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Our reference
2020019308

Date 28 April 2020
Subject GVS assessment of pentosan polysulfate sodium (Elmiron®)

Dear Mr van Rijn,

In your letter of 9 March 2020 (CIBG-20-0120), you requested Zorginstituut Nederland to assess whether pentosan polysulfate sodium (PPS-Na) (Elmiron®) is interchangeable with a product that is included in the medication reimbursement system (GVS). The Zorginstituut has now completed its assessment. The considerations are included in the GVS report attached to this letter, with the pharmaco-therapeutic report and the budget impact analysis.

Elmiron® is registered for the treatment of bladder pain syndrome characterized by either glomerulations or Hunner's lesions in adults with moderate to severe pain, urgency and frequency of micturition.
Elmiron® is available as a hard capsule containing 100 mg of pentosan polysulfate sodium. The recommended dosage of Elmiron® is one capsule of 100 mg orally, three times a day. The therapy response should be reviewed every 6 months. If no improvement has been achieved 6 months after the treatment was established, the treatment with Elmiron® must be stopped. In those who do respond, the treatment with Elmiron® must be continued routinely as long as the response continues.

The manufacturer is asking for inclusion on List 1B of the Health Insurance Regulation.

Assessment outcome
Assessment of interchangeability
Based on the criteria for interchangeability, Elmiron® is not interchangeable with other medicinal products included in the GVS. Based on this, Elmiron® cannot be placed on List 1A. Next, the Zorginstituut assessed whether Elmiron® is eligible for inclusion on List 1B and was advised on this matter by the Scientific Advisory Board (WAR).

Therapeutic value
Reimbursement is requested for the treatment of bladder pain syndrome in patients with glomerulations or HL according to the registered indication. At present, in these patients, when transurethral treatment is not possible, a test

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treatment of bladder irrigation with a GAG layer recovering fluid can be started. In 2013, the Zorginstituut (at the time the Health Care Insurance Board) assessed whether bladder instillation with bladder irrigation fluids meets the established medical science and medical practice. From the 'Background report on the established medical science and medical practice for bladder irrigation fluids with chondroitin sulfate and/or hyaluronic acid', it appeared that the existing evidence is not sufficient to assign a possible effect to intravesical treatment with these bladder irrigation fluids for the treatment of interstitial cystitis, and thus it does not comply with the established medical science and medical practice[1]. In November 2019, bladder installations were designated as potential candidates for conditional inclusion to the basic health care package of the Health Insurance Act (Zvw) and information on its effectiveness is being collected.

There is hardly any evidence available for bladder irrigation at the moment. In formal terms, this treatment cannot be regarded as a comparative treatment and there is therefore no comparator (even if it is included in the guideline). For these reasons, it was not possible in the assessment to draw a comparison with these GAG bladder irrigations.

Zorginstituut Nederland has come to the final conclusion that clinically relevant improvements are found in subjective patient-reported outcome parameters after treatment with Elmiron® in placebo-controlled studies for bladder pain syndrome characterised by glomerulations or Hunner's lesions (HL). Given the high unfulfilled treatment needs and the likely positive effect on the quality of life, pentosan polysulfate sodium (Elmiron®) has an added value.

Budget analysis and cost effectiveness
The application of PPS-Na (Elmiron®) for the treatment of BPS characterised by glomerulations or Hunner's lesions will be accompanied by costs estimated at €4.5 million in the third year after inclusion in the package. Only the medical costs are included in the budget analysis. When estimating the budget impact, there is uncertainty about the number of patients with BPS in the Netherlands, and what proportion of these patients have glomerulations or Hunner's lesions. It is also possible that some of the BPS patients with Hunner's lesions can be treated transurethrally and therefore are no longer eligible for PPS-Na. Therefore, the calculated budget impact may be overestimated.
As the budget impact is expected to reach a maximum of €4.5 million in the third year after inclusion in the package, the product has been exempt from a cost-effectiveness analysis.

Advice on inclusion in the GVS
On the basis of the criteria for interchangeability, PPS-Na (Elmiron®) is not eligible for inclusion on List 1A. Based on the considerations mentioned above, the Zorginstituut advises that PPS-Na (Elmiron®) is included in List 1B and List 2 of the Health Insurance Regulation. Inclusion in List 1B will lead to additional costs.

List 2 condition PPS-Na (Elmiron®)
Only for an insured person aged 18 years or older with bladder pain syndrome characterized by either glomerulations or Hunner's lesions in adults with moderate

[1] Health Care Insurance Board - Bladder irrigation fluids with chondroitin sulfate and/or hyaluronic acid - 2013

to severe pain, urgency and frequency of micturition.

Yours sincerely,

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