

East Surrey CCG, Guildford & Waverley CCG, North West Surrey CCG, Surrey Downs CCG, Surrey Heath CCG, Crawley CCG, Horsham & Mid-Sussex CCG

Briefing Paper for Area Prescribing Committee on NICE Technology Appraisal TA610

NICE TA Guidance	Pentosan polysulfate sodium for treating bladder pain syndrome
Date of issue	13 November 2019
Available at	https://www.nice.org.uk/guidance/ta610

Medicine details	
Name, brand name	Pentosan polysulfate sodium, Elmiron®
Manufacturer	Consilient Health Ltd
Licensed indication	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
Formulation	Hard capsule
NICE recommended dosage/schedule	300 mg per day taken as 1 × 100-mg capsule orally 3 times daily. Treatment is stopped if no improvement is reached 6 months after starting treatment. In people whose condition responds, treatment should be continued as long as the response is maintained. Response to treatment should be reassessed every 6 months.

Disease and potential patient group	
Brief description of disease	Bladder pain syndrome is a chronic bladder condition characterised by pain, urinary urgency, frequency and getting up at night to pass urine. There is currently no cure for the condition and treatments generally aim to control symptoms. ¹
Potential patient numbers per 100,000	Bladder pain syndrome may affect approximately 400,000 people in the UK ² . It is more common in women than men; 90% of people with the condition are women in their fifth and sixth decades of life. Up to 50% of patients with symptoms of bladder pain syndrome will have spontaneous resolution in time. ³ Estimates of the prevalence of bladder pain syndrome associated with inflammation in the bladder (for example, characterised by Hunner's lesions or glomerulations) range from 0.3 to 10.2 per 10,000 patients. ¹

SUMMARY

Guidance

Pentosan polysulfate sodium is recommended as an option for treating bladder pain syndrome with glomerulations or Hunner's lesions in adults with urinary urgency and frequency, and moderate to severe pain, only if:

- their condition has not responded to an adequate trial of standard oral treatments
- it is not offered in combination with bladder instillations

- any previous treatment with bladder instillations was not stopped because of lack of response
- it is used in secondary care and
- the company provides pentosan polysulfate sodium according to the commercial arrangement.

Cost implications

Cost:

NB: NICE TA, therefore funding is mandatory.

The list price of pentosan polysulfate sodium, Elmiron® is £450.00 per 90 capsules (excluding VAT; BNF accessed online December 2019).

Cost-effectiveness estimates (extract from NICE)

Compared with bladder instillations: The Evidence Review Group's (ERG) revised incremental cost-effectiveness ratios (ICER) using the committee's preferred assumptions and applying the confidential commercial arrangement was £14,418 per QALY gained when compared with bladder instillations. Based on the ERG's analysis, the committee concluded that the most plausible cost-effectiveness estimate for pentosan polysulfate sodium compared with bladder instillations was likely to be a cost-effective use of NHS resources.

Compared with best supportive care: The ERG's revised ICER using the committee's preferred assumptions and applying the confidential commercial arrangement was £50,740 per QALY gained when compared with best supportive care. The committee concluded that the most plausible cost-effectiveness estimate for pentosan polysulfate sodium compared with best supportive care was higher than usually considered a cost-effective use of NHS resources.

Availability of PAS and details (if appropriate):

The company has a commercial arrangement. This makes pentosan polysulfate sodium available to the NHS with a discount. The size of the discount is commercial in confidence. It is the company's responsibility to let relevant NHS organisations know details of the discount.

Availability of homecare service (if appropriate):

Not required.

Alternative treatments and cost per patient per year

Treatment options for people with bladder pain syndrome and either glomerulations or Hunner's lesions include:

- oral treatments (such as amitriptyline, gabapentin, pregabalin, paracetamol, non-steroidal anti-inflammatory drugs, hydroxyzine, cimetidine and ranitidine) and
- bladder instillations (a plastic tube inserted into the bladder to administer liquid medication).

Patients often need multiple treatments to manage the symptoms. The clinical experts explained that bladder instillations were invasive and can cause adverse effects. The patient and clinical experts explained that pentosan polysulfate sodium may also affect quality of life because it has to be taken 3 times a day on an empty stomach, which affects mealtimes. The committee concluded that there was an unmet need for effective treatment options that can be used instead of invasive bladder instillations.

Impact to patients

An additional treatment option for patients

- Less invasive than bladder instillations

- Three times daily dosing (on an empty stomach) may affect quality of life
Impact to primary care
<ul style="list-style-type: none"> • This is not a PbRe drug, it is included in the national tariff. • There should be no prescribing in primary care. NICE only recommend if used in secondary care. • Primary care prescribers should be aware that their patient is receiving pentosan polysulfate sodium and ensure that this is recorded in the patient's notes in order to be alert to potential side-effects and interactions with other medicines prescribed in primary care. This will ensure that GP records, which are accessed by other healthcare providers, are a true and accurate reflection of the patient's medication.
Impact to secondary care
<ul style="list-style-type: none"> • The initiation, administration and on-going treatment is managed by secondary care as per NICE TA. • All prescribing is recommended to be retained by secondary care. • Any specialist starting pentosan polysulfate sodium must write to the patient's GP to inform them that it is being prescribed within secondary care so that this can be recorded on the primary care clinical system. • The technology is a further treatment option after standard oral treatments have been unsuccessful - provider Trusts to update bladder pain syndrome pathways • NICE do not expect treatment costs to be significant due to reduced numbers of patients requiring bladder instillations (resource impact of implementing the recommendations in England will be less than or £9,000 per 100,000 population).
Impact to CCGs
<ul style="list-style-type: none"> • The technology is not commissioned by Clinical Commissioning Groups (CCGs). • Providers are NHS hospital trusts.
Implementation
NICE TA implementation must be within 3 months of publication (13 November 2019).
Recommendation to PCN
<p>PbRe – No. It is included in the national tariff</p> <p>APC to consider RED Traffic Light Status as per NICE TA requirement that “it is used in secondary care”.</p>

References:

1. National Institute for Health and Care Excellence. Technology appraisal guidance [TA610]: Pentosan polysulfate sodium for treating bladder pain syndrome (2019) [Online] Available at: <https://www.nice.org.uk/guidance/ta610/chapter/1-Recommendations> (Accessed: December 2019)
2. The Urology Foundation Bladder related statistics [Online] Available at: <https://www.theurologyfoundation.org/professionals/healthcare-resources-and-reports/urology-resources/facts-and-figures/bladder-related-statistics> (Accessed: December 2019)
3. European Public Assessment Report. Elmiron (2017) [Online] Available at: https://www.ema.europa.eu/en/documents/assessment-report/elmiron-epar-public-assessment-report_en.pdf (accessed December 2019)

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VERSION CONTROL SHEET

Version	Date	Author	Status	Comment
V1.0	24/12/19	Jemma Hives	Draft	
V1.1	27/01/20	Jemma Hives	Final	Addition of comment

Appendix 1

Comments received:

Dr Tharani Nitkunun, Consultant Urologist, Epsom and St Helier University Hospitals NHS Trust

It would be good to have Elmiron (pentosan polysulfate) in our armamentarium for our bladder pain syndrome patients. As this tablet does come at a cost, I would suggest that patients who are offered this should be discussed in our pelvic floor MDT.

Tharani