SUMMARY

brolucizumab

BEOVU 120 mg/ml, solution for injection, vial and pre-filled syringe

Indication extension

Original French opinion adopted by the Transparency Committee on 5 July 2023

The legally binding text is the original French opinion version

Transparency Committee’s conclusions

Clinical Benefit

➔ Age-related macular degeneration (AMD) is the leading cause of visual disability 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.

➔ BEOVU 120 mg/ml (brolucizumab) solution for injection, vial and pre-filled syringe, is a curative treatment for the consequences of the disease.

➔ The efficacy/adverse effects ratio is high.

➔ This is a first-line treatment for retrofoveal wet age-related macular degeneration (AMD) in adults, in view of the therapies available. When initiating treatment, screening and investigation for a history of intraocular inflammation (in particular retinal vasculitis or retinal vascular occlusion) must be put in place, along with increased monitoring during the first three months of treatment to identify any of these inflammatory eye conditions, which warrant immediate treatment discontinuation.

➔ Public health benefit

Considering:

– the seriousness of the disease and its prevalence;
– the partially met medical need;
– the partial response to the identified need:
  • the lack of any additional impact on morbidity,
  • the absence of an additional impact on the organisation of care,
  • a demonstrated additional impact on the care pathway (reduction in the number of injections compared to aflibercept),
the absence of a demonstrated impact on patients’ quality of life;
BEOVU 120 mg/ml (brolucizumab) is unlikely to have an additional impact on public health.

Considering all these elements, the Committee deems that the clinical benefit of BEOVU 120 mg/ml (brolucizumab) solution for injection, vial and pre-filled syringe, is:

- substantial in the treatment of retrofoveal neovascular (wet) age-related macular degeneration (AMD) in adults;
- insufficient to justify public funding in extrafoveal forms of wet AMD in view of the available alternatives.

The Committee issues:

- a favourable opinion for inclusion of BEOVU 120 mg/ml (brolucizumab) solution for injection, vial and pre-filled syringe, in both the hospital formulary list and the retail formulary list of reimbursed proprietary medicinal products approved for use in the indications only within the scope retained and at the MA dosages;
- an unfavourable opinion for its inclusion in extrafoveal forms of wet AMD.

Recommended reimbursement rate for inclusion in the retail list of reimbursed proprietary medicinal products approved for use: 65%

Clinical Added Value

Considering:

- demonstration in a multicentre, randomised, double-blind, comparative phase IIIb study (TALON), in patients with retrofoveal neovascular (wet) age-related macular degeneration (AMD) who had not previously received VEGF inhibitors, having compared brolucizumab 6 mg with aflibercept 2 mg, administered at variable intervals depending on disease activity (intervals of 8, 12 or 16 weeks), of:
  - the non-inferiority of brolucizumab compared to aflibercept in terms of the mean variation in best corrected visual acuity (BCVA) at week 32,
  - the superiority of brolucizumab compared to aflibercept in terms of increase in the last treatment interval (p < 0.0001) with, in particular, a percentage of patients having had a 12-week interval of 38.5% in the brolucizumab group versus 19.8% in the aflibercept group;
- the absence of robust evidence in this study of a superiority of brolucizumab compared to aflibercept on anatomical parameters (central retinal thickness and presence of intraretinal or subretinal fluid);
- the absence of demonstration of a superiority of brolucizumab compared to aflibercept in terms of quality of life;
- a comparable safety to that of other VEGF inhibitors but with an additional risk of intraocular inflammation, in particular a risk of retinal vasculitis or retinal vascular occlusion, requiring investigation of history and screening for intraocular inflammation at the time of treatment initiation, along with increased monitoring of the patient during the first three months of treatment and discontinuation of treatment in the event of the onset of these adverse effects;
the Committee deems that BEOVU 120 mg/ml (brolucizumab) solution for injection, vial and pre-filled syringe, provides no clinical added value (CAV V) compared to EYLEA (aflibercept) in the management of retrofoveolar wet AMD.