SUMMARY

glycopyrronium bromide

RYBRILA 160 µg/ml,

oral solution

First assessment

Original French opinion adopted by the Transparency Committee on 22 March 2023

The legally binding text is the original French opinion version

Key points

Favourable opinion on the inclusion of RYBRILA (glycopyrronium bromide) in the “symptomatic treatment of severe sialorrhoea (chronic pathological drooling) in children and adolescents aged 3 years and older with chronic neurological disorders".

Role in the care pathway?

RYBRILA (glycopyrronium bromide), an antimuscarinic anticholinergic agent, is the second medicinal product indicated in France in the treatment of severe sialorrhoea in children and adolescents aged 3 years and older after SIALANAR. The role of RYBRILA is similar to that of SIALANAR: it lies in second-line treatment after failure of a sufficiently long period of appropriate re-education in the treatment of severe sialorrhoea in children and adolescents aged 3 years and older. As there are limited long-term data, the duration of use must be short and intermittent. These two medicinal products must not be administered to children with mild-to-moderate sialorrhoea.

Changing from one product to the other without appropriate dosage adjustments may lead to an overdose and to anticholinerginic toxicity.

Transparency Committee's Conclusions

Clinical Benefit

- Although sialorrhoea is considered physiological during the very first years of life, it is considered pathological after 3 to 6 years of age. Pathological drooling may cause significant social embarrassment and problems with hygiene, skin irritation that can impact quality of life.
- It is a symptomatic treatment.
- The superiority of glycopyrronium bromide compared to placebo in the improvement of drooling has been demonstrated in short-term (8 weeks) clinical studies conducted in small numbers of subjects and containing many methodological limitations. Long-term tolerance data are limited. The efficacy/adverse effect ratio is low.
- It is a second-line treatment after failure of a sufficiently long period of appropriate re-education.

Public health benefit

In view of:

- the gravity of the disease (risk of aspiration and severe consequences for oral quality) and its prevalence;
- the partially met medical need;
- the partial response to the need identified with no additional expected impact on severe sialorrhoea and quality of life;
- the absence of additional expected impact on the organisation of care, the care pathway and/or the life course;

RYBRILA (glycopyrronium bromide) is not liable to have an additional impact on public health.

In view of all of these elements, the Committee considers that the clinical benefit provided by RYBRILA (glycopyrronium bromide), oral solution is moderate in the MA indications.

The Committee gives a favourable opinion on the inclusion of RYBRILA (glycopyrronium bromide) on the list of medicinal products reimbursable to persons insured under social security schemes and on the list of medicinal products approved for the use of communities in the MA indication. The Committee stresses that treatment in the community, and not just in hospital, would facilitate access to the drug.

Reimbursement rate: 30 %

Clinical Added Value

The Committee considers that RYBRILA, like SIALANAR, medicinal products based on glycopyrronium bromide, provides no clinical added value (CAV V) in the management of severe sialorrhoea in children and adolescents aged 3 years and older.