INAHTA Brief

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Title HEMANGIOL– A Health Technology Assessment

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Reference link to full report in French
https://www.has-sante.fr/jcms/pprd_2984731/fr/hemangiol

Aim

Assessment of HEMANGIOL (propranolol) with a view to funding by the French national health insurance system and of its clinical contribution compared to other strategies in the indication treatment of infantile proliferative haemangiomas requiring systemic treatment: haemangiomas leading to a life-threatening or functional risk, painful ulcerated haemangiomas and/or not responding to simple treatment, haemangiomas with a risk of permanent scarring or disfigurement.

Conclusions of Transparency Committee

Clinical Benefit

- Infantile haemangioma is a benign tumour, which, further to complications, can threaten the aesthetic or functional prognosis and survival in children.
- HEMANGIOL (propranolol) is a curative treatment for infantile proliferative haemangioma requiring systemic treatment.
- Its efficacy/adverse effects ratio is high.
- Alternatives are available for the treatment of infantile proliferative haemangiomas requiring systemic corticosteroid treatment.
- HEMANGIOL 3.75 mg/mL, oral solution (propranolol) is a 1st line treatment.
- HEMANGIOL (propranolol) is unlikely to have an additional impact on public health.

Considering all of the above, the Committee deems that the clinical benefit of HEMANGIOL (propanolol) remains substantial in the MA indication.

Clinical Added Value

The data from new studies do not modify the conclusions of the Committee's previous opinion: HEMANGIOL 3.75 mg/ml oral solution provides moderate Clinical Added Value (CAV III) in the treatment of infantile proliferative haemangioma.

Recommendations

The Transparency Committee maintains its favourable opinion for the funding of HEMANGIOL (propranolol) by the French national health insurance system in the indication treatment of infantile proliferative haemangioma requiring systemic treatment (haemangiomas leading to a life-threatening or functional risk, painful ulcerated haemangiomas or with a risk of permanent scarring or disfigurement). The treatment must be started in children age 5 weeks to 5 months.

Methods

The assessment of HEMANGIOL (propranolol) was founded on evidence-based medicine with a critical analysis of the clinical data.

Written by

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