SUMMARY

aflibercept

EYLEA 114.3 mg/mL

solution for injection in vials

First listing

Original French opinion adopted by the Transparency Committee on 3 July 2024

The legally binding text is the original French opinion version

Summary of opinion

Favourable opinion for reimbursement only for the treatment of neovascular (wet) age-related macular degeneration (AMD) in adults.

Unfavourable opinion for reimbursement in the other situations covered by the MA indication.

Transparency Committee's conclusions

Clinical Benefit

- Age-related macular degeneration (AMD) is the leading cause of blindness in France in patients over the age of 50. Among severe forms of AMD, wet or neovascular forms are responsible for the largest number of severe visual acuity reductions.
- EYLEA 114.3 mg/mL (aflibercept) solution for injection in vials is a curative treatment for the consequences of the disease.
- The efficacy/adverse effects ratio is high.
- This is a first-line treatment for neovascular (wet) age-related macular degeneration (AMD) in view of the therapies available.

Public health benefit

Considering:

- the seriousness of the disease, progressing to visual disability, and its incidence,
- the partially met medical need,
- the partial response to the identified need given:

- the lack of evidence of an additional impact compared to EYLEA 40 mg/mL (aflibercept) in terms of visual acuity (functional clinical endpoint) after 48 and 60 weeks of treatment, although a superiority has been demonstrated for the proportion of patients with no intraretinal fluid (IRF) and no subretinal fluid (SRF) in the central subfield (anatomical endpoint),
- the lack of robust evidence of an impact on quality of life (exploratory endpoint),
- the lack of evidence of an additional impact on the patient's care or life pathway compared to other VEGF inhibitors administered using a Treat & Extend regimen despite a dosing regimen enabling the injections to be given at intervals of up to 5 months,

EYLEA 114.3 mg/mL (aflibercept) solution for injection in vials is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of EYLEA 114.3 mg/mL (aflibercept) solution for injection in vials is:

- **substantial only for the treatment of neovascular (wet) age-related macular degeneration (AMD) in adults,**
- **insufficient to justify public funding cover in the other MA situations.**

The Committee issues the following opinions:

- **a favourable opinion for inclusion of EYLEA 114.3 mg/mL (aflibercept) solution for injection in vials in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the indications only within the scope retained and at the MA dosages.**
- **an unfavourable opinion for inclusion of EYLEA 114.3 mg (aflibercept) solution for injection in vials in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the other situations covered by the MA indication.**

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

Clinical Added Value

Considering:

- the phase 3 PULSAR trial having compared aflibercept 8 mg every 12 weeks (Q12W) or every 16 weeks (Q16W) with a variable dosing regimen (after 3 monthly of injections) with aflibercept 2 mg every 8 weeks (Q8W) with a fixed dosing regimen (after 3 monthly injections) in adults with neovascular (wet) AMD, the results of which demonstrated:
  - the non-inferiority, without demonstration of a superiority, of the aflibercept 8 mg Q12W and 8 mg Q16W groups compared to the aflibercept 2 mg Q8W group in terms of change in best corrected visual acuity (BCVA, ETDRS) after 48 (primary endpoint) and 60 weeks (secondary endpoint) of treatment compared to baseline;
  - the superiority of aflibercept 8 mg Q12W + Q16W (grouped analysis) compared to aflibercept 2 mg Q8W on the percentage of patients with no intraretinal fluid (IRF) and no subretinal fluid (SRF) in the central subfield at week 16;
- a comparable tolerance between aflibercept 8 mg Q12W or Q16W and aflibercept 2 mg Q8W;

- the absence of demonstration of a superiority of aflibercept 8 mg Q12W or Q16W compared to aflibercept 2 mg Q8W in terms of quality of life;
- a simplified dosing regimen for EYLEA 114.3 mg/mL (aflibercept) compared to EYLEA 40 mg/mL (aflibercept) during the maintenance phase (interval of up to 5 months between two injections) but with no evidence of an additional impact on the organisation of care or the care or life pathway of patients compared to the other VEGF inhibitors used with a Treat & Extend regimen;

the Committee deems that EYLEA 114.3 mg/mL (aflibercept) solution for injection in vials provides no clinical added value (CAV V) compared to EYLEA 40 mg/mL (aflibercept) solution for injection in vials and pre-filled syringe.

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