Lesinurad (Zurampic®) for the treatment of hyperuricaemia in gout patients

Summary of recommendations by *Zorginstituut Nederland* (National Health Care Institute, the Netherlands) dated 4 December 2018

Zorginstituut Nederland carried out an assessment of the medicinal product Lesinurad (Zurampic®), whereby they came to the following conclusion.

In a letter dated 10 April 2018 (CIBG-18-06116), the Minister of VWS asked *Zorginstituut Nederland* to assess whether lesinurad (Zurampic®) is interchangeable with any product that is already included in the Medicine Reimbursement System (GVS). The *Zorginstituut* has completed its assessment.

The manufacturer has asked for inclusion on List 1B of the Health Insurance Decree.

Lesinurad (Zurampic®), in combination with a xanthine oxidase inhibitor (allopurinol or febuxostat), is indicated in adults for the supplementary treatment of hyperuricaemia in gout patients (with or without tophi) who have not achieved target serum uric acid levels with an adequate dose of a xanthine oxidase inhibitor alone.
Lesinurad is available as 200 mg film-coated tablets. The recommended dose is 200 mg once daily in the morning.

Outcome of the assessment
Deliberations in the pharmacotherapeutic report show that patients in the lesinurad+allopurinol studies and the lesinurad+febuxostat study were not treated according to the Dutch guidelines, as too low a dose of allopurinol monotherapy or febuxostat monotherapy was given to patients before lesinurad was added to the treatment. A sub-group analysis (not defined in advance) of patients who were treated with an adequate dose of allopurinol, >300 mg/day, was too small to be able to make firm statements about the effects of adding lesinurad.

Advised by the Scientific Advisory Board (WAR), the *Zorginstituut* concludes that lesinurad, as supplementary treatment for adult patients with gout, has a lower therapeutic value due to insufficient data on its effectiveness on patients who have received an adequate dose of xanthine oxidase inhibitor in accordance with the Dutch guidelines.

Advice
Based on the above considerations, the *Zorginstituut* advises the Minister not to include lesinurad in the GVS.

Conditional inclusion?
Since 1 January 2012, the Minister of VWS can decide to accept into the insured package, for a specific period, care that does not fulfil the statutory criterion 'established medical science and medical practice'. This is subject to the condition that within that period, data are collected on the care's effectiveness and cost-effectiveness. Based on these details, after this period of conditional reimbursement, we can determine whether the care can definitely be included in the insured package.

We checked, based on the criteria for conditional inclusion – insofar as these can

be assessed based on the data currently available –, whether this intervention is a possible candidate for conditional inclusion in the basic insured package.[1]
The *Zorginstituut* does not consider lesinurad a suitable candidate for conditional inclusion. The reasons are as follows. The product is given for a disorder for which treatment options already exist. Based on the studies currently available, there are no clear signs that lesinurad is effective as a supplementary treatment on gout patients who have received an adequate dose of xanthine oxidase inhibitor in accordance with the Dutch guidelines.

Future developments
Naturally, the *Zorginstituut* is willing to re-consider the possibility of including lesinurad in the GVS if scientific publications result from supplementary research data not yet assessed by the *Zorginstituut*.

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The original text of this excerpt from advice of Zorginstituut Nederland was in Dutch. Although great care was taken in translating the text from Dutch to English, the translation may nevertheless have resulted in discrepancies. Rights may only be derived on the basis of the Dutch version of Zorginstituut Nederland's advice.
Furthermore, Zorginstituut Nederland points out that only the summary of this report was translated. A proper understanding of all relevant considerations and facts would require familiarity with the Dutch version of this report, including all appendices.

[1] The criteria can be found in the most recent version of the letter on the procedures for the conditional inclusion of medical care. The letter can be found on our website www.zorginstituutnederland.nl.