HAUTE AUTORITÉ DE SANTÉ

TRANSPARENCY COMMITTEE
OPINION
18 MARCH 2020

ranibizumab
LUCENTIS 10 mg/ml solution for injection

New indication

Key points

Unfavourable opinion for reimbursement in the indication extension for the treatment of retinopathy of prematurity (ROP).

COMMITTEE'S CONCLUSIONS

Clinical Benefit

◗ Retinopathy of prematurity (ROP) is a retinal vascular development abnormality that affects premature babies. In the majority of cases, ROP regresses spontaneously. However it can progress to forms with retinal scarring, causing irreversible visual impairment or even blindness.

◗ This proprietary medicinal product is a curative treatment.

◗ In the absence of conclusive research evidence of its efficacy compared to laser treatment and given uncertainties with respect to the long-term visual prognosis and its long-term safety (particularly with respect to neurological and psychomotor development), the efficacy/adverse effects ratio cannot be established.

◗ LUCENTIS (ranibizumab) has no role in the care pathway for the treatment of ROP (see "Role of the medicinal product in the care pathway" section).

◗ There is a non-medicinal therapeutic alternative (laser photocoagulation).

Public health impact:
Considering:
- the seriousness of the disease, which, in its most severe forms, can cause irreversible visual impairment or even lead to blindness,
- the rarity of the disease,
- the partially met medical need,
- the lack of response to the identified need (superiority not demonstrated compared to laser surgery in terms of success rate at 24 weeks, numerous methodological limitations of the RAINBOW study, uncertainties with respect to efficacy and long-terms safety),
- the non-established impact on quality of life due to a lack of data,
- the non-established impact on the organisation of care,

LUCENTIS (ranibizumab) is unlikely to have an impact on public health.

Considering these elements, the Committee deems that the clinical benefit of LUCENTIS 10 mg/ml solution for injection is insufficient in the indication extension for the treatment of retinopathy of prematurity to justify its funding by the French national health insurance system.

The Committee issues an unfavourable opinion for inclusion in the hospital formulary list of reimbursed proprietary medicinal products approved for use in the indication extension for the treatment of retinopathy of prematurity.

Clinical Added Value

Not applicable.