

BRIEF SUMMARY OF THE TRANSPARENCY COMMITTEE OPINION

KINERET (anakinra), immunosuppressant

Significant clinical added value in the management of patients with cryopyrin-associated periodic syndromes

Main points

- ▶ KINERET, an interleukin-1 antagonist for daily injection, has Marketing Authorisation in the treatment of Cryopyrin-Associated Periodic Syndromes (CAPS) in patients from the age of 8 months, including: Chronic Infantile Neurological, Cutaneous, Articular Syndrome (CINCA), Neonatal-Onset Multisystem Inflammatory Disease (NOMID), Muckle-Wells Syndrome (MWS), Familial Cold Autoinflammatory Syndrome (FCAS).
- ▶ It has been shown to be effective in reducing the intensity of symptoms in the most serious form of CAPS (the CINCA form) during a study with methodological limitations.

Therapeutic use

- The management of CAPS must be started early so as to prevent the development of neurological lesions and particularly potentially irreversible neurosensory ones.
- The therapeutic use varies with the seriousness of the condition: it ranges from withholding treatment to treatment with interleukin-1 antagonists, including symptomatic treatments. Long-term treatment with IL-1 antagonists (canakinumab or anakinra) must be offered to patients with MWS and CINCA to avoid flares of the disease and to try and prevent the development of secondary amyloidosis. It must also be offered to patients with severe FCAS, beyond cold-induced urticaria.
- **Role of the medicinal product in the therapeutic strategy**
KINERET is a first-line treatment for CAPS in adults and children over 2 years of age, in the same way as canakinumab. Between the age of 8 months and 2 years, anakinra is the only treatment that has been proven effective and has Marketing Authorisation.

Clinical data

- A prospective, single-centre, non-comparative study that included 43 patients with CINCA showed a reduction in the daily symptom severity score (fever, rash, joint pain, vomiting, headache) averaging 3.5 points, range 4.6 to 0.9, over a period of 3 to 6 months. The median level of SAA (inflammation proteins) changed from 149 mg/l on inclusion to 6 mg/l at the end of treatment. Certain organic disorders (secondary endpoints) were improved.
- The most commonly reported adverse events were headache, infections and injection site reactions.

Prescribing conditions

Exception drug status

Medicine for initial annual hospital prescription

Prescription medicine restricted to certain healthcare professionals: specialists in rheumatology, internal medicine, paediatrics and dermatology.

Benefit of the medicinal product

- The actual benefit* of KINERET is substantial.
- Given its proven efficiency in severe forms of cryopyrinopathies (CINCA syndrome/NOMID), despite the methodological limitations of the studies available, its ability to cross the blood-brain barrier, the absence of any alternative treatment in patients aged under 2 years and despite the need for daily injections, KINERET, like ILARIS, provides significant clinical added value** (CAV II) in the treatment of cryopyrin-associated periodic syndromes (CAPS) in adults, adolescents, children and babies from the age of 8 months and with a body weight of at least 10 kg.
- Recommends inclusion on the list of reimbursable products for supply by pharmacists and for hospital use.



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This document was created on the basis of the Transparency Committee Opinion of 22 October 2014 (CT-13127) and is available at www.has-sante.fr

* The actual benefit (AB) of a proprietary medicinal product describes its benefit primarily in terms of its clinical efficacy and the seriousness of the condition being treated. The HAS Transparency Committee assesses the AB, which can be substantial, moderate, low or insufficient for reimbursement for hospital use.

** The clinical added value (CAV) describes the improvement provided by a medicinal product compared with existing treatments. The HAS Transparency Committee assesses the degree of CAV on a scale from I (major) to IV (minor). A level V CAV means "no clinical added value".