INAHTA Brief

Issue 2020/026

Title DUPIXENT – A Health Technology Assessment

Agency HAS, French National Authority for Health (Haute Autorité de santé)
2 avenue du Stade de France – F 93218 La Plaine Cedex, France
Tel: +33 (0)1 55 93 70 00 – Fax: +33 (0)1 55 93 74 35, contact.sem@has-sante.fr, www.has-sante.fr

Reference link to full report in French
https://www.has-sante.fr/jcms/pprd_2983161/fr/dupixent

Aim

Assessment of DUPIXENT (dupilumab) with a view to funding by the French national health insurance system, and of its clinical contribution compared to other strategies, in the indication for the treatment of moderate to severe atopic dermatitis in adolescents age 12 years and over, requiring systemic treatment.

Conclusions of Transparency Committee

Clinical Benefit

- Atopic dermatitis is not a serious disease, however in its moderate to severe forms, it significantly affects patient quality-of-life and comes with a high social impact.
- DUPIXENT (dupilumab) has a suspensive effect on symptoms.
- Its efficacy/adverse effect ratio is significant in adolescents from the age of 12.
- It is to be used as second-line systemic treatment in adolescents, in moderate to severe atopic dermatitis not responding to topical treatments.
- There are therapeutic alternatives, especially cyclosporine (from 16 years according to the MA), and off-label immunosuppressants, of which only short courses should be prescribed due to their toxicity.
- DUPIXENT (dupilumab) is unlikely to have an additional impact on public health.

Considering all of the above, the Committee deems that the clinical benefit of DUPIXENT (dupilumab) 200 mg and 300 mg is substantial in the indication "treatment of moderate to severe atopic dermatitis in adolescents age 12 years and over, requiring systemic treatment" and at the MA dosages.

Clinical Added Value
Considering:

- the superiority of dupilumab over the placebo is demonstrated in adolescents with moderate to severe atopic dermatitis requiring systemic treatment, based on the two primary endpoints assessed after 16 weeks' treatment, namely
  - the percentage of patients achieving an IGA score 0 or 1 with ≥ 2 point-reduction (24.4% versus 2.4%, $p < 0.0001$) and,
  - the percentage of EASI-75 responses (41.5% versus 8.2%, $p < 0.0001$),

with a substantial additional and clinically-relevant effect size,

- demonstration of a statistically-significant improvement in quality-of-life but which was non-clinically-relevant versus the placebo,
- uncertainties as to continued efficacy beyond 16 weeks and as to long-term safety profile (52 weeks' mean exposure in the OLE study) and,
- the small number of alternatives available to treat adolescents requiring systemic treatment, namely cyclosporine from 16 years only and off-label immunosuppressants (to be used however in short courses due to their toxicity).

The proprietary medicinal products DUPIXENT (dupilumab) 200 mg and 300 mg provide moderate clinical added value (CAV III) in the treatment of moderate to severe atopic dermatitis in adolescents age 12 years and over requiring systemic treatment.

Recommendations

The Transparency Committee issued its approval for the funding of DUPIXENT (dupilumab) by the French national health insurance system (retail and hospital) in the indication for the treatment of moderate to severe atopic dermatitis in adolescents age 12 years and over, requiring systemic treatment.

Methods

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

Written by

HAS (Haute Autorité de santé), French National Authority for Health