Zorginstituut Nederland

> Return address PO Box 320, 1110 AH Diemen

Minister of Medical Care and Sports
PO Box 20350
2500 EJ THE HAGUE

2022009357

National Health Care Institute
Care
Medicinal Products

Willem Dudokhof 1
1112 ZA Diemen
PO Box 320
1110 AH Diemen
www.zorginstituutnederland.nl
info@zinl.nl

T +31 (0)20 797 85 55

Date 17 October 2022
Subject Evaluation and reassessment of further conditions for fampridine (Fampyra®)

Our reference
2022009357

Dear Mr Kuipers,

The National Health Care Institute has, in accordance with previous agreements, evaluated a part of the List 2 conditions (the annual review of the trial treatment and walk test) for fampridine (Fampyra®) with the stakeholders. On the basis of this evaluation, the National Health Care Institute has reassessed whether the current List 2 conditions contribute to the appropriate use of fampridine. In this letter, you will find a summary of this evaluation and the advisory report of the National Health Care Institute regarding the List 2 conditions for fampridine.

Current situation
Since 1 September 2019, fampridine (Fampyra®) has been included in the medicine reimbursement system (GVS) on List 1B, subject to further reimbursement conditions.
The further condition for fampridine is:

Only for an insured person eighteen years or older with multiple sclerosis with an Expanded Disability Status Scale rating from 4 to 7 (EDSS 4-7) and a severely limited walking capacity with a Timed 25 Foot Walk Test score of at least 6 seconds (T25FWT ≥ 6 seconds) meeting the requirements of the trial treatment strategy:

1. at the start a two-week trial treatment with this medicinal product;
2. after an initial trial treatment, an improvement of at least 20 percent on the T25FWT is achieved;
3. if the treatment is continued, the trial treatment shall be repeated at least once a year, with the treatment being discontinued for a minimum of 48 hours, after which the first T25FWT is carried out and after the two-week renewed trial treatment an improvement of at least 20 percent on the latest T25FWT (compared to the first T25FWT) is achieved.

History
In 2019, the National Health Care Institute issued a positive advisory report on the reimbursement of fampridine for a subgroup of patients with multiple

National Health Care Institute
Care
Medicinal Products

Date
17 October 2022

Our reference
2022009357

sclerosis. This was after negative advisory reports were issued in previous reviews in 2012 and 2018 because of a lack of sufficient evidence of effectiveness for the entire registered indication of fampridine. Part of the positive advice in 2019 was the condition that, at the start of the treatment with fampridine, a trial treatment with walk test should determine whether this medicinal product is sufficiently effective. The trial treatment and the walk test must be repeated annually in accordance with the List 2 conditions. For this purpose, a patient must temporarily stop taking fampridine (at least 48 hours in advance), perform a walk test, and after 2 weeks repeat the walk test. It was agreed that patients who were already using fampridine (dating back to the conditional admission) should do a trial treatment with walk test within one year (after temporary cessation of the treatment). In 2019, the National Health Care Institute, when drafting the advisory report, established that after two years, the usefulness and necessity of the annual repetition of the trial treatment and walk test would be evaluated together with the stakeholders, in the context of appropriateness.

Evaluation
The evaluation has been carried out both quantitatively (pharmacy dispensing data) and qualitatively (experiences of patients, doctors and health insurers). The evaluation has highlighted the following points:

- The implementation of the trial treatment and (annually repeated) walk test, has been applied less often than expected due to the COVID-19 pandemic, among other things as a result of the scaling down of regular care;
- The implementation and results of the walk tests for fampridine users in the Netherlands are not recorded sufficiently centrally recorded;
- Of the people who have stopped taking fampridine, no user, if reported, stopped as a result of the annual walk test. No effect of the treatment and other reasons were the reason to discontinue fampridine after at least one year of use. It is estimated that about one third of these people are existing users, but the exact duration of use cannot be determined for this user group;
- The total number of fampridine users in the Netherlands, after correction of recent prevalence and pricing data, is in line with the expected number of users as calculated for the budget impact analysis in the 2019 assessment;
- The qualitative results show that the annual repetition of the walk test is not considered useful and even considered potentially harmful by both neurologists and patients;
- MS patients who use fampridine find the walk test very stressful. They report symptoms such as reduced walking capacity, fatigue and additional falls when the treatment is interrupted;
- Neurologists indicate that they do not consider the annual repeating of the walk test (unlike the trial treatment at the start) useful. They also report on the complaints of patients about the treatment interruption;
- Health insurers do not monitor the implementation of the annual walk test, as this is not prioritised in their risk-oriented approach;
- The implementation of the annual walk test requires two measuring moments (with a few days interval). This is a burden on the healthcare capacity, especially in view of staff shortages, and with the high pressure of work in healthcare, this annual test is not a priority.

The National Health Care Institute concludes, on the basis of quantitative and qualitative data, that an annual repetition of the walk test by MS patients who use

fampridine has disadvantages: it is perceived as not useful and stressful (temporary worsening of symptoms) by both neurologists and patients and it imposes a burden on the healthcare capacity. The advantages are not clear either. The COVID-19 pandemic has reduced the number of walk tests that could be expected in a regular situation, but there is no evidence that the medicinal product is not being used appropriately.

National Health Care Institute
Care
Medicinal Products

Date
17 October 2022

Our reference
2022009357

Advice

Fampridine (Fampyra®) is already included on list 1B with further conditions. Following the evaluation, the National Health Care Institute recommends that the List 2 conditions be revised and that the annual repetition of the trial treatment and walk test be cancelled.

Revision further condition of fampridine (Fampyra®)
Only for an insured person eighteen years or older with multiple sclerosis with an Expanded Disability Status Scale rating from 4 to 7 (EDSS 4-7) and a severely limited walking capacity with a Timed 25 Foot Walk Test score of at least 6 seconds (T25FWT ≥ 6 seconds) meeting the requirements of the trial treatment strategy:

1. at the start a two-week trial treatment with this medicinal product;
2. after this trial treatment, an improvement of at least 20 percent on the T25FWT is achieved.

Yours sincerely,

Sjaak Wijma
Chairperson of the Executive Board

Annex: Report on the evaluation of the legal condition for the reimbursement of fampridine (Fampyra®)