**SUMMARY**

canakinumab

# ILARIS 150 mg/ml

**solution for injection**

Reassessment at the request of the CT

**Original French opinion adopted by the Transparency Committee on 15 May 2024**

**The legally binding text is the original French opinion version**

## Summary of opinion

**Favourable opinion for reimbursement in the "symptomatic treatment of adult patients with frequent gouty arthritis attacks (at least 3 attacks in the previous 12 months) in whom non-steroidal anti-inflammatory drugs (NSAIDs) and colchicine are contraindicated, are not tolerated, or do not provide an adequate response, and in whom repeated courses of corticosteroids are not appropriate".**

# Transparency Committee's conclusions

## Clinical Benefit

- In patients with frequent attacks not responding to or unable to receive conventional therapies, advanced gout causes disability and a marked deterioration in quality of life related to joint or renal involvement (lithiasis, kidney disease).
- This is a symptomatic medicinal product.
- The efficacy/adverse effects ratio remains high.
- Uncertainty concerning the Committee's initial request for access to data on the characteristics of patients treated for gouty arthritis in France given the methodological limitations of the study and the small number of patients included. This is a first-line treatment in view of the therapies available.

### Public health benefit

Considering:

- the seriousness of the disease and its significant impact on patients' quality of life,
- the prevalence of the disease (0.9% of the French population),
- the partially met medical need, in patients with frequent attacks not responding to treatment with NSAIDs, colchicine and corticosteroids, or unable to receive these,

- the partial response to the identified need given:
  - the demonstrated moderate impact in terms of morbidity (reduction in pain on a VAS and reduction in the probability of the occurrence of another gout attack within 12 weeks following treatment) versus corticosteroids,
  - the lack of evidence of an impact in terms of mortality and quality of life,
  - the lack of evidence of an impact on the organisation of care,

ILARIS (canakinumab) is unlikely to have an additional impact on public health.

**Considering all these elements, the Committee deems that the clinical benefit of ILARIS (canakinumab) 150 mg/ml solution for injection remains substantial in the MA indication.**

**The Committee issues a favourable opinion for maintenance of the inclusion of ILARIS (canakinumab) 150 mg/ml solution for injection in both the list of covered drugs for outpatients and the list of covered drugs for inpatients approved for use in the MA indication and at the MA dosages.**

➔ **Recommended reimbursement rate for inclusion in the list of covered drugs for outpatients: 65%**

## Clinical Added Value

Considering:

- demonstration of the efficacy of ILARIS (canakinumab) compared to triamcinolone acetonide (KENACORT RETARD) on the reduction in pain and the probability of the occurrence of a new gout attack (result to be interpreted with caution in view of the difference in terms of the half-life of these two products);
- a safety profile deemed to be acceptable despite the frequent occurrence of adverse events related to infections;
- a partially met medical need for the treatment of attacks in patients with gout not responding to treatment with NSAIDs, colchicine and in whom corticosteroids are not appropriate;

but in view of:

- the low level of evidence of the available data (post hoc subgroup analysis) in the MA population;
- the absence of data enabling its role to be assessed compared to KINERET (anakinra), a clinically relevant comparator;
- the results of the PRS concerning a small number of patients (15 patients) and not responding to the Committee's initial request for access to data on the characteristics of patients treated with ILARIS (canakinumab) in France for gouty arthritis based on a cohort study,

**the Committee deems that ILARIS (canakinumab) 150 mg/ml solution for injection provides no clinical added value (CAV V) in the current care pathway, which includes the clinically relevant comparator for ILARIS: KINERET (anakinra), used off-label in attacks of gouty arthritis refractory to first-line treatments.**