**Fampridine (Fampyra®) in cases of multiple sclerosis (MS)**

Summary of recommendations by *Zorginstituut Nederland* (National Health Care Institute, the Netherlands) dated 1 March 2018

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

In a letter dated 16 October 2017 (CIBG-17-05240), the Minister of Health, Welfare and Sport (VWS) asked *Zorginstituut Nederland* (National Health Care Institute, the Netherlands) to re-assess fampridine (Fampyra®) following a period of conditional inclusion in the insured standard package. The *Zorginstituut* has now completed its assessment, after being advised by the Scientific Advisory Board (WAR). Based on the outcomes of the assessment, the Executive Board of the Zorginstituut advised the Minister not to include fampridine in the insured standard package.

The considerations on which this conclusion is based were sent to the Minister in a pharmacotherapeutic report and a budget impact analysis. The advice is explained in more detail below.

**Use of fampridine**
Fampridine is intended for patients with multiple sclerosis (MS) who are not yet confined to a wheelchair (in such cases the severity of the disease, expressed in the so-called EDSS scale, ranges between 4 to 7). Patients can take fampridine to increase their walking ability. Fampridine has no effect on the underlying disease of MS itself.

**Fampridine was included in the standard package subject to conditions**
Fampridine was assessed in 2012 for inclusion in the insured package. The *Zorginstituut* concluded at the time that the product was not good enough for inclusion in the insured standard package: its effects were too limited.
Ultimately, the Minister van VWS decided to include fampridine (in top–down procedures) temporarily into List 1B of the insured package, subject to List 2 conditions. These conditions are as follows:
*"Only in the period from 1 April 2016 to 1 April 2018 and only for an insured person aged eighteen years or older with multiple sclerosis and a score between 4 and 7 on the Expanded Disability Status Scale, insofar as the insured person participates in research on Fampyra as defined in article 2.2, second paragraph".*

**Agreements noted in a covenant**
A covenant was drawn up between the manufacturer, treatment centres, patients' associations and the Dutch Association for Neurology, establishing agreements on the parties' roles during and after the period covered by the covenant.
Furthermore, three studies would take place to determine the (cost-)effectiveness of fampridine. Treatment with fampridine was reimbursed within the framework of conditional registration as long as patients participated in one of the following studies:

(1) ENHANCE, an international, placebo-controlled RCT (randomized controlled trial).

(2) LIBERATE, an international, observational study into, among other things, the safety and use of fampridine in clinical practice

(3) Fampridine Treatment Monitoring Program (TMP), a register of the use of fampridine in the Netherlands.

In October 2017 the manufacturer submitted the dossier for reassessment, containing the outcomes of the above-named supplementary studies.

Conclusion

Fampridine does not belong in the insured package. There is no evidence that it is more effective than current standard care in the Netherlands, but it is more expensive (in medical terms: the therapeutic value of fampridine is lower than that of the standard care). In such cases, the Zorginstituut issues negative advice.

This means that after 1 April 2018, fampridine will no longer be reimbursed.

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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.*