority of glycopyrronium bromide compared to placebo:
  - on the change in total DIS score from baseline to day 84 of treatment compared to baseline (primary endpoint), with a mean change of -25.5 points versus -8.8 points ($p<0.001$),
  - on all the ranked secondary endpoints, particularly in terms of responder rate and impact on drooling at days 84 and 28 of treatment,
- robust efficacy data versus placebo limited to a duration of 12 weeks, in a chronic disease context, and non-comparative long-term follow-up data suggesting a sustainability of the therapeutic effect for up to 252 days of treatment,
- the insufficiently covered medical need in an off-label context for medicinal products not authorised in paediatric patients,
- the absence of data relative to the possibility of retreatment;
- the lack of evidence of an improvement in quality of life, in the absence of robust data,
- the safety profile of glycopyrronium bromide in children and adolescents marked by the known typical anticholinergic adverse effects,

the Committee deems that SIALANAR (glycopyrronium bromide) 320 µg/mL oral solution provides a minor clinical added value (CAV IV) in the current care pathway for the symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders.