SUMMARY

latanoprost

CATIOLANZE 50 µg/mL

eye drops, emulsion

First listing

Adopted by the Transparency Committee on 9 October 2024

Summary of opinion

Favourable opinion for reimbursement in the reduction of elevated intraocular pressure (IOP):

- **in adult patients with open angle glaucoma or ocular hypertension,**
- **in children from 4 years of age and adolescents with elevated IOP and paediatric glaucoma.**

Transparency Committee's conclusions

Clinical Benefit

- Glaucoma is a severe condition that can cause blindness.
- CATIOLANZE 50 µg/ml eye drops, emulsion is a curative treatment for elevated intraocular pressure and a preventive treatment for complications of the condition.
- The efficacy/adverse effects ratio is high.
- This is a first or second-line treatment in view of the therapies available for the reduction of elevated IOP:
  - in adult patients with open angle glaucoma or ocular hypertension,
  - in children from 4 years of age and adolescents with elevated IOP and paediatric glaucoma.

Public health benefit

Considering:

- the seriousness of the disease and its prevalence,
- the need currently met by numerous alternatives,
- the partial response to the identified need given:
  - evidence of its non-inferiority compared to the reference medicinal product XALATAN (latanoprost), in terms of reduction of intraocular pressure morning and evening after 12 weeks,
  - the lack of evidence of an additional impact on morbidity or quality of life,

- the lack of evidence of an additional impact of the organisation of care or on the patient's care or life pathway,

CATIOLANZE (latanoprost) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of CATIOLANZE 50 µg/ml eye drops, emulsion is substantial in the MA indications.

The Committee issues a favourable opinion for inclusion of CATIOLANZE 50 µg/ml eye drops, emulsion in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the MA indications and at the MA dosages.

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

Clinical Added Value

Considering:

- evidence of the non-inferiority of CATIOLANZE (preservative-free latanoprost) compared to XALATAN (latanoprost with preservative) on the reduction of intraocular pressure morning and evening after 12 weeks of treatment,
- evidence of the superiority of CATIOLANZE compared to XALATAN on the reduction in corneal fluorescein staining (CFS) score in patients with a CFS score ≥ 1 at baseline, after 12 weeks of treatment,

but:

- the lack of evidence of a superiority of CATIOLANZE compared to XALATAN after 12 weeks for:
  - the reduction of IOP morning and evening, given the non-significant difference between the two groups for the evening measurement,
  - the change in ocular surface disease (OSD) score, in patients with a mean score of > 0 at baseline,
- the short-term safety profile (12 weeks) of CATIOLANZE similar to that of XALATAN and primarily marked by ocular adverse events, such as ocular and conjunctival hyperaemia, eye irritation, punctate keratitis, eye pain, photophobia or conjunctivitis, and adverse effects related to the prostaglandin analogue class (iris hyperpigmentation, eyelash growth),
- the absence of long-term comparative safety data versus XALATAN enabling an advantage of the preservative-free formulation to be demonstrated,

the Committee deems that CATIOLANZE 50 µg/ml eye drops, emulsion provides no clinical added value (CAV V) compared to XALATAN (latanoprost) eye drops, solution.