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**10 October 2019**

**NICE APPRAISAL COMMITTEE RECOMMENDS ELMIRON®
FOR THE TREATMENT OF BLADDER PAIN SYNDROME**

Consilient Health welcomes the draft final appraisal document published today by the National Institute for Health and Care Excellence (NICE) Appraisal Committee recommending elmiron**®** (pentosan polysulfate sodium) for bladder pain syndrome (BPS) within its marketing authorisation1. NICE has recommended that elmiron**®** ,the only licensed oral medication for BPS with glomerulations or Hunner’s lesions (referred to as interstitial cystitis/BPS), is used in accordance with specified considerations 1,2,3.

The recommendation came after Consilient Health agreed a Patient Access Scheme with NICE which makes elmiron**®** available to the National Health Service (NHS).

Reiterating his previous comments during the NICE appraisal, Mr Jonathan Goddard, Consultant Urological Surgeon, Leicester General Hospital said: “BPS is a chronic condition and difficult to treat, and patients often try several treatments before finding one that is effective. It’s crucial that clinicians have access to a range of treatments; elmiron**®** is effective and well-tolerated, and should be an available option.”

On behalf of Bladder Health UK Susannah Fraser, Communication and Media Manager said: “BPS is a debilitating condition and can have a considerable detrimental impact on the individual’s lifestyle, ability to work, emotional health and relationships. It’s important that individuals with BPS have access to a range of treatment options.”

The Department of Health asked NICE to produce guidance on the use of elmiron**®** for use to the NHS in England. The draft Final Appraisal Determination (FAD) available today is now open for consultation and comment; the FAD is expected to be published on the 13th November 2019.

Amanda Paxon, Consilient Health UK Country Manager Pharmaceuticals said: “This is a condition with significant unmet clinical need, and elmiron**®** is a much needed treatment option. Consilient Health is hopeful that this draft document will be formally agreed by November.”

**ENDS**

**Notes to editor**

Interstitial cystitis (IC)/bladder pain syndrome (BPS)4,5
BPS is a condition defined as chronic (i.e. more than six months) pelvic pain, pressure or discomfort perceived to be related to the bladder and accompanied by at least one other urinary symptom e.g. urinary urgency or frequency. A subset of individuals with BPS have lesions on the inside of the bladder wall, either glomerulations or Hunner’s lesions and this is referred to as IC/BPS. Approximately 90% of individuals with IC/BPS are women, and the condition has a considerable detrimental impact on the individual’s lifestyle, work, emotional health and relationships. Their quality of life is hugely compromised.

elmiron**®** (pentosan polysulfate sodium)2,6,7
elmiron**®** is a medicine that contains the active substance pentosan polysulfate sodium. After taking the medicine it passes into the urine and attaches to the lining of the bladder, helping to form a protective layer6. elmiron**®** is licensed for the treatment of BPS characterised by either glomerulations or Hunner's lesions in adults with moderate to severe pain, urgency and frequency of micturition. elmiron**®** improves the pain, urgency to urinate, need to urinate more often and gives patients an improved quality of life2.

elmiron**®** is thought to work by restoring a damaged, thin, or ‘leaky’ bladder surface. This surface (glycosaminoglycans or GAG layer) has a coating of mucus which protects the bladder wall from bacteria and irritating substances in urine. It is believed that elmiron**®** functions as a synthetic GAG layer, but its exact mechanism of action in IC/BPS is unclear7.

NICE recommendation1
elmiron**®** is recommended as an option for treating BPS within its marketing authorisation, but only if:
• The individual’s 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
• The company provides elmiron**®**according to the commercial arrangement

Consilient Health
Established in 2005 with headquarters in Ireland, Consilient Health is an independent, dynamic and rapidly growing pharmaceutical company with a rich heritage of commercialising products in complex markets in therapeutic areas such as women’s health, urology and endocrinology. The company has a strategy of partnering with innovative companies to bring to medicines to market that serve a clear unmet clinical need. In 2018 Consilient Health signed a long-term exclusive distribution agreement with bene-Arzneimittel GmbH to distribute elmiron**®** in the UK.

**References**1. National Institute for Health and Care Excellence. Draft final appraisal determination. Pentosan polysulfate sodium for treating bladder pain syndrome. October 2019.
2. bene-Arzneimittel GmbH. elmiron**®** (pentosan polysulfate sodium) 100 mg hard capsules Summary of Product Characteristics. July 2019
3. Committee for Medicinal Products for Human Use (CHMP) Assessment report elmiron**®** EMA/287422/2017 23 March 2016. <http://www.ema.europa.eu/docs/en_GB/document_library/EPAR_-Public_assessment_report/human/004246/WC500229392.pdf>
4. National Institute for Health Research. Pentosan polysulfate sodium (elmiron**®**) for bladder pain syndrome (interstitial cystitis) NIHRIO (HSRIC) ID: 13742 NICE ID: 9517 <http://www.io.nihr.ac.uk/wp-content/uploads/migrated_new/13742-Pentosan.pdf> (accessed July 2019).
5. National Health Service. Interstitial cystitis. <https://www.nhs.uk/conditions/interstitial-cystitis/> (accessed July 2019).
6. bene-Arzneimittel GmbH. elmiron® (pentosan polysulfate sodium) 100 mg hard capsules Patient Information Leaflet. July 2019
7. Interstitial Cystitis Association website <https://www.ichelp.org/diagnosis-treatment/treatments/pentosan-polysulfate-sodium> (accessed September 2019).

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