HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
OPINION
22 JANUARY 2020

ciclosporin
VERKAZIA 1 mg/ml eye drops, emulsion

First assessment

Key points

Favourable opinion for reimbursement in the treatment of severe vernal keratoconjunctivitis (VKC) in children from 4 years of age and adolescents.

What therapeutic improvement?

Slight therapeutic improvement.

Role in the care pathway?

The current treatment of VKC defined by the French Society of Ophthalmology (2015) consists, firstly, of rinsing the eye with normal saline, anti-allergy eye drops and local corticosteroids prescribed in the short term due to the risk of glaucoma and cataract.

In severe corticosteroid-dependent forms with corneal complications, topical ciclosporin is the reference option, enabling corticosteroid therapy sparing.

Oral corticosteroids may be necessary in very rare, vision-threatening forms resistant to all other treatments, with a treatment duration that is as short as possible.

Role of the medicinal product in the care pathway

VERKAZIA is a second-line treatment in severe VKC in children and adolescents who have not responded to anti-allergy eye drops and are corticosteroid-dependent.

COMMITTEE'S CONCLUSIONS

Clinical Benefit

◗ Vernal keratoconjunctivitis (VKC) in children and adolescents is a usually benign disease that generally disappears spontaneously after adolescence. However, due to its symptoms, it impairs quality of life and, in severe forms, irreversible damage to the corneal surface may result in reduced visual acuity or even blindness.
◗ VERKAZIA is a symptomatic treatment.
◗ The efficacy/adverse effects ratio is high.
◗ There are no other proprietary medicinal products containing ciclosporin in eye drop form with an MA in severe VKC in children and adolescents. Only non-standardised hospital preparations, the use of which has not been validated in this indication by robust clinical studies, are currently available.
◗ This proprietary medicinal product is a second-line treatment in severe VKC in children and adolescents who have not responded to anti-allergy eye drops and are corticosteroid-dependent.

Public health impact

Considering:
- the impact of VKC on quality of life and the risks of serious complications in severe forms,
- its low prevalence (rare disease),
- the identified partially met medical need,
- the impact in terms of morbidity demonstrated only in the short term on a composite endpoint including the severity of corneal lesions, the need for rescue local corticosteroid therapy and the occurrence of corneal ulceration, assessed after 4 months of treatment,
- the absence of any conclusively demonstrated impact on quality of life and the organisation of care, particularly in terms of reduction in hospitalisations,

VERKAZIA is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of VERKAZIA 1 mg/ml eye drops, emulsion is substantial in the MA indication.

The Committee issues a favourable opinion for inclusion in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the marketing authorisation indication(s) and dosages.

Clinical Added Value

Considering:
- **the demonstration of the superiority of VERKAZIA compared to its vehicle (emulsion) with a modest effect size on a composite endpoint assessed after 4 months of treatment, taking into account the severity of corneal lesions, the need to use rescue treatment (dexamethasone eye drops) and the occurrence of corneal ulceration,**
- **the absence of conclusive demonstration of a superiority in terms of quality of life,**
- **the absence of long-term efficacy and safety data in a disease requiring long-term treatment,**
- **the partially met medical need,**

the Committee considers that VERKAZIA 1 mg/ml eye drops, emulsion provides a minor clinical added value (CAV IV) in the treatment of severe vernal keratoconjunctivitis (VKC) in children from 4 years of age and adolescents.