SUMMARY

dexamethasone

OZURDEX 700 µg,

intravitreal implant in applicator

Reassessment at the request of the CT

Adopted by the Transparency Committee on 25 September 2024

Summary of opinion

Favourable opinion for maintenance of reimbursement in the treatment of adult patients with inflammation of the posterior segment of the eye presenting as non-infectious uveitis.

Transparency Committee's conclusions

Clinical Benefit

- Inflammation of the posterior segment of the eye related to non-infectious uveitis and its complications (cystoid macular oedema, cataract, glaucoma, retinal detachment) is characterised by painful symptoms and reduced visual acuity, which can be sudden and severe and may progress to blindness, leading to functional disability and a marked deterioration in quality of life.
- OZURDEX 700 µg (dexamethasone) intravitreal implant in applicator is a symptomatic treatment.
- The efficacy/adverse effects ratio is high.
- This is a first-line treatment in view of the therapies available.

Public health benefit

The new data available are not of a nature to modify the previous assessment of the public health benefit: OZURDEX (dexamethasone) is unlikely to have an additional impact on public health.

Considering all of these elements, the Committee deems that the clinical benefit of OZURDEX 700 µg (dexamethasone) intravitreal implant in applicator remains substantial in the MA indication.

The Committee issues a favourable opinion for maintenance of inclusion of OZURDEX 700 µg (dexamethasone) intravitreal implant in applicator in both the list of covered drugs for outpatients and the list of covered drugs for inpatients 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:

- evidence of the superiority of dexamethasone intravitreal implant (OZURDEX 700 µg) compared to a simulated injection on the proportion of patients with a vitreous haze score of 0 (absence) at week 8 (46.8% versus 11.8%, p < 0.001) in the phase 3 HURON study conducted in adult patients with inflammation of the posterior segment of the eye related to non-infectious uveitis;
- a percentage of patients with an improvement in best-corrected visual acuity (BCVA) ≥ 15 letters (ETDRS scale) of 42.9% in the OZURDEX 700 µg group versus 6.6% in the simulated injection group (exploratory results in the absence of control of the alpha risk);
- the safety profile marked primarily by ocular adverse effects, in particular those related to the administration of a corticosteroid (elevated intraocular pressure, cataract) and the implant injection procedure (reduced visual acuity, vitreous detachment, vitreous floaters, vitreous opacities, blepharitis, eye pain, photopsia, conjunctival oedema, conjunctival hyperaemia);
- data from the French LOUVRE 2 observational study, which are not of a nature to modify the previous assessment of OZURDEX 700 µg (dexamethasone),

the Committee deems that the clinical added value of OZURDEX 700 µg (dexamethasone) intravitreal implant in applicator remains moderate (CAV III) in the management of adult patients with inflammation of the posterior segment of the eye presenting as non-infectious uveitis.